Royal Manchester Children's Hospital

Spinal Safety Look Back Review

Royal Manchester Children's Hospital

February 2024

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1 Executive Summary

In February 2022, Manchester University NHS Foundation Trust (MFT) were informed by the Northern Care Alliance NHS Foundation Trust (NCA), that they would be undertaking a safety look back, in relation to the care provided by Spinal Surgeon A who had previously been in their employment.

In November 2022, the Northern Care Alliance confirmed to MFT that their external expert review of 4 index cases raised considerable concerns about Spinal Surgeon A's practice during the period he operated at Salford Royal Hospital (now within the NCA) and Royal Manchester Children's Hospital (RMCH) (now within MFT).

The NCA advised that the concerns raised mainly focused on probity, the professional practice of the individual, and potential harm to patients.

In light of these significant concerns, and the fact that Spinal Surgeon A had performed surgery on children between 1991 and 2011, the senior leadership team (SLT) at Royal Manchester Children's Hospital (RMCH) were fully briefed on the review and agreed that a similar Spinal Safety Look Back was required for patients operated on by Spinal Surgeon A at RMCH.

The RMCH Spinal Safety Look Back review formally began on 22 May 2023. The investigation team included two experienced paediatric spinal surgeons from UK Children's Hospitals. These reviewers were external to RMCH.

The team set out to review patients identified through the following criteria:

- Had instrumental spinal surgery under Spinal Surgeon A between 1st January 2006 and 31st December 2011
- Additional patients outside of the time period above identified via
    - NCA: patients included in their review but who were also operated on at RMCH
    - RMCH Spinal Surgeons raising concerns regarding specific cases
    - PALS and formal complaints
    - Legal claims
    - Incidents

- Patients or families contacting RMCH or the review team directly with concerns regarding care

Following administrative review, case notes of patients included in the review were passed on to the RMCH spinal surgeons for a clinical 'primary review'. The primary review included reviewing hard copy medical case notes and x-rays, and information available on electronic patient record systems including electronic imaging.

Any potential clinical concerns or concerns regarding patient harm were noted; and if there were any concerns identified the case was highlighted as needing to proceed to the next stage of the process comprising a more detailed review including external scrutiny ('secondary desktop review').

Any patients for which there had already been concerns raised by any route automatically proceeded to a 'secondary desktop review'.

The secondary desktop reviews were a series of multi-disciplinary team (MDT) meetings including an independent external expert to review each patient's care in detail.

The secondary desktop review team noted concerns raised and feedback from patients and families regarding their experience of care, either from meetings with patients and families or from telephone or written communication. Any relevant incidents, complaints or legal claims and their findings were also noted.

The hard copy case notes including written medical records, consent form and operation notes were reviewed alongside electronic information including x-ray imaging and clinic letters.

A structured approach was used to assess aspects of a patient's care and to identify issues and any recurring themes throughout the overall review process.

There was an overall assessment of any identified harm attributable to issues with care. The level of harm was assessed and agreed in line with the current MFT governance process and patient safety incident matrix.

The RMCH Spinal Safety Look Back Review team considered it to be very important that patients' and families' voices were heard, listened to, and reflected in the reviews. An appropriate meeting was arranged in every case where a patient or family had requested to meet with the team and share their experiences.

The review team acknowledge there are significant limitations of carrying out retrospective reviews of clinical notes many years later without speaking to the staff involved and, in many cases, not having direct input from the patients and families themselves. In some cases, the reviews were further impacted by limited clinical information being available for the team to review; for example, absent or incomplete sets of x-ray imaging or medical notes.

The review team have sought to identify and acknowledge harm and issues with care and record them as accurately as possible within the limitations of information available to the review process.

For each patient identified from the initial searches of medical records and other sources, an initial advisory letter was sent.

For all cases that underwent secondary desktop review, a final letter was sent detailing the outcome of the review and offering a meeting with the patients and families to further discuss the findings.

The main themes highlighted from the secondary desktop reviews of patients' hard copy and electronic records are:

- Inadequate consent (36/56 = 64%)
- Misplaced screws (16/56 = 29%)
- Concerns regarding consent and documentation for research trial (7/56 = 13%)
- Concerns regarding duty of candour or competence (7/56 = 13%)
- Wrong operative level (5/56 = 9%)

There was an assessment of physical harm for the 56 cases with completed secondary desktop reviews. Of these the following levels of harm were identified:

- 43 No Harm
- 4 Low/Mild Harm
- 6 Moderate Harm
- 3 Severe Harm
- 0 Catastrophic Harm

Themes that emerged during conversations with patients and families included:

- Families did not always feel fully involved in the decision making regarding the type of treatment/surgery offered.
- Families reported a lack of follow up arrangements and noted that they did not feel supported once the surgical procedures had concluded.
- Patients and families were in some cases unsure if the surgeries had been a ‘success’ and whether the outcome they experienced was as expected. Some described ongoing symptoms and were unsure if these were the result of surgery or could in fact be attributed to their underlying condition.
- Some families and patients who experienced complications following surgery, such as infection, felt unable to discuss their concerns at the time and felt ‘unheard.’
- Some families felt that there was little joined-up community support available, following discharge after surgery.
- Some patients/families were entirely satisfied with the care and treatment received and were ‘delighted’ with the outcome of their procedures. The reviewers also identified evidence of good outcomes; some in very complex cases.

Conclusions:

- The findings of this review highlight concerns with aspects of Spinal Surgeon A’s practice which has contributed to patient harm in a number of cases.
- There are issues relating to consent, information-sharing and pre-operative discussion identified by both patients and families and the review team.
- The majority of the issues and complications experienced by patients including those causing harm were recognised risks of surgery.
- There was no evidence that these issues were reported as ‘incidents’ at the time, or an apology offered to the patient or family even when there was severe harm to a patient.
- This failure may have been influenced by the acknowledgement that these were recognised risks of the procedure undertaken.
- However, this lack of formal acknowledgement of complications may have contributed to a lack of recognition of their frequency or severity arising through the care of Spinal Surgeon A.

- As a senior consultant the majority of Spinal Surgeon A's practice including clinics and operations was independent; and so there was no opportunity for potential scrutiny by an appropriately trained peer.

Recommendations:

- A copy of this report will be shared where appropriate with external stakeholders including the NCA, NHS Resolution (NHSR), the General Medical Council (GMC), Spire Manchester Hospital (private provider where Spinal Surgeon A had practised), Spinal Surgeon A and their Responsible Officer.
- MFT, along with the review team, will consider if any further reviews are required for other patients who have received care under Spinal Surgeon A outside of the time period reviewed, particularly if concerns come to light from other patients and families.
- A summary of the review and its findings will be presented at relevant RMCH and MFT Quality and Safety meetings to ensure learning from the issues highlighted by the report; and assurance provided that all actions have been completed to the Board-level Quality and Performance Scrutiny Committee.
- RMCH will review the clinical governance structure and processes within the paediatric spinal service and ensure that they are aligned to the recently implemented National Patient Safety Incident Response Framework (PSIRF); and assurance provided to the RMCH Quality and Safety Committee and Group Quality and Performance Scrutiny Committee.
- RMCH will review the potential indications for, and implications of, dual consultant operating by spinal surgeons and benchmark current practice against other UK children's hospitals and any national standards.
- The Group Research Governance Committee will oversee and carry out further investigation into the clinical trial identified as part of this review, and the associated research governance.

2 Background

In February 2022, MFT were informed by NCA, that they would be undertaking a Spinal Patient Safety Look Back Review, in relation to the care provided by Spinal Surgeon A who had previously been in their employment.

MFT were informed as Spinal Surgeon A was identified as a clinician who had performed surgery at both the NCA and RMCH under an honorary contract agreement between the Trusts. Spinal Surgeon A worked and performed surgery at the RMCH sites between 1991 and 2011.

Prior to 2009, the services and specialties provided at the existing RMCH were split between two sites, namely Booth Hall Children's Hospital and Royal Manchester Children's Hospital, Pendlebury. For the remainder of this document the term 'Royal Manchester Children's Hospital' will be used in reference to children's services as a whole, at the two historic sites and the current Oxford Road site.

The NCA advised that from their perspective, the concerns raised mainly focused on probity, the professional practice of the individual and potential harm to patients.

In light of these significant concerns, and the fact that Spinal Surgeon A had performed surgery on children, the senior leadership team (SLT) at RMCH were fully briefed on the review and agreed that a similar Spinal Safety Look Back was required for patients operated on at RMCH.

Early contact was made with the NCA governance and legal teams, to better understand the processes being utilised for their Look Back, their initial findings and to request that the documents and process used for their review were shared with RMCH.

Detailed consideration was given to the most suitable format for the patient reviews and appropriate timescales of cases for review. It was noted that there would be challenges around reviewing patients who were now adults, and that bringing each patient back for clinical review within a children's hospital setting was neither possible nor appropriate. It was also noted that there are inherent challenges in reviewing historical medical records and that depending on the length of time since the patient's care, some elements such as paper case notes may be

archived or destroyed in line with NHS Records Management Code of Practice; or not easily accessible or in a suitable condition to be reviewed (e.g., x-rays on film).

The terms of reference set out in section 3 of this report reflect the agreed approach with RMCH SLT prior to starting the review.

Contact was made with NHSR prior to starting the review to ensure they were fully aware that RMCH would be conducting such a review, and to establish regular contact to ensure transparency with the findings of the patient reviews.

The NCA published the report detailing their Spinal Patient Safety Look Back Review on 31 July 2023, which was during the time period the RMCH review was ongoing.

3 Terms of Reference

The RMCH Spinal Safety Look Back Review formally began on 22 May 2023. Full time administrative and project management support was provided by the RMCH Quality Governance Team Leader. Clinical leadership and oversight was provided by the RMCH Associate Medical Director for Quality and Safety.

The team set out to review patients identified through the following criteria:

- Had instrumental spinal surgery under Spinal Surgeon A between 1 January 2006 and 31 December 2011
- Additional patients outside of the time period above identified via
    - NCA: patients included in their review but who were also operated on at RMCH
    - RMCH Spinal Surgeons raising concerns regarding specific cases
    - PALS and formal complaints
    - Legal claims
    - Incidents
    - Patients or families contacting RMCH or the review team directly with concerns regarding care

The time period during which cases would be identified for review was selected:

- with acknowledgement that reviewing care pre-2006 would be limited due to records availability
- to include the years covering the majority of the concerns identified from the NCA report
- to include the final years of employment of Spinal Surgeon A at RMCH.

Searches were undertaken of legal claims and incidents relating to spinal surgery under Spinal Surgeon A. Other sources such as Patient Advice and Liaison Service (PALS) concerns, complaints and direct patient contact were used to ensure that if there were any concerns raised, via any known source, that the relevant patient's care was reviewed.

It was acknowledged that extension of this time period and/or further reviews outside of this may be required if further information came to light.

Each patient's case was reviewed using the methodology outlined in section 5 of this report.

The key aims of the review process were to consider for each patient's clinical care:

- if the management was appropriate
- whether there was any evidence of physical harm relating to issues with care
- if there were specific issues, themes and trends relating to Spinal Surgeon A's clinical and professional practice.

4 Membership

Membership of the RMCH Spinal Safety Look Back Review Team included:

- Associate Medical Director for Quality and Safety Royal Manchester Children's Hospital and the Senior Responsible Officer for the RMCH Spinal Safety Look Back Review
- Medical Director, Royal Manchester Children's Hospital with overall oversight of the Spinal Safety Look Back Review
- Quality Governance Team Lead, Royal Manchester Children's Hospital responsible for project management and patient/family liaison
- Assistant Director of Quality Governance and Patient Experience, Royal Manchester Children's Hospital with Quality Governance oversight of the Spinal Safety Look Back Review

- RMCH Spinal Surgery Team
- Two Consultant Spinal Surgeons from outside MFT acting as independent clinical experts.

5 Methodology: Information and evidence gathered

5.1 Identification of patients, data searches and case note recall

The informatics team supported the Spinal Safety Look Back Review team in searching a variety of sources to identify possible patients who had instrumental spinal surgery under Spinal Surgeon A between 1 January 2006 and 31 December 2011 inclusive.

These included searches of:

- Admitted patient care (APC) episodes under Spinal Surgeon A
- Theatre activity under Spinal Surgeon A
- Coding information from case notes indicating care under Spinal Surgeon A

Additional patients were identified through the following criteria:

- NCA: patients included in their review but who were also operated on at RMCH
- RMCH Spinal Surgeons raising concerns regarding specific cases
- PALS and formal complaints
- Legal claims
- Incidents
- Patients or families contacting RMCH or the review team directly with concerns regarding care.

A master database was set up with all patients identified to allow tracking of progress throughout the review process and to track communication with patients and families.

The remainder of this section outlines the stages of the process through which cases could potentially progress, and the methods used at each stage. An overall flowchart with the numbers of patients at each stage and the outcome of the reviews is detailed in section 7 of this report.

5.2 Administrative review

Hard copy case notes were requested from storage for all potential patients identified via any of the methods above. An administrative review was then carried out by the Quality Governance Team Leader and the medical records team to cross reference hard copy and electronic sources of information and ensure that the patient was appropriately identified in line with the terms of reference of the review.

It was identified in a number of cases that the patient's case did not fit with the terms of reference of the review and should be excluded.

Reasons for this included:

- A patient being admitted under Spinal Surgeon A but not having an operation or instrumental procedure.
- A patient being admitted under Spinal Surgeon A for a minor, non-instrumental procedure e.g., fitting of a spinal jacket.
- A patient documented in one source as being operated on by Spinal Surgeon A but a review of the case notes and operation note confirming the procedure was in that instance performed by a different Spinal Surgeon.

For the patients whose care did fall under the terms of reference of the review, the notes were prepared in advance for the next stage of the review process, the primary review. This included ensuring that where possible appropriate and relevant aspects of the medical records were available and clearly labelled including operation notes, consent forms, x-rays and medical illustration images.

There were some patients for whom there was insufficient information available to proceed with a review. This was the case for a limited number of patients whose case note records had been lost or destroyed in line with NHS Records Management Code of Practice.

There were also patients for whom there was limited or no x-ray imaging particularly pre-operatively, and this significantly limited the conclusions that could be drawn from the review of the patient’s clinical care.

5.3 Primary review with spinal surgeon

Following administrative review, case notes of patients included in the review were passed on to the RMCH spinal surgeons for a clinical 'primary review'. The primary review included reviewing hard copy medical case notes and x-rays, and information available on electronic patient record systems including electronic imaging.

Any potential clinical concerns or concerns regarding patient harm were noted; and if there were any concerns identified the case was highlighted as needing to proceed to the next stage of the process comprising a more detailed review including external scrutiny ('secondary desktop review').

Any patients for which there had already been concerns raised by any route automatically proceeded to a 'secondary desktop review'.

5.4 Secondary desktop reviews with independent expert reviewer

A series of multi-disciplinary team (MDT) meetings were arranged including an independent expert to review each patient's care in detail. The two independent experts used are experienced paediatric spinal surgeons from specialist UK children's hospitals. Both experts offer impartiality, with no conflict of interest declared or identified. In addition, neither expert has been employed by or worked in RMCH. One of the experts had experience of supporting the NCA spinal review.

The secondary desktop review team noted concerns raised and feedback from patients and families regarding their experience, either from meetings with patients and families or from telephone or written communication. Any relevant incidents, complaints or legal claims and their findings were also noted.

The hard copy case notes including written medical records, consent form and operation notes were reviewed alongside electronic information including x-ray imaging and clinic letters.

The structure and proforma used for these reviews followed a structured judgement approach with assessments of each aspect of the patient's care and management focusing on:

- Pre-operative planning

- Consent
- Surgery
- Post-operative care
- Follow up

Each element was assessed and recorded in detail to capture issues with an individual patient's care and to identify any recurring themes throughout the overall review process.

There was an overall assessment of any identified harm attributable to issues with care. The level of harm was assessed and agreed in line with the current MFT governance process and patient safety incident matrix.

5.5 Definitions of harm and duty of candour

In line with national NHS practice MFT assesses the degree of physical harm from any patient safety incident. The degree of harm relates to the actual impact on a patient from the particular incident or issue with care rather than the potential for harm.

The following grading system for physical harm was used

1. No harm
2. Low/mild harm
3. Moderate harm
4. Severe harm
5. Catastrophic harm/fatal

For this review harm was recorded if there was physical harm that was considered to result directly from an issue with care identified as part of the review. The review team acknowledge that some patients may have experienced complications of surgery that may be distressing and require additional interventions and hospital care. However, these complications have not been recorded as harm in this context unless the reviewer considered they were directly related to sub-optimal care determined to have been causative.

All patients were sent letters following completion of their review. In cases where harm has been identified appropriate NHS and MFT duty of candour processes have been followed to

ensure any concerns highlighted by the review have been shared openly and honestly with patients and families.

5.6 Meetings with patients and families

The RMCH Spinal Safety Look Back Review team considered it to be very important that patients' and families' voices were heard, listened to and reflected in the reviews. This gives a different perspective from the review of medical records and is in line with MFT's adoption of the new national NHS Patient Safety Incident Response Framework (PSIRF).

It was acknowledged that it would not be possible within the scope and timescale of the review to meet with every patient and family. However, an appropriate meeting was arranged in every case where a patient or family had requested to meet with the team and share their experiences.

These meetings were attended by the Assistant Director for Quality Governance and Patient Experience and the Quality Governance Team Leader. The purpose of these meetings was not to discuss in depth the clinical detail of the patient's care, but to hear and learn from the patients and families regarding their experience of care at RMCH under Spinal Surgeon A.

The RMCH Spinal Safety Look Back review team would like to sincerely thank the patients and families for their time, insight and honesty in sharing their experiences; and to acknowledge that doing so may have caused additional distress.

5.7 Clinical patient recall

For any patients identified by the secondary desktop review process as having potential ongoing clinical concern, it was checked whether they had existing spinal follow up. If they did not and there was a need for a clinician review or further investigations, then this was arranged promptly.

5.8 Limitations and declarations

The review team acknowledge there are significant limitations of carrying out retrospective reviews of clinical notes many years later without speaking to the staff involved and, in many cases, not having direct input from the patients and families themselves. In some cases, the reviews were further impacted by limited clinical information being available for the team to review; for example, absent or incomplete sets of x-ray imaging or medical notes.

The review team have sought to identify and acknowledge harm and issues with care and record them as accurately as possible within the limitations of information available to the review process.

It is acknowledged it is particularly difficult to comment when information is absent, or to be aware of discrepancies in accounts unless they are clear from review of the case notes. This is particularly relevant to issues such as consent, where what is documented is part of a process that involves an in-depth discussion with a patient and their family.

The review team also acknowledge that it is not possible for them to accurately comment on or quantify patients' and families' experience of care and/or the potential psychological impact of any issues encountered with their care and treatment.

6 Communication with patients and families

For each patient identified from the initial searches of medical records and other sources, an initial advisory letter was sent. These letters were sent from the RMCH Chief Executive to the patient or to the next of kin where appropriate, to inform them that a review was taking place, that their care would be reviewed as part of this but that there was no immediate concern or actions that they needed to take. Contact details (telephone number and email address) for the RMCH Spinal Safety Look Back Review team were provided to ensure that any concerns or queries from patients and families could be promptly and appropriately addressed.

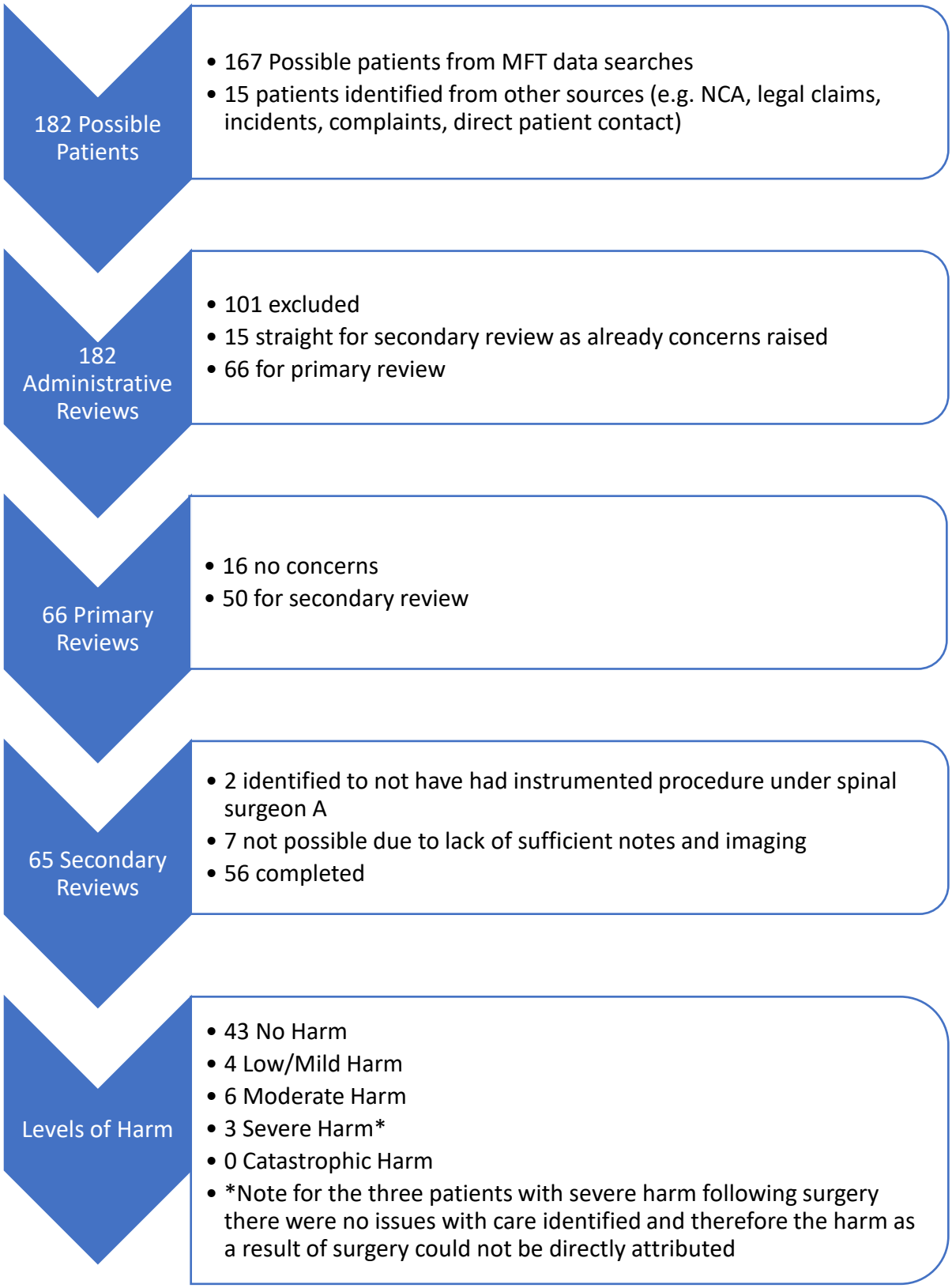
Follow up letters were sent to patients and families during the review process to either provide reassurance that their care did not require further review, or to keep in touch and inform them that their case was still moving through the review process. In order to provide clarification to

patient and families, a further letter was sent informing them that Spinal Surgeon A had not worked at RMCH (or MFT) after 2011.

For all cases that underwent secondary desktop review, a final letter was sent detailing the outcome of the review and offering a meeting with the patients and families to further discuss the findings.

Appropriate statutory duty of candour guidance was followed as detailed in section 5.5 of this report.

7 Findings


182 Possible Patients
• 167 Possible patients from MFT data searches
• 15 patients identified from other sources (e.g. NCA, legal claims, incidents, complaints, direct patient contact)
182 Administrative Reviews
• 101 excluded
• 15 straight for secondary review as already concerns raised
• 66 for primary review
66 Primary Reviews
• 16 no concerns
• 50 for secondary review
65 Secondary Reviews
• 2 identified to not have had instrumented procedure under spinal surgeon A
• 7 not possible due to lack of sufficient notes and imaging
• 56 completed
Levels of Harm
• 43 No Harm
• 4 Low/Mild Harm
• 6 Moderate Harm
• 3 Severe Harm*
• 0 Catastrophic Harm
• *Note for the three patients with severe harm following surgery there were no issues with care identified and therefore the harm as a result of surgery could not be directly attributed

7.1 Themes

The main themes highlighted from the secondary desktop reviews of 56 patients' hard copy and electronic records are:

Inadequate consent (36/56 = 64%)

- In a large number of cases there was inadequate evidence of consent.
- The pre-operative clinic letters often did not outline or detail specific risks or the expected outcomes of the surgery. Where there was more than one potential approach to their treatment, it was not always clear if these options had been explained to the patients and families.
- The written consent forms only listed a few risks and were frequently missing critical risks such as curve progression, failure of metalwork and the need for further surgery.
- For more complex cases, particularly children with significant medical problems, additional risks, or increased risk of certain complications, were not reflected on the consent form or in the pre-operative clinic letters.
- Whilst the review team acknowledge that standards for consent have changed over the years and the standards expected now are higher, they still considered that the issues identified fell below reasonably expected standards for the time.

Misplaced screws (16/56 = 29%)

- There were a number of patients in which there were screws that were found to be misplaced, malpositioned or too long.
- The frequency of this finding was felt to be higher than that typically expected[1, 2] and it was the opinion of the review team that this may reflect issues with intra-operative care and attention to screw placement during the procedure.
- Three of these patients had to have additional operations for screw removal as it was felt the screws posed a significant potential risk.

Concerns regarding consent and documentation for research trial (7/56 = 13%)

- There were several patients who had novel metalwork implanted as part of a clinical research trial.

- Not all of these patients had a consent form in their case notes and the consent form did not detail the potential risks of the novel metalwork.
- There is reference in the consent form to a patient information leaflet but there is no documentation to support that these were given to patients and families.
- Two of these patients had a break in their metalwork requiring additional operations.

Concerns regarding duty of candour or competence (7/56 = 13%)

- There were several cases in which apparent issues either intra-operatively or post-operatively did not appear to have been appropriately documented as being recognised or discussed with the patients or families.
- The review team believe this reflects either a lack of appropriate duty of candour and being open and honest with patients and families; or alternatively could reflect a lack of appropriate competence to recognise the issues noted by the review team.

Wrong operative level (5/56 = 9%)

- There were 5 cases in which the wrong operative level (how far down the spine the attached metalwork is extended) appeared to have been chosen based on the patient's spinal curvature.
- This could potentially reflect either poor pre-operative planning or poor care intra-operatively.

7.2 Identified harm

There was an assessment of physical harm for the 56 cases with completed secondary desktop reviews. Of these the following levels of harm were identified:

- 43 No Harm
- 4 Low/Mild Harm
    - These included cases of patients requiring additional care such as additional imaging
- 6 Moderate Harm

- These were cases where issues identified with the care provided by Spinal Surgeon A contributed to complications and additional operations being required, with an associated increased length of hospital stay for each procedure.
- The complications occurring were recognised risks of surgery but there was not always evidence that they had been discussed with the patient and family during the consent process.
- The review team could not find evidence that these were incident-reported or that an apology was offered to the patient or family.

- 3 Severe Harm
  - These were cases where patients were left with on-going significant neurological issues as a result of surgery. However, in all 3 cases, the outcome could not be directly attributed to the care of Spinal Surgeon A.
  - It is noted that in one of these cases there was limited information available to review including a lack of available pre-operative x-ray images.
  - Two of these cases have been the subject of legal claims and in both cases the judgment was found in favour of MFT.
  - Nerve damage and paralysis are recognised risks of spinal surgery and were shared with the patients and families during the consent process.
  - The review team could not find evidence that these were incident-reported or that an apology was offered to the patient or family.
- 0 Catastrophic Harm

7.3. Summary of issues identified by patients and families

The Patient Voice

MFT recognises the importance of the patient voice. By hearing first-hand accounts of patient and family experiences, we are able to learn, grow and most importantly, place patients at the heart of the healthcare we provide now and in future.

MFT extended an open offer to all patients and families to speak with us and share their recollections of the spinal surgery that they or their loved ones experienced. Although this care and treatment was provided many years ago, it is clear that for some, the experience remains fresh in the memory and was distressing to recall. The reviewers would like to express their gratitude to those that met or spoke with us to share their stories and to help us to understand their experience.

Below, we outline some of the themes that emerged during our conversations.

- Families did not always feel fully involved in the decision making regarding the type of treatment/surgery offered. This included perceived delays to surgery which they did not feel were fully explained and which some felt may have contributed to significant deterioration of their loved one.
- Families reported a lack of follow up arrangements and noted that they did not feel supported once the surgical procedures had concluded.
- Patients and families were in some cases unsure if the surgeries had been a ‘success’ and whether the outcome they experienced was as expected. Some described ongoing symptoms and were unsure if these were the result of surgery or could in fact be attributed to their underlying condition.
- Some families and patients who experienced complications following surgery, such as infection, felt unable to discuss their concerns at the time and felt ‘unheard.’
- Some families felt that there was little joined-up community support available, following discharge after surgery.

Manchester University NHS FT would like to apologise for the experiences described and to assure patients and families that the information they have provided will be used to improve

care and treatment provided in future, particularly in relation to improving communication and engagement with patients and families.

Lastly, it is important to note that some patients/families were entirely satisfied with the care and treatment received and were ‘delighted’ with the outcome of their procedures. The reviewers also identified evidence of good outcomes, some in very complex cases, and many families expressed their gratitude for the service they received generally from the medical and nursing teams involved in their care and treatment.

8 Data sharing and communication

Meetings were held with the NCA spinal review and governance teams prior to commencing the RMCH review. These meetings ensured the RMCH spinal review team had a clear understanding of the concerns, issues and process for the NCA review.

A data sharing agreement is in place between MFT and the NCA; where relevant and appropriate, patient records and information have been requested and shared.

NHSR have been kept up to date regarding the commissioning of the RMCH review and progress during the review. Findings will be appropriately shared with them following appropriate communication with patients and families.

RMCH senior leadership team, MFT Group Executives, the legal team and communications team have been kept up to date with the overall progress of the review throughout.

9 Summary of Findings

- RMCH have carried out a review of patients who underwent instrumental procedures under the care of Spinal Surgeon A between 2006 and 2011, plus any other patients of Spinal Surgeon A about whom there had been concerns raised by any other route. This included incidents, complaints, legal claims and direct contact from patients and families.
- 56 cases were reviewed in detail by a multi-disciplinary team including an external expert reviewer.

- 6 patients were found to have suffered moderate harm and required additional operations, the harm being contributed to by issues with Spinal Surgeon A's care.
- 3 patients were found to have suffered severe harm as a result of their operations. However, the outcome could not be directly attributed to the care of Spinal Surgeon A.
- The issues occurring were recognised risks of complex procedures and do not appear to have been reported as patient safety incidents at the time.
- There were recurring themes identified across the cases reviewed, including inadequate consent, misplaced screws, concerns regarding research governance and consent, inappropriate operative level and concerns regarding duty of candour in acknowledging issues had occurred.
- Themes identified by patients and families included a lack of involvement in decision making, inadequate explanation of risks and expected outcomes, feeling 'unheard' by Spinal Surgeon A and a lack of follow up support.

10 Conclusions and lessons to be learned

- The findings of this review highlight concerns with aspects of Spinal Surgeon A's practice which have contributed to patient harm in a number of cases.
- There are issues relating to consent, information-sharing and pre-operative discussion identified by both patients and families and the review team.
- The majority of the issues and complications experienced by patients including those causing harm were recognised risks of surgery.
- There was no evidence that these issues were reported as 'incidents' at the time, or an apology offered to the patient or family even when there was severe harm to a patient.
- This failure may have been influenced by the acknowledgement that these were recognised risks of the procedure undertaken.
- However, this lack of formal acknowledgement of complications may have contributed to a lack of recognition of their frequency or severity arising through the care of Spinal Surgeon A.
- As a senior consultant the majority of Spinal Surgeon A's practice including clinics and operations was independent, and so there was no opportunity for potential scrutiny by an appropriately trained peer.

11. Recommendations and next steps

- All patients and families have been sent summary letters outlining the outcome of their reviews.
- Clinical follow up has been arranged if required.
- Duty of candour letters have been sent to patients and families for whom there have been findings of moderate or severe harm, and meetings offered to discuss the findings in more detail.
- A copy of this report will be shared where appropriate with external stakeholders including the NCA, NHSR, the GMC, Spire Manchester Hospital (private provider where Spinal Surgeon A had practised), Spinal Surgeon A and their Responsible Officer.
- MFT, along with the review team, will consider if any further reviews are required for other patients who have received care under Spinal Surgeon A outside of the time period reviewed, particularly if concerns come to light from other patients and families.
- A summary of the review and its findings will be presented at relevant RMCH and MFT Quality and Safety meetings to ensure learning from the issues highlighted by the report; and assurance provided that all actions have been completed to the Board-level Quality and Performance Scrutiny Committee.
- RMCH will review the clinical governance structure and processes within the paediatric spinal service and ensure that they are aligned to the recently implemented National Patient Safety Incident Response Framework (PSIRF); and assurance provided to the RMCH Quality and Safety Committee and Group Quality and Performance Scrutiny Committee.
- RMCH will review the potential indications for, and implications of, dual consultant operating by spinal surgeons and benchmark current practice against other UK children's hospitals and any national standards.
- The Group Research Governance Committee will oversee and carry out further investigation into the clinical trial identified as part of this review, and the associated research governance.

Appendices

Appendix 1 - Terms of Reference

<table>
<tr><td colspan="2">Terms of Reference

Spinal Patient Safety Look Back Exercise</td><td rowspan="3">Royal Manchester Children’s Hospital, part of Manchester Foundation Trust</td></tr>
<tr><td colspan="2">Authors Name:</td></tr>
<tr><td colspan="2">Contact Name:</td></tr>
<tr><td colspan="2">Contact Phone No:</td><td></td></tr>
<tr><td colspan="2">Scope:</td><td>Classification: Terms of Reference</td></tr>
<tr><td colspan="2">Keywords: Moderate Harm, Investigation, Serious Incidents</td><td>Replaces: Null</td></tr>
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<tr><td colspan="2">To be Authorised by:</td><td>Authorisation Date:</td></tr>
<tr><td colspan="3">Document for Public Display: No</td></tr>
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1.0 Definition

1.1 The Spinal Patient Safety Look Back Review is established to investigate and manage potential Serious Incidents caused by the errors attributed to clinics, surgery and/or consultation sunder taken by one Consultant Spinal Surgeon between 1991 and 2011

1.2 Concerns have been raised regarding the Consultant Spinal Surgeon's clinical practice.

1.3 Harm is defined in the National Reporting and Learning System and set out in the Trust Serious Incident Management Policy as below.

Level of Harm	NRLS	Level of response
No Harm / Near Miss	**No harm (Impact prevented)** – Any patient safety incident that had the potential to cause harm but was prevented, resulting in no harm to people receiving NHS- funded care. This may be locally termed a **'near miss'.** **No harm (impact not prevented)** - Any patient safety incident that ran to completion, but no harm occurred to people receiving NHS funded care.	Duty of Candour does not apply.
Low Harm	**Low (Minimal harm - patient(s) required extra observation or minor treatment)** Any unexpected or unintended incident that required extra observation or minor treatment and caused minimal harm to one or more persons receiving NHS-funded care.	Open discussion between the staff providing the patient's care and the patient and/or their carers. The core principles of openness, transparency and candour will apply.
Moderate Harm	**Moderate (short term harm – patient(s)required further treatment or procedure)** Any unexpected or unintended incident that resulted in a moderate increase in treatment, possible surgical intervention, cancelling of treatment, or transfer to another area, and which caused significant but not permanent harm, to one or more persons receiving NHS-funded care.	These are Notifiable patient safety incidents* that have caused significant harm to a patient/ service user and statutory Duty of Candour applies.
Severe Harm	**Severe (Permanent or long-term harm)** Any unexpected or unintended incident that appears to have resulted in permanent harm to one or more persons.	
Death	**Death (Caused by the Patient Safety Incident)** Any unexpected or unintended incident that directly resulted in the death of one or more persons.	

2.0 Scope

2.1 All patients who:

2.1.1 had instrumental surgery under the Consultant Spinal Surgeon in the 5-year period from 2006 – 2011, or have been identified to have:

- Had subsequent surgery.
- New information.
- Self-identified.
- Brought litigation action.
- Brought a complaint
- Have had an inquests

Patients are to be reviewed to ascertain whether their management was appropriate, whether any harm is identified that requires further assessment and to identify whether there are any concerns regarding the Consultant Spinal Surgeon's probity or shortcomings in duty of candour that need to be rectified.

2.2 The result of the initial review outlined above will determine the widening of the scope of the review.

3.0 Key Responsibilities and Duties

To provide assurance that:

3.0 Harm levels will be clinically validated and declared in line with Trust policy, (entered on Strategic Executive Information System StEIS where required) and may be escalated or de- escalated as appropriate following investigation.

3.1 Duty of Candour requirements are met for all related Serious Incidents, complaints, and claims.

3.4 All potential patients that are highlighted as requiring review and or clinical escalation will be referred to Spinal Services at the Northern Care Alliance to determine if they should be booked and scheduled into a clinic as they will no longer be appropriate to be reviewed in RMCH.

3.5 The progress of investigations and actions arising from both the meeting and outside communications will be monitored.

3.6 Following the Spinal Patient Safety Look Back Review, patients with confirmed harm will be investigated as per the Organisation's incident procedures and a log maintained to monitor progress at this group.

4.0 Frequency of Meetings

4.1 The Spinal Patient Safety Look Back Review Meetings will take place monthly. The First formal meeting will be held in March 2023.

4.2 All members are requested to attend the meetings to engage and ensure progress, alternatively, if attendance is not possible then a deputy is to be agreed and sent as a replacement.

4.3 Deputy attendees must be able to contribute to the investigations and actions update.

5.0 Membership

5.1 Membership of the Spinal Patient Safety Look Back Review Meeting will consist of:

- Associate Medical Director, Q&S RMCH, **Chair**
- Assistant Director of Quality Governance and Patient Experience.
- Medical Director **(Deputy Chair)**
- Head of Legal Services
- Consultant Spinal Surgeons
- Representation from Hill Dickinson

6.0 Chairmanship

6.1 The Chair will be the RMCH Associate Medical Director for Quality and Safety. The RMCH Medical Director will deputise as Chair when the Chair is unable to a**t**tend.

7.0 Management

The Project Manager will ensure:

1. Creation and management of the action plan.
2. Follow up and collation of all action plan updates.
3. Creating and maintaining monitoring reports to manage progress of harm incidents, providing reports as required for escalation.

8.0 Quorum

8.0 A minimum of one member from each staff group is required for the Spinal Patient Safety Look Back Review Meeting to take place, as follows.

- Chair
- Project Manager
- Consultant Spinal Surgeons

9.0 Reporting Arrangements

9.1 Progress of the Spinal Patient Safety Look Back Review will be reported to:

1. Weekly RMCH Quality and Safety Panel.
2. Monthly Divisional Quality and Safety meeting.
3. Monthly RMCH Quality and Safety meeting.
4. Group Quality and Safety Meeting – as required.

Appendix 2 - Primary Review form

Spinal Patient Safety Look Back Review Desktop Review				
Review conducted by				
Patient Name				
Hospital ID				
Date of procedure				
Was this an instrumented procedure	Yes	No		
Is there a minimum of 2 years follow-up	Yes	No		
Was there a negative outcome	Yes	No		
	Failure to achieve desired outcome i.e., pain relief or deformity correction			
	Complication (early or late)			
	Adverse event			
	Return to theatre or need for additional procedure not routinely anticipated			
	Post-operative failure including implant failure			
	Death			
Are there any other clinical concerns	Yes	No		
Details of clinical concerns				
Are there concerns of ongoing harm, surgical failure, or negative outcome	Yes	No		
Are there any concerns related to record keeping or documentation?	Yes	No		
(Including significant variations in events recorded by JBW and others, patients, radiology, or incomplete records)				
Details of concerns related to record keeping or documentation				
Concerns regarding probity	Yes	No		
Is a full review needed for this case (yes to any question)	Yes	No		

Appendix 3 - Secondary desktop review form

Spinal Patient Safety Look Back Review Clinical Review				
Patient Name				
Hospital ID				
Diagnosis				
Primary Procedure				
Date of procedure				
Subsequent procedures	a			
	b			
	c			
	d			
	e			
Awaiting further procedure to spine		Yes	No	
Structured Review of Care				
Pre-operative care				
Pre-operative care score				
Operative care				
Operative care score				
Immediate inpatient post-operative care				
Immediate inpatient post-operative care score				
Outpatient post-operative care				
Outpatient post-operative care score				
Documentation:				
Documentation score				

Governance:			
Governance score			
Duty of Candour:			
Duty of Candour score			
Patient's comments or concerns, if any, with the care they have received:			
Negative outcome	Yes	No	
Level of Harm			
	No harm / Near miss		
	Low harm		
	Moderate harm		
	Severe harm		
	Death		
Evidence of ongoing harm or negative outcome requiring further clinical review	Yes	No	
Recurring Themes Identified			
	Concerns regarding duty of candour/being open and honest		
	Inadequate consent		
	Research Patient		
	Other Issues with pre operative care or planning		
	Issues with operative care		
	Misplaced Screw		
	Missing/Inadequate Operation Note		
	Inaccurate or inconsistent documentation		
	Issues with post operative care		
	Professional concerns (conduct, communication, behaviour)		
Additional comments:			

Appendix 4 - Definitions of harm

LOW/MILD PHYSICAL HARM

Low physical harm is when all of the following apply:

- minimal harm occurred – patient(s) required extra observation or minor treatment
- did not or is unlikely to need further healthcare beyond a single GP, community healthcare professional, emergency department or clinic visit
- did not or is unlikely to need further treatment beyond dressing changes or short courses of oral medication
- did not or is unlikely to affect that patient's independence
- did not or is unlikely to affect the success of treatment for existing health conditions.

MODERATE PHYSICAL HARM

Moderate harm is when at least one of the following apply:

- has needed or is likely to need healthcare beyond a single GP, community healthcare professional, emergency department or clinic visit, and beyond dressing changes or short courses of medication, but less than 2 weeks additional inpatient care and/or less than 6 months of further treatment, and did not need immediate life-saving intervention
- has limited or is likely to limit the patient's independence, but for less than 6 months
- has affected or is likely to affect the success of treatment, but without meeting the criteria for reduced life expectancy or accelerated disability described under severe harm.

SEVERE PHYSICAL HARM

Severe harm is when at least one of the following apply:

- permanent harm/permanent alteration of the physiology
- needed immediate life-saving clinical intervention
- is likely to have reduced the patient's life expectancy

- needed or is likely to need additional inpatient care of more than 2 weeks and/or more than 6 months of further treatment
- has, or is likely to have, exacerbated or hastened permanent or long term (greater than 6 months) disability, of their existing health conditions
- has limited or is likely to limit the patient's independence for 6 months or more.

CATASTROPHIC HARM/FATAL

When a patient has died and an incident or issue with care may have contributed to the death

Appendix 5 - References

1. Kosmopoulos, V, Schizas, C. (2007) ‘Pedicle Screw Placement Accuracy, A Meta-analysis’, *Spine*, 32(3), pages E111-E120.
2. Perdomo-Pantoja, A et al. (2019) ‘Accuracy of Current Techniques for Placement of Pedicle Screws in the Spine: A Comprehensive Systematic Review and Meta-Analysis of 51,161 Screws’, *World Neurosurgery*, Volume 126, pages 664-678.