Northern Care Alliance
NHS Foundation Trust

A report for the Northern Care Alliance NHS Foundation Trust

Spinal Patient Safety Look Back Review ("SPSLBR")

Alistair Craig, Senior Responsible Officer for the SPSLBR

Contents **Page**

Appendices

1. Introduction

1.1. Summary

In 2021, a multi-professional staff support group was established under the Northern Care Alliance NHS Foundation Trust's Freedom to Speak Up process which raised new questions and concerns around the probity and clinical standards of a Consultant Spinal Surgeon ("Consultant Spinal Surgeon A") whilst they were employed at Salford Royal NHS Foundation Trust (now part of the Northern Care Alliance NHS Foundation Trust) ("the Trust"). As a result, the Trust commissioned the Spinal Patient Safety Look Back Review ("SPSLBR") and Investigation Group to evaluate these concerns, including obtaining independent expert advice.

In January 2022, the Trust commenced the SPSLBR to investigate and manage patient safety concerns raised in respect of Consultant Spinal Surgeon A who was employed at Salford Royal NHS Foundation Trust (now part of the Northern Care Alliance NHS Foundation Trust) between 1991 and January 2015.

This report outlines the investigation carried out by the SPSLBR Investigation Group on behalf of the Trust to investigate and manage potential Serious Incidents ("SI") caused by the errors and omissions attributable to clinics, surgery and/or consultations undertaken by Consultant Spinal Surgeon A within the scope identified in the Terms of Reference.

1.2. Background

Consultant Spinal Surgeon A was employed at the Trust between 1991 and January 2015 as a Consultant Spinal Surgeon. Between 2011 and 2015, they were the Head of Division for Neurosciences & Renal Medicine. They also held external roles with the Royal College of Surgeons acting as an examiner and an assessor and was part of their review team. They were previously the President of the British Scoliosis Society and had served on their executive committee.

In August 2014, an anonymous whistleblower contacted Salford Royal NHS Foundation Trust (now known as the Northern Care Alliance NHS Foundation Trust), General Medical Council ("GMC"), Care Quality Commission ("CQC") and Sir Robert Francis then QC, now KC, (a barrister who has chaired several high-profile medical inquiries) with concerns about Consultant Spinal Surgeon A. The letter from the anonymous whistleblower described a number of areas of concern relating to Consultant Spinal Surgeon A's behaviour, conduct, probity and capability.

An investigation was opened in response and the GMC were notified of the Trust's response to the letter.

Consultant Spinal Surgeon A was dismissed from the Trust in January 2015. This decision was appealed and heard in July 2015, but the appeal was unsuccessful. At the time of their dismissal, Consultant Spinal Surgeon A was the Chair of the Neurosciences Division, a position they had held since May 2011. Prior to this, the Investigation Group understands that Consultant Spinal Surgeon A was the Clinical Lead for Spinal Surgery at the Trust from 2005.

Consultant Spinal Surgeon A has not worked for the Trust since January 2015. It is understood that during the time they were employed by the Trust, they also worked at Royal Manchester Children's Hospital (now managed by Manchester University NHS Foundation Trust ("MFT")). It is understood that Consultant Spinal Surgeon A also enjoyed practising privileges at Spire Manchester Hospital, a private healthcare provider.

In September 2015, the Trust contacted the Royal College of Surgeons to request an Invited Service Review of the Trust's spinal surgery service and to undertake a clinical review of 10 clinical records relating to patients at the Trust who had been under the care of Consultant Spinal Surgeon A[1].

The Royal College of Surgeons visited the Trust in December 2015. Their Invited Service Review report identified no significant concerns regarding current safety of spinal surgery at Salford Royal Hospital (then known as Salford Royal Hospital NHS Foundation Trust). Their case note clinical review concluded that:

> *"there were no overall concerns about the standard of care provided to the patients that formed part of the review, although a series of complications were acknowledged. From the information present in the clinical records, it appears that the way in which the complications were managed once identified was appropriate in each case."*

In 2016, an internal request was made to review 17 patients to determine if any required either a clinical follow up or an appointment to determine possible preventable harm. The SPSLBR has been unable to determine if this progressed as the review did not follow the usual governance processes and at the time of producing this report, it has not been possible to determine why this was the case.

In 2021, a multi-professional staff support group was established under the Trust's Freedom to Speak Up process which raised new questions and concerns around the conduct, probity and capability of Consultant Spinal Surgeon A whilst they were employed by the Trust. This group raised concerns directly with the Trust Chief Executive and following this, the concerns were

[1] One of the ten cases fell outside the scope of the SPSLBR Terms of Reference as when reviewed, it was identified that Consultant Spinal Surgeon A was involved in obtaining a radiology review as part of a post incident investigation. The SPSLBR could not identify any evidence that Consultant Spinal Surgeon A was involved clinically.

triangulated, leading to the realisation that clinical notes cannot be taken as accurate and correct, and emerging themes were identified with specific concerns around Consultant Spinal Surgeon A's conduct, probity and capability whilst they were employed by the Trust. As a result, in January 2022, the Trust commissioned the SPSLBR Investigation Group to investigate these concerns.

Dr Chris Brookes, the then Chief Medical Officer and Deputy Chief Executive (also known colloquially as the Chief Doctor), was appointed to oversee the SPSLBR investigation as Senior Responsible Officer and act as a direct link to the Trust's Group Risk and Assurance Committee (now known as the Quality Performance Committee) and the Trust's Board. Dr Alistair Craig, interim Chief Medical Officer took over this role in December 2022 following Dr Brookes' retirement.

The SPSLBR Investigation Group was formed and expert advice from the Independent Expert Reviewer was commissioned. Informal weekly and formal monthly meetings were arranged and the Terms of Reference and membership for the SPSLBR investigation were agreed. The first formal meeting was held on 23 February 2022 and monthly meetings were held thereafter. The final formal meeting was held on 15 March 2023.

Spire Manchester and MFT (which now manages Royal Manchester Children's Hospital) are conducting their own investigations. Regular liaison has taken place with those organisations throughout the SPSLBR to ensure information sharing. They were informed that the Trust was undertaking the SPSLBR on 25 February 2022.

2. Terms of Reference

All patients who:

a. Had instrumental surgery under the Consultant Spinal Surgeon [Consultant Spinal Surgeon A] in the 5-year period from August 2009 – September 2014, or

b. Have been identified to have:

i. Had subsequent surgery;
ii. New information;
iii. Subsequently been seen in clinic;
iv. Self-identified;
v. Brought litigation action;
vi. Brought a complaint;
vii. Had an inquest; and/or
viii. Had subsequent AIRs [Adverse Incident Reports].

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 A's probity or shortcomings in duty of candour that need to be rectified.

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.

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

All potential patients that are highlighted as requiring review and or clinical escalation will be booked and scheduled into a clinic.

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

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.

3. Membership

Membership of the SPSLBR included:

- Dr Chris Brookes, Chief Medical Officer and Deputy Chief Executive until December 2022, Senior Responsible Officer for the SPSLBR (involvement ceased December 2022)
- Dr Alistair Craig, Interim Chief Medical Officer from December 2022 until 21 February 2023, Medical Director Diagnostics and Pharmacy, Senior Responsible Officer for the SPSLBR (involvement from December 2022 until conclusion in April 2023)
- Dr Pete Turkington, Medical Director, Salford Care Organisation (involvement ceased December 2022)
- Kirsty Macdonald, Associate Director of Patient Safety and Governance and Patient Safety Lead for the SPSLBR (involvement ceased September 2022)
- Alison Dwyer, Governance and Patient Safety Lead for the SPSLBR (involvement from September 2022)
- Joanna Trewin, Partner at Hill Dickinson LLP, Legal Support
- Leah Selkirk, Senior Associate at Hill Dickinson LLP, Project Manager
- Consultant Spinal Surgeons:
    - Mr Naveed Yasin, Clinical Lead for the SPSLBR
    - Mr Saeed Mohammed

    - Mr Irfan Siddique
    - Mr Rajat Verma
- Mr Lee Breakwell, Consultant Adult & Paediatric Orthopaedic Spinal Surgeon and independent expert to the SPSLBR, ("Independent Expert Reviewer")

The following members were also invited to attend meetings:

- Dr Simon Tomlinson, Chair of Local Negotiating Committee
- Dr Tina Chrysochou, Freedom to Speak Up Champion
- Dr Glyn Smurthwaite, Consultant Anaesthetist
- Jenny Aldersley, Communications

4. Executive Summary

Please see Executive Summary at Appendix A.

5. Methodology: information and evidence gathered

5.1 Index cases reviewed by the Independent Expert Reviewer

The Independent Expert Reviewer was initially instructed to provide an in-depth expert review of 5 cases where known concerns existed and were identified through the Freedom to Speak Up process.

Mr Breakwell, Consultant Adult & Paediatric Orthopaedic Spinal Surgeon from Sheffield Children's & Teaching Hospitals NHS Foundation Trust, the Independent Expert Reviewer to the SPSLBR has reported on these 5 cases.

The themes identified from the Independent Expert Reviewer's review of these cases are:

- Poor pre-operative planning;
- Decision making against MDT advice/agreement;
- Lack of informed consent;
- Poor post-operative planning;
- Poor post-operative review:
    - Lack of arranging post-operative cover for patients, including cover when on annual leave
    - Poor reliability in documentation
    - Assessments and clinical opinions inconsistent with those of other clinical staff
- Patients experiencing intra-operative and post-operative blood loss higher than expected;

- Substandard surgery due to lack of care and attention in uncomplicated surgery;
- Causing long term pain and mobility issues;
- Failure to meet the standards of being open and honest in line with the professional duty of candour as set out in GMC's good medical practice in place at the time (i.e. 2006 – 2013 and 2013 – present);
- Delays during surgery;
- Poor communication;
- Unacceptable and unprofessional behaviour;
- Documentation was found to be inaccurate or inconsistent with other records completed by healthcare professionals;
- Poor patient experience in relation to communication and behaviours; and
- Poor reporting culture.

During the Trust's Consultant Spinal Surgeons' discussions with patients, a theme emerged that patients specifically sought out Consultant Spinal Surgeon A due to them holding senior roles in national professional bodies in the spinal surgical field. The patients' interpretation of them holding such roles was that this demonstrated their clinical ability and that they were one of the leading surgeons in their field. These were non-elected roles. It is recommended that a copy of this SI report and action plan will be shared with those organisations where Consultant Spinal Surgeon A held senior roles and with their current Responsible Officer.

The Trust has completed a serious incident (SI) investigation in index case 1. [redacted] A copy of the SI is at Appendix B. [redacted]

The remaining index cases have a detailed chronological timeline and answer questions raised by the patient. Duty of candour has been completed in all cases and copies of the Independent Expert Reviewer's reports have been shared with the patients and/or their families.

In two of the five index cases, the patient was under the age of 18 years old. In one case that was previously investigated in 2007, an action stemming from that investigation was that *"care will be appropriate for those patients who come under Child Protection Legislation".* All Anaesthetists and surgeons complete safeguarding children training which is now mandatory across the Trust. In

the other case that was previously investigated in 2013, no safeguarding issues were identified.

For all the cases reviewed by the Independent Expert Reviewer, Consultant Spinal Surgeon A was provided with copies of all relevant documents including the patient's medical records and asked to provide responses to the Independent Expert Reviewer's reports, and any specific concerns raised by the patient. Consultant Spinal Surgeon A has not provided any comments in response.

Table 1: Harm identified in the cases reviewed by the Independent Expert Reviewer

Case	Level of harm
Index case 1 (Appendix B)	Severe
Index case 2 (Appendix C)	Severe
Index case 3 (Appendix D)	Moderate
Index case 4 (Appendix E)	No harm
Index case 5 (Appendix F)	Moderate
Additional case reviewed (Appendix G)	Low

5.2 Collation of data, methodology and patient recall system

Terms of Reference 1 (a) and (b), 4 and 5.

In accordance with the Terms of Reference, patients who fell within the identified scope of the SPSLBR were to be reviewed to ascertain whether their management was appropriate, whether any harm was identified that required further assessment and to identify whether there were any concerns regarding Consultant Spinal Surgeon A's conduct, probity and capability.

To ensure all patients were captured, a search was undertaken by the Trust's clinical coding team. A full procedure list for patients who had instrumental surgery under Consultant Spinal Surgeon A in the 5-year period from August 2009 – September 2014 was obtained which included all operations completed by Consultant Spinal Surgeon A from two datasets:

1. Theatreman (operating theatre management system used at the Trust); and
2. Admitted Patient Care Episode (APC) to capture any cases where Consultant Spinal Surgeon A may have operated under another surgeon's Theatreman list.

This list was then manually reviewed and cross referenced by one of the Trust's Consultant Spinal Surgeons to remove any duplicate cases and to exclude all un-instrumented cases.

Searches were also completed to identify patients who had:

- Subsequent surgery;
- Subsequently been seen in clinic;
- Patients who approached the Trust with concerns about their own care;
- Brought litigation action;
- Brought a complaint;
- An inquest; and/or
- Subsequent AIRs.

Along with the datasets referred to above, searches also took place on the Trust's governance and incident systems against Consultant Spinal Surgeon A's name. The Datix incident management system has been in place at the Trust since 2017. Before this, the incident management system used was Ulysses. Both systems were searched as part of the review. The earliest case identified from the search on the Trust's governance and incident systems is from 2005.

It was recognised that patients may have been seen by Consultant Spinal Surgeon A at Spire Manchester Hospital or the Children's Hospital (MFT) and that records from organisations outside the Trust may have needed to be reviewed in order to appropriately assess the patient's pathway. As a result, Data Sharing Agreements were put in place between the organisations to allow the sharing of records.

Contact was also made with Consultant Spinal Surgeon A to request copies of any medical records that they may hold for patients who they had seen privately. Consultant Spinal Surgeon A has not provided any clinical records for these patients to the Trust. The SPSLBR has not identified any private records completed by Consultant Spinal Surgeon A within the NHS notes or referral letters of patients falling within the identified scope of the SPSLBR.

A root cause analysis has not been applied to each of the individual cases identified. This is due to the historic nature of some individual cases and the difficulties in retrieving the full set of historical medical notes. In compliance with the forthcoming changes to Patient Safety Incident

Response Framework (PSIRF), a detailed chronology has been prepared based on the available records and witness statements. This has identified the issues and allowed a thematic review to take place. Any learning identified has been incorporated into an individual action plan and/or the action plan attached to this investigation report.

In August 2022, NHS England released PSIRF. This sets out the approach to develop and maintain effective systems and processes for responding to patient safety incidents for the purpose of learning and improving patient safety. It promotes a proportionate approach to responding to patient safety incidents by ensuring resources allocated to learning are balanced with those needed to deliver improvement. The four key features are:

1. Compassionate engagement and involvement of those affected by patient safety incidents;
2. Application of a range of system-based approaches to learning from patient safety incidents;
3. Considered and proportionate responses to patient safety incidents; and
4. Supportive oversight focused on strengthening response system functioning and improvement.

The flexibility embedded in the PSIRF approach makes it easier to address concerns specific to health inequalities and provides the opportunity to learn from patient safety incidents that did not meet the definition of a SI. It also endorses a system-based approach instead of a 'person focused' approach.

Whilst PSIRF has not yet been implemented at the Trust, its approach has been adopted and applied by the SPSLBR Investigation Group as a pilot ahead of the Trust finalising its defined approach to PSIRF with reference to reporting and developing appropriate actions to address system wide learning. In particular, the contributory factors relating to this patient safety incident (including the health inequalities identified by the review) and the efficacy of the consequent safety actions, along with the monitoring of their delivery.

During the completion of the review of the 5 index cases, the patient safety review process was adapted in that the Independent Expert Reviewer's reviews took the form of a round table MDT meeting with the Trust's Consultant Spinal Surgeons presenting each case for independent analysis and ratification. Whilst this differed slightly from the original patient review process, this variation was agreed in order to ensure that the review proceeded efficiently and proportionately and delivered the best outcome for patients, whilst applying a PSIRF methodology.

Table 2:

Scope identification	No of patients
1a) Patients who had had instrumental surgery under Consultant Spinal Surgeon A in the 5 year period from August 2009 – September 2014	110
1b) Patients identified as having: i. Had subsequent surgery; ii. Subsequently been seen in clinic; iii. Patients who approached the Trust with concerns about their own care; iv. Brought litigation action; v. Brought a complaint; vi. An inquest; and/or vii. Subsequent AIRs.	28
	Total: 138 (110 + 28)

5.3 Desktop review, pathway, methodology

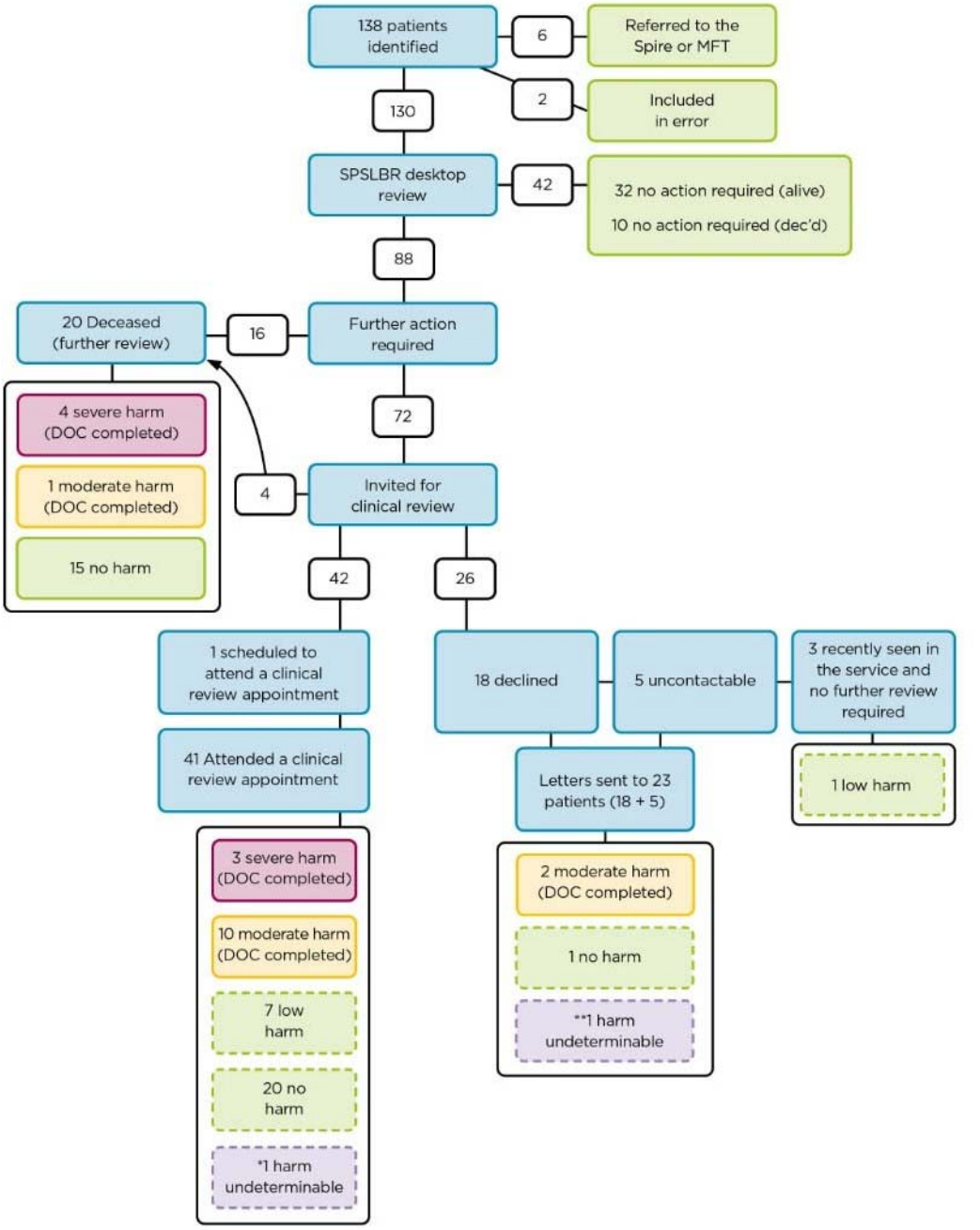
A patient review process was agreed by the SPSLBR Investigation Group. This is attached at Appendix M. For each patient identified, a structured case review methodology was applied. A desktop review was completed to exclude cases where:

- There was sufficient evidence to exclude harm, complication, return to theatre or a negative surgical outcome; or
- There was no evidence of disagreement of recorded facts.

Attached at Appendix N is copy of the template desktop proforma.

This also identified patients who required a full review (clinical recall appointment) in clinic with one of the Trust's Consultant Spinal Surgeons.

Image 1: Flowchart



* patient suffered psychological harm that cannot be quantified
** patient who didn't wish to be seen and the level of harm cannot be quantified

Table 3:

Indication for desktop review	No of patients
Patients have undergone a desktop review by a Trust Consultant Spinal Surgeon	130
Initial review by the Trust's Consultant Spinal Surgeons determined that no spinal treatment or care was delivered at the Trust and the patient was seen by Consultant Spinal Surgeon A in either Spire Manchester Hospital or Children's Hospital (MFT). The patient was referred to the relevant organisation	6
Initial review by the Trust's Spinal Surgeons determined that the patient had been included within the scope in error	2
	Total: 138 (130 + 6 + 2)

Table 4:

Outcome of Desktop review	No of patients
No further action	32
Identified for clinical recall	72
Deceased (no further clinical action)	10
Deceased (further review)	16
	Total: 130 (32 + 72 + 10 + 16)

Of the 130 patients identified in the SPSLBR where a desktop review was completed, 42 patients (including deceased patients) required no further action following a desktop review. Further action was therefore required in the remaining 88 cases.

5.4 Clinical recall, pathway, methodology

The structured case review methodology was employed for the clinical component of the SPSLBR. This method allows the case reviewer to assess each patient in a standardised manner, reflecting the complexity and variations in the cases being reviewed.

This method allowed each case to be reviewed to assess the quality of care as well as inspect the

clinical medical records, fulfilling duty of candour and governance outcomes.

The structured review is broken down into its sub-components in a generalised framework that allows the reviewer to examine individual parts of the patient's journey. This methodology allows explicit judgment statements to be made on each of the overall phases:

- Pre-operative Care
- Operative Care
- Immediate Inpatient Post-operative Care
- Outpatient Post-operative Care
- Documentation
- Governance
- Duty of Candour/being open and honest

Attached at Appendix O is copy of the template clinical review proforma.

Table 5:

Clinical review	**No of patients**
Patients have since been identified as deceased and require further review	4
Patients didn't wish to be seen	18
Patients were uncontactable despite best endeavours	5
Patients had been seen by the Trust's Consultant Spinal Surgeons in the service recently and didn't require further review as there was no ongoing harm identified	3
Patients attended a clinical review appointment	41
Patients not yet seen but scheduled to attend a clinical appointment	1
	Total: 72 (4 + 18 + 5 + 3 + 41 + 1)

Final letters (attached at Appendix P) were sent to the patients (18) who were contacted to attend a clinical review appointment and who did not wish to be seen, and to the patients where the Trust was unable to make contact with despite best endeavours (5). The letter confirmed that the Trust would not contact the patient again in relation to the review and that if the patient changed their

mind or if they started to experience any symptoms relating to their spine, they should contact their GP. A copy of the letter was also sent to the patient's GP.

Of the 72 patients identified for clinical recall:

- 35 patients were identified through the SPSLBR that were not previously known from previous spinal governance reviews as detailed above and did not have any associated claim / inquest / complaint / incident.
- 18 patients were identified through the SPSLBR that were not previously known from previous spinal governance reviews as detailed above but had an associated claim / inquest / complaint / incident, although this was not necessarily relevant to the spinal surgery that they received by Consultant Spinal Surgeon A.
- 19 patients had been included in previous spinal governance reviews.

The SPSLBR identified that there was a culture of low reporting of spinal surgical incidents within the timeframe of cases considered. Of the 72 patients identified for clinical recall, 27 patients had an associated incident raised, although this was not necessarily relevant to the spinal surgery that they received by Consultant Spinal Surgeon A.

5.5 Thematic reviews

Of the 88 cases where the outcome of the desktop review was that further action was required, thematic reviews have taken place in 66 cases to determine outcomes and next steps. These cases were selected and prioritised based on concerns expressed by the Trust's Consultant Spinal Surgeons:

- 41 patients who attended a clinical review appointment;
- 20 deceased patients who were identified for further review (at both desktop and clinical review stages);
- 4 patients who did not wish to be seen (including 2 of the 5 index case patients); and
- 1 patient who had been seen by the Trust's Consultant Spinal Surgeons in the service recently and didn't require further review as there was no ongoing harm identified.

Thematic reviews have not taken place in 22 cases:

- 14 patients who did not wish to be seen;
- 5 patients who were uncontactable despite best endeavours;
- 2 patients who had been seen by the Trust's Consultant Spinal Surgeons in the service recently and didn't require further review as there was no ongoing harm

identified;

- 1 patient who was scheduled to attend a clinical appointment;

Table 6:

Theme	No of cases (%)
In 66 cases that underwent a thematic review, it was determined that **34 of these had a requirement for Consultant Spinal Surgeon A to be open and honest with patients (in line with the professional duty of candour standards as set out in GMC's good medical practice in place at the time (i.e. 2006 – 2013 and 2013 – present).** In 31 of these cases there was no evidence that this had taken place.	31/**34** = 91%
Issues identified with consent	40/**66** = 61%
Issues identified with conduct / communication / behaviour	37/**66** = 56%
Negative outcome	36/**66** = 56%
Issues identified with operative care	35/**66** = 53%
Issues identified with documentation	34/**66** = 52%
Issues identified with post-op care	30/**66** = 45%
During their recall appointment, the patient described a negative experience of previous care received from Consultant Spinal Surgeon A **(where applicable in 41 cases where the patient attended a recall appointment).**	12/**41** = 29%
Issues identified with governance	17/**66** = 26%
Issues identified with pre-op care	15/**66** = 23%
Other issues identified	5/**66** = 8%

The main themes identified are:

- **No evidence identified of Consultant Spinal Surgeon A being open and honest**

with patients where applicable (91%).

The statutory duty of candour came into force on 27 November 2014 for NHS Trusts and therefore post-dates many of the patients who fall within the scope of the SPSLBR.

Professional duty of candour is overseen by individual healthcare professions such as the GMC for doctors.

The GMC's Good medical practice guidelines from 2013 – to date states:

"55: You must be open and honest with patients if things go wrong. If a patient under your care has suffered harm or distress, you should:

a. Put matter right (if that is possible)

b. Offer an apology

c. Explain fully and promptly what has happened and the likely short-term and long-term effects."

The GMC's Good medical practice guidelines from 2006-2013 states:

"30: If a patient under your care has suffered harm or distress, you must act immediately to put matters right, if that is possible. You should offer an apology and explain fully and promptly to the patient what has happened and the likely short-term and long-term effects.

31: Patients who complain about the care or treatment they have received have a right to expect a prompt, open, constructive and honest response including an explanation and if appropriate, an apology. You must not allow a patient's complaint to affect adversely the care or treatment you provide or arrange."

- **Inadequate consent** (61%); Examples include:
  - There was little information on the consent forms;
  - The risks documented on the consent form and associated documentation did not reflect those of the proposed surgery;
  - It was noted from a review of the consent forms completed that there was a theme with the same four risks documented in spite of the variation of the proposed surgery;
  - There was little evidence in other documentation of informed consent discussion with patients pre-operatively.
- **Surgical clinical issues/issues with operative care** (53%); Examples include:
  - In 23 cases, issues with screw placement and screws being misplaced were identified;

- In 3 cases, Consultant Spinal Surgeon A incorrectly applied paediatric surgical practice and concepts to more complex adult surgical patients;
- In 13 cases, surgery was poorly planned.
- In 5 cases, the patient suffered atypically high levels of blood loss for the surgery performed.

- **Inaccurate or inconsistent documentation with other records** (52%);
- **Surgical clinical issues/post-op care** (45%): Examples include:
  - In 9 cases there was a failure to recognise and/or investigate or act on post operative complications in a timely way, if at all.
- **Significant professional issues:**
  - A separate document at Appendix Q has been developed to include details of the significant professional issues identified. Given the nature of the serious and frequently occurring significant professional issues identified, the Trust should share a copy of this report and any associated concerns regarding conduct, probity and capability with the General Medical Council.

Some patients were identified as being lost to follow up following Consultant Spinal Surgeon A leaving the organisation in 2015.

In order to avoid patients being lost to follow up, the usual process at the Trust now is that this is completed manually by administrative staff when typing a clinic letter – a patient is either booked into a follow up appointment or added to the outpatient waiting list. If the patient is referred for a diagnostic investigation (i.e. an MRI scan or x-ray), they will be added to an investigation log. This is reviewed weekly to check if results are back, at which point the Consultant is notified. A clinician leaving the Trust should not lead to a patient being lost to follow up as the above systems remain in place. The patient on the outpatient waiting list or booked onto a scheduled appointment would be transferred to another clinician for care and management.

5.6 Clinical MDT with Independent Expert Reviewer

Terms of Reference 2 and 6.

Due to the volume of patients identified as requiring an external clinical review by the Independent Expert Reviewer to determine if there was a breach of duty with resultant harm, in accordance with the SPSLBR Investigation Group's agreed patient review process (Appendix M), it was agreed that the Independent Expert Reviewer's reviews would take the form of a round table MDT meeting with the Trust's Consultant Spinal Surgeons. This variation to the original process was agreed to ensure that the review proceeded efficiently and proportionately. This provided a clear methodology for the Independent Expert Reviewer's clinical reviews and reporting. Cases where

concerns were identified were presented by the reviewing surgeon, including the sharing of Computerised Tomography (CT) and Magnetic Resonance Imaging (MRI) scan images for example, discussed, and the outcome agreed with any next steps appropriately recorded.

The first of the MDT meetings was held on 7 December 2022. The cases discussed were prioritised based on the anticipated levels of harm. Further MDT meetings took place between December 2022 and March 2023.

Many of the patients involved in the SPSLBR would be considered to have a disability as defined under the Equality Act 2010 as a result of their spinal condition. Any concern about equality, diversity and inclusion tends to be focused upon whether any person with a protected characteristic (i.e. disability) has been treated differently and to their detriment (either directly or indirectly), because of that protected characteristic. This has not been specifically investigated by the Investigation Group as it falls outside the Terms of Reference for the SPSLBR. However, it was not apparent that there was a difference in treatment provided by Consultant Spinal Surgeon A between patients who would be considered to have a disability and those who would not.

5.7 Identified harm

Reviews as to the applicable level of harm have taken place in 66 cases, including harm identified in the index cases as set out in Table 1. These cases were selected based on concerns expressed by the Trust's Consultant Spinal Surgeons:

Table 7:

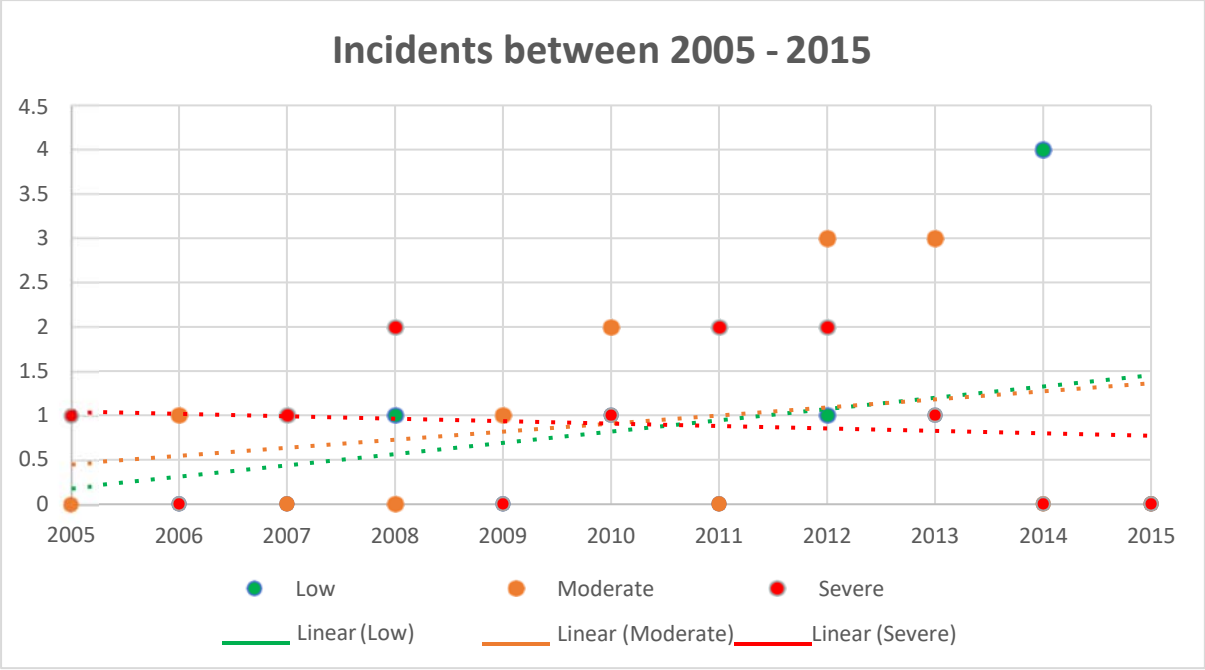
Level of harm	No of cases
Severe harm	7 (3 patients who attended a clinical review + 4 deceased patients)
Moderate harm	13 (10[2] patients who attended a clinical review + 1 deceased patient + 2 patients who did not wish to be seen *[index cases]*)

[2] In one case, the MDT concluded that the patient had suffered moderate harm. One of the Trust's Consultant Spinal Surgeons is of the view that the patient suffered severe harm. The Spinal Patient Safety Look Back Review Investigation Group agrees with the MDT's conclusion.

Level of harm	No of cases
Low harm	8 (7 patients who attended a clinical review + 1 patient had been seen by the Trust's Consultant Spinal Surgeons in the service recently and didn't require further review as there was no ongoing harm identified)
No harm	36 (20 patients who attended a clinical review[3] + 15 deceased patients + 1 patient who did not wish to be seen *[index case]*)
Unquantifiable harm	2 (1 patient who attended a clinical review and suffered psychological harm that cannot be quantified + 1 patient who didn't wish to be seen and the level of harm cannot be quantified)
	Total: 66 (7 + 13 + 8 + 36 + 2)

Image 2:

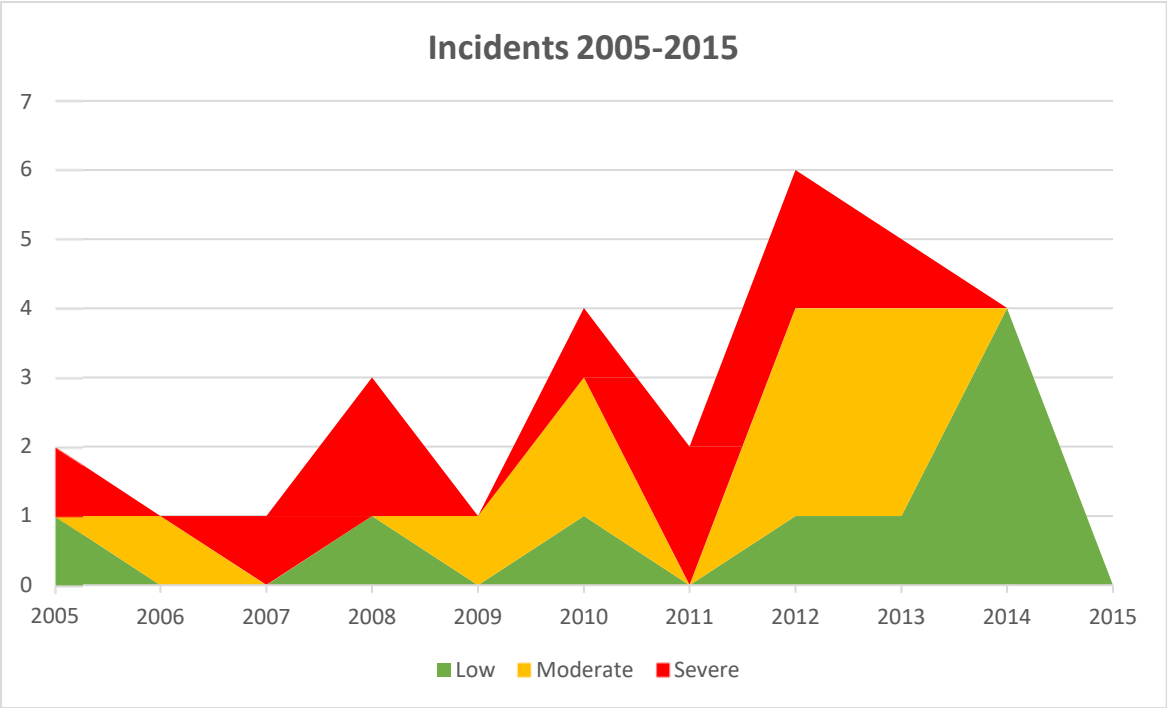
This scattergram shows the trend in the level of harm (between low and severe) for patients who fell within the scope of the SPSLBR scope.



[3] In one case the MDT concluded that the patient had a poor clinical outcome but no harm. One of the Trust's Consultant Spinal Surgeons is of the view that the patient suffered harm. The Spinal Patient Safety Look Back Review Investigation Group agrees with the MDT's conclusion.

Image 3:

This graph shows the cases identified as severe, moderate and low harm for patients who fell within the scope of the SPSLBR scope.



Where severe harm has been identified, this has been externally validated by the Independent External Reviewer. A separate datix has then been linked to the SPSLBR datix serious incident.

5.8 Duty of candour

Terms of Reference 3

For all cases identified as severe or moderate harm, duty of candour has taken place in accordance with the Duty of Candour Regulations under the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

This has either been completed in clinic by the Trust Consultant Spinal Surgeon who conducted the clinical review with the patient, through separately organised bespoke duty of candour meetings or discussions with deceased patients' next of kin.

5.9 Deceased patients

Of the 130 patients who have undergone a desktop review, 30 patients are deceased. As set out above, a further review in terms of identifying the level of harm applicable and themes has taken place for 20 patients. The themes identified are captured within the data above.

The remaining 10 patients required no further action as determined at the desktop review stage. These cases were excluded as:

- There was sufficient evidence to exclude harm, complication, return to theatre or a negative surgical outcome; or
- There was no evidence of disagreement of recorded facts.

5.10 Data sharing

A Data Sharing Agreement was entered into between Spire Manchester and the Trust on 5 September 2022. A Data Sharing Agreement was already in place with MFT. This was to allow the secure transfer of patient records where a patient had been seen in more than one organisation.

5.11 Other stakeholders

NHS Resolution have been kept informed throughout the SPSLBR via their Significant Concerns Group.

Information regarding the SPSLBR has also been shared with the Care Quality Commission and relevant Integrated Care Board.

Meetings have taken place with senior colleagues at Spire Manchester and MFT. Both organisations are conducting independent reviews. A copy of the SPSLBR's Terms of Reference have been shared with both organisations along with template documentation.

All organisations continue to work closely to ensure a coordinated approach and no duplication insofar as contacting patients that might have been seen in more than one organisation. An agreed process is in place regarding transfer of records.

A pathway has been agreed with MFT for patients whose care is under review at MFT as they were seen by Consultant Spinal Surgeon A there, but where a referral is needed in the adult spinal service at Salford Royal Hospital.

5.12 Royal College of Surgeons' report

In September 2015, the Trust contacted the Royal College of Surgeons to request a review of the Trust's spinal surgery service, in addition to a clinical review of 10 patients who had been under

the care of Consultant Spinal Surgeon A[4]. The Royal College of Surgeons visited the Trust in December 2015.

Their Invited Service Review report (issued to Salford Royal Hospital on the 20 January 2016) identified no significant concerns regarding the safety of the spinal surgery service at the Trust post dismissal of Consultant Spinal Surgeon A.

Their clinical review of Consultant Spinal Surgeon A's 10 clinical cases (issued to Salford Royal Hospital on the 6 February 2016) concluded:

"There were no overall concerns about the standard of care provided to the patients that formed part of the review.
From the information in the clinical records, it appears that the way in which the complications were managed once identified was appropriate in each case."

Of the 10 patient cases that were sent to the Royal College of Surgeons for review, 9 cases fell within the scope of the SPSLBR Terms of Reference[5]. Separate reports have been completed by the Independent Expert Reviewer in 3 cases. In these 3 cases, the Independent Expert Reviewer's findings contradict the conclusions of the Royal College of Surgeons' clinical review. The remaining 6 cases were reviewed in line with the MDT processes implemented by the SPSLBR as described in section 5.6 above.

Where the Royal College of Surgeons reported that "*there were no overall concerns about the standard of care provided to the patients*" the SPSLBR found:

Table 8:

Level of harm	**No of cases (/9[6])**
Severe harm	2 (22.2%)
Moderate harm	4 (44.4%)
Low harm	1 (11.1%)
No harm	1 (11.1%)
Unquantifiable[7]	1 (11.1%)

[4] See footnote 1.
[5] As above.
[6] See footnote 1.
[7] This patient required a full review (clinical recall appointment) in clinic with one of the Trust's Consultant Spinal Surgeons but was uncontactable despite best endeavours.

In all 9 of the cases reviewed, significant contradictions were identified between the Royal College of Surgeons' clinical review and the SPSLBR findings. In light of this, the SPSLBR Investigation Group recommends that the Trust should share such findings with the Royal College of Surgeons for comment and appropriate action.

6. Communications

Where patients were identified for clinical recall, they were contacted by the Spinal Services Team at the Trust. Calls were made at various times including evenings and weekends in order to maximise the chances of contacting patients. Where contact was not possible by telephone, details were checked using the NHS Spine (this system supports the IT infrastructure for health and social care in England, joining together over 23,000 healthcare IT systems in 20,500 organisations) and by contacting last known GPs. Letters were also sent to patients requesting that they made contact via telephone or by email.

A detailed patient communications brief and strategy to minimise distress or concern to patients and the Trust's local community was discussed and agreed in May 2022, but unfortunately this strategy could not be implemented as prior to its implementation, The Times newspaper published a report on 17 July 2022 with details of the SPSLBR. A statement was prepared by the Trust in response and was included within the newspaper report. The Trust's website was updated as follows:

> *"We are aware that coverage in one of the national newspapers (Sunday Times) about a current Patient Safety Look Back Review at Salford Royal may have concerned some patients.*
>
> *We reassure patients that this review only involves some patients who received spinal surgery performed by this Consultant Surgeon* [Consultant Spinal Surgeon A]*. This surgeon has not worked at the Trust since 2015.*
>
> *Patients should be assured that if concerns are identified with their care or treatment then they will be contacted by our organisation.*
>
> *A patient might then be asked to attend for a clinic appointment with one of our consultant spinal surgeons. This might be to discuss medical history, previous spinal surgery, progress since spinal surgery (even if this was some time ago) and current condition. This will help to determine if anything further needs to take place.*

We are sorry for any distress or concern that patients may have experienced and we hope this information provides patients with some reassurance. We emphasise that any patient where concerns are identified with their previous spinal surgery or treatment – they will be contacted by the Trust.

However, any patient who does still has concerns is welcome to call 0161 206 5117 where your query will be listened to and responded to."

The hotline, as described on the Trust's website was set up for any concerned patients to contact the Trust. This led to 8 patients coming forward who were captured within the scope of the review and reviewed in accordance with the Terms of Reference. Of these, 2 patients have had a clinical review. The remaining 6 patients have been referred to the Spire Manchester Hospital or the Children's Hospital (MFT).

The Trust's hotline remains open.

7. Patients falling outside the scope of the SPSLBR Terms of Reference

As set out above, the Terms of Reference of the SPSLBR includes all patients who:

a. *Had instrumental surgery under the Consultant Spinal Surgeon [Consultant Spinal Surgeon A] in the 5-year period from August 2009 – September 2014, or*
b. *Have been identified to have:*
    i. *Had subsequent surgery;*
    ii. *New information;*
    iii. *Subsequently been seen in clinic;*
    iv. *Self-identified;*

Some members of the multi-professional staff support group that was established under the Trust's Freedom to Speak Up process referred to at paragraph 1.1 have expressed views that all patients who were seen by Consultant Spinal Surgeon A should undergo a full review to ensure their safety and determine if they require any further care. This would include patients who had:

- non-instrumental surgery during the 5-year period from August 2009 – September 2014;
- instrumental and non-instrumental surgery outside the period of August 2009 – September 2014 (Consultant Spinal Surgeon A began working for the Trust in 1991);
- surgery and patient consultations elsewhere.

The SPSLBR Investigation Group does not consider that any additional themes are likely to be identified requiring actions that are not already specified within the SPSLBR report and detailed below. Moreover, there are foreseeable challenges with conducting a review of these patients such as, but not limited to:

- availability of records will be an issue the earlier a patient was seen, particularly at a time before the implementation of the Electronic Patient Record;
- as a consequence of the introduction of the picture archiving and communication system (PACs – the digital imaging record) in 2005, the majority of imaging tests will be unavailable for review, making an essential part of the investigation impossible to undertake;
- availability of patients for recall is likely to be lower in the cohort treated prior to the dates in the Terms of Reference of the SPSLBR due to emigration, death or other factors;
- witness statements will be challenging to obtain for similar reasons and the reliability of any accounts will be affected by the long time period since the events;
- reviews by external organisations fall outside the remit of the Trust; and
- ensuring cross organisational alignment of such reviews also falls outside the remit of the Trust.

In the context of these challenges, there are mitigations which the process to date has provided:

- the earlier cohort has been sampled through the methodology of reviewing all incidents, complaints and litigation;
- the risks associated with patients who have undergone non-instrumental procedures are likely to be low;
- although the methodology has been imprecise, the graph in Image 3 would suggest that harms increased towards the end of Consultant Spinal Surgeon A's employment at Salford Royal NHS Foundation Trust, and that the number of incidents within the earlier cohort may be lower.

The SPSLBR Investigation Group has therefore outlined three possible options in order to address this patient cohort below and made a recommendation in light of the above.

8. Summary of findings

8.1 A desktop review has taken place of all identified patients who had either undergone instrumented surgery under Consultant Spinal Surgeon A in the 5-year period from

August 2009 and September 2014, or who had been identified to have:

- Had subsequent surgery;
- Subsequently been seen in clinic;
- Patients who approached the Trust with concerns about their own care;
- Brought litigation action;
- Brought a complaint;
- Have had an inquests; and/or
- Had subsequent AIRs.

This identified 72 patients who required a clinical recall appointment with one of the Trust's Consultant Spinal Surgeons.

8.2 A patient clinical recall system was successfully put in place. Where patients have ongoing clinical requirements, these are either being managed by the service, or they have been appropriately referred elsewhere.

8.3 Individual investigations have taken place in respect of 7 patients where severe harm has been identified.

8.4 13 patients were found to have suffered moderate harm.

8.5 Themes have been collated which identify significant patient safety and professional concerns with Consultant Spinal Surgeon A's practice.

8.6 Failings in being open and honest with patients were identified. This has now been addressed. Duty of candour has been completed where applicable in all known cases to date and copies of the Independent Expert Reviewer's reports have been shared with the patients and/or their families.

8.7 Some patients were identified as being lost to follow up following Consultant Spinal Surgeon A leaving the organisation in 2015. This is a known risk across the Trust.

8.8 Significant professional issues in respect of the Consultant Spinal Surgeon A's practice have been identified throughout this process and a separate document appended (Appendix Q) has been prepared detailing those concerns.

8.9 Within the timeframe of cases considered in this review (from 2005 – 2014), there

were issues with reporting incidents and a culture of low reporting in relation to spinal surgical incidents.

8.10 Within the timeframe of cases considered in this review (from 2005 – 2014), there were suboptimal governance practices for investigation of incidents. There is evidence of issues identified inappropriately as recognised complications (rather than clinical incidents), hence the clinical events not being fully investigated to improve patient safety and implement future learning.

9. Conclusions

9.1. Findings relating to Consultant Spinal Surgeon A's practice:

a) Their documentation was poor and found to be inaccurate or inconsistent with other records completed by healthcare professionals in a high number of cases.

b) Their compliance with informed consent processes was found to be poor in a high number of cases. The risks documented on the consent form and associated documentation did not reflect those of the proposed surgery. It was noted from a review of the consent forms completed that there was a theme with the same four risks identified, in spite of the variation of the proposed surgery. This was further evidenced during discussion with patients about their experience under Consultant Spinal Surgeon A.

c) Their surgical technique was judged to be poor in multiple cases. Issues with screw placement and screws being misplaced were identified in a high number of cases. In a number of cases, surgery was found to be poorly planned and patients suffered high blood loss for the surgery performed. They also incorrectly applied paediatric surgical practice and concepts to more complex adult surgical patients.

d) Their communication with many patients was poor. Failings in being open and honest with patients were identified in a high number of cases.

e) Significant professional issues have been identified in Consultant Spinal Surgeon A's practice. These issues have been identified through review of the available medical records, discussion and written accounts received from

patients and written accounts from staff. These have been collated separately and are attached at Appendix Q. In summary, the SPSLBR has found:

i. Unacceptable and unprofessional conduct with patients;
ii. Unacceptable and unprofessional conduct with staff;
iii. Lack of probity in documentation;
iv. Lack of probity with being open and honest with patients;

9.2. Findings relating to the Spinal Service between 2005 and 2014:

a) Within the timeframe of cases considered in this review, there was a poor culture of incident reporting within the spinal service. It was identified that not all incidents identified had been reported through the Trust's incident reporting system.

b) There were suboptimal governance practices for investigation of incidents. There is evidence of issues identified inappropriately as recognised complications (rather than clinical incidents), hence the clinical events not being fully investigated to improve patient safety and implement future learning.

c) Multiple significant contradictions have been identified between the Royal College of Surgeons' clinical review of 10[8] patients under the care of Consultant Spinal Surgeon A and the SPSLBR findings.

10. Lessons to be learned and recommendations

It is recommended that:

10.1. Where severe harm has been identified and externally validated by the Independent External Reviewer, a separate datix will be raised and linked to the SPSLBR datix serious incident.

10.2. The Trust should implement a patient safety framework in line with national requirements following implementation of a PSIRF by Autumn 2023.

10.3. In light of multiple significant contradictions identified in the Royal College of Surgeons' clinical review of 10 patients under the care of Consultant Spinal Surgeon

[8] One patient was not included in the SPSLBR Terms of Reference scope, the remaining 9 cases fell within the scope. See footnote 1.

A and the SPSLBR findings having reviewed 9[9] of these patients, the Trust should share such findings with the Royal College of Surgeons.

10.4. A copy of the SPSLBR report should be shared with interested external stakeholders including:

a) Consultant Spinal Surgeon A
b) Consultant Spinal Surgeon A's Responsible Officer
c) NHS Resolution's Significant Concerns Group
d) Spire Manchester
e) MFT
f) Care Quality Commission
g) Integrated Care Board, and
h) National professional bodies such as Royal College of Surgeons and the British Scoliosis Society.

10.5. Given the nature of the serious and frequently occurring significant professional issues identified, the Trust should share a copy of this report and any associated concerns within Appendix Q regarding conduct, probity and capability with the General Medical Council.

10.6. A copy of Appendix A (Executive Summary) to the SPSLBR should be shared with patients who fall within the scope of the SPSLBR and relevant internal stakeholders, if requested.

10.7. In respect of recommendations 10.4, 10.5 and 10.6, consideration should be given to the sequence in which a copy of this report is shared with the interested external stakeholders identified.

10.8. A deep dive review should take place of the patients who were noted to be lost to follow up to identify whether there were any other drivers that may have caused the issue and to identify any areas of learning.

10.9. It is recommended that the Trust considers whether patients falling outside the scope of SPSLBR require separate review. The SPSLBR Investigation Group considers that there are three options in this regard and recommends option 10.9 (b):

a) Take no further action;
b) Adopt a risk stratified approach that may take the form of:

[9] One patient was not included in the SPSLBR Terms of Reference scope. See footnote 1.

i. Invite all patients seen by Consultant Spinal Surgeon A whilst employed at the Trust for a review of their care, if the patient wishes;

ii. Following any likely media publication of the outcomes of the SPSLBR, issue a media invitation for a desktop review to any patients who have concerns.

c) Complete a full review according to the Terms of Reference and methods within the SPSLBR for every patient who has been seen by Consultant Spinal Surgeon A since they began working for the Trust in 1991.

11. Action plan

Action	How this action will lower the risk of re-occurrence
ACTION 1 **MDT process** **Confirm Governance processes are fit for purpose within Spinal MDT** *[This action is also included within the index case 1 action plan]* **Summary of changes already implemented since 2007:** Implementation of MDT co-ordinator to support the clinical pathway and theatre planning. There now exists a clearly identified list of procedures that require two operating surgeons. Where dual surgery requirement is identified this is documented in the clinical letter and on the operation list The MDT is job planned for all consultant spinal surgeons. MDT is chaired by a consultant surgeon on a rotational basis. The consultant chair is responsible for the dictation on the outcomes from the MDT that are then entered in the patient electronic record. Following Spinal MDT discussion where identified, complex dual surgeon cases will progress onto a	**Complete** The MDT process is now robust and well documented providing clarity for the entire multi-disciplinary team around the agreed requirements for a surgical procedure. The MDT takes responsibility for decision making to ensure consistency in approach and compliance with policies including dual surgery requirements. Consultant Spinal Surgeon A was dismissed from Salford Royal Hospital in Jan 2015 for matters relating to behaviour and misconduct but remains registered with the GMC. The standardised approach within the MDT ensures relevant clinical issues are discussed, documented and communicated with the wider team. All requirements for operating including personnel and any specialist equipment are recorded on the theatre listings. The World Health Organisation ("WHO") theatre checklist (team brief) as identified in the actions is a final failsafe check.

further Spinal / Anaesthetic pre-op assessment. The patient and their family to be invited to the Spinal/Anaesthetic pre-op meeting. This will include a discussion of: • The anaesthetic and surgical difficulties anticipated; • How those risks can be mitigated; • Appropriate interventions agreed; and • Clear communication on circumstances in which surgery should be abandoned. Discussions are dictated and transcribed into Electronic Patient Records. <u>Learning from incidents</u> Any matter where there is joint learning across surgery and anaesthesia are shared between the governance leads to discuss at their governance meetings. Clinical incidents are discussed at Spinal Morbidity and Mortality meetings as well as clinical governance meetings. **Summary of the learning from 2007 investigation action plan:** • Informed consent process, including an elective surgical pathway and consent pathway developed in February 2007 across surgical specialties. • Child Protection Training, All Anaesthetists and surgeons complete safeguarding children mandatory training which is now mandatory. • Pre-operative planning improvements (including blood loss and ICS). • Process for activation of major haemorrhage protocol introduced. • Visiting surgeons involved in	Open culture of learning for clinical incidents, complaints and concerns reflects a good patient safety culture. **Outstanding assurance** Terms of Reference to be drafted for the MDT. By September 2023, the Spinal Clinical Governance Team will complete: • An audit of M&M, MDT and governance minutes; and • Triangulation with theatre listings, team brief and WHO checklist. This will ensure processes are in place to monitor competency through the clinical governance framework. (See action plan below)

direct care or interventions now have honorary contracts where necessary.	
ACTION 2 **Pre-operative surgical planning** *[This action is also included within the index case 1 action plan]* A surgical listing form has since been introduced. This has a list of mandatory fields, including dates listed in clinic and the planned procedure date. There is also a free text description of surgery taking place with a checklist for the level of clinical priority, estimated length of stay, and the bed required post-operatively. It also has a section to cover the patient's Mental Capacity, any disability and the estimated time required for the surgery. The clinic letter, which is sent to the patient will also be a description of what surgery is going to take place and the risks associated. This is now included in letters as standard. **Learning from 2007 investigation** Visiting surgeons involved in direct care or interventions will have honorary contracts where necessary. The individual department would contact the HR department through the Clinical Attachments inbox. This is then supported through a checks process either as a clinical attachment or honorary contract depending on the particular circumstance. Both of these processes are now embedded in place.	**Complete** Standardisation of process in relation to theatre listings has improved reliability of listing, ensuring equipment and personnel meet requirements. The WHO checklist and team brief is the final safety check in this process. This is continuously audited by the theatre team. **Outstanding assurance** By September 2023, the Spinal Clinical Governance Team will complete: • Triangulation of theatre WHO checklists with MDT outcomes and theatre listings. • Review of the audit of the anaesthetic pre-op assessments, which was identified in the 2007 investigation. (See action plan below)

ACTION 3 **Surgical Team Brief** *[This action is also included within the index case 1 action plan]* Formalise discussion between the theatre MDT on the morning of the surgery. Documented MDT discussions, and thorough pre-operative planning notes, picked up as part of this process as an additional safety process.	**Complete** The process is now formalised in the World Health Organisation (WHO) team brief. This is included in every theatre list. This is audited on a continuous cycle by the theatre team. **Outstanding assurance** By September 2023, the Spinal Clinical Governance Team will complete: • Triangulation of theatre WHO checklists with MDT outcomes and theatre listings. (See action plan below)
ACTION 4 **Informed Consent** *[This action is also included within the index case 1 action plan]* Formal consent training is now included in junior doctor induction. Consent Lead and policy Regional consent training session completed. Consent Audit embedded in practice Review of consent process and documentation: • Consent forms • Patient information • Timing of consent • Competency • ICATs/Consent Clinics **Learning from 2007 investigation** Development of the elective surgical pathway. This is still in use and was last updated in 2021. A delegated consent register was established at the time. This was in use until early 2022. It has since been superseded with the unified NCA wide consent policy. This was implemented in October 2022.	**Complete** The embedded process for informed consent ensures that the risks associated with surgery are discussed and documented in the clinical patient record. Regular audit provides assurance of consent practice. **Further assurance planned** MIAA (Mersey Internal Audit agency) independent consent audit to be completed in the 3rd quarter of 2022/2023. The outcomes from this will be actioned. A wider review of consent processes will take place, ensuring this is in line with best practice and is integrated in digital systems, when this becomes available. (See action plan below)

Outstanding Digital system for shared decision making.	
ACTION 5 **Incident investigation and Governance** *[This action is also included within the index case 1 action plan]* Governance processes have become more robust since 2007 and 2017. Processes of incident reporting validation and confirmation of harm levels are in place across the NCA and in line with: • Serious Incident Framework, Supporting Learning to prevent Recurrence – NHS England (2015); • National Patient Safety agency Root Cause Analysis toolkit (2015); • Never Events policy and framework – NHS Improvement 2018; and • Regulation 20: Duty of Candour – Care Quality Commission since 2014. Current organisational governance strategies ensure patient harms are managed in line with policy through the clinical incident management system Datix (introduced to Salford in 2019). This provides reliable documentation of incident management processes in line with internal standards and acts as a repository for all duty of candour letters and investigation findings. The Freedom to Speak Up Team are a safety valve in the organisation where staff can raise concerns where they feel that the existing assurance mechanisms have not	**Incident / harm recognition in the NCA** The NCA have a patient safety policy in place that outlines all governance mechanisms for identifying, reporting and investigation patient safety incidents. There is a strong incident reporting culture within the NCA with incident reporting increasing year on year. This is now monitored through the Quality Performance Committee. The standardised approach to incident management recording in conjunction with monitoring processes of incident investigation is embedded within the divisions of Salford Care Organisation, and therefore prevent incident processes from being brought to conclusion without substantive documentation. Where incidents or patient harms are not initially recognised, internal governance processes have been developed and matured to capture potential patient harms through the following mechanisms: • M&M reviews of adverse patient outcomes; • Care Quality Review, Structured Judgement Reviews or internal mortality review; • Medical examiner's office review • Inquest processes and outcomes; and • Complaints, PALS and Claims. Matters of professional conduct and competency are managed through separate HR and professional regulatory body processes. The investigation findings where gaps in

worked. As outlined above, in 2021 a multi-professional group was established under the Trust's Freedom to Speak Up Process which in turn led to the commissioning of the SPSLBR. The new Freedom to Speak Up Policy will be released by the end of November 2022 and this, in addition to enhanced communication during Freedom to Speak Up Month (October), will help promote awareness of this service should staff feel that future governance processes are lacking. Duty of Candour is monitored at the following patient safety forums to ensure this duty is executed in a timely manner: • M&M reviews of adverse patient outcomes; • Care Quality Review (CQR) Structured Judgement Reviews (SJR) or internal mortality review; • Medical examiner's office review; • Inquest processes and outcomes; and • Complaints, PALS and Claims. The focus of patient safety reviews is on learning and improvement to reduce the risk of future harm. Duty of Candour is performed within national guidance promoting an open and honest discussion with patients and their family members. Where the need for an independent review is identified from an incident, an external review will be commissioned. **Learning from 2007 investigation** The incident investigation findings and action plan followed governance processes, with prompt actions to improve safety in relation to management of major haemorrhage. There is, however, no evidence that	governance processes were identified to be shared with the Director of Patient Safety and the Associate Directors of Governance for wider NCA learning, and to inform the 2022/23 review of current incident management systems. A search of the Datix incident management system from October 2021 to September 2022 has not revealed any themes relating to documentation and patient harm. Learning from incidents is in place within the care organisation, governance cascade and newly established patient safety forum (MDT approach to learning incorporating human factor methodology). The new Freedom to Speak Up Policy was finalised in January 2023. **Outstanding** Learning from this investigation through the sharing of findings via governance cascade in Salford Care Organisation and across the NCA to include a reminder to be circulated to emphasise the importance of completing surgical records contemporaneously, followed up by a notes audit to ascertain the time lag between surgery and notes entered. The new Freedom to Speak Up Policy was finalised in January 2023. Implementation of the Patient Safety Incident Response Framework (PSIRF) by Autumn 2023 in line with national requirements.

the findings were shared with the patient's family.	
ACTION 6 Where severe harm has been identified and externally validated by the Independent External Reviewer, a separate datix will be raised and linked to the SPSLBR datix serious incident.	This will provide assurance around governance processes and lesson learning.
ACTION 7 In light of multiple significant contradictions identified in the Royal College of Surgeons' clinical review of 10 patients under the care of Consultant Spinal Surgeon A and the SPSLBR findings in 9 cases falling within the SPSLBR Terms of Reference, the Trust should share such findings with the Royal College of Surgeons.	This will allow the Royal College of Surgeons to take forward any steps they consider necessary in respect of the Invited Case Review that was completed in 2015.
ACTION 8 A copy of this report will be shared with Consultant Spinal Surgeon A.	This will provide Consultant Spinal Surgeon A with the findings of the review and allow any personal reflection to take place. It should be noted that for all the cases reviewed by the Independent Expert Reviewer, Consultant Spinal Surgeon A was provided with copies of all relevant documents including the patient's medical notes and asked to provide responses to the Independent Expert Reviewer's reports, and any specific concerns raised by the patient. Consultant Spinal Surgeon A has not provided any comments in response. Consideration should be given to the sequence in which a copy of this report is shared with the interested external stakeholders identified.

ACTION 9 This SI report and action plan will be shared with interested stakeholders including: • Consultant Spinal Surgeon A's Responsible Officer • NHS Resolution's Significant Concerns Group • Spire Manchester • MFT • CQC • ICB • GMC • Royal College of Surgeons • The British Scoliosis Society. **ACTION 10** A deep dive review will take place of the patients who were noted to be lost to follow up during the desktop review process.	This will allow any recipient external organisations to take forward any steps they consider necessary. Sharing of learning across external organisations. Consideration should be given to the sequence in which a copy of this report is shared with the interested external stakeholders identified. This will identify whether there are any other drivers that may have caused this and will inform any further learning.
ACTION 11 The Trust to consider whether patients falling outside the scope of SPSLBR require separate review. The SPSLBR Investigation Group recommends adopting a risk stratified approach in respect of any separate review.	

5 June 2023

Appendix R – Action plan

Action ref. no.	Recommendation	Action required	Lead Person (Name and Job Title)	Target Date for Completion	Progress notes	Date of Actual Completion	Evidence of completion
1, 2, 3	MDT	Audit of MDT minutes for accuracy and reliability to be triangulated with theatre listings and WHO checklist sampling governance and M&M meeting minutes for learning. Audit of anaesthetic charts will be undertaken for the recording of blood loss, to ensure contemporaneous recording of bleeding. Terms of Reference to be formalised for MDT meetings.	Associate Director of Governance for Salford Anaesthesia audit lead Spinal Clinical Governance Team	September 2023 September 2023 September 2023	Minutes and audit data requested for triangulation (Oct 2022)		
4	Consent	MIAA consent audit to be completed 3rd quarter of 2022/3. Findings to be actioned and implemented.	NCA Patient Safety Team	End of 2023			
5, 6	Incident investigation and governance	Learning from this investigation through the sharing of findings via governance cascade in Salford Care Organisation and across the NCA to include a reminder to be circulated to emphasise the importance of completing surgical records contemporaneously, followed up by a notes audit to ascertain the time lag between surgery and notes entered.	Associate Directors ofGovernance	End of June 2023			
		Implementation of the Patient Safety Incident Response Framework (PSIRF) by Autumn 2023 in line with national requirements.	NCA Patient Safety Team	Autumn2023			

		Where severe harm has been identified and externally validated by the Independent External Reviewer, a separate datix will be raised and linked to the SPSLBR datix serious incident.	**Governance Lead for the SPSLBR**	**End of May 2023**			
		Evidence of reporting culture improvements in the spinal service to be reported to the Quality Performance Committee.	**Spinal ClinicalGovernance Team**	**September 2023**			
		Strategy for assurance that clinical standards in the spinal service meet national standards to be reported to the Quality Performance Committee.	**Spinal ClinicalGovernance Team**	**September 2023**			
11	**Lost to follow up**	**A deep dive review will take place of the patients who were noted to be lost to follow up during the desktop review process.**	**GPAA Director and Waiting List Surveillance Group**	**September 2023**	**In June 2023, the SPSLBR SRO wrote to the to the GPAA Director and Waiting List Surveillance Group to progress this action.**		

5, 6	**Incident investigation and governance**	**Learning from this investigation through the sharing of findings via governance cascade in Salford Care Organisation and across the NCA to include a reminder to be circulated to emphasise the importance of completing surgical records contemporaneously, followed up by a notes audit to ascertain the time lag between surgery and notes entered.** **Implementation of the Patient Safety Incident Response Framework (PSIRF) by Autumn 2023 in line with national requirements.** **Where severe harm has been identified and externally validated by the Independent External Reviewer, a separate datix will be raised and linked to the SPSLBR datix serious incident.** **Evidence of reporting culture improvements in the spinal service to be reported to the Quality Performance Committee.** **Strategy for assurance that clinical standards in the spinal service meet national standards to be reported to the Quality Performance Committee.**	**Associate Directors of Governance** **NCA Patient Safety Team** **Governance Lead for the SPSLBR** **Spinal ClinicalGovernance Team** **Spinal ClinicalGovernance Team**	**End of June 2023** **Autumn2023** **End of May 2023** **September 2023** **September 2023**			
11	**Lost to follow up**	**A deep dive review will take place of the patients who were noted to be lost to follow up during the desktop review process.**	**GPAA Director and Waiting List Surveillance Group**	**September 2023**			