Policy Document

National Ophthalmology Database Audit: Outliers Policy

June 2018

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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
1.0	BB, RJ, JS	26/06/2015	Steering Group	22/02/2016	First draft
1.1	BB, JS	02/06/2017	Steering Group	19/09/2017	Updated with revised HQIP guidance (involvement of CQC)
1.2	BB	14/02/2018	Steering Group	14/03/2018	Updated with cause for concern guidance
1.3	JS	11/06/2018			Section 2.2 updated with the revised overall consultant rates (benchmarks)

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 second prospective data collection and analysis in 2017/2018.

1.2 Background

NHS England has confirmed that the Consultant Outcomes Publications Programme will continue to expand and in 2014 The RCOphth was commissioned by the Healthcare Quality Improvement Partnership (HQIP) to run the first National Ophthalmology Database (NOD) Audit following a competitive tender in 2013. The project officially started on 1 September 2014 and consists of a National Cataract Audit (England and Wales).

The NCAPOP (National Clinical Audit and Patient Outcomes Programme) is a set of national clinical audits, registries, Clinical Outcomes Publication (COP) and outcome review programmes which measure healthcare practice on specific conditions against accepted standards. These projects give individual surgeons, healthcare providers and the public benchmarked reports on performance, with the aim of improving the care provided. All NHS funded centres are expected to contribute data.

1.3 Outliers

COP has 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 is needed to ensure 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

Unavoidable differences between national clinical audits, and the medical specialties they represent, mean that common principles, not methodologies are needed.

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.

1.4 Developing this guidance

This guidance was developed by the NCAPOP National Ophthalmology Steering Group of The Royal College of Ophthalmologists (see Appendix 3). This guidance was 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) http://www.hqip.org.uk/resources/clinical-outcomes-publication-technical-manual/ and HQIP's 'Detection and management of outliers for National Clinical Audits (May 2017) 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.

Much of the day-to-day activity relating to national clinical audit is conducted locally within organisations and by individual employees, with support provided by the organisation.

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 closely 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.

2 The role of the regulator, The Royal College of Ophthalmologists and HQIP

The Care Quality Commission (CQC) has a responsibility for organisational regulation of the quality of care, the General Medical Council (GMC) has a responsibility for regulating individual clinicians, and HQIP has a responsibility for managing the COP process. The CQC is included in this guidance to provide it with assurance that organisations are engaging appropriately in the process.

This is a complex issue; 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 NCA provider is responsible for managing the outlier process of data alert and alarms at both organisational and individual level as part of the 2014 COP process. This information will be passed on to the GMC as appropriate.

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, and 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. HQIP plans to develop a memorandum of understanding about these issues with the regulators, in conjunction with the profession, prior to the 2014 COP outputs.

For alarm level outliers, 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.

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

Where there is an individual outlier at the "alarm" level the College's national clinical audit lead 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 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 CQC of the situation.

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

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

HQIP expects to be informed in writing that the above processes have been followed. Failure to give such reassurance would lead HQIP to enter discussion with the Clinical Lead of the Audit. HQIP reserves the right to contact the CQC and/or the GMC if satisfactory action has not been taken.

2.2 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-factoral 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 National Ophthalmology 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 benchmarked in case complexity adjusted analyses is 1.1%. Similarly, the overall benchmark rate for 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

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 consent is not required for publication of Consultant Outcomes Programme (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 contact cop@hqip.org.uk

4 Indemnity

National Clinical Audits that are part of NCAPOP are required by a clause in their headline contract with HQIP to obtain a) professional indemnity and b) public liability insurance cover for a minimum of £5 million for both a) and b).

4.1 Consultants practicing outside of England

Where data for consultants practicing outside of England are collected by an audit, it is for individual audits to decide and communicate whether analysis of these consultants should be published.

4.2 Private Practice

Where private practice data are collected, it is for individual audits to decide whether and how to include these data in analysis. Projects may wish to make a distinction between private practice carried out in NHS hospitals, and private practice carried out in private units.

4.3 Minimum numbers for inclusion

Provided the ONS (Office of National Statistics) 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 episodes.

4.4 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 only being appointed recently. The methodology used to do so should be decided by the audit provider.

4.5 Multiple responsible consultants

Where it has been agreed with HQIP 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.

4.6 Quality Measures

The minimum requirement for COP is:

- The number of procedures carried out by consultant
- Risk adjusted adverse event rate/numbers by consultant

4.7 Audit Period

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

4.8 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 2017/2018 and 2018/2019.

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 Consultant Outcomes Data.

Participating organisations should, upon request, provide assurance to national clinical audits that all eligible consultants are participating fully in data submission and validation.

Organisations should make participation in the COP audits a priority and should support the process. In the exceptional event that this cannot be achieved, projects may wish to allow organisations to include an explanation for any non-participation in the report.

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 many produce confounding information.

Outcomes data are the most crucial fields as 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. This reinforces the requirement that accurate data is submitted in the first instance, and that individuals and organisations assure themselves that this is the case.

Audits must ensure that the validation process is documented clearly, along with the rationale behind the methodology and timeframes allowed.

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, on the basis of supporting information provided, within a given timeframe.

The National Ophthalmology Audit should run as a real time audit within local ophthalmology departments. 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 his/her 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 Royal College, Professional Society, audit clinical lead, or the HQIP Medical Director. 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 rehearsed 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 be reassured at all times 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 prior to publication through email from the provider (Royal College of Ophthalmologists). Where possible errors are identified these must be checked by the audit provider. Any outlier surgeon or centre must be contacted individually in regard to 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 has the opportunity to produce a response to go alongside their published results if the figures are published.

6 Outlier Management

Actions Summary

Stage	Action required	Who?	Timing
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 College 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*	The Royal College of Ophthalmologists	Within 10 working days
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.	Royal College clinical audit lead	Within 5 working days
3	Lead Clinician (in conjunction with the individual clinician) to provide written response to NCA supplier.	Provider lead clinician	Within 25 working days
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	College audit lead	Within 20 working days

	recorded. • Lead Clinician (and individual) notified in writing copying in provider organisation CEO and Medical Director • Request from the College 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. **'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.*		
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', NCA supplier to inform CQC*. 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	College audit lead	Within 5 working days

* Via clinicalaudits@cqc.org.uk

† Via nhsi.medicaldirectorate@nhs.net

	with other governance information to see if any further action is required. CEO informed the NCA supplier will be publishing information on comparative performance that will identify providers (and individuals).		
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[‡].	Provider Chief Executive	Within 10 working days
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[§]	College audit lead	Within 5 working days
8	Public disclosure of comparative information that identifies providers (e.g. annual report of NCA, data publication online	Royal College of Ophthalmologists	

[‡] Via clinicalaudits@cqc.org.uk

[§] Via clinicalaudit@cqc.org.uk

7 Cause for Concern

NCAPOP 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 NCAPOP Provider find example(s) of clinical practice or system failure that presents a risk of harm to patients. Instances in which a cause for concern process may be utilised as opposed to an outlier management process include:

- Where the project does not collect patient or unit level data
- Where a sampling methodology is employed and no benchmarked figure can be achieved for a unit
- Where high or complete case ascertainment and / or completion has not been achieved and there is a possibility that the data collected is not representative of the overall quality of care of a unit

Below is a non-exhaustive list of the types of incidents which may constitute a cause for concern:

- Standards in care that indicate a dysfunctional or dangerous department or organisation, or grossly inadequate service provision
- High proportion of responses from a survey that indicate sub optimal healthcare provision for a provider unit (for example, a dementia carer survey indicates that 95% of returns for Hospital A are graded at 'very poor' by carers.

7.1 Process

If an NCAPOP project identifies a potential care incident that prompts a cause of concern, they should:

- Notify the HQIP NCAPOP Associate Director
- Write to the Trust Medical Director, copying in the Trust Chief Executive Officer and HQIP.

The letter should include:

1. An outline of the data submitted and from which the 'Cause for concern' has originated
2. A request that the letter is formally acknowledged within twenty-five working days from receipt of the communication
3. A request that details of any investigation and remedial action that has been taken to address the possible underlying causes of the concern be summarised and communicated back to the NCAPOP Project raising the 'Cause for concern'.
4. A request to provide details of any submission of the incident(s) to the healthcare and/or professional regulator (if appropriate)
5. Providing a link to the published project 'Cause for concern' policy.

If a formal response has not been received within twenty-five working days of the initial letter raising the 'Cause for concern', a reminder letter should be sent to the Medical Director and Chief Executive Officer and HQIP notified. If no response is received within a further **10 working days**, or the response is felt by the NCAPOP Provider to be

unsatisfactory, the Provider should discuss the issue with HQIP. Agreement should then be reached on whether the healthcare and/or professional regulators should be notified.

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 will be presented on the National Ophthalmology Audit website: https://www.nodaudit.org.uk/

10 NHS Choices

Analysis aggregated to consultant level must be provided to NHS Choices in an Excel workbook as per a template to be disseminated by NHS Choices so that all analyses can be presented in a simple and consistent format on the NHS Choices website.

Requirements will include:

- Number of procedures
- Indicator(s) (i.e. quality measure)
- Identification of current trust/Hospital
- GMC code
- Consultant name & gender
- Specialty
- Procedure(s)
- Audit period

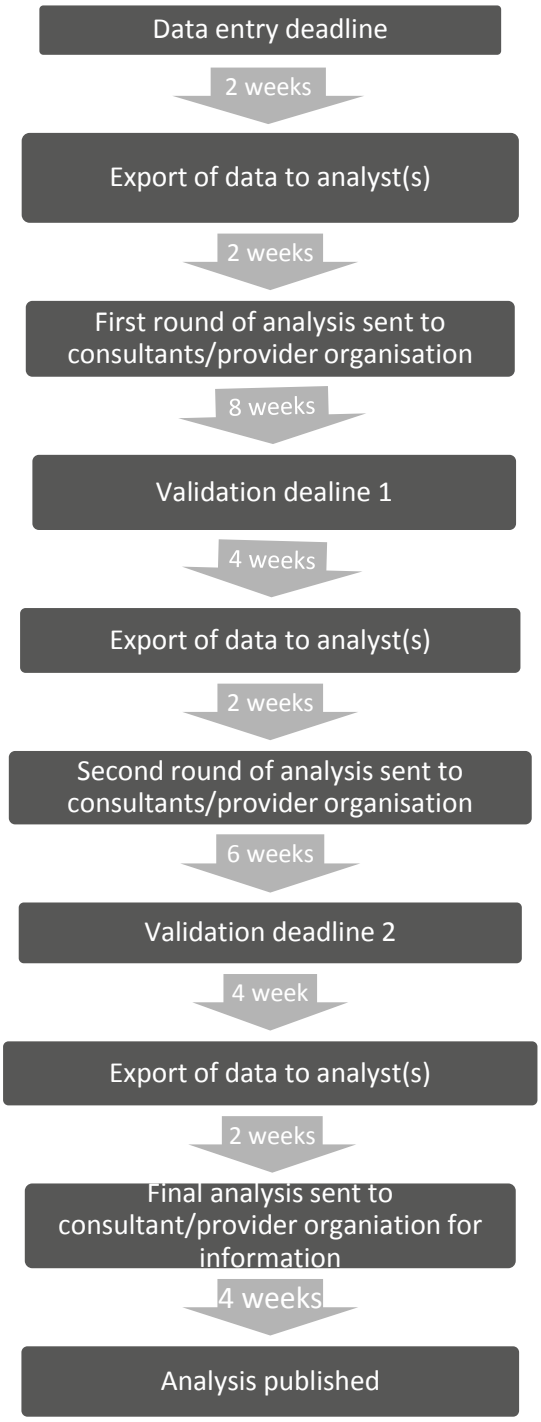
10.1 Freedom of Information (FOI) Requests

NHS Choices is a publicly funded body and therefore subject to FOI requests. As such, any data passed on to NHS Choices as part of COP is potentially disclosable under the Freedom of Information Act, whether or not it was generated by a publicly funded body.

However, once information has been published by NHS Choices on its website **there would be no obligations to release the Excel workbook/spreadsheet in response to a Request for Information.**

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 2: Outlier management templates

Template A: NCA 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 Healthcare Quality Improvement Partnership (HQIP) guidance, which can be downloaded from http://www.hqip.org.uk/resources/detection-and-management-outliers-national-clinical-audits/ 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. Template terms of reference for this inquiry can be downloaded from the HQIP website. 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 ourselves is mandated at this stage.

I enclosed a copy of the HQIP Consultant Outcomes Programme (COP) escalation route, which describes the process in more detail.

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
Audit Lead

Miss Melanie Hingorani
Chair of Professional Standards Committee

Template B: Provider organisation 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

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, 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.

Template D: Outlying data – action plan

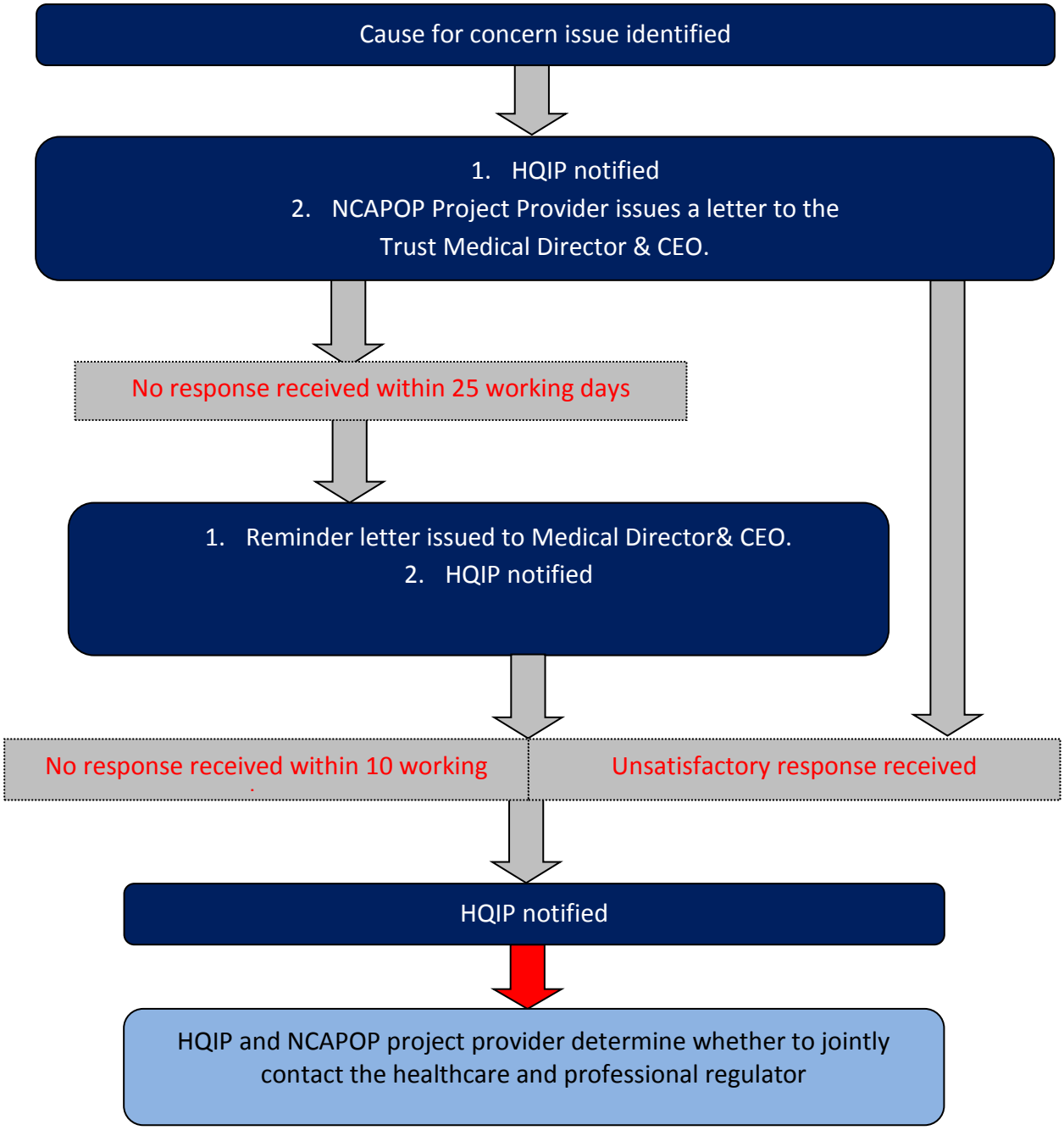
Contains examples for reference

Table 1 Write caption here

Issue	Action	Priority	Owner	Due Date	Date complete
Submitted audit data incomplete	Validation audit submission against surgical logbook	Med	Data clerk	30/06/2015	25/06/2015
Complications data not being fully entered into EMR system	Training session	High	Clinical Audit lead	01/07/2015	15/07/2015

Appendix 3: Cause for Concern Process Flow

Process Flow



Appendix 4: National Ophthalmology Database Audit Steering Group

Name	Designation
Andrew Frost	Cataract Representative The Royal College of Ophthalmologists
Anthony King	Cataract Representative The Royal College of Ophthalmologists
Beth Barnes	Head of the Professional Standards Department The Royal College of Ophthalmologists
Catherine Dennison	Senior Manager of Research and Policy Royal National Institute of Blind People
Chris Rogers	Independent Statistician The University of Bristol
David Parkins	The College of Optometrists Practicing Optometrist
David Yorston	Cataract Representative The Royal College of Ophthalmologists
Janet Bax	Patient Representative The Patients Association
John Sparrow	Chairman Clinical Lead for RCOphth National Ophthalmology Database Audit
Kathy Evans	Chief Executive The Royal College of Ophthalmologists
Matt Broom	Lay Group Representative The Royal College of Ophthalmologists and Vision UK
Melanie Hingorani	Cataract Representative The Royal College of Ophthalmologists
Raghu Ram	Wales Representative The Royal College of Ophthalmologists
Sasha Hewitt	Associate Director of Quality and Development Healthcare Quality Improvement Partnership (HQIP)
Tasneem Hoosain	Project Manager Healthcare Quality Improvement Partnership (HQIP)
Wendy Newsom	The College of Optometrists Practicing Optometrist

Appendix 5 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
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