Policy Document

National Ophthalmology Database Audit: Outliers Policy

March 2020

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Document Location

The master copy of the document can be found in the RCOphth shared drive

Version History

Version #	Implemented By	Revision Date	Approved By	Approval Date	Reason
1.1	BB	06/01/2020	N/A	N/A	First draft
1.2	BB	22/01/2020			Amendments following feedback from JS, and Northern Ireland
1.3	BB	06/03/2020	N/A	N/A	Amendments following feedback from HQIP and Wales
1.4	BB	10/03/2020	Professional Standards Committee	07/02/2020	Approval granted by Professional Standards Committee subject to NOD team finalising any outstanding queries from Wales

Contents

1 Introduction

1.1 Purpose of Paper

This document is designed to describe the process followed by the National Cataract Audit in identifying and dealing with outliers. This process will be followed for the analysis of data from the fourth prospective audit year that covered September 2018 to August 2019.

1.2 Background

National Cataract Audit results are reported to The Care Quality Commission, on the audit website (www.nodaudit.org.uk) and in annual reports. At the end of a reporting cycle, aggregated centre level data is uploaded to data.gov and is accessed by the Getting It Right First Time Programme. Centre level results include operations performed by trainee surgeons, and publicly available named surgeons. Surgeon level results do not include operations performed by trainees.

The RCOphth national cataract audit is part of the Clinical Outcomes Publication (COP), an NHS England initiative, managed by HQIP, to publish quality measures at the level of individual consultant, team and unit level. The directory supports ongoing data transparency and wider engagement with national clinical audit data whilst rationalising the data provided directly on the NHS website: https://www.nhs.uk/mynhs/specialties.html

1.3 Outliers

Every analysis of national clinical audit data is likely to detect some rates of clinical outcome that are significantly higher, or lower, than expected. High rates may indicate performance issues that may need to be addressed. Low rates may indicate excellent practice that would be beneficial to describe in detail and disseminate to other healthcare providers.

NHS England/Improvement and the Health Quality Improvement Partnership (HQIP) have placed increased emphasis on the processes used by national clinical audits to identify and manage outcomes data that falls outside of the expected statistical range. HQIP recommends that definition of outliers is based on a two-sided statistical approach with threshold p values of 0.05 for 'alert' and 0.002 for 'alarm'. There is a need for increased consistency of approach across all national clinical audits that collect data on the quality of clinical care, irrespective of their level of maturity or technical infrastructure. Consistently applied national guidance ensures the quality of patient outcomes, as well as for:

- Maintenance of public trust
- Data accuracy
- Clinical understanding of variation (e.g. case mix)
- Reflective practice and professional development
- Ensuring the quality of the appraisal and revalidation processes

1.4 Developing this guidance

The RCOphth NOD follows the principles of outlier management developed with HQIP, information is available on the HQIP website https://www.hqip.org.uk/outlier-management-for-national-clinical-audits/#.XhMWqdI3Zjo. This guidance is based on the HQIP/Department of Health 'Detection and management of outliers: Guidance prepared by National Clinical Audit Advisory Group (31 January 2011, Gateway Reference 14911) and the HQIP 'Technical

Manual for the Clinical Outcomes Publication (COP), HQIP's 'Detection and management of outliers for National Clinical Audits (May 2018) and Detection and management of outliers for National Clinical Audits in Wales (November 2018). This document should be read in conjunction with these documents.

1.5 Escalation Route

Clinical audit and quality improvement within provider organisations is a shared responsibility of many colleagues, including data clerks, IT departments, individual clinicians and the medical director.

It is the responsibility of the organisation Board, through the medical director, to assure that this activity is taking place and leading to quality improvement and reassurance.

Provider organisation senior management may not be involved in the process of collecting data and working with resulting analysis unless issues arise. Problems may involve data collection and validation issues or investigations into the results of clinical audit. Organisational buy-in may be essential to resolve these problems when they arise, but some issues can be effectively dealt with at departmental level – on occasion it may be organisation level resource and infrastructure that leads to outlying data, not the performance of individual clinicians.

Issuing guidance that is specific to every scenario is challenging; but any analysis that suggests mortality, complication rates or morbidity are higher than expected should trigger appropriate discussion and action within the organisation concerned. The organisation Board should be reassured that their services are safe and effective, as outlined in this policy.

2 The role of the regulators and The Royal College of Ophthalmologists

In England, the Care Quality Commission (CQC) has a responsibility for organisational regulation of the quality of care and in Wales, the Welsh Government monitors the actions of organisations responding to outliers and takes further action when required. In Northern Ireland performance issues are raised with the Department of Health as Early Alerts. The General Medical Council (GMC) has a responsibility for regulating individual clinicians in the UK.

It is important that the processes ensure patients safety and quality of care but does not inappropriately affect organisations, individuals or the national clinical audit programme. The RCOphth NOD is responsible for managing the outlier process of data alert and alarms at both organisational and individual level as part of the COP process.

2.1 Alert

For individual data alerts, it is expected that there should be an anonymous (by individual) notification to the GMC that there is an individual data alert in a named organisation.

In Northern Ireland performance issues are raised with the Department of Health as Early Alerts. The process will then be managed by liaising with the appropriate Medical Director and clinical service lead. It is anticipated that this will lead to a dialogue between the GMC and

that organisation's responsible officer to provide reassurance that this is not related to concerns with respect to individual performance.

2.2 Alarm

For alarm level outliers in England, the CQC expects to see evidences of appropriate initial and substantive action plans. The CQC will consider the data as part of its monitoring process. The CQC will not usually take regulatory action if organisations are responding appropriately to each stage of the outlier management process at alert and alarm level.

For alarm level outliers in Wales, the Welsh Government monitors the actions of organisations and takes further action as and when required. Health Inspectorate Wales (HIW) does not act as regulator and cannot take regulatory action in relation to NHS providers. However, HIW can request information on the actions undertaken by organisations to ensure safe services are being delivered. The Welsh Government can share information with HIW where appropriate and advise on the robustness of plans in place to improve audit results and outcomes.

2.3 The Royal College of Ophthalmologists as a national clinical audit provider

2.3.1 Individual

Where there is an individual outlier at the "alarm" level the RCOphth will communicate with the clinician and the department clinical lead. This is followed by a letter to the Medical Director and Chief Executive copied to the department clinical lead and the clinician. The letter sets out the concerns and informs the Medical Director (MD) and Chief Executive of their responsibilities including their responsibility to inform the regulator. Responsible Officer (ROs)/MDs should routinely be discussing "alarm" level concerns with their GMC Employment Liaison Adviser (ELA) and what local steps are being taken to address them.

For an individual outlier at the "alarm" level, the RO of that individual should have a discussion with the GMC ELA so that the ELA is aware of the situation.

2.3.2 Institution

For an institutional outlier at the "alarm" level there will be communication from the College's national clinical audit lead to the Clinical Lead, Organisation Medical Director and Chief Executive to inform them of their responsibility to inform the relevant organisations and individuals.

If there is no reassurance from the organisation to the RCOphth that such communication has taken place or if there is a refusal to communicate, the RCOphth audit clinical lead will communicate directly with the relevant regulator.

2.4 Definitions

A founding principle is that any identification of 'outlier' status indicates a statistically significant value and does not necessarily mean outlying performance by a consultant or an organisation. Judgements on performance can only be made after a full examination of all the issues involved in the delivery of care, and this may be multi-factorial and complex. It will always be possible to trigger as an outlier due to chance alone, and any abnormal findings may not represent poor care.

The definition of an outlier is based on setting a target for an indicator and defining what level of variation from that target is acceptable, based on theories of statistical probability and/or clinical judgement.

For the RCOphth NOD national cataract audit, the targets are drawn from published literature of direct relevance to NHS practice (The Royal College of Ophthalmologists' National Ophthalmology Database study of cataract surgery: report 1, visual outcomes and complications, Day AC et al., Eye 2015; 29, 552–560). Currently the overall intra-operative complication rate for posterior capsular rupture or vitreous prolapse or both (abbreviated as PCR) against which surgeons and institutions are compared to in case complexity adjusted analyses is 1.1%. Similarly, the overall comparison rate for visual acuity (VA) loss (a doubling of worse of the visual angle from pre-operatively to post-operatively) is 0.9%. These rates need to reflect the practice of consultant surgeons and will be kept under review and will be considered for revision if the rates observed in the audit deviate from these by more than +/- 3%.

Data alerts and alarms

Data alerts and alarms are defined in the existing DoH/HQIP document 'Detection and management of outliers: Guidance prepared by National Clinical Audit Advisory Group (31 January 2011, Gateway Reference 14911): "Data more than 2 standard deviations from the target is deemed an 'alert'; more than 3 standard deviations is deemed an 'alarm'." A target may be a national average or clinical standard. In this audit the targets are pegged to national averages.

The statistical methodology for identifying outliers is covered in detail in this existing DoH/HQIP guidance. This includes recommendations about adjustments that should be made for over-dispersion and multiple comparisons.

National clinical audits

'National Clinical Audits' (NCA) in this context are the organisation(s) that lead and provide the project management infrastructure to the NCA. This includes both medical specialist associations and third-party suppliers, which may work in partnership to deliver an NCA.

Organisations

This includes the provider organisation Medical Director, Audit Clinical Lead and individual clinician about whose data an alert or alarm relates. There is a personal responsibility for any clinician to submit accurate data, and to respond to the audit results appropriately.

3 Consent

HQIP advice is that surgeon consent is not required for publication of Clinical Outcomes Publication (COP) results for all eligible consultants provided that all reasonable steps are taken to:

1. Communicate to eligible consultants that their data are to be published.
2. Ensure published data are adequate and accurate: this should be achieved by allowing and communicating reasonable time periods for data to be checked and corrected if necessary, prior to publication (see appendix 1: data validation timetable example).
3. Ensure that support and improvement mechanisms are in place for statistical outliers.

4. Demonstrate that COP is necessary to achieve legitimate aims (e.g. to improve the quality of care).

For more information please refer to: HQIP 'Technical Manual for the Clinical Outcomes Publication (COP), section 8.1: Legal framework, or contact cop@hqip.org.uk

4 Indemnity

Although the RCOphth NOD is no longer part of the NCAPOP, the RCOphth NOD follows the guidance that national clinical audit providers to obtain a) professional indemnity and b) public liability insurance cover for a minimum of £5 million for both a) and b).

4.1 Private Practice

The RCOphth NOD is happy to include information from organisations that offer privately funded cataract surgery.

4.2 Minimum numbers for inclusion

Provided the Office of National Statistics (ONS) small numbers policy is adhered to, project teams may decide the most appropriate minimum number of episodes to render a consultant eligible for inclusion in consultant outcomes publication. For the national cataract audit, this will be a minimum of 50 completed eligible episodes per consultant.

4.3 New vs low volume consultants

It is important for patients to be aware of how many procedures their consultant has carried out during the analysis period. This should include analysis of established consultants who do low volumes of procedures where possible. It is important to enable the public to distinguish between a consultant who carries out a small number of procedures over time, and a consultant who, for example has a small number of procedures due to their recent appointment. The methodology used to do so should be decided by the audit provider.

4.4 Multiple responsible consultants

Where it is agreed that more than one consultant is genuinely responsible for the care of a patient, the GMC codes of all consultants should be collected, and the procedure outcomes should be allocated to all relevant consultants. This methodology must be clearly explained, as it will differ from other National Clinical Audits, and result in a number of episodes per consultant adding up to more than the total episodes per hospital.

4.5 Quality Measures

The minimum requirement for outcome reporting is:

- The number of procedures carried out by consultant and centres
- Completeness of reporting by centres
- Risk adjusted adverse event rate/numbers by consultant and by centre

4.6 Audit Period

Audit periods must cover at least 12 months but may cover longer timeframes if appropriate. The RCOphth NOD National Cataract Audit will cover 12 months in the first instance, building to 24 months as deemed appropriate by the Audit Advisory Group.

4.7 Case Ascertainment

The General Medical Council (GMC) 'Supporting information for appraisal and revalidation' states that doctors must give "evidence of effective participation in clinical audit or an equivalent quality improvement exercise that measures the care with which an individual doctor has been directly involved". Compliance with this recommendation should be ensured by organisations through the appraisal and revalidation processes. Ultimately, this falls to the Responsible Officers, as compliance with national audit processes must be a prerequisite for professional revalidation.

Organisation participation in COP audits is also mandated by the NHS Standard Contract 2018/2019 and 2019/2020, 2020/21 (https://www.england.nhs.uk/nhs-standard-contract/20-21/)

National Clinical Audits should identify non-participating organisations, using administrative data such as Hospital Episode Statistics, and contact any organisation that is eligible but not participating, advising it to begin doing so within a given timeframe. Non-participating organisations should be named upon publication of Clinical Outcomes Publication (England). Participating organisations should provide assurance to national clinical audits that all eligible consultants are participating fully in data submission and validation.

5 Data Validation

Complete case ascertainment with full data still requires the data to be valid. Both the outcome data fields and those used for risk adjustment must be valid or analyses may produce inaccurate information.

Outcomes data are the most crucial fields. Even small errors in either the numerator or denominator of an analysis may have profound implications.

It is vital that organisations are given the opportunity to check and add/amend data where necessary prior to publication. A recommended timeline for data validation is noted in Appendix 1.

5.1 Responsibilities

- Provider organisations and its employees are responsible for submitting accurate and complete data to National Clinical Audits.
- National clinical audit providers are responsible for assuring the quality of this data and communicating data irregularities before analysis based upon them are used for outlier processes or publication. This assurance should be provided by national clinical audits implementing clear minimum data standards and communicating unexpected variation in data used to risk adjust analysis or calculate measures of quality.
- It is the duty of individual clinicians and provider organisation to respond appropriately to requests from national clinical audits to validate data, based on supporting information provided, within a given timeframe.

The RCOphth NOD data can be run as a real time audit in ophthalmology departments with EMRs that have the functionality to run real time reports. In this way, any individual whose

outcome data strays close to unacceptable confidence limits will be identified at an early stage. This will enable prompt identification of any underlying adverse issues enabling the individual to be aware of this and work within the department and organisation to rectify the situation so that the chance that patients may have a poor experience will be minimised. In addition, the individual, the department and the provider organisation can be assured that all patients are experiencing good care.

A medical director, when faced with information suggesting one of their consultants is an outlier, would need to discuss the situation with the consultant, who should ideally already be aware, and with the Clinical Lead for the department. Prior to initiating exclusion or investigative actions, the Medical Director should seek help and advice from the RCOphth, Professional Society or the audit clinical lead. Organisational HR input may or may not be appropriate. There will be occasions when the medical director is concerned that patient safety may be compromised and, under Maintaining High Professional Standards, might wish to exclude or restrict an individual pending an investigation. The MD/RO should also consider discussing the issue with their GMC Employment Liaison Adviser (ELA). The Clinical Audit Lead for the audit should be available for discussion with the MD if requested so that such issues could be discussed, and unnecessary exclusions avoided.

Analysis suggests that complication rates that are higher than expected should trigger appropriate discussion and action within the organisation concerned. The provider organisation Board must always be reassured that their services are safe and effective.

We would emphasise that medical practice should not be restricted or suspended, unless indicated as necessary by other factors, while the above processes are being followed.

5.2 Assurance of data submission

Contributing surgeons are invited to check their data behind a secure log in on the audit website prior to publication and is contacted to do this through email from the RCOphth NOD. Where possible errors are identified these must be referred to the RCOphth NOD for checking. Any outlier surgeon or centre must be contacted individually regarding checking accuracy of data (see Section 6).

5.3 Conflict resolution

Point of contact to help support decision making and process for resolving potential conflicts that arise as a result noa.project@rcophth.ac.uk

5.4 Right to respond

Any individual who is identified as a negative outlier can produce a response to go alongside their published results if the figures are published.

6 Outlier Management

Actions Summary

In accordance with the RCOphth NOD Outlier Policy the following action is required from you:

Stage	Action required	Who?	Timing	Action required by individual / organisation
1.	When an individual or organisation flags up with one or more of their performance indicators as a negative outlier at an 'alert' or 'alarm' level, the RCOphth NOD scrutinises the data and analyses performed to determine whether there is: '**No case to answer'** • Potential outlier status not confirmed • Data and results revised in NCA records • Details formally recorded **'Case to answer'** • Potential outlier status • *Proceed to stage 2*	RCOphth NOD	Within 10 working days	**Within 10 working days of receipt of this letter** An email or letter from yourselves acknowledging this notification must be received by us
2	The Lead Clinician in the provider organisation (and individual involved) informed about the potential outlier status and requested to identify any data errors or justifiable data explanations. All relevant data and analyses should be made available to the Lead Clinician (and individual). A copy of the request should also be sent to the provider organisation CEO and Medical Director.	RCOphth NOD clinical audit lead/ Chair of Professional Standards Committee	Within 5 working days	
3	Lead Clinician (in conjunction with the individual clinician) to provide written response to the RCOphth NOD.	Provider lead clinician	Within 25 working days	**Within 25 working days of receipt of this letter** Following an internal review, an email or letter detailing whether inaccurate or missing data relevant to the above

				outcome measure and consultant have been detected must be received by us
4	Review of Lead Clinician's response to determine: '**No case to answer'** • It is confirmed that the data originally supplied by the provider contained inaccuracies. Reanalysis of accurate data no longer indicate outlier status. • Data and results revised in audit records. Details of the provider's response and review result recorded. • Lead Clinician (and individual) notified in writing copying in provider organisation CEO and Medical Director • Request from the RCOphth NOD audit lead to provider organisation Lead Clinician as to why the original data was inaccurate and what has been put in place to prevent a reoccurrence. • Request from the RCOphth NOD audit lead to provider organisation Lead Clinician (and individual) to make relevant corrections to source data to correct errors in local patient records. **'Case to answer'** • It is confirmed that although the data originally supplied by the provider were inaccurate, analysis still indicates outlier status; or • It is confirmed that the data originally supplied were accurate, thus confirming the initial designation of outlier status. • *Proceed to stage 5.*	RCOphth NOD audit lead	Within 20 working days	

5	Contact Lead Clinician (and individual) by telephone, prior to written confirmation of potential outlier status to Chief Executive copied to Lead Clinician and Medical Director, (and individual clinician). All relevant data and statistical analysis, including previous response from the Lead Clinician, made available to Medical Director and Chief Executive. In the case of an 'alarm', the RCOphth NOD will inform CQC[*], Welsh Government[†], Department of Health (NI). Provider CEO advised to inform commissioners NHS Improvement[‡], relevant royal colleges (and the GMC ELA if individual alarm). In the case of an 'alert', it is expected that the Medical Director and departmental clinical lead would initiate a local review and might wish to triangulate this information with other governance information to see if any further action is required. CEO informed the RCOphth NOD will be publishing information on comparative performance that will identify providers (and individuals).	RCOphth NOD audit lead	Within 5 working days	
6	Acknowledgement of receipt of the letter confirming a local investigation will be undertaken with independent assurance of the validity of the exercise for alarm level outliers, copying in the CQC[§]or Welsh Government[**], Department of Health (NI).	Provider Chief Executive	Within 10 working days	**Within 10 working days** Acknowledge-ment of receipt of the letter confirming a local investigation will be undertaken with independent assurance of the validity of

[*] Via clinicalaudits@cqc.org.uk

[†] Via Wgclinicalaudit@gov.wales

[‡] Via nhsi.medicaldirectorate@nhs.net

[§] Via clinicalaudits@cqc.org.uk

[**] Via Wgclinicalaudit@gov.wales

				the exercise for alarm level outliers, copying in the CQC[††] or Welsh Government[‡‡], Department of Health (NI).
7	If no acknowledgement received, a reminder letter should be sent to the CEO, copied to CQC. If not received within 5 working days, CQC[§§] or Welsh Government[***] notified of non-compliance.	RCOphth NOD audit lead	Within 5 working days	
8	Public disclosure of comparative information that identifies providers (e.g. annual report of NCA, data publication online	RCOphth NOD		
	Next steps			
9	If inaccurate or incomplete data are identified, these must be resubmitted to the National Cataract Audit within 25 days of our receipt of the data accuracy report			Resubmit to the National Cataract Audit **within 25 days of our receipt of the data accuracy report**
10	**<FOR DATA ALARMS>**			
	If data are found to be complete and accurate, therefore remaining unchanged, your organisation must establish the root cause of the variation in patient outcomes. The resultant report must be received by us within 25 days of the data quality report.			The resultant report must be received by us **within 25 days of the data quality report.**
11	**<FOR DATA ALERTS>**			
	If data are found to be complete and accurate, therefore remaining unchanged, an internal root cause investigation is recommended, at your discretion. No further interaction with RCOphth is mandated at this stage.			**At your discretion**

[††] Via clinicalaudits@cqc.org.uk

[‡‡] Via Wgclinicalaudit@gov.wales

[§§] Via clinicalaudit@cqc.org.uk

[***] Via Wgclinicalaudit@gov.wales

7 Cause for Concern

National Clinical Audit Providers that collect and analyse data on the quality of care at participating individual or unit level have a responsibility to alert the Medical Director (MD) and Chief Executive Officer (CEO) in healthcare provider units or organisations, if the information submitted to the audit suggest the presence of very serious issues with clinical practice or system failure that presents a risk of harm to patients.

The table below describes three categories of concern which may be identified and describes some potential scenarios for each category.

Category no.	Category description	Example scenarios
Category 1	Single case record level evidence	Evidence from the care delivered to a single individual (the source of which may be a case record / PROM or other) reflects care which: • Has put the patient at significant risk of harm or has caused significant harm • Indicates a dysfunctional or dangerous department or organisation • Indicates a staff member displaying the following behaviours (and where it is unclear if the incident has been reported to senior staff): ○ Serious professional misconduct ○ Dangerous lack of competency
Category 2	Cluster of case record-level evidence	A cluster of discrete events for example: • More than one case record review from the same healthcare provider cohort indicates significant risk of harm or has caused significant harm • More than one source of evidence of dangerous or dysfunctional individual or team behaviours.
Category 3	Emerging aggregate data trends	Emerging data within years suggests a spike in concerns at team or organisation level, which is significantly out of keeping with comparable healthcare providers.

7.1 Process

If the RCOphth NOD team identifies a potential care incident that prompts a cause for concern the escalation process in section 6 above applies. Due to the more heterogeneous nature of the information that could trigger a cause for concern; the initial stage (stage 1 – Outlier management) will include a discussion and agreement of the process for each case between the RCOphth NOD or other relevant organisation, which in some circumstances will mean that

the escalation stages and / or timelines are shortened or omitted. In other circumstances both may agree that escalation is not warranted.

8 Risk Adjustment

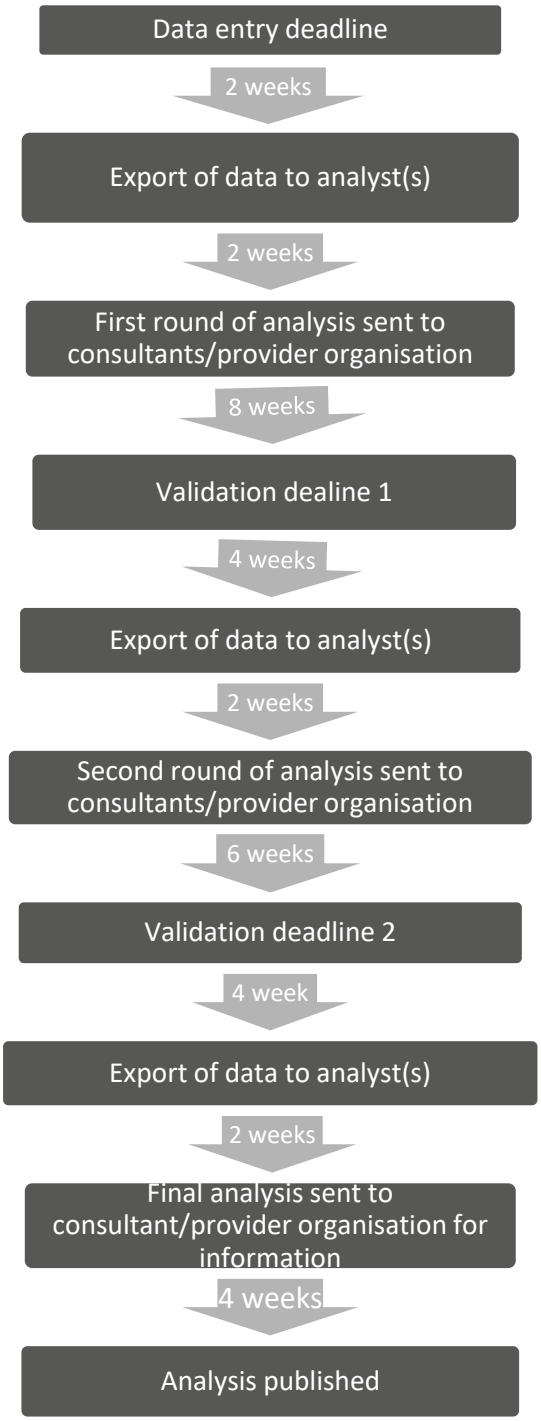
It is important that all data are risk adjusted using a robust methodology that is calibrated to a contemporary cohort. Risk adjustment methodologies for the National Cataract Audit adopt a published approach (The cataract national data set electronic multi-centre audit of 55 567 operations: case-mix adjusted surgeon's outcomes for posterior capsule rupture J M Sparrow, H Taylor, K Qureshi, R Smith and R L Johnston the UK EPR user group, Eye 2011;25:1010-5), have been agreed by the Audit Steering Group and are described on the audit website (https://www.nodaudit.org.uk/). The published methodology has been applied to a more recent set of data collected over a 4 year period up to March 2015.

9 Presentation of Information

Information is presented on the RCOphth NOD website: https://www.nodaudit.org.uk/

Appendix 1: Timetable for data validation

Timescales will vary and are included here as example only. Timescales for validation at local level represent the minimum advised time period. Two separate rounds of validation are recommended.



Appendix 2a: Outlier management templates

Template A: RCOphth NOD notification to provider organisation of outlying data alarm

Dear <Medical Director>, <Audit Clinical Lead>, and <Individual Consultant>

Notification of outlying data

Your organisation submits data to the National Cataract Audit. Between <date> and <date> surgeons were asked to check the data submitted to this audit for <procedures> during <audit period> for accuracy and completeness. We are writing to notify you that preliminary analysis has shown that the <indicator description e.g. <PCR rate> for <full name and GMC code of consultant> is higher than we would expect based on <the national average>.

Data can appear above the expected limit for many reasons; data issues, specialist practice involving high risk patients, operational issues, multidisciplinary team factors, or individual's practice.

Before exploring the cause of the outlying data further, it is vital that firstly the data submitted to the National Cataract Audit are checked thoroughly for accuracy and completeness. If missing or incorrect data is found, amendments can be submitted to the audit and analysis redone.

In accordance with the RCOphth NOD Outlier Policy the following action is required from you:

- **Within 10 working days of receipt of this letter**
  An email or letter from yourselves acknowledging this notification must be received by us
- **Within 25 working days of receipt of this letter**
  Following an internal review, an email or letter detailing whether inaccurate or missing data relevant to the above outcome measure and consultant have been detected must be received by us
- **Next steps:**
  If inaccurate or incomplete data are identified, these must be resubmitted to the National Cataract Audit **within 25 days of our receipt of the data accuracy report**
- <**FOR DATA ALARMS>**
  If data are found to be complete and accurate, therefore remaining unchanged, your organisation must establish the root cause of the variation in patient outcomes. The resultant report must be received by us **within 25 days of the data quality report.**
- **<FOR DATA ALERTS>**
  If data are found to be complete and accurate, therefore remaining unchanged, an internal root cause investigation is recommended, at your discretion. No further interaction with RCOphth is mandated at this stage.

At this stage, medical practice should not be restricted or suspended unless indicated by other factors.

Once the process outlined is complete. Comparative information that identifies consultants and outlying data will be published.

All email correspondence relating to this notification should be directed to noa.project@rcophth.ac.uk

We understand management of outlying data can be a difficult process for both organisation and individual doctors. If clinical input or member support is required, please contact <Chair of Professional Standards Committee at the RCOphth>.

We look forward to hearing from you.

……

Professor John Sparrow	**Mrs Melanie Hingorani**
RCOphth NOD Clinical Lead	Chair of Professional Standards Committee

Appendix 2b: Outlier management templates

Template B: RCOphth NOD outlying data inquiry Terms of Reference

It is recommended that the Terms of Reference for an inquiry into outlying consultant-level data comprise the following:

- Membership, which should specify the inquiry lead, and include as a minimum
    - Audit clinical lead
    - Nursing representative
    - External clinical expertise (i.e. via specialist association) <may be RCOphth Invited Service Review>
    - The consultant about whom the outlying data relates
- Scope of the group
- Aims of the group
- A description of the inquiry
- The timeline of the inquiry and key milestones
- Meeting medium (remote, in person), frequency and quorum
- Declarations of conflicts of interest

Appendix 2c: Outlier management templates

Template C: Outlying data – root cause report

Introduction

Brief introduction to the investigation, its relationship with any investigations by other bodies and the procedures and regulations governing the present investigation.

Methods

For example, review of patient records, audit of a specific set of cases, prescribing reviews, interviews with specified patients and/or colleagues. There should be a list of all people interviewed and the capacity in which they were involved in the investigation.

Findings of fact

What has happened set out in chronological order and with supporting evidence identified. Where the findings of fact include the opinion of case investigators or other experts on a standard of care, the required standards of care should be quoted. The findings should draw attention to any conflicts of evidence and whether it was necessary to resolve the conflicts in order to complete the investigation. Grounds should be given for preferring one version of events to another.

Conclusions

The conclusion reached on each of the points listed in the Terms of Reference, should be cross-referenced to the findings of fact.

The report must be signed by the provider organisation medical director, audit clinical lead, and individual consultant about whom the outlying data relates.

Appendix 2d: Outlier management templates

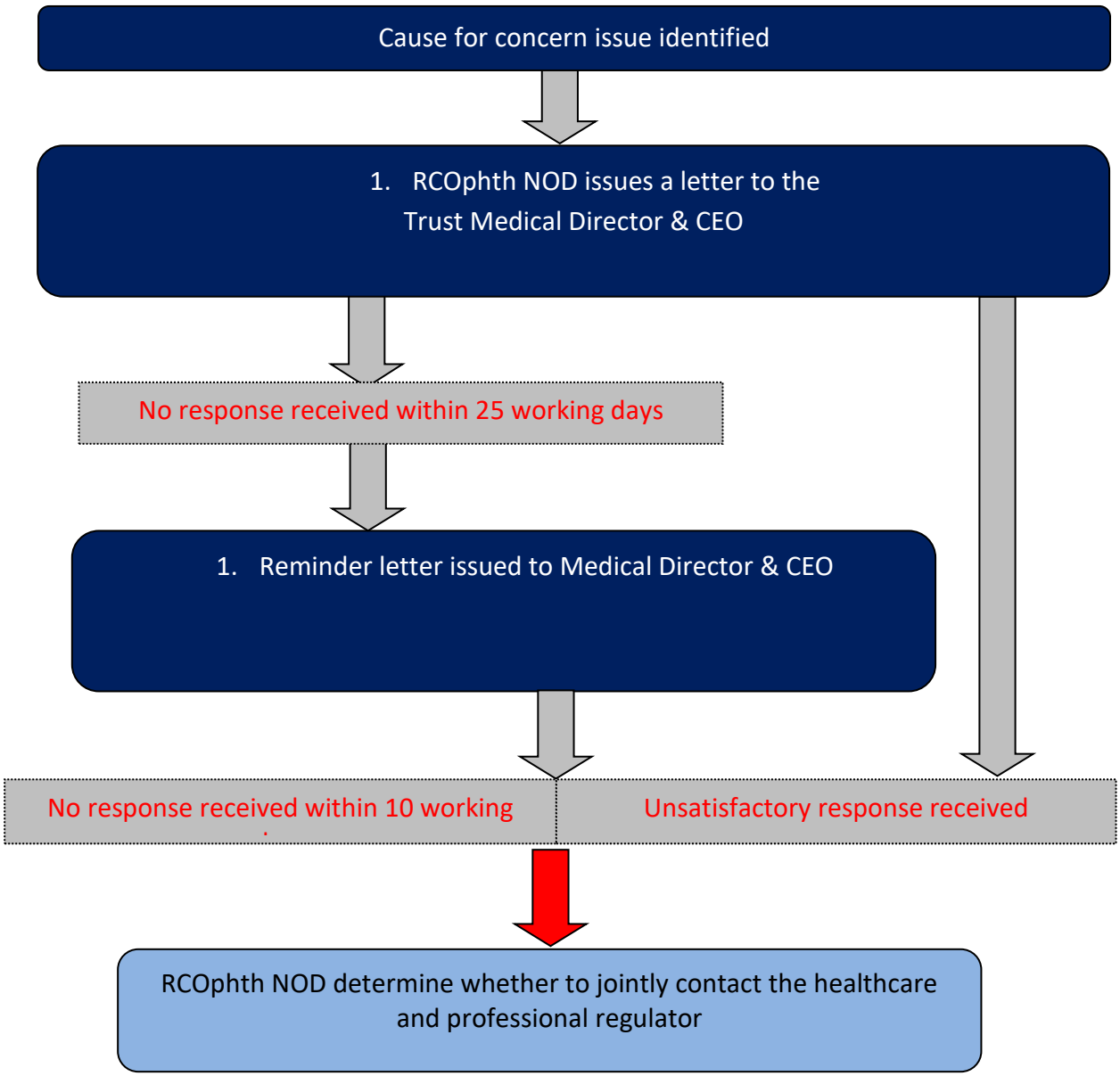
Template D: Outlying data – action plan
Contains examples for reference

Table 1

Issue	Action	Priority	Owner	Due Date	Date complete
Submitted audit data incomplete	Validation audit submission against surgical logbook	Medium	Data clerk	30/06/2018	25/06/2018
Complications data not being fully entered into EMR system	Training session	High	Clinical audit lead	01/07/2018	15/07/2018

Appendix *3: Cause for Concern Process Flow*

Process Flow



Appendix 4 Glossary of Terms

COP	Clinical Outcomes Publication
CQC	Care Quality Commission
ELA	Employment Liaison Adviser (GMC)
EMR	Electronic Medical Record
GMC	General Medical Council
HES	Hospital Episode Statistics
HIW	Health Inspectorate Wales
HR	Human Resources
HQIP	Healthcare Quality Improvement Partnership
MD	Medical Director
NCA	National Clinical Audit
NCAPOP	National Clinical Audit and Patient Outcomes Programme
NOD	National Ophthalmology Database
PCR	Posterior Capsular Rupture
RCOphth	Royal College of Ophthalmologists
RO	Responsible Officer
VA	Visual Acuity