Terms of Reference

Independent Patient Safety Investigation into Great Ormond Street Hospital for Children NHS Foundation Trust limb lengthening services

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Terms of Reference

1. Introduction and background

NHS England London region (NHSE- London) is commissioning an independent patient safety investigation (IPSI) into limb lengthening services at Great Ormond Street Hospital for Children NHS Foundation Trust (GOSH).

The investigation, led by an independent Chair, will have a specific focus on identifying whether there are any lessons to be learned regarding governance[1] and culture which might also be applicable to other highly complex low volume services. It will not assess clinical harm or consider specific patient cases which are subject to a separate process.

1.1 Great Ormond Street Hospital (GOSH) and the lower limb service

GOSH is situated in North Central London. It is an international centre of excellence in child healthcare and its mission is to put the "child first and always".

With their research partner, the University College London Great Ormond Street Institute of Child Health, GOSH hosts the UK's only paediatric National institute for Health Research (NIHR) Biomedical Research Centre (BRC).

GOSH provides over 67 different specialised services, the widest range at any one site in the UK. The Trust sees around 76,000 children each year, with over 100 inpatient admissions and 30 operations per day[2].

The GOSH Orthopaedic Department is a tertiary and quaternary referral centre for specialist paediatric orthopaedic lower limb surgery and some upper limb conditions. Many patients travel from afar, including from the devolved regions of the UK, the Republic of Ireland, Gibraltar, Malta as well as all over England. GOSH is a predominantly elective only centre, with no accident or emergency, or trauma covered within the site[3].

[1] See footnotes 6 and 7
[2] Who we are | Great Ormond Street Hospital
[3] Invited Service Review Report. Report on the paediatric orthopaedics/ the lower limb lengthening reconstruction/ Ilizarov service on behalf of GOSH. October 23. See. GOSH Board Papers. October 24. Appendix B- Service Overview information, p90. Available from: PUBLIC_TB_agenda_and_papers_241024_3mMK1nB.pdf (p103)

1.2 Background

In September 2022 the Chief Medical Officer of Great Ormond Street invited the Royal College of Surgeons (RCS) to undertake a service review of paediatric orthopaedic services. This was following concerns raised by staff[4].

A specific focus of the review was the lower limb lengthening and reconstruction/Ilizarov surgical service, part of the Body, Bones and Mind Directorate, which includes the spinal and Orthopaedic Department of GOSH. The Trust asked that the review focused on orthopaedics, and not the spinal aspects of the department[5].

In October 2023 the Royal College of Surgeons published their Invited Service Review Report: Report on the paediatric orthopaedics/the lower limb lengthening and reconstruction/Ilizarov service on behalf of Great Ormond Street Hospital for Children NHS Foundation Trust'.

An action plan to address the key areas of the RCS report, themed against the seven pillars of clinical governance, was put in place.

GOSH also established an overarching improvement programme chaired by the Chief Medical Officer and supported by the wider Executive Management Team.

2. Scope of the investigation

NHS England London region is commissioning an Independent Patient Safety Investigation (IPSI) into limb lengthening services at Great Ormond Street Hospital to provide an independent assessment of the responsiveness of the Trust when they identified potential harm in the complex clinical pathway to lengthen limbs in children.

The focus of the IPSI will be clinical governance[6] and corporate governance[7]. It will look at processes in place and timeliness of response when concerns were raised, with the aim of identifying whether there is any learning applicable to GOSH and more widely, particularly in relation to similar specialised services.

2.1.The investigation should cover 4 issues:

- Was the governance in place at GOSH sufficient to identify concerns with patient safety at the earliest opportunity?

- Did GOSH respond in a robust way once they knew there was a problem?

[4] GOSH Board papers. October 24. Attachment N. Available from: PUBLIC_TB_agenda_and_papers_241024_3mMK1nB.pdf
[5] Invited Service Review Report. Report on the paediatric orthopaedics/ the lower limb lengthening reconstruction/ Ilizarov service on behalf of GOSH. October 23. P5. Available from: PUBLIC_TB_agenda_and_papers_241024_3mMK1nB.pdf
[6] A system through which NHS organisations are accountable for continuously improving the quality of services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish.
[7] The means by which boards lead and direct their organisations so that decision making is effective, risk is managed and the right outcomes are delivered.

- What is the culture for whistle-blowers to raise concerns at GOSH, and how are they responded to? Were there clear and effective processes in place for staff and family members to raise concerns?

- What recommendations for improvement can be made specifically at GOSH? What principles and learning can be derived more widely for the commissioning and delivery of low volume highly specialised services?

The investigation will exclude review of individual patient records and assessment of clinical harm caused as this has been addressed with the Royal College of Surgeons review and trust response to this. This governance investigation is designed to complement existing work and requires both a retrospective view and a contemporary view on the current state. It should seek to identify any residual gaps and improvement actions going forwards, ensuring that recommendations do not repeat actions underway. Families will be invited to take part, with the findings used to inform the investigation's focus on governance, culture and processes at GOSH.

2.2 The IPSI should involve relevant parties as follows:

- Engage with relevant stakeholders within the Trust to fulfil the investigation remit. This will include Board members, those responsible for clinical and corporate governance at all levels, and an assessment as to whether any issues raised by external providers and patients/ families were addressed appropriately.

- Engagement with NHSE and GOSH to ensure that patients and families are informed and updated about the investigation and its progress.

- Communications about the review process will be managed by the NHSE London regional communications team, with oversight by the Senior Responsible Officer (SRO) for the investigation and input via the clinical and managerial leaders.

2.3 Timescale

- The investigation will start when the investigators receive all the relevant documentation. The investigation should submit a draft report within 6 months of this date.

- Monthly progress reports on the steps taken in the review and any risks to completion within the agreed timeframe must be provided to NHS England London regional team.

- The investigator must immediately raise concerns to the Trust and NHS England London region if any critical safety governance learning is identified.

- The scope is anticipated to cover the period from when the surgeon initially joined the Trust in 2017 to current practice. Should further issues arise after this they will be subject to discussion.

3. Methodology

The IPSI will follow the principles of a Just Culture, focusing on learning does not blame. The IPSI will use the SEIPS (System Engineering Initiative for Patient Safety) approach recommended by the National Patient Safety team[8]. This is a framework for understanding outcomes within complex socio-technical systems. Within this framework the investigation will analyse different components of a work system and their interactions to understand how they influence processes and thus shape outcomes. Using SEIPS will help the IPSI team plan appropriate evidence collection, which documents will need to be reviewed, which processes should be observed, and which stakeholders should be interviewed.

The following six headings will be used to guide the evidence collection. Indicative key lines of enquiry are detailed below.

Organisation:

- Is there a full understanding of all the events along the timeline relating to Consultant A's practice? Particularly events along the timeline which may have contributed to an increase in pressure or reduction in accountability or standards? The timeline commences in 2017 and lasts until the cessation of Consultant A's practice at the Trust.
- Were the systems, processes and controls surrounding the department sufficient to identify improper or substandard practice? (Ward to Board clinical governance).
- How has safeguarding been engaged within the safety system and is safeguarding escalation reliable?
- How did the organisation respond to the external raising of concerns (for example, via the Patient Advice and Liaison Service (PALS) – what was the translation rate of informal concerns to formal complaints.
- Were there clear and effective processes in place for staff and family members to raise concerns and were these issues handled appropriately in line with expected practice? Was the environment psychologically safe and conducive to raising concerns?
- What concerns were raised via internal speak-up mechanisms and how were these translated into learning and improvement actions?
- Has the organisation sufficiently executed its Duty of Candour?
- What information did the Board (and delegated Board Committees) receive along the timeline of events?
- Is the operational governance interface effective at surfacing issues?

[8] Holden RJ, Carayon P, (2021), SEIPS 101 and seven simple SEIPS tools. BMJ Quality and Safety 30 1-10.

Task:

- What interventional actions were put into place along the timeline, and were these sufficiently decisive?
- How were improvement actions assessed and assured?
- How effective were local clinical policies, Standard Operating Procedures (SOPs) and National Institute of Clinical Excellence (NICE) guidelines along the timeline?
- What other policies were in place and available to support the delivery of safe care? (World Health Organisation checklist, consent, risk management, clinical audit etc.)?
- What was the adherence to local policies along the timeline?
- Did staff feel safe in the delivery of their role and was the safety culture conducive to staff raising relevant challenges?
- Was there effective sharing of information between departments, directorates, trust sites, and the independent sector?

People:

- What was the chain of command and lines of accountability in relation to this Consultant?
- What were the mechanisms for ongoing consultant oversight, appraisal and revalidation?
- How were any concerns raised to HR handled?
- How effective were Multi-Disciplinary Team (MDT) approaches in ensuring patient safety – were all team members treated with parity?
- Were the knowledge, skills and experience of people in the MDT sufficient to provide challenge?
- Were the team dynamics within the MDT and Directorate conducive to patient safety?
- What was and is the culture around two-consultant operating- a collaborative practice where two surgeons work together during a surgical procedure?
- What is the safety culture within the Orthopaedic Department?

  How embedded was psychological safety in the team and across the Trust?

Technical tools and equipment:

- Was the organisation 'measuring the right things' – with lower volume, complex surgeries it can be difficult to establish confidence intervals within the data. Is there the availability of any 'triggers' within the data for unexpected variations?
- Is record keeping reliable?
- How are recommendations translated into action and how have these been implemented?
- Does the service ensure that all devices and equipment used in procedures are appropriately recorded?
- What is the incident reporting culture and how does this translate to learning?
- Was the quality of internal investigations sufficient to surface the facts of the matter?

Internal environment:

- Is the physical environment conducive to effective governance?
- Is the timing, organisation of, and space sufficient to support the multi-disciplinary team?
- Do teams have enough time to discuss patients fully?
- Was there robust safety governance in place for patients transferred between GOSH and independent providers?
- Was there robust safety governance in place to discuss deteriorating patients post operatively and post discharge?

External environment:

- How were external agencies and regulators engaged and what was their role in monitoring? For example, the Regional Quality Committee?
- What were matters arising from previous external reviews?
- What, if any, has been the involvement of the General Medical Council (GMC) and how were standards applied?
- What were the NHS England commissioning standards for limb lengthening service and the British Society for Children's Orthopaedic Surgery (BCOS) process standards for lower limb elective surgery in children standards and

guidance? Was the scope of the RCS invited review report sufficient, and might there be residual areas of risk?

3.1 Stages to Investigation

- Phase 1: Preparation
- Phase 2A: Document review
- Phase 3: Analysing and triangulating
- Phase 4: Drafting the report
- Phase 5: Due diligence
- Phase 6: Publication

The draft report will require factual accuracy checks by all relevant stakeholders. Recommendations must be meaningful and sustainable for the NHS system. In addition, potential wider learning across the NHS regarding low volume highly specialised surgery will need to be considered. NHS England is committed to maintaining openness and transparency and intends to publish the report in full once it has been finalised.

4. Governance

The IPSI will be commissioned and led by NHS England London region. The NHS Team will establish a governance group to oversee the investigation.

5. Expected outputs / intended outcomes

Provision of a written report which:

- Is clear, concise and written in language which meets the requirements of the NHS style guide and is suitable for publication e.g. with recognised references, executive summary and synopsis of findings.
- Satisfies the agreed Terms of Reference
- Complies with all appropriate legal guidance and views including but not limited to Scott/Salmon Principals.
- Has a high-level view of chronology to explore any learning actions and inactions.
- Demonstrates engagement, communication and co production with all relevant stakeholders. If recommendations are proposed, these should be consistent with the CREATED SMART framework, including being developed with the input of those who will implement them. They should be appropriate to the scope of the

investigation, particularly considering local, regional and national learning with a particular focus on highly specialised low volume services.

- Includes an Equality and Health Impact Assessment to comply with the Equality Act 2010 and consider wider health implications particularly for vulnerable and disadvantaged groups.