Scottish Arthroplasty Project Outlier Process

Cumulative sum of outcomes (CUSUM) Outlier Governance Process

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Version 1.0

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Version history

Version	Date	Summary of changes
V0.1	5 Oct 2023	First draft written by Mr Alan Howieson
V0.2	29 Nov 2023	Updated version circulated for commented
V0.3	30 Nov 2023	Updated version following comments.
V0.4	6 Dec 2023	Updated version following comments.
V1.0	14 March 2024	Final version reviewed and endorsed by the Scottish Committee for Orthopaedics and Trauma (SCOT) and the Scottish Arthroplasty Project (SAP) steering group.

Contents

Background

The Scottish Arthroplasty Project (SAP) provides quality assurance for the Scottish population and allows surgeons to monitor their surgical outcomes in terms of key performance indicators. As part of the clinical governance process, it is recognised that some surgeons may have results that fall out with the main body of practice, and in these situations, it is important to analyse, in a collegiate manner, the reason for this. It is recognised that surgeons will have different patient populations and different scopes of practice. The purpose of the outlier process is to provide robust clinical governance and to advise and support surgeons.

The purpose of this document is to provide guidance for surgeons whose practice has been identified as having outlying data. It is important that Scottish orthopaedic surgeons can support their practice with solid data analysis and reassure patients they are providing high quality care. Many of the outlier responses received by SAP share a common theme, and by producing this guidance, SAP aims to help surgeons review any issues and to reflect on their practice.

Some themes arise in the majority of replies and are discussed here. The first is the accuracy of the SAP data and it should be noted SAP relies on the data submitted by each hospital. Surgeons can access their own data via the Public Health Scotland (PHS) website and we would encourage surgeons to regularly review their data to ensure they are accurate. Secondly, it is often stated that the results do not include a complete data set (usually missing private sector data) but to re-analyse the data with private sector data included would necessitate re-analysing the entire Scottish surgical cohort – it needs to be recognised that the comparator surgeons have all had their data analysed based on the same set of patients. One of the aims of SAP is to ultimately include private sector data, and discussions with the private sector are ongoing.

The aim of the outlier review is to provide clinical governance for patients and to guide surgeons' practice. We would hope that only in rare circumstances would it

require a didactic approach to a surgeon's practice and that surgeons actively engage in the process to ensure the best outcome for patients in Scotland.

General recommendations

- The Scottish Committee for Orthopaedics and Trauma (SCOT) recommends that individual SAP data are included in the annual consultant appraisal.
- SAP aims to introduce an alert process for any surgeons at risk of becoming outliers. This would be set at rates between the 95% and 99.8% control limits. At this time, we would ask surgeons to review their local outcomes and ensure that their data are accurate.

First time outlier process

Key recommendations

- Carry out data validation to ensure that all cases are correctly included and no other similar cases are omitted.
- To discuss the cases as a cohort of cases at their local department's documented morbidity and mortality meeting.
- Completion of a proforma containing a minimum dataset regarding the actual outlier cases (see appendix 1).
- Completion of an action plan (see appendix 2).
- Review and action plan to be discussed and signed off by the orthopaedic clinical lead, another arthroplasty consultant within the department, and the clinical manager responsible for service delivery in the specific area.

Recurrent outliers

Please note the cumulative summation (CUSUM) analysis resets to zero once a consultant has initially been flagged as an outlier, so identification of a second outlier episode represents a true deviation from average data.

General recommendations

- Consultant receives a 'recurrent outlier' specific letter.
- Consultant reviews cases as per first time outlier process.
- SAP will offer to carry out a six-month interim analysis to provide data on ongoing practice.

Complication specific recommendations

Recommendations for high levels of joint infection (hips and knees)

- Compare individual surgeon data with the unit data.
- Inform local hospital infection control team and request a review.
- Review of overall patient cohort:
- Is it a general cohort with some high risk patients?
- Is it a true high risk/ tertiary practice with the majority of patients exceptional?

Recommendations for high levels of hip dislocations

- Detailed review of implants used, component positioning and approach.
- Review of patient factors.

- Consider technical factors such as head sizes (particularly if the consultant uses smaller head sizes), lipped liners, templating.

Recommendations for high revision rates (knee and hip)

- There is usually no single factor that explains high or low revision rates.
- Contributing factors to be considered include:
- Patient selection.
- Implant selection.
- Surgical technique.
- Revising surgeon's revision threshold.
- Ensure potential revision cases are discussed at an arthroplasty multi-disciplinary team (MDT) meeting.
- Confirm implants used have adequate orthopaedic data evaluation panel (ODEP) ratings and there are no developing implant concerns.

Recommendations for high rates of venous thromboembolism (VTE) within 90 days of surgery

- Review of unit policy on VTE thromboprophylaxis and ensure it meets current guidelines. Consider intra-operative measures, chemical thromboprophylaxis, and early mobilisation.
- Ensure completion of VTE thromboprophylaxis for the required duration/ early discontinuation of thromboprophylaxis.

Third time outliers

Key recommendations

- Consultant carries out a detailed review of their involved cases, their case mix and their volume of cases, with reference to the specific complication of concern and risk factors for that.
- Inform the clinical lead for orthopaedics and the clinical manager responsible for service delivery in the specific area of the outlier status.
- Consultant and the orthopaedic clinical team should review the problem and formulate an action plan.
- Involved consultant and orthopaedic clinical lead to then inform the medical director (post review of cases) with results of the review and the action plan. The aim of this is for clinical governance, as at this stage the senior medical management should be made aware of the situation. However, it would be hoped that by following the preceding process, overall control of the situation remains with the consultant and the orthopaedic team and, with engagement, good clinical outcomes are achieved.

Potential action plans to consider including:

- Changing to a different implant.
- For low volume procedures, consider referring patients to colleagues with a higher volume practice, or alternatively, actively seeking to increase surgical volumes.
- Dual consultant operating for complex cases.
- Additional training and support from colleagues.

- Very high-risk patients (extreme body mass index (BMI), neurological disorders, significantly immunocompromised, etc.) – consider modifying practice/ referring to more specialised or experienced colleagues.

Conclusion

The aforementioned process aims to provide consultants with a structured template to work with to enable them to analyse their complications and to ensure high quality surgery within NHS Scotland.

It is recognised that arthroplasty surgery and surgical outcome is already highly scrutinised, and this process is designed to provide robust quality assurance and governance for patients and surgeons.

It is also recognised that this may be a stressful or worrying experience for a surgeon to discover that their outcomes are out with the expected normal range. The alert process will aim to give surgeons advance warning that a problem may be developing and the SAP committee and PHS are committed to helping any surgeon identified as an outlier with data analysis, or simply to discuss the process, provide support and answer any questions in a timely manner.

Appendix 1: SAP outlier response proforma

1. Data validation

2. Range of practice comment

(Please consider volume of particular operation, other considerations such as very high risk patients etc.)

Individual case reviews

Case 1

Patient characteristics

Characteristic	Yes/No	Details (if necessary)
BMI		
American Society of Anaesthesiologists (ASA) grade		
Co-morbidities		
Immunosuppressant use		
Anticoagulant use		
Previous surgery at the same site		
Other factors		

Pre-operative workup

Test	Yes/No/Not done	Results
Normal pre-operative bloods?		
Normal pre-operative midstream specimen of urine (MSU)?		
Co-morbidities		
Immunosuppressant use		
Anticoagulant use		
Previous surgery at the same site		
Other factors		

Peri-operative

Information required	Details
Lead surgeon	
Assistant	
Surgical approach	
Implants used	
Operating time (start)	
Operating time (finish)	
Operating time (total)	
Any intra-operative issues?	

Post-operative

Information required	Details
Post-operative review of radiographs	
Chronology of post-operative problem and actions taken: (Please expand box as necessary)	

Has the case series been discussed at the departmental M&M meeting?

Yes/ No

If yes, details of discussion:

Appendix 2: SAP outlier action plan

No.	Action	Responsible	Completed
1			
2			
3			
4			