The Royal College of Ophthalmologists' National Ophthalmology Database Audit

RCOphth NOD Audit Posterior Capsular Rupture statistical model

Fifth year of the prospective audit

Document author

Paul Henry John Donachie

Medical Statistician for the RCOphth NOD

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1 The RCOphth NOD 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

Xolani Annakie – 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 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
AUROC	Area under the receiver operator curve
AMD	Age-related Macular Degeneration
CI	Confidence Interval
CNS	Central nervous system
CQC	Care Quality Commission
CV	Comparator Value
DR	Diabetic Retinopathy
EMR	Electronic Medical Record
GIRFT	Getting It Right First Time Programme
IMD	Index of multiple deprivations
IOL	Intra-ocular lens
NHS	National Health Service
NOD	National Ophthalmology Database
PCR	Posterior capsule rupture
RCOphth	Royal College of Ophthalmologists'
SD	Standard Deviation
UK	United Kingdom
VEGF	Vascular Endothelial Growth Factor

3 Acknowledgements

The National Ophthalmology Database Audit (NOD) is conducted under the auspices of the Royal College of Ophthalmologists (RCOphth) and conducts the National Cataract Audit focusing 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 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 all providers of both National Health Service (NHS) and privately funded cataract surgery in England, Scotland, Northern Ireland, Wales and the Channel Islands. 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.

Every year, around 400,000 patients in England and 20,000 patients in Wales undergo NHS cataract surgery – the most frequently performed incisional surgical procedure in the UK. A widely accepted indicator of surgical quality is the frequency of posterior capsule rupture with or without vitreous prolapse into the anterior chamber of the eye, or zonule rupture with vitreous loss, abbreviated as PCR. This operative complication arises on average in approximately 1 operation in 50 but the risk of this event varies by as much as 50 fold depending on preoperative risk factors associated with the patient, their eye and the grade of the surgeon. When this surgical complication occurs there is a 6 fold higher chance of significant visual loss after surgery.

Case-complexity adjustment is therefore necessary for fair comparisons between surgeons and centres performing cataract surgery. Case complexity adjusted PCR and visual loss were chosen as the two primary outcome measures of cataract surgery in the National Cataract Audit.

This document contains the methodology that was used to create the case complexity adjusted PCR model that has applied to the prospective cataract audit. The model was created from 'legacy' data extracted from 40 contributing centres, 34 of which contributed cataract surgery data.

Full details of the RCOphth NOD can be found on the RCOphth NOD websites (www.nodaudit.org.uk).

5 Statistical methods

Data were extracted from participating centres that used the Medisoft (Medisoft Ophthalmology, Medisoft Limited, Leeds, UK) electronic medical record (EMR) system in November 2015 and all analysis was conducted using STATA version 11, (StataCorp. 2009. Stata Statistical Software: Release 11. College Station, TX: StataCorp LP). Centre participation was approved by the Caldicott Guardian (responsible for data protection) and Clinical Lead for Ophthalmology.

A mixed effects logistic regression model was fitted to all eligible cataract operations performed during the 2011 – 2014 NHS years (01 April 2011 – 31 March 2015). The criteria for an eligible cataract operation can be found on the RCOphth NOD website (https://www.nodaudit.org.uk/resources/methodology) and the outcome variable was PCR which was defined as follows;

PCR was identified from four stages of the cataract pathway, intra-operative complications, operative procedures, post-operative complications and post-cataract surgery. Thus PCR was considered to have occurred if any of these parts of the cataract operation had PCR indicated.

Intra-operative procedures: If any of the following were recorded then PCR was considered to have occurred;

- IOL into the vitreous
- Nuclear/ epinuclear fragment into vitreous / lens fragments into vitreous
- PC rupture - vitreous loss
- PC rupture – no vitreous loss
- Vitreous loss
- Vitreous to the section at end of surgery

- Zonule rupture – vitreous loss

Operative procedures: If any of the following were performed in combination with the phacoemulsification cataract procedure then PCR was considered to have occurred;

- Sponge and scissors vitrectomy
- Automated anterior vitrectomy
- Scleral fixed IOL
- Fragmatome lensectomy ± IOL
- Removal of retained lens fragments combined with a pars plana vitrectomy

Post-operative complications/surgery: If any of the following were recorded then PCR was considered to have occurred;

- If either of 'vitreous to the section' or 'vitreous in the AC' are recorded within 8 weeks of cataract surgery, (including the day of cataract surgery)*
- If there is a record of a dropped nucleus operation with 90 days of cataract surgery, (including the day of cataract surgery)

* Medisoft have indicated that they will be adding the provision for the recording of a post-operative complication of "spontaneous egress of vitreous anteriorly not attributable to intra-operative complication" to reduce misclassification of such cases as PCR.

All covariates of interest were fitted to the model as fixed effects and the individual surgeons were fitted as the random effect. 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.

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 to the multivariate models on a 'test sample' using backwards selection and a significance level of 5% to remain in the model. The final model from the 'test' sample was then applied to a 'validation' sample for comparison.

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.

Model diagnostics utilised were comparing the deviance residuals to the model predicted values and the model fitting process also automatically performs a comparison with a fixed effects logistic regression model to ascertain if the random effects are needed.

From the final model on the 'test' sample case complexity adjusted PCR graphs for surgeons and centres are created using funnel plots for the audit period being reported (see annual reports at https://www.nodaudit.org.uk). The case complexity adjusted PCR graphs include 95% and 99.8% confidence limits plotted using the logit transform and a comparator value of 1.1% which has been reduced from 2.0% used in 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 categorisation of each covariate under investigation in the PCR mixed effects logistic regression model are detailed in Table 1.

Table 1: Variables for consideration in the mixed effects logistic regression model

Variable	Categorisation	Additional information
Surgeon grade	Consultant	
	Career grade non-consultant	Staff grade associate specialists trust doctors
	Experienced trainee	Fellows registrars specialty registrars' years 3 - 7 specialty trainees' years 3 – 7
	Inexperienced trainee	SHO specialty trainees' years 1-2 specialty registrars' years 1 - 2 foundation doctors years 1 - 2
Patient variables		
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 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

Patient ability to lie flat	No Yes	If missing, assume “Yes”
Patient ability to co-operate	No Yes	If missing, assume “Yes”
Eye variables		
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”
Pupil size	Large Medium Small	If missing, assume “Large”
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.
Ocular co-pathology / known risk indicator		
	AMD	In the legacy data Wet AMD and Dry AMD could not be separated, in the prospective data this is now possible
	Amblyopia	
	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 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 terms could not be separated, in the prospective data this is now possible
	Uveitis / Synaechiae	
	Other	

In the ‘legacy’ data Epiretinal Membrane, Macular Hole and Retinal Detachment were recorded as ocular co-pathologies without specifying if with or without a previous vitrectomy surgery. In the model fitting both Epiretinal Membrane and Macular Hole were classified as “Other macular pathology” while Retinal Detachment was classified as “Previous vitrectomy”. In the prospective analysis these terms can be recorded and specified as with a previous vitrectomy surgery or not and could be fitted into any model of prospective data separately.

6 PCR case complexity adjustment modelling results

In total, 34 centres recorded 602,459 eligible cataract operations on the RCOphth NOD, 287,093 of which were performed since the start of the 2011 NHS year and were eligible for use in the PCR case complexity adjustment model development. PCR was recorded in 4,672 (1.7%) operations.

The rates of PCR for each covariate under consideration for inclusion in the PCR model are shown in Table 2, by the random allocation of operations to the 'test sample' and the 'validation sample' and with univariate analysis on the whole sample.

There were some discrepancies between the proportion of eyes with PCR in the 'test sample' and 'validation sample' for the following covariates, axial length, optic nerve / CNS disease, ability to lie flat, ability to co-operate, inherited eye disease, other macular pathology and other retinal pathology. Discrepancies in the outcome variable between samples used for model fitting are not ideal, but the allocation was random, discrepancies can occur randomly and the covariates with a discrepancy are rare prevalence events.

The covariates that were significant at the 10% level from the univariate Chi-Squared tests were as follows; surgeon grade, patient gender, age at surgery, IMD scores, patient ability to lie flat, first eyes surgery, pupil size, amblyopia, brunescent / white cataract, DR, glaucoma, high myopia, no fundal view / vitreous opacities, optic nerve / CNS disease, other macular pathology, previous trabeculectomy, previous vitrectomy, pseudoexfoliation / phacodonesis and unspecified other co-pathology. These covariates were all investigated in the PCR mixed effects model.

Table 2: Covariates under consideration in the PCR model with rates of PCR for each covariate by the 'test sample' and the 'validation sample', and with univariate hypothesis testing on the whole sample.

	Test sample N = 143,489		Validation sample N = 143,604		Overall PCR N = 287,093		
	No PCR	PCR	No PCR	PCR	No PCR	PCR	p-value
Number of eyes	**141,170**	**2,319 (1.6)**	**141,251**	**2,353 (1.6)**	**282,421**	**4,672 (1.7)**	**N/A**
Surgeon grade							
Consultants	86,143	1,109 (1.3)	85,714	1,172 (1.3)	171,857	2,281 (1.3)	
Career grade non-consultants	18,031	270 (1.5)	18,459	292 (1.6)	36,490	562 (1.5)	<0.001
Experienced trainees	32,346	781 (2.4)	32,526	752 (2.3)	64,872	1,533 (2.3)	
Inexperienced trainees	4,650	159 (3.3)	4,552	137 (2.9)	9,202	296 (3.1)	
Patient variables							
Age (years)							
<70	36,370	528 (1.4)	36,461	576 (1.6)	72,831	1,104 (1.5)	
70 – 74	22,012	340 (1.5)	22,055	347 (1.5)	44,067	687 (1.5)	
75 – 79	29,973	458 (1.5)	29,854	427 (1.4)	59,827	885 (1.5)	<0.001
80 – 84	28,875	510 (1.7)	28,895	490 (1.7)	57,770	1,000 (1.7)	
85 – 89	17,648	337 (1.9)	17,642	357 (2.0)	35,290	694 (1.9)	
≥90	6,292	146 (2.3)	6,344	156 (2.4)	12,636	302 (2.3)	
Gender							
Female	82,393	1,292 (1.5)	82,216	1,304 (1.6)	164,609	2,596 (1.6)	<0.001
Male	58,777	1,027 (1.7)	59,035	1,049 (1.7)	117,812	2,076 (1.7)	
Index of multiple deprivation							
First quintile	30,812	485 (1.5)	30,742	466 (1.5)	61,554	951 (1.5)	
Second quintile	29,059	412 (1.4)	29,264	446 (1.5)	58,323	858 (1.4)	
Third quintile	27,462	421 (1.5)	27,359	417 (1.5)	54,821	838 (1.5)	<0.001
Fourth quintile	27,821	480 (1.7)	27,771	494 (1.7)	55,592	974 (1.7)	
Fifth quintile	26,016	521 (2.0)	26,115	530 (2.0)	52,131	1,051 (2.0)	

Taking alpha-blockers							
No	131,455	2,170 (1.6)	131,581	2,181 (1.6)	263,036	4,351 (1.6)	0.985
Yes	9,715	149 (1.5)	9,670	172 (1.7)	19,385	321 (1.6)	
Able to lie flat							
Yes	140,302	2,296 (1.6)	140,450	2,325 (1.6)	280,752	4,621 (1.6)	<0.001
No	868	23 (2.6)	801	28 (3.4)	1,669	51 (3.0)	
Able to cooperate							
Yes	140,200	2,303 (1.6)	140,314	2,343 (1.6)	280,514	4,646 (1.6)	0.325
No	970	16 (1.6)	937	10 (1.1)	1,907	26 (1.3)	
Eye variables							
1st or 2nd treated eye							
1st treated eye	82.,838	1,441 (1.7)	82,898	1,480 (1.8)	165,736	2,921 (1.7)	<0.001
2nd treated eye	58,332	878 (1.5)	58,353	873 (1.5)	116,685	1,751 (1.5)	
Pupil size							
Large	108,003	1,693 (1.5)	107,982	1,708 (1.6)	215,985	3,401 (1.6)	
Medium	27,742	495 (1.8)	27,774	503 (1.8)	55,516	998 (1.8)	<0.001
Small	5,425	131 (2.4)	5,495	142 (2.5)	10,920	273 (2.4)	
Axial Length							
< 21 mm	211	2 (0.9)	223	5 (2.2)	434	7 (1.6)	
21 – 28 mm	139,445	2,288 (1.6)	139,460	2,318 (1.6)	278,905	4,606 (1.6)	0.534
>28 mm	1,514	29 (1.9)	1,568	30 (1.9)	3,082	59 (1.9)	
Ocular co-pathology / known risk indicator							
AMD							
No	126,487	2,045 (1.6)	126,377	2,108 (1.6)	252,864	4,153 (1.6)	0.155
Yes	14,683	274 (1.8)	14,874	245 (1.6)	29,557	519 (1.7)	
Amblyopia							
No	138,930	2,263 (1.6)	138,975	2,297 (1.6)	277,905	4,560 (1.6)	<0.001
Yes	2,240	56 (2.4)	2,276	56 (2.4)	4,516	112 (2.4)	
Brunescent / white							

cataract							
No	135,905	2,047 (1.5)	135,846	2,067 (1.5)	271,751	4,114 (1.5)	<0.001
Yes	5,265	272 (4.9)	5,405	286 (5.0)	10,670	558 (5.0)	
Corneal pathology							
No	136,891	2,255 (1.6)	136,925	2,278 (1.6)	273,816	4,533 (1.6)	0.777
Yes	4,279	64 (1.5)	4,326	75 (1.7)	8,605	139 (1.6)	
Diabetic retinopathy							
No	132,071	2,134 (1.6)	132,012	2,167 (1.6)	264,083	4,301 (1.6)	<0.001
Yes	9,099	185 (2.0)	9,239	186 (2.0)	18,338	371 (2.0)	
Glaucoma							
No	127,592	2,077 (1.6)	127,697	2,101 (1.6)	255,289	4,178 (1.6)	0.026
Yes	13,578	242 (1.8)	13,554	252 (1.8)	27,132	494 (1.8)	
High Myopia							
No	135,117	2,189 (1.6)	135,150	2,248 (1.6)	270,267	4,437 (1.6)	0.015
Yes	6,053	130 (2.1)	6,101	105 (1.7)	12,154	235 (1.9)	
Inherited eye disease							
No	140,929	2,317 (1.6)	141,001	2,347 (1.6)	281,930	4,664 (1.6)	0.966
Yes	241	2 (0.8)	250	6 (2.3)	491	8 (1.6)	
No fundal view / vitreous opacities							
No	139,783	2,246 (1.6)	139,779	2,282 (1.6)	279,562	4,528 (1.6)	<0.001
Yes	1,387	73 (5.0)	1,472	71 (4.6)	2,859	144 (4.8)	
Optic nerve / CNS disease							
No	140,609	2,317 (1.6)	140,674	2,346 (1.6)	281,283	4,663 (1.6)	0.024
Yes	561	2 (0.4)	577	7 (1.2)	1,138	9 (0.8)	
Other macular pathology							
No	138,615	2,290 (1.6)	138,726	2,313 (1.6)	277,341	4,603 (1.6)	0.100
Yes	2,555	29 (1.1)	2,525	40 (1.6)	5,080	69 (1.3)	
Other retinal pathology							

No	139,577	2,286 (1.6)	139,677	2,325 (1.6)	279,254	4,611 (1.6)	0.236
Yes	1,593	33 (2.0)	1,574	28 (1.7)	3,167	61 (1.9)	
Previous trabeculectomy							
No	140,338	2,292 (1.6)	140,419	2,331 (1.6)	280,757	4,623 (1.6)	<0.001
Yes	832	27 (3.1)	832	22 (2.6)	1,664	49 (2.9)	
Previous vitrectomy							
No	138,451	2,270 (1.6)	138,446	2,295 (1.6)	276,897	4,565 (1.6)	0.102
Yes	2,719	49 (1.8)	2,805	58 (2.0)	5,524	107 (1.9)	
Pseudoexfoliation / phacodenesis							
No	139,655	2,238 (1.6)	139,742	2,280 (1.6)	279,397	4,518 (1.6)	<0.001
Yes	1,515	81 (5.1)	1,509	73 (4.6)	3,024	154 (4.8)	
Uveitis / Synaechiae							
No	139,815	2,290 (1.6)	139,871	2,328 (1.6)	279,686	4,618 (1.6)	0.195
Yes	1,355	29 (2.1)	1,380	25 (1.8)	2,735	54 (1.9)	
Unspecified Other							
No	135,238	2,158 (1.6)	135,254	2,190 (1.6)	270,492	4,348 (1.6)	<0.001
Yes	5,932	161 (2.6)	5,997	163 (2.6)	11,929	324 (2.6)	

‘Test sample’ model fitting;

The best fitting model (‘test sample’) did not include pupil size, glaucoma or previous vitrectomy surgery, Table 3. The comparison with a fixed effect logistic regression model yielded a p-value of <0.001 in favour of the inclusion of the random effect.

‘Validation sample’ model fitting;

The best fitting model from the ‘test sample’ was applied to the ‘validation sample’, Table 4. The comparison with a fixed effects logistic regression model yielded a p-value of <0.001 in favour of inclusion of the random effect.

PCR model comparisons;

There were only minor differences between the ‘test’ and ‘validation’ models, which were for optic nerve / CNS disease and other macular pathology which were both massively non-significant in the validation model. Both of these ocular co-pathologies were covariates with a discrepancy in the random allocation to the model groups regarding the proportion of eyes with PCR, and other macular co-pathology was a borderline covariate for inclusion in the model. At present, these differences are not sufficient for the rejection of the ‘test’ model.

Neither of the ‘test sample’ or ‘validation sample’ PCR models were perfect fits to the data, as can be seen in Figures 1 and 2 there is curvature in the graphs of the deviance residuals against the model predicted values. The ‘test sample’ estimates as predictors for the ‘validation sample’ fitted adequately considering that the outcome is a ‘rare’ event and some surgeons have a small number of operations, these two aspects can lead to ‘zero’ inflation in a sample, Figure 3.

Table 3 Fixed effect estimates from the PCR model on the 'test sample'

Covariate	Odds ratio	coefficient	P>z	95% CI for coefficient
Constant term	N/A	-4.771	<0.000	-4.972 to -4.571
Consultant surgeons	REF	0	N/A	N/A
Career grade non-consultant surgeons	1.568	0.450	<0.001	0.234 to 0.666
More experienced trainee surgeons	1.964	0.675	<0.001	0.539 to 0.811
Less experienced trainee surgeons	2.982	1.093	<0.001	0.868 to 1.317
Age at surgery (years)				
Aged <70	REF	0	N/A	N/A
Aged 70 – 74	1.127	0.119	0.094	-0.020 to 0.259
Aged 75 – 79	1.146	0.136	0.038	0.007 to 0.266
Aged 80 – 84	1.342	0.294	<0.001	0.167 to 0.420
Aged 85 – 89	1.460	0.378	<0.001	0.236 to 0.521
Aged ≥90	1.709	0.536	<0.001	0.344 to 0.727
Quintiles of IMD				
First quintile	REF	0	N/A	N/A
Second quintile	0.922	-0.081	0.238	-0.216 to 0.054
Third quintile	1.004	0.004	0.951	-0.131 to 0.139
Fourth quintile	1.080	0.077	0.254	-0.056 to 0.210
Fifth quintile	1.188	0.172	0.013	0.036 to 0.308
Not able to lie flat	1.753	0.561	0.010	0.135 to 0.987
Females	REF	0	N/A	N/A
Males	1.124	0.117	0.007	0.033 to 0.201
First treated eye	REF	0	N/A	N/A
Second treated eye	0.896	-0.109	0.013	-0.196 to -0.023
Presence of an ocular co-pathology / known risk indicator				
Amblyopia	1.525	0.422	0.003	0.147 to 0.696
Brunescent / white cataract	3.130	1.141	<0.001	0.993 to 1.289
Diabetic retinopathy	1.303	0.265	0.001	0.108 to 0.422
High myopia	1.619	0.482	<0.001	0.297 to 0.667
No fundal view / vitreous opacities	1.677	0.517	<0.001	0.251 to 0.783
Optic nerve / CNS disease	0.221	-1.509	0.034	-2.902 to -0.116
Other macular pathology	0.670	-0.401	0.035	-0.773 to -0.028
Previous trabeculectomy	2.004	0.695	0.001	0.294 to 1.097
Psuedoexfoliation / phacodenesis	3.030	1.108	<0.001	0.870 to 1.345
Unspecified other co-pathology	1.699	0.530	<0.001	0.361 to 0.699

Table 4 Fixed effect estimates from the PCR model on the 'validation sample'

Covariate	Odds ratio	coefficient	P>z	95% CI for coefficient
Constant term	N/A	-4.624	<0.001	-4.822 to -4.425
Consultant surgeons	REF	0	N/A	N/A
Career grade non-consultant surgeons	1.753	0.561	<0.001	0.348 to 0.775
More experienced trainee surgeons	1.732	0.549	<0.001	0.412 to 0.686
Less experienced trainee surgeons	2.346	0.853	<0.001	0.617 to 1.088
Age at surgery (years)				
Aged <70	REF	0	N/A	N/A
Aged 70 – 74	1.072	0.070	0.316	-0.067 to 0.206
Aged 75 – 79	0.972	-0.029	0.664	-0.157 to 0.100
Aged 80 – 84	1.183	0.168	0.009	0.043 to 0.293
Aged 85 – 89	1.386	0.326	<0.001	0.189 to 0.464
Aged ≥90	1.641	0.495	<0.001	0.310 to 0.680
Quintiles of IMD				
First quintile	REF	0	N/A	N/A
Second quintile	1.022	0.022	0.748	-0.111 to 0.155
Third quintile	1.034	0.033	0.630	-0.103 to 0.170
Fourth quintile	1.163	0.151	0.027	0.017 to 0.285
Fifth quintile	1.261	0.232	0.001	0.095 to 0.368
Not able to lie flat	2.189	0.784	<0.001	0.393 to 1.174
Females	REF	0	N/A	N/A
Males	1.125	0.118	0.006	0.034 to 0.201
First treated eye	REF	0	N/A	N/A
Second treated eye	0.866	-0.144	0.001	-0.230 to -0.059
Presence of an ocular co-pathology / known risk indicator				
Amblyopia	1.426	0.355	0.011	0.080 to 0.629
Brunescent / white cataract	3.287	1.190	<0.001	1.046 to 1.334
Diabetic retinopathy	1.232	0.209	0.009	0.052 to 0.365
High myopia	1.236	0.212	0.041	0.009 to 0.415
No fundal view / vitreous opacities	1.316	0.274	0.046	0.005 to 0.544
Optic nerve / CNS disease	0.722	-0.325	0.397	-1.078 to 0.427
Other macular pathology	0.949	-0.052	0.750	-0.372 to 0.268
Previous trabeculectomy	1.718	-0.541	0.016	0.103 to 0.980
Pseudoexfoliation / phacodonesis	2.649	0.974	<0.001	0.724 to 1.224
Unspecified other co-pathology	1.683	0.521	<0.001	0.353 to 0.688

Figure 1: A graph of the deviance residuals vs. predicted values for the 'test sample' model

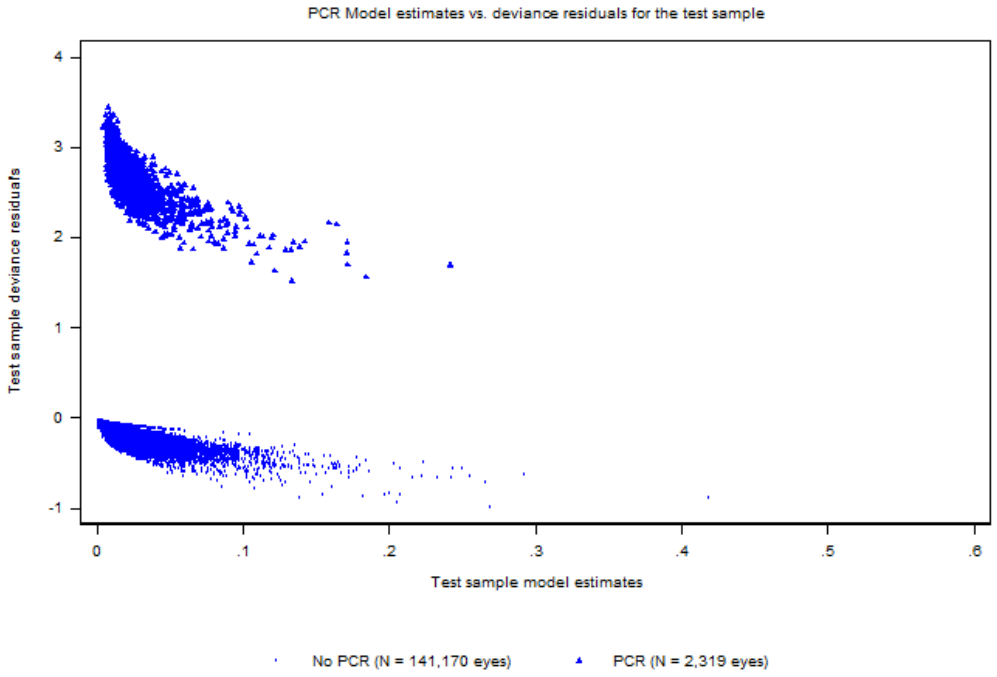


Figure 2: A graph of the deviance residuals vs. predicted values for the 'validation sample' model

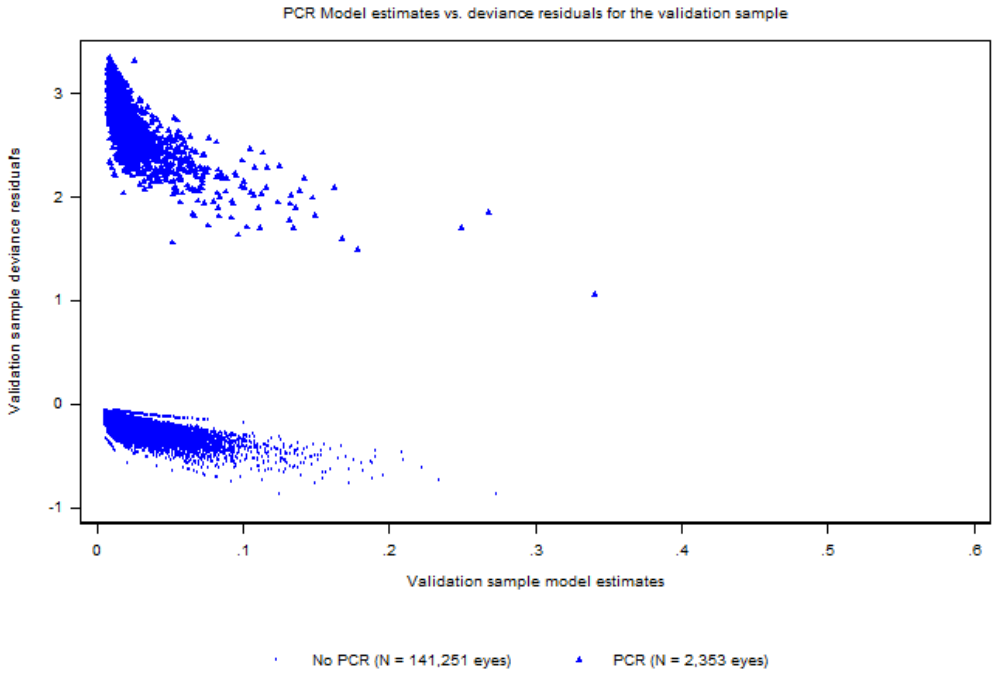
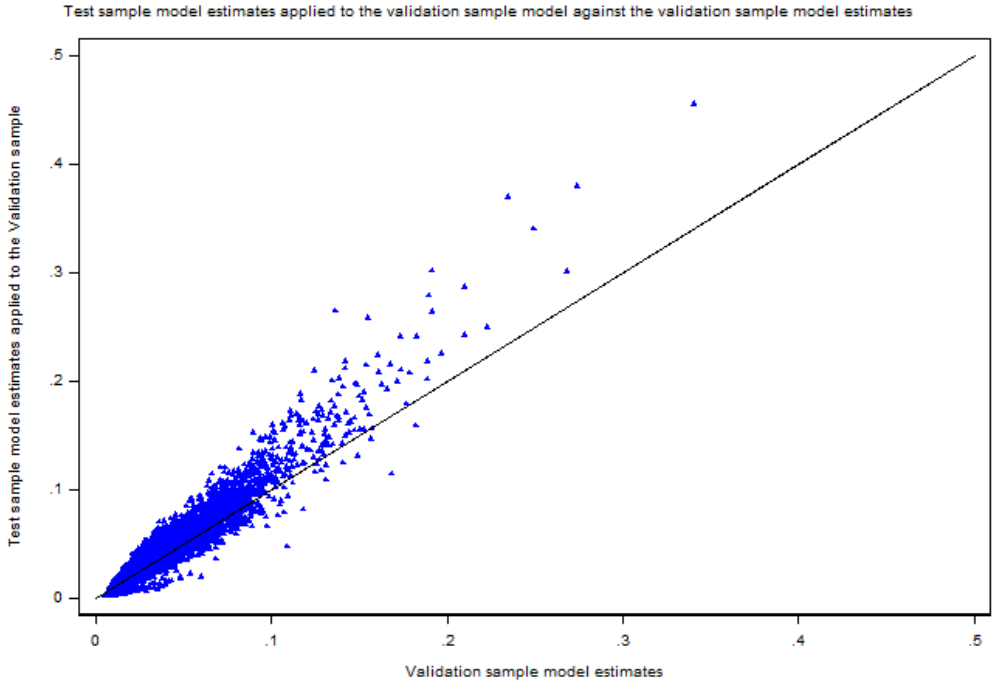


Figure 3: A graph of the 'test sample' PCR model estimates applied to the 'validation sample' against the PCR model estimates from the 'validation sample'



Missing data imputations used in the model;

For this sample the patient's gender was not recorded for 294 (0.1%) operations and was assigned as female. The patient's age was missing for 6 (<0.1%) operations and the mean age by treated eye was inferred respectively (5 first treated eyes and 1 second treated eye). Axial length measurements were missing for 160 (<0.1%) eyes and assigned as 21 – 28 mm. The patient's IMD score was not calculable for 9,393 (3.3%) of operations and each contributing centre had at least 31 operations where the IMD score was not calculable. Within each centre the mean IMD score was inferred for these eyes.

Otherwise no missing data imputations were used. For many variables the non-recording of data is assumed to indicate absence of the issue, for example; no record of the patient taking alpha blockers is assumed to indicate that the patient is not taking alpha blockers and no record of a patient not being able to lie flat or co-operate is assumed to indicate that these were not problems during the operation.

PCR model output examples

Examples of unadjusted and adjusted for case complexity PCR graphs are shown for consultant surgeons and career grade non-consultant surgeons in Figures 4 and 5, and for centres including data from trainee surgeons in Figures 6 and 7. These graphs use data submitted for the completed prospective audit year 3.

Figure 4: Unadjusted for case complexity PCR graph for consultant and career grade non-consultant surgeons; data for audit year 3.

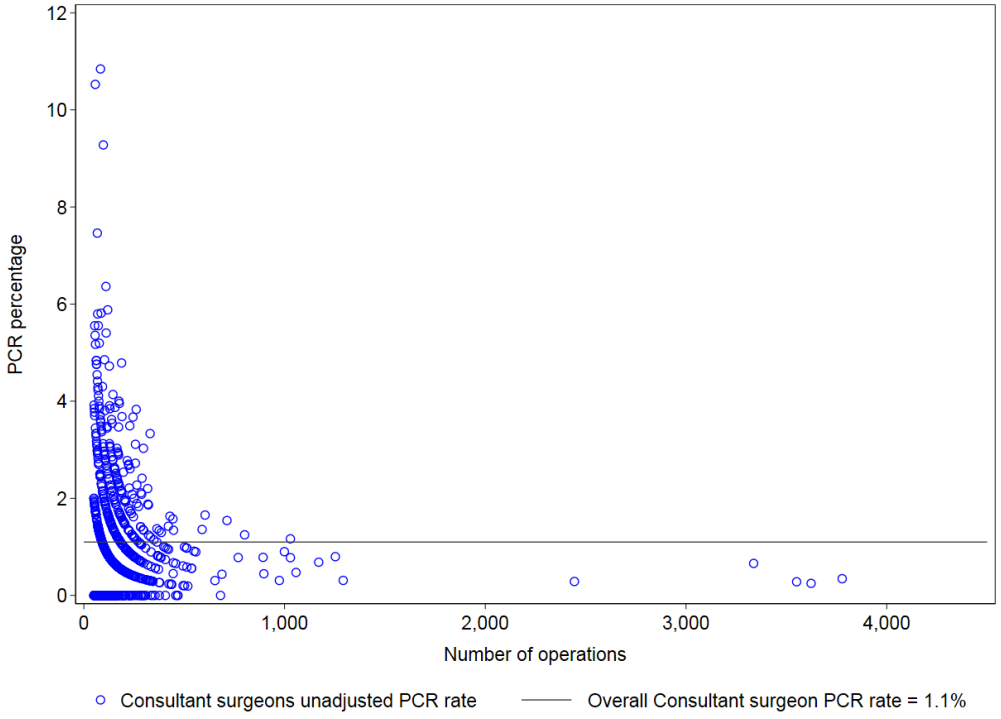


Figure 5: adjusted for case complexity PCR graph for surgeons and career grade non-consultant surgeons; data for audit year 3.

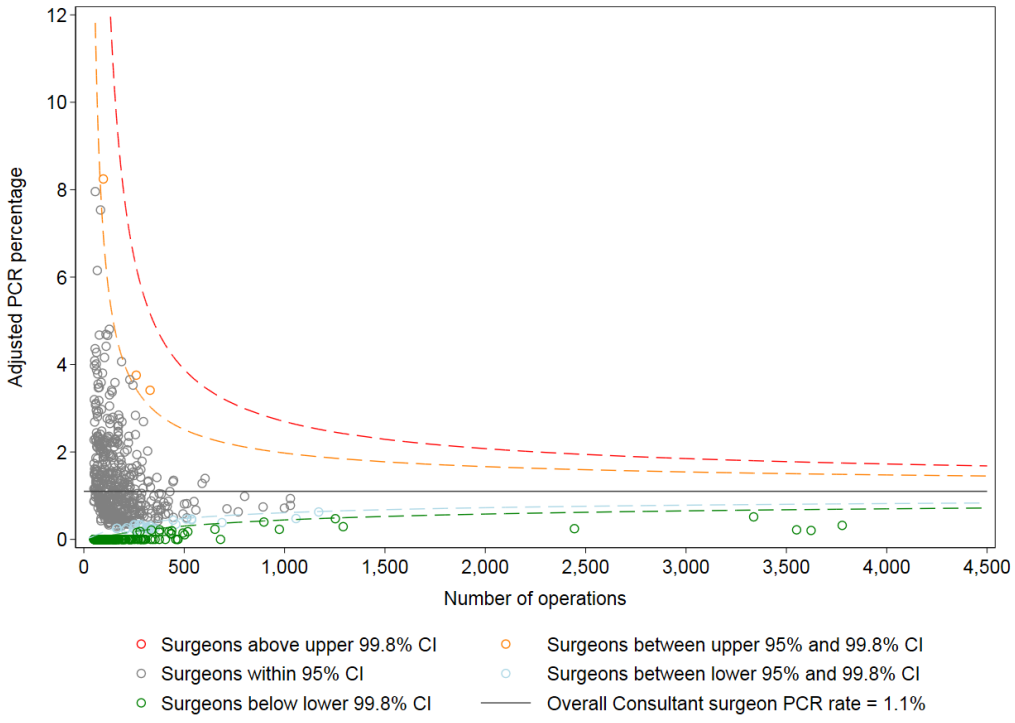


Figure 6: Unadjusted for case complexity PCR graph for centres including all grades of surgeon; data for audit year 3.

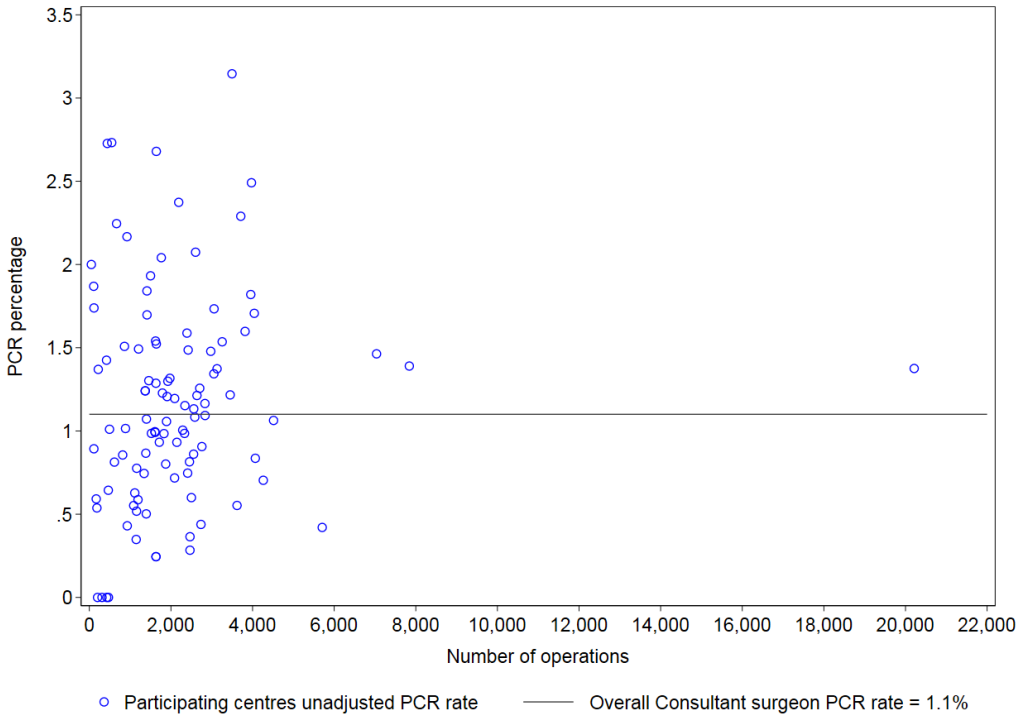
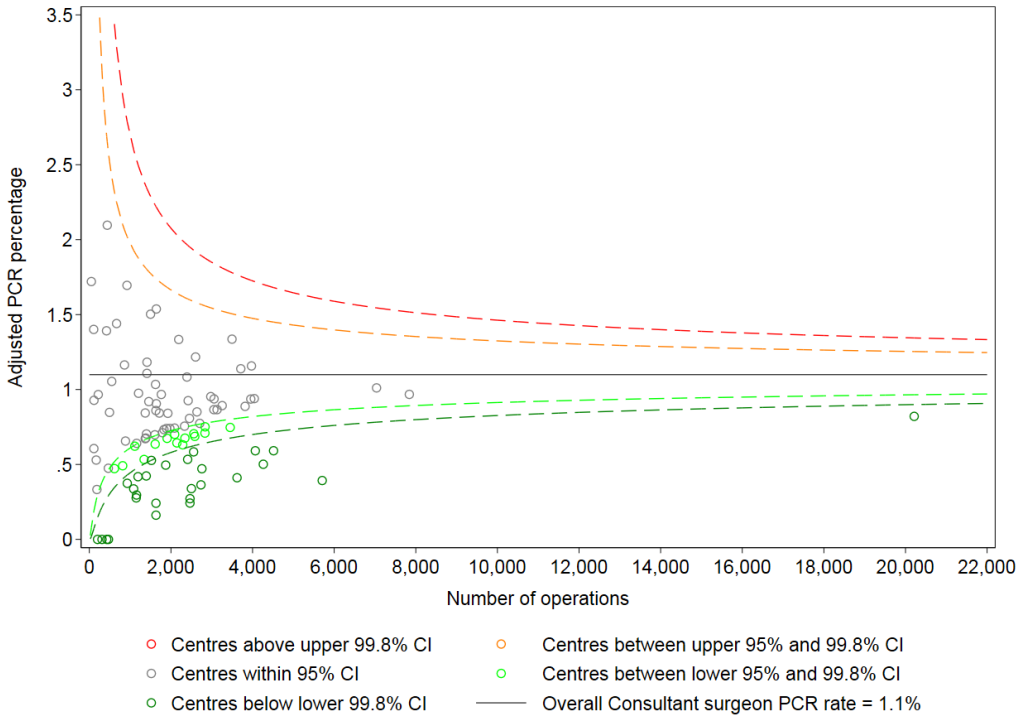


Figure 7: Adjusted for case complexity PCR graph for centres including all grades of surgeon; data for audit year 3.



7 Possible refinements to the PCR model

The current case complexity adjustment PCR model is not a perfect fit to the data and could potentially be improved by the following:

- Testing for over dispersion and exploring different methodologies to estimate the confidence intervals may improve the model and interpretation of the output; these have not been done due to time constraints.
- The model contains the patients' age fitted as a categorical variable. The patient's age is actually a continuous variable that is categorised, this process leads to a loss of information and an alternative approach would be to fit the patient's age as a continuous variable, although this would greatly increase the computational aspects of model fitting. If the patients' age remains as a categorical variable then the current categories could be altered. The model does provide some evidence that PCR is linked to higher age and thus the lower age categories could be condensed.
- The patient's IMD score is only significant for the higher values of deprivation and it is possible that using a different form of categorisation of this data may help with model fitting. The allocation of an operation to the quintile of IMD scores was performed on the whole sample provided to the RCOphth NOD (2000 – 2015) as this is a more accurate reflection of the deprivation levels for the patient undergoing cataract surgery with data recorded on the RCOphth NOD. This process does lead to unbalanced 'quintiles' for the model sample (2011 – 2015). In the prospective cataract audit the RCOphth NOD now collect the IMD rank and national decile from centres using the Medisoft EMR, centres using the Open Eyes EMR will in the future be contributing this data, and some non-EMR centres have contributed this data,

although they have to calculate this themselves while the RCOphth NOD does not have permission to receive the full patient postcode. In preparation of the third prospective year of the audit, the RCOphth NOD created an explanatory document for how a non-EMR centre can do this. The use of IMD national decile would be a more appropriate method to fit social deprivation data to a future risk factor model.

- The comparator value is periodically reviewed as more centres and surgeons contribute data. This was changed for the second prospective audit year, where the value was reduced from 2.0% to 1.1%.

In the prospective cataract audit there are changes to the collection of some of the covariates considered as possible risk factors for PCR, these are as follows;

- Pseudoexfoliation / phacodonesis can be recorded as separated terms
- Age-related macular degeneration can be recorded separately for geographic atrophy / dry AMD and neovascular / wet AMD
- Uveitis / Synaechiae can be recorded as separate terms
- Vitreoretinal co-pathologies (macular hole, epiretinal membrane, retinal detachment and vitrectomy) can be recorded with or without a previous vitrectomy

The reason for altering the above ocular co-pathology data is to provide more information on these ocular conditions which may improve the model fitting. There is data that can now be collected in the prospective cataract audit which was not being collected when the risk factor models were fitted, for example sub-type of cataract, floppy iris syndrome, anaesthesia data and previous anti-VEGF therapy. These changes are in preparation for future re-fitting of the risk factor models.

Any risk model can only be as good as the quality of data collected and it is unlikely that all theoretically plausible risk factors can be investigated, due to data collection, funding and time constraints. The RCOphth NOD is committed to using risk models based on scientific evidence and reflect current practice as accurately as possible. If new risk factors are discovered the RCOphth NOD will attempt with the resources available at that time to account for this new information and when time is available the RCOphth NOD plan to re-fit the risk models, and at the time of writing the re-fitting of the PCR model is provisionally scheduled for early 2022.

8 PCR case complexity adjustment calculation

Analysis of large sets of cataract surgery data allows the risk indicators for PCR to be identified and quantified through construction of a statistical model. This statistical model can then be 'reversed' for use as a prediction tool to calculate the predicted probability of PCR occurring for an individual operation on the basis of the preoperative risk indicators identified in the model. The risk indicators can be thought of as representing a measure of the 'case complexity' or surgical difficulty for that particular operation.

To adjust for the case complexity of a series of operations undertaken by a surgeon, the predicted probability that a complication will arise is calculated for each of their operations. An average of the individual operation predicted probabilities is then calculated for the operative series and this is the surgeon's expected complication rate. To adjust for the surgeon's case complexity (i.e. give credit for how complex or difficult their cases are), this expected rate is compared against the actual observed complication rate by dividing one by the other. If the surgeon is performing to exactly the standard expected for their case complexity then the ratio would be 1.0, if better than expectation the ratio would be <1.0 and if less well the ratio would be >1.0. This ratio is then multiplied by the comparator value (underlying consultant rate) to set the case complexity adjusted estimates in contextual comparison to the underlying rate for consultant surgeons.

This adjusted rate is plotted on the funnel plot vertical axis with the number of operations on the horizontal axis. Calculations at the surgeon level are performed differently for each grade at which an individual surgeon has data recorded, i.e. if a surgeon has data for operations they performed as a trainee surgeon and as a consultant surgeon, they will have

adjustments applicable to the relevant grade at the time that each of their operations was performed. Results for centres include all grades of surgeon (consultant and trainees).

Details of case complexity adjustment method

The process of converting the PCR risk model output into an adjusted PCR rate per surgeon and surgeon grade is as follows;

The first two steps are on the operation level:

1: Sum the PCR risk model coefficients (including the constant term) relating to the operation to calculate Y, where Y = ∑relevant model coefficients for each operation plus the constant term.

2: Using the logit transformation convert Y to calculate Z, where Z = exp(Y) / (1 + exp(Y)) and exp = the exponential function.

The next 3 steps are on the surgeon level are calculations are performed separately for each surgeon.

3: Calculate the expected PCR rate (E_{PCR}) where $E_{PCR} = \sum Z / n$ and

n = the number of operations that surgeon has performed

4: Calculate the observed PCR rate (O_{PCR}) where $O_{PCR} = n_{PCR} / n_{operations}$ and

n_{PCR} = the number of operations performed by a surgeon that had PCR

$n_{operations}$ = the number of operations that surgeon performed

5: Calculate the adjusted PCR rate (A_{PCR}) where

A_{PCR} = comparator value multiplied by (O_{PCR} / E_{PCR})

To convert the adjusted PCR rates to the percentage scale multiply A_{PCR} by 100.

To calculate adjusted PCR rates per contributing centre repeat steps 3 – 5 for contributing centres instead of surgeons.

Example: A consultant surgeon performs an operation on the second treated eye of an 80 year old male patient who lives in the most deprived quintile of IMD. This patient cannot lie flat and has the following ocular co-pathology / known risk indicators in the operated eye, Amblyopia, Brunescent / white cataract and Diabetic Retinopathy. In this case;

Y = -4.771 + 0 + -0.109 + 0.294 + 0.117 + 0.172 + 0.561 + 0.422 + 1.141 + 0.265

Y = -1.908

And Z = exp(-1.908) / (1 + exp(-1.908)) = 0.129

Let's say that this consultant surgeon performed 9 further operations with the following Z values: 0.181; 0.237; 0.025; 0.0186; 0.0143; 0.013; 0.012; 0.009; 0.008

For this surgeon the equivalent sum of the Z values would be ∑Z = 0.6469 and their expected PCR rate would be E_{PCR} = 0.6469 / 10 = 0.0647 or 6.47%

The adjusted PCR rates for this surgeon are shown in Table 5 for each possible observed PCR rate based on the possible number of operations they performed that could have had PCR.

Table 5: Adjusted PCR rates for each number of operations that could have had PCR for the example surgeon

Number of operations with PCR	CV*	O_{PCR}	E_{PCR}	A_{PCR}	A_{PCR} (%)
0	0.011	0.0	0.0647	0.0	0.00
1	0.011	0.1	0.0647	0.017	1.7
2	0.011	0.2	0.0647	0.034	3.4.
3	0.011	0.3	0.0647	0.051	5.1
4	0.011	0.4	0.0647	0.068	6.8
5	0.011	0.5	0.0647	0.085	8.5
6	0.011	0.6	0.0647	0.102	10.2
7	0.011	0.7	0.0647	0.119	11.9
8	0.011	0.8	0.0647	0.136	13.6
9	0.011	0.9	0.0647	0.153	15.3
10	0.011	1.0	0.0647	0.170	17.0

*CV = the comparator value of 1.1% used for case complexity adjusted PCR

Any rounding of estimates is only performed for the adjusted PCR rate and not at any earlier point in the calculations.

Estimating the 95% and 99.8% confidence intervals

1: The 95% and 99.8% confidence intervals are created using the following equation;

$y = x \pm \alpha(se(x))$ where;

$x = \ln (p / (1 - p))$

p = the comparator value and ln = the natural logarithm

α = the z-values from the normal distribution corresponding to the 95% and 99.8% cut-off points used for the confidence intervals, these are 1.96 and 3.01 respectively.

se(x) = the standard error of x which is calculated from the following equation;

$se(x) = \sqrt{(1 / (n(x)(1-x))}$ where n = the number of operations performed

2: By using the logit transformation convert to the appropriate scale to create the confidence interval values (CI) where

$CI = \exp(y) / (1 + \exp(y))$ and exp = the exponential function.

To convert the confidence interval values to the percentage scale multiple CI by 100.

The confidence intervals are calculated for the range of the number of operations performed by the surgeons in the sample. When producing adjusted PCR rates for contributing centres, the confidence intervals are produced for the range of operations performed by the contributing centres and the upper boundaries of the 95% and 99.8% confidence intervals equate to alert and alarm levels in public reporting and these are displayed in Table 6 for the comparator values used in the audit.

Table 6: 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%)	
Number of operations	**Alert level (+2 SD)**	**Alarm level (+3 SD)**
50	13.69	39.71
100	6.79	16.62
150	4.91	10.50
200	4.03	7.88
300	3.19	5.56
400	2.77	4.50
500	2.51	3.89
600	2.34	3.49
700	2.21	3.20
800	2.12	2.99
900	2.04	2.83
1,000	1.98	2.70
1,100	1.92	2.59
1,200	1.88	2.49
1,300	1.84	2.42
1,400	1.80	2.35
1,500	1.77	2.29
2,000	1.66	2.08
3,000	1.54	1.85
4,000	1.47	1.73
5,000	1.43	1.65
6,000	1.40	1.59
7,000	1.37	1.55
8,000	1.35	1.51
9,000	1.34	1.49
10,000	1.32	1.46
15,000	1.28	1.39

9 Fixed effects only model

As a further model diagnostic, the final PCR model covariates were fitted to a fixed effects only model and the area under the receiver operator curve (AUROC) produced. The AUROC should only be interpreted as a rough guide to the contribution the fixed effects make to the final PCR model and not an exact measure of this contribution as the final PCR model contains both fixed effects and random effects, the combination of both types of effects cannot be measured using AUROC.

The AUROC for a fixed effect only model using the final PCR model covariates is displayed in Figure 8 for the 'test' sample and Figure 9 for the 'validation' sample.

Figure 8: AUROC graph from a fixed effects only model of the final PCR model covariates using the 'test' sample

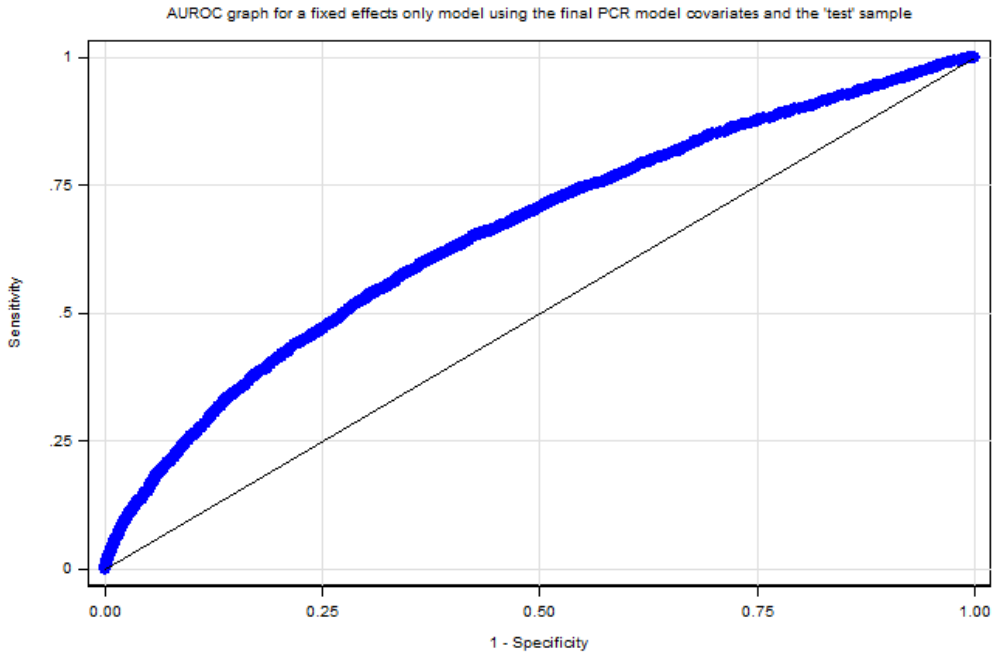
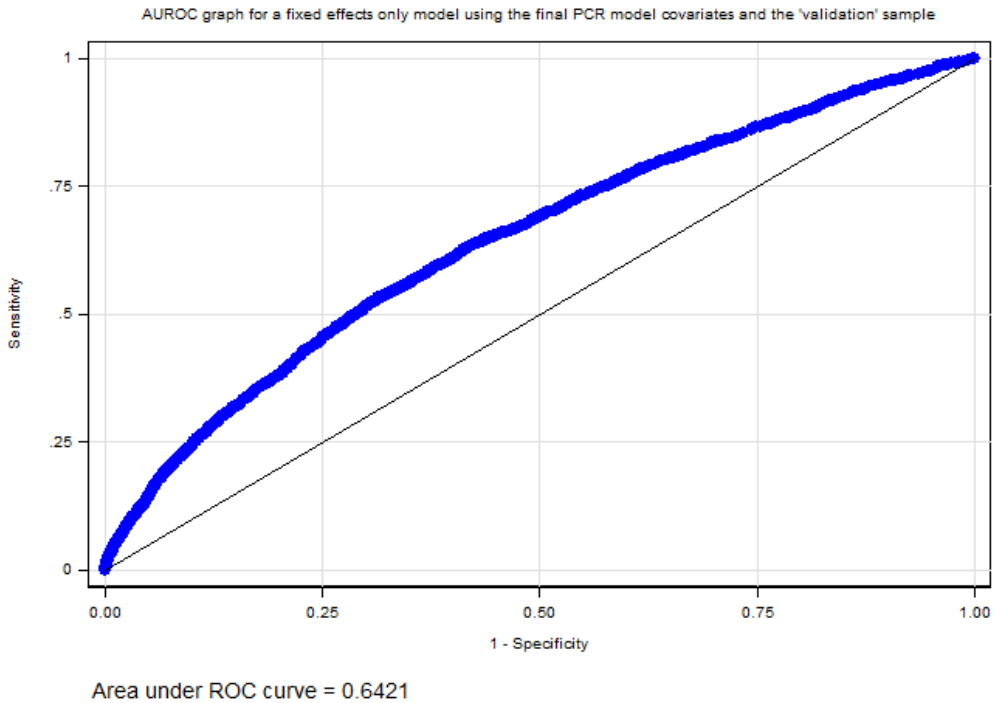


Figure 9: AUROC graph from a fixed effects only model of the final PCR model covariates using the 'validation' sample



10 Changes to the PCR model for the prospective audit

Three of the covariates used in the development of the PCR case complexity adjustment model are not 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 macular pathology
- Index of multiple deprivation

The two ocular co-pathologies were 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 not all centres can contribute this data. Although these protective effects could be counter-intuitive, if they are again found to be protective to a similar or greater magnitude when the risk factor models are refitted then we would consider including them as this would suggest that the portion of the data added since the first risk factor models were fitted is showing the same or greater effect in the same direction

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 second prospective year of the audit onwards, 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.

11 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 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 mix adjusted graphs will display the 99.8% confidence interval, but not the 95% confidence interval.

For the CQC - Centre adjusted PCR 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 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. Filtering results by surgeon grade and location of surgery are planned future developments of the website. 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 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.