

WALSALL HEALTHCARE NHS TRUST

OFFICIAL DOCUMENT

Final Report on the Patient Notification Exercise (PNE) and Patient Recall regarding patients under the care of Mr Mian Munawar Shah

11 March 2025

Trust Headquarters,
Wilbraham Court,
Moat Road,
Walsall,
West Midlands
WS2 9PS.



Trauma and Orthopaedics Patient Recall Report

Table of Contents

Table of Contents	2
1 Executive Summary	4
2 Background	5
2.1 Key dates	5
2.2 RCS 1	6
2.3 The Wrightington review	7
2.4 Identification of Never event and further restrictions	8
2.5 RCS 2	8
2.6 Trust SI Investigation Report: T&O Cluster review and NJR data	9
3 Patient recall design	10
3.1 Oversight and scrutiny	11
3.2 Staffing	12
3.3 Inclusion and exclusion criteria	12
3.4 Approach to clarifying inclusion and exclusion criteria	13
3.5 Assurance re: inclusion and exclusion criteria	15
3.5.1 Exclusion of cases prior to 2010	15
3.5.2 Upper limb audit	17
3.5.3 Results of upper limb audit	18
3.5.4 Hand and wrist audit	19
3.5.5 Lower limb audit	21
3.5.6 Extended review of knee replacement surgery	22
3.5.7 Measures of outcome by clinical domain across all audit patients	23
3.5.8 Summary of critical analysis of inclusion / exclusion criteria of PNE:	25
3.6 Initiation of the PNE	26
3.7 Assessment of quality of care	27
3.8 Definitions of harm	28
3.9 Other patients whose cases were assessed (complaints)	29
3.10 Patient involvement and communication strategy	29
3.11 Helpline workload and project integration	30
4 Results	30
4.1 Overall workload	31
4.2 Outcome for procedures of concern	33
4.3 Deceased patient cohort	37
4.4 Background to phase 2 Hand and wrist (H&W) cohort extension	37
4.4.1 Extended hand and wrist (phase 2) case review process	38
4.4.2 Patient selection	38
4.4.3 Modifications to the proforma	39
4.4.4 Results	39
4.4.5 Discussion	42
4.4.6 Summary of clinical concerns	43
4.4.7 Wrong bone excision in wrist surgery	43

Trauma and Orthopaedics Patient Recall: Report

4.4.8	Summary.....	45
4.5	Outpatient requirements	45
4.6	Patterns of clinical concerns identified.....	46
4.7	Interface with private sector / Spire Healthcare.....	49
4.8	Interface with complaints	51
4.9	Complex cases panel: Function and findings	52
4.9.1	Complex cases panel workload	52
4.9.2	Findings of RCA type assessment of 7 severe harm cases.....	52
4.9.3	Summary of findings of Complex cases panel RCA meeting.....	56
4.10	Medicolegal workload	57
5	Summary.....	57
6	Recommendations / outstanding actions.....	58
7	Appendices.....	60
7.1	Appendix A: Explanations used as basis for written communications with patients .	60
7.2	Appendix B: RCS 1 recommendations: Report issued November 2020.....	70
7.3	Appendix C: RCS 2 Recommendations: 19 th April 2022.....	73
7.4	Appendix D: ToR of complex case assurance group.....	75
7.5	Appendix E: Blank proforma for data collection	81
7.6	Appendix F: Recall administrative processes.....	87
7.7	Appendix G: Example codes used for primary upper limb PNE patient identification	88
Table 1: Key events leading up to the patient recall		6
Table 2: Initial Inclusion and Exclusion Criteria		14
Table 3: Overview of Domains and Performance Grades		16
Table 4: Number of Procrdurs per Patient		31
Table 5: No. of Patients Suffering Harm due to Treatment.....		35
Table 6: Assessment of Harm by Treatment Site.....		36
Table 7: Number of Latarjet Procedures by Year		36
Table 8: Summary of Phase 2 Hand and Wrist Cases.....		40
Table 9: Quantitative Scores for Each Clinical Domain (%) - H&W.....		41
Figure 1: Risk Balance of expansive vs restrictive recall.....		13
Figure 2: Scores of Upper Limb by Clinical Domain		18
Figure 3: Hand and wrist audit scores (%) by domain		20
Figure 4: Assessment of quality of care by domain for lower limb audit patients.....		21
Figure 5: TKR and THR numbers by yeari.....		22
Figure 6: Measures of outcome by clinical domain.....		24
Figure 7: Outline of PNE Processes		27
Figure 8: Admissions by Year.....		32
Figure 9: Rate of Harm by Year		32
Figure 10: Annotated diagram of carpal (wrist) bones.....		43

1 Executive Summary

Following concerns raised in early 2020 about surgical outcomes of an individual orthopaedic Surgeon, Mr Mian Munawar Shah, his employer, Walsall Healthcare NHS Trust (the Trust) sought external review of a small number (17) of complex upper limb surgery cases by a specialist team from the Royal College of Surgeons (the RCS) through the invited review mechanism. This reported in November 2020 and identified some concerns regarding practice within the trauma and orthopaedic department. The Trust subsequently requested a further RCS review specifically of Mr Shah's practise, to more fully assess possible concerns regarding outcome after his surgery. Through this the total number of cases reviewed by the RCS was extended to 99. The results of this review were released in April 2022, and following evaluation of both reviews, the Trust decided to undertake a patient notification exercise (PNE) and recall (hereafter referred to as recall) of patients who had undergone complex upper limb surgery by Mr Shah. The recall was initiated in September 2022, the final patient case reviews being completed in September 2024. This report describes the process, oversight, scrutiny and findings of that recall.

The areas of concern identified related to a subset of Mr Shah's practise, specifically complex upper limb surgery, and the recall comprised the following phases:

- Clarification of the procedures of concern (PoC)
- Contacting affected patients and keeping them informed throughout
- Arranging independent external clinical reviews of cases
- Delivering additional clinical follow up and treatment where required
- Fulfilling duty of candour where appropriate
- Identifying and addressing individual and systemic factors which may have contributed
- Completing a critical review of the process to facilitate future learning and reduce recurrence risk.

Overall, the notes of 382 patients who had been coded as having been admitted under Mr Shah's care and undergone a procedure of concern since 2010 were reviewed. It became apparent that there were concerns relating to technical competence with regard to shoulder and elbow replacement, shoulder stabilisation procedures involving bone grafts (the Latarjet procedure), and hand and wrist surgery involving bone fusion and bone grafts. There were lower level more generalised concerns about documentation and decision making prior to surgery, but these concerns were significantly less likely to be associated with causing direct patient harm than the technical difficulties in surgical technique that were observed. There were no significant concerns identified about outcomes following soft tissue surgery, or lower limb surgery. An additional 32 hand and wrist cases were assessed as part of a limited extension to the review.

It seems that Mr Shah was originally undertaking the duties of a more "general" trauma and orthopaedic Consultant, but as his career progressed he moved into more specialist and more complex upper limb surgery without apparently having developed the necessary competencies. In the division of surgery and the organisation at the time, it seems that governance processes, outcome data and some aspects of departmental organisation were not sufficiently robust to prevent this "mission creep" in terms of scope of practise or to oversee that it was being undertaken safely. Nor did existing national surveillance systems (e.g. National joint registry, NJR) make it easy to identify emerging difficulties with outcome for

upper limb joint replacement surgery within the Trust. Overall, it seems that alongside a deficit in competence and insight there was a deficit of sufficiently robust oversight.

Concerns were identified in 24% of the 382 cases, where the care offered was considered to have been sufficiently suboptimal to have caused moderate or severe harm to patients. This represents a significant rate of harm for specific elective complex upper limb procedures that Mr Shah was apparently not fully competent to perform. Contributory factors (individual and organisational) are considered and interventions that would minimise future risk are discussed.

Note: Lay explanations of the clinical terms used in this report are included in *7.1 Appendix A: Explanations used as basis for written communications with patients*. This wording formed the basis of the written communication with patients to try to ensure that they had a clear understanding of the procedures that had been performed and that they understood the external assessors' analysis of their treatment.

2 Background

2.1 Key dates

There were a number of individual concerns and investigations that culminated in the Trust's assessment that it was necessary to undertake a patient recall. The initial focus of concerns related to outcomes for patients undergoing shoulder replacement surgery and a specific operation for shoulder dislocation - the Latarjet procedure. Key events leading up to the patient recall can be summarised as follows:

2004	Mr Shah appointed
2010	2 nd Consultant with upper limb interest appointed
Pre 2018	Litigation cases: 21 litigation claims 2010-2018
October 2019	GMC complaint from a patient following a complaint to the Trust in 2018
23 rd January 2020	GMC making provisional enquiries about fitness to practise and issue restrictions.
Jan-Feb 2020	Local 5yr audit of shoulder outcomes -> concerns re: high complication rate
25 th February 2020	Mr Shah restricted from performing shoulder or elbow replacement and Latarjet procedure. Spire Little Aston informed.
March 2020	Spire healthcare shared that their physiotherapy team had raised concerns re 3 hand and wrist patients which had been investigated in line with their policy.
9 th March 2020-> 10 th November 2020	RCS 1 review was commissioned, and reported November 2020 – recommendations focussed on departmental level changes
February 2021	Report of external clinical review (The "Wrightington review") of 5 of the most concerning cases from RCS 1 - this identified significant concerns re: Mr Shah's practise, and advised a wider review of his current scope of practise
March 2021	The Trust offered Mr Shah retraining and peer support

Trauma and Orthopaedics Patient Recall: Report

April 2021	Never event identified relating to wrong site surgery - Mr Shah was suspended from all surgical activities and patient facing work
May 2021 ->19 th April 2022	RCS 2 commissioned, reported 19 th April 2022. Recommended a review of Mr Shah's wider practise, and some further departmental recommendations
14 th Sept 2021->12 th April 2022	Trust SI group initiated a cluster review of 19 cases of concern - reported 12 th April 2022.

Table 1: Key events leading up to the patient recall

Events were not as linear as represented in this table, with reports taking a number of months from initiation through completion to publication due to the complex and confidential nature of this type of inquiry.

The clearest trigger for this process began when a patient reported Mr Shah to the GMC in October 2019, with the GMC writing to the Medical Director of the Trust on 23rd January 2020. In this letter the GMC stated that they were making provisional enquiries into concerns about Mr Shah's fitness to practice. At around the same time (January 2020), the Trust's second specialist upper limb Consultant initiated a 5-year audit of shoulder surgery. This was in response to observations of an increased rate of early failures of shoulder replacement and anecdotal feedback from colleagues at the Royal Orthopaedic Hospital (ROH) that they were seeing an atypical number of patients requiring redo surgery.

There were concerns that the internal audit (completed in February 2020) showed an increased complication rate for Mr Shah's shoulder replacement surgery and then on 12th February 2020 another patient suffered an early failure of shoulder replacement surgery. This triggered escalation of concerns to the then Divisional Director of Operations for Surgery and the Acting Medical Director. Mr Shah's practise was immediately restricted – he ceased to undertake shoulder or elbow replacement surgery, or the Latarjet procedure -and the Royal College of Surgeons (RCS) was asked to perform an initial service review, known as RCS1 which was commissioned in March 2020 and reported in November 2020.

2.2 RCS 1

On March 9th 2020, the Trust's Medical Director wrote to the Chair of the Invited Review Mechanism (IRM) at the RCS to request an invited service review of the healthcare organisation's trauma and orthopaedic (T&O) service. In particular, the request highlighted concern regarding the upper limb service that had been raised through various channels. The request was considered by the Chair of the RCS IRM and a representative of the British Orthopaedic Association (BOA), and it was agreed that an invited service review would take place. A review team was appointed and an invited review of 17 cases of concern took place between 27th – 28th July 2020. In its introduction, the RCS1 report stated that within T&O in the preceding 2 years there had been 885 incidents, 6 serious incidents and 90 complaints. These incidents do not relate to Mr Shah, but rather across the whole T&O service. It is not possible to benchmark these numbers, but the number of incidents suggests an active reporting culture.

The RCS team reported that between August 2015 and July 2020, the Trust had undertaken 217 shoulder replacements, 8% of which were revisions, and stated that this would be considered an acceptable revision rate by a reasonable body of orthopaedic surgeons but

noted that smaller and often variable denominators made drawing conclusions based on revision rates difficult.

The published report was released to the Trust in November 2020 and included four urgent recommendations relating to the clinical care of one patient, patient pathways, physiotherapy provision and the implementation of National Safety Standards for Invasive Procedures (NatSSIPs). An additional twelve recommendations, for consideration by the Trust, were aimed at the future improvement and development of the upper limb service. The recommendations included a range of departmental, organisational and Trust governance actions relating to the need to establish MDTs, a review of consent processes, the development of robust M&M meetings as well as enhanced governance procedures such as the inclusion of National joint registry (NJR) data in annual appraisal. Other recommendations related to adequacy of resource and training for audit and wider governance activities as well as the provision of improved granularity of outcome data. The full recommendations of the RCS 1 report are included in *7.2 Appendix B: RCS 1 recommendations: Report issued November 2020*.

The first RCS report included no specific recommendations relating to Mr Shah's individual practise.

2.3 The Wrightington review

In February 2021 the Trust commissioned an external tertiary T&O Consultant to review 5 complex shoulder cases where concerns had been identified from the RCS 1 review. The assessor commented that "all five of these cases demonstrate significant concerns with regard to decision making, clarity of thought, note keeping, and technical application". Furthermore, for the first time more specific concerns were raised about aspects of Mr Shah's wider practise:

"In all of the cases, the clinical notes are very brief. There is very limited evidence of formal examination of patients. There is often not enough detailed information from which to judge the thought processes that have gone into clinical decisions made..... Whilst all surgeons have a spectrum of outcomes and surgical complications are inevitable, each of these five cases has shown significant technical deficiencies that would be outside the realm of accepted shoulder surgery practice given the recurrent nature of similar problems in each of the cases. The specific complications of graft and implant malposition are almost always due to inadequate surgical exposure. Given the repeated nature of the specific deficiencies over a short timescale, I find it concerning that Mr Shah did not himself independently reflect on his practice.

I think it entirely reasonable for the Trust to request Mr Shah not to continue to perform Latarjet and shoulder arthroplasty without a period of retraining. I cannot comment on the remainder of the largely arthroscopic aspects of Mr Shah's practice however his misinterpretation of the clinical images in X's case raises concern. It would be entirely appropriate to conduct a wider review of his current scope of practice."

It was this report and the subsequently identified need for further assurance on Mr Shah's wider practise that triggered a second invited review by the RCS (see section 2.5).

2.4 Identification of Never event and further restrictions

In April 2021, a Never Event (wrong site surgery) dating back to 2019 was identified, raising concerns about Mr Shah's consent taking, perioperative management, completion of the WHO Surgical Safety Checklist and his probity (for non-disclosure of the Never Event). Further restrictions from all theatre activity and patient facing work were implemented.

2.5 RCS 2

On 21 May 2021, the Trust's Medical Director wrote to the Chair of the Invited Review Mechanism (IRM) to request an invited clinical record review of a range trauma and orthopaedic cases of patients who had been under the care of Mr Shah. This was to undertake a more detailed review of Mr Shah's surgical outcome and to provide a more reliable indicator of level of concern to decide on next steps. In particular, the review highlighted specific cases in which there had been concerns raised about Mr Shah's patients requiring revision shoulder surgery, but also included a range of randomly selected cases across the wider scope of his surgical practise.

This request was considered by the Chair of the RCS England IRM and a representative of the British Orthopaedic Association (BOA), and it was agreed that an invited clinical record review would take place. By this time, Mr Shah had already had his practice restricted, initially only in relation to shoulder surgery cases, however, by April 2021 this been extended to all patient facing contacts. In June 2021 the GMC issued an interim restriction to practice order concerning Mr Shah.

An invited review of the cases was undertaken on 16th and 17th August 2021. The patient selection included upper and lower limb orthopaedics, acute trauma and elective surgery and was designed to comprise 20 shoulder cases, 10-20 elbow cases, 20 hand cases plus 40 acute trauma admissions. Clinical case analysis included the review of the clinical records, and supporting information such as x-rays and clinic letters which were provided to the review team by the Trust. Mr Shah was interviewed by the review team, using remote videoconferencing, on 31st August 2021. 9 patients had been excluded from the original selection of 91 due to either duplication or lack of availability of medical records, so 82 cases were reviewed in detail

The report from the RCS 2 review was released to the Trust on 19th April 2022 (see 7.3 *Appendix C: RCS 2 Recommendations: 19th April 2022* for summary of recommendations). It included a range of recommendations based on the review of 82 complete sets of patients notes. Some of these overlapped with the departmental wide recommendations from RCS 1 and can be summarised as:

1. The Trust should complete statutory duty of candour (SDOC) for relevant patients.
2. Review consent taking procedures within T&O. It should ensure that consent practices are compliant with the Montgomery ruling.
3. Share findings with surgeon to give opportunity for reflection
4. Ensure there is appropriate MDT input, and that decisions and communications are adequately documented
5. The Trust should consider improvement of trainee supervision and consistent consultant oversight at all stages.

6. Need to develop approaches to patients with ongoing pain and that patients should be reassessed to establish (1) absence of pain and (2) have repeat radiographs to assess union
7. **Trust should undertake a review of Mr Shah's wider practice**
8. The Trust should improve the quality of record keeping in clinical records / review adequacy of medical records.
9. The Trust should audit the standard of clinical documentation to ensure there are contemporaneous and comprehensive notes of patient care at each stage of the surgical pathway.

The 2 recommendations specific to Mr Shah included a recommendation that the Trust should undertake a review of Mr Shah's wider practise, and that the findings of the case assessments should be shared with him to enable reflection. The Trust developed a separate action plan to address the wider T&O departmental issues raised by the RCS and these have been implemented and signed off by the RCS.

2.6 Trust SI Investigation Report: T&O Cluster review and NJR data

Whilst awaiting the RCS 2 report, an Extraordinary Serious Incident Group met on 14th September 2021 and commissioned a cluster review of 19 cases of shoulder surgery where there was an early failure of the procedure necessitating further treatment. The Trust had commissioned a review of data from the NJR and noted that there was little evidence of concern with regard to the Trust's outcome data, and that nationally the overall revision rate was 3%. The NJR for shoulder replacement surgery was felt to be relatively immature compared to the data available for more well-established joints such as hip joint replacement surgery. It was noted that compliance with data submission to the NJR for shoulder replacement had deteriorated since 2018.

The cases reviewed by the Trust included 17 reverse shoulder replacements, one Latarjet procedure and one shoulder hemiarthroplasty - i.e. at this stage the reviews had remained confined to issues relating to shoulder surgery and were focussed predominantly on shoulder replacement.

17 of the cases had been performed by Mr Shah, with the hemiarthroplasty and one of the reverse shoulder replacements having been undertaken by the second upper limb Consultant. The commonest issues identified relating to Mr Shah's practise were:

- Problems with surgical technique contributing to dislocation
- Interpretation of x-rays
- Documentation, including poor quality operation notes, illegible consent forms, lack of quantification of risk on consent forms

These were essentially the same themes as identified by the expert Wrightington and RCS 2 reviews - importantly the concerns about surgical technique were a concern in terms of the effect on long term patient outcome. A new concern was raised about radiology.

The experts were critical of the surgical technique in 14 of the 17 cases that had been operated on by Mr Shah. A recurrent issue included misplacement of the base plate. Whilst malrotation of the base plate does not invariably lead to adverse outcomes, it does predispose to dislocation. These issues were often visible on post-operative x-rays, though these issues

were not recognised by the (usually) middle grade staff reviewing the x-rays in out-patients and X-rays were mostly not reviewed by Mr Shah himself. This raises concerns about whether there was adequate competence and supervision of the non-consultant grades to review these post operative films and also whether Mr Shah was aware of concerns about his surgical technique and patient outcomes (because of paucity of direct outpatient follow up or critical review of his radiographic outcomes).

The report additionally commented about the lack of quantification of risk within consent forms, and illegibility of consent forms.

Examination of the numbers of complaints over the previous 5 years showed an increase in the number of complaints received in the financial years 2018/19 and 2019/20 which had not been identified by the complaints team, the Division or Care Group (complaints increased from a baseline of 1 per annum to 4 and then 6 in 2018-19-20). The low numbers do not lend themselves well as a stand-alone indicator of poor performance. Concerns about upper limb surgery being a historical outlier in terms of medicolegal cases some 5 years previously were also mentioned in the Trust SI report but not quantified. Concerns about the culture within the T&O department as well as the effectiveness of governance systems and processes were identified.

Ultimately, both the Wrightington review of 5 cases in February 2021, backed up with a larger review of 82 patients' care by RCS2 raised serious concerns about Mr Shah's performance with regard to his shoulder practise. Both recommended a wider review of Mr Shah's scope of practise. The detailed external assessments undertaken as part of the Trust's internal cluster review corroborated these concerns and at a meeting of the Trust board on 8th June 2022 the Trust CMO and Group Director of Assurance recommended that a patient recall should be undertaken. Recruitment and planning for the recall were undertaken over the summer months and the full patient recall was initiated in September 2022.

3 Patient recall design

Neither the RCS nor the Wrightington review had offered the Trust specific advice about which types of procedures should be included in the wider review of Mr Shah's scope of practise, and it was not clear whether this advice related to a recall of all patients who had undergone shoulder replacement surgery under Mr Shah's care, or whether in fact it was necessary to consider a wider range of procedures as being of possible concern. The Trust was not aware of any red flags with regard to other procedures, but some of the concerns about practice that had been identified might have had wider implications (for example concerns about documentation, concerns about consent, follow up and Xray interpretation). There was only one additional clinical red flag that had been identified - concerns about hand and wrist outcomes that had previously been reported by a physiotherapist at Spire Little Aston which had been investigated in line with their policy.

There was therefore little direction about the design or scope of the planned recall.

Just as the patient recall was being initiated NHSE Quality Board published a National patient recall framework in June 2022 (see [B1631 national-patient-recall-framework.pdf \(england.nhs.uk\)](https://www.england.nhs.uk/publications/b1631-national-patient-recall-framework.pdf)). This document makes it clear that the overall objective of a patient recall is to *"limit or mitigate the harm to patients and provide a clear focus for their ongoing care.*

Patient safety is the priority concern for all recall processes. Additionally, while the process of learning and improvement should be carried out as a separate process to the recall, it should follow immediately from it and be informed by what is found through the recall process.” The document is a helpful summary of the principles underlying a patient recall, with an absolute focus on patient safety and the need to identify the need for ongoing clinical assessment or treatment, but there is limited practical advice or guidance for teams who are attempting to design a patient recall de novo.

The patient recall framework includes some important principles relating to the importance of patient involvement including feedback on the review process itself, as well as the need to work closely to try and align inclusion and exclusion criteria with other organisations that might also be needing to undertake a recall of patients.

Most importantly, it is clear that the primary focus of a patient recall is the identification of patients who might have suffered harm as a result of suboptimal treatment and in particular those who might need further treatment. A patient recall is not primarily directed at reviewing the competence or otherwise of an individual clinician, but at ensuring that all patients who might need further treatment are identified and seen and treated as necessary.

3.1 Oversight and scrutiny

An assurance board – known as the complex case assurance group - was established as soon as the patient recall was initiated. This included representation from a range of external stakeholders, including NHSE, the ICB, CQC and representatives of Spire Healthcare. For ToR see *7.4 Appendix D: ToR of Complex Case Assurance Group*.

This proved to be an invaluable independent and critical forum for the project team. Not only was progress against all KPIs (mainly related to the rate of patients’ assessment, fulfilment of SDOC and completion of outpatient assessment) reported and monitored, but the assurance group was comprised of individuals with extensive external advice and expertise in complex patient recalls as well as wider governance concerns and NHS processes. The assurance group sought additional clarity regarding a few key areas which triggered considerable further analysis to offer assurance about patient selection, most importantly making sure that the review had sufficiently identified all patients who had undergone a procedure where there were systemic concerns about Mr Shah’s competence - the group was instrumental in reaching agreement about appropriate inclusion and exclusion criteria for the recall). Other issues that were reviewed in detail included the rationale around the 2010 cut off date (see *Exclusion of cases prior to 2010*), and the ethics and legal responsibilities relating to relatives of deceased patients who had been harmed (see *Deceased patient cohort*).

A critical part of the function of the assurance group was that it provided a forum where the Trust could work closely with governance teams at Spire Healthcare, who were simultaneously undertaking a review of Mr Shah’s practice at Spire Little Aston Hospital. In line with NHSE guidance it was important that inclusion and exclusion criteria were shared across both organisations, as well as the overall design of the recall process within the public and private sector. As well as collaborating on recall design, the two providers shared results and findings as they came available. This collaborative approach meant that from inception to conclusion the reviews across the two services were aligned. Sharing results meant that if a new concern or area for review emerged in either organisation it was reviewed and investigated by the other, ensuring both consistency and equity of approach and minimising the chances of either

organisation missing an area of concern. Some differences in findings were identified, and these were further explored and are discussed within the results section of this report. The differences in some findings provided valuable insight into factors which might have been modifiable within each organisation and provided as much learning as the areas where findings were closely aligned.

The Trust and the assurance group were aware that there would be some patients who had not undergone a procedure of concern but who would have concerns about their outcome following their operation i.e. the review would not identify every patient who had ever experienced a poor outcome under Mr Shah, but rather had carefully identified the procedures where the rate of adverse outcome was unacceptably high and there were fundamental concerns about surgical competence. Therefore, all patients who contacted the Trust with any concerns or complaints about their care (regardless of the procedure that had been undertaken) were also offered an external and independent review of their care by the external Consultant team, the findings were shared with them in detail and SDOC was fulfilled (where relevant). These numbers were not included in the PNE as they had not undergone a PoC. Their numbers and outcome have been reported and managed via the Trust's complaints processes and rates of concern were low.

3.2 Staffing

The Trust appointed external staff to lead and deliver the recall. An experienced NHS medical Consultant with extensive experience within Governance and safety including patient recall was appointed. A panel of external trauma and orthopaedic Consultants were recruited, who had special interest and experience in upper limb surgery (1 tertiary shoulder specialist, 2 upper limb Consultants, an elbow specialist, 2 specialist hand and wrist surgeons). All had extensive relevant clinical experience and were approved / endorsed by the British Orthopaedic Association. Administrative and additional clinical support was delivered by a clinical nurse specialist with previous patient recall experience, an extended role physiotherapist who offered phone based clinical advice and signposting, and project management and administrative support from local NHS staff who were seconded to the project for its duration.

3.3 Inclusion and exclusion criteria

The NHSE patient recall framework makes general recommendations about patient inclusion:

“3.1.1. There should be a robust process for identifying which patients are in and out of scope for the patient recall. This should be evidence-based where possible. Flexibility may be required in amending the criteria if new information comes to light.

3.1.2 There are a number of factors to consider when prioritising patients, including the impact of involving patients in review and the potential harm that may cause.

3.1.3 It can be potentially stressful for a patient when they are recalled for a review of their care or treatment, therefore ensuring that you do not include patients unnecessarily is important. Each patient experience will be unique and must be reviewed with patient safety as the priority concern.

3.1.4 *If the patient recall started through another organisation, the agreed inclusion and exclusion criteria should align as much as possible. A main contact must be nominated by the lead organisation before contacting the patient.*

The assurance group considered the careful balance that needed to be struck to minimise the risk of missing patients who might have ongoing health risks as a result of their treatment, vs the need to avoid overinclusion, with the excess anxiety, workload and cost this might incur for patients as well as for the local health economy and local health service delivery.

Risk balance of expansive vs restrictive recall

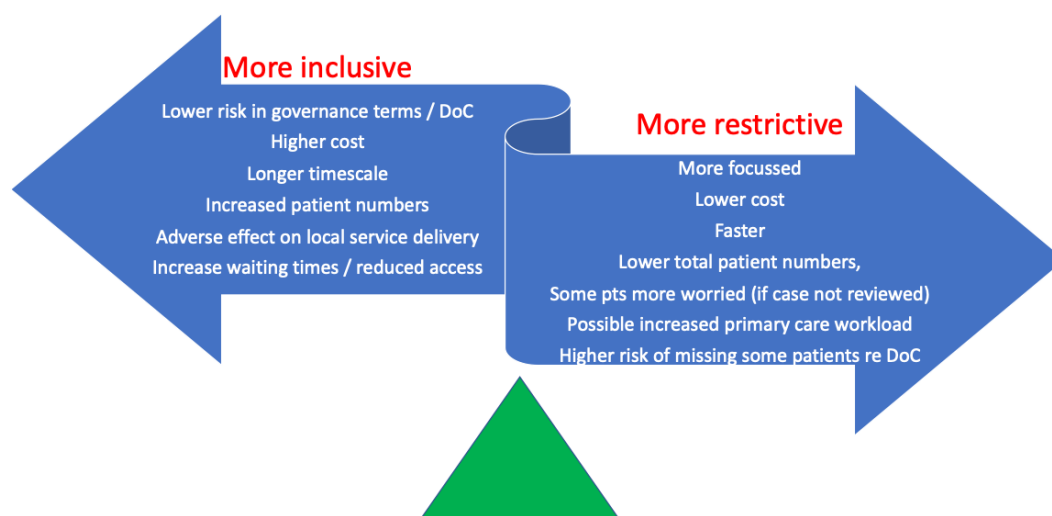


Figure 1: Risk Balance of expansive vs restrictive recall

The starting point for the identification of possible patients for inclusion was to identify all patients who had been coded as having been admitted under the care of Mr Shah. The IT team provided information by year of procedure from every patient who had been admitted under Mr Shah's care and included codes (operative and diagnostic). It was possible to identify all patients who had been admitted under Mr Shah's care since records were fully computerised at the beginning of 2010 - this amounted to 7578 admissions coded under Mr Shah's care. A significant proportion of these patients were not operated on by Mr Shah himself, but by wider members of the T&O team – but their admissions had been under the Consultant care of Mr Shah. A further significant minority had been admitted to Hospital under Mr Shah's care but had not undergone surgery.

3.4 Approach to clarifying inclusion and exclusion criteria

A very substantial portion of the work undertaken by the recall team, overseen by the assurance group, focussed on accurate definition of appropriate inclusion and exclusion criteria, that would reach an appropriate balance of minimising the chances of missing patients at risk of harm, as well as not overly expanding the recall in low or no risk patients. It was clear that all patients who had undergone shoulder or elbow replacement surgery, or the Latarjet procedure needed to have their care reassessed, but there was a need to consider more fully whether there might be other procedures or patients which merited inclusion.

There were three components that informed this decision-making process:

Trauma and Orthopaedics Patient Recall: Report

- Detailed analysis of the nature cases that had already been externally reviewed by the 2 RCS invited reviews
- A series of additional audits of Mr Shah’s wider practise relating to procedures where there was no apparent concern – testing of exclusion criteria (see 2.1.1 for further details)
- The advice of the external independent Consultant assessors

Detailed analysis of externally and previously reviewed cases:

An analysis of all the cases that had been independently / externally assessed was undertaken, to see if patterns of areas of concern could be identified. Therefore, all cases involved in the RCS 1 and 2 reviews, the Wrightington cases, and the cluster investigation were reviewed and analysed by patient demographics, site and nature of surgery and outcome. Between the two reviews, the RCS had completed 99 independent external case reviews and careful analysis of the rate of harm by procedure enabled initial identification of the highest risk procedures. Using this data the initial inclusion / exclusion criteria were defined as follows:

Included as procedure of concern (PoC)	Excluded (no evidence of concern)
Shoulder replacement surgery: - Total shoulder replacement - Reverse shoulder replacement - Shoulder hemiarthroplasty - Humeral resurfacing procedures	Trauma surgery, particularly general orthopaedic “take” patients #NOF Total Hip Replacement Hip hemiarthroplasty
Latarjet procedure	Upper and lower limb fractures
Elbow joint replacement	Paediatric patients (all minor trauma)
Hand and wrist surgery that included fusion / bone grafting	Knee replacement surgery
Thus, the procedures of concern (PoC) can be generalised as all complex (generally elective) upper limb surgery that involved open (non-arthroscopic) procedures requiring bone grafting and/or insertion of metalwork or joint replacement. Patients who had undergone these procedures performed by Mr Shah were to be included in the recall.	

Table 2: Initial Inclusion and Exclusion Criteria

The workload relating to Mr Shah’s general trauma take patients and lower limb surgery was not found to be of concern within the RCS or other reviews / information sources. Patient selection remained an iterative process throughout the review as per NHSE guidance and was ultimately extended in a few limited areas - subsequent clinical opinion resulted in expansion of the inclusion criteria to include patients requiring open reduction and internal fixation (ORIF) for proximal and distal humeral fractures and these were added to the list of PoC as initially defined following detailed analysis of the RCS case reviews. Once the reviewers undertook assessment of some of the H&W procedures it became clear that this was an area of significant concern and that it was necessary to expand the scope of the H&W cohort.

3.5 Assurance re: inclusion and exclusion criteria

The Complex Case Assurance Group were integrally involved in the decisions around inclusion and exclusion criteria throughout the duration of the patient recall. The findings of the RCS 1 and 2 invited reviews were analysed and presented in detail, and this gave rise to the initial inclusion criteria – broadly shoulder replacement surgery, shoulder stabilisation, elbow replacement). Thereafter, however this was necessarily an iterative process, and modifications and extensions were made- most notably the inclusion of proximal and distal humeral fractures requiring surgery, and then the considerable expansion of patients undergoing complex hand and wrist surgery – which culminated in a second phase of the recall (see *Background to phase 2 hand and wrist (H&W) cohort*).

Of even greater importance from a patient safety perspective were the decisions relating to which patients did not require automatic inclusion in the recall. The Complex Case Assurance Group requested systematic review of a range of patients who had not been included in the main patient recall so that they could be sure that all procedures that had placed patients at risk of harm had been included in the recall. Further analysis included assessment of the medical records of cases that were excluded by date of surgery (prior to 2010) and audits of medical records of patients who had undergone a range of other upper and lower limb procedures under Mr Shah's care. The results of this more detailed work are presented below.

It is important to remember that in addition to these measures, any patient who contacted the Trust with concerns about their treatment under Mr Shah could ask to have their case reviewed independently by the external Consultant team, using exactly the same methodology as the full review. It was considered that this safety net meant that any patient of Mr Shah's who had concerns could access the same level of external scrutiny of their care as patients who were included in the recall. This applied to all patients, regardless of procedure or site of surgery or date of their treatment. The Trust had gone to considerable lengths to raise awareness of this via local media, the Trust's website and putting in place a dedicated phone line for any patients with concerns. The numbers of patients who sought this additional review were limited and the rates of harm were low, but nonetheless the opportunity for any of Mr Shah's former patients to be able to request a full independent external review of their care, regardless of procedure or whether they met PNE inclusion criteria was an important additional safety net and offered additional assurance to patients.

3.5.1 Exclusion of cases prior to 2010

The initial inclusion criteria comprised patients who had undergone surgery from 2010 onwards. The initial rationale behind this initial decision had been that data from the RCS and other case reviews had shown that the patients who had been operated on a long time previously and who had a poor outcome had, in general, already represented to clinical services with ongoing symptoms i.e. the chances of *unidentified* harm were significantly lower in the earlier patient cohorts. In addition, the rates of harm were lower earlier in Mr Shah's career, so the risk of harm were also lower in patients operated on prior to 2010. There were also logistic difficulties in accessing accurate medical notes and records for the earliest patient cohorts.

The assurance group revisited this decision early in the review process and considered whether the patient recall should be extended to include patients whose surgery dated from 2009 or earlier.

Trauma and Orthopaedics Patient Recall: Report

A review of the electronic records of all the 127 patients who had undergone PoCs prior to 2010 was undertaken and identified that only 51 patients were living and only 37 of these patients were traceable. Analysis of letters from follow up clinics and radiology for these patients found no cases where there was evidence of concern about long term outcome. 3 patients prior to 2010 (non PoC) had initiated complaints which were fully investigated using the same process as the PNE, but in all 3 cases the findings had been inconclusive due to lack of availability of clinical records and imaging. 10 patients had already been included in the patient recall as they had later gone on to undergo further procedures after 2010.

The risk: benefit of extending the PNE to include patients prior to 2010 was considered carefully and was felt to be negative following this analysis of the cases. The available evidence had suggested that the rate of harm was low (no cases of poor outcome) and contacting all traceable patients who had undergone PoC and offering OPD review was felt unlikely to add to existing clinical treatment options i.e. patients who had concerns could have re-attended via GP at any stage in the last 14 years or could have contacted the Trust directly via the dedicated helpline. Overall, it was considered that contacting patients who had undergone surgery prior to 2010 could expose patients to considerable anxiety/ worry without any clear evidence of likely clinical gain. The indicators were that the levels of risk / harm were low. This position was unanimously supported by the assurance group and the recall was not extended to include surgery dates prior to 2010.

An additional requirement of the assurance group was that audits of additional cases who had undergone apparently “lower risk” procedures should be undertaken. It was considered that this should comprise 30 additional upper limb procedures and 30 lower limb procedures. These additional 60 cases were to be approximately allocated as 10 additional procedures for each of the shoulder, elbow, wrist, hip, knee and ankle joint.

An audit proforma was used which graded 7 domains of practise with 5 levels of performance:

Domain	Assessment grades
Initial care and pre-operative assessment	1: Very poor care
Decision making and indication for surgery	2: Poor care
Adequacy of consent	3: Adequate care
Surgery – technical aspects	4: Good care
Post operative care and follow up	5: Excellent care
Communication and documentation	Note: Scoring system is aligned to the RCPCH SJR assessment system (see nqb-national-guidance-learning-from-deaths.pdf (england.nhs.uk))
Assessment of care overall	

Table 3: Overview of Domains and Performance Grades

3.5.2 Upper limb audit

Cases were randomly selected, to try and analyse the wider spectrum of Mr Shah's upper limb practise – both traumatic / emergency and elective procedures. It was considered most appropriate to select procedures performed in the latter years (due to clinical relevance for patients, also the accessibility of clinical information and because complaint and governance data had suggested that the concerns about Mr Shah's practise emerged later in his career at the Trust).

There were difficulties identifying sufficient patients for the audit, for the following reasons:

- a) The majority of Mr Shah's complex upper limb surgical procedures had already been included in the formal patient recall exercise
- b) Of the residual procedures a large proportion had not been undertaken by Mr Shah. This was partly because they were less complex procedures and had more often been performed by SAS or SpR members (resident Doctors) of his team. In other of cases the patient had been coded as admitted under Mr Shah's care but operated on by other orthopaedic Consultants.
- c) The external assessors considered that it would not be easy to objectively audit the quality of arthroscopic procedures, or those that related to soft tissue procedures, because without radiographic evidence of post operative findings it would not be possible to offer a definitive opinion about the technical quality of the surgery. The assessment would be limited to a review of the operation notes which would be unlikely to enable a critical assessment of the procedure. This assessment was based on their experience assessing the case notes of patients who had undergone PoC – many had also undergone arthroscopy or soft tissue procedures as part of their treatment pathways, but it was not possible to make any objective assessment of the quality or effectiveness of these procedures, as the only information available was that included within the operation notes, with no radiographic imaging to allow objective analysis.
- d) The older procedures had limited information available within the records or on Fusion (electronic patient record) such that accurate assessment was not possible.

In total 178 sets of medical records were reviewed to reach a final cohort of 60 who were eligible for inclusion in the upper and lower limb audit, by virtue of the fact that they had been operated on by Mr Shah in person, and that there was sufficient information available in the notes about an eligible procedure to enable adequate assessment. This was a labour intensive process, involving a manual review of all 178 sets of notes, because the majority of patients who were coded as having been admitted under Mr Shah did not have a relevant surgical procedure performed by him personally.

As the patient recall and then subsequent audit unfolded, the upper limb surgeons considered that there were concerns about Mr Shah's execution of surgery for patients with proximal and distal humeral shaft open reduction and internal fixation (ORIF). As a result of this, all proximal and distal humeral fracture patients were moved into the patient recall (i.e. the scope of the recall was extended on the basis of expert advice) and these patients were removed from the audit, which reduced audit numbers, but expanded the PNE.

In total, the results of 22 additional shoulder and elbow procedures were included in the audit covering the range of Mr Shah's non joint replacement upper limb clinical practice. by Mr Shah.

Trauma and Orthopaedics Patient Recall: Report

The cases included in the upper limb audit therefore comprised:

- Surgilig procedure 6
- Acromioclavicular joint (ACJ) repair 4
- Bankart procedure 2
- Subacromial decompression +/- balloon insertion 7
- Sternoclavicular joint surgery 1
- Open reduction and internal fixation (clavicle) 1
- Humerus 1

3.5.3 Results of upper limb audit

The data presented relate to patients who underwent upper limb surgery (procedures as outlined above), but did not undergo a procedure of concern (PoC).

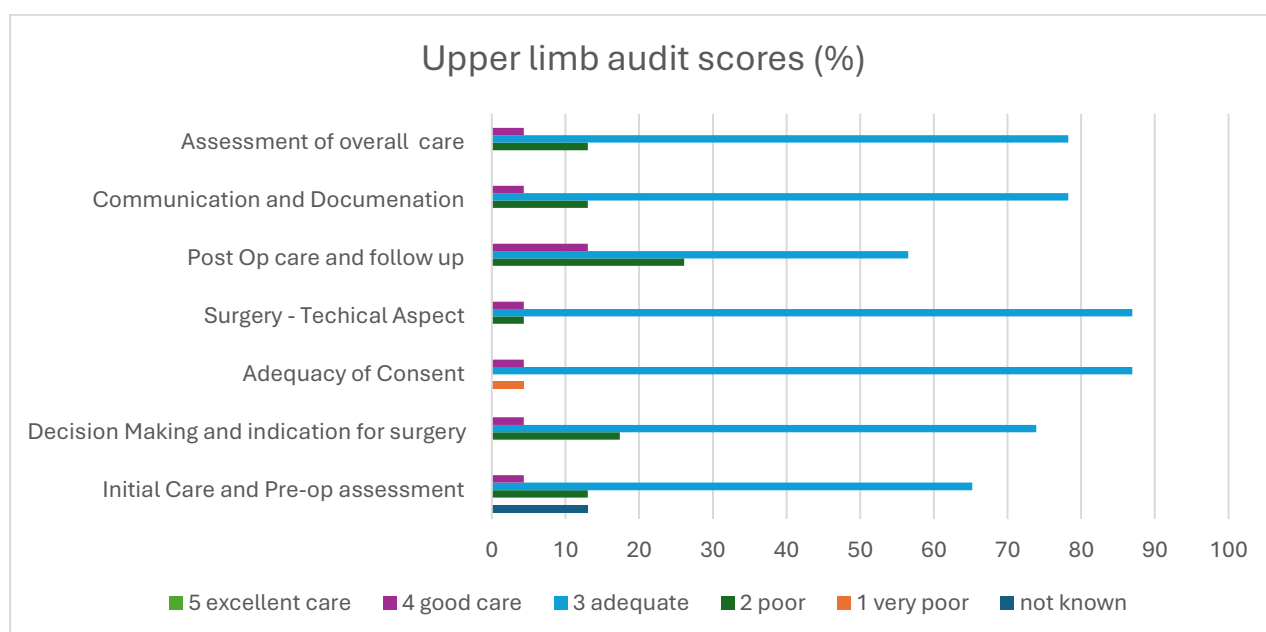


Figure 2: Scores of Upper Limb by Clinical Domain

Results were reassuring and in only one case was the treatment considered to have been suboptimal with the patient considered to have suffered harm as a result of the treatment they were offered. These data suggested that there was no evidence that there were significant concerns about Mr Shah's practise in less complex upper limb surgery.

In terms of the areas which were scored as poor or very poor, the following detail can be noted:

In only one of the upper limb audit cases were concerns about surgical technique documented - this was a case where a patient suffered acromioclavicular joint disruption following a fall. The assessor did not consider that surgery was necessarily indicated, nor that the surgery was adequately performed. Mr Shah's operation did not improve the patient's symptoms, and the patient's care had already been transferred to another Consultant. In all other cases the surgery was considered appropriate and to have been adequately performed.

The area of consent was reviewed more carefully, because the Spire Healthcare team had expressed some concerns about the quality of Mr Shah's consent processes as undertaken at Spire Little Aston. In one case (1/22 case notes reviewed) the assessor expressed concerns about the adequacy of the consent process - in all other cases the consent was considered to be adequate. In the case of concern, the patient had been consented for an open ACJ construction, but in fact an arthroscopic procedure was performed. There were no concerns about the patient's outcome (limited documentation) and the procedure performed was less invasive than that the patient consented to, but nonetheless the procedure undertaken was not the same as the procedure named in the primary consent form. The consent was rated "very poor". The patient's outcome was good. The adequacy of consent was also assessed in more detail in the lower limb cohort and the H&W patients.

The lowest scores related to the adequacy of post operative surgical follow up (graded as poor in 25% of cases), an area that was not directly due to Mr Shah's own practise – it was an area that had already been recognised by the RCS 2 review to be a departmental wide issue that needed to be addressed.

3.5.4 Hand and wrist audit

There had been limited flags from the RCS and other external reviews around hand and wrist (H&W) procedures and this was not, initially, an area of significant concern for the recall team. A physiotherapist at Spire Little Aston had previously raised concerns about the outcome for some patients following H&W surgery, which were investigated in line with their policy. At this time, these were not noted to be a trend. There had been no concerns raised via the Trust's complaints team, or any local governance processes at the Trust. However, as the 36 cases within the initial patient recall were being assessed, significant concerns were raised by the external H&W surgeons.

The external H&W Consultants were mainly concerned about H&W operations where wrist bone fusion or excision was undertaken. It also became clear that less precise coding systems around H&W surgery meant that patient identification of the H&W cohort was more complex and this made it difficult to be confident that all relevant patients had been identified. There were therefore concerns that the scope of patient inclusion from the H&W cohort was not adequate i.e. that a greater number of H&W patients needed to be reviewed.

As a result of these concerns, a more extensive audit of extended H&W procedures was undertaken:

- A manual review of all patients on the database: 2018->2021 was undertaken
- More complex cases including fusion or excision, redo surgery etc. were selected. Codes included W210, W231, W192, W281, W164, W232 and others
- Procedures: Malunion, non-union, metacarpal fractures, CMC fusion, trapeziectomy, i.e. "higher complexity" cases were reviewed in the H&W audit.

A further 18 H&W cases who underwent surgery between 2018-2021 inclusive were identified for audit. In 6/18 (33%) cases the overall quality of care was assessed as "poor or very poor" (see figure) and the pattern of concerns was consistent with concerns identified in Spire Healthcare's ongoing PNE

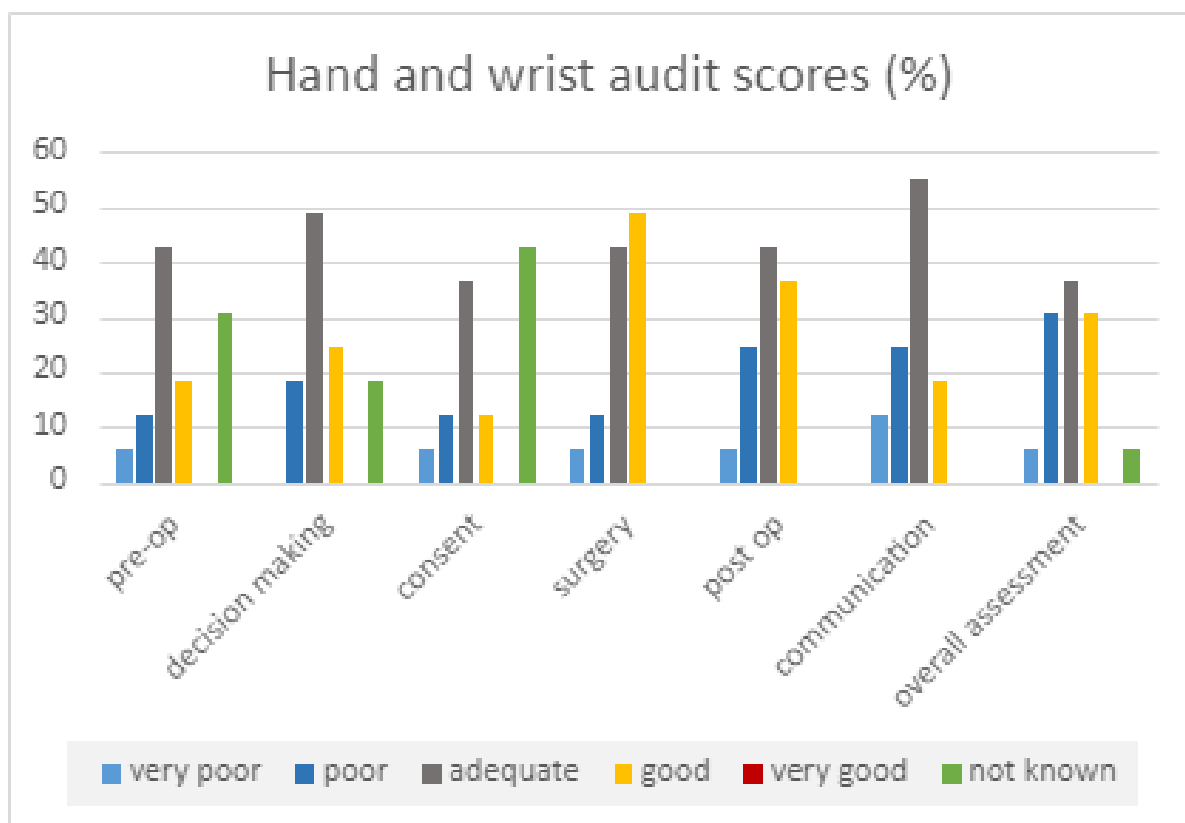


Figure 3: Hand and wrist audit scores (%) by domain

Hand and wrist audit scores (%) by domain

When the results of the audit relating to the additional 18 H&W patients was presented to the assurance group it triggered a decision to undertake an extension (“phase 2”) of the patient recall. Some 36 hand and wrist cases had already been included in the primary patient recall and a decision was made that to ensure appropriate assessment and follow up of all higher risk hand and wrist patients this needed to be extended.

Coding was a particular challenge for the hand and wrist surgery, as operative codes are less well defined than for the major joint procedures such as shoulder and elbow replacement. Ultimately it was necessary to undertake a manual review of the whole patient database to identify individual diagnostic and operative codes for every patient undergoing H&W surgery since 2010 to ensure full patient inclusion. A further 32 patients were identified who underwent complex H&W fusion or excision surgery, where review of their medical records and pre and post op X-rays suggest possible concerns and these additional patients were included in a limited phase 2 patient recall (see *Background to phase 2 hand and wrist (H&W) cohort*). Therefore, concerns about H&W surgery were identified during the recall as a result of an extended audit and this resulted in a relative delay in their inclusion in a second phase of the PNE. All patients who underwent a H&W procedure of concern have now had their treatment assessed and have been informed of the results of that assessment. The detailed findings of this extension of the PNE are available in *Extended hand and wrist (phase 2) case review*.

3.5.5 Lower limb audit

Similarly to the upper limb patients it proved to be relatively difficult to identify additional patients who had undergone lower limb surgery performed by Mr Shah personally - because the majority of the lower limb / emergency and general procedures performed on patients under his care were actually operated on by wider members of the T&O team. Ultimately, a review of 160 sets of patient notes yielded 23 procedures in 22 patients for inclusion in the extended assessment of patients who had undergone lower limb surgery.

- Neck of femur (NOF) / nailed / screwed / hemiarthroplasty: 7
- Total hip replacement (THR): 4
- Knee: Total knee replacement (TKR): 4
- Open reduction and internal fixation (ORIF) of fractures: 8 (includes distal femoral fracture, patella fractures, fractures of tibia and fibula)

Overall, in assessment of these 23 cases there was one case where there was an assessment of harm – a fractured NOF case where the assessor considered that there was suboptimal insertion of a hemiarthroplasty prosthesis. It was considered that there were no major additional concerns identified and the observed rate of adverse events was considered to be within an accepted range. The scores for patient care in each of the 7 domains were reassuring (see figure):

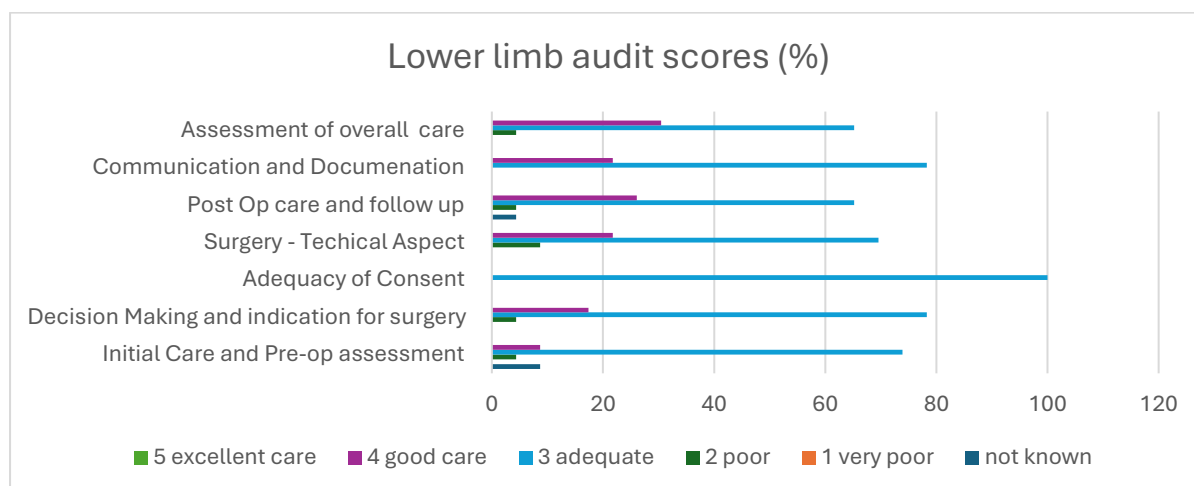


Figure 4: Assessment of quality of care by domain for lower limb audit patients

Assessment of quality of care by domain for lower limb audit patients

There were no concerns about the quality of consent procedures, with 100% considered adequate. The lowest scores related to the adequacy of post op surgical follow up, an area that was not directly related to Mr Shah's own practise, and one that the RCS 2 review had already recognised to be a departmental wide issue that needed to be addressed i.e. this was a generic rather than a Mr Shah specific issue. The Trust has previously identified a comprehensive action plan relating to generic issues identified by the RCS review and the PNE. These "generic" issues (for example deficits in orthopaedic follow up arrangements) will not be included in this report which is necessarily focussed on the findings of the patient recall itself. It should be noted that the assessment identified some areas of good and excellent care.

3.5.6 Extended review of knee replacement surgery

The Spire Healthcare team identified significant concerns relating to technical aspects of TKR replacement surgery the detail of which was shared through joint working between Spire and the Trust.

The RCS reviews had included 10 patients who had undergone surgery within or around the knee joint - although no elective TKR patients had been included. There were no concerns identified in any of these 10 knee operations in the RCS review. The lower limb audit undertaken as part of the assessment of exclusion criteria had included a number of cases relating to surgery around the knee joint, but only 4 TKRs. A decision was taken to assess an increased number of TKR cases operated on within the Trust, by reviewing all pre and post operative X-rays, and pre and post operative clinic letters to assess pre-operative symptoms and post-operative outcome.

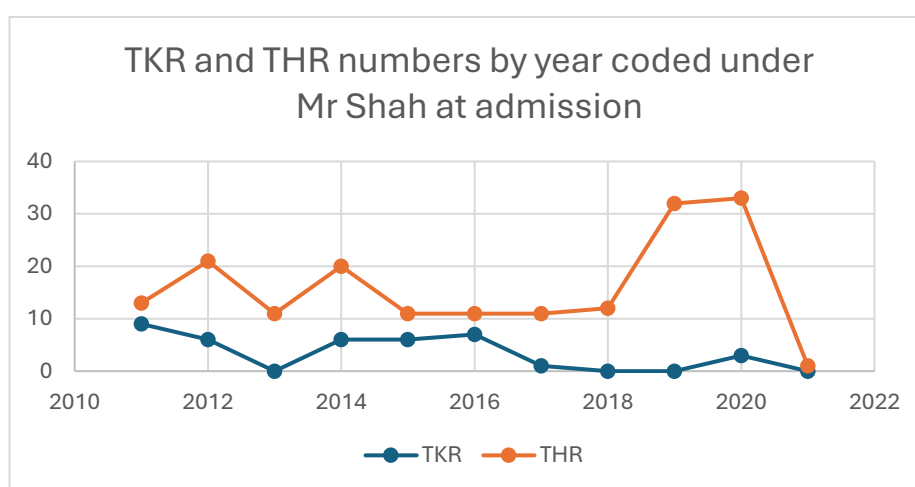


Figure 5: TKR and THR numbers by year

It became clear that Mr Shah had not performed many knee replacement procedures within the NHS - this graph shows patients coded as admitted under Mr Shah for TKR and THR- but a significant proportion of these patients underwent surgery by other members of the orthopaedic team, or other Consultants within the department.

All patients who had been coded as admitted under Mr Shah's care and who underwent TKR were identified. Patients who had not been operated on by Mr Shah and deceased patients were excluded from the audit. 4 TKR cases had already been included in the initial lower limb audit, and no concerns had been raised. An audit of a further 17 TKR cases was initiated. 4 patients were not operated on by Mr Shah, and one procedure was surgery for a complex fracture following trauma after previous TKR surgery, rather than de novo TKR. The pre and post op X-rays and clinic letters of the remaining 12 patients were reviewed, and no concerns were identified in 11 cases. In the one case of concern, issues relating to technical aspects of surgery were identified- the TKR was felt to have been indicated for the patient, but the prosthetic joint was not well aligned - the knee was in a valgus position (with the knee positioned inwards / in a knock knee position) having been in varus alignment (in a more bow legged position) pre-operatively. This was considered to be out-with expected variation. This had already been identified by the orthopaedic team during routine patient follow up and no additional governance response was required. With this as the single negative finding

following review of nearly all of Mr Shah's TKR cases the assurance group concluded that there was no evidence of major concern relating to TKR surgery within Mr Shah's NHS practise.

There is not always a direct relationship between radiographic findings post-operatively and the patient's functional outcome – i.e. it is reasonable to analyse technical aspects of surgery using post-operative radiographs, but the patient's outcome may not directly correlate with these x-ray findings. It is the patient's reported outcome and symptoms after surgery that are the most important measure of the success of an operation, rather than the appearances of X- rays.

Extensive discussions were had where differences in findings were identified between the two reviews, in particular with reference to total knee replacement practice. Despite working through the technical details, the potential reasons behind the differences in findings for the 2 organisations' review of TKR practices regarding the consultant could not be identified beyond speculation. It was not within the scope of the Trust's PNE review to try to resolve that issue, but rather to report on its own review and findings

3.5.7 Measures of outcome by clinical domain across all audit patients

To assess the concerns relating to non-surgical aspects of practise, the audit results were reanalysed by domain rather than by procedure. It should be noted that the only aspect of care that was solely delivered by Mr Shah was the surgical intervention, and so concerns identified in other domains will relate to the assessment of care delivered by the wider orthopaedic team rather than Mr Shah's personal practise. The scores for each domain were analysed across upper and lower limb are expressed in percentage terms:



Trauma and Orthopaedics Patient Recall: Report

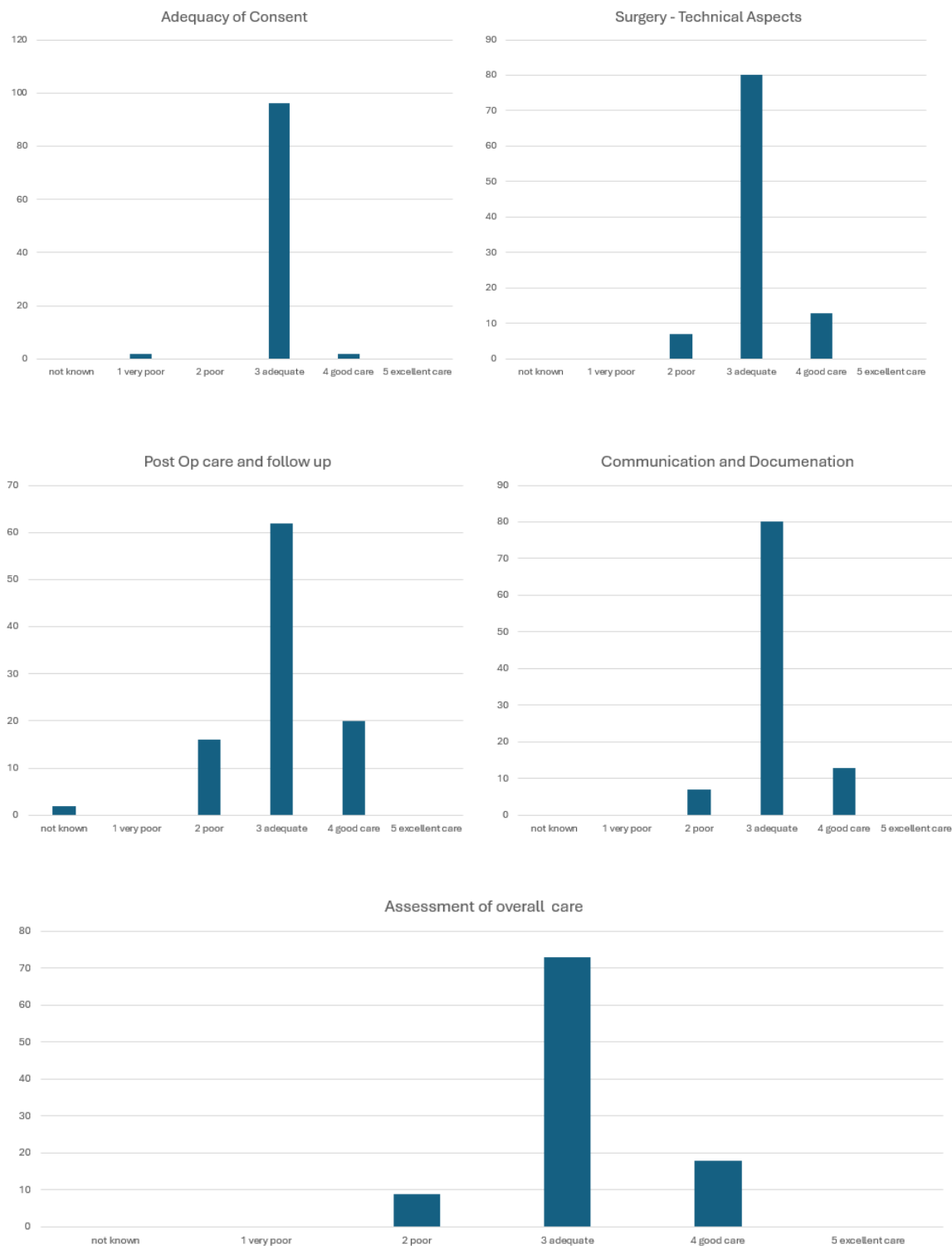


Figure 6: Measures of outcome by clinical domain

When the scores for each area of practice are analysed individually it suggests that overall standards of care in these patients who had procedures outside the remit of the PNE fitted within an acceptable range of performance – and this includes the scored assessment of consent.

When the patient narratives in cases of concern are considered a pattern emerges whereby **if** the procedure being undertaken was outside Mr Shah's area of competence, then a number of aspects of care were found to be suboptimal - areas of suboptimal practice tended to cluster in cases where the procedure did not fit within Mr Shah's recognised competence. These patients' stories can be characterised by inadequate pre-operative assessment and then poor decision-making around the most appropriate procedure, a consent process that was considered suboptimal because the pre-operative discussion did not include appropriate alternative treatment options followed by a technically poor procedure with inadequate follow up and under recognition of poor outcomes. This "Swiss cheese" model of poor practise resulted in significant poor practise and patient harm in cases where Mr Shah was acting outside his competence or experience. Importantly, the audit data suggests this pattern was procedure specific (when undertaking procedures for which Mr Shah had either inadequate training or experience) rather than being spread across his whole orthopaedic practise. The scores from the more general upper limb and lower limb procedures were felt to fit comfortably within the acceptable range and the data suggest that the assessment of Mr Shah's more general T&O practise demonstrated adequate standards of care. This was consistent with the findings of the 2 RCS reviews and offered assurance that the scope of the patient recall did not require further expansion beyond the agreed changes of inclusion of proximal and distal humeral fractures and more extension of the H&W cohort.

3.5.8 Summary of critical analysis of inclusion / exclusion criteria of PNE:

Overall, the extended audits that were undertaken into wider aspects of Mr Shah's practise were felt to be reassuring with regard to his less specialist upper limb (shoulder and elbow) and lower limb practise including TKR surgery, but non reassuring with regard to hand and wrist surgery. A decision was made to extend the scope and scale of the H&W patients included in the patient recall. A "phase 2" PNE has been undertaken to deliver this small scale extension of the patient recall. 32 living patients' care, and 2 deceased patients' notes have been assessed as part of that H&W extension, the findings of which are outlined in *Extended hand and wrist (phase 2) case review*.

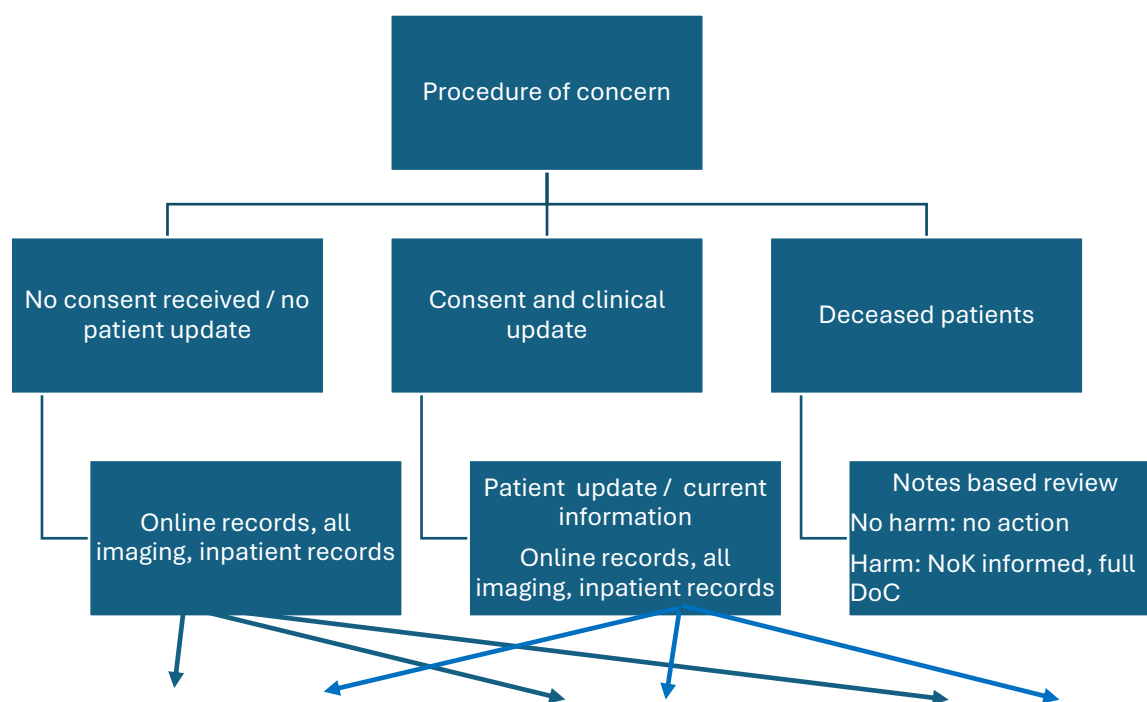
This critical appraisal of Mr Shah's wider practise included assessment of an additional set of 170 cases and detailed analysis of 75 cases across the whole range of orthopaedic practice. The rate of concern in the hand and wrist cohort (6/18) resulted in an extension of the patient recall to expand this cohort. There were no additional procedures of concern identified and the assurance group considered that combined with the results from the 99 externally reviewed RCS cases there was no evidence suggesting that the inclusion criteria of the recall required further extension. There was further reassurance in this regard arising from feedback from the legal team that although a large number of other patients (non PoC) had contacted the Trust with a view to taking legal action, the rates of concern in the non PNE cohort were low. Similarly, patients who had contacted the Trust with any concern during the PNE had their cases independently reviewed by the external team and rates of harm in this group who were outside the PNE inclusion criteria were also low. Overall, the assurance group considered that the extended audit suggested that it was necessary to extend the PNE to include a greater number of hand and wrist patients but that there was no evidence that a wider extension of the patient recall inclusion criteria to include other more general orthopaedic procedures was indicated.

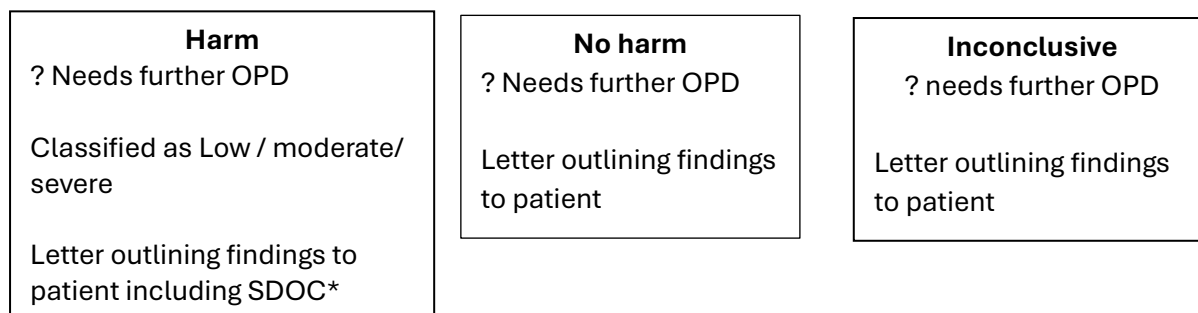
Overall audit findings:

- 170 case notes reviewed - but the majority were operated on by members of Mr Shah's team rather than Mr Shah personally i.e. many of Mr Shah's coded admissions did not undergo to a procedure performed by Mr Shah himself.
- 22 upper limb, 23 lower limb and 18 H&W procedures selected and assessed in detail by external consultants, as well as an additional 12 TKR cases following concerns identified in the private sector. A total of 75 additional cases were assessed across the full range of Mr Shah's surgical practice.
- Harm was identified in 1 upper limb, 1 lower limb, and 6 (H&W) cases respectively. As a result of this, the patient recall was extended to include assessment of a considerable number of additional hand and wrist cases, referred to hereafter as "phase 2" and described more fully in Appendix G.
- There were no significant / systemic concerns about the quality of patient consent within the Trust.
- Where concerns in practise were identified these were consistent with those previously noted within the patient recall:
 - Documentation - particularly of examination findings
 - Poor follow up - clinically and radiographically.
 - Clinical decision making re: choice of surgery (H&W cases only)
 - Technical concerns re: H&W surgery (see appendix G for extended review of H&W cases)

3.6 Initiation of the PNE

In practise, analysis of cases that were known to be included (such as shoulder replacement cases) commenced as soon as the external orthopaedic Consultants were in post, and the critical appraisal of exclusion criteria went along in parallel as the earliest cases were reviewed. Cases were processed as follows:





*SDOC= statutory duty of candour

Figure 7: Outline of PNE Processes

The decision to recruit external and independent specialists meant that the clinical notes and investigations needed to be remotely accessible. The recall team established secure online repositories and shared information that was compliant with information governance and security requirements and could therefore be accessed securely and remotely by all clinicians. External Consultants had remote access to all pathology results and imaging as well as outpatient letters. Operation notes and consent forms and other handwritten information were accessed remotely having been scanned and uploaded to a confidential shared drive.

3.7 Assessment of quality of care

In each case, the quality of care in 9 domains was assessed – these were based on the same domains used by the RCS in their patient reviews to provide consistency of reporting across the review processes. Pre-formatted proformas for case analysis were developed. These are attached at

7.5 *Appendix E: Blank proforma for data collection.* The proformas were pre-populated by the project team to include a clinical update from the patient (when available), demographic data, a summary of the patient's clinical course and all imaging. Details of involvement in any previous investigation (RCS reviews), complaint or legal processes were included. Once a Consultant completed their assessment this was uploaded to the shared file, whereafter the patient outcome (assessment of quality of care, harm or no harm and need for SDOC, plus need for follow up) was recorded and actioned (See 7.6 *Appendix F: Recall administrative processes*).

The proforma covered the following areas:

1. History taking examination and diagnosis
2. Pre-operative investigation and preparation for surgery
3. Consent
4. Treatment including technical competence of surgery.
5. Communication with patient / family / GP
6. Team working including communication with wider team / MDT etc
7. Compliance with national standards (e.g. NICE etc)
8. Adherence to safety process measures (e.g. WHO checklist)
9. Post operative reviews, discharge and outcome
10. Wider professional behaviour (probity etc)
11. Overall assessment of standard of care
12. If standard of care was suboptimal whether this reached the threshold for harm

3.8 Definitions of harm

NHSE definitions of harm (see [Severity Mapping and Examples \(england.nhs.uk\)](https://www.england.nhs.uk/quality/severity-mapping-and-examples/) for more detail) were used as follows:

- A: No harm
- B: Low (minimal harm -patient required extra observation or minor treatment)
- C: Moderate (short term harm – patient required further treatment or procedure)
- D: Severe (permanent or long term harm)
- E: Death

Although all Consultants were experienced NHS clinicians, the whole team undertook a shared session on analysis of quality of care and NHSE assessments of harm before starting individual case assessment. Upon completion of assessment of each case, the assessing Consultant reached an opinion taking into account the patient's long term symptomatic and functional outcome as well as an assessment of quality of care.

It was clarified that:

- adverse clinical outcome alone does not necessarily equate to harm if the clinical practice was of an adequate standard and the poor outcome fitted within the range of possible outcomes even with best practise
- suboptimal practise (for example with regards to documentation, or inadequate period of follow up) might not result in causing direct patient harm if the patient's outcome was not adversely affected by this

To reach an assessment of harm, the clinical practice would need to have been assessed to have been suboptimal *and* the patient would have needed to have suffered a poor outcome or required additional treatment as a result of this. Every patient received a detailed summary of their clinical treatment and the assessment of all aspects of the quality of that treatment, regardless of whether the threshold for harm was reached. In all cases where a conclusion of moderate or severe harm was reached then SDOC was triggered. The letters sent to patients also included a specific request for feedback from patients about the review process itself, and included an offer of counselling and support, direct contact with the nurse specialist within the review team, and advice about how to take forward further concerns, either via the health service ombudsman or to seek independent legal advice. All patients who required further clinic follow up had this explained, and an outpatient appointment was arranged for them.

Cases which were opined to have caused severe harm were taken to a complex cases panel for review by a panel of at least 3 of the external Consultants to confirm the findings. Similarly, cases that were felt to be borderline in terms of the quality of care or where the primary assessors had any queries or uncertainties about their assessment were also taken to a panel for a team based discussion of care.

3.9 Other patients whose cases were assessed (complaints)

As well as undertaking extended audits of randomly selected upper and lower limb cases, the external review team undertook the independent assessments of any patients who contacted the Trust with concerns about their treatment or outcome following procedures performed by Mr Shah. These investigations related to procedures that had not been included in the patient recall. Whilst the care was assessed using the same structured assessment tools and same outcome measures, the outcomes of these patients were not included in the overall data analysis of the patient recall as the patients had not undergone a PoC.

The patient recall team drafted the clinical summary of the assessment of care and the content of the response to the patient, but the complaint response was managed within existing complaint procedures, and processed and tracked by the Trust's PALS and complaint team.

3.10 Patient involvement and communication strategy

The Trust developed an active programme of open engagement and communication with the public and patients. This began with interviews with a local BBC news correspondent at the launch of the patient recall where the concerns about Mr Shah's practise were clearly outlined and patients with concerns were invited to contact the Trust directly. A dedicated patient phonenumber was established with trained staff, who dealt with the administrative aspects of patient queries. Any clinical concerns were forwarded to the clinical members of the project team which included a nurse and an extended role physiotherapist.

All patients who had been identified as having undergone a PoC were sent a letter outlining the details of the review, seeking their consent for information sharing and asking for an update about any concerns they might have and their current clinical status.

It took nearly 18 months to complete the specialist assessment of the nearly 400 cases that were included in the review, and so patients whose cases were analysed later in the review were updated in writing after 6 months. In general, patients who were in pain, or had clinical

concerns, or had other features of concern (high levels of vulnerability or anxiety) were processed first.

There was a delay in identifying and recruiting suitably experienced hand and wrist Consultants, and so the hand and wrist assessments were completed after the review of the other upper limb procedures. This was separately communicated to the hand and wrist patients.

At all times the Trust website included contact details for the helpline, as well as general updates about the progress of the patient recall. When patients received the summary letter with the assessment of their case, the letter included the opportunity for feedback about the review process as well as contact details for a senior clinical nurse, and information about further steps that could be considered if they had ongoing concerns. There was very limited detailed feedback received about the review process itself - a few patients made comments about perceived inaccuracies in their case summaries – but there was very limited specific feedback. The assurance group considered this was not surprising at a time when patients would have been focussing on issues relating to their own clinical care, and a further opportunity for feedback will be provided when patients are informed about the review's overall findings and the publication of a summary report.

3.11 Helpline workload and project integration

This service was staffed by the Patient Relations Team. The telephone helpline experienced extremely variable workload – mainly characterised by a very large number of calls after the initial BBC interview and then occasional peaks with further local news updates, or local solicitors' publicity campaigns. Between 26th September 2022 and 11th October 2022, the helpline received 456 calls relating to patients who had been treated by Mr Shah, with a total talk time of 31 hours and 29 minutes. In addition, the team received 109 emails, with many relating to patients still experiencing pain, having multiple procedures without resolution, reduced movement in the area of surgery or those that felt "left" following their procedure.

The helpline team updated a single spreadsheet on a secure shared drive that was routinely accessed by the recall team, and copies of all complaints and concerns were uploaded into the patient's review folders so that the external Consultant assessors could be fully informed about patients' current worries and concerns. It was important that the complaints were managed within existing systems and processes, but also that the complaints team were recognised as an integral part of the recall team. Weekly Teams meetings between the recall team and wider parts of the Trust's governance infrastructure were an integral part of the process and included staff from the patient relations team, medical records and portering, the communication team, the legal team as well as administrative and project management support.

4 Results

A patient recall involving this number of potential patients and of this complexity is necessarily an iterative process, and during the timescale of the review the absolute numbers of patients sitting within each category (Included or excluded, PoC or not, contactable, deceased) varied as relevant clinical information became more distilled or clarified. Thus, the data that are

presented here are finalised, but they are different to the earliest versions of results that were reported, and an extensive data cleansing programme has been undertaken to ensure maximum accuracy.

4.1 Overall workload

The Trust IT team identified a total of 7578 episodes of patients who had been coded as having been admitted under Mr Shah’s care (not necessarily had surgery performed by Mr Shah personally) between 2010 and his final coded admission in June 2022. 59 patients had been coded as admitted under Mr Shah from June 2021 after he had discontinued undertaking patient facing duties and so likely reflect duties undertaken by locum staff or other Walsall healthcare Trust T&O team members. It became clear that historically coding was not 100% accurate and individual medical records were the most reliable source material available to the team.

1336 (18%) of the whole patient cohort had passed away, in keeping with the age demographic of patients treated within T&O services. Up to 10 diagnostic codes and up to 10 operative codes were available for every patient. 1335 (18%) patients had no operative code i.e. although the patient was admitted to the Trust under Mr Shah’s care, no surgical procedure had been performed. Thus, the total number of procedures undertaken was 6243. Not all surgical procedures were undertaken by Mr Shah personally – but a clear pattern emerged, whereby the more complex surgical procedures, particularly upper limb joint replacement and the PoC were most often performed by Mr Shah himself, often with a middle grade assistant. More general T&O procedures, and particularly common post trauma surgery (such as fractured femur patients undergoing hip replacement, reduction of fractures etc) were performed by other members of his team. It is not possible to be clear about the precise surgeon in each procedure without reviewing every set of notes or going through individual theatre records so this was not undertaken in cases when the operation performed was not a PoC.

A number of patients were admitted under Mr Shah’s care on more than one occasion, as follows:

	Number of admissions							
	1	2	3	4	5	6	7	8
Number of patients	5002	762	216	51	24	7	2	3

Table 4: Number of Procedures per Patient

Whilst it is not uncommon for patients to be admitted for procedures on more than one occasion (for example, if definitive surgery is offered after diagnostic arthroscopy), in general, the rate of concern was higher in the patients undergoing the highest number of surgical interventions. This pattern was seen more often in patients whose early interventions did not go well, or who had particularly complex problems that might have merited early onward referral to tertiary colleagues rather than continued management within a less specialist setting.

In summary, 6067 patients were coded as being admitted under Mr Shah’s care between 2010- 2022 inclusive, between them undergoing 6243 procedures. It must be emphasised that

Trauma and Orthopaedics Patient Recall: Report

a significant proportion of patients will have undergone surgery by a member of Mr Shah's team, rather than by Mr Shah himself. A number of patients had multiple admissions and repeated episodes of surgical intervention, and some of these represented patients whose care raised the most significant concerns. 87 patients underwent 4 or more surgical interventions under Mr Shah's care.

There were alterations in the patterns of Mr Shah's surgical practise as his career progressed. Data analysed from 2010 onwards showed:

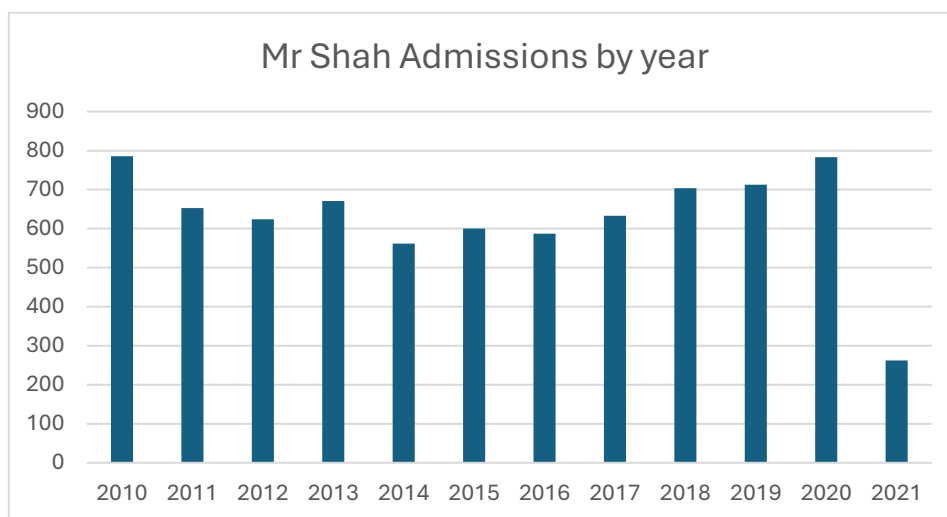


Figure 8: Admissions by Year

The data suggest a career that began as a busy generalist, total case numbers decreased in number before accelerating from 2016 onwards. An analysis of surgical case mix suggests that it was during this latter phase of his career that Mr Shah developed an increasingly subspecialist and complex upper limb surgical caseload.

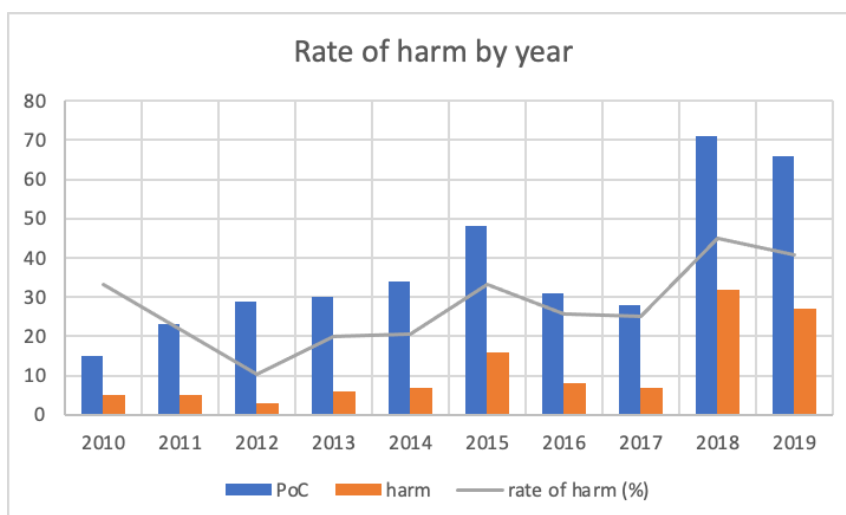


Figure 9: Rate of Harm by Year

This suggests a relatively low rate of specialist upper limb surgery during the early part of Mr Shah's career (around 10-15 PoC/ complex upper limb surgery cases per annum), followed

by a steady escalation in terms of the total numbers of complex upper limb procedures. This accelerated to 2015, there was a reduction in 2016/17 for reasons which are not clear, and then a rapid acceleration in the number of PoC in 2018/19. The graph also records the rate of “harm” (moderate or severe) for the procedures of concern, and it suggests that as Mr Shah accelerated the number and range of procedures of concern from 2018 onwards, the rate of harm and absolute numbers of cases of concern clearly and dramatically escalated. By 2018 the number of cases which were opined harm (retrospectively) had increased to over 30 in a single year. By this time the legal department had recorded 21 litigation claims that had arisen between 2010-2018. Finally, a patient who had complained in 2018 followed that complaint with a referral to the GMC in 2019 and within months a local / internal audit had confirmed concerns about shoulder surgery outcomes. By February 2020 Mr Shah’s practise was restricted to exclude complex shoulder and elbow surgery.

The data suggest that Mr Shah’s early practise included a steady workload in general and lower limb orthopaedic practise - he / his team were performing between 10-20 TKR or THR surgeries per annum between 2011 and 2014. A reduction in lower limb orthopaedic procedures was seen commensurate with the steady increase in the number of PoC (complex upper limb joint replacement). This “more general” and lower limb orthopaedic practise reduced steadily thereafter, until 2019-2020, when restrictions in his upper limb practise resulted in a rebound increase in lower limb procedures as illustrated when Mr Shah’s practise reverted to more general orthopaedic duties. Review of case records and operation notes suggests that a significant proportion of this more general workload, particularly the NOF / THR work, was delivered by members of his team rather than by Mr Shah himself.

The association of this rapidly extending scope of practice and increase in the rate of harm meant that in the period 2010-2017, although there were cases of concern, these amounted (generally) to single figure cases of concern in each year until 2017. These patients numbered possibly 5-10 cases of concern per annum until around 2017 out of a total annual throughput of between 500-800 patients. This emphasises the importance of detailed outcome data by procedure and by individual surgeon and demonstrates how difficult it can be for an organisation to identify poor practise within a small subsection of a Consultant’s practise. There is further discussion relating to surveillance systems that can detect this type of low volume / poor outcome scenario in the discussion and recommendations section of this paper. It also emphasises the critical complimentary role of “soft intelligence” in clinical governance -the value of high quality audit at departmental level, the importance of culture in an organisation and how this facilitates challenge to senior clinical staff, freedom to speak up and other measures that have proved effective in earlier identification of poor practise. It should be noted that many of these initiatives have only been formalised in recent years and were not formally recognised or even in existence in the earlier parts of Mr Shah’s career.

4.2 Outcome for procedures of concern

Careful analysis of the previous external reviews had enabled the identification of a limited number of operations where concern had been identified about the patient outcome. These operations were classified as “procedures of concern” (PoC) and broadly comprised:

- all types of shoulder replacement
 - total shoulder replacement
 - hemiarthroplasty
 - resurfacing hemiarthroplasty

Trauma and Orthopaedics Patient Recall: Report

- reverse shoulder replacement
- shoulder stabilisation surgery, specifically the Latarjet procedure
- proximal and distal humeral fractures requiring ORIF (included after external Consultants expressed concern and audit was non reassuring)
- Complex hand and wrist surgery (mainly including bone fusion and grafts)

The codes for the H&W procedures are diverse and the final PoC procedure list included a very large number of primary procedure codes - see 7.7 Appendix G: Example codes used for primary upper limb PNE patient identification which is not exhaustive and is included for illustrative purposes. The coding for shoulder and elbow replacement surgery was more reproducible and in general allowed for more accurate patient identification than the coding for H&W procedures - it was necessary to manually search the database to identify the H&W patients.

This list of procedural codes and operative titles is not exhaustive and is included to demonstrate how complex coding around orthopaedic procedures can be. An apparently identical surgical intervention could have different primary coding, meaning it was difficult to use coding alone to identify all patients who had undergone a procedure of concern. In many cases the primary operative code was not sufficient, on its own, to accurately identify a patient who had undergone a procedure of concern, and it was necessary to assess up to 9 other operative codes which might include site of surgery, or more detailed technical information. In many cases it was necessary to also review the diagnostic codes, which could number up to 10 per patient. This complexity makes it possible that despite the review team's best efforts it is possible that there are patients who underwent procedures of concern who were omitted from the review. The risks of this have been mitigated by the high profile of the patient recall in the local press and the prominence and publicity given to the recall on the Trust's website. The wider importance of the complexities of coding is that it demonstrates how difficult it is for the Trust to set up automated reports relating to activity, throughput or outcome by procedure. This means that surveillance of outcomes on a procedure specific basis would need to be a manual / prospective process. For an organisation to have effective governance processes, a combination of both "top down" surveillance combined with "bottom up" clinician insight, self-reporting and internal challenge are essential.

These data also demonstrate why accurate patient inclusion was necessarily an iterative process - some patients initially included on the basis of coding were (once notes were available) found not to have undergone a PoC. Other cases were not initially identified as a PoC and were later included following either an expansion of inclusion criteria (for example the proximal and distal humeral ORIF patients) or after several individual reviews of the database looking at diagnostic and other codes to ensure that no cases had been missed using primary operative codes alone.

After all case notes had been reviewed, and the database had been carefully reviewed on multiple occasions a final position was reached whereby 382 patients were identified to be included in the recall. Of these, 93 were deceased by the time of the patient recall, so there were 289 living patients, and a subgroup of 36 patients had undergone hand and wrist surgery.

The case notes relating to the care offered to these patients were reviewed by the external assessors – the information provided to the external Consultants included information held in the paper based Hospital records (some older OPD notes, operative notes, consent forms and post operative inpatient care) as well as the online electronic records held in Fusion (the vast

Trauma and Orthopaedics Patient Recall: Report

majority of outpatient documentation / letters plus laboratory blood test results) and all imaging and reports (via PACS). The Consultants were provided with Trust laptops so that they had unfettered access to all Hospital pathology and radiology systems as well as all outpatient letters across all specialties.

Overall, of the patients who had undergone a procedure of concern, 24% were found to have suffered harm as a result of the treatment they were offered by Mr Shah

	Total living (291)	Of which: hand subgroup =36	Deceased (93)
Assessed	291 (100%)	36 (100%)	93 (100%)
No harm	171 (59%)	13 (36%)	78 (84%)
Inconclusive	20 (7%)	7 (19%)	It was not easy to be categorical about levels of harm in deceased patients, as in many cases there was only very limited duration of clinic follow up, and there was no patient feedback about the patient's long term symptomatic or functional outcome.
Low harm	23 (8%)	6 (17%)	
Moderate*	33 (11%)	5 (14%)	
Severe*	37 (13%)	2 (6%)	15 (16%)
Moderate/severe*	75 (26%)	10 (28%)	24% mod/severe harm across whole patient recall cohort

Table 5: No. of Patients Suffering Harm due to Treatment

* In some cases it was not possible to be categorical about the level of harm (moderate vs severe) because of lack of detail about the patient's current status -for example if the patient was deceased or because of lack of adequate follow up. Hence, for a limited number of patients, the level of harm was simply categorised as "moderate/severe".

Because of the varied nature of coding and the diverse number of codes used outcomes were analysed by surgical site - it was not possible to gain accurate outcome data for each individual procedure. Assessments of harm were analysed for individual patients, and many patients had undergone more than one procedure – so rates are not specific to every procedure but to the overall package of care received by a patient during their care under Mr Shah. Not all procedures are included - for example proximal and distal humeral fractures were limited in number and not included in this analysis. The results give indicative but not precise information about rates of concern by joint and procedure type.

	N	No harm (%)	Inconclusive (%)	Low (%)	Moderate (%)	Severe (%)	Moderate or severe (%)
Shoulder replacement	297	205(69)	11(4)	17(6)	28(9)	33(11)	64(22)
Latarjet	21	6(29)	6(29)	0(0)	4(19)	5(24)	9(43)
Elbow replacement	18	10(56)	0(0)	3(17)	0(0)	5(28)	5(28)
Hand/wrist	36	13(36)	7(19)	6(17)	5(14)	2(6)	10(28)
TOTAL	372	63%	6%	11%	10%	12%	24%

Table 6: Assessment of Harm by Treatment Site

The data confirm broadly similar rates of moderate or severe harm (the triggers for SDOC) across all joints / procedures, other than the Latarjet procedure, where 43% of patients were opined to have suffered moderate or severe harm and in a further 29% of cases there was insufficient information to reach a definitive opinion, usually because of insufficient follow up. As previously discussed, both RCS reviews and the patient recall identified problems with paucity of follow up in patients who had undergone complex upper limb surgery. See *Outpatient requirements* for further information about additional follow up requirements.

Number of Latarjet procedures by year, and number of cases opined harm

Analysis of the number of Latarjet procedures and rate of harm by year show that Mr Shah was performing a low number of these procedures each year, and that although volume increased towards the latter part of Mr Shah's employment, the rates of acceptable outcome did not particularly change.

	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
No.	2	1	1	1	1	4	1	2	5	3
Harm	0	1	1	1	0	2	1	0	2	2

Table 7: Number of Latarjet Procedures by Year

The data raise questions about scope of practise and how the Trust can gain assurance that a Consultant is undertaking a sufficient number of procedures to gain and maintain competence. Competence in surgery is however not solely determined by a specific number of operations per annum, but involves a combination of experience, ongoing learning, and adherence to professional standards.

In 2019 the RCS published guidance on the development and dissemination of new surgical techniques – see [Surgical Innovation New Techniques and Technologies.pdf](#). Whilst this document focusses on de novo techniques, it includes detailed sections on the processes of dissemination and the internal checks and measures which should be considered when an individual or an organisation is considering extending the scope of procedures being offered and may be helpful to revisit specifically with regard to new techniques within the division of surgery on an ongoing basis.

4.3 Deceased patient cohort

There was extensive discussion at the assurance group about the most appropriate ways to balance fulfilling statutory duty of candour (SDOC) for relatives of deceased patients, without causing undue distress by informing relatives of possible historical harm, when there was no chance of modifying any adverse outcome that might have arisen as a result of this. Ethical and legal advice confirmed that the legal requirement to fulfil SDOC related as equally to relatives / next of kin (NoK) or legal representatives of deceased patients as it did to patients themselves or delegated relatives of living patients. It is important to state that there was no evidence that any patient's death had been directly or indirectly related to the treatment they had received under Mr Shah's care. Some of the patients had died many years before the patient recall. A decision was made that whilst it was appropriate to attempt to contact all NoK / direct relatives of deceased patients the risk of upset through receipt of an unsolicited letter should be minimised. An experienced nurse initiated contact by way of a telephone call to all relatives where care of their loved one had been considered suboptimal and when it was considered that moderate or severe harm might have arisen as a result of this. It was not considered appropriate to contact relatives of previously deceased patients whose care had been assessed but in whom no concerns or only low-level concerns had been identified.

In 15 of 93 cases where the patient had already passed away, a retrospective assessment of moderate or severe harm was made. Attempts were made to contact all next of kin, with the following outcomes:

- 4: there was no traceable NoK
- 11: NoK traceable and attempted contacted by phone
 - 3 non contactable (no answer, multiple messages left, but no contact returned)
 - 5 NoK did not wish to receive further information
 - 3 relatives requested detailed information about the assessment of care, and SDOC fulfilled.

Three letters were sent to relatives outlining in full the rationale behind the assessment of harm, fulfilling SDOC requirements. It seemed that the relatives who sought further information were those who were more likely to have been closely involved in the decision to undergo surgery, or those who had been most closely involved in their loved one's post operative care. The Trust received one direct response as a result of this exercise, thanking all staff involved in review and the Trust for its detailed explanation of their relative's care. In this case the relatives expressed that they were sad to discover that an operation that had caused their father considerable pain had been judged to be unnecessary, but closed by stating that they had no wish to take legal or other formal action.

4.4 Background to phase 2 hand and wrist (H&W) cohort extension

A total of 36 patients of the initial group of recall patients had undergone H&W surgery under Mr Shah's care. This subgroup was analysed later than the other cases, because there was a delay in the identification and recruitment of 2 experienced hand and wrist Consultants to undertake the review. The H&W cases were first assessed at the end of August 2023, nearly 12 months after the patient recall was first initiated. When the results of the assessment of the H&W cohort began to emerge, it became clear that there were significant concerns about technical aspects of surgery in this anatomical domain. Simultaneously, Spire Healthcare

were reporting significant concerns around the same issues - decision making around individual surgical procedures, and technical aspects of surgery. A review of coding, and concerns from the H&W surgeons about the extent of suboptimal practise precipitated an audit of other H&W cases. 18 further H&W cases were assessed in detail in an audit, and care was considered poor or very poor in a third of cases. As a result of this, the assurance group agreed that the patient recall should be extended into a limited second phase ("phase 2") to include additional H&W cases which were identified via a further manual review of all H&W patients who had previously been operated on by Mr Shah. This second phase was launched in May 2024 and was completed in September 2024.

4.4.1 Extended hand and wrist (phase 2) case review process

The primary patient notification exercise (PNE) included a limited number of patients who had undergone hand and wrist (H&W) surgery, and it became clear that there were significant concerns about practice in this domain. Concerns with regard to H&W surgery had not been specifically identified through local reporting systems, or the RCS reviews.

The concerns identified within the primary review precipitated an extension to the primary PNE ("phase 2") which was focussed on complex H&W surgery. The overall processes were the same as the main PNE as outlined in the main report with the following exceptions:

4.4.2 Patient selection

- Initial assessment of the database of nearly 7000 patients had clarified that there were no easily identifiable codes that would accurately identify all relevant complex H&W procedures and / or patients. Therefore, primary selection could only be undertaken by a manual review by an experienced H&W consultant of the whole database, seeking patients who had undergone complex hand and wrist procedures, such as operations involving bone fusion or excision. Ninety-nine patients who had undergone hand and wrist procedures were identified between 2010-2020 inclusive.
- An audit of all electronic records of patients who had undergone these more complex procedures was undertaken - all 99 cases were analysed, reviewing pre and post operative x-rays and clinic letters. This H&W audit was undertaken to more fully assess the scope and scale of concerns about H&W surgery which were not clearly understood at that stage.
- If x-rays demonstrated an accepted pre-operative indication and a good technical outcome, and clinic letters suggested a good clinical outcome, cases were not taken forward for full review within the phase 2 PNE. This was because the experience of assessing some 400 prior cases had shown that if these criteria were met the chances of a patient having suffered clinical harm as a result of their treatment was extremely low.
- Any cases where there was doubt about any of these factors were taken forward to formal review as part of the full PNE. The process commenced with patient notification, seeking consent and a clinical update about their current status and then a formal review of all medical records including x-rays, OPD letters, in patient notes, operation notes and clinical consent process i.e. the process was the same as that applied to patients in the full PNE / phase 1.

The important implication of this modified case selection procedure is that it was likely to result in a high rate of harm, because cases were selected on the basis that the radiographic findings were of concern. It had not been possible to find a better way for relevant case selection due to the fact that coding within hand and wrist operations was complex and less structured than for the major joint replacement surgery of the other upper limb procedures. Agreement for this design - which was felt to most effectively target resources and minimise the disruption or

upset to patients who likely had been successfully and appropriately treated - had been agreed at the assurance group.

4.4.3 Modifications to the proforma

The initial (phase 1) proforma was based on the same questions used by the RCS as there was a desire for continuity and comparability between the two assessment processes. The outputs were narrative i.e. described the practice and outlined any concerns, and separately assessed whether the patient had suffered harm and if so, what level of harm as per NHSE definitions.

A semi-quantitative scoring system was subsequently introduced into the audit of exclusion criteria, and in this audit a semi-structured scoring system was used, whereby 7 domains were assessed and as well as a clinical commentary a numerical “score” was given to try and help quantify the level of performance in each domain. This quantification had proved extremely useful in the audit and was continued into the phase 2 H&W extension. The domains assessed were:

- Pre-operative assessment
- Decision making and indication for surgery
- Consent
- Technical aspects of surgery
- Post-operative care
- Communication and documentation
- Overall care.

Each domain was assessed, and as well as a narrative commentary a “score” was attributed as follows:

1. Very poor care
2. Poor care
3. Adequate care
4. Good care
5. Excellent care

This scoring system is aligned to the RCPCH SJR assessment system (see [nqb-national-guidance-learning-from-deaths.pdf \(england.nhs.uk\)](https://www.england.nhs.uk/nqb-national-guidance-learning-from-deaths/pdf)) and was taken through into the assessment of H&W cases as the quantification had been considered helpful in getting a better understanding of overall performance rather than seeing the data as a series of individual qualitative clinical case analyses. Thus the proforma for case analysis was slightly adjusted to include a semiquantitative assessment of performance in each of 7 domains, but the process was otherwise unaltered.

Specialist Consultants were engaged to assess the H&W cases. Both were orthopaedic Consultants with an interest in hand and wrist surgery working in busy General hospitals. The standards set were those that could be reasonably expected of a newly appointed Consultant in orthopaedics at the level set by the Intercollegiate Specialty Examination in Trauma & Orthopaedic Surgery. The complexity of the cases was not felt to be especially high and were considered to fit well within a DGH upper limb consultant's remit. The cases would not have been expected to have been referred primarily to a tertiary hand surgery centre.

4.4.4 Results

32 cases were identified where bone fusion or excision had been undertaken and pre and post operative x-rays were concerning. 5 cases had already been assessed as part of the phase 1 review, but these cases were reassessed, because it was considered beneficial to have the

cases assessed by specialist hand and wrist consultants, and also it was considered helpful to have the quantitative analysis that had been undertaken as outlined above.

H&W Cases

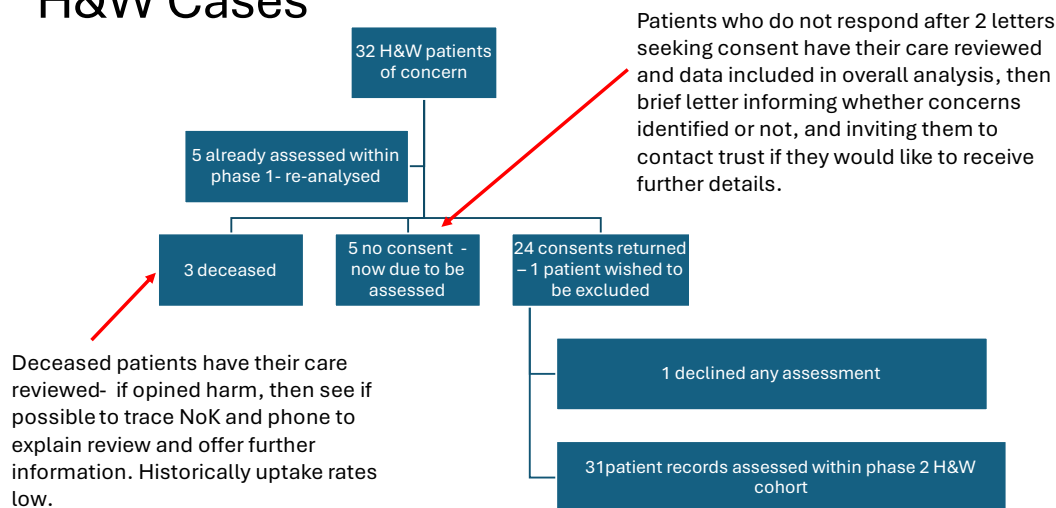


Table 8: Summary of Phase 2 Hand and Wrist Cases

The notes of the three deceased patients have been reviewed. One patient was opined no harm, of the two where harm was opined, one family has already stated that they do not wish to be contacted. Efforts are underway to contact the NoK of the other harmed patient.

Mr Shah's specialist H&W workload was relatively low volume - and the number of more complex cases varied significantly from year to year. Soft tissue surgery in the hand and wrist area has not been included in the analysis of total workload as it was considered to be a low-risk area. There was no meaningful relationship between volume and rates of concern on a year to year basis - but if the total volume of H&W cases is taken to be a reasonable denominator, then the overall rate of harm across all H&W surgery was around 25%, which represents similar rates of harm across the whole complex upper limb cohort. There is clearly an important issue relating to competence and experience when considering complex cases that are infrequently undertaken in a non specialist setting.

It is important to remember, when considering the H&W cohort, that the total number of cases reviewed in phase 2 is only 36 across a 10 year period, so statistical analysis will always be flawed by low patient numbers and should not assume undue weight.

The scores that were given to each domain across the 31 patients who were analysed in detail as part of phase 2 can be seen in the figure below:

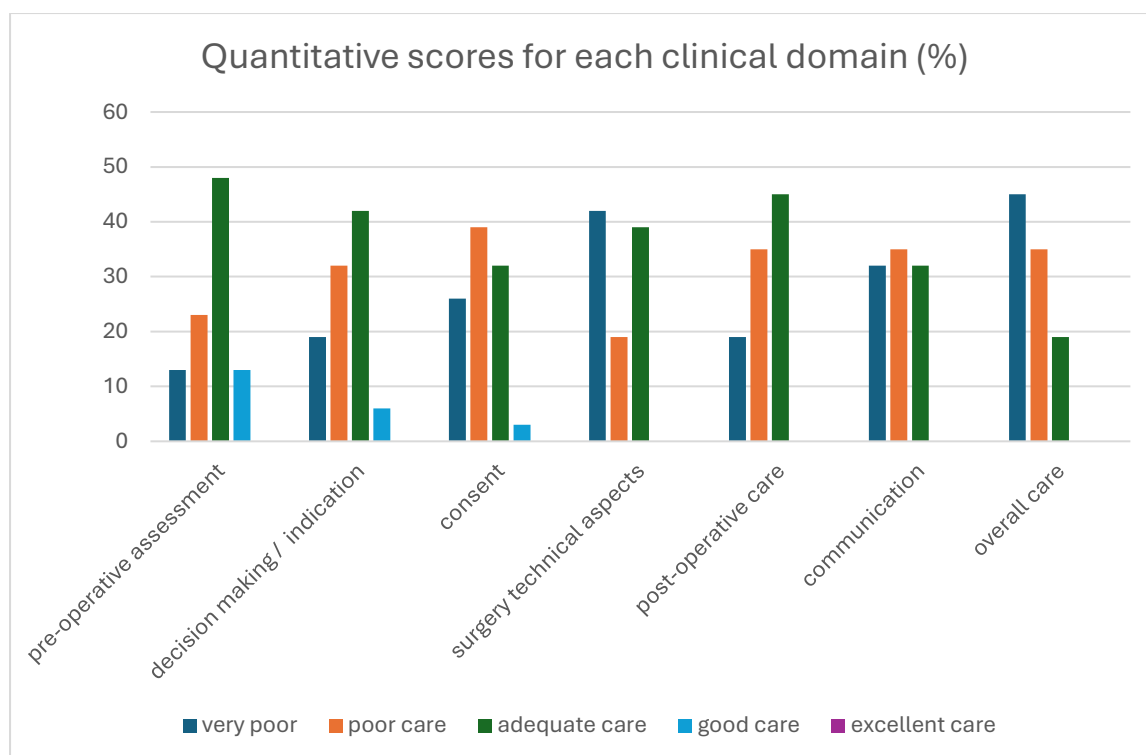


Table 9: Quantitative Scores for Each Clinical Domain (%) - H&W

The most significant rates of concern about practice were seen in the domain of technical aspects of surgery, where 42% of cases were assessed as very poor and 19% as poor. It is not surprising that this domain was closely associated with an assessment of poor care overall and the highest rates of harm.

The concerns about the quality of consent were unique to the H&W cohort and had not been seen in the cases reviewed in the whole PNE cohort, or indeed in any of the other extended audits (including lower limb practise). They were specific to H&W surgery, and were not linked to the Trust’s internal consent processes, which seemed to be robust. It is important to reflect that standards and best practise with regard to consent have changed considerably over the last 20 years and that assessments of the quality of consent are made in the context of practise at the time.

The recurring themes of concern about consent in the H&W case analyses related to the following factors:

- Poor documentation of discussions about alternative therapeutic options in OPD – particularly it was felt that Mr Shah repeatedly offered an inappropriate operation for arthritis at the base of the thumb - tending to offer CMC fusion rather than the more straightforward trapeziectomy. As the option of trapeziectomy was not offered, the OPD discussions about surgical options was not felt to be adequate.
- Technical difficulties with the surgery itself (struggling to accurately identify individual bones in the wrist) meant there were cases where the operation that was undertaken was not the same as that which the patient had consented to (most commonly the planned surgery was trapeziectomy, but a different bone in the wrist was removed). Thus patients underwent a procedure they were not consented to, because of mistakes correctly identifying the anatomy within the wrist.

Overall rates of harm in the cohort of patients included in the phase 2 H&W cohort have found to be 55% (17 cases), inconclusive in 13% (4 cases), low harm in 1 case (3%) and no harm in 29% (9 cases). It is important to remember that these cases have already been pre-selected

to only include cases where the pre and post operative x-ray findings had raised concerns i.e. they are a preselected high risk group.

The majority of patients have not yet been seen again in clinic since the early post operative period, so their current clinical status is based upon patient feedback from their questionnaires. This means that although it was relatively straightforward to reach a decision about suboptimal or poor practice (breach of duty), it was not always possible to be clear about whether this had caused patient harm (causation) as this depends on the resultant patient symptomatology rather than just the standard of care. It is particularly difficult to differentiate accurately between levels of harm (moderate or severe) until the patients' face to face reviews have been completed. Thus, in the H&W cohort there are a considerable proportion of patients whose assessments were of poor quality care but inconclusive with regard to harm, or where it was not possible to accurately discriminate between moderate or severe harm.

The cases reviewed are not considered representative of Mr Shah's whole practice with regard to H&W surgery as they were pre-selected to identify cases of concern on radiographic grounds but this extended review of H&W patients did raise significant concerns about the quality of care in this part of his surgical practice.

4.4.5 Discussion

Clearly the assessments demonstrate very significant concerns about the standard of care for patients in this selected cohort who underwent H&W surgery and whose pre and post operative x-rays were concerning- but it is important to remember that the outcomes as expressed in percentage terms cannot be taken as an absolute rate of risk - because the denominator relates to cases included in this phase 2 review, not the whole cohort of Mr Shah's H&W workload, let alone his total clinical case load. Rates of harm in this selected cohort were 55% with an additional 13% of cases inconclusive in this review. The best estimate we have equates to overall rates of harm in the whole H&W cohort of around 20-25%- but Mr Shah's overall casemix will include other patients who underwent less complex H&W surgery.

There is a very obvious difference in the rates of concern identified relating to the consent process in this cohort compared to previous cases analysed in phase 1. This is due to factors that were specific to Mr Shah's difficulties within H&W surgery. The medical records were felt to show a lack of clarity in terms of clinical decision making, such that a clear diagnosis and then the full range of therapeutic options were not discussed in clinic with patients - so the first part of the consent process (the decision about whether to proceed, and discussion about suitable alternatives) was not adequately fulfilled. The second problem, which arose in a number of cases, was that due to technical problems with surgery and accurate identification of anatomy, the bone that was operated on (fused or removed) was not always the one that was intended, and therefore was not the procedure the patient had consented to. In general, the Trust's consent procedures seemed to be robust - with the formal consent forms adequately completed in terms of risks and benefits of the procedure - as in phase 1 of this review. The specific difficulties lay within the pre-operative discussions and then sequelae of the technical difficulties Mr Shah experienced in anatomical identification of individual wrist bones. These are clearly significant clinical concerns, and were felt to adequately explain the differences in levels of adequacy of consent between the H&W and other upper limb cohorts.

It is notable that there were no "red flags" about H&W surgery arising either from the local team, Trust governance systems or the external RCS reviews - and in some ways the findings of this new domain of concern is an endorsement of the systematic approach of the primary PNE design, which included inbuilt audits of apparently "low risk" areas. It seems reasonable to consider that the difficulties identifying concerns within the H&W services relates to the fact that this was a low volume service. Also, Mr Shah was the only surgeon offering H&W surgery, so cases were less likely to be referred on to other colleagues, or identified as being of concern within the department as there was no other Consultant with H&W interest. This issue raises

a debate about how to support (and monitor) single handed Consultants within a Provider unit, and whether, de facto, they should all work across sites or within a network or have enhanced surveillance and cross site support systems in place.

16 (50%) patients have been invited back for further outpatient review and arrangements have been made for these patients to be seen initially within the Trust, with referrals being made on to tertiary referral centres if required after imaging and further clinical assessment.

4.4.6 Summary of clinical concerns

The case narratives yield more detail about the pattern of the concerns that were raised, and these predominantly related to:

- Inadequate detail in initial assessment (clinical and radiographic) which led to a lack of clarity of underlying pathology, particularly there was a lack of clarity about which specific joints were involved in an arthritic pathology.
- Inadequate consideration of alternative non-surgical or surgical treatment options - a “tunnel vision” about the most appropriate treatment option (which was not always the most appropriate treatment for the patient).
- Poor decision making in terms of appropriate surgical intervention, specifically offering CMC fusion for arthritis at base of thumb when trapeziectomy would have been more appropriate for the majority of this patient cohort.
- Misidentifying anatomy, particularly when attempting trapeziectomy, when instead Mr Shah removed the distal scaphoid or part of the trapezioid bone (see figure for clarification of anatomy). The primary error occurred at the time of surgery but was not identified on radiographic review by Mr Shah and his team or members of the radiology department during post operative follow up



Figure 10: Annotated diagram of carpal (wrist) bones

4.4.7 Wrong bone excision in wrist surgery

The first time the Trust became aware of this specific problem with accurate anatomical identification of the bones of the wrist was in late 2024 during phase 2 of the H&W review, when an external assessor suggested that these technical errors amounted to “wrong site surgery” i.e. a never event. This issue was discussed at length at the assurance group, and

a literature review was undertaken. There has been extensive discussion re: whether the technical difficulties encountered (removal of, for example the scaphoid as opposed to the trapezium) amounted to “wrong site “surgery. A literature review identified that this specific error is a recognised complication within H&W surgery (see Caggiano NM, Nelson DL Kaplan SJ, Matullo KS. Wrong-Bone Excision in Hand Surgery. *Hand (N Y)*. 2017 Sep;12(5):467-470. doi: 10.1177/1558944716672202. Epub 2016 Oct 3. PMID: 28832204; PMCID: PMC5684923.). This paper describes that nearly 25% of H&W surgeons **who responded to the survey** reported that they had removed the wrong bone at the time of wrist surgery, and that the commonest mistake was removing the scaphoid when the plan had been to remove the trapezium. This is the same mistake made by Mr Shah, but unlike Mr Shah, the respondents had recognised this error when reviewing intra- or post operative X-rays. They additionally described that some patients do get an improvement in H&W arthritic symptoms with removal of the distal scaphoid. This error was made repeatedly but did not seem to be recognised (by Mr Shah, members of the T&O team or radiology colleagues).

There was extensive discussion with both the external assessors and members of the assurance group as to whether this retrospective finding of technical difficulties with identification of the bones of the wrist should constitute wrong site surgery in terms of the NHSE definitions of a never event. It was initially considered that the primary deficit was of clinical and technical competence leading to wrongly identified carpal bones (wrong bone excision), and this did not meet the spirit or criteria of NHSE wrong site / NE criteria as there were no system wide organisational factors that had contributed to these errors. Furthermore SDOC had been completed in all cases, and as Mr Shah was no longer a practising orthopaedic surgeon there were no future interventions needed to prevent recurrence. Whilst it was initially considered that these cases did not merit retrospective reporting as historical never events, ultimately the Trust decided that in the interests of accuracy and transparency never event reporting should be initiated in case there could be wider learning from these cases. This will result in an apparent “blip” in Never event cases for the Trust, but is explicable because of the retrospective nature of this type of review, spanning some 15years of historical practise, and the fact this error was not recognised and was therefore not learnt from.

In terms of a clinical explanation as to how this specific error could repeatedly occur, the view of the external Consultants was that this difficulty is seen with inadequate surgical exposure. During a trapeziectomy operation it is crucial to release all the soft tissues surrounding the trapezium such that the classic shape of the bone is confirmed, all the joint surfaces can be seen and as this bone sits immediately under the 1st metacarpal bone, the trapezium is easy to identify and remove. The repetition of Mr Shah’s error is avoidable if the problems with anatomical misidentification have been identified and the surgical approach improved. The apparent lack of recognition of the difficulties differentiating between the trapezium and the distal scaphoid meant that Mr Shah continued to make the same surgical error on a number of occasions. Interestingly, the upper limb specialists expressed the same concerns about adequate surgical exposure as an important factor in some of the difficulties Mr Shah experienced – just as the Consultants reviewing the larger scale operations undertaken in shoulder replacement surgery had suggested.

The other similarities of themes included:

- Wider technical problems with appropriate sizing of plates / prosthetics as seen in phase 1 patient cohort
- Inadequate periods of post operative follow up confounded by a post operative follow up service that was delivered, almost exclusively by SAS staff and resident doctors rather than at Consultant level.

Trauma and Orthopaedics Patient Recall: Report

- Misinterpretation of x-rays by wider T&O team and radiology department (most commonly, but not exclusively, not noticing that the trapezium was still present after apparent trapeziectomy).
- A higher rate of concern about consent processes - the majority of these consent concerns related to the fact the planned procedure was, inadvertently, not the procedure undertaken due to technical deficiencies and poor pre-operative decision making.
- Misdiagnosis of persistent post-operative pain as Complex Regional Pain Syndrome (CRPS) instead of recognising that pain was persisting as a result of technically poor surgery / ongoing orthopaedic pathology.

These findings mirrored findings of other upper limb / non H&W patients from phase 1.

4.4.8 Summary

Whilst the core issues are the same in complex H&W surgery as those in complex /open upper limb procedures, the case selection undertaken in the audit has led to very high apparent rates of harm - but as fraction of whole H&W cohort, rates of harm are similar to the complex upper limb cohort. In low case numbers it is important that the statistical analysis does not hold more value than the quantitative assessments of harm which have been thematically analysed in this appendix.

- The two issues **specific** to H&W procedures are:
 - clear difficulties accurately identifying anatomy, both at surgery and radiographically/ post operatively
 - Concerns around consent that relate to the fact that the performed procedure was not the same as planned procedure, due to above difficulties with accurate anatomical identification.

The phase 2 H&W review has identified an additional 21 patients who were opined to have suffered potential harm as a result of undergoing complex H&W surgery under Mr Shah's care (17 clear harm, 4 inconclusive), and an additional 16 patients who have been recalled to hospital to be re- evaluated in case further treatment is required or can be offered to them to improve current symptomatology.

No additional actions are required within the Trust that have not already been identified and/or addressed following the phase 1 review, and although the hand and wrist extension has confirmed this was an additional area of concern within Mr Shah's practice, it has been concluded that this phase 2 extension to the primary review has not raised any de novo concerns that have not already been addressed within the Trust's action plan.

4.5 Outpatient requirements

A very significant proportion of patients were judged to require additional outpatient review. This requirement was not restricted to patients whose care was considered to have been suboptimal.

In total, of the 291 living patients whose care was assessed as part of the recall, the external assessors considered that 143 patients (49%) required additional clinical review. The following should be noted:

- All patients requiring further follow up outpatient review have now been seen in clinic, with the exception of the H&W cohort whose assessments were completed later than the

shoulder and elbow patients. 21 of 36 (58%) H&W patients included in the first phase of the review were considered to require further out-patient assessment.

- A significant proportion (36%) of “no harm” patients were considered to need follow up, because the practise within Mr Shah’s clinics offered very short term follow up even for patients who had undergone joint replacement surgery.
- Not all “harmed” patients were brought back for follow up, as a significant proportion had already received additional follow up and/or treatment, either from other specialists or specialties in the Trust or following referral to specialist upper limb services in other Trusts.
- The additional outpatient capacity has, in general, been provided by other members of the Trust’s upper limb T&O team, who undertook additional clinics at weekends. The majority of these clinics were supported by radiology and physiotherapy colleagues. They were complex clinics offering the first face to face review for patients who had often had difficult clinical journeys, many of whom had recently been informed of concerns about possible harm arising from previous surgery at the Trust.
- A significant proportion of the H&W cohort who require follow up have been referred to tertiary H&W services within nearby NHS Trusts. The Royal Orthopaedic Hospital H&W team have agreed to prioritise review of patients who have been recalled to outpatients following surgery by Mr Shah.

4.6 Patterns of clinical concerns identified

As a growing number of cases were reviewed, the pattern of concern relating to Mr Shah’s clinical practise became clearer to the assessing team. Every patient was fully informed about the assessors’ opinion of their individual treatment on a case-by-case basis - but it is helpful to consider the themes that emerged during the detailed analysis of nearly 400 high risk procedures. These themes can be summarised thematically as follows:

- *History taking, examination and diagnosis*

In general, the documentation available in the medical records was not detailed and in particular it was not always clear that the patient’s history and physical examination had been completed in a sufficiently detailed manner.

- *Pre-operative investigation and preparation for surgery*

In the majority of cases the pre-operative investigations (mainly imaging) were sufficiently detailed - but there were some cases where the assessors considered that higher levels of imaging (for example CT or MRI scanning rather than just plain x-rays) would have been helpful in both patient assessment and planning the most appropriate surgical intervention.

- *Consent*

Generally, standards of pre-operative consent were felt to be adequate. This was largely because the Trust’s processes were relatively robust in this regard and most often consent was undertaken as a 2-stage procedure. Most commonly the initial formal consent was taken by a member of Mr Shah’s team, with final consent sought on the day of surgery and countersigned by both Mr Shah and the patient. The details of more complex discussions about the alternatives to surgical intervention, and the pros and cons of different approaches (for example considering pain management as opposed to surgery) were not well documented in the pre-operative outpatient letters from Mr Shah and it was not clear that patients were

always offered non-surgical interventions or that conservative measures were actively considered as alternatives to surgery. The assessors considered that in some cases the combination of lack of detail in the pre-operative assessment combined with the lack of consideration of the full range of treatment options meant that on occasion the clinical decision making around the most appropriate treatment to offer was not supported. In these cases, there was insufficient consideration about the possible benefits of non-surgical treatment, and when surgery was offered there were concerns where the operation offered was more invasive / extensive than was always deemed necessary. It is important to be aware that standards and expectations of consent processes and the detail included in documentation have changed significantly during the timescale of this review and it is therefore imperative to judge the quality of consent with the standard practise "at the time".

There were specific concerns about consent in H&W surgery which related to unrecognised technical issues with removal of the wrong bone / a portion of the wrong bone, rendering consent inadequate /inaccurate.

- *Treatment including technical competence of surgery.*

Concerns about technical competence of the operations performed was the most significant area of concern relating to Mr Shah's practise - and it was the area of concern that was by far most likely to be assessed as having contributed to having caused direct patient harm. Assessment of operative notes and intra-operative and post operative x-rays were an important part of the assessment of the quality of surgery that was offered. A recurring pattern of errors were recognised. Examples included misplacement of prostheses (and base plates in shoulder replacement in particular), using the wrong sized prosthesis, misplaced screws or the wrong length of screws to provide joint stability etc. These errors did not seem to be apparent to Mr Shah or to others reviewing post operative x-rays and even when patients presented again with ongoing pain or restricted movement, the primary problems with surgical technique were apparently not recognised by Mr Shah and his team. The external assessors considered that a likely recurring causal factor was lack of adequacy of exposure and that this may have resulted in many of the technical problems Mr Shah experienced during his procedures.

- *Communication with patient / family / GP*

There were no systemic problems identified in this domain - it was notable that clinic letters were brief and included limited details (for example of clinical examination findings) and were not generally copied to patients. This is a practise that has not been fully developed within the Trust and was not unique to Mr Shah and his team.

- *Team working including communication with wider team / MDT*

Although the detail included in written communications was generally brief there were no specific concerns relating to team working. It was noted that the physiotherapy team did not generally document their findings and treatment plans within the patient's medical record (they keep separate physiotherapy notes), and that this information would be helpful to the treating medical team, but again this is not an issue that was specific to Mr Shah's practise during the period covered by the review.

Trauma and Orthopaedics Patient Recall: Report

- *Compliance with national standards (e.g. NICE etc)*

There was limited national guidance available at this time relating to upper limb T&O surgery, and there were no specific concerns about noncompliance with National standards.

- *Adherence to safety process measures (e.g. WHO checklist)*

WHO Checklists were included in the medical records of nearly all cases and there was no evidence to suggest noncompliance with National safety process measures.

A separate analysis of National joint registry (NJR) data showed that rates of data entry had fallen - but it was also clear that the NJR data relating to shoulder and elbow replacement was not as mature / informative as data relating to hip and knee replacement - NJR data did not identify any red flag signals for the Trust about shoulder replacement outcomes and had not proved to be helpful as an identifier of an individual surgeon with competence concerns.

- *Post operative reviews, discharge and outcome.*

There was considerable discussion about the post operative follow up for patients following upper limb surgery at the Trust. Overall, patient follow up was found to be inadequate:

- There was no structured follow up programme, either in terms of clinic frequency or duration or radiographic follow up, even for patients who had undergone joint replacement surgery or complex joint reconstruction (Latarjet)
- Many patients were discharged from routine clinic follow up after a very limited period after surgery.
- The majority of patients were seen by a large team of middle grade staff (SAS and SpR staff / resident doctors) – often patients did not see the same doctor, and they were rarely seen by Mr Shah himself in the post operative period. This may have been an important contributory factor in his lack of awareness about problems with technique and poor outcome, but on its own is not sufficient justification for the lack of professional curiosity about quality and outcome, nor for the problems with interpretation of radiological examinations that meant many adverse surgical outcomes were not recognised.

There was inadequate radiographic follow up, the views that were requested were not always optimal and abnormalities on x-rays were not always recognised or documented in the patient medical records. Organisational factors that may have contributed to this pattern of service delivery included the fact that post operative patients were often followed up in fracture clinic rather than a planned Consultant led OPD follow up clinic - predominantly delivered by a moving team of middle grade Doctors, without formal reporting of x-rays and no formal follow up guidelines.

Contractual and “efficiency” drivers have historically attempted to reduce new: follow up ratios - there has been an increasing focus on moving towards less “routine” follow up after elective surgery with reducing remuneration for this activity. Whilst this might be appropriate for some procedures, there are other procedures where covert pathology may be significant before symptoms appear where ongoing follow up is necessary. Joint replacement therapy likely fits within this domain. Published best practise guidance suggests follow up to 5 year’s post operatively, with annual imaging (or longer), others suggest 2 years follow up. Many patients were followed up for considerably less than this.

In patients presenting post operatively to clinic with ongoing pain or reduced range of movement, there was a tendency to offer ever increasingly complex surgical intervention, when in some cases a switch to a symptom-based approach (e.g. pain control) would have been more suitable. Both the RCS and the Trust's assessors felt that these non-surgical interventions were not sufficiently considered as a therapeutic intervention of value for patients with pain. There were some concerns that infection (when it occurred) was recognised late or inadequately treated.

The pattern of follow up seen in Mr Shah's clinic contributed to late identification of poor surgical outcome or post operative complications but was not necessarily a reflection on his practise as an individual, but was also considered to be the result of contracting / financial drivers as well as departmental organisational issues.

- *Wider professional behaviour (probity etc)*

There were no specific concerns in this domain - specifically no concerns of widespread problems of probity. In a small number of cases of concern, review of the medical records suggested that Mr Shah had not recognised the problems with the treatment that had been offered to patients. In some cases where he was referring patients on to tertiary specialists his referral letters were not felt to explicitly describe the problems that had arisen. Similarly, there were occasions where adverse events had arisen, for example intra-operatively or in the early post operative period, where patients did not seem to have received a full and open explanation of the causes behind the adverse outcome. Statutory duty of candour was brought into law in 2014 for NHS Trusts and 2015 for all other providers and is now seen as a crucial, underpinning aspect of a safe, open and transparent culture. It was not however routine practise prior to 2014. There was some (but relatively limited) evidence that duty of candour was embraced by Mr Shah during his time as a Consultant, but other occasions when this was less apparent. It is not clear to what degree this shortfall in transparency might have been related to a lack of insight into the problems in his practice that were emerging or if it may have represented a degree of self-protection, conscious or subconscious. The latter seemed to be a possible factor in some of the referrals to tertiary colleagues, where the referral letters were not felt to be wholly representative of the patient's journey. These instances are few in number and relatively few patients were referred on for more specialist care, even when they had already undergone multiple procedures without apparent successful outcome. Late escalation - or non-escalation - of patients for tertiary or more subspecialist input when it would have been a helpful treatment option was a theme that emerged from Mr Shah's more complex patient cohort.

4.7 Interface with private sector / Spire Healthcare

From their earliest days the project teams at the Trust and at Spire Healthcare worked closely to align the structure of the reviews being undertaken across both organisations, and to share relevant information regarding areas of concern and findings relating to Mr Shah's practice. The Trust initiated its review first, and once relevant operative codes for PoC had been identified these were shared with the Spire team, so that the initial patient inclusion criteria would be comparable across both organisations. Information about progress was shared formally each month at the assurance group. There was a clear consistency about the patterns of clinical concerns that were identified as outlined above – but importantly there were some areas of difference that were identified. These can be summarised as:

Trauma and Orthopaedics Patient Recall: Report

- The two providers used different criteria for determining low level harm. The Trust review used NHSE definitions of harm, as described in section 3.8 *Definitions of harm*. Spire healthcare's definition of harm included other lower levels of harm - termed "technical harm". Examples of technical harm included suboptimal consent processes, or suboptimal radiology reporting - even if clinical care was otherwise acceptable and the patient's outcome not affected.
- Both the NHS and Spire Healthcare reviews identified concerns about consent processes but the prevalence of this was higher in the Spire review. Similar concerns were identified in both reviews: namely lack of details or quantification of the potential risks of surgery and lack of alternatives to surgical intervention. In the NHS a significant part of consent processes were undertaken by other staff within the wider T&O team, including staff grade team members and Doctors in training (resident Doctors). Consent within the NHS usually took place as a two-stage procedure resulting in reasonable levels of detail and adequate documentation. When the quality of consent was individually scored as part of the audit there were no systemic concerns about consent within the NHS pathway. When there were concerns it related to lack of detail or quantification of the potential risks of surgery and lack of alternatives to surgical intervention, particularly as discussed within the out-patient consultations prior to surgery. It is also important to consider that best practise in standards of surgical consent have developed very significantly in the 14 years since the earliest cases included in this patient recall have undergone surgery. Similarly, duty of candour and the development of differing surgical techniques have all evolved considerably since Mr Shah's earliest practise as an NHS Consultant, so that all aspects of a clinician's performance need to be judged by standards of the time rather than against current best practice.
- A higher rate of concern was identified relating to knee replacement surgery at Spire. The audit undertaken within the NHS trust did not identify systemic concerns about any of the lower limb surgery – and even when the audit was extended to more fully assess the TKR cohort no additional concerns were identified. It seemed that this was a procedure that was more often performed in the earliest part of his career within the NHS. The audit undertaken does not make it possible to be categorical about the reasons for the difference between the findings between the two organisations.
- Physiotherapy staff at Spire were the first to identify and report concerns about the outcome for hand and wrist (H&W) patients. The subsequent review of a greater number of H&W cases within the NHS confirmed these concerns. Both organisations extended their inclusion of H&W patients and then reported very similar findings - for example, both teams identified significant concerns relating to decision making around surgical intervention in patients with arthritis in the base of the thumb - opting for carpometacarpal (CMC) fusion when trapeziectomy would be a lower risk and more appropriate intervention. The sharing of information from the Spire Healthcare team was invaluable in identifying this as an area of concern and ultimately precipitating the inclusion of an extended cohort of H&W patients.
- This review did not identify any evidence of patients being diverted from the NHS to the private sector by Mr Shah for financial gain.

There were some differences in the review processes that may (or may not) be contributory to the differences in findings between the organisations. Within the NHS review, decision making process was such that each case was reviewed by a senior external Consultant who was independent of the Trust and subcontracted to provide an independent medical opinion. If they considered the case sat unequivocally within the "no harm" or "moderate harm" groups their assessment would be taken at face value and the patient would be informed directly of

the results. The external Consultants had the option to take cases of “severe harm” or equivocal or borderline cases to a panel (the complex cases panel) for further discussion and a team decision.

In contrast, Spire healthcare took all cases to a panel decision.

The definitions of harm used by Spire Healthcare and the Trust were slightly different, although not fundamentally different at moderate and severe levels of harm. The Trust used definitions of harm as defined by NHSE, which include the fact that the patient has suffered short, medium or long term adverse outcome (broadly mild, moderate or severe harm respectively - see section 3.8 *Definitions of harm*). Spire healthcare included a category of “technical harm” – when, for example, X-rays were not properly interpreted, or the consent process was felt to be suboptimal - but the patient did not necessarily suffer adverse outcome as a result of this. This meant that “low level” harm was more frequently reported within Spire’s patient cohort than the Trust’s cohort. As an NHS organisation, the trust considered it was important to adhere to NHSE definitions of harm, for both consistency and transparency.

Whilst the differences between the two organisations’ approaches might not be materially significant, it is important to define them to fully understand differences in findings, for example between rates of harm in some procedures, or in assessment of the quality of consent. The findings of both review teams and the progress of the reviews were fully shared each month at the assurance group. The collaborative and open sharing between the two review teams and the organisations up to Medical Director level materially improved the quality and alignment of both reviews.

In summary: there were differences in the findings between Spire healthcare and the Trust, but after careful consideration the assurance group considered that these were not material to patient care in the upper limb cohort, with a range of possible contributory factors for lower limb patients that could explain these differences and that there was unlikely to be an oversight or omission in the Trust recall.

4.8 Interface with complaints

The Trust put considerable efforts into making sure that the local population were aware of the review into upper limb care in Walsall (see [Surgeon sacked after shoulder op patient recall in Walsall - BBC News](#) and [Hundreds recalled over shoulder op concerns at Walsall hospital - BBC News](#)) - detailed interviews with local media were held and included information about the phonenumber and email contact details, so that any patients who had concerns but who had not been contacted as part of the patient recall could also access support and an independent review of their care.

There were relatively few additional complaints from patients who had not been included in the recall. Some 12 months into the PNE 5 had been received in total, all were assessed by the external Consultants rather than an internal review. In 2 cases the complaint was upheld, and the external assessor considered that harm had been caused. In one case care had been considered suboptimal but the assessor considered that no harm had been caused, and in 2 cases there was no cause for concern identified. An additional 3 complaints were received from patients who were already part of the review, so these patients received a formal review of care from the external Consultants, and SDOC where appropriate. There was one final contact from a patient who had previously been through the complaint process in 2019, and

the external review team provided an updated assessment and response in light of their concerns.

This additional information about complaints suggests that the majority of cases of concern had been accurately identified and included as part of the patient recall, and that despite extensive local media coverage and widespread publicity via the trust website, there were limited additional cases of concern. This suggests that the criteria for inclusion within the patient recall resulted in the majority of high-risk patients or adverse outcome patients being included in the recall i.e. the inclusion criteria were appropriate.

4.9 Complex cases panel: Function and findings

A complex cases panel was established soon after the patient recall team had started their work. This served a number of functions:

- a) It served as a forum where cases which were assessed as having caused “serious harm” could be assessed on a panel basis, to ensure that there was consistency of approach and decision-making.
- b) Any cases where there was uncertainty about the assessment - if the primary assessor felt the case might sit on the threshold between any specific level of harm, or was just uncertain how to grade a case – could be brought for wider discussion.
- c) Cases where the primary assessor felt there were wider learning points that could be shared with the group.
- d) The complex cases panel undertook an additional session that was designated for analysis not of individual cases but of underlying factors which might have contributed to the difficulties Mr Shah experienced, and to consider which surveillance processes could have been expected to identify the governance concerns.

4.9.1 Complex cases panel workload

A total of 6 complex cases panels were held. The complex cases panels were chaired by an independent clinician representing the assurance group (either an NHSE or ICB board representative) and attended by the project lead and at least 3 of the external Consultants. One case was considered more appropriate to be dealt with by the Spire Healthcare team. Overall, 47% of cases were opined harm, 24% inconclusive and 29% no harm. This was felt to reflect the case mix of cases brought to the panel, which comprised either severe harm cases or uncertain / borderline cases that merited closer review. No new concerns were identified by a panel-based review of the cases of greatest concern, but it was an important forum for the external assessors to meet and discuss complex or borderline cases to ensure consistency of assessment and decision making across the team.

4.9.2 Findings of RCA type assessment of 7 severe harm cases

Seven cases were taken to the complex cases panel and discussed in more detail -analysing not the individual patient care, but the pattern of underlying performance issues that had contributed, and considering which existing NHS systems and processes could have identified concerns. Final consideration was given to whether new surveillance measures needed to be implemented to prevent a similar episode in the future.

Trauma and Orthopaedics Patient Recall: Report

The 7 “severe harm” cases that were reviewed were not representative of Mr Shah’s overall practise, but in these highly selected cases various aspects of clinical practise were felt to be “gravely below standards”. As detailed earlier, concerns related to a number of factors:

- Adequacy of Pre-op clinical assessment and investigation

(Because of this) poor operative choices / concerns re: indication – usually over aggressive surgical interventions, lack of staging of interventions / conservative management.

The above two factors were felt to result in a combination of “wrong assessment, wrong procedure”.

- Surgery - choice of procedure, technique (felt to be likely due to difficulties with approach / access /exposure)
- Follow up – inadequate, and also failure to recognise / address significant ongoing symptomatology and pathology. Delayed onward referral after adverse outcome.
- Concerns about radiology (image quality, reporting by T&O as well as within radiology)
- Documentation

The panel considered factors that might have contributed to these concerns, at personal, departmental, trust and national level, and also considered which protective measures should have mitigated some of the risks /adverse factors that were observed.

Personal factors
Lack of detail within clinical assessment and lack of clarity around decision making
Inadequate training and experience in the more subspecialist aspects of the field in which he was working
Low levels of clinical and surgical competence in some subspecialist domains (upper limb joint replacement, shoulder stabilisation and H&W surgery)
Lack of insight / awareness of own limitations
Isolated worker
Atypical pattern of workload e.g. multiple new prostheses, wide ranging and “cutting edge” techniques. ¹
Departmental factors
Lack of MDT for joint replacement surgery – to assess decisions to operate, as well post op Xray review, readmission and redo surgery etc.
Inadequate departmental audit ⁴ (documentation, throughput, outcome, complications by procedure and clinician etc)
Organisation of T&O clinics
Patient follow up delivered via fracture clinic.

<p>Effectiveness of CD role, and divisional audit and governance processes and teams</p> <p>New technique oversight</p> <p>Lack of Consultant challenge by other staff, colleagues – doctors, physios, theatre staff, clinical managers etc</p> <p>Competence and supervision of SAS and middle grade staff (in follow up, radiology interpretation etc)</p> <p>Failure to speak up (particularly trainees)</p> <p>Lack of oversight over scope of practise</p> <p>Lack of patient reported outcome measures</p>
<p>Organisational factors</p>
<p>Inadequacy of appraisal, particularly paucity of outcome data.³</p> <p>Lack of oversight of divisional governance</p> <p>Lack of focus on quality, networking, oversight of new techniques within the organisation</p> <p>Large numbers of pts lost to follow up.</p> <p>Role of legal and complaints department</p> <p>Empowerment of patients</p> <p>Controls over introduction of new techniques</p> <p>Whistleblowing and safety culture within the trust</p> <p>Concerns about quality of radiology support and reporting</p> <p>Consultant appointment process and assessment of technical competence</p> <p>Role of theatre management team e.g. new techniques / equipment</p> <p>Consultant challenge</p>
<p>NHS factors</p>
<p>Need for improved detail within joint registry data, particularly with regard to upper limb joint replacement</p> <p>Drive to reduce N:F/U “across the board” rather than on a procedure specific basis</p> <p>Balance of low-cost vs high quality and how to drive this contractually</p>

Empowerment of trainees

Whistleblowing and safety culture across the NHS

Table: Analysis of Causal Factors - Individual, Departmental & NHS Level

Areas for discussion:

1: Introduction of new techniques: the panel considered that whilst the theory of new technique introduction is straightforward (a practitioner introducing a new technique to the Trust needs to develop not only a business case, but also a governance and safety case - where effectiveness is demonstrated, adequacy of training is proven and a systematic approach to surveillance of outcomes is embedded) the practise was often more subtle. For example, the differences between a new technique and “creeping edge” changes in services are complex - is a new prosthesis a new procedure? What defines a new implant - is a standard implant manufactured by a new company a new implant? Or does the modification of an established implant / prosthesis become a new implant or a new technique? The external Consultants considered that often within T&O the situation is one of incremental developments and the categorical definition of a new technique was not as easy as one might consider. That aside, during the case discussions it was noted that Mr Shah seemed to change implants and providers with surprising regularity, and that he was an early adopter of some very complex new techniques – many of which have remained in the realm of highly complex and expensive tertiary subspecialist surgical interventions. The reasons behind this enthusiasm for using wide ranging implants and techniques was not clear, but it was not felt to be conducive to the development of technical excellence.

It was noted that historically there was more freedom for clinicians to develop their service or their practise in whatever way they chose, and that in recent years as cost considerations and procurement had gained a higher profile these unilateral changes in practise have become more restricted. Regardless of historical freedoms, the extent to which Mr Shah had almost complete clinical freedom was considered highly atypical - for example one case involved a hemiarthroplasty with biologic interposition. This was felt to be a highly atypical new procedure for a DGH Consultant to be undertaking, which was considered costly as well as highly specialist.

2: The “covid factor”: it should be recognised that the highest volume of cases and the highest rate of harm arose during the Covid and post covid era. The case reviews suggested that the Trust already had problems with the reliability of its follow up processes and many patients seemed to get “lost to follow up”- i.e. the clinician planned to see the patient again in clinic after a certain period, but for reasons that were not possible to elucidate the appointment never materialised- and most times the patients did not seem to be in a position to bring this to the Trust’s attention. This problem was significantly exacerbated during and after Covid- when a much greater proportion of patients were lost to follow up - presumably having been placed on some form of pending list. In addition, the majority of follow up appointments that did occur were delivered by phone meaning that the opportunity to undertake checks of post-operative x-rays or any clinical or functional assessment was lost. With the benefit of hindsight, for some services (such as those where radiographic F/U is an essential part of the assessment, for example after joint replacement surgery) this was not an effective way of offering ongoing F/U. There were obviously wider pressures on the NHS and on Trusts at this

time, that were not specific to T&O or to Walsall Healthcare NHS Trust and the whole NHS was under very considerable pressure across the whole range of practise.

3: Appraisal: There was extensive discussion about the apparent failure of the appraisal system in identification of the difficulties Mr Shah was facing with his clinical and technical competency and how these were missed by the Trust's appraisal and governance processes apparently throughout Mr Shah's employment in the Trust. The data provided to Mr Shah and his appraisers has not been reviewed as part of this PNE but there was general agreement that the quality and granularity of routinely available outcome data was not sufficiently detailed to allow individual Consultants, appraisers or Trusts to get a clear idea about suboptimal patient outcomes – specifically about outcomes that do not impact mortality or readmission rates. There was consensus that to look effectively at patient outcome one needed patient level and department level data, that was benchmarked at individual and National level. Ideally this would include patient reported outcome measures, to complement the current 5 yearly patient feedback which only relates to outpatient experience. The NJR data is not apparently mature enough to offer this level of detail yet for shoulder and elbow replacement surgery - and indeed the Trust's data entry rates had fallen in the years before these concerns were identified.

The complex cases panel recommended that Mr Shah's appraisals should be reviewed to ascertain the information that was available to Mr Shah himself and to his appraiser, to assess whether the information itself was lacking, or whether there was insufficient escalation of concerns that could have been identified from the appraisal information. Helpful information could be gained from reviewing 360-degree feedback, patient feedback, as well as the detail provided to appraisees and appraisers about complaints or incidents or legal cases. It would be helpful for the Trust to gain clarity about whether the information provided at the time of appraisal was sufficient to identify the emerging concerns but was not acted upon, or whether the level of information provided was not sufficient to shed light on the concerns about practise and outcome.

4: Audit: Once the concerns about Mr Shah's outcome had been raised following a patient report to the GMC, an internal audit of returns to theatre for shoulder replacement surgery confirmed differences in outcome and raised the level of concern. There is no evidence of the quality of any proactive audit programmes that were ongoing prior to this date, and similarly there seems to have been a paucity of structured audit and reporting systems at departmental and divisional level. During an extensive debriefing of staff within T&O it seemed that a focus on throughput and activity had put some pressure on the time available for core governance and quality activities- for example M&M meetings, MDT meetings, audit meetings do not seem to have protected time within job plans or indeed to have been compulsory. This is an area that will require further investment - the department seems to have fallen behind in terms of investment in medical time in the development and delivery of safety and quality. Similarly, there seemed to be a lack of oversight at divisional level.

4.9.3 Summary of findings of Complex cases panel RCA meeting

The panel considered that existing systems and processes should be sufficient, in theory, to identify the types of issues experienced in this case. It was considered that the most effective way forward is to improve the data quality and granularity of existing governance systems within the Trust. It was recommended that the Trust continued to work on development of existing systems:

- Appointment processes, particularly assessment of technical competencies and scope of practise at appointment
- Robust oversight of new techniques
- Appraisal processes and data
- Development of robust MDT processes - prior to listing for joint replacement and to include early post operative imaging / redo surgery rates etc
- Robust and fully attended M and M processes - to include morbidity > mortality
- Development of Clinical director role
- Higher profile and more robust Trust and divisional Governance and Assurance processes

Other changes identified that are necessary to support quality and safety may have long term capacity / workload implications for the department:

- a. Increased Consultant input into post operative follow up
- b. More structured and longer-term F/U, particularly after joint replacement and invasive orthopaedic procedures (introduction of metalwork / joint fusion etc.)
- c. Increased MDT time – for all joint replacement surgery, hand surgery, include a degree of patient outcome, for example review of first post operative X-rays etc)
- d. Increased support / liaison with pain services

4.10 Medicolegal workload

The patient recall and the raised public awareness of concerns about Mr Shah's practise resulted in a significant number of patients seeking advice about potential legal action against the Trust. There is a significant time lag between patients within the PNE being notified of concerns about their care, and the initiation of legal action, so it seems likely this workload will continue to increase over the coming months. A significant proportion of potential litigants had been operated on by Mr Shah in the past, but had not undergone a PoC. Preliminary data suggests that only a small proportion of these cases are felt to have a strong medicolegal case. This again offers further assurance that the PoC as currently defined have identified the majority of cases of concern with regard to Mr Shah's practice.

5 Summary

Analysing the rate of harm by procedure arising from some 110 case reviews undertaken by the RCS, the Wrightington review, and internal audit enabled the identification of procedures that were felt to be higher risk in terms of quality of care - the so called "procedures of concern". These broadly comprised shoulder and elbow replacement surgery, and complex hand and wrist surgery. The identified rate of moderate or severe harm was 24%, across all patient cohorts, with the exception of those undergoing the Latarjet procedure, where 43% were considered to have suffered harm as a result of the treatment they received. An additional review of some 32 H&W cases in a second phase of the PNE identified concerns in nearly 50% of cases reviewed. Additional audits did not identify other areas where there were concerns about significant levels of harm or major malpractice.

The assessors considered the most important factors leading to actual patient harm in some subspecialist areas of upper limb practise was a patient journey that was characterised by inadequate pre-operative assessment, leading to a poorly thought through treatment strategy

with inappropriate surgery that tended to be over aggressive, with the most significant concerns relating to competence of the surgical technique. Other concerns regarding suboptimal practise related to the low quality of documentation. There were systemic problems with inadequate radiographic and clinical follow up.

All patients have now received a detailed letter outlining the findings of the external assessment of the care they received. Statutory Duty of Candour has been completed in all relevant cases. All patients who were considered to need further outpatient follow-up for further assessment have been reviewed with the exception of a limited number of H&W patients. Their long-term needs in terms of possible further surgery are not yet known and will not be for some considerable period of time. There is a considerable ongoing medicolegal tail, but preliminary data suggests that the rates of concern outside the PoC are low.

Further complaints or patients seeking legal redress will be managed within existing Trust processes. The primary recall has now been completed.

6 Recommendations / outstanding actions

- 6.1 The Trust has been working closely with the GMC and other external agencies throughout this recall - once signed off by the board this report should be shared with the Complex Case Assurance Group and other relevant stakeholders
- 6.2 The Trust should develop a detailed communication strategy which ensures that patients involved in the recall process, other patients who have been treated by Mr Shah and the wider population are aware that the review has been completed, the key findings and resulting actions. This should include a further opportunity for patients involved in the review to offer final comments about the experience of being involved in the review process.
- 6.3 Further dissemination within the trust, and shared learning with other staff members outside the department of Trauma and orthopaedics needs to continue
- 6.4 There are a number of internal actions that have already been completed as part of the Trust's response to the RCS reviews - but there are a number of areas that will require further development to ensure ongoing quality and safety within T&O. These mainly reflect a historical lack of structure and rigor to internal governance, assurance, safety and oversight. These will necessarily result in increased cost and reduced productivity, at least initially, to deliver assurance around quality and patient experience. The ICB and commissioning colleagues will need to actively support this process. Required measures might include:
 - Protected MDT time for all patients undergoing upper limb joint replacement, and the Latarjet procedure.
 - Consideration should be given to improved objectivity of surgical outcome data - for example post operative / intra-operative films to be reviewed at MDT
 - Reorganisation of post operative follow up clinics - likely to need increased Consultant input, standardised clinical and radiographic follow up after joint replacement surgery
 - Review of patient pathways, for example hand and wrist surgery or other low volume procedures
 - Protected time and recorded attendance for T&O medical staff at M&M and audit meetings
 - Inclusion of physiotherapy records within Fusion

Trauma and Orthopaedics Patient Recall: Report

- Review of departmental / divisional and Trust wide governance and appraisal rigour, including granularity of data, and possible inclusion of PROMs.
Trust to develop robust arrangements regarding patients waiting follow up in OPD to minimise the risk of patients being “lost” to follow up
- Enhanced supervision and support of trainees and career grade staff within T&O
- The Trust should ensure a robust policy of copying patients in to all correspondence, or otherwise move directly to writing all letters direct to patients – see [NHS England » ROAN information sheet 23: Quality improvement: best practice for clinical letters](#) - otherwise implementation of proposals for letters to be written to patients as per Academy of Medical royal colleges and NHS best practise advice – see [Please write to me Guidance 010918.pdf \(aomrc.org.uk\)](#).
- Further development of the Freedom to speak up culture, supportive challenge to Consultants, openness and transparency, plus enhanced patient empowerment.
- Revisit new techniques policy to ensure it is compliant with RCS guidance and sufficiently focussed on surgical techniques that are either new to the Trust or to an individual or team.
- Develop infrastructure to ensure that the operating surgeon personally writes the operative notes, and that these are typed or dictated to improve legibility and quality of documentation.
- Undertake an audit of coding of admissions, and operative coding within T&O and possibly more widely.
- Consideration of increased supportive oversight of medical practice using an early detection assurance system to support doctors in difficulty and protect patients, professionals and the organisation from avoidable harm.

7.0 Appendices

7.1 Appendix A: Explanations used as basis for written communications with patients

The scaphoid bone is one of the eight small wrist bones.

De Quervain's syndrome is a painful condition affecting the tendons on the thumb side of the wrist. If you have de Quervain's syndrome, you will probably feel pain when you turn your wrist, grasp anything or make a fist. Although the exact cause of de Quervain's syndrome isn't known, any activity that relies on repetitive hand or wrist movement — such as working in the garden, playing golf or racket sports, or lifting a baby — can make it worse.

Pantrapezial arthritis: The universal joint at the base of the thumb, between the metacarpal and trapezium bones, often becomes arthritic as people get older. It is osteoarthritis, which is loss of the smooth cartilage surface covering the ends of the bones in the joints. The cartilage becomes thin and rough, and the bone ends can rub together. Osteoarthritis can develop at any age, but usually appears after the age of 45. It may run in families, and it sometimes follows a fracture involving the joint many years before.

Arthritis of the basal joint of the thumb is common in women and rather less common in men. X-rays show it is present in about 25% of women over the age of 55, but many people with arthritis of this joint have no significant pain.

Scapholunate disruption or insufficient is a condition where the scaphoid and lunate bones in the wrist move apart. This happens when the ligament, which is holding the bones together, tears or stretches. The ligament can be injured by a fall on the hand, repeated strains, or loosening with age. The injury causes wrist pain, swelling and instability. It can also lead to joint damage (arthritis in the joint) and decreased range of motion. The diagnosis is made by physical examination and imaging tests.

Arthrodesis refers to the fusion of two or more bones in a joint. This surgery relieves pain caused by arthritis by eliminating motion in the joint.

Complex regional pain syndrome (CRPS) is a form of chronic pain that usually affects an arm or a leg. CRPS typically develops after an injury or surgery. The pain is out of proportion to the severity of the initial injury.

Scaphoid fracture: A scaphoid fracture is a break of the scaphoid bone in the wrist. Symptoms generally includes pain at the base of the thumb which is worse with use of the hand. Because of its location and size, the scaphoid bone is the most common wrist bone to fracture. In most cases, falling causes the fracture. The location and severity of the break will dictate if casting or surgery is required for treatment of a scaphoid fracture.

Carpometacarpal (CMC) arthritis is a condition that affects the joint at the base of the thumb. It occurs when the cartilage that covers the ends of the bones in the joint wears away, causing the bones to rub against each other. This can lead to pain, swelling, stiffness, and decreased range of motion in the thumb. The condition is common with aging and can also be caused

Trauma and Orthopaedics Patient Recall: Report

by previous trauma or injury to the thumb joint. Treatment options include medication, splints, and surgery.

CMC arthrodesis or joint fusion is a procedure that joins the surfaces of the thumb metacarpal and the trapezium so they don't move or cause pain. This surgery is usually done on younger patients who have to have a lot of thumb strength on the job, such as carpenters who need to use a hammer all day. Once the CMC joint is fused, pain is usually significantly reduced. There is often a reduction in the range of movement at the joint, but patients usually still have a good ability to grip and pinch.

The metacarpophalangeal joints (MCP) are a collection of joints that connect the bones that together sit under the palm of the hand to the fingers. There are five separate metacarpophalangeal joints that connect each metacarpal bone to the corresponding bone in each finger. The MCP joint is also known as "the knuckle" and allows for a full range of movement in each finger.

The trapeziometacarpal joint, also known as the carpometacarpal joint of the thumb, is a **joint** that connects the trapezium bone of the wrist with the base of the first metacarpal bone of the thumb.

We would normally expect fusion to occur by around 3months or at the latest 6months after surgery, but your follow up X-rays on 3rd August 2020 show an obvious CMC joint persists despite 9/12 after surgery- i.e. the bones have not fused.

Pantrapezial arthritis is a type of thumb arthritis. It is characterized by an aching pain in the ball of the thumb, which may radiate up the forearm. The joint can be swollen and can make a grinding sound or cause pain on movement. Imaging techniques, usually X-rays, can reveal signs of thumb arthritis, including bone spurs, worn-down cartilage, and loss of joint space. In the early stages of thumb arthritis, treatment usually involves a combination of non-surgical therapies such as medication, splinting, and injections. If your thumb arthritis is severe, surgery might be necessary

A trapeziectomy involves removing the bone called the trapezium from your wrist that sits at the base of the thumb. It is removed to help patients move the hand comfortably in daily activities and to help reduce any pain in the thumb due to arthritis.

Bone lucency: While bones typically appear white on X-rays due to their density, certain bone abnormalities can exhibit areas of lucency. This might be seen in conditions like osteoporosis, where bones become less dense and show darker regions.

DISI: Dorsal intercalated segment instability - Dorsal intercalated segment instability (DISI) is a deformity of the wrist where the lunate bone angulates to the dorsal side of the hand.

The main cause of DISI is wrist trauma, with or without a fracture:

- Scaphoid fracture: bony DISI
- Distal radius fracture: compensatory DISI
- Malunion of radius fracture: adaptive DISI
- Scapholunate ligament instability: ligamentous DISI

Trauma and Orthopaedics Patient Recall: Report

AVN: Avascular necrosis (AVN), also called bone infarction, is death of bone tissue due to interruption of the blood supply.

A Surgilig™ is an artificial polyester ligament which loops around the clavicle and the coracoid bone (a bony prominence at the front of the shoulder) in the shoulder, replacing the torn ligaments. This helps to stabilise the ACJ and prevent recurrent instability and pain. The Surgilig™ is inserted through an incision (cut) made on the top and the front of the shoulder. The ligament is secured to the clavicle with a screw.

In the biceps tenodesis procedure, your surgeon releases your torn biceps tendon from your labrum.

The term SLAP stands for Superior Labrum Anterior and Posterior. In a SLAP injury, the top (superior) part of the labrum is injured. This top area is also where the biceps tendon attaches to the labrum. A SLAP tear occurs both in front (anterior) and back (posterior) of this attachment point.

The shoulder labrum is a type of rubbery cartilage that lines the shoulder socket (called the glenoid) of the shoulder joint. The labrum helps keep your shoulder joint in place.

Debridement involves removing loose fragments of tendon, thickened bursa, and other debris from around the shoulder joint.

A shoulder hemiarthroplasty is a partial shoulder replacement, which is the surgical removal of the rounded top portion of the humerus (the upper arm bone) and replacement with a prosthesis.

Pyrocarbon hemiarthroplasty: Shoulder hemiarthroplasty is a viable option in young patients with an intact rotator cuff in order to preserve the native glenoid. To avoid the dreaded and expected wear of the glenoid in very active shoulders, implants with humeral head coated with a high resistant and elastic material—pyrolytic carbon—are now an option.

Total shoulder replacement, also known as total shoulder arthroplasty, is a procedure where portions of the bones in the shoulder joint are removed and replaced with artificial implants. It helps restore the function and mobility of the shoulder joint, while also reducing pain. This surgery may be recommended for a variety of conditions, such as degenerative joint disease (osteoarthritis) or severe fractures of the upper arm bone (humerus).

Some people may need a reverse total shoulder replacement, where the anatomy of the ball and socket joint is reversed with the artificial implants. Surgeons select the reverse approach for patients with badly-injured rotator cuffs, arm weakness, severe arthritis paired with a rotator cuff tear, or a failed total replacement surgery

The shoulder joint is made up of three main bones: the upper arm bone (humerus), the shoulder blade (scapula), and the collarbone (clavicle). These three bones are connected with ligaments and cartilage, which protects the ends of the bones where they meet. The head of the humerus meets the scapula at the socket (glenoid), forming the joint that allows range of motion of the upper arm and shoulder.

Trauma and Orthopaedics Patient Recall: Report

A supracondylar humerus fracture is a fracture of the lower part of the humerus (the long bone in the upper arm) just above the elbow joint.

Nerve conduction studies: A study of nerve damage by measuring the speed and strength of impulses of nerves in response to stimulation.

In a total shoulder replacement, the damaged head of the humerus and the surface of the glenoid are removed. Then, artificial implants are placed to make the joint area smooth and functional, mimicking the size of the patient's bone that was removed.² By removing the damaged portions of the bone and cartilage, patients experience less pain and increased range of motion.

A Hills-Sachs lesion is an injury to the back portion of the rounded top of your upper arm bone (humerus). This injury occurs when you dislocate your shoulder.

When the shoulder socket is damaged, the socket (known as the glenoid) may progressively get worn away. As this occurs, the chance of recurrent dislocation goes up. In fact, bone loss in the shoulder socket can get to the point where patients have a hard time keeping the shoulder in the socket at all. One treatment for glenoid bone loss is called Latarjet surgery.

The Latarjet procedure is an operation designed to build up the glenoid with additional bone. The bone comes from the scapula (shoulder blade) and is a hook of bone called the coracoid which sits in the front of the shoulder blade and is the attachment for several muscles. During Latarjet surgery, the surgeon removes the coracoid from the scapula and moves the coracoid, and the muscle attachments, a few centimetres to the front of the shoulder socket. Once in position, the coracoid is screwed to the shoulder socket. This increases the amount of bone to the front of the shoulder socket to restore bone that had been lost and reduce the chances of the arm bone (humerus) dislocating. Second, the muscles attached to the coracoid create a sling, to help support the shoulder in the front of the shoulder joint and this also helps reduce future dislocation.

The musculocutaneous nerve is a nerve in your outer arm. It is one of the end nerves from the brachial plexus that extends from your neck to your armpit. The musculocutaneous nerve carries fibres for both motor function (movement) and sensory function (feeling).

Arthroscopy is a type of keyhole surgery for checking or repairing your joints.

Shoulder Labrum Tear: this is a tear to the specialized cartilage tissue in the shoulder known as the labrum can cause pain and instability in the shoulder.

The four stages of osteoarthritis (OA) have been graded on the basis of X-ray findings. Higher grades indicate more severe signs of OA and the need for surgery.

- **Grade 0** is the stage when the joint is healthy—there are no signs on X-ray.
- **Grade 1:** Doubtful narrowing of the joint space with possible bone spurs (tiny pointed bony growth)
- **Grade 2:** Definite bone spurs with possible reduced joint space
- **Grade 3:** Definite moderate joint space narrowing (at least 50%)
 - Multiple bone spurs present
 - Possible deformity of the bone contour

- **Grade 4:** Most severe stage of OA
 - Large bone spurs
 - Dramatic reduction in the joint space
 - Definite deformity of the bone contour

The symptoms experienced at each stage may vary from individual to individual. Some people have few symptoms despite the deterioration of their joints. Others experience pain and stiffness that hamper their routine chores.

Supraspinatus muscle: Supraspinatus is a small muscle of the upper arm. It's one of the four muscles that make up the rotator cuff. It helps lift your arm up and keeps the head of the humerus (upper arm bone) stable in the shoulder socket.

Glenoid: the socket in the shoulder that the upper arm bone fits into)

Osteophytes (bone spurs) are bony lumps that grow on the bones in the spine or around joints. They form when a joint or bone has been damaged by arthritis.

Elbow replacement: Although elbow joint replacement is much less common than knee, hip, or shoulder replacement, it is just as successful in relieving joint pain and returning people to daily activities.

In total elbow replacement surgery, the damaged parts of the humerus and ulna are replaced with artificial components. The artificial elbow joint is made up of a metal and plastic hinge with two metal stems. The stems fit inside the hollow part of the bone called the canal.

There are different types of elbow replacements, and components come in different sizes. There are also partial elbow replacements, which may be used in very specific situations. A discussion with your doctor will help to determine what type of elbow replacement is best for you.

MDT meeting: A multi-disciplinary team meeting (MDT) is a weekly or monthly meeting that takes place between health care professionals, to discuss individual patient cases

A resurfacing hemiarthroplasty involves joint replacement surgery (arthroplasty). This is a partial replacement of the shoulder joint in which the humerus (arm bone) is replaced with a metal covering or cap, keeping the bone underneath. The other half of the shoulder joint (the top half of the ball and socket joint) is left intact. It is a useful operation for shoulder joint problems where only the head of the humerus (the arm bone) is damaged.

Shoulder resurfacing is a surgical procedure that replaces the damaged surface of the humeral head (the ball of the shoulder joint) with a metal cap. It is less invasive than a total shoulder replacement and preserves more of the natural bone.

Radial head excision is a surgical procedure that involves the removal of the radial head (the smaller bone of the forearm that makes up the elbow joint) after severe damage following trauma or as a result of degenerative changes associated with arthritis.

Trauma and Orthopaedics Patient Recall: Report

Elbow replacement surgery removes damaged areas of the elbow joint and replaces them with parts made of metal and plastic (implants). This surgery is also called elbow arthroplasty. Three bones meet in the elbow. The upper arm bone (humerus) connects like a loose hinge to the larger of the two forearm bones (ulna). The two forearm bones (radius and ulna) work together to provide rotation.

The olecranon is the part of the ulna that cups the lower end of the humerus, creating a hinge for elbow movement.

Overstuffing of the total shoulder arthroplasty or shoulder hemiarthroplasty is secondary to an oversized humeral component or inaccurate positioning of the prosthetic humeral head, which can lead to subacromial impingement from malposition with attritional rotator cuff tears

An alternative to total shoulder arthroplasty (replacement), shoulder resurfacing involves only repairing the surface of the humeral head. In a typical total shoulder replacement, the shoulder surgeon would have to replace both parts that make up the joint; the humeral head and the glenoid cavity.

The rotator cuff is a group of muscles and tendons that surround the shoulder joint, keeping the head of the upper arm bone firmly within the shallow socket of the shoulder. A rotator cuff injury can cause a dull ache in the shoulder that worsens at night. Rotator cuff injuries are common and increase with age.

Your rotator cuff is the group of muscles and tendons that surround your shoulder joint. You can injure your rotator cuff suddenly, or it can happen over time, due to wear and tear on your shoulder joint.

The rotator cuff helps to keep your shoulder stable and working well. If the rotator cuff is torn it does not work normally and the shoulder joint is not held in a stable position and the head of the humerus no longer rotates smoothly in the shoulder socket. Initially that can reduce the range of movement of the shoulder joint, but in time it also causes damage to the socket because of uneven wear and tear on the bones forming the socket of the shoulder joint. This is called arthropathy and in time it causes a painful arthritis of the shoulder joint. Your main problem was therefore a tear in the rotator cuff muscles which eventually resulted in arthritis affecting the shoulder joint.

The cuff tear arthropathy (CTA) prosthesis is replacement for the damaged ball (humeral head) that has an extended surface to fit in the coracoacromial arch. It has a stem that fits down the shaft of the arm bone (humerus). An artificial socket is not usually used with this prosthesis.

If the rotator cuff is damaged beyond repair, a specific type of shoulder replacement may be performed. This surgery - called a reverse shoulder replacement - is performed to alter the mechanics of the shoulder joint in order to allow for a functioning replacement despite the damage to the rotator cuff.

Overstuffing: In shoulder arthroplasty, particularly in the earlier days of this surgery, larger replacement joints were used- particularly there was a well-recognised tendency to use larger replacements for the head of the humerus. This has become known as “overstuffing” the joint. When a larger replacement head is put onto the humerus this is now known to cause tension

and traction on the muscles and ligaments surrounding the shoulder joint -the rotator cuff – and this can cause pain and restriction of movement. The assessor felt that your x-rays suggested the shoulder joint was “overstuffed” and felt this might explain some of your symptoms, but emphasised that was common practise in shoulder joint replacement in the past.

Heterotopic ossification (HO) occurs when bone tissue develops in your soft tissues. Often, people get HO after an injury or major surgery. In HO, you develop a bony, painful lump underneath your skin. If the lump is near a joint it may restrict your range of motion.

In a reverse shoulder replacement, the normal ball-and-socket structure is reversed. An artificial ball is attached to the shoulder blade. An artificial socket is attached to the top of the arm bone.

Shoulder impingement happens if lifting your arm puts too much pressure on the tendons. When the tendons press against the shoulder blade above them, this causes pain. You may also find it harder to move your arm.

Shoulder impingement has lots of different causes. These include:

- your tendons getting swollen or torn from overuse (if you're doing a lot of sports) or 'wear and tear' as you get older
- the shape of the bone at the top of your shoulder blade (your acromion), which rubs against your tendons
- getting bony growths (spurs) on your acromion as you get older

Subacromial decompression surgery is usually performed arthroscopically (key hole surgery).

The surgeon makes several small incisions (cuts) in the shoulder area. A miniature telescope is inserted into the joint area providing full view via a monitor. Other surgical instruments are inserted to clean the area and repair any damaged tendons. Subacromial decompression surgery smooths down the surface of your bones around the shoulder joint so they don't rub against the tendons. This helps to ease the pain that patients are experiencing.

An ACJ resection involves the surgical removal of the last 0.5inches (1.3cms) of the collarbone. This removal leaves a space between the acromion and the cut end of the collarbone where the AC joint used to be. The joint is replaced by scar tissue, which allows movement to occur, but prevents the rubbing of the bone ends

In a 'biceps tenotomy' procedure the long head of biceps tendon is released from its attachment in the shoulder joint, allowing it to fall down into the upper arm and out of the shoulder joint. This removes the damaged, inflamed tissue by releasing it from the joint.

Acromioclavicular joint (AC joint) is where the collarbone and the **shoulder blade meet** at the top of the shoulder.

Simple AC injuries are classified in three grades ranging from a mild dislocation to a complete separation:

Grade I - A slight displacement of the joint. The acromioclavicular ligament may be stretched or partially torn. **This is the most common type of injury to the AC joint.**

Grade II - A partial dislocation of the joint in which there may be some displacement that may not be obvious during a physical examination. The acromioclavicular ligament is completely torn, while the coracoclavicular ligaments remain intact.

Grade III - A complete separation of the joint. The acromioclavicular ligament, the coracoclavicular ligaments, and the capsule surrounding the joint are torn. Usually, the displacement is obvious on clinical exam. Without any ligament support, the shoulder falls under the weight of the arm and the clavicle is pushed up, causing a bump on the shoulder.

Acromioclavicular joint resection (ACJ resection) is also done as a keyhole operation and involves removing a segment of bone at the end of the clavicle (collarbone). Resection of a painful AC joint can be very effective in relieving pain. The purpose of the operation is to try and smooth the surface of the bones forming the shoulder socket so they do not carry on rubbing and causing irritation to the tendons and muscles around the shoulder.

Capsulitis is another name for frozen shoulder, and is a painful condition in which the movement of the shoulder becomes limited. Frozen shoulder occurs when the strong connective tissue surrounding the shoulder joint (called the shoulder joint capsule) becomes thick, stiff and inflamed. The joint capsule contains the ligaments that attach the top of the upper arm bone (the humeral head) to the shoulder socket (the glenoid), firmly holding the joint in place. This is more commonly known as the “ball and socket” joint of the shoulder.

The condition is called “frozen” shoulder because the more pain is felt the less likely the shoulder will be used. Lack of use causes the shoulder capsule to thicken and become tight, making the shoulder even more difficult to move - it is “frozen” in its position.

Descriptions of levels of arthritis: [The 4 Stages of Osteoarthritis: Symptoms and Treatment \(verywellhealth.com\)](https://www.verywellhealth.com)

ACJ coplaning removes inferior “spurs” (spikes of bone, or roughened areas of bone) at the end of the clavicle to decrease injury to the nearby muscles which form the rotator cuff.

Your rotator cuff is the group of muscles and tendons that surround your shoulder joint. Tendons are strong bands of tissue that connect muscles to bones. Your rotator cuff helps to keep your shoulder stable and working well. If the rotator cuff is not working normally the shoulder joint is not held in a stable position and the head of the humerus no longer rotates smoothly in the socket. Initially that can reduce the range of movement of the shoulder joint, but in time it also causes damage to the socket because of uneven wear and tear on the bones forming the socket of the shoulder joint. This is called arthropathy and in time it causes a painful arthritis of the shoulder joint.

You can injure your rotator cuff suddenly, or it can happen over time, due to wear and tear on your shoulder joint.

The base of the thumb where it meets the hand is called the carpometacarpal (CMC) joint.

Trauma and Orthopaedics Patient Recall: Report

ACJ: The acromioclavicular (AC) joint is formed by the cap of the shoulder (acromion) and the collar bone (clavicle).

Rotator cuff tear. This is when one or more of the muscles and tendons that make up your rotator cuff tears. You can have a partial or a full tear. A tear can happen suddenly, after a single injury. Or it can develop gradually, over time.

Tendinopathy. This term covers many different conditions affecting the tendons around your shoulder. Some of the tendons can become trapped between a bone at the top of your arm and the top of your shoulder blade. This is called subacromial or shoulder impingement. The tendon can eventually tear over time.

Shoulder impingement is a common cause of shoulder pain that occurs when a tendon inside your shoulder rubs or catches on nearby tissue and bone as you lift your arm. The rotator cuff tendon, which connects the muscles around your shoulder joint to the top of your arm, is usually affected

Symptoms of shoulder impingement can start suddenly or come on gradually and include:

- Pain in the top and outer side of your shoulder
- Pain that's worse when you lift your arm, especially when you lift it above your head
- Pain or aching at night, which can affect your sleep
- Weakness in your arm

A Bankart repair of the shoulder is a surgical procedure to re-attach the torn labrum (cartilage) surrounding the glenoid (shoulder joint). The shoulder is constructed of the humerus, scapula and clavicle. The head of the humerus sits in a shallow cavity on the scapula called the glenoid and is surrounded by the labrum and capsule (series of ligaments connecting the humerus to the glenoid). Due to its shallow nature, the shoulder joint is inherently unstable and so these structures help to promote stability and reinforce the joint.

A Bankart lesion is a tear specific to the anterior/inferior portion of the labrum, where the labrum is torn off the glenoid, caused through dislocation of the shoulder and tearing of the inferior glenohumeral ligament. When dislocating your shoulder, it is very common to for you to cause a Bankart lesion resulting in an unstable shoulder which could lead to further dislocation.

Capsular release of the shoulder is a type of minimally invasive surgery which can help to relieve pain and severe stiffness caused by a condition called frozen shoulder. This condition is when the flexible tissue that surrounds the shoulder joint (the capsule) becomes inflamed and thickened.

Shoulder debridement: This minimally invasive shoulder surgery is used to remove tissue in the shoulder joint that has been damaged from arthritis, overuse or injury. The shoulder surgeon uses a small camera, called an arthroscope, which is inserted into the shoulder joint. Bone spurs may be filed down and loose or damaged cartilage may be removed.

The glenohumeral joint is located where the rounded head of the arm's humerus bone meets the shoulder blade, and is stabilized by the surrounding rotator cuff muscles.

Trauma and Orthopaedics Patient Recall: Report

Bone spurs, or osteophytes, are smooth, bony growths, usually near joints. They develop over time in patients with arthritis or joint damage.

7.2 Appendix B: RCS 1 recommendations: Report issued November 2020

Urgent recommendations to address patient safety risks

The recommendations below are considered to be highly important actions for the Trust to take to ensure patient safety is protected.

1. The trust should review the care provided to patient A5 and ensure that any clinical, legal and ethical obligations to the patient are met, including Duty of Candour.
2. The Trust should ensure that all patients undergoing shoulder surgery have equitable and timely access to allied health input, including physiotherapy, during the surgical pathway. The Trust should also ensure that there are equitable and comparable rotas for allied health staff supporting the trauma and orthopaedic service.
3. The Trust should ensure that the National Safety Standards for Invasive Procedures (NatSSIPs) are implemented without delay and that this is audited regularly to ensure that practices are supporting safer surgery for patients⁴.
4. The Trust should review the MDT and pathway arrangements for patients undergoing shoulder surgery to ensure that there is appropriate MDT-input into decision-making and a standardised pathway for every patient. This should include discussion at the regional level for complex and revision surgeries, including consideration of the best provider to be delivering treatment for the patient. It is recommended that a pathway for the treatment of these patients by the tertiary referral centre is developed as soon as practically possible.

Recommendations for service improvement

The following recommendations are considered important actions to be taken by the Trust to improve the service.

5. The Trust should ensure that consent practices for patients undergoing upper limb surgery are compliant with the Montgomery ruling⁵. The surgical consent form should be signed and completed before admission to hospital and a record of the discussion (including any contemporaneous documentation of the key points of the consultation, hard copies or web links of any further information provided to the patient), should be included in the patient's case notes. There needs to be written evidence to show that:
 - a. The discussion has been tailored to the individual patient;
 - b. All reasonable treatment options, along with their implications, have been explained with balanced risks and benefits of both;
 - c. Material risks for each option have been discussed with the patient. The test of materiality is twofold: whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, and the doctor is, or should reasonably be, aware that the particular patient would likely attach significance to it.

Trauma and Orthopaedics Patient Recall: Report

6. The service should improve the Mortality and Morbidity (M & M) review process with reference to the RCS guidance. This should include comprehensively minuting M & M meetings with documented learning points and action plans. These minutes should be circulated to all attendees. The Trust should ensure that all necessary cases are discussed and that there is a standardised and reliable system to identifying morbidity cases for discussion.

7. The Trust should ensure that the conduct and behaviour of all consultant trauma and orthopaedic surgeons is compliant with organisational and professional standards, and supports high quality and safe care for patients. Deviation from these standards should be acted upon in a timely and appropriate manner.

8. The Trust should undertake a comprehensive review of its clinical governance processes relating to upper limb surgery in order to ensure that it can monitor performance more robustly and detect any issues as early as possible. The clinical governance structure needs to be robust and adhered to so that issues are escalated through appropriate channels.

9. The Trust should review consultant upper limb surgeons' job plans to ensure they allow the consultants to provide high quality care and that they are meeting the service's needs. This should consider joint-operating practices and ensure that the case mix of operating lists is appropriate for the available post-operative care.

10. Clinical outcome data should be collected prospectively by the Trust, and made available to all trauma and orthopaedic consultants. Service and individual data should be audited and analysed at least every six months to ensure that any concerns are highlighted at an early stage. If any concerns are raised by the data, they should be investigated promptly and appropriate measures implemented to ensure patient safety is maintained.

11. Concerns regarding unexpected or negative trends with this data should be discussed with the relevant surgeon and highlighted within their appraisal to provide an adequate opportunity for reflection. The download of NJR surgeon level data is an expected part of annual appraisal.

12. Data should be analysed and presented at the trauma and orthopaedic surgery audit meeting, where all of the consultant surgeons are present. The data to be presented at this meeting should be anonymised. Any learnings from this data should then be used to drive and deliver service improvements.

13. The Trust should ensure that all appropriate data is being entered into the NJR. It is recommended that the Trust engage with the NJR Compliance Officer team to seek assistance in achieving compliance with NJR's Key Performance Indicators.

14. The Trust should undertake a comprehensive review of clinical governance processes in surgery in order to ensure that they can robustly and proportionately address any issues or concerns as early as possible. The clinical governance structure needs to be robust and adhered to so that issues are escalated through appropriate channels. This should also inspire confidence through transparency and accountability.

15. As part of the review outlined in recommendation 14, the Trust should also review the capacity and resources allocated to ensure there are appropriate staffing levels to support robust clinical governance processes.

16. As part of the review outlined in recommendations 14 and 15, the Trust should consider how it supports clinical audit and the support provided to clinicians to improve the quality of surgical care through audit.

RECOMMENDATIONS FOR PRACTICE AND SERVICE DEVELOPMENT:

- The Trust has a duty of candour to each of these patients to the detail suboptimal aspects of their care.
- A 12-month practice audit should be performed of all of Shah's cases to ascertain the number of early revisions and complications in the remainder of his practice.
- As a matter of urgency, I would recommend increased and regular use of axillary radiographs in shoulder imaging. These should be obligatory in the investigation of all shoulder trauma (to determine evidence of dislocation) and in all glenoid surgery including Latarjet procedures. This would have potentially allowed early identification of graft malposition, which could then have been addressed immediately, and the subsequent joint destruction avoided. Missed posterior dislocation remains a leading cause of negligence cases.
- I would recommend establishment of a regular Multidisciplinary and Arthroplasty Review Meetings. These should discuss complex cases, revision surgery and all arthroplasty. External oversight would have identified the repeated cases of glenoid malposition. Given the small nature of the shoulder service in Walsall this should ideally be done on a wider regional basis such that the local shoulder surgeons can be supported. If such a service cannot be established the hospital should assess the appropriateness of performing revision surgery and in particular revision arthroplasty without oversight.
- National recommendations are that periprosthetic joint infection should be managed in a tertiary setting or at least in a regional network.
- A robust Trust wide system should be in place to review novel and uncommon procedures before they are adopted into clinical practice. In these cases, the appropriateness of using biological glenoid resurfacing in a small volume practice could have been reviewed. In the wider field costly, novel procedures (for example superior capsular reconstruction) are being performed by low volume users when national guidance is clear that they should only be performed in high volume centres, as part of research studies, until evidence of superiority is clearly demonstrated.
- The nature of this report and the restrictions on Mr Shah's practice should be shared with all local private hospitals to ensure transparency outside of the organisation.

7.3 Appendix C: RCS 2 Recommendations: 19th April 2022

The recommendations below are considered to be highly important actions for the healthcare organisation to take to ensure patient safety is protected.

1. The Trust should consider the conclusions of this report, as well as the other information it holds, and on this basis, provide further follow-up of any patients for which it considers this to be required, in particular those patients identified in section 3.11 of this report. This should protect patient safety and ensure that patients or their families have received communication in line with the responsibilities set out in the Health and Social Care Act 2008 (Regulated activities) Regulations 2014, Regulation 20.

2. The Trust should review the comments made in this report, alongside the local information it holds, and determine if the patient records contain the information they would expect for the patient episode(s). The Trust should ensure that the current practice meet the agreed standards as set out in the RCS England good practice guide.

3. The Trust should review the consent-taking practices within the trauma and orthopaedic service to ensure appropriate discussion of risks, benefits and alternatives of treatment takes place and is legibly documented. Clinical records should clearly detail the giving of information and the decisions made by the patient. It should ensure that consent practices are compliant with the Montgomery ruling.

The RCS England good practice guide may be of assistance in this process.

4. In addition to recommendation 3, the Trust should review this sample of records and ensure that there was appropriate informed consent obtained for each procedure or operation.

5. The Trust should share this report with the operating consultant surgeon³⁵ for the 82 cases reviewed and discuss its contents with them, in the context of their wider practice. The operating surgeon(s) should be given the opportunity to reflect on the contents of the report and consider how they can learn from it and develop their practice.

6. The Trust should review the MDT and pathway arrangements for those undergoing upper limb surgeries to ensure that there is appropriate MDT input into the decision-making for every patient. All MDT decisions and communication should be adequately documented in each patient's record.

7. The review team found it concerning that the operations and the majority of aftercare assessments appeared to be provided by different clinicians resulting in lack of continuity throughout the patient's clinical pathway. The Trust should consider the improvement of trainee supervision in order to ensure that there is consistent consultant oversight at all stages and patient safety is not compromised.

8. When patients experience persistent pain following surgery, the review team observed that there was no clear plan to identify causes and suggestions on how these could be addressed. The review team were of the opinion that a change in the units' approach to patients in ongoing pain should be considered by the Trust. The review team considered that these patients should be reviewed to establish (1) absence of pain and (2) have repeat radiographs to assess union.

The Trust should consider the conclusions of this report, as well as the other information it holds, and on this basis, provide further follow-up of any patients for which it considers this to be required, in particular those patients identified in section 3.11 of this report. This should protect patient safety and ensure that patients or their families have received communication in line with the responsibilities set out in the Health and Social Care Act 2008 (Regulated activities) Regulations 2014, Regulation 20.

9. The Trust should undertake a review of Mr Mian Manuwar Shah's wider practice following the conclusions and recommendations made in this report and determine whether the current restrictions in his practice should continue.

RCS England may be able to support the Trust to seek assurance on these matters through an invited individual review, if the Trust considers this the most appropriate course of action.

7.4 Appendix D: ToR of Complex Case Assurance Group

Complex Case Assurance Group

Terms of Reference

Purpose

The overall objective of this complex patient recall is to limit or mitigate the harm to patients and provide a clear focus for their ongoing care. Patient safety is the priority concern for all recall processes. To enable the Walsall Healthcare NHS Trust (WHT) to fulfil its duty of candour in relation to any patient who may have been adversely affected or whose care falls below accepted recognised standards or relevant guidelines whilst receiving treatment at the Trust under the care of a Consultant Orthopaedic Surgeon. The review will also encompass patients receiving treatment under this consultant's care at other healthcare institutions including in the independent provider sector.

The **Complex Review Assurance Group** will work in partnership with statutory and regulatory partners (NHSE/I, CQC and BCWB ICS) to ensure that the requirements and recommendations made by this review process are completed. This is to ensure the needs of patients of all ages who receive care in **WHT, Spire Little Aston** and elsewhere (see above) are given equal parity to their physical health needs.

The **Complex Review Assurance Group** will focus on overcoming the barriers to offering high quality healthcare to Trust patients, paying particular attention to those who receive care within Walsall Manor Hospital (WMH). The focus will be on personalisation, prevention and inclusion aimed at improving patient outcomes.

The **Complex Review Assurance Group** will monitor how the Trust applies internal control and risk management principles and will bring to the attention of the Group any areas of risk or limited assurance.

Constitution

The **Complex Review Assurance Group** has been established at the request of the Walsall Healthcare Trust Board and external partners. The **Deputy Chief Executive at WHT** is the executive lead for **Complex Review Assurance Group**. The Chief Executive Officer has executive responsibility for the safeguarding of Trust patients; this includes ensuring that effective systems and processes are in place to uphold the rights.

Where required, the **Complex Review Assurance Group** will establish short-term sub-groups or working groups to carry out identified pieces of work.

The **Complex Review Assurance Group** is an **advisory** committee to the Trust Board and **has/no** executive powers, **other than those specifically delegated** in these Terms of Reference.

Background

Trauma and Orthopaedics Patient Recall: Report

The Consultant is currently employed at the Trust. The consultant will not be undertaking independent clinical duties until the Trust processes are complete. The Consultant has been absent from clinical duties since August 2021.

Several concerns have been identified relating to his clinical work which promoted the commissioning of this independent external review of case notes. This review follows several other key investigations which have included:

- RCS 1 – 20 Nov 2020 (invited Service Review Report on the Upper Limb Surgical Service)
- Wrightington Report – Undated but believed to be Dec 2020 (Practice Review on Treatment Provided by the Consultant)
- Cluster Review – 12 April 2022 (Serious Incident Investigation Report – Trauma and Orthopaedic Cluster Review)
- RCS 2 - 19 April 2022 (Clinical Record Review Report on 82 Clinical Records relating to Trauma and Orthopaedic Surgery)
- MHPS – May 2022 (Investigation into the conduct of the Consultant)

This review will comprise in the first instance:

- Case review of all patients who underwent surgery of the Consultant's practice since he joined the Trust in 2005 to present.
- Case review of all patients who underwent surgery of the Consultant's practice at any other Healthcare Provider since he was appointed as a consultant.

The outcome of the above will inform the decision whether to expand the review beyond the stated timelines. The decision on this matter will be made jointly by the Trust, NHSE/I and the CCG.

Complex Review Assurance Group members will:

- Be responsible for providing approvals and decisions affecting the team's progress and programme delivery.
- Set the direction for the programme, support the Programme Leads in decision-making and oversee the overall progress of the programme.
- Have technical input to decisions affecting the programme or project.
- Be an effective decision-making body and have accountability for the programme delivery.
- Approve the programme's identification and definition, signing off relevant documentation, and agreeing all major plans.
- Confirm and communicate the programme's vision.
- Approve the programme's blueprint (how the programme vision is to be achieved) and the means of achieving it.
- Authorise any major deviations from the agreed programme plans to ensure to communicate and inform all major stakeholders.
- Ensure the required resources are available for the success of the programme.
- Ensure quality assurance for the programme and its associated projects.
- Resolve deviations from plans or escalate to WHT Trust Board
- To produce and monitor **Complex Review Assurance Group action plan**.
- To develop and review internal and inter organisational policies and protocols with the aim of better supporting patients and staff.
- To ensure effective operational systems and processes between all partner organisations to effectively meet the requirements of the **Complex Review Assurance Group**.
- To discuss and share learning from the programme of work.
- To provide regular reports to the WHT Trust Board when required.

Trauma and Orthopaedics Patient Recall: Report

- Be guided by the national patient recall framework (https://www.england.nhs.uk/wp-content/uploads/2022/06/B1631_national-patient-recall-framework.pdf)

Reporting

Minutes of the **Complex Review Assurance Group** meetings will be formally recorded via teams and a summary of the work of the Group retained within the project plan. Reports will include positive assurances received as well as escalating any gaps in control that have been identified.

The Chair of **Complex Review Assurance Group** will draw to the attention of the Group any issues that require disclosure to the WHT Trust Board, or which require executive action.

Membership

The membership of the **Complex Review Assurance Group** will include the following:

Stakeholder	Designation	Stake/role in relation to the programme
Dr Jonathan Odum	Group Chief Medical Officer	Chair
Dr Manjeet Shehmar	Chief Medical Officer WHT	WHT Executive Sponsor
Dr Julian Parkes	Non-Executive Director	WHT NED for Quality advisor
Kevin Bostock	Group Director of Assurance	WHT Governance Representative
	Spire Healthcare	Spire Little Aston - Hospital Director and Director of Clinical Services
	Spire Healthcare	Spire Little Aston - PNE Project Lead
	CQC	CQC Representative
Rebecca Mann	PNE Clinical Project Lead	Clinical Lead/Advisor/ External Project Lead
Sally Roberts	ICB Chief Nurse	Black Country ICB Representative
Dr Ananta Dave	ICB Chief Medical Officer	Black Country ICB Representative
Dr Jessica Sokolov	NHSE Midlands – Regional Medical Director	NHSE - Clinical Representative
Bhavisha Pattani	NHSE Midlands – Director of Patient Safety and System Improvement	NHSE - Clinical Representative
Sally Evans	Group Director of Communications and Stakeholder Engagement	WHT Communication Representative
Robin Smith	NHSE Communication Manager	NHSE Representative
Emma Thomas	Programme Lead	WHT Project Manager

Chair – Dr Jonathan Odum

Co-Chair – Manjeet Shehmar

Clinical Leads / Representative – Rebecca Mann

NHS England/Improvement - Bhavisha Pattani / Dr Jessica Sokolov

Trust Executive lead– Ned Hobbs

Review of Membership – include statement if required

Membership of the group will be reviewed annually or as required for the duration of the project.

Meetings

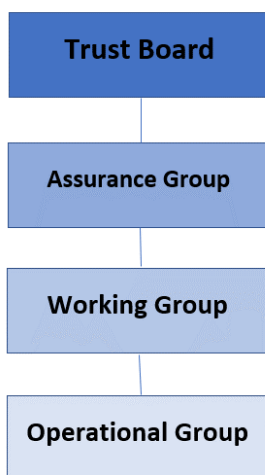
Frequency of meetings – monthly, to be reviewed on a meeting-by-meeting basis.

Admin support for meetings **will provide the Complex Review Assurance Group** with an agenda, minutes of last meeting and an action plan as standard prior to each meeting along with any ad-hoc paperwork required.

Reporting / Governance

The **Complex Review Assurance Group** will provide progress reports and the final report to:

- WHT Trust Board



Risk Management

The Group will identify critical risks promptly and will provide assurance to WHT Trust Board on actions being taken to reduce significant clinical risks via WHT usual governance process. Risks will be included in the Risk Register and Corporate Risk Register where deemed appropriate.

Key Responsibilities of the Complex Review Assurance Group

- To provide oversight of the programme of work and associated projects conducted within it.
- To advise on appropriate resources that are required to support the programme, projects and who shall be responsible for providing them.
- To monitor progress and drive forward the programme of work.
- To advise an appropriate communication strategy between organisations.
- To advise an appropriate communication plan for publication of the report, including media handling strategy, and communication with the patients who form part of the programme.

Trauma and Orthopaedics Patient Recall: Report

- To consider any request for changes to the terms of reference from the clinical lead of the programme and associated projects.
- To liaise with other inter organisational partners if required (e.g. Health Education England, GMC, NHS Resolution, CQC).
- To receive any urgent patient safety concerns arising from the programme which might require immediate action and facilitate a remedial action plan, if necessary.
- To receive the draft report of the clinical programme and associated projects for factual accuracy check and make any amendments to the final report.

Decision Making

The **Complex Review Assurance Group** are expected to work collaboratively to provide the trust with sufficient information and evidence to make informed judgements/decisions regarding the care and treatment provided by or under the care of the Consultant in Trauma and Orthopaedics.

Quoracy

The **Complex Review Assurance Group** are not an authoritative body therefore the recommendation is that at least 50% of the stakeholders should be present at each meeting to be effective.

Standing Agenda

A standing agenda will be utilised at each meeting and will be amended to reflect current requirements. Standing items will include:

Agenda Item	Lead	Time Allocation
Welcome, Introductions and Apologies	Chair	2 minutes
Action log review for this meeting	Chair	10 minutes
Items for discussion	All	45 minutes
Group risks, quality concerns and issues	Governance Lead	10 minutes
Date & time of next meeting	Chair	

Conflicts of Interest

Any conflicts of interest will be dealt with in line with appropriate organisational policy. All members will declare interests with their own employing organisation in line with its own policy for management of conflict of interests. Additionally, all members will declare these fully at the commencement of every meeting as is best practice.

Equality Statement

The **Complex Review Assurance Group** will ensure that these terms of reference are applied in a fair and reasonable manner that does not discriminate on such grounds as race, gender,

Trauma and Orthopaedics Patient Recall: Report

disability, sexual orientation, age, religion, gender reassignment, marriage/civil partnership, pregnancy/maternity, or belief.

Information Governance

The **Complex Review Assurance Group** members are bound by confidentiality and the requirements of the UK General Data Protection Regulations (GDPR) and Data Protection Act (DPA) 2018. Patient level data is not deemed 'essential' in the discharge of the Groups duties without the explicit authority of the Chair.

All documentation exchanged between members shall be via secure email with password protection.

Any meeting recordings shall comply with the requirements of the Organisation and must not be re-presented, copied, or divulged in any way without the explicit permission of the Chair.

All members shall comply with their obligations under the DPA18. Each member warrants that in providing other members with information, under the Terms of Reference, it is not, and will not be in breach of the Data Protection provisions and all subordinate legislation relating to the principles of practice.

Approval & Review

The approval of these Terms of Reference was ensured by the following:

Body of Approval	Date of Approval	Date of Review
Complex Review Assurance Group		

The Terms of Reference will be reviewed annually or sooner if required.

7.5 Appendix E: Blank proforma for data collection

Name of Consultant Specialist	Date of notes review
Assessor please complete name and date of review	

- All notes' entries by support team be in red
- Comments by assessors to be in black

Patient details	Prepopulate by governance support team
Patient Details	Patient Name NHS Number Manor Number Date of Birth
Date of notes review:	
Operation: op1	
Index procedure	
Op 2 (if applicable)	
Op 3 (if applicable)	
Brief summary of clinical course: populate by notes prep team	
Any other comments from notes prep team? Other comments e.g. missing documents, other practical info	
Update from patient consent form	

Table 1. History taking, examination and diagnosis	
Criterion	Adequate detail in history and examination enabling initial effective clinical assessment?
Notes / comments	
Overall assessment of History taking, examination and diagnosis: please delete /add comment as appropriate	

Good? /Adequate? /Concerns? /Insufficient information?

Summary:

Table 2: Investigations and imaging undertaken, including pre-operative investigations and preparation of patient for surgery

Criterion	Investigation sufficient and appropriately interpreted to justify decision to operate. Include clinical decision making, appropriateness for surgery, whether offered alternative treatments if appropriate etc.
-----------	--

Notes / comments

Overall assessment of Investigations and imaging undertaken, including pre-operative investigations: please delete /add comment as appropriate

Good? /Adequate? / Concerns? /Insufficient information?

Summary:

Table 3: Consent

Criterion	Sufficient evidence of detailed provision of information about procedure, verbally and ideally in writing prior to surgery. Adequate information about risks and benefits of proposed surgery. Adequacy of content / detail of formal consent form Consider whether information provided was sufficient to allow patient to give adequately informed consent, remember to judge according to standard practise at the time as this area has evolved considerably during period of review.
-----------	---

Notes / comments

Overall assessment of Consent process: please delete /add comment as appropriate

Good? /Adequate? / Concerns? /Insufficient information?

Summary:

Table 4: Treatment including technical competence of surgery, adequacy of intra-operative management (including imaging) and “on table” or immediate complications	
Criterion	Standard technical approach, with appropriate intra-operative assessment /management.
Notes / comments	
Overall assessment of Treatment including clinical decision-making, case-selection, preparation of patient for surgery, operation or procedures and complications	
Good? / Adequate? /Concerns? / Insufficient information?	
Summary:	

Table 5: Communication with the patient, their family and/or carers, their GP	
Criterion	Communication which enables the sender and recipient to reach a clear understanding of the information being exchanged
Notes / comments	
Overall assessment of Communication with the patient, their family and/or carers, their GP	
Good? /Adequate? /Concerns? /Insufficient information?	
Summary:	

Table 6: Team working including communication with other members of the care team, MDT discussions if appropriate /available and working with colleagues	
Criterion	Multiprofessional team members communicate with each other, as well as merging their observations, expertise and decision-making responsibilities to optimize patients' care
Notes / comments	

Overall assessment of Team working
Good? /Adequate? / Concerns? /Insufficient information? / N/A?
Summary:

Table 7: If you have identified concerns about Compliance with any National Standards please document here

Criterion	Compliance with clear national standards that were active /established at time of procedures
Notes / comments	

Table 8 If you have identified concerns about Adherence to safety process measures, including WHO checklists please document here

Criterion	Compliance with mandatory process measures if established best practise at time of procedure
Notes / comments	

Table 9: Post-operative reviews, surgical discharge and outcome

Criterion	<p>Concerns about post-operative care both during inpatient and out-patient services. Consider adequacy of post operative clinical assessment, imaging, duration of follow up and operative outcome</p> <p>At the time of discharge from follow up, or from patient feedback does it seem the patient had an outcome that was within the predicted range of outcome for the presenting complaint and surgery?</p> <p><i>Overall: was outcome and current level of symptomatology within the range that might be expected for patient with underlying pathology and operative intervention as outlined?</i></p>
Notes / comments	

Table 9: Wider professional behaviour	
Criterion	Any comments about wider professional behaviour from patient feedback or from medical records – e.g. concerns about probity or inappropriate behaviour
Notes / Comments:	
Overall assessment of post-operative reviews and surgical discharge and outcome	
Good? /Adequate? /Concerns? /Insufficient information?	
<p>Summary: please comment on whether outcome seemed reasonable / within predicted range for presenting complaint and surgery offered.</p>	
<p>Is further follow up required on clinical grounds? If yes please define whether imaging +/- OPD review,</p>	

Table 10: Overall assessment of quality of care	
Criterion	Overall, did the patients care fit within a recognised range of accepted care for the time? If not was care of sufficient concern to have possibly caused harm?
Notes /comments	
Overall assessment of quality of care	
Good? /Adequate? /Concerns? /Insufficient information?	

Table 11: If the standard of care was suboptimal, did this reach the threshold to be considered likely to have caused harm?	
Criterion	Overall, did the patients care fit within a recognised range of accepted care for the time? If not was care of sufficient concern to have possibly caused harm? See levels:
	A: No harm

	<p>B: Low (minimal harm -patient required extra observation or minor treatment)</p> <p>C: Moderate (short term harm – patient required further treatment or procedure)</p> <p>D: Severe (permanent or long term harm)</p> <p>E: death</p> <p><i>The degree of harm is the ACTUAL impact on a patient from a particular, individual incident. So, for example, inadequate documentation or early discharge without adequate post assessment / imaging constitutes suboptimal practise – and may result in the need for additional follow up, but does not constitute or contribute to an assessment of “harm”</i></p>
--	--

Next steps: Choose one option and delete non applicable.....

1. No harm or low level concern (A or B) **and no follow up is required** – letter to patient closing investigation
2. No harm or low level concern (A or B) about care **but the patient needs F/U**: orthopaedic F/U / other F/U (e.g. physio/ortho / imaging only) -please advise
3. On the information available it is not possible to reach a definitive opinion **and no follow up required**– inconclusive. Letter stating insufficient evidence but no other action
4. On the information available it is not possible to reach a definitive opinion – inconclusive. Letter stating insufficient evidence **but patient requires clinical follow up**: orthopaedic F/U / other F/U (e.g. physio/ortho / imaging only) -please advise specifically
5. The care offered fell sufficiently short of expected care so as to constitute moderate or severe harm * (level C or D) **but no further clinical follow up is required** (e.g. already under F/U, no further intervention required)– patient to get SDOC letter explaining this but no further clinical input /action
6. The care offered fall sufficiently short of expected care so as to constitute moderate or severe harm * (level C or D) **and the patient needs F/U**: orthopaedic F/U / other F/U (e.g. physio/ortho / imaging only) -please advise. Patient to get SDOC letter explaining decision re: harm and requires clinic F/U etc.

12. OTHER COMMENTS from notes review

Criterion	Anything you would like to add / not already covered
Comments:	

7.6 Appendix F: Recall administrative processes

<u>Complaints team</u>	Process the patient complaints and upload the information to the master excel in the shared drive. Update the project team of any urgent issues that need to be addressed. Upload/scan the patients returned consents to the folder called "patient consent returns" in the shared drive. At the weekly ops meeting update the team of any new returns and any concerns that need to be addressed.
<u>Project Admin Team</u>	Monitor the returned consent form folder and create patient folders in the "living-patient document folders for patients of concern" of any new patient consent returns ensuring to save the consent form to it. Update the master excel with the details requested in the orange tab sections. Request the notes via ████████ (records Mgr) where required, and update the prep team of the intended notes arrival. Once the notes arrive, store them in the lockable cabinets in the THQ Board room, ready for the prep team.
<u>Prep Team</u>	<p>Prep team to review the notes to obtain or extract from the patients EPR or records, the following documents: -</p> <ul style="list-style-type: none"> • Clinical letters • Consent forms • EDS • Operational notes • Pre op care <p>Admin support to scan the above documents to the patient's folder in the shared drive and update the master excel (blue section) where applicable. Admin support to liaise with Liz Miller to collect the notes that are completed as and when.</p>
<u>External Review</u>	Admin support informs the Project Manager of the names of those patients who are now ready for review. Those names are sent via teams to the external consultants. The external consultants review the patient(s) folder in teams and complete the enclosed proforma template. The external reviewer notifies the project manager of the names of the patients they have completed and the number of hours they are claiming so their payment can be processed.
<u>Prep Team and project admin team</u>	The admin support will update the master excel yellow section to confirm the date that the review had taken place and by whom. They will also rename the patient folder with "review completed - at the front of the px's name". They will then notify the prep team, who will extract the clinical information from the proforma and update the remaining clinical sections in yellow on the master excel. Once complete, notify the clinical project lead who will prepare the patient letters and forward them to the admin person for editing, then checked and signed by the Trust's Chief Medical officer. Once she has approved and signed letter, her admin PA to post the letter and confirm the date of this to the project admin support, so they can update the master excel. The admin support will then save the letter to the patient's folder in the shared drive. The admin support will take note of the number of patients requiring an appointment to present at the weekly ops meeting and or email the ops mgr when
<u>Operational apt scheduling team and project admin</u>	Once the number of patients for appointment have been confirmed, the ops mgr to start to arrange/allocate WLI's as soon as possible. Ops Mgr to notify the Project admin support once clinics have been arranged. The admin support will then confirm the patient names and IDs of those patients whose letter has been posted to them and are now ready to receive their appointment letter. The ops mgr to then arrange the appointments and confirm the date of them to the admin support who will update the excel with the appointment dates. The admin support will then copy the patients shared folder files to the patients EPR record prior to the patient's appointment.

7.7 Appendix G: Example codes used for primary upper limb PNE patient identification

The list is illustrative, not exhaustive, and is included to demonstrate the complexities in accurate and complete case identification.

Surgical Code	Procedure
O061	PRIM. HYBRID PROS. REP./SHOULDER JOINT/CEMENTED HUMERAL COMP
O071	PRIM. HYBRID PROS. REP./SHOULDER JOINT/CEMENTED GLENOID COMP
O211	PRIMARY TOTAL PROSTHETIC REPL ELBOW JOINT USING CEMENT
O221	PRIMARY TOTAL PROSTHETIC REPL ELBOW JOINT NOT USING CEMENT
O278	OTHER STABILISING OPERATIONS ON JOINT OTHER SPECIFIED
O279	OTHER STABILISING OPERATIONS ON JOINT UNSPECIFIED
W281	APPLICATION OF INTERNAL FIXATION TO BONE NEC
W338	OTHER OPEN OPERATIONS ON BONE OTHER SPECIFIED
W491	PRIMARY PROSTHETIC REPLACEMENT OF HEAD OF HUMERUS USING CEME
W493	REVISION OF PROSTHETIC REPLACEMENT OF HEAD OF HUMERUS USING
W501	PRIMARY PROSTHETIC REPLACEMENT OF HEAD OF HUMERUS NOT USING
W502	CONVERSION TO PROSTHETIC REPLACEMENT OF HEAD OF HUMERUS NOT
W503	REVISION OF PROSTHETIC REPLACEMENT OF HEAD OF HUMERUS NOT
W504	RESURFACING HEMIARTHROPLASTY/HEAD//HUMERUS NOT USING CEMENT
W511	PRIMARY PROSTHETIC REPLACEMENT OF HEAD OF HUMERUS NEC
W515	RESURFACING HEMIARTHROPLASTY OF HEAD OF HUMERUS NEC
W518	OTHER PROSTHETIC REPLACEMENT OF HEAD OF HUMERUS OTHER SPECIFIED
W521	PRIMARY PROSTHETIC REPLACEMENT OF ARTICULATION OF BONE USING
W562	PRIMARY INTERPOSITION ARTHROPLASTY OF JOINT NEC
W563	REVISION OF INTERPOSITION ARTHROPLASTY OF JOINT NEC
W581	PRIMARY RESURFACING ARTHROPLASTY OF JOINT
W582	REVISION OF RESURFACING ARTHROPLASTY OF JOINT
W589	OTHER RECONSTRUCTION OF JOINT UNSPECIFIED
W711	OPEN DRILLING OF ARTICULAR CARTILAGE
W731	PRIMARY EXTRA-ARTICULAR PROSTHETIC AUGMENTATION OF INTRA-ART
W773	BLOCKING OPERATIONS ON JOINT USING PROSTHESIS FOR STABILISAT
W774	BLOCKING OPERATIONS ON JOINT USING BONE FOR STABILISATION
W778	STABILISING OPERATIONS ON JOINT OTHER SPECIFIED
W779	STABILISING OPERATIONS ON JOINT UNSPECIFIED
W913	MANPULATION OF PROSTHETIC JOINT NEC
W918	OTHER MANIPULATION OF JOINT OTHER SPECIFIED
W961	PRIMARY TOT. PROSTHETIC REPLACEMENT OF SHOULDER JOINT/CEMENT
W962	CONV.TO TOT. PROSTHETIC REPLACEMENT OF SHOULDER JOINT/CEMENT
W963	REV.OF TOT. PROSTHETIC REPLACEMENT OF SHOULDER JOINT/CEMENT
W964	REV./ONE COMP./TOT. PROSTHETIC REP. SHOULDER JOINT/CEMENT
W965	PRIM REVERSE POLAR TOTAL PROST REPL SHOUL JOINT USING CEMENT
W971	PRIMARY TOT. PROSTHETIC REP. OF SHOULDER JOINT NOT CEMENT
W972	CONV.TO TOT. PROSTHETIC REP. OF SHOULDER JOINT NOT CEMENT
W973	REV.OF TOT. PROSTHETIC REP. OF SHOULDER JOINT NOT CEMENT
W974	REV./ONE COMP./TOT. PROSTHETIC REP. SHOULDER JOINT NOT CEMEN
W975	PRIM REV POLAR TOTAL PROST REPL SHOUL JOINT NOT USING CEMENT
W976	REVIS REV POLAR TOTAL PROST REPL SHOUL JOINT NOT USING CEM
W981	PRIMARY TOTAL PROSTHETIC REPLACEMENT OF SHOULDER JOINT NEC
W982	CONVERSION TO TOTAL PROSTHETIC REPLACEMENT OF SHOULDER JOINT
W983	REVISION OF TOT. PROSTHETIC REPLACE. SHOULDER JOINT NEC
W984	ATTENTION TO TOT. PROSTHETIC REPLACE. OF SHOULDER JOINT NEC

Trauma and Orthopaedics Patient Recall: Report

W986	PRIMARY REVERSE POLARITY TOTAL PROST REPL SHOULDER JOINT NEC
W987	REVISION REVERSE POLAR TOTAL PROST REPL SHOULDER JOINT NEC
Y767	OPEN DEBRIDEMENT OF JOINT NEC
Z697	OTHER DIVISION OF BONE UNSPECIFIED
Z728	REVISION OF ARTHRODESIS AND INTERNAL FIXATION NEC
Z812	OTHER RECONSTRUCTION OF JOINT OTHER SPECIFIED
Z812	REVISION OF EXCISION ARTHROPLASTY OF JOINT
Z828	OTHER PRIMARY FUSION OF OTHER JOINT OTHER SPECIFIED
Z832	PRIMARY ARTHRODESIS AND INTERNAL FIXATION OF JOINT NEC
Z943	REVISION OF TOTAL PROSTHETIC REPLACEMENT OF ELBOW JOINT NEC
Z943	REVISION ONE COMPONENT TOTAL PROST REPL ELBOW JOINT NEC