Statistical Analysis Plan for the RCOphth NOD National Cataract Audit

Sixth year of the prospective National Cataract Audit version

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Document authors

Paul HJ Donachie

John C Buchan

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1 The RCOphth NOD Cataract Audit team

RCOphth project clinical lead

John C Buchan - Consultant Ophthalmologist, Leeds Teaching Hospitals NHS Trust and Assistant Professor at the International Centre for Eye Health

RCOphth project executive lead

Ms Kathy Evans – Chief Executive, Royal College of Ophthalmologists

The RCOphth NOD audit project office:

Ms Beth Barnes – Head of Professional Standards

Ms Martina Olaitan – RCOphth NOD Cataract Audit Project Manager

The Royal College of Ophthalmologists

18 Stephenson Way

London

NW1 2HD

Tel: +44 (0) 20 7935 0702 Fax: +44 (0) 20 7383 5258

Email: noa.project@rcophth.ac.uk

The RCOphth NOD delivery unit:

Mr Paul Henry John Donachie – RCOphth NOD Senior Medical Statistician

Charlotte Norridge – Medical Statistician

Marta Gruszka-Goh – Medical Statistician

Professor Peter Scanlon – Consultant Ophthalmologist

Gloucestershire Retinal Research Group office

Above Oakley Ward

Cheltenham General Hospital

Gloucestershire

GL53 7AN

Phone: 03004 22 2852 Email: ghn-tr.nod@nhs.net

2 Abbreviations

Abbreviation	Description
AC	Anterior chamber
AMD	Age-related Macular Degeneration
CDVA	Corrected distance visual acuity
CF	Count fingers
CNS	Central nervous system
CQC	Care Quality Commission
DHCW	Digital Health and Care Wales
DR	Diabetic Retinopathy
EMR	Electronic Medical Record
GIRFT	Getting It Right First Time Programme
GMC	General Medical Council
HM	Hand movements
IMD	Index of multiple deprivation
IOL	Intra-ocular lens
LogMAR	Logarithm of the Minimum Angle of Resolution
NHS	National Health Service
NIHR	National Institute for Health Research
NOD	National Ophthalmology Database
NPL	No perception of light
PCR	Posterior capsule rupture
PHVA	Pinhole visual acuity
PL	Perception of light
RCOphth	Royal College of Ophthalmologists
SD	Standard Deviation
UDVA	Uncorrected distance visual acuity
VA	Visual acuity
VEGF	Vascular Endothelial Growth Factor

3 Acknowledgment

The National Ophthalmology Database Audit (NOD) is conducted under the auspices of the Royal College of Ophthalmologists (RCOphth) and conducts the National Cataract Audit focussing on publically funded cataract surgery.

We acknowledge the support of the hospitals that are participating in the RCOphth NOD and thank our medical and non-medical colleagues for the considerable time and effort devoted to data collection. All participating centres are listed on the RCOphth NOD website (www.nodaudit.org.uk).

We acknowledge with thanks the contribution of Professor John Sparrow who provided diligent clinical and academic oversight and leadership of the NOD over many years to bring it to its current stature. It is with gratitude that we remember the contribution of our friend and colleague Robert Johnston, who sadly died in September 2016. Without his inspirational vision, determination and career long commitment to quality improvement in ophthalmology this work would not have been possible

4 Introduction

The Royal College of Ophthalmologists (RCOphth) is the governing authority for the National Ophthalmology Database Audit (NOD) and conducts The National Cataract Audit on data concerning cataract surgery. The audit is open to providers of both National Health Service (NHS) and privately funded cataract surgery in England, Guernsey, Scotland, Northern Ireland and Wales. The data is collected as part of routine clinical care on electronic medical record (EMR) systems or in-house data collection systems and the analysis is performed by the RCOphth NOD Audit statisticians based in Cheltenham General Hospital.

Results are published on the RCOphth NOD website (www.nodaudit.org.uk), provided to the Care Quality Commission (CQC), produced for peer review journals and published in annual reports. Centre level results include operations performed by trainee surgeons, and publicly available named surgeon level results do not. This document concerns the statistical analysis plan for the prospective cataract audit analysis.

The initial methodology for the National Cataract Audit was established using a 'legacy' extract of historical data. This extract was also used for the completed feasibility studies into outcomes of wet age-related macular degeneration, trabeculectomy surgery & visual field preservation in eyes with glaucoma and rhegmatogenous retinal detachment surgery.

The 'legacy' cataract analysis was performed on retrospective data collected as part of routine clinical care and recorded on existing EMR systems, whilst the prospective audit analyses are performed on data collected on existing EMR systems and the RCOphth NOD commissioned audit tools, which started collecting data in September 2015 and are available to all centres that offer publically funded cataract surgery.

The RCOphth NOD receives data collected on multiple systems that can have different ways to record the information. For this reason, the terminology used in this document is the wording used in the supplied information.

5 Cataract Inclusion/Exclusion criteria

Eligibility for any cataract analysis

The definition of an eligible operation is constructed to include all cases in which the intention had been to undertake a phacoemulsification cataract extraction and lens implant as a standalone procedure (potentially accompanied by other adjuncts such as pupil stretching or injections of therapeutic substances that are either intrinsic to the cataract operation or are incidental additions which would not be expected to impact intra-operative complications, such as sub-tenons injection of triamcinolone for patients unable to instil their own anti-inflammatory eye drops post-operatively due to dementia).

Cataract operations are included in RCOphth NOD analyses if they comply with the conditions listed below; if not then they are excluded from cataract analyses;

- Operation performed in adults (aged 18 or above)
- Operation included a phacoemulsification procedure
- Operation has a recorded date of surgery
- Operative data includes a surgeon identifier
- Operative data includes a valid grade of surgeon
- Operation included a “cataract” indication for surgery*
- Operation without any of the ineligible cataract indications for surgery or diagnosis*
- Operation did not include any ineligible operative procedures*
- Cataract operations that included a pars plana vitrectomy with no vitreoretinal indication for surgery and no other vitreoretinal procedures except for sponge and scissor vitrectomy or automated anterior vitrectomy* (Phaco-vitrectomy for other indication is excluded, but cataract operations that ended up needing a vitrectomy remain eligible)

National Ophthalmology Database Cataract Audit specific criteria

For the national ophthalmology database audit of cataract surgery further criteria apply, these are;

- For named centre and named surgeon results, at least 50 eligible operations are required
- For published named surgeons a valid General Medical Council (GMC) number is required
- For post-cataract Vision Loss, both a preoperative and postoperative VA measurement is required, operations performed in the final 2 months of an audit year are not included, and there has to be <40% of operations with missing visual acuity data for a result to be produced for a centre or surgeon.

*Full details of the eligibility criteria can be found on the RCOphth NOD audit website www.nodaudit.org.uk/resources/methodology

6 Contributing centre numbers

All contributing centres are allocated an audit centre identifier which is a number generated as 1 – n based on the volume of operations contributed to the analysis, and created in the audit year that the RCOphth NOD first receives at least 50 eligible operations from the centre, this number is then fixed for the centre in all RCOphth NOD reports.

For the first prospective audit year this assigned numbers 1- 56 to the centres with at least 50 eligible cataract operations, where centre 1 was the centre with the most operations and centre 56 the centre with the fewest operations.

For the second prospective audit year centres 1 – 56 remained as assigned, newly contributing centres were assigned numbers 57 – 87 based on the number of operations they had eligible for the second audit year. For the third prospective audit year the newly contributing centres were assigned numbers 88 – 108, for the fourth prospective audit year the newly contributing centres were assigned numbers 109 – 122, and for the fifth prospective audit year the newly joining centres were assigned numbers 123 – 159. Centre 160 first contributed data to the fifth prospective audit year, but with only data for historic time periods, and no results for the fifth prospective audit year. For the sixth prospective audit year the newly joining centres are assigned 161 to 188, with numbers 189 to 205 assigned to centres participating in the National Age-related Macular Degeneration Audit who have not appeared in any prospective cataract audit report.

These ‘numeric tags’ are used in tables in official reports that include results for named centres and this approach will be followed in subsequent audit years.

Some centre numbers have become redundant due to mergers of NHS Trusts or one NHS Trust taking over the ophthalmology service in another NHS Trust and some centres have contributed data to an audit year and not done so in subsequent audit years.

7 Index of multiple deprivation score

The Index of Multiple Deprivation (IMD) score, national ranks and national deciles are calculated during the data extraction. For patients treated in English centres, the English Indices of Deprivation 2019 (https://www.gov.uk/government/statistics/english-indices-of-deprivation-2019) are used, and for patients treated in Welsh centres the Welsh Index of Multiple Deprivation 2019 (https://statswales.gov.wales/Catalogue/Community-Safety-and-Social-Inclusion/Welsh-Index-of-Multiple-Deprivation) are used.

Reasons for missing IMD data are the non-recording of a patient's postcode on the hospital admission system, a patient's postcode not recognisable in the IMD conversions or no matching to deprivation data during data extraction.

For the sixth prospective audit year, the RCOphth NOD received IMD data from centres using the Medisoft EMR. The Open Eyes EMR team have added to the Open Eyes data extraction the inclusion of IMD data which will be submitted once centres upgrade their version of Open Eyes. The RCOphth NOD have created a document explaining how English centres using an in-house database can calculate and submit IMD data for their patients. Currently there is no equivalent system for 'batch uploading' of postcodes to match to social deprivation data for Wales as there is for England, thus non-EMR enabled Welsh centres cannot submit this data.

If the RCOphth NOD is granted section 251 exemption, then future data extractions could include the patients full post code and the matching to social deprivation data would be possible for all centres from regions where social deprivation data can be matched to a postcode.

8 Pupil size

Certain operative procedures are conducted on small pupils, thus the recording of the procedures can infer the eye has a small pupil, these operative procedures are as follows;

- Broad iridectomy
- Insertion of iris hooks
- Insertion of pupil ring expander
- Sphincterotomy
- Stretching of the iris
- Synaechiolysis

9 Operative complications

On the supplying data systems to the RCOphth NOD, intra-operative complications are a mandated field. If a surgeon indicates that an intra-operative complication has occurred then on some systems they have to select from a pre-populated list of complications specific to the type of surgery being performed, on other systems they record the intra-operative complication using free text.

Post-operative complications can be recorded in clinic, but not all centres using EMR systems have the EMR in use in all areas of the hospital eye service, and patients do not always return for follow up assessments, thus post-surgery data can be missing. Analysis is limited to post-operative complications recorded within 2 months of cataract surgery in centres that have recorded post-operative data, either 'none' or a specified post-operative complication. As not all post-operative complications are recorded in the 'postoperative complication' sections of EMR systems, or the patients could be seen in non-cataract clinics, inferences for the occurrence of selected postoperative complications are possible from diagnostic and treatment data. Full details on these inferences can be found on the audit website (www.nodaudit.org.uk/resources/methodology).

10 Posterior Capsular Rupture (PCR) definition

Posterior capsular rupture is defined as occurring if:

Any of the following intraoperative complications are recorded during surgery:

- IOL into the vitreous
- Lens fragments into vitreous
- Lens matter in posterior segment
- Nuclear/ epinuclear fragment into vitreous
- Nuclear matter in posterior segment
- PC rupture - vitreous loss
- PC rupture – no vitreous loss
- Vitreous loss
- Vitreous to the section at end of surgery
- Zonule rupture – vitreous loss

Or if any of the following occurred:

- The operation includes any of 'Sponge and scissors vitrectomy', 'Automated anterior vitrectomy' or 'Scleral fixed IOL'
- The operative procedure includes 'Fragmatome lensectomy ± IOL' with a combined phacoemulsification procedure
- The operative procedure includes either 'Removal of lens fragments' or 'removal of lens nucleus' combined with a vitrectomy and phacoemulsification procedures

If any of 'lens matter in posterior segment', 'nuclear matter in posterior segment', 'vitreous to the section' or 'vitreous in the AC' are recorded within 8 weeks of cataract surgery, (including the day of cataract surgery). It is recognised that vitreous egress is possible in rare cases, despite the absence of compromise of the capsule or zonules. This still represents a complication of surgery, however EMR providers may offer a diagnosis of post-operative complication that identifies such cases of vitreous in the anterior chamber unrelated to intra-operative complication.

- If there is a record of a dropped nucleus operation with 90 days of cataract surgery, note this includes the day of cataract surgery in the time frame

11 Visual Acuity criteria

Visual Acuity (VA) abbreviations

- Corrected distance visual acuity = CDVA
- Uncorrected distance visual acuity = UDVA
- Pin hole visual acuity = PHVA
- Count fingers = CF
- Hand movements = HM
- Perception of light = PL
- No perception of light = NPL

Preoperative VA

- Uses the VA measurement closest to the date of surgery, including the day of surgery and within 6 months prior to surgery. This interval has been extended from 90 days prior to surgery which was used in the 'legacy' analysis and the first year of the prospective audit, and from 4 months prior to surgery which was used in the second prospective audit year
- Uses the better of CDVA and UDVA. PHVA measurements are not eligible pre-operatively

Postoperative VA

- Uses VA measurements within 8 days and 6 months (inclusive) of cataract surgery. This interval has been extended from 14 days to 4 months (inclusive) of cataract surgery which was used in the 'legacy' analysis and prospective audit years 1 and 2
- Uses the best measurement of CDVA, UDVA or PHVA within the time period

For estimates of visual acuity for a contributing centre (i.e. the median preoperative VA), at least 50 eligible operations with VA measurements are required.

Postoperative Vision Loss

Postoperative Vision Loss is defined according to the difference between preoperative and postoperative VA as in Table 1.

Table 1: Postoperative Vision Loss classification.

Preoperative VA	Postoperative Vision Loss
<1.00 LogMAR	A loss of ≥0.30 LogMAR
≥1.00 to <CF	Postoperative VA of HM, PL or NPL
CF	Postoperative VA of PL or NPL
HM	Postoperative VA of NPL
PL	VA loss not considered
NPL	VA loss not considered

Catastrophic Visual Loss

A new result that will be reported in the sixth prospective cataract audit report is postoperative catastrophic visual acuity loss. This information will be reported at the aggregate and centre level, at the unadjusted level as no case complexity adjusted model has been created.

Postoperative catastrophic visual loss is defined as a loss of ≥0.60 LogMAR between preoperative and postoperative VA measurement. This is only considered for eyes with a preoperative VA of HM or better, while for eyes with a preoperative VA of PL or NPL, catastrophic visual loss is not considered.

12 Diabetic status

It is possible for an eye to have a record of diabetic retinopathy (DR) as an ocular co-pathology while the patient is not recorded as having diabetes mellitus, the DR ocular co-pathology data can therefore be used to infer diabetic status as follows;

For single eye operated patients, if the eye has a record of DR as an ocular co-pathology then the patient can be considered to have diabetes mellitus.

For both eye operated patients;

- If the first operated eye has a record of DR as an ocular co-pathology then the patient can be considered as having diabetes mellitus for both operations
- If the first operated eye has no record of DR as an ocular co-pathology, and the second operated eye does, the patient can be considered as having diabetes mellitus for the second cataract operation

13 Ocular co-pathology / known risk indicator

Ocular co-pathology / known risk indicators are a major component of case complexity adjustment and it is very important to record this data accurately. From centres that supply data for pre-cataract diagnoses, assessments and treatments, certain ocular conditions can be inferred from these pre-cataract records.

Full details of the inferences of the various conditions can be found on the RCOphth NOD audit website.

www.nodaudit.org.uk/resources/methodology

14 Previous Anti-VEGF therapy

For centres recording data on EMR systems, the medication and treatment data prior to cataract surgery can be used to identify eyes receiving, and the number of injections of, anti-vascular endothelial growth factors (anti-VEGF) prior to cataract surgery. Centres using in-house databases can also supply this information. Medications classified as Anti-VEGF are as follows;

- Abicipar Pegol
- Aflibercept
- Bevacizumab
- Brolucizumab
- Conbercept
- Faricimab
- Ranibizumab

15 Case Ascertainment

Case ascertainment is an estimate of the proportion of operations a centre performs that they have provided data to the audit for. This is useful when interpreting centre results. For example centres with high case ascertainment percentages are providing to the audit data for a high proportion of their cases, and thus their results are likely to be representative of their case load.

Case ascertainment is reported as a percentage where the numerator is the number of operations using phacoemulsification provided to the audit which is calculated from the submitted data, and the denominator is the number of operations using phacoemulsification reported to NHS Digital for English centres, and to the Digital Health and Care Wales (DHCW) (formerly National Wales Informatics Service) for Cymru centres.

The denominator is adjusted pro-rata to account for centres not having the facility to collect data for the complete audit year, for example if they implemented an EMR within an audit year. The proportion of the audit year the centre has supplied data for is multiplied by the NHS Digital or DCHW totals, for example a centre whose first date of surgery is 6 months before the end of the audit year will have their NHS Digital or DCHW total multiplied by 0.5, i.e., divided by 2. This multiplication proportion is set to 1 for all centres whose date of first surgery in an audit year is within the first week of the audit year, and for all centres who have provided data for the previous audit year where the date of first surgery in the previous audit year was in the first 6 months of the previous audit year. The aim of the latter adjustment is to not artificially increase a centres case ascertainment percentage if they have the ability to collect data and are not doing so, using the information that they have provided data for an operation performed at least 6 months before the start of an audit year, and thus the assumption that they had the ability to record data for all operations in the subsequent audit year. Note, this latter adjustment does not apply to the 2020 NHS year due to the service disruption form COVID-19.

16 Posterior Capsular Rupture (PCR) and Vision Loss analyses

PCR and Vision Loss graphs

The RCOphth NOD Audit website displays both unadjusted and adjusted for case complexity PCR and Vision Loss results for surgeons and centres using funnel plots. The unadjusted graphs do not have confidence limits plotted, whilst the adjusted for case complexity graphs have 95% and 99.8% confidence limits plotted using the logit transform and comparator values of 1.1% for PCR and 0.9% for visual loss. The comparator values were lowered for the second year of the prospective audit from 2.0% for PCR and 1.5% for Vision Loss which were used for the 'legacy' analysis and the first prospective year of the audit. These updated comparator values reflect the current average rates for the reference group, the consultant surgeons.

The case complexity adjustment models used were developed from the 'legacy' analyses, where the 'legacy' report included anonymised funnel plots showing all non-trainee surgeons' data, and separately, anonymised plots of centres' data which includes all contributing surgeons (non-trainees and trainees). Examples of both unadjusted and adjusted for case complexity PCR graphs are shown in Figures 1 and 2.

Individual surgeons who have contributed data to the RCOphth NOD have access to funnel plots on the RCOphth NOD Audit website allowing a surgeon to view their personal data in the context of their anonymised peers and to view their centre's data in the context of all other contributing centres.

As surgeons progress through training, they can have data at more than one grade, can work in multiple contributing centres and use more than one of the audit data collection systems. In the prospective cataract audit the surgeon's GMC number is used as part of the registration for the RCOphth NOD website. This allows the matching of records for surgeons who have data for more than one centre or more than one contributing data collection system.

The results on the RCOphth NOD website include a filter for the date of surgery which allows results to be presented for the time period of choice from 1st April 2010 up to the most recent completed audit year. There are plans to add filters for the surgeon grade to enable a surgeon to view their results for the different grades they have had in their career, and for the centre results to display where a contributing centre's surgeons on a specific grade relate to other centres surgeons on the same grade, for example trainees surgeons. Another filter in the planning is for the site of surgery which would allow centres to see their results separately for the locations they perform surgery in.

The confidence intervals are derived from the number of operations and the comparator values, where the upper boundaries of the 95% and 99.8% confidence intervals equate to alert and alarm levels in public reporting. These are displayed in Table 2 for the comparator values used in the RCOphth NOD.

Figure 1: *An example of an unadjusted for case complexity PCR graph*

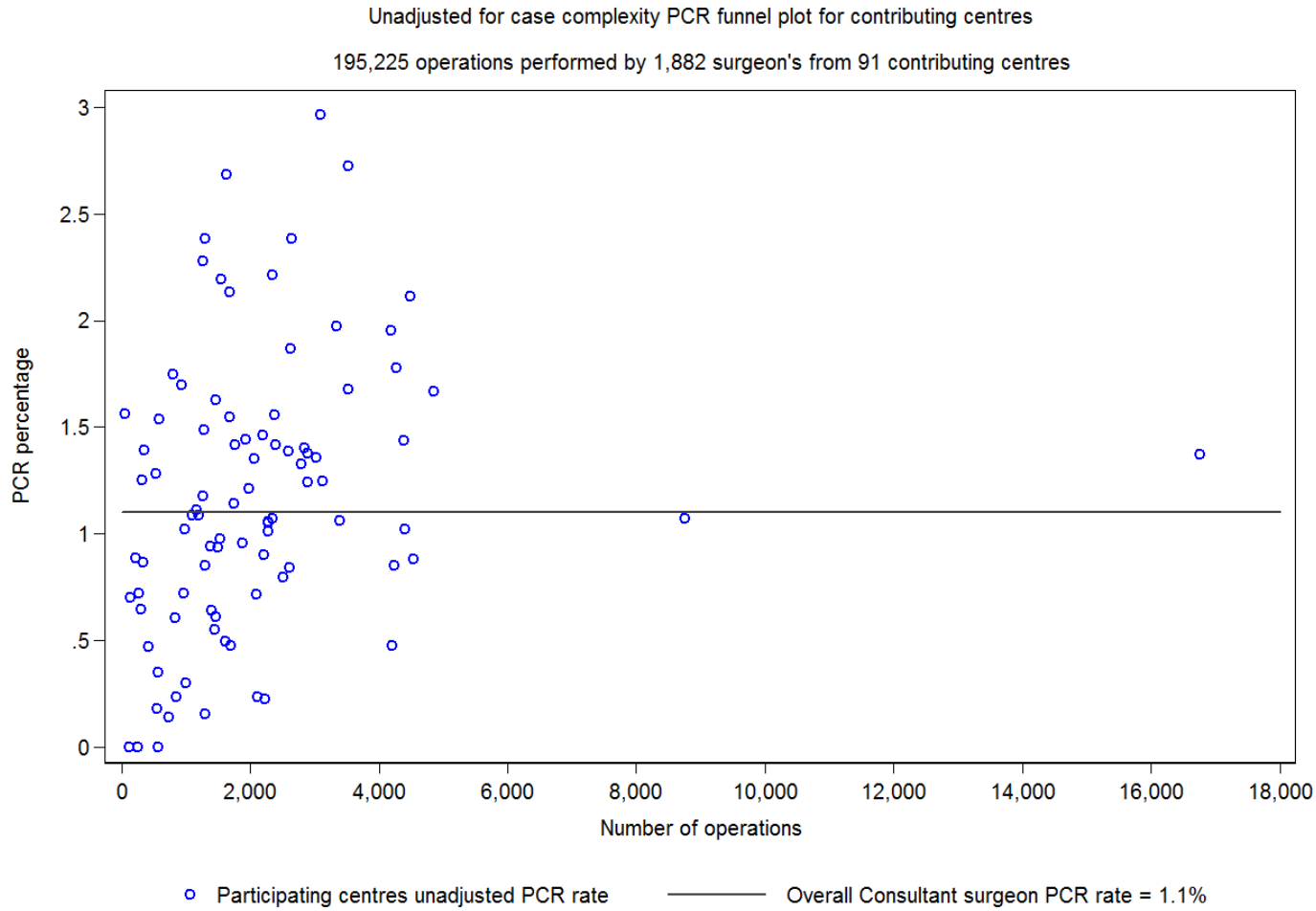

Figure 2: An example of an adjusted for case complexity PCR graph

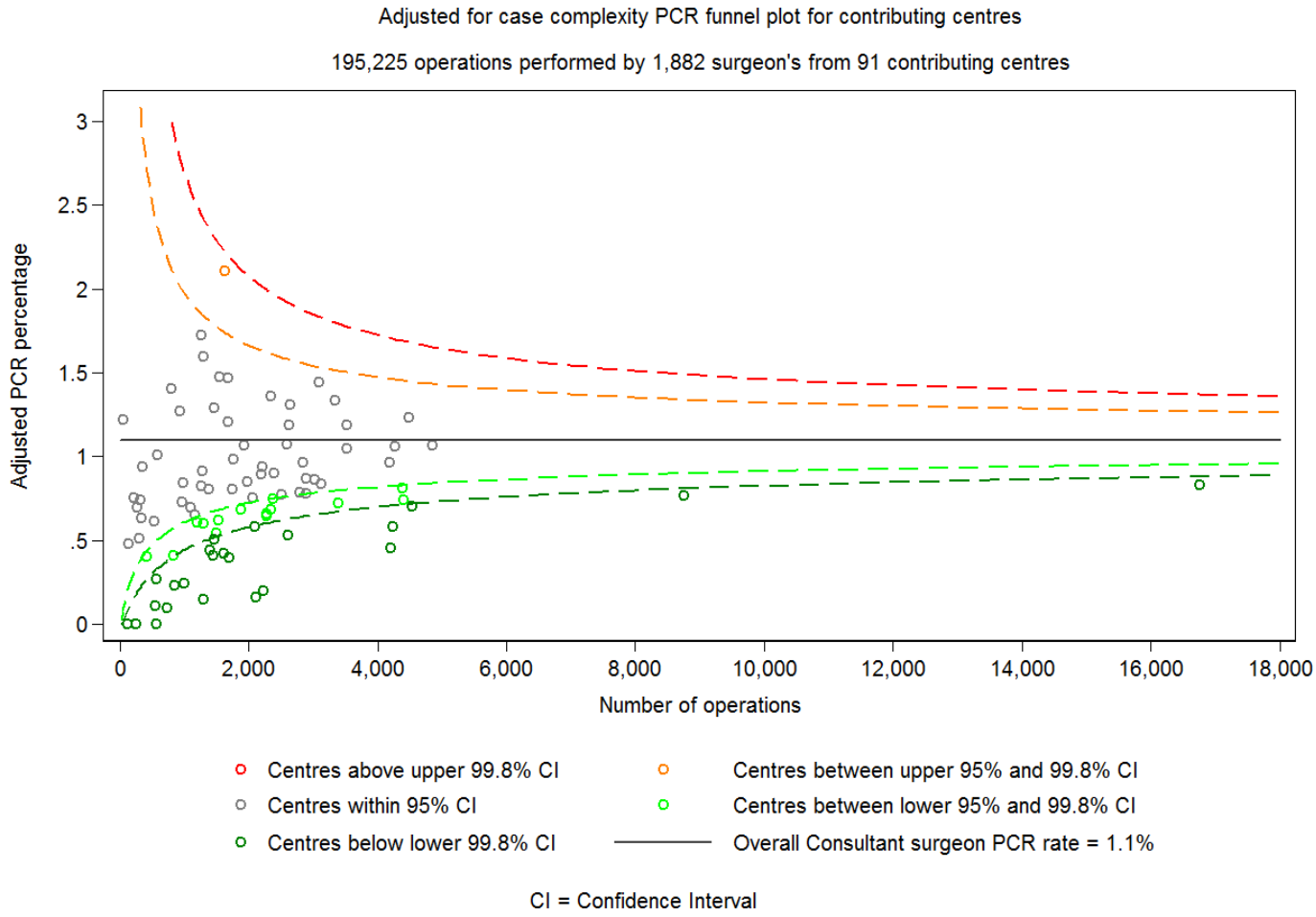

Table 2: Upper boundaries of the 95% (alert level) and 99.8% (alarm level) confidence intervals for the RCOphth NOD comparator values

	PCR (comparator value = 1.1%)		Vision Loss (comparator value = 0.9%)	
Number of operations	Alert level (+2 SD)	Alarm level (+3 SD)	Alert level (+2 SD)	Alarm level (+3 SD)
50	13.69	39.71	14.60	45.16
100	6.79	16.62	6.75	18.03
150	4.91	10.50	4.71	10.92
200	4.03	7.88	3.79	7.96
300	3.19	5.56	2.92	5.41
400	2.77	4.50	2.50	4.28
500	2.51	3.89	2.25	3.64
600	2.34	3.49	2.08	3.23
700	2.21	3.20	1.95	2.94
800	2.12	2.99	1.86	2.73
900	2.04	2.83	1.78	2.56
1,000	1.98	2.70	1.72	2.43
1,100	1.92	2.59	1.67	2.32
1,200	1.88	2.49	1.63	2.23
1,300	1.84	2.42	1.59	2.15
1,400	1.80	2.35	1.56	2.08
1,500	1.77	2.29	1.53	2.03
2,000	1.66	2.08	1.42	1.82
3,000	1.54	1.85	1.31	1.60
4,000	1.47	1.73	1.25	1.48
5,000	1.43	1.65	1.20	1.41
6,000	1.40	1.59	1.17	1.35
7,000	1.37	1.55	1.15	1.31
8,000	1.35	1.51	1.13	1.28
9,000	1.34	1.49	1.12	1.25
10,000	1.32	1.46	1.11	1.23
15,000	1.28	1.39	1.06	1.16

PCR and Vision Loss model fitting

The categorisation of each covariate considered for the PCR and Vision Loss mixed effects logistic regression models are detailed in Table 3. The models were fitted on the sample of all eligible operations performed in the 2011-12 to 2014-15 NHS years. The prospective audit reported yearly periods between 1st September and 31st August and for the models developed from the 'legacy' data. Starting from the prospective audit year 5, the audit year has changed to the NHS year (1st April to 31st March) with the first NHS year being the 2020 NHS year, and all pre-year 5 results estimated for the equivalent previous NHS years.

The same model fitting approach was used for both PCR and Vision Loss models, where covariates of interest were first investigated on the univariate level using Pearson's Chi-squared tests. Covariates that were significant at the 10% level were fitted into the multivariate models on a 'test sample' using backwards selection and a significance level of 5% to remain in the model. The individual surgeons were considered as the random effect and all other covariates were fitted as fixed effects. An identity matrix was used to model the covariance structure, this sets equal variances for the random effects and all covariance's to be zero and is the appropriate structure to use when factor variables are specified in a model.

To create the 'test sample' and the 'validation sample' a random number generating allocation from a multivariate normal distribution was used, where negative random numbers allocated an operation to the 'test sample' and positive random numbers allocated an operation to the 'validation sample'. Before the random number allocation was performed the data was sorted (ordered) on all covariates under consideration. The random allocation was performed separately for the PCR and Vision Loss models to remove the potential imbalances that could arise if operations in either the 'test sample' or 'validation sample' for the PCR model did not have the required VA data for inclusion in the Vision Loss model.

Model diagnostics utilised were comparing the deviance residuals to the model predicted values and a comparison with a fixed effects logistic regression model. The final model was then applied to the 'validation sample' for further validation. Full details on the model fitting can be found in separate documents for the PCR and Vision Loss models on the audit website (www.nodaudit.org.uk/resources/methodology).

The data used to fit the PCR and visual loss models was shared with an existing collaboration as part of an NIHR funded cataract research programme for assessment of stability over time.

Table 3: Variables for consideration in a logistic regression model

Variable	Categorisation	Additional information
PCR occurred	No Yes	The dependant variable in the PCR model and an independent variable in the Vision Loss model
Vision Loss occurred	No Yes	The dependent variable in the Vision Loss model and not considered in the PCR model
Preoperative VA (LogMAR)	<0.00 0.00 – 0.30 >0.30 – 0.60 >0.60 – 0.90 >0.90 – 1.20 >1.20	An independent variable in the Vision Loss model and not considered in the PCR model
Age at surgery	<70 years 70 – 74 years 75 – 79 years 80 – 84 years 85 – 89 years ≥90 years	If missing data constitutes <2% of the sample, then impute the mean age of patients with data using first treated eyes for missing first treated eye age and second treated eyes for missing second treated eye age. If missing age constitutes ≥2% of the sample then fit into the models as a variable level.
Gender	Female Male	If missing gender or gender recorded as "Not Specified" allocate as "Female" unless missing data constitutes ≥2% of the sample, if so fit as a variable level in the models
Index of multiple deprivations (IMD) score	Quintiles	If missing, infer within each centre the mean IMD score for that centre.
Patient ability to lie flat	No Yes	If missing, assume "Yes"
Patient ability to co-operate	No Yes	If missing, assume "Yes"
Patient taking any alpha-blockers	No Yes	"No" if no medication recorded or "Not taking medication" is recorded "Yes" if patient taking any of; Alfuzosin Doxazosin Indoramin Parazosin Tamzolosin Terazosin

Axial length	<20 mm 20 – 28 mm >28 mm	If missing data constitutes <2% of the sample allocate to "20 – 28 mm", if ≥2% of the sample fit as a variable level in the models.
Pupil size	Large Medium Small	If missing, assume "Large"
Surgeon grade	Consultant Career grade non-consultant Experienced trainee Inexperienced trainee	 Staff grade associate specialists trust doctors Fellows registrars specialty registrars' years 3 - 7 specialty trainees' years 3 – 7 SHO specialty trainees' years 1-2 specialty registrars' years 1 - 2 foundation doctors years 1 - 2
First eye surgery	No Yes	Bilateral surgery can be included with "Yes" for both eyes under the assumption that any difference in PCR likelihood between a first and second eye operation from the patients age and grade of operating surgery do not apply to bilateral surgery. If missing and only one operated eye per patient, assume "Yes"
Ocular co-pathology / known risk indicator	Amblyopia	
	AMD	In the legacy data Wet AMD and Dry AMD could not be separated, in the prospective data this is now possible
	Brunescent / White Cataract	
	Corneal Pathology	
	DR	
	Glaucoma	
	High Myopia	

	Inherited eye disease	
	No fundal view / Vitreous Opacities	
	Optic nerve / CNS disease	
	Other Macular pathology	Including 'Epiretinal Membrane' and 'Macular Hole' as recorded ocular co-pathology.
	Other Retinal Vascular pathology	
	Previous Trabeculectomy	
	Previous Vitrectomy*	Any previous operation that included a Pars Plana Vitrectomy, plus 'Retinal Detachment' as a recorded ocular co-pathology.
	Psuedoexfoliation / Phacodenesis	In the legacy analysis these could not be separated, in the prospective data this is now possible
	Uveitis / Synaechiae	
	Other	

*In the 'legacy' data used to create the case complexity adjustment models, Epiretinal Membrane, Macular Hole and Retinal Detachment were recorded as ocular co-pathologies without specifying if with or without a previous vitrectomy surgery. For the case complexity adjustment models both Epiretinal Membrane and Macular Hole are classified as "Other macular pathology" while Retinal Detachment is classified as "Previous vitrectomy". In the prospective analysis these terms can be recorded and specified with a previous vitrectomy surgery or not to allow better modelling of these complex eye conditions in any future re-fitted risk model using the prospective data.

17 Changes for the prospective national cataract audit

Audit year

For the prospective cataract audit years 1, 2, 3 and 4 the audit year was 1st September to 31st August. Starting from the prospective audit year 5, the audit year changed to the NHS year (1st April to 31st March) with all previous year's results in the audit reports equating to previous NHS years.

Posterior capsule rupture

Three of the covariates used in the development of the PCR case complexity adjustment model are not currently used in the calculation of reported adjusted PCR rates in the prospective national cataract audit, these are;

- the presence of optic nerve / CNS disease
- the presence of other macular pathology
- Index of multiple deprivation (IMD)

The two ocular co-pathologies are not used due to concerns raised by surgeons that the PCR risk model suggested a protective effect against PCR. This view is considered to be counter-intuitive by many ophthalmologists and as these results were based on small numbers, it is possible that the seemingly protective effect was an artefact of the rareness of the conditions in the model sample. The IMD is not used as many centres did not historically contribute this data.

The comparator value used for the case complexity adjustment of PCR has been lowered from 2.0% used in the 'legacy' analysis and the first prospective year of the audit to 1.1% for the subsequent prospective audit years; this decision was made after considering the decreasing rates of PCR for the equivalent audit year periods from 2010 to 2017. The chosen value closely reflects the current average for the reference group, i.e. consultant surgeons.

Visual acuity

For the second prospective year of the audit, the preoperative VA time period was extended from 90 days prior to surgery to 4 months prior to surgery, and for the third prospective audit year to 6 months prior to surgery. This was to increase the sample of eyes with a preoperative VA from centres that might have longer times between original assessment and listing for surgery to the actual day of surgery. In the annual reports information is provided for each centre on the proportion of eyes that had a preoperative VA measurement if using different time period prior to cataract surgery, for example 3 months, 4 months, 5 month and 6 months.

Postoperative Vision Loss

Two of the covariates used in the development of the postoperative Vision Loss case complexity adjustment model are not used in the calculation of reported adjusted visual loss rates for the prospective national cataract audit, these are;

- the presence of high myopia
- the occurrence of PCR

The presence of high myopia is not used due to concerns raised by surgeons that the Vision Loss risk model suggested a protective effect against visual acuity loss. This view is considered to be counter-intuitive by many ophthalmologists and as this result was based on small numbers, it is possible that the seemingly protective effect was an artefact of the rareness of the condition in the model sample. There are optical explanations for the protective effect of myopia, in that spectacles for myopes minify images, hence creating an artefactually poor visual acuity and explaining the superior acuity gained by contact lens use in myopes. In axial myopia there is some compensation for this minification as the retina is further away from the lens, hence there is relative magnification of the image at the retina. After cataract surgery, in which the refractive aim will usually be closer to emmetropia than pre-operatively, the magnification of images due to greater axial length remains, but the spectacle minification does not, hence myopes derive greater acuity gains from cataract surgery which could protect them from appearing as cases of visual loss in the audit. We therefore anticipate including high myopia in a future re-fitted Vision Loss model.

Adjustment for the occurrence of PCR in the Vision Loss model is not done as doing so would artificially reduce the adverse VA impact of this event on VA outcome. For a surgeon or centre,

a Vision Loss result is only produced if there is less than 40% of their sample with missing preoperative and postoperative VA data, and at least 50 eligible operations with both a preoperative and postoperative VA measurement.

The comparator value used for the case complexity adjustment of postoperative Vision Loss has been lowered from 1.5% used in the 'legacy' analysis and the first prospective year of the audit to 0.9% for subsequent prospective audit years; this decision was made after considering the decreasing rate of Vision Loss for the equivalent audit years from 2010 to 2017. The chosen value more closely reflects the current average for the reference group, i.e., consultant surgeons, while still using a value higher than the observed postoperative Vision Loss as a precaution due to the variable amount of missing VA data between centres.

Ocular co-pathology / known risk indicator

In the case complexity models the national cataract audit analysis has to assume that absence of any record of ocular co-pathology / know risk indicator data equates to the absence of the ocular co-pathology / known risk indicator in the eye.

The data submission for Open Eyes centres includes a description of the terms allocated to 'unspecified other' ocular co-pathology; these descriptions include existing ocular co-pathologies, cataract subtypes and systemic diseases or eye conditions that are not an ocular co-pathology for cataract surgery. This information has been used to improve the accuracy of the ocular co-pathology / known risk indicator data for centres using the Open Eyes EMR.

In the prospective cataract audit both Adnexal and Oculomotility are included with "Unspecified other". When the risk factor models are re-fitted both of these conditions will be investigated and if indicative of increased risk, introduced as new ocular co-pathology / known risk indicator used in the audit.

Currently in the prospective national cataract audit results, Fuchs's Endothelial Dystrophy is combined to corneal pathology and Stickler syndrome combined with "unspecified other" due to the infrequency of the recording of these conditions.

Full details for how ocular co-pathology / known risk factors are classified in the RCOphth NOD audits can be found on the audit website (www.nodaudit.org.uk/resources/methodology).

Case ascertainment

For national cataract audit years 1 to 4, case ascertainment was reported for the September to August audit year and the denominator was provided to the audit for these time periods by NHS Digital and DCHW (from audit year 2 onwards). As of prospective audit year 5, the time period for reporting is the NHS year (April to March) and the audit has received data for this time period since.

For the 2016, 2017 and 2018 NHS years, the denominator is re-calculated using fractions of consecutive previous audit year September to August totals, with 5/12 of the 'first' year total and 7/12 of the 'second' year total to account for the previous audit year time periods overlapping NHS years. This is only possible from the 2016 NHS year onwards.

18 Risk model reviewing

The RCOphth NOD aims to use case complexity adjustment models that reflect current practice as accurately as we can, we aim to adequately adjust for the risk factors that the models indicate are significant. For this to be achieved requires periodic reviewing of the comparator values and the model risk factors, the comparator values were lowered for the second year of the prospective audit, the Vision Loss definition has been revised, preparation for re-fitting the PCR risk factor model has started, and the re-fitting of the PCR model is scheduled for May 2023.

19 Audit reporting destinations

Reporting destinations

The prospective national cataract audit results are published in annual reports available on the RCOphth NOD website. Results for centres are supplied to the Care Quality Commission (CQC) and on the completion of an audit year; a data set is uploaded to data.gov and is accessed by the Getting It Right First Time Programme (GIRFT).

Annual reports - Centre adjusted PCR and Vision Loss results are provided for all operations performed in a centre including operations performed by trainee surgeons. A minimum of 50 eligible operations per centre is required for inclusion. Case complexity adjusted graphs display the 99.8% confidence interval, but not the 95% confidence interval. For results of VA measurements, at least 50 eligible operations with a VA measurement are required.

For the CQC - Centre adjusted PCR and Vision Loss results are provided for all operations performed in a centre including operations performed by trainee surgeons. A minimum of 50 eligible operations per centre is required for inclusion. The CQC will have the data for displaying both the 95% and 99.8% confidence intervals.

For the RCOphth NOD website (www.nodaudit.org.uk):

Behind the secure log-in - Centre and surgeon unadjusted and adjusted PCR and Vision Loss results are available behind a secure log-in for access by relevant staff in participating centres. Date searching functionality is available when the data covers a period longer than the official prospective audit period. The adjusted graphs display the 95% and 99.8% confidence intervals. The aim is for clinical staff from participating centres to be able to use these results for internal audits and revalidation.

Public facing – The RCOphth NOD website has a public facing section where centres and individual surgeons adjusted PCR and Vision Loss results for the audit period are available. All surgeons data is included in the centres results, while named surgeons results do not include trainee surgeons.

For data.gov – Once reporting of the data to all sources has been completed the audit data sets are uploaded to data.gov.

For GIRFT – Once the data sets have been uploaded to data.gov, the GIRFT programme are informed so that the GIRFT team can access the data for their use.