Title Page

Cataract Surgery:

Measuring and predicting patient level vision related health benefits and harms

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Author selected keywords (alphabetical):

Cataract; Cataract Surgery; Decision Support; Electronic Medical Records; Health Economic Indices; Outcome Calibration; Outcomes Assessment; Psychometric Performance; Quality of Life; Risk Models; Self-Reported Outcomes; Visual Acuity

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Corresponding Author

Professor John Sparrow D Phil, FRCS, FRCOphth

Bristol Eye Hospital

Lower Maudlin Street

Bristol BS1 2LX

John.Sparrow@doctors.org.uk

Abstract

Background

Cataract surgery is the most frequently undertaken surgical procedure in the NHS with approximately 450,000 operations performed annually. Surgery for established cataract is highly cost-effective and uncontroversial, yet there remains uncertainty for individuals about when to proceed and when to delay surgery during the early stages of cataract.

Objective

The aim of this programme is to improve decision making for cataract surgery through development of evidence based clinical tools which provide not only general information but also personalized risk and benefit information.

Design

The design comprised a series of mixed methodology work packages:

Work Package 1

- Iterative development and validation of a brief, psychometrically robust, Rasch calibrated and responsive NHS implementable patient self-reported measure of visual difficulty from cataract and its relief from surgery. The instrument was named 'Cat-PROM5'.

Work Package 2

- Review and refinement of risk models for adverse surgical events, posterior capsule rupture and visual acuity loss related to cataract surgery based on detailed information derived from electronic medical records.

Work Package 3

- Development of prediction models for Cat-PROM5 based self-reported outcomes from a cohort study of 1500 patients.
- Assessment of the validity of established and emerging preference-based health economic indices, and calibration of Cat-PROM5 to these.
- Qualitative assessment of patients and healthcare professionals views on presentation formats for risk-benefit information, usefulness of the self-reported outcome measure, the value of personalised risk-benefit information, information items which are of importance to a person approaching a cataract procedure, the importance of and current practice of shared patient-clinician decision making.

- Development of a frequently asked questions format Cataract Decision Aid incorporating personalised estimates of both the risks of an adverse outcome and the probability of self-reported benefit.
- Development of a Cataract Decision Quality Measure to assess the quality of decision making in cataract surgery.

Work Package 4

- A mixed methods feasibility study for a possible future fully powered RCT of the use of the Cataract Decision Aid to assess recruitment, sample size, additional cost, patients' decision quality, and patients' and health professionals' views of the value of a Cataract Decision Aid.
- A qualitative study of discordant or mis-matching outcomes where the patient's and health professional's perceptions are at odds.

Participants and Data Sources

Four English NHS recruitment centres participated in the programme, Bristol (lead centre), Brighton, Gloucestershire and Torbay.

Work Package 1

- All four centres participated (822 participants)

Work Package 2

- Electronic medical record derived data were obtained from the National Ophthalmology Database through data sharing agreements with the Health Quality Improvement Partnership (final set >1M operations).

Work Package 3

- Bristol (1200) and Gloucestershire (300) recruited 1500 cohort study participants.
- All four centres participated in the qualitative work and the development of the CDA. Participants included both patients and health professionals.

Work Package 4

- Bristol, Brighton, and Torbay participated in recruitment of patients for the feasibility RCT (42) and health professionals for the qualitative elements.

Results

Work Package 1

- Cat-PROM5 was developed and validated with excellent to good psychometric properties and excellent responsiveness to surgical intervention.

Work Package 2

- Earlier risk models for posterior capsule rupture and visual acuity loss were broadly affirmed.
- Additional analyses assessed stability through time, outcomes in people aged 90 and over, and refractive outcomes.

Work Package 3

- Cat-PROM5 based self-reported outcomes models were derived.
- Of four preference-based health economic indices assessed, two demonstrated reasonable performance. Cat-PROM5 was successfully calibrated to health economic indices.
- Personalised risk information was generally perceived as beneficial although caution was raised regarding time and workload related implementation barriers.
- A Cataract Decision Aid and Cataract Decision Quality Measure were developed based on the views and preferences of patients and health professionals.

Work Package 4

- A fully powered RCT of a Cataract Decision Aid would be feasible following refinement of the primary outcome.
- The Cataract Decision Aid was generally well received by patients and health professionals, caution being raised regarding time and workload barriers to implementation.
- Discordant outcomes identified were mostly negative and frequently related to unrealistic expectations due to inadequate explanation / understanding of the intended postoperative (refractive) result.

Limitations and future work

- The performance of the statistical model for self-reported final outcome was reasonable though the model for pre- to postoperative change performed less well.
- Aspects of the Cataract Decision Quality Measure would need to be refined prior to use in a future RCT of the Cataract Decision Aid
- The sample size for the discordant outcomes study was small, this occurrence is uncommon and in addition the study team experienced difficulty in identifying affected patients.

(Abstract: 745 words)

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Author list

Professor John Sparrow (Chief Investigator, University Hospitals Bristol NHS Foundation Trust)
Mariusz Grzeda (University Hospitals Bristol NHS Foundation Trust, University of Bristol)
Dr Andrew Frost (PI and co-applicant Torbay & South Devon NHS Foundation Trust)
Professor Christopher Liu (PI and co-applicant Brighton & Sussex University Hospitals NHS Foundation Trust, Brighton and Sussex Medical School, Tongdean Eye Clinic (Hove, UK).)
Mr Robert Johnston (PI and co-applicant, Gloucestershire Hospitals NHS Foundation Trust, deceased)
Professor Peter H Scanlon (PI and co-applicant, Gloucestershire Hospitals NHS Foundation Trust)
Dr Christalla Pithara (The National Institute for Health Research Collaboration for Leadership in Applied Health Research and Care West (NIHR CLAHRC West) at University Hospitals Bristol NHS Foundation Trust *and* Population Health Sciences, University of Bristol)
Dr Daisy Elliott (University of Bristol)
Professor Jenny Donovan (Co-applicant, Population Health Sciences, University of Bristol)
Dr Natalie Joseph-Williams (Co-applicant, Cardiff University)
Dr Daniella Holland-Hart (Cardiff University)
Paul H J Donachie (Gloucestershire Hospitals NHS Foundation Trust, The Royal College of Ophthalmologists' National Ophthalmology Database)
Dr Padraig Dixon (University of Bristol)
Hazel Taylor (Co-applicant, University Hospitals Bristol NHS Foundation Trust)
Katie Breheny (University of Bristol)
Professor Jonathan Sterne (Co-applicant, University of Bristol)
Professor William Hollingworth (Co-applicant, University of Bristol)
Professor David Evans (Co-applicant, University of the West of England)
Dr Fiona Fox (University of Bristol)
Dr Sofia Theodoropoulou (University Hospitals Bristol NHS Foundation Trust)
Dr Rachael Hughes (University of Bristol)
Matthew Quinn (Brighton & Sussex Medical School)
Daniel Gray (Cardiff University)
Mr Larry Benjamin (Chair, Steering Committee, Buckinghamshire Healthcare NHS Trust)
Abi Loose (Programme Manager, University Hospitals Bristol NHS Foundation Trust)
Lara Edwards (Programme Manager, The National Institute for Health Research Collaboration for Leadership in Applied Health Research and Care West (NIHR CLAHRC West) at University Hospitals Bristol NHS Foundation Trust *and* University Hospitals Bristol NHS Foundation Trust)
Pippa Craggs (Programme Manager, University Hospitals Bristol NHS Foundation Trust)
Frances Paget (Programme Manager, University Hospitals Bristol NHS Foundation Trust)
Ketan Kapoor (Optometrist, University Hospitals Bristol NHS Foundation Trust)
Jason Searle (Optometrist, University Hospitals Bristol NHS Foundation Trust)

Conflicts of interest

Mr Robert Johnston was a director for the EMR company from which data on cataract surgery was extracted for analyses in Work Package 2.
Mr Paul HJ Donachie is the statistician for the Royal College of Ophthalmologists' National Ophthalmology Database

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Abbreviations

BEH	Bristol Eye Hospital
Cat-PROM5	A 5-item Cataract Patient Reported Outcome Measure
CDA	Cataract Decision Aid
CDQM	Cataract Decision Quality Measure
CU	Cardiff University
EMR	Electronic Medical Record
EQ-5D-3L	EuroQol 5-dimension health-related preference-based quality of life utility with 3 levels
EQ-5D-3L+VIS	EuroQol 5-dimension health-related preference-based quality of life utility with 3 levels and a vision 'bolt-on' domain
EQ-5D-5L	EuroQol 5-dimension health-related preference-based quality of life utility with 5 levels
GHNHSFT	Gloucestershire Hospitals NHS Foundation Trust, includes hospital sites in and around Gloucester and Cheltenham
HQIP	Health Quality Improvement Partnership
ICECAP-O	A health-related preference-based quality of life capability instrument for older people
IOL	Intra Ocular Lens
LE	Left Eye
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health Research
PAG	Patient Advisory Group
PCR	Posterior Capsule Rupture
PI	Principal Investigator
PPI	Patient and Public Involvement
PREM	Patient Reported Effectiveness Measure
PROM	Patient Reported Outcome Measure
PrSC	Programme Steering Committee
RE	Right Eye
UHBristol	University Hospitals NHS Foundation Trust
UoB	University of Bristol
UWE	University of the West of England
VA	Visual Acuity
VCM1	Vision Core Measure 1 questionnaire
VSQ	Visual Symptoms and Quality of life questionnaire
WP1	Work Package 1
WP2	Work Package 2
WP3	Work Package 3
WP4	Work Package 4
VRQoL	Vision-Related Quality of Life

Plain English Summary

Decisions about whether to opt for cataract surgery right away, or to hold off, are mostly based on a patient's ability to read a letter chart rather than on their real-world experience of their vision. This can mean that patients are sent for surgery before they really need it, or (more commonly) have to wait longer, until their vision is deemed poor enough. In order for the decision-making process to be more patient-friendly, we developed and tested a series of decision supporting 'tools' which give individual patients, and their doctors, a better understanding of how badly everyday vision is affected by their cataract(s).

To enable patients to express how their vision affects them day-to-day, we developed a short questionnaire, Cat-PROM5, which has been shown to work well. Cat-PROM5 can be completed by patients before they see their eye doctor and considered alongside the letter chart results. Cat-PROM5 can also be completed after surgery, which is useful for doctors to measure how much a patient has benefitted from surgery. Furthermore, our analysis allows the eye doctor to predict how good a patient's vision is likely to be after the surgery, should they decide to go ahead.

People considering an operation usually also want to know what the risk is of things turning out badly. We have therefore developed a way to predict the risk of a complication occurring during the surgery and of loss of vision following the surgery, based on things like age and eye health.

Using these predictions, we created a cataract decision aid which also includes general cataract surgery information and frequently asked questions. This was tested and most of the patients and doctors thought it was useful, though it, and the way it is used, could still be improved.

Scientific Summary

Background

Cataract surgery is the most frequently undertaken surgical procedure in the NHS. In this programme, we have aimed to improve decision making for cataract surgery through development of clinical tools which allow the patient's voice to be more clearly expressed regarding their own perceptions of their 'lived vision' in the complex dynamic everyday visual environments in which they live. Formal measurement of self-reported visual difficulty related to cataract can provide important information complimentary to standard clinical parameters used to assess need for surgery and we have developed a brief, psychometrically robust, responsive, NHS implementable and free to use cataract patient reported outcome measure for this purpose.

A patient focused measurement of 'lived vision' also allows for assessment of relief of visual difficulty following surgery, providing direct insight into the surgical outcome as perceived by the patient. Detailed knowledge of self-reported visual difficulty status at both preoperative and postoperative points, along with other relevant preoperative parameters allows for statistical modelling of outcome and the building of statistical prediction tools relevant to personalised potential benefits for individuals considering surgery. In this programme, we have developed statistical models to predict self-reported outcome from surgery.

The other side of the coin for a person considering surgery is the risk of coming to harm, and we have likewise developed statistical models for estimating predicted probabilities of adverse events. The adverse outcomes modelled are 1. a significant intraoperative complication and 2. visual harm related to surgery. These statistical predictors have been incorporated into a Cataract Decision Aid which provides general information about cataracts and cataract surgery in a frequently asked questions format, as well as personalised predictions of the likely benefits and harms from surgery. The Cataract Decision Aid has been trialled in a feasibility RCT for a possible future fully powered RCT of its use for cataract surgery decision support.

The quantitative research undertaken has been fully supported at all stages by qualitative evaluations of the tools being developed from both patients' and health professionals' perspectives. The perceived importance and usefulness of the tools have been assessed, with iterative refinements through development and assessment of the fully developed instruments. In addition,

significant health economic work has been undertaken with established and emerging preference-based utility measures being assessed for sensitivity and responsiveness to visual difficulty from cataract, and its relief through surgery. The questionnaire instrument for measurement of self-reported visual difficulty has been mapped to health economic measures with a view to providing a future mechanism for undertaking cost effectiveness studies based on a cross walk from the self-reported visual difficulty measure to a preference-based health economic measure.

Aims and intended outputs

Work Package 1

WP1 took place at the start of the programme across all four collaborating NHS trusts (Bristol, Torbay, Gloucestershire, Brighton) and lasted just over a year.

WP1 Aims

- To develop a brief, psychometrically robust and responsive cataract patient reported outcome questionnaire measuring the construct 'visual difficulty related to cataract', suitable for use in high volume surgical environments.
- To compare and contrast the newly developed PROM with the current 'best of class' alternative instrument available for use in routine cataract surgical services using both quantitative and qualitative methodologies.

WP1 intended outputs

The key intended output of WP1 was a brief, psychometrically robust and responsive cataract self-reported questionnaire for preoperative visual difficulty and postoperative visual outcome measuring the construct 'visual difficulty related to cataract'. This has been successfully achieved, the 5-item Cat-PROM5, is sufficiently brief for service implementation and performs as well as or better than the existing longer questionnaires, including the 9-item questionnaire previously regarded as the existing 'best of class' option. Cat-PROM5 is sufficiently flexible to allow patients to map their visual difficulties to the questions, unlike the more restrictive questions used by instruments which enquire about specific scenarios which may have limited or no applicability for the individuals completing them. Cat-PROM5 is suitable for high volume routine clinical use, it is brief, has excellent psychometric properties and is highly responsive to cataract surgery.

Work Package 2

WP2 started towards the beginning of the programme, the first analysis being completed within the first year. The 'added value' components were undertaken during the second half of the programme. This work was based in Bristol.

WP2 Aim

- To validate or update existing risk models for posterior capsule rupture (PCR) and monocular visual acuity harm using multicentre data from 180,000 electronic medical records (EMR) for cataract surgery.

WP2 intended outputs

The key intended output for WP2 was updating of our previously published risk prediction models for the index cataract surgical complication, posterior capsule rupture (PCR) and for monocular visual acuity loss related to cataract surgery. These two adverse outcomes directly address a fundamental medical and surgical principle of 'do no harm' and relate to the NHS safety domain. Our analysis of fresh data on 180,000 cataract operations undertaken between 2006 and 2010 confirmed that the identified risk factors for these adverse events were broadly similar to those previously published by our group on 55,000 operations from the earlier period of 2000 to 2006.

Following on from this key intended output it was possible also to deliver added value to the programme through two further analyses based on a larger sample of data obtained through a fresh data sharing agreement with the National Ophthalmology Database (NOD) and Health Quality Improvement Partnership (HQIP). This second multicentre EMR-derived sample of over 600,000 cataract procedures covered the full period from 2000 to 2014.

The first of these additional analyses aimed to consider in greater detail the stability through time of the risk model for PCR. The data on the PCR adverse outcome are complete as this data item is a compulsory field in the EMR and must be completed at the time of surgery. To ensure adequate statistical power for each annual period the first few years of data were excluded as the volumes of recorded operations early on were insufficient. Using a range of statistical techniques, the analysis across the 10-year period from 2005 to 2014 revealed model stability from 2005 to 2011, followed by a 'rogue' year in 2012, and stability for 2013 to 2014. This shift corresponds in time to when the NOD began to present outcomes back to surgeons via a website and it could be speculated that the shift in the risk prediction model occurred as a result of changes in surgeons' behaviour once they had seen their results presented back to them on funnel plots.

The second additional analysis was a subgroup analysis of outcomes for people aged 90 years and older when undergoing cataract surgery. This demographic group of increasing importance is associated with multi-morbidity and accompanying surgical challenges when undertaking cataract

surgery. The outcomes of our analyses were reassuring in that although the PCR adverse event rate was somewhat higher than for younger people it remained acceptable. Visual acuity outcomes were likewise less good than for younger people but still acceptable overall. These analyses confirmed that most very elderly people with cataract gain benefit from surgery and that a favourable outcome can be anticipated for the majority of operations undertaken for people in this age group.

The third additional analysis was a proof of concept feasibility assessment of the use of a complex numbers-based analysis of postoperative refractive outcomes. The data used derived from a third multicentre EMR sample of cataract procedures undertaken from 2010 to 2018. The primary trivariate outcome variable (sphere, cylinder, axis) was modelled using a multivariate normal multilevel model and four different multilevel structures. Despite the methodological complexity it was feasible to apply the method to model indicators of postoperative refraction with several significant eye health factors being revealed as important to the postoperative refractive outcome. This method will be of interest to surgeons for outcomes assessment and refinement of refractive outcomes.

Work Package 3

WP3 occupied three out of the five years of the programme and took the form of a cohort study profiling typical NHS patients undergoing cataract surgery. The start of the work was delayed due to difficulty securing a clinical examination area in which to conduct the study. Despite a slow start full recruitment of 1500 patient participants across two NHS Trusts (Bristol and Gloucestershire) was achieved, along with good retention at follow up. The main cohort study was supported by a series of qualitative elements involving cataract patients and eye health professionals. The qualitative work was undertaken by two teams, the Part 1 investigatory work was based in the University of Bristol and the Part 2 instrument development work for the cataract decision aid based at Cardiff University. The health economics work utilised data collected in the main cohort study and was based in Bristol. The research team are grateful to the NIHR for agreeing a no-cost extension which allowed subsequent WP4 feasibility trial work to be completed.

WP3 Aims

Quantitative aims

- To develop of a benefits prediction model for personalised prediction of self-reported Cat-PROM5 benefit from cataract surgery

Qualitative aims - Element 1

- To identify the most acceptable way of presenting risk and benefit probability information to patients as part of a Cataract Decision Aid
- To identify from patients and health care professionals, cataract surgery specific Frequently Asked Questions to inform development of a Cataract Decision Aid
- To explore the acceptability of Cat-PROM5 to healthcare providers
- To explore with patients and health care professionals, issues of shared and informed decision-making during cataract surgery patient counselling to inform the development and implementation of a Cataract Decision Aid in routine practice

Qualitative aims - Element 2

- To develop a Cataract Decision Aid (CDA) in a 'frequently asked questions' (FAQ) format in which the likelihood of self-reported benefit is set alongside risks of harm (surgical complications / VA Loss) to provide an integrated decision-support tool with personalised prediction of outcomes
- To develop a Cataract Decision Quality Measure (CDQM) for the cataract surgery decision
- To conduct qualitative user testing of the personalised CDA with patients and clinicians to assess usability, acceptability, utility and expected impact
- To refine the personalised CDA and CDQM for use in WP4 (feasibility trial)

Health Economic aims

- To evaluate performance of existing and emerging health economic indices (preference-based measures EQ-5D-3L, EQ-5D-3L+VIS, EQ-5D-5L, ICECAP-O) in people undergoing cataract surgery
- To investigate how cataract related visual disability measured using Cat-PROM5 can be calibrated or mapped against existing and emerging health economic indices of utility

WP3 intended outputs

The key quantitative outcome for WP3 was development of prediction models for Cat-PROM5 self-reported outcome and benefit from surgery. This output was achieved, with two model forms produced, each based on preoperative predictors. The first model addressed the question of

prediction of self-reported Cat-PROM5 postoperative outcome, and the second addressed the question of prediction of the change in Cat-PROM5 score from pre- to postoperative status, i.e. self-reported benefit.

The outputs from the Part 1 qualitative work paved the way to the Part 2 work. These outputs included identification of patients' preferred presentation format for risk and benefit data (to be used in the CDA), identification of key information and issues of concern arising preoperatively for patients approaching cataract surgery (to inform the content of FAQ's for the CDA), understanding the views of health professionals regarding the usefulness of Cat-PROM5 as a self-reported patient focused measure of visual difficulty, understanding views on, attitudes towards and current practice of shared decision making and probing attitudes, issues and barriers related to implementation of a cataract decision aid incorporating personalised risk and benefits prediction in routine surgical practice.

Informed and guided by the Part 1 qualitative work and the programme PPI Patient Advisory Group, Part 2 outputs consisted of a FAQ format CDA which included general information of importance and concern for preoperative patients as well as estimated personalised risks (of an operative complication – PCR and separately of postoperative VA Loss) on the one hand, and benefit (Cat-PROM5 self-reported outcome) on the other. The development of the CDA was an iterative process with draft versions refined in response to qualitative study feedback. The second key output for Part 2 comprised a Cataract Decision Quality Measure, similarly iteratively developed, to be used to assess the quality of decision making for patients considering the option of cataract surgery. Both these outputs were taken forward for use in the WP4 feasibility RCT.

Two key health economic outputs were produced in WP3. The first consisted of assessment of the performance of established and novel preference-based health economic utility indices for validity and responsiveness to visual difficulty from cataract and its relief through surgery. These assessments revealed clear differences between the tested indices with EQ-3D-5L+vision and the ICECAP questionnaires clearly outperforming EQ-5D-3L and EQ-5D-5L, outputs which will be of value to researchers wishing to undertake health economic analyses in future cataract studies. The second health economic output was a mapping or calibration of Cat-PROM5 to preference-based health economic indices. Adjusted limited dependent variable mixture models offered good to excellent fit. This important output will allow results of future cataract studies to collect Cat-PROM5 data which

can then be mapped across to preference-based measures for health economic analysis, thus reducing the questionnaire burden for future research participants.

Work Package 4

WP4 took place in the final year of the programme across three collaborating NHS trusts (Bristol, Brighton, Torbay) and two academic institutions (University of Bristol and Cardiff University).

WP4 Aims

Quantitative Aims

- To undertake a feasibility study for a possible future fully powered randomised controlled trial (RCT) of the use of a cataract decision aid (CDA) incorporating personalised risk and benefit information to improve shared decision making in cataract surgery
- To estimate the sample size for a possible future fully powered RCT
- To assess the accuracy of the self-reported outcomes and benefits prediction model developed in the programme

WP4 Qualitative Aims – Element 1

- To explore how a CDA incorporating personalised risk and benefit information influences preoperative shared decision making for cataract patients and health professionals
- To explore how patients and health professionals perceive the CDA in the context of routine care

WP4 Qualitative Aims – Element 2

- To explore background and specific instances of discordance of outcomes where the perception of the health professional was at odds with that of the patient following cataract surgery

WP4 Health Economic Aims

- To estimate the implementation costs and potential savings of the use of a Cataract Decision Aid (CDA)

WP4 intended outputs

The intended outputs referred to the feasibility of undertaking a possible future fully powered RCT of cataract decision support for shared decision making using the CDA developed in the programme as an intervention. Elements of this included feasibility of recruitment to a possible future trial, consideration of primary and secondary trial outcomes and sample size, costs associated with use of

the CDA, health professionals perceptions of the potential usefulness of a CDA, perceived barriers to CDA implementation, attitudes towards and current practice of shared decision making, patient perceptions of the use of a CDA and its influence on shared decision making and patients' perceptions of shared decision making. Developing these outputs required a mixed methods approach involving quantitative, qualitative and health economic elements.

The final intended output related to qualitative exploration with patients and health professionals of discordant or mismatching outcomes where perceptions of the outcome of surgery from the patient's perspective was at odds with that of the health professional. This work revealed a number of themes which will be of use to health professionals and cataract surgery providers to help them to pre-empt and thus minimise such situations arising in their services through better communication and management of expectations.

Trial Registration

Title: A feasibility study of the use of a cataract surgery decision aid which includes personalised estimates of risks and benefits
Trial ID: ISRCTN11309852
Date registered: 16/05/2019
Link: https://www.isrctn.com/ISRCTN11309852

Synopsis

Cataract surgery is one of the most frequently undertaken surgical procedures with approximately 450,000 operations undertaken annually by the NHS at an estimated cost of £450M[1]. The cost effectiveness of cataract surgery for established cataracts is uncontroversial and surgery is recommended by NICE[2]. For individuals affected by a gradual onset and progression of visual difficulty from cataract, the decision as to when to delay and when to proceed with cataract surgery remains a matter of judgement, with many, sometimes competing factors, requiring consideration. Although most cataract surgery is highly successful, there are inevitable risks associated with the procedure and these need to be considered in the contexts of visual requirements, visual difficulty and potential to benefit. Standard preoperative assessment for cataract surgery currently relies heavily on measurement of visual acuity, a test conducted one eye at a time in a darkened space, with self-reported visual difficulty all too frequently receiving, at best, secondary consideration. Tight health budgets are known to distort clinical priorities and legitimate need remains unmet for many individuals[3].

Programme Overview

The overarching aim of this programme has been to improve decision making related to cataract surgery through the development and testing of clinical tools.

- The programme aimed to enhance the patient voice in the contexts of assessment of need for cataract surgery and measurement of surgical outcome through development of a brief 'whole person' patient focused measure of self-reported visual difficulty from cataract, and its relief from surgery
    - ✓ Cat-PROM5, a brief psychometrically robust patient reported outcome measure (PROM) which captures information relevant to peoples' every day visual experience has been developed and validated[4, 5]. Performance of this questionnaire instrument has been assessed quantitatively and Rasch calibrated to provide a single measure on a unidimensional continuous scale (WP1). In addition, Cat-PROM5 has been qualitatively assessed with patients and health care professionals (WP1 & WP3). Following on from this:

- Cat-PROM5 is being piloted in the National Ophthalmology Database Audit as a patient focused outcome measure[6]
- The NICE Quality Standard for Serious Eye Disorders have recommended that patients with cataract should not be referred on the basis of visual acuity alone and go on to suggest Cat-PROM5 as a suitable patient reported outcome measure for cataract[7]
- The most widely used ophthalmology electronic medical record provider in the NHS has incorporated Cat-PROM5 data collection functionality into their software. Completion can take place both in the care setting and at home by patients on their own device. The second most widely used ophthalmology electronic medical record provider is currently also deploying Cat-PROM5 into their software.
- Cat-PROM5 has been prioritised for implementation across all cataract surgery services in Wales
- The Welsh PROMs and PREMs programme have developed an electronic platform for Cat-PROM5 data collection
- Cat-PROM5 has been translated into Welsh
- Cat-PROM5 was chosen for use in an RCT of laser assisted cataract surgery[8]

- The programme aimed to validate personalised prediction models for harm related to cataract surgery (surgical complications and visual acuity loss)
  - ✓ Risk models for the index cataract surgery operative complication, posterior capsule rupture (PCR) have been refined on fresh data from 180,000 operations (WP2) and stability through time has been evaluated on over 600,000 operations (WP2 – Added value). Subgroup analysis of cataract surgery in around 25,000 people aged 90 years and over has been undertaken defining the outcomes in this increasingly important demographic group of elderly people[9] (WP2 – Added value). The feasibility of analysing refractive outcomes of surgery (requirement for spectacles postoperatively) using a novel method to better understand indicators of outcome has been assessed in a proof of concept study (WP2 Added value). Following on from this:
    - Our approach to risk prediction has been implemented into risk calculators embedded into the two most widely used ophthalmological electronic medical record systems in the NHS

- Risk calculators allow for more accurate consent procedures as personalised risks can be provided to patients preoperatively
- Service providers can use risk calculators to risk assess patients preoperatively and ensure that high risk patients are exclusively operated on by the most experienced surgeons
- Our approach is used in the National Cataract Surgery Audit for risk adjustment of named centre and surgeon outcomes which are placed in the public domain[6]
- The most recently published National Audit annual report uses this methodology to risk adjust around 218,000 operations undertaken by around 2000 surgeons from over 100 NHS surgical centres during a 12-month data capture period[1]
- Around 2,500 contributing surgeons and over 100 centres now have access to their risk adjusted results on around 1.1M operations through the period 2010 to 2018 (website registration required)[6]
- As a result of the national audit showing surgeons and centres their results the rate of complications has reduced between 2010 and 2018 by almost 40%, reducing morbidity and saving the NHS an estimated £2M annually as a result of avoided additional treatments to deal with complications[1]

- The programme aimed to develop models for personalised prediction of likely Cat-PROM5 self-reported visual benefit from surgery. Following on from this:
  - ✓ Prediction models for Cat-PROM5 derived self-reported final postoperative outcome and visual improvement (pre- to postoperative change in score) following surgery have been developed (WP3). This work led to:
    - Options for presentation of risk information were evaluated qualitatively to identify the preferred and most easily understood risk presentation formats for patients (WP3 – Qualitative elements)
    - The benefits and harms prediction calculators were incorporated into a Cataract Decision Aid to provide personalised estimates of risk and benefit to patients preoperatively (WP3 – Qualitative elements)
    - The validity of the self-reported benefits prediction models was evaluated on a (small) independent sample (WP4)
- The programme aimed to investigate options for health economic evaluation in cataract surgery

- ✓ The performance of established and novel health economics utilities for sensitivity to cataract visual disability and responsiveness to surgical intervention has been evaluated (WP3 – Health Economics elements).
  - ➢ The construct validity and responsiveness of the EQ-5D-3L, EQ-5D-5L, EQ-5D-3L+VIS and ICECAP-O utilities have been evaluated in cataract surgery patients
- ✓ Cat-PROM5 has been mapped to established and novel health economics utilities
  - ➢ Cat-PROM5 has been mapped to the Quality of Life measures EQ-5D-3L, EQ-5D-5L and the Capability measure ICECAP-O in cataract surgery patients

- The programme aimed to develop a cataract decision support tool for people considering cataract surgery
  - ✓ Issues of importance or concern were developed into frequently asked questions (FAQs) with extensive input from patient participants, health care professionals and the programme patient advisory group (WP3 – Qualitative elements). Following on from this:
    - ➢ Risk presentation formats for presentation of risk information to patients were explored with patients and eye health professionals
    - ➢ A Cataract Decision Aid (CDA) was developed incorporating FAQs, general information and personalised risk and benefits information
    - ➢ The risks and benefits calculators were taken forward and formed part of the CDA providing the personalised risk and benefits information
    - ➢ Perceptions of the need for and usability of the CDA were evaluated with patient and health professional participants
    - ➢ Current use, and potential for possible future use of decision support tools supporting shared decision making in routine service environments was evaluated
- The programme aimed to conduct a small-scale feasibility randomised controlled trial (RCT) on the use of the Cataract Decision Aid (CDA) developed in the programme to inform the feasibility of a possible future fully powered RCT of the CDA
  - ✓ A feasibility RCT of the use of the cataract decision aid (CDA) was undertaken to assess the feasibility of a possible future fully powered CDA RCT (WP4 – Quantitative and Qualitative elements)
    - ➢ A Cataract Decision Quality Measure was developed as a candidate primary outcome

- Feasibility of recruiting to a trial, performance of candidate primary and secondary outcomes, sample size for a possible fully powered trial and cost of CDA implementation were assessed

Programme Work Packages

Work Package 1 – Development of Cat-PROM5, a brief Cataract Patient Reported Outcome Measure

WP1 Aim

- To develop a short, psychometrically robust and responsive cataract patient reported outcome questionnaire measuring the construct 'visual difficulty related to cataract', suitable for use in high volume surgical environments.
- To compare and contrast the newly developed PROM with the current 'best of class' alternative instrument available for use in routine cataract surgical services using both quantitative and qualitative methodologies.

Approach

From our earlier questionnaire work candidate questions were harvested from two published questionnaires, the VCM1 (vision core module one)[10] and the VSQ (Visual Symptoms and Quality of life)[11] cataract PROMs. Under the construct 'visual difficulty due to cataract', 21 Questions were re-operationalized into the first developmental version of the questionnaire. Iterative cycles of questionnaire administration, analysis and item reduction were used to arrive at the final item set of five questions, the psychometric performance of these being confirmed in a final cycle of data collection and analysis. The final item set was compared in a head-to-head study with the existing 'best of class' 9-item longer questionnaire. In a separate qualitative exercise, the final item set was evaluated in a group of patients which included people who had both cataract and other ocular comorbidities.

Data collection

People with age related cataract who were awaiting first or second eye cataract surgery at four participating centres (Bristol, Torbay, Gloucestershire and Brighton) were potentially eligible for recruitment.

Inclusion criteria were age 50 years or older, ability to understand and complete development versions of Cat-PROM and Catquest-9SF in English, willingness to participate and to provide informed consent. Exclusion criteria were visually significant ocular or systemic comorbidity.

Three iterative cycles of data collection and analysis were undertaken. The initial 'Cycle 0', or pilot was restricted to pre-operative questionnaire completions and took place predominantly in Bristol. The development 'Cycle 1' and the confirmatory 'Cycle 2' each collected both pre- and postoperative data.

Data analysis

Rasch analysis was the primary analytical method used. Among the many advantages of Rasch analysis are that it allows for selection of unidimensional questions (items) which together measure an underlying latent trait (here difficulty with vision due to cataract), it assesses the performance of the individual items (fit, differential item functioning), it indicates the overall reliability of the item set and it delivers a continuous scale or measurement of the underlying latent trait.

Data were collected by participants completing developmental versions of the new Cat-PROM questionnaire as well as the established Catquest9-SF for purposes of comparison.

Cat-PROM development

Analysis of the 200 'Cycle 0' completions resulted in removal of ten items based on a range of statistical techniques including sequential Rasch (partial credit model) analyses (items excluded with disordered thresholds, poor fit, category average disordering, and the less well performing item of an intentionally included pair of duplicate questions), Principal Components Analysis and Confirmatory Factor Analysis.

The resulting unidimensional 11-item set was taken forward to a development 'Cycle 1' in which 316 patients completed questionnaires at both pre- and postoperative time points. Preliminary analysis revealed that selection of fewer than five items resulted in a consistent and significant drop in psychometric performance and it was decided to aim for a 5-item final set. The two best performing items were selected for inclusion, followed by a systematic search for next best three items based on

84 possible combinations. Through a comprehensive selection process that included assessment of Rasch performance parameters, responsiveness to surgery, patient preferences as advised by the Programme's Patient Advisory PPI Group and expert opinion, the remaining three items were chosen.

The final five item set was checked in a confirmatory 'Cycle 2' in which 306 pre- and post-operative completions were made.

Comparison with Catquest9-SF

Psychometric Rasch analysis confirmed that the 5-item set performed at least as well or better than the longer and more restrictive previous 'best of class' instrument Catquest9-SF.

Qualitative element

A qualitative study on a separate small group of patients explored the face-validity and acceptability of both the Cat-PROM5 and Catquest9-SF questionnaires. In this group participants included people with visually significant comorbidities. Semi-structured face-to-face interviews were guided by a topic guide, with new points added as analysis progressed to enable exploration of emerging themes. Data were analysed using techniques of constant comparison derived from grounded theory methodology, and emerging themes and codes within transcripts and across the dataset were then compared to look for shared or disparate views among participants. Data collection and analysis continued until the point of data saturation. 16 interviews were conducted with nine men and seven women, eleven patients were awaiting their cataract surgery, and five had recently undergone surgery. Thirteen participants had other visual comorbidities. Overall both questionnaires were well received, although patients with severe visual comorbidities commented that it was difficult to differentiate between how the cataract and other conditions affected their quality of life. Most participants preferred the large-font format of Cat-PROM5. Some preferred questions with more response options as in Cat-PROM5, and others fewer response options as in Catquest-9SF. The specific scenarios of Catquest-9SF created some uncertainty where other health problems affected the issue being addressed, and where the issue was not relevant to their lives, respondents were uncertain about how to respond. In contrast, Cat-PROM5 enabled them to determine the individual vision-related factors which they perceived to be important, and to respond to the questions easily.

Limitations

In order to develop Cat-PROM5 as an instrument specific to visual difficulty related to cataract the developmental cycles excluded people with visually significant non-cataract ocular or systemic comorbidities. This approach could have affected the generalisability of the new questionnaire and this issue was addressed by undertaking a separate qualitative study of the final Cat-PROM5 questionnaire to understand the potential impact of this issue. The qualitative findings were reassuring (as were subsequent studies which included people with visually significant comorbidities).

Key findings

A brief psychometrically robust questionnaire was developed which performed at least as well or better than the previous 'best of class' longer alternative. The Cat-PROM5 questionnaire is flexible, allowing patients to map their personal visual difficulties to the questions and it is sufficiently brief to make it feasible to implement it into routine high-volume cataract surgical services.

The final five-item Cat-PROM5 set of questions comprise:

1. In the past month, have you felt that your bad eye is affecting or interfering with your vision overall?

    No, never
    Yes, some of the time
    Yes, most of the time
    Yes, all of the time

2. In the past month, how much has your eyesight interfered with your life in general?

    Not at all
    Hardly at all
    A little
    A fair amount
    A lot
    An extremely large amount

3. How would you describe your vision overall in the past month - with both eyes open, wearing glasses or contact lenses if you usually do?

Excellent
Very good
Quite good
Average
Quite poor
Very poor
Appalling

4. In the past month, how often has your eyesight prevented you from doing the things you would like to do?

Never
Some of the time
Most of the time
All of the time

5. In the past month, have you had difficulty reading normal print in books or newspapers because of trouble with your eyesight?

No difficulty
Yes, a little difficulty
Yes, some difficulty
Yes, a great deal of difficulty
I cannot read any more because of my eyesight
I cannot read because of other reasons

Relationship with other work packages

Cat-PROM5 was established as the cataract patient reported outcome measure for the programme and was taken forward to WP3: Predict-CAT (development of benefits prediction models; presentation of risk information; development of cataract decision aid) and WP4: Involve-CAT (measure of self-reported benefit in feasibility study for possible future fully powered RCT).

Further Information

- **Appendix 1** contains the Cat-PROM5 questionnaire.

Full details on the development of Cat-PROM5 have been published and are available as open access papers:

Sparrow JM, Grzeda MT, Frost NA, Johnston RL, Liu CSC, Edwards L, Loose A, Donovan JL. *Cat-PROM5: A brief psychometrically robust self-report questionnaire instrument for cataract surgery*. Eye 2018; 32:796-805.
Open access: https://www.nature.com/articles/eye20181.

Sparrow JM, Grzeda MT, Frost NA, Johnston RL, Liu CSC, Edwards L, Loose A, Elliott D, Donovan JL. *Cataract Surgery Patient Reported Outcome Measures: A head-to-head comparison of the psychometric performance and patient acceptability of the Cat-PROM5 and Catquest-9SF self-report questionnaires*. Eye 2018; 32:788-795.
Open access: http://www.nature.com/articles/eye2017297.

Work Package 2 – Cataract Surgery Risk Models for PCR and VA Loss

WP2 Aim

- Validate or update existing risk models for posterior capsule rupture (PCR) and monocular visual acuity harm using multicentre data from 180,000 electronic medical records (EMR) for cataract surgery.

Approach

Two key outcomes of importance in cataract surgery were modelled. These are the two primary safety outcomes used in the NOD audit.

Posterior capsular rupture (PCR) is defined for the purposes of the National Audit as "posterior capsule rupture with or without vitreous prolapse or zonule rupture with vitreous prolapse" and abbreviated simply as PCR. It should be noted that the definition excludes zonule dehiscence where no vitreous prolapse has occurred. PCR is the most frequent intraoperative complication and when it occurs as defined above there is an approximately 6-fold increased risk of vision loss, an approximately 40-fold increased risk of post cataract retinal detachment and an approximately 8-fold increased risk of endophthalmitis (serious postoperative infection in the eye).

Visual Acuity (VA) Loss in the eye undergoing surgery is vision which is significantly worse after the operation than before as measured by the sight test letter reading chart. VA Loss is defined as a doubling or worse of the visual angle.

Data collection

Multi-centre data were obtained from the National Ophthalmology Database (NOD) through a data sharing agreement with the data controller HQIP. The data covered cataract surgery undertaken by participating centres between 2006 and 2010. The anonymised sample consisted of 180,114 eyes from 127,685 patients.

Data analysis

Known and suspected candidate predictors for PCR and VA Loss were evaluated in a logistic regression analysis.

Posterior Capsule Rupture. PCR data were complete, PCR arose in 3514/180114 = 1.95% of eyes. The candidate predictors age, gender, pupil size, surgeon grade, any alpha blocker, axial length; glaucoma, age related macular degeneration, amblyopia, brunescent / white cataract, diabetic retinopathy, corneal pathology, high myopia, no fundal view/ vitreous opacities, previous vitrectomy, pseudoexfoliation / phacodonesis, uveitis synaechaie, other ocular pathology, other macular pathology and other retinal vascular pathology were offered to the logistic regression model.

Visual Acuity Loss. The VA data were less complete. Of the 180,114 eyes in the sample, 147,962 had pre-op visual acuity readings. For 104,437 (70.6%), they were corrected visual acuity readings and for 43,525 (29.4%), they were uncorrected readings. A further 1,591 eyes had preoperative pin hole readings only, but these were not used in this analysis. Of the 180,114 eyes in the sample, 116,038 eyes had post-op visual acuity readings. For 74,887 (64.5%), they were corrected visual acuity readings, for 28,678 (24.7%), they were uncorrected visual acuity readings and for 12,473 (10.8%) they were pin-hole visual acuity readings, which were accepted postoperatively. Of the 147,962 eyes with pre-op visual acuity readings, 95,561 (64.6%) had post-op visual acuity readings. For 60,578 (63.4%), they were corrected visual acuity readings, for 24,460 (25.6%), they were uncorrected visual acuity readings and for 10,523 (11.0%) they were pin-hole visual acuity readings. For 1,455/95,561 (1.52%) eyes, the visual acuity got worse after cataract surgery.

The candidate predictors PCR, age, gender, any alpha blocker, able to lie flat, inability to co-operate, axial length in quintiles, glaucoma, age related macular degeneration, amblyopia, brunescent / white cataract, diabetic retinopathy, corneal pathology, high myopia, no fundal view/ vitreous opacities, previous vitrectomy, pseudoexfoliation / phacodonesis, uveitis / synaechiae, inherited eye disease, optic nerve / CNS disease, other ocular pathology, other macular pathology, other retinal vascular pathology, surgeon grade, and pupil size were offered to the logistic regression model for VA Loss, adjusting for pre-operative VA.

Backwards and forwards logistic regression was carried out, taking account of the clustered nature of the data (the fact that left and right eyes from the same patient are unlikely to be independent).

Key findings

PCR. The following variables entered into / remained in the logistic regression model: age, surgeon grade, pupil size, glaucoma, brunescent / white cataract, no fundal view/ vitreous opacities, previous vitrectomy, pseudoexfoliation/ phacodonesis and other ocular pathology. The area under the ROC curve (C-stat) for this model was 0.64 indicating reasonable fit.

VA Loss. The following variables entered into / remained in the logistic regression model: PCR, age, axial length, pupil size, gender and the co-pathologies; glaucoma, age-related macular degeneration, diabetic retinopathy, corneal pathology, brunescent / white cataract, previous vitrectomy, other macular pathology, other retinal vascular pathology and other ocular pathology. The area under the ROC curve (C-stat) for this model was 0.71 indicating reasonable fit.

Both the PCR and VA Loss models were broadly similar to our earlier work carried out on 55,678 cataract operations up to 2006[12] suggesting that the models were reasonably stable through time.

Limitations

The main limitation of this work overall was the fact that the data obtained related to surgery undertaken between 2006 and 2010. In addition, VA data were not complete with only 64.6% of eye operations having both a pre- and a postoperative VA measurement available for calculation of the VA Loss measure.

In order to address the limitation of the surgery being from a relatively early cohort of operations, fresh data were requested from the NOD through a data sharing agreement with the data controller (HQIP). The fresh data allowed analysis of model stability through time to be performed for PCR on data up to 2014, reported below under the heading of WP2 Added Value PCR model stability through time.

Relationship with other work packages

Based on these approaches calculators estimating the risk of PCR and VA Loss were taken forward to WP3 for determination of patients' preferred mode of risk presentation and identification of issues of concern to patients for FAQs and development of the Cataract Decision Aid (CDA). The CDA was subsequently tested in the WP4 feasibility RCT.

Work Package 2 Added Value – PCR model stability through time

WP2 Added Value – Aim

- To review methodological options for development of the risk prediction model for PCR on extended more up-to-date data, and to assess PCR model stability through time.

Approach

Available options for logistic regression model building were reviewed and applied to the data. In this methodological exercise we chose to analyse PCR only as the data for this key surgical outcome were complete.

Data collection

Multi-centre data were obtained from the National Ophthalmology Database (NOD) through a data sharing agreement with the data controller HQIP. The data covered cataract surgery undertaken by participating centres between 2000 and 2014. The anonymised sample consisted of 602,459 operations conducted on the eyes of 404,857 patients.

Data analysis

Four statistical approaches were used: 1. A naïve approach in which nesting of eyes within patients was ignored; 2. Robust standard errors; 3. Generalized estimating equations; and 4. Multilevel models. Each of these approaches was followed using three approaches to candidate risk predictor selection for model building: a) A clinically sound list of predictors; b) Chi-square p-value $p<0.10$ for predictors to exclude at the outset those unlikely to be statistically important; c) Univariate regression effect size satisfying $0.9>OR>1.20$ to exclude small and therefore clinically unimportant effects. Each of the four analytical approaches resulted in the same set of predictor variables for the three selection options (a,b,c).

Following on from these analyses, stability through time was considered. Early years were excluded as the sample sizes were smaller and the less common risk indicators were too few which would generate unstable results. The 10-year period from 2005 to 2014 was taken forward to assess model stability through time. The models derived from the three options for initial selection of candidate predictors were applied to each year separately and assessed for stability across the ten years.

Key findings

The four statistical approaches all returned the same list of predictors with only minor variations in ORs within each of the three candidate predictor selector options (clinically sound or chi-square p<0.1 or 0.9>OR>1.20). The three candidate predictor selection options however resulted in slightly different lists of predictors indicating that the method of selection of candidate predictors (clinically sound or chi-square p<0.1 or 0.9>OR>1.20) was more important in these data. Model fit was fair to moderate for all the models with C-statistics near or slightly above 0.6.

Since the four statistical approaches were essentially equivalent in these data, only the naïve approach (ignoring nesting of eyes within patients) was used to assess stability through time. This was done separately for each of the models derived from the three options for initial selection of the candidate indicators (clinically sound or chi-square p<0.1 or 0.9>OR>1.20).

The models, which had been derived on the full set of data, were separately applied to each of the years separately and parameters examined for stability across the years. For a number of variables statistical significance within years was not consistently achieved. Overall, for all the initial candidate selection options the models for the period 2005 to 2011 were stable. 2012 appeared as a 'rogue' year and was not consistent with earlier or later periods. 2013 and 2014 were comparable.

These results confirm that although the models are generally temporally stable there are inconsistencies through time which underlines the importance of reviewing risk models from time to time where these are being used to adjust for outcomes of centres and surgeons.

Limitations

The data used in these analyses are now four years old and these analyses could be brought up to date through analysis of a fresh sample.
Because of the problem of missing VA data, it was not deemed appropriate to extend the analysis to include VA Loss.

Relationship with other work packages

This 'added value' item in the programme has provided key information about stability of the PCR risk model and the model-based risk calculator used in the Cataract Decision Aid (WP4).

The wider implications of these findings include confirmation that the risk model, although stable across certain periods, is prone to shifts which emphasises the need to review and revise the models which are being used in national audits to adjust for case complexity of centres and surgeons.

Work Package 2 Added Value – Cataract Outcomes in people aged 90 years and over

WP2 Added Value – Aim

- To report operative complications (PCR) and Visual Acuity outcomes for cataract surgery in people aged 90 years and over

Approach

Analysis of elderly patients undergoing cataract surgery

Data collection and analysis

A subgroup analysis of data obtained through a data sharing agreement with the NOD and HQIP (as noted above) was undertaken. Outcomes of 25,856 cataract operations undertaken between 2000 and 2014 in 19,166 people of 90 years and older were analysed[9].

Key findings

- A significant operative complication, posterior capsule rupture (PCR) occurred in 2.7% of all operations. While this is higher than the rate found among younger patients the surgical risk remains relatively low in comparison with the potential for older people to gain visual benefit
- Postoperative VA was available for 61.8% eyes, being good enough to drive (6/12) in 74.4% overall and reaching this level in 84.7% for those without visually significant co-morbidity

Limitations

The main limitation of this study was the reduced proportion of patients with a postoperative visual acuity recording

Relationship with other work packages

This work was a stand-alone sub-study offering added value to the programme overall.

Work Package 2 Added Value – Refractive outcomes of cataract surgery

Postoperative refraction (spectacle requirement) is determined by choice of the replacement lens implanted into the eye during a cataract operation. The outcome of the refraction dictates the spectacle correction required following surgery.

WP2 Added Value – Aim

- To undertake a proof of concept analysis for identification of indicators of refractive outcome using complex numbers as a basis for analysis.

Approach

Measurement of refraction consists of three variables (sphere, cylinder, axis) which makes the analysis and reporting of refraction problematic and a variety of simplified measures are used clinically to choose an appropriate lens implant at the time of surgery. A comprehensive measure of refraction can however be achieved using complex numbers[13]. This complex numbers approach has been used in this proof of concept analysis to assess its methodological feasibility for use as a comprehensive refractive outcome measure for cataract surgery.

Data collection and analysis

A fresh set of data were obtained from the NOD through an updated data sharing agreement with HQIP. Data on 1,070,601 cataract operations were received. Of these, the primary outcome of interest was available for 491,414 operations. The primary outcome was trivariate and was modelled using a multivariate normal multilevel model and four different multilevel structures.

Key findings

Despite the methodological complexity of the analytical approach it has been feasible to apply the method to refractive outcome data and to rigorously model indicators of postoperative refraction. Several significant eye health factors have been revealed as being of importance to the postoperative refractive outcome. This method will be of interest to surgeons for outcomes assessment and refinement of refractive outcomes.

Limitations

Less than half of the full set of data contained all the information required for the analysis, potentially reducing generalisability of the results. The purpose of the analysis however was to demonstrate feasibility through a proof of concept analysis which has been achieved.

Relationship with other work packages

This analysis is a stand-alone item in regard to other work packages, but postoperative refraction is highly relevant to patients' postoperative perception of their surgical outcome. The relationship between refractive outcome and patients' self-reported opinion has been highlighted in the findings of the WP4 discordant outcomes study.

Further Information

- **Appendix 2** provides additional detail on the logistic regression analyses undertaken based on 180,000 cataract procedures.
- **Appendix 3** provides additional detail on the stability through time of the risk models based on 600,000 cataract procedures.
- **Appendix 4** provides additional detail on outcomes for people aged 90 years and over based on 25,000 cataract procedures.
- **Appendix 5** provides additional detail on indicators of refractive outcomes using a novel approach to analysis of refraction data based on the subgroup of 491,414 operations where relevant pre- and postoperative data were available.

Work Package 3

WP3 Quantitative Elements – the Predict-CAT Cohort Study

WP3 Quantitative Aim

- To develop a benefits prediction model for personalised prediction of self-reported Cat-PROM5 benefit from cataract surgery

Approach

Conduct a cohort study of 1500 people undergoing cataract surgery to phenotype participants with a view to identification of preoperative indicators of postoperative self-reported benefit from surgery in terms of final postoperative outcome and improvement from preoperative baseline.

Data collection

The cohort study took place at two sites, Bristol and Gloucestershire. Preoperative patients approaching cataract surgery were invited to participate. Inclusion criteria were age 50 years or older, approaching either first or second eye cataract surgery, willingness to participate and to provide informed consent, ability to understand and complete Cat-PROM5, EQ-5D-3L, EQ-3D-5L +vision, EQ-5D-5L and ICECAP-O questionnaire instruments as required. Full recruitment of 1506 participants was achieved, with 1204 patients recruited in Bristol and 302 in Gloucestershire. It is noteworthy that encouragement by our Patient Advisory Group to introduce a self-referral option resulted in 15% of Bristol's recruitment being through this route. Following withdrawals, losses to follow up and data cleaning, 1181 participants had valid data for analysis.

CONSORT

TRANSPARENT REPORTING of TRIALS

Predict-CAT CONSORT 2010 Flow Diagram

Enrolment

Potentially eligible
(BEH n=10898; GHNHSFT n=4696)

Excluded (n= 2236)
- Screen fail (n=6)
- Declined to participate (n=2230*)

(BEH n=1479; GHNHSFT n=751.
*Known reasons: No appts prior to surgery n=164; Transport/travel issues n=521; Too many appts n=181; Family bereavement n=4; Caring for family member n=66; Too busy n=103; Does not want drops n=4; Poor health n=256; Language difficulties n=5; Anxiety n=13; Private patient n=5, Not interested/unwilling to wait n= 674, NK n=294)

Pre-Op Baseline

Randomised HE (n= 1506)
(BEH n=1204; GHNHSFT n=302)

Group 1
Allocated to **EQ-5D-3L (n=502)**
- Completed baseline (n=436^)
- Did not complete baseline (n=66*)

(*Reasons: No longer wished to participate n=41; Surgery before baseline appt n=15;
DNA appt n=4;
Cancelled appt n=3;
Retrospective screen fail (not listed/listed in error) n=2;
Became ineligible due to deteriorating health/capacity) n=1)
^number analysed varies between reports due to data completion

Group 2
Allocated to **EQ-5D-3L+Vision (n=501)**
- Completed baseline (n=438^)
- Did not complete baseline (n=63*)

(*Reasons: Cancelled appt n=1;
Deceased n=1
DNA appt n=5
No longer wishes to participate n=42
Retrospective screen fail (age/health/capacity) n=3;
Not listed/removed from list n=1;
Surgery before baseline appt n=10)
^number analysed varies between reports due to data completion

Group 3
Allocated to **EQ-5D-5L (n=503)**
- Completed baseline (n=444^)
- Did not complete baseline (n=59*)

(Reasons: Cancelled appt n=3;
DNA appt n=6;
Lost to follow-up (px not contactable to arrange appt) n=2;
No longer wishes to participate n=36;
Surgery before baseline appt n=12)
^number analysed varies between reports due to data completion

Post-Op Follow-Up

Proceeded to follow-up (n=436)
- Completed follow-up1 (n=413)
- Lost to follow-up (n=23*)

(*Reasons: Deceased n=3;
Lost to follow-up n=1;
No longer wishes to participate n=4;
Retrospective screen fail (due to type of planned surgery) n=2;
Not listed/removed from list n= 5;
Post-op beyond study timelines n=5;
Removed from surgery waiting list n=3)

Proceeded to follow-up (n=438)
- Completed follow-up1 (n=418)
- Lost to follow-up (n=20*)

(*Reasons: Deceased n=1;
Lost to follow-up n=2;
No longer wishes to participate n=4;
Became ineligible (health) n=1;
Not listed/removed from list n=5;
Surgery delayed n=2;
Surgical complications n=1
Post-op beyond study timelines n=4)

Proceeded to follow-up (n=444)
- Completed follow-up1 (n=412)
- Lost to follow-up (n=32)

(*Reasons: Deceased n=2;
Lost to follow up n=3;
DNA n=1;
No longer wishes to participate n=6;
Not listed/removed from list n=11;
Post-op beyond study timelines n=9)

Follow-up2 sub-set - BEH only (n=42)
- Completed follow-up2 (n=36)
- Lost to follow-up2 (n=6)

(Reasons: withdrawn from Predict-CAT n=4; did not return FU2 Cat-PROM5 n=2)

Follow-up2 sub-set - BEH only (n=41)
- Completed follow-up2 (n=36)
- Lost to follow-up2 (n=5)

(Reasons: withdrawn from Predict-CAT n=4; did not return FU2 Cat-PROM5 n=1)

Follow-up2 sub-set - BEH only (n=42)
- Completed follow-up2 (n=36)
- Lost to follow-up2 (n=6)

(Reasons: withdrawn from Predict-CAT n=4; did not return FU2 Cat-PROM5 n=2)

Data Analysis

Among the 1181 participants with valid data there remained scattered missing data items. In order to preserve the sample from further attrition these missing data items were imputed using multivariate imputation by chained equations (MICE) in which 20 datasets were created with missing data replaced by imputed values, each entailing ten cycles of regression switching. This method relies on the Missing at Random (MAR) assumption. In parallel with the analyses based on the multiple imputation routine, complete case analyses were also undertaken (missing values ignored). These were based on 1089 complete cases.

Initial descriptive analyses of candidate predictor and outcome variables was undertaken, followed by linear regression modelling of two Cat-PROM5 Rasch calibrated outcome variables. The final outcome was modelled as the postoperative score and the improvement from baseline as the difference between the pre- and postoperative scores (delta approach). Potential predictors were categorised into blocks according to a timeline order, earlier to later, and from the most general diseases to the most specific. All models included age, gender and the baseline Cat-PROM5 status as predictors regardless of their observed 'statistical importance'. Skewed distributions were transformed if necessary and variables were entered into the model in ordered blocks and an F test performed for each block as a whole. If the p-value for the block was above 0.05 then the whole block was rejected. Where the p-value of the test for the block was less than 0.05, the specific predictors were examined and those with small effects iteratively removed. After each stage all the predictors were reviewed by an experienced ophthalmologist as to whether the list and the model made clinical sense and predictors without plausible clinical meaning removed. Following model construction, the model diagnostics were checked and acted upon if necessary.

Results

The results from both approaches (ignoring missing values and applying multiple imputation) produced very similar results. The models based on analysis of the multiply imputed sets of data for Cat-PROM5 postoperative final outcome achieved an R2 of 29.1% and that for improvement in Cat-PROM5 from pre- to postoperatively an R2 of 31.2%. The final models, with and without imputation, are available in Appendix 6 of this report.

Key Findings

- Full recruitment to the cohort study was achieved. Losses to follow up were below the planned for 20%. Some further losses arose due to missing key variables but the resulting sample of just under 1200 was sufficiently powerful for the intended analyses with and without multiple imputation.
- Models with and without imputation produced similar results.
- The benefit indicators required for the model comprise data items readily accessible within the context of patient care. The only indicator which is not routinely collected in preoperative clinics is reading vision, but this is easily tested, and its requirement should not present a significant barrier to implementation.

Limitations

- The main limitation of this element of the work was the moderate fit of the prediction models, each with an $R^2 \approx 0.30$.
- Performance of these models will be further assessed on fresh data in WP4 of the programme.

Relationship with other work packages

The self-reported benefits prediction models will be set alongside the models predicting adverse outcome risk from WP2, these all being taken forward into the Cataract Decision Aid being developed in the Phase Two qualitative element of WP3. The Cataract Decision Aid will in turn be taken forward to the WP4 feasibility RCT.

Work Package 3 Qualitative Element 1, Predict-CAT-QUAL – Presentation, Content and Perceptions of Usefulness of Information for Cataract Patients

WP3 Qualitative aims, Element 1

- To identify the most acceptable way of presenting risk and benefit probability information to patients as part of a Cataract Decision Aid
- To identify from patients and health care professionals, cataract surgery specific Frequently Asked Questions to inform development of a Cataract Decision Aid
- To explore the acceptability of Cat-PROM5 to healthcare providers
- To explore with patients and health care professionals, issues of shared and informed decision-making during cataract surgery patient counselling to inform the development and implementation of a Cataract Decision Aid in routine practice

Approach

Qualitative research elements ran alongside the quantitative research. The purpose of this work was to gather views and insights which could be used inform development of the decision support tools being developed in the programme.

This work included:

- Conducting focus groups and interviews with patients
    - To inform presentation format of risk information for a risk and benefit probability calculator development
    - To inform presentation, issues of concern, supporting information and FAQs for development a Cataract Decision Aid
- Conducting interviews with healthcare professionals (HCPs)
    - To explore the acceptability of Cat-PROM5
    - To inform content development and explore the usefulness of decision aids in clinical practice
    - To consider attitude towards and practice of shared decision making

Data collection

Patients: Two focus groups and 15 one-to-one semi-structured interviews were conducted with 33 individuals attending the Bristol clinics and two attending the Gloucestershire clinics. The mean age of patient participants was 77, with the youngest participant being 55 years old and the oldest 86. Out of the 33 patient participants, fourteen were women, all but one was White British, and English

was the first language of all patient participants. The majority of patient participants were from more affluent geographical areas. Most were suffering from other eye co-morbidities. In addition to the formal qualitative approach, the interpretation of the findings was supported by the programme PPI Patient Advisory Group.

Healthcare professional (HCP) interviews: Eight interviews with clinicians based in Bristol and three with clinicians based in Gloucestershire were conducted between March 2017 and February 2018 (11 interviews in total). Eight of the HCP participants were female. Four HCP participants were ophthalmologists, three nurses, and four were optometrists.

Results

Risk benefit information

Patients participating in the study were shown four different numerical ways of presenting risk and benefit information, each accompanied by a pictogram representing visually that probability: N out of 100 individuals; number of people treated for one to experience benefit/complication; and probability as a decimal. Patient participants preferred "N out of 100 individuals" as the most easily understood format to present both risks and benefits, which corresponded with the preferred option of the Patient Advisory Group. In terms of the pictograms, there was no general agreement as to which was the most useful to aid understanding of probabilities, or indeed whether pictograms are needed at all when presenting this information.

Information for Frequently Asked Questions (FAQs) for a Cataract Decision Aid, Patients Frequently Asked Questions (FAQs) were identified through patient participants' narratives discussing the information they found useful at the time, questions they would have asked now but didn't ask then, and emerging gaps in knowledge of surgery-specific issues.

Items of specific concern to patients included

- What the surgery will entail (dispelling myths and alleviating anxiety)
- The potential risks in relation to the potential benefits from the surgery
- Post-surgery complications and self-care
- Information about the Intra Ocular Lens (IOL) options and refractive implications post-surgery
- How long is it safe to wait to have the surgery before risks overtake benefits
- The impact of comorbidities on the risks and benefits
- Other people's experiences

Information for Frequently Asked Questions (FAQs) for a Cataract Decision Aid, Healthcare Professionals:

Information of importance highlighted by HCPs included

- Risks and benefits
- Providing information about refractive outcomes
- About the surgery and surgery after-care
- Whether surgery is needed
- Waiting times

Cataract Decision Aid, Healthcare Professionals views on Cat-PROM5:

Overall participants thought Cat-PROM5 captures how vision-related quality of life might be impacted on by cataracts. The majority thought the outcome measure was short, simple and easy for patients to complete on their own. Participants thought it captured information of importance to HCPs, but a few commented on the usefulness of knowing the specific areas affected by cataract, something not captured by the Cat-PROM5. Several believed the Cat-PROM5 captured information already used to inform decision-making. Participants thought having a structured way of capturing VRQoL information would make more consistent the discussions taking place during consultations, introduce the patient perspective in decision-making, standardise and formalise the way VRQoL information is collected and recorded, and facilitate post-surgery assessment of surgery outcome. Some challenges were raised relating the relevance of Cat-PROM5 to the role of the HCP at different stages of the care pathway, including whether responses to the questions would be influenced by patients' and/or their family's wish to have the surgery and attitudes of HCPs towards its effectiveness and added value in clinical practice.

Shared-decision making, Healthcare Professionals: Shared-decision making appears to be inconsistently practiced by HCPs. The majority of HCP participants thought there is variability in practice and inconsistencies in the kind of information discussed with patients, the way this information is discussed and explained, and how decisions are made by individual clinicians. For some, this variability can result in inequities in who is offered surgery. All HCP participants agreed that the introduction of standardised and structured ways to support the information exchange process would enhance practice, for example the introduction of Cat-PROM5 that would ensure VRQoL of each patient is taken into consideration but also formally reported in patients' health

records, and the use of FAQs and decision support tools to enhance the information exchange process and support informed and shared decision-making.

HCPs were open to the use of decision-support tools in clinical practice, but several challenges to implementation were discussed, mainly the time needed to implement in routine practice and how well the decision support tool and its aims fit in with current care pathways. Some HCP participants thought the need to discuss individualised information, such as the individualised risk and benefit probabilities, would introduce certain complexities in practice: it would require time, access to individualised patient information at the time of the consultation, and expertise from the part of the clinician seeing the patient that might not always be possible in the current care context. Implications for informed consent and the time available to patients to reflect on the information given in order to make informed decisions were raised.

Key findings

- Patients preferred N out of 100 as the most easily understood risk presentation format
- Issues of interest, concern or importance for cataract surgery were elicited from patients and health care professionals. This knowledge will inform the development of the Frequently Asked Questions section of the Cataract Decision Aid (Part Two of the qualitative WP3 work)
- Cat-PROM5, as part of a cataract decision aid, was seen as worthwhile by healthcare professionals in terms of standardising the assessment of self-reported difficulty suffered by patients with cataract
- A cataract decision aid and shared decision making in cataract surgery was mostly seen as relevant and necessary by healthcare professions, with risk information considered an important aspect of a shared discussion.

Limitations

Moderate sample sizes may limit the generalizability of these findings although recruitment continued until saturation was achieved which will ameliorate this potential risk

Relationship with other work packages

The format for presentation of the personalised risk / benefit information and information content for FAQs were taken forward directly to the Cataract Decision Aid (CDA) in the WP3 Predict-CAT qualitative Phase Two instrument development stage.
The acceptability to health care professionals of Cat-PROM5 and views on shared decision making informed the approach to engagement with this service critical group in regard to the setting up of the WP4 feasibility RCT.

Work Package 3 Qualitative Element 2 – Development of a Cataract Decision Aid and a Cataract Decision Quality Measure

WP3 Qualitative aims, Element 2

- To develop a Cataract Decision Aid (CDA) in a 'frequently asked questions' (FAQ) format in which the likelihood of self-reported benefit is set alongside risks of harm (surgical complications / VA Loss) to provide an integrated decision-support tool with personalised prediction of outcomes
- To develop a Cataract Decision Quality Measure (CDQM) for the cataract surgery decision
- To conduct qualitative user testing of the personalised CDA with patients and clinicians to assess usability, acceptability, utility and expected impact
- To refine the personalised CDA and CDQM for use in WP4 (feasibility trial)

Approach

The International Patient Decision Aid Standards (IPDAS) Collaboration Checklist for the development and quality assessment of patient decision aids was used to guide the development of the CDA. We used a collaborative multi-stage development process, involving key stakeholders, and we conducted qualitative user-testing interviews with patients and clinicians.

Development of the prototype CDA

The multi-stage, iterative process used to develop and refine the CDA included a number of key activities and data sources.

- A CDA User Reference Group (URG) of Healthcare Professionals and patient representatives was convened. The role of the URG was to act as an editorial team to oversee the development of the CDA (including agreeing the clinical evidence content and patients' FAQs) and the associated CDQM.
    - 16 individuals were recruited to the URG, including two patient representatives, six members of the Study Team, and eight clinicians (working within cataract services of the four NHS Trusts participating in the Cataract Research Programme). The URG was consulted via teleconferences and email to obtain feedback on different versions of the CDA. Suggestions made by the URG were integrated into the revised versions of the CDA, and its implementation plans, when feasible.
- A focus group was conducted with the Cataract Research Programme PPI Patient Advisory Group (PAG) members. The PAG members had all undergone cataract surgery previously, and so they were able to draw upon their own personal experiences of making the treatment decision and their experiences of the surgery and recovery.
    - Five members of the Patient Advisory Group attended the focus group session. The audio recorded focus group was transcribed, and feedback gathered. Recommendations were integrated into the developing CDA.
- To further inform the evidence-based content of the CDA, several sources of data / evidence were consulted
    - Focus groups and patient interviews previously conducted as part of the Phase One WP3 Qualitative Work
    - Scoping review of published guidelines and literature
    - Expert opinion
    - Predicted harm models (WP2)

A prototype CDA was developed in agreement with the User Reference Group, using the data gathered as outlined above.

The prototype CDA comprised these elements:

- Introduction page
    - This page introduces the patient to the CDA, explaining the purpose of the tool, and outlines the structure / content. It reinforces the message that patient's preferences are important when making decisions about cataract surgery
- Section A: Frequently Asked Questions (FAQs)
    - This section uses general information to provide answers to some of the questions patients frequently ask about cataract surgery. It will help patients to think about the things that matter most to them.
- Section B: What matters to you? What questions do you have?
    - This section provides space for patients to write notes or any questions they have for their clinician during their upcoming appointment.
- Section C: Personalised information about your likely outcomes
    - The clinician will use this section with patients during their appointment to provide personalised information about their likely outcomes, and to discuss any issues that are specific to them personally.

This version of the CDA was used for the user testing interviews.

User testing of the prototype CDA

User testing of the CDA was conducted with patients and clinicians to assess usability, acceptability, utility and expected impact. The four NHS cataract surgical centres involved in the Cataract Research Programme, Bristol, Gloucestershire, Torbay and Brighton were used to identify and recruit patients and clinicians for the user testing interviews.

Patients were eligible to participate if they were post-operative patients who had undergone cataract surgery (at least six weeks previously), were able to provide informed consent, were able to understand English, and were willing to take part in a telephone interview. We aimed to recruit five patients from each site (total of 20 patient participants), and purposively sample to achieve a cross-section of participants (age, gender, ethnicity, and with varying symptoms/comorbidities). User testing interviews were conducted with a total of 26 participants: 20 patient participants (10 male and ten female) across the four participating sites, and six clinician participants (four

ophthalmologists, one nurse, one optometrist) across three of the four participating sites. Clinician input was augmented by the User Reference Group and the Study Management Team.

Semi-structured interview questions for the patient participants covered the following topics: views on usefulness of the CDA, understanding of the content (including terminology, presentation of risks etc.), views on the FAQs included and the ranking of the FAQs (inclusion of any other FAQs), views on the different parts of the CDA (e.g. personalised risk section, space for questions), layout / design, readability, when / how they would like to receive the CDA and potential improvements.

We aimed to recruit 8-12 clinician participants across the four participating sites using a snowballing technique. Clinicians were eligible to participate if they were involved in the management or treatment of patients undergoing cataract surgery. Semi-structured interview questions for the clinician participants covered the following topics: views on usefulness of CDA (for themselves and for patients), accuracy / comprehensiveness of the content, views on the different parts of the CDA (e.g. personalised risk section, space for questions), fit within local clinical systems, potential influence on their behaviour, perceived barriers / facilitators to use, contextual factors that might impact future implementation.

Patient and clinician participants were sent a copy of the prototype CDA prior to the telephone interview taking place. They were instructed to read through the CDA prior to the interview and were encouraged to make a note of any initial reactions and feedback that they wished to provide to the researcher. All audio recordings (patient and clinician) were transcribed verbatim for qualitative analysis and were imported into NVivo. A Framework Analysis approach was used to analyse the data, based on the key topic areas covered by the interview guide (e.g. usefulness, use in clinical practice) and the different components of the CDA (e.g. FAQs, personalised information section). Framework analysis included the following stages: a) familiarisation of the data, b) coding of the data, c) charting the data by each code, d) reviewing and summarising each of the charted codes for the groups of participants. When new themes emerged that were not captured by the initial framework, these were added.

Framework analysis was conducted on 26 user testing interview transcripts. Patient and clinician data were analysed together, but any key differences in perspective were noted. The initial framework was guided by the interview schedule and consisted of five categories, including: 1) Initial thoughts on the CDA and the purpose of the CDA; 2) perceived usefulness of the CDA; 3) CDA

content; 4) CDA design / format; 5) implementation in a clinical setting. Two new codes were added to the framework during analysis: 1) information provision and preferences; 2) decision making role and experiences. Data were summarised into a matrix for each category in the analytical framework. Verbatim quotes were extracted and entered.

Refining the prototype CDA

The results from the user testing interviews with patients and clinicians were used to refine the prototype CDA. The key sections included in the prototype CDA remained the same, but the booklet increased from seven to nine pages. Additional questions were added to Section A (Frequently Asked Questions), and further clarification and details were added for the questions that were already included. Presentational changes were made to Section C (Personalised Information About Your Likely Outcomes), technical terms were replaced with plain English terms, and an additional page for notes was added. This revised version was circulated to the Predict-CAT Study Management Group for further feedback and agreement on the version that would subsequently be used in the WP4 randomised feasibility trial.

Cataract Decision Quality Measure (CDQM)

Decision Quality Measures (DQMs) are condition-specific instruments that have been developed to assess patients' understanding of available treatment options, their personal preferences, perceived readiness to make a decision, and the alignment between their preferences and preferred option. DQMs are made up of four key sections: A) Knowing your options (knowledge questions); B) What is important to you? (preference questions); C) Thinking about the decision you face (readiness to decide, standard items that are not condition specific); D) Choice of treatment (assesses current treatment preference). We drew on our experience of developing DQMs for other clinical areas (e.g. breast cancer, tonsillectomy) as part of a shared decision-making implementation programme.

We aimed to develop a Cataract Decision Quality Measure (CDQM), which would subsequently be used in the WP4 randomised feasibility trial. The content of the CDA was used to inform the knowledge questions used in the CDQM (Section A). The candidate FAQs included in the CDA and the feedback received from patients during the user testing interviews and the Patient Advisory Group focus group (about those things that mattered most to them) informed the preference questions (Section B). The readiness to decide questions (Section C) were standardised generic questions that have been used in other previously developed DQMs. Section D (Choice of treatment) was guided by the available options.

Key Findings

By involving key stakeholders in the development of the CDA, we have been able to ensure that input from patients and clinicians has been considered in terms of the content, format, and planned use, and that the CDA best reflects the needs of the end users. Initial input from the cataract Patient Advisory Group highlighted those issues that matter most to patients when making the decision about cataract surgery (including likelihood of success / benefits, pain, what happens during the surgery, side effects / risks, eye sight changes, and post-surgery recovery), and this was incorporated into the CDA. Evidence syntheses ensured that the information provided in the CDA was evidence-based (FAQs in Section A), the risk-calculator element (developed as part of WP2) that was incorporated (Section C) ensured that individualised risk-information could be provided to patients, and further input from clinicians helped to ratify the accuracy of the CDA content.

Qualitative user-testing interviews found that patients and clinicians were generally positive about the CDA, and they felt that it would be useful to both patients and clinicians when discussing cataract surgery. Both patients and clinicians felt that it would provide a trustworthy source of information, including adequate and accurate information; clinicians felt it would act as a framework and a reminder to cover certain information that they might otherwise not cover, and patients felt that the CDA provided them with answers to those questions they would want answered before making a decision. Patients and clinicians felt that the CDA would reinforce the idea that a 'choice' does exists with regard to cataract surgery, it would encourage better patient involvement in cataract surgery decisions, it was easy to understand, and it could feasibly be integrated into clinical care pathways. Some concerns were expressed by clinicians regarding the time needed to complete the personalised risk element of the CDA in the consultation, and they had some reservations over how much information patients would want about their individualised risks. However, there was a disparity between what clinicians' felt their patients might want in terms of risk information, and what patients said they wanted, after reflecting on previous experiences where they had not received this information. These factors were considered during refinement of the CDA and will be considered during the implementation of the CDA during the feasibility RCT (WP4). Although some patients and clinicians suggested alterative digital formats of the CDA, most felt that the most usable and feasible format would be a paper based CDA. Overall, it was felt that the CDA would be feasible to use in routine clinical settings, however, some key issues were raised during the user-testing

interviews, which will be considered during the feasibility RCT (WP4) and future refinement of the CDA.

Limitations

Despite significant efforts to recruit clinicians from all four collaborating sites it was not possible to recruit from one site. The clinical input was however strong from the user reference group and the research programme team.

Relationship with other work packages

Predict-CAT qualitative work (FAQs etc.) fed directly into the development of the Cataract Decision Aid (CDA). Both the CDA and the Cataract Decision Quality Measure (CDQM) were taken forward to as key instruments in the WP4 feasibility RCT.

Work Package 3 Health Economics – Performance of Health Utilities and Calibration of Cat-PROM5

WP3 Health Economic aims

- To evaluate performance of existing and emerging health economic indices (preference-based measures EQ-5D-3L, EQ-5D-3L+VIS, EQ-5D-5L, ICECAP-O) in people undergoing cataract surgery
- To investigate how cataract related visual disability measured using Cat-PROM5 can be calibrated or mapped against existing and emerging health economic indices of utility

Data collection

Data for these health economic elements of the programme were collected as part of the WP3 Predict-CAT cohort study undertaken at two sites in England. Questionnaires were completed both pre- and postoperatively for all participants with questionnaire data being available for 1315 participants. Cat-PROM5 and ICECAP-O data were collected from all participants, with collection of the other three health economic utilities, EQ-5D-3L, EQ-5D-3L+VIS, EQ-5D-5L, on a 1:1:1 random allocation basis.

Data analysis

Performance. Descriptive statistics for each of the instruments were considered in terms of floor and ceiling effects, convergent validity, known groups and responsiveness to surgery. There are currently two algorithms to generate EQ-5D-5L preference-based utilities for a UK sample; A Value Set for England (EQ-5D-5L-VSE) [8] and the EQ-5D Crosswalk (EQ-5D-5L CW) [9]). For completeness, both were used here.

Calibration. Linear models and adjusted limited dependent variable mixture models were estimated. Full data for 1,181 patients undergoing cataract surgery were available. The Cat-PROM5 was mapped to two quality of life measures (EQ-5D-3L and EQ-5D-5L) and one capability measure (ICECAP-O). We did not map to the EQ-5D-3L with vision “bolt-on” questionnaire due to the infrequent use of that questionnaire and unclear relevance to the calculation of quality-adjusted life years. Separate models were estimated for pre- and postoperative outcomes. Model performance was assessed using likelihood statistics, graphical inspections of model fit and error measurements including mean square error.

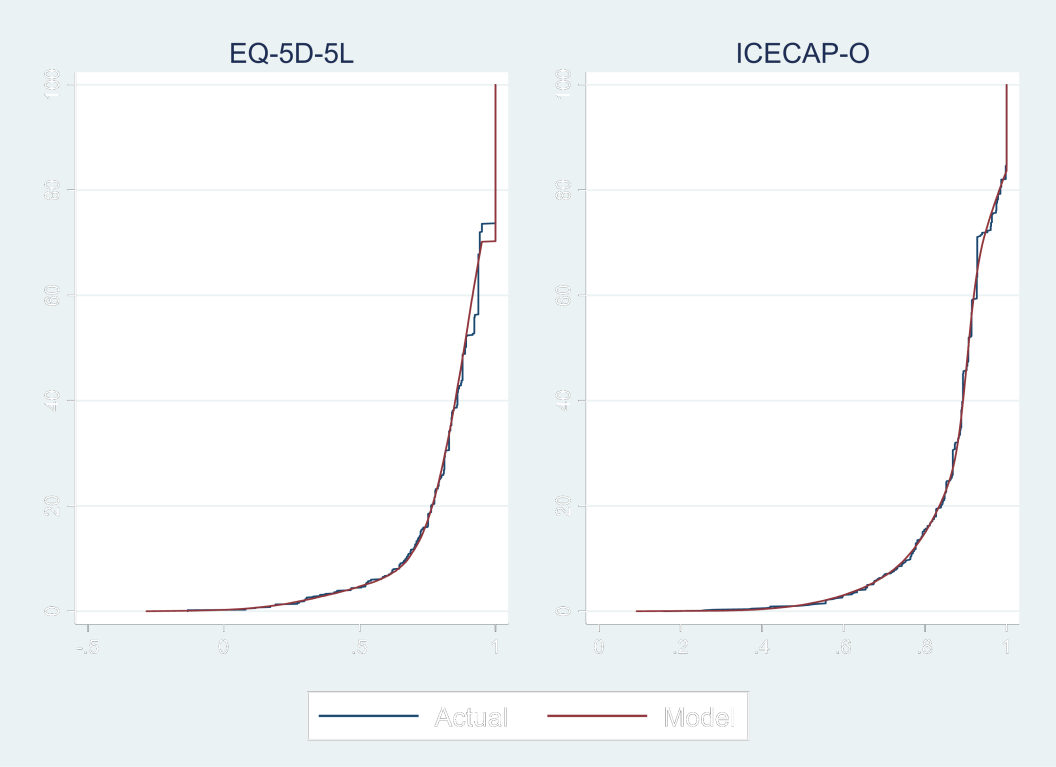
Results

Table 1 Summary of Preference Based Measure performance against criteria evaluated

Criteria			Preference based measure				
			EQ-5D-3L+VIS	EQ-5D-3L	EQ-5D-5L VSE	EQ-5D-5L-CW	ICECAP-O
Ceiling effect			✓	×	×	×	✓
Floor effect			✓	✓	✓	✓	✓
Convergent validity	Cat-PROM5 correlation		✓	×	✓	×	?[a]
	Visual acuity correlation		×	×	×	×	×
Known groups validity	First eye or second eye surgery		×	×	×	×	×
	Habitual near visual acuity in the operated eye (logMAR)		✓	×	×	×	?[b]
	Ocular comorbidities		×	×	×	×	×
Responsiveness	Change scores and effect sizes	Visual QOL	×	×	×	×	✓
		Patient perceived benefit of surgery	×	×	×	×	?[c]
		Change in near visual acuity in operated eye	×	×	×	×	×

Visual QOL and Patient perceived benefit obtained from post-operative supplementary questionnaire
Ceiling effect - greater than 15% scoring the maximum of one
First eye or second eye surgery - Second eye surgery patients were expected to report significantly better HRQL
Habitual near visual acuity in the operated eye (logMAR) - Patients with worse visual acuity were expected to report significantly lower HRQL
Ocular comorbidities - Patients with ocular comorbidities were expected to report lower HRQL
Floor effect - greater than 15% scoring the minimum possible score
? indicates conflicting results for EQ-5D randomisation groups
[a] EQ-5D-3L group correlation coefficient did not exceed 0.3
[b] Between group differences significant ($p<0.05$) for the EQ-5D-3L group only
[c] No difference in change scores for the EQ-5D-3L group

Figure 2 Calibration / Mapping: Comparison of actual and predicted follow-up distributions



Key findings

Performance. The EQ-5D-3L and EQ-5D-5L did not perform well across almost every measure of validity and responsiveness and had the largest ceiling effects (Table 6). The EQ-5D-3L+VIS had a lower ceiling effect and better convergent validity with the Cat-PROM5. It was able to differentiate between patient groups who did and did not report benefit from surgery and improved quality of life after surgery. However, it also identified small positive effect sizes in patients who reported no benefit or improved quality of life after surgery. The ICECAP-O also had a low ceiling effect and there was some evidence of convergent validity with the Cat-PROM5. It performed best on many measures of responsiveness.

Calibration / Mapping. Adjusted limited dependent variable mixture models dominated linear models on all performance criteria. Mixture models offered good to excellent fit. Three component models that allowed component membership to be a function of covariates (sex, age and diabetic status) and which conditioned on some or all of these covariates (depending on the target measure and pre- and post-operative status) had superior performance to models with fewer components and which did not condition on covariates.

Limitations

A limitation of the study is that the three versions of the EQ-5D questionnaire were completed by different patient cohorts. If participants were to have completed every questionnaire, response burden would have been excessive.

Relationship with other work packages

In addition to linkages and dependencies noted here within the Predict-CAT WP3 cohort study, these Health Economics elements of the programme link Cat-PROM5, developed in WP1, to established and emerging health economic utilities which are preference-based measures. This work is indirectly linked to the WP4 feasibility RCT as it would inform any fully powered future RCT on the choice of a preference-based measure to be included in such a future study. Furthermore, the calibration or mapping exercise would allow health economic analyses to be undertaken based on Cat-PROM5 data without the need to increase questionnaire completion burden through adding a health economics preference-based measure to the trial protocol.

Further Information

- **Appendix 6**. Provides further information on the Predict-CAT cohort study and the development of the self-reported outcomes and benefits models
- **Appendix 7**. Provides further information on the qualitative elements of WP3 relating to format and content of information for patients derived from patients and healthcare professionals
- **Appendix 8**. Provides further information on the development of the Cataract Decision Aid
- **Appendix 9**. Provides further information on the performance of existing and emerging health economic indices when used for cataract surgery
- **Appendix 10**. Provides further information on calibration or mapping of Cat-PROM5 to emerging health economic indices

Work Package 4

WP4 Quantitative Elements – Feasibility of a Cataract Decision Aid RCT and Validation of Benefits Prediction Models

WP4 Quantitative Aims

- To undertake a feasibility study for a possible future fully powered randomised controlled trial (RCT) of the use of a cataract decision aid (CDA) incorporating personalised risk and benefit information to improve shared decision making in cataract surgery
- To estimate the sample size for a possible future fully powered RCT
- To assess the accuracy of the self-reported outcomes and benefits prediction model developed in the programme

Approach

This feasibility study, named 'Involve-CAT' took a form of a two-arm RCT with the CDA as an intervention. The intervention group was defined as a group of patients in which the CDA was used while patients in the control group underwent standard NHS care. The allocation of patients to groups was conducted through a 1:1 block randomisation process by centre. It was assumed that within each centre 5-6 participants should be allocated within each arm (receiving the CDA intervention vs. not receiving the intervention). The research process was multistage, starting with pre-screening and proceeding through assessment of patient eligibility for the study, recruitment, obtaining consent, randomisation, baseline clinical and self-reported pre-operative vision assessment with Cat PROM5, randomisation to either the CDA intervention or defaulting to standard care, making a shared decision about surgery, and finally documenting the outcome of the operation, including a post-operative self-reported vision difficulty assessment with Cat-PROM5.

The Cataract Decision Quality Measure (CDQM) developed as a part of WP3 was used to assess patients' decision quality. The CDQM is a measure intended to capture patient's knowledge about options, preferences and readiness to make a decision about the treatment. It was treated as a primary outcome in this study. The CDQM questionnaire was completed twice, first before the consultation at the baseline visit and then immediately following the consultation. A secondary quantitative outcome was Cat-PROM5, a self-reported measure of vision quality developed and validated in WP1 of the grant programme. The Cat-PROM5 questionnaire was completed by patients

twice, initially at the baseline pre-operative time-point and then at the post-operative follow-up visit.

Preoperative parameters were used to predict the expected postoperative Cat-PROM5 responses based on the two 'benefits prediction' models developed in WP3. The predicted responses were then compared against the actual self-reported outcomes following surgery to assess the validity of the predictions.

Sample size calculations were undertaken to assess the size of a possible future fully powered RCT.

Data collection

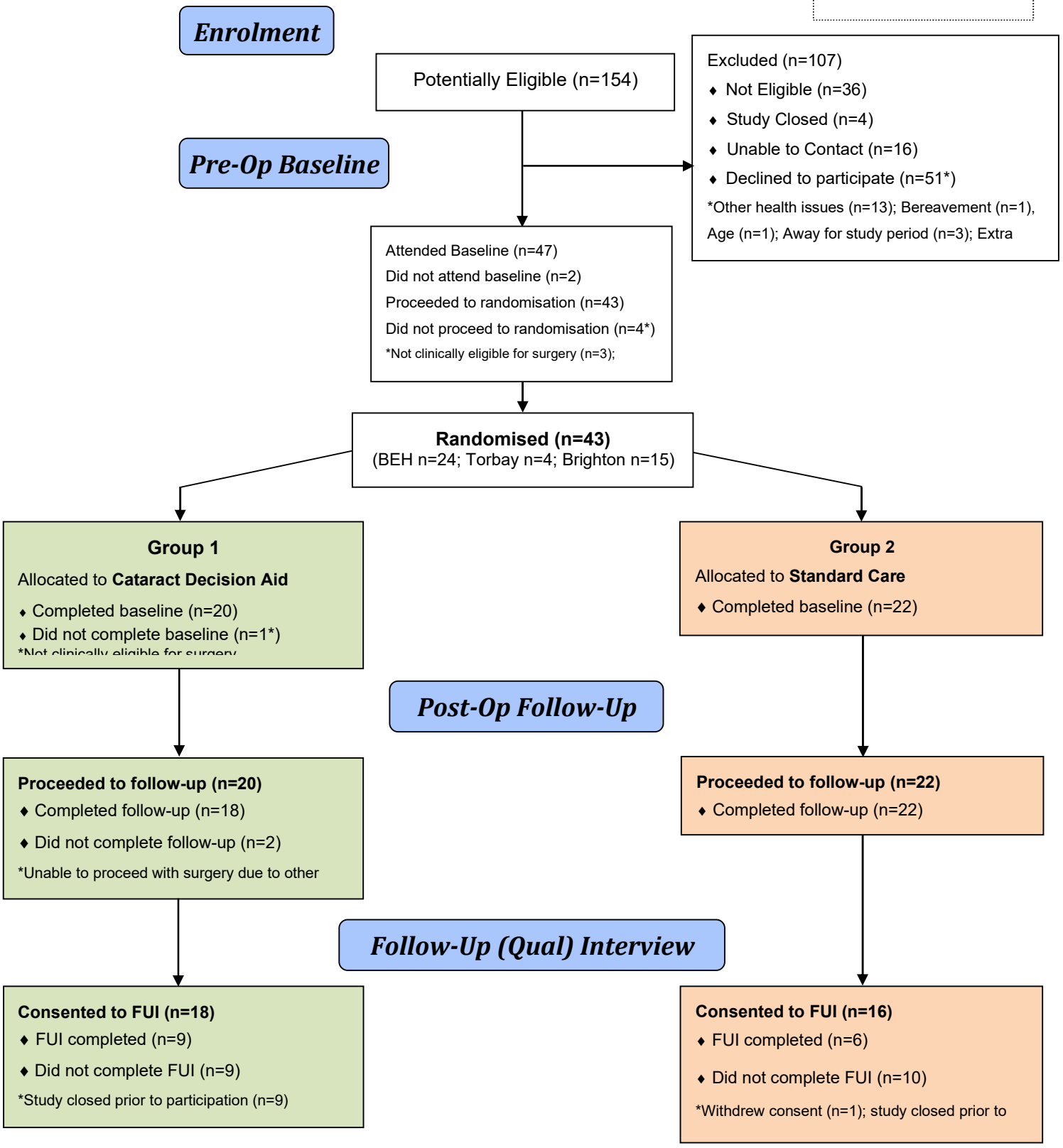
The study assumed recruitment of 40 participants from four cataract research centres (Bristol, Torbay, Brighton, Gloucestershire), ten patients each per centre. During the study however it became clear that Gloucestershire would be unable to join the study due to local capacity issues and Torbay only able to join late due to staff illness. This required over-recruitment by Bristol and Brighton, with full recruitment of 42 patients none-the-less being successfully achieved.

CONSORT

TRANSPARENT REPORTING of TRIALS

Involve-CAT CONSORT 2010 Flow Diagram

As at 15th July 2019



Data analysis

The effects of the intervention were analysed in two ways. For the summary scores expressed by a single value (knowledge about cataract (Section A), readiness for decision making (Section C) and Cat-PROM5) t-tests for both dependent (paired) samples and independent samples were undertaken. Tests for dependent samples were performed to assess the importance of the intra-individual changes in CDQM scores and Cat-PROM5 measures from before to after the consultation. The t-tests for independent samples were used to assess the differences post-consultation and post-surgery respectively for those two measures between study arms.

For the linked sections of the CDQM questionnaire comparing reported preferences with the decisions actually made (Sections B and D) the Spearman's Rho was calculated as a basic statistic capturing levels of concordance between what is reported as being important for patients and what is then actually chosen.

To inform a sample size estimate a power study was undertaken providing calculations of sample sizes needed for a possible future fully powered RCT to investigate the impact of the CDA on the quality of patient decisions. The magnitudes of effect sizes were chosen according to Cohen's classification of standardised effect sizes (standard deviation of unity).

Bland and Altman plots were used to compare predicted outcomes with observed outcomes for the two benefits prediction models, i.e. prediction of final postoperative outcome and prediction of improvement in score from pre- to postoperatively.

Results

The intervention and control groups were similar across key variables at baseline indicating successful randomisation.

Table 2 Comparisons of primary (CDQM) and secondary outcomes (Cat-PROM5) across intervention and standard care groups, for before and after consultation / operation

	Intervention group (n=20)	Standard Care group (n=22)	Total (n=42)	t-test for independent samples comparing intervention group with standard care group t, df, p
Results for CDQM scores (candidate primary outcomes)				
Knowledge, Section A: mean (SD, n)				
Before consultation	5.00 (1.59, 20)	4.75 (1.12, 20)	4.88 (1.34, 40)	1.059, 40, 0.296
After consultation	4.95 (1.32, 20)	5.05 (1.36, 20)	5.00 (1,32, 40)	*-0.237, 38, 0.814*
t-test for dependent samples (paired t-test) comparing intra-individual changes before and after consultation: t, df, p	0.129, 19, 0.899	-1.371, 19, 0.186	-0.565, 39, 0.575	
Readiness for decision, Section C: mean (SD, n)				
Before consultation	2.85 (3.18, 20)	1.82 (2.86, 22)	2.31 (3.02, 42)	1.107, 40, 0.275
After consultation	0.55 (1.39, 20)	0.77 (1.60, 22)	0.67 (1.49, 42)	*-0.478, 40, 0.635*
t-test for dependent samples (paired t-test) comparing intra-individual changes before and after consultation: t, df, p	3.049, 19, 0.007	1.479, 21, 0.154	3.166, 41, 0.003	
Results for quality of vision (Candidate secondary outcome)				
Cat-PROM5: mean (SD, n)				
Before surgery	-0.33 (2.36, 20)	-0.29 (1.88, 22)	-0.31 (2.00, 42)	-0.408, 40, 0.685
After surgery	-3.73, (2.83, 17)	-3.01 (3.45, 22)	-3.32 (3.17, 39)	*-0.695, 37, 0.491*
t-test for dependent samples (paired t-test) comparing intra-individual changes before and after surgery: t, df, p	7.872, 16, <0.001	4.025, 21, 0.001	6.801, 38, <0.001	

Primary outcome, CDQM: The tests (for independent samples) conducted after the consultation/ operation show no important differences between the CDA intervention group and the standard care control groups at prior to the consultation (baseline) or after the consultation (follow up) for knowledge (Section A) or readiness to decide (Section C). This suggests that using the cataract decision aid does not improve the knowledge or readiness to decide about cataract and its treatment.

Comparisons between baseline and post-consultation showed no change for knowledge in either group. Unexpectedly however, readiness to make a decision declined after the consultation in the intervention group with little change observed for the standard care group.

Additional basic psychometric analyses were undertaken for questions in section A and C using classical test theory (CTT) to detect possibly malfunctioning questions. The properties of the set of questions conceived as a scale of knowledge (Section A) reveal that it would benefit from review and further refinement (low Cronbach's alphas and low item to total correlations including some negative correlations). On the other hand, the basic CTT analyses performed on items deemed as a scale of readiness to make a decision about cataract surgery (Section C) shows that it has promising features and the scale could form the subject of further analyses conducted from a modern test theory perspective.

Secondary outcome, Cat-PROM5: No significant differences were observed between the intervention and control groups at either preoperative baseline or postoperative points for Cat-PROM5 scores. As expected, significant improvements in Cat-PROM5 scores were observed between baseline and post-operative completions for both groups (paired t-tests). Despite there being no significant differences in Cat-PROM5 scores post-operatively, the score improvement in the CDA intervention group (3.40) was almost half a logit greater than in the control group (2.96).

Sample size estimate: In the absence of a clear primary outcome effect size emerging from the feasibility study, a standard power calculation approach was adopted for sample size estimation for a possible future RCT. For t-tests for independent groups, a small effect size (0.2SD) would be detectable with 80% power by a sample size of 800 (1:1 allocation, 400 in each group). A medium effect size (0.5SD) would be detectable with >90% power by a sample size of 200 (1:1 allocation, 100 in each group). The secondary outcome, Cat-PROM5 did however demonstrate non-significant higher levels of self-reported outcome in the intervention group. Based on this observed secondary outcome effect size and a 1:1 group allocation a total sample of 250 would be required for detection of this effect with 80% power and 325 needed for 90% power.

Performance of the Cat-PROM5 benefits prediction models: The correlation coefficients between predicted outcome and actual outcome were 0.57 for the final postoperative outcome and 0.21 for the change in score between pre- and post-operative Cat-PROM5 completions.

Key findings

- It was feasible to achieve timely and full recruitment despite one of the study sites being unable to participate due to lack of capacity to undertake the research, and the start at another site being delayed for staff health reasons.
- The primary trial outcome measurement instrument, the CDQM did not demonstrate benefit from the intervention based on between group comparisons at follow up.
- Unexpectedly, a decline in readiness to make a decision was observed in the intervention group between baseline and follow up, suggesting that the greater volume of information provided to participants who received the CDA intervention may have caused confusion and undermined their readiness to decide.
- The knowledge section of the CDQM demonstrated psychometric imperfections and would benefit from review and revision.
- The self-reported Cat-PROM5 benefit between baseline and postoperative follow up was greater in the CDA intervention group.
- For independent groups, a small effect size (0.2SD) would be detectable with 80% power by a sample size of 800 (1:1 allocation, 400 in each group), a medium effect size (0.5SD) would be detectable with 90% power by a sample size of 200 (1:1 allocation, 100 in each group)
- The performance of the prediction model for final Cat-PROM5 postoperative outcome was superior to the model for prediction of change in Cat-PROM5 score from pre- to postoperative time points.

Limitations

A limitation of WP4 related to the cataract decision quality measure (CDQM), the knowledge section of which would benefit from further development work prior to further consideration of its use as an outcome in a fully powered RCT. The CDQM readiness to make a decision section unfortunately produced an unexpected result in which the CDA arm became less ready to make a decision following the consultation. These issues limited the ability to base a power calculation directly on outcomes of the feasibility RCT.

A further limitation was the fact that the prediction model developed in the WP3 Predict-CAT cohort study for a change in Cat-PROM5 score did not demonstrate high predictive power in the WP4 model validation exercise. This is explained by the fact that a subtraction of two measures (post-minus preoperative Cat-PROM5 scores) has greater variance and is therefore subject to higher uncertainty. The final Cat-PROM5 prediction model however was confirmed as having reasonable predictive power.

Relationship with other work packages

This WP4 has depended on outputs from all the earlier work packages:

- Cat-PROM5 from WP1
- Risk models for PCR and VA Loss from WP2
- Benefits prediction models, qualitative elements guiding instrument development, CDA and CDQM from WP3

Work Package 4, Qualitative – Perceptions of the Cataract Decision Aid (CDA) for Shared Decision Making

WP4 Qualitative Aims, Element 1

- To explore how a CDA incorporating personalised risk and benefit information influences preoperative shared decision making for cataract patients and health professionals
- To explore how patients and health professionals perceive the CDA in the context of routine care

Approach

Using a mixed-methods approach, qualitative and quantitative analysis of the cataract decision aid (CDA) was conducted. This included quantitatively scoring consultations using the OPTION 5 Observer instrument, comparing appointments with the CDA (Intervention Group) and without the CDA (Standard Care Group) of the feasibility RCT.

Data collection and analysis

Recordings of the RCT appointments were each scored in relation to shared decision making. The 'used a framework' approach was employed to qualitatively analyse the consultations. Additionally, interviews were conducted with patients and clinicians and their perceptions of the appointments and the decision aid qualitatively analysed.

Key Findings

Several key issues arose that would likely impact on the effectiveness of the CDA and the extent to which it could be easily integrated into routine care or as part of a possible future full-scale RCT.

- Overall, observer OPTION 5 scores revealed that there was a significant difference in mean total scores between the CDA and the Standard Care (SC) arms with all five items scoring higher on average in the CDA consultations compared to the SC consultations. These results indicate that when clinicians use the CDA with patients, more SDM behaviours are present, and they are carried out to a greater extent.
- Analyses revealed that the key SDM tasks of introducing the choice and eliciting patient's preferences were not always carried out, regardless of whether the CDA was used.
- Consultants did not consistently perceive the choices of 'surgery, delay or decline' as useful or even legitimate and therefore some did not agree with the presentation of choices in the decision aid.
- For many of the patients, they had strong prior preferences and had already decided that they wanted the surgery. Thus, it would be difficult to re-introduce the choice talk at the consultation stage. This indicates that the shared decision-making discussion around having or declining cataract surgery might be better placed earlier in the clinical care pathway or at least initiated earlier, before patients had formed strong prior preferences of what they wanted.
- The CDA was very effective at providing information to patients about their options, including their personalised risk, but it did little in the way of supporting the introduction of choice or the elicitation of patients' preferences, partly because of the patients' prior preferences.
- A number of approaches could help to rebalance the process towards SDM including: more work could be done in the consultation to re-introduce the concept of choice, emphasising that surgery is not a foregone conclusion, and providing a clear rationale for patient involvement in the decision making process; or, the introduction of choice could be initiated earlier in the care pathway (e.g. with an optician).
- Overall, clinicians felt that the CDA could be integrated into routine clinical settings, and delivered as part of a larger RCT. However, changes would need to be made to the way in which the CDA is delivered, options including:
    - The CDA should be used as part of a two-stage process. The CDA should be introduced to patients before the consultation, ideally being sent to patients with

appointment letters. At the consultation the 'what matters to me' and personalised 'risks and benefits' could be elaborated and discussed.

- Possibly introduce the CDA at an earlier point in the care pathway such as prior to referral to the hospital.
- Provide more consistent and adequate clinician training in SDM to the wider team of health professionals who will be delivering the CDA.
- The risk calculators should be better integrated into the local clinical systems with as much of the information as possible pre-populated prior to the consultation.

Limitations

Cataract patient pathways vary considerably between centres. This study involved three centres and different implementation considerations may apply in other centres. The sample sizes were not large but saturation indicated that these were reasonable.

Relationship with other work packages

Earlier work packages all fed into this element of the work which looks forward to a possible future RCT of the cataract decision aid which acknowledges lessons learnt here.

Work Package 4 Qualitative, Element 2 – Mismatching Outcomes

WP4 Qualitative Aims, Element 2

- To explore background and specific instances of discordance of outcomes where the perception of the health professional was at odds with that of the patient following cataract surgery

Approach

Patients with discordant or mismatching outcomes were sought among the Predict-CAT WP3 cohort study participants and consultants at the four collaborating centres were also asked to separately identify and recruit patients in their centre with discordant outcomes. Health care professionals with experience of this relatively uncommon phenomenon were invited from the collaborating centres to join the study.

Discordance could be either positive or negative, defined as

Negative mismatching outcomes:

- The patient is unhappy with good surgery and VA outcome: Patients who are dissatisfied with the outcome of their surgery or perceive a negative outcome, even though there is no clear clinical explanation for experiencing a poor outcome. Examples might include dysphotopsia, reflections, glare, residual minor refractive error.

Positive mismatching outcomes:

- The patient is happy with poor surgery or VA outcome: Patients who are reporting satisfaction/positive outcomes where the VA or technical elements of the surgery appear to indicate that a normally symptomatic clinical problem exists of which the patient seems to be unaware. Examples might include reduced VA, IOL subluxed, mild to moderate macular dysfunction.

Data collection

Data collection for this sub-study was organised in two separate strands.

The first strand included semi-structured, one-to-one interviews carried out face-to-face or over the phone with patients falling within the mismatching outcomes definition. The second strand of the study involved semi-structured, one-to-one interviews with healthcare professionals (HCPs) involved in cataract care delivery, who had experiences with the discordant outcome phenomenon.

Interviews with seven patients took place. Three patient participants were identified through the Predict-CAT study, and four were identified by HCPs during clinics and using the mismatching outcomes definitions disseminated to each centre. Nine HCPs were interviewed, one participant was an optometrist, and eight were consultant ophthalmologists.

Data analysis

All interviews were, with participants' consent, voice recorded, fully transcribed and anonymised. Anonymised transcripts were analysed in NVivo 10 (computer software for the collation, storage, analysis, and management of qualitative data) guided by principles of thematic analysis.

Key findings

- Discordance in most patients' experience was the result of unexpected changes in visual ability after surgery, for example changed spectacle prescriptions, problems with peripheral vision, whilst two participants experienced unexpected symptoms such as floaters and dry eyes which they felt compromised their quality of life.

- Patient narratives highlighted the nuanced and multi-dimensional "lived experience" of vision, whereby patients might be happy with one aspect of vision, e.g. distance vision, but dissatisfied with another, perhaps more valued aspect that determined their overall judgement on the outcome of surgery.
- The factors raised by HCPs to explain the phenomenon were linked to medical practice, doctor-patient communication, and patient-specific attributes. Factors linked to medical practice were primarily the technologies used, for example the choice of IOL and unintended optical side effects resulting from individual lenses, and the use of measurement and testing devices able to capture the visual experiences of the patients.
- Quality of the doctor-patient relationship was thought by both HCPs and patients to shape patients' perceptions of outcome. Both believed there was a need for shared decision-making when making decisions on lens choice and refractive aims of the surgery.
- Participants discussed the need for a more personalised approach to patient counselling to address discordances thought to exist between patients' and HCPs' understanding of what "good vision" means; to address patient preferences and expectations and realign these to a more realistic understanding of the potential outcome; and provide accurate and individualised information on what the patient should expect in their visual abilities after surgery, including use of spectacles for near and distance vision, and any potential compromises in aspects of vision other than VA.
- For patients, trust towards the HCPs was also important, and this trust was found to be compromised through breakdowns in the process of care delivery, for example continuity of care, ease of access to post-op follow-up, and trust in the providers' abilities to carry out ophthalmological examinations and procedures.
- HCPs thought it was important to understand the "discordant outcomes" case profile in order to identify determinants of discordance, and target patients who might be more prone to be dissatisfied with their outcome for more intensive patient counselling.
- Presence of co-morbidities and a more complex clinical profile, the patients' visual abilities before the surgery, the patients' personality, and social characteristics were thought by HCPs to explain discordant outcomes.
- The only positive mismatching outcome recruited to the study also appeared to suffer the most significant visual disability before the surgery.
- For patients the quality of cataract surgery counselling received prior to their surgery i.e. trust in HCPs, quality of their relationship with the HCPs and being engaged in informed and shared decision-making were what shaped their post-operative experiences.

- Several barriers to changing practice were identified however, more often linked to the challenges of changing current ways of working, and the time available to HCPs to engage in such in-depth personalised conversations with patients.

Limitations

This relatively uncommon phenomenon made it difficult to identify patients who had experienced a discordant outcome following their cataract surgery. There was however a consistency between the perceptions of affected patients and HCPs with experience of the phenomenon.

Relationship with other work packages

The WP3 Predict-CAT cohort study was used as a source of patients with discordant outcomes and HCPs from the collaborating centres who had knowledge of the programme and its aims assisted with finding patients and with undertaking interviews. This aspect of the work was however relatively self-standing, although it did relate to the key programme themes of patient focused care and improved shared decision making.

Work Package 4 Health Economic elements – Implementation Costs of a Cataract Decision Aid

WP4 Health Economic Aims

- To estimate the implementation costs and potential savings of the use of a Cataract Decision Aid (CDA)

Approach

This study compared the additional resources incurred as a result of implementing the CDA compared to standard care in the Involve-CAT pilot RCT study. The additional resource is the time taken to collect data needed for the CDA and administer it during the shared decision making (SDM) discussion and subsequent impact on discussions in the remaining appointment. There is also the potential for the CDA to impact the number of patients choosing to have surgery and, if it affects the risk profile of patients having surgery, the healthcare use following surgery (e.g. A&E visits).

Data collection and analysis

The start and end time of each stage of the pilot RCT study appointment were recorded by the clinicians undertaking the research assessment and clinical assessment appointment. Costs were

obtained from the Personal Social Services Research Unit (PSSRU). The cost per minute of the clinician's time was calculated and used to estimate the total resource use for each participant's clinic appointment. The clinical assessment and SDA were predominantly led by consultant ophthalmologists. The CDA required an additional assessment of near vision. Secondary analysis included the cost of this additional near vision assessment. Cost differences between study arms were assessed using two-sample t-tests.

Key findings

- The mean and median duration was longer in the CDA arm for all intervals reported.
- Two optometrists recorded how long the assessment of near vision took for a subset of patients in the CDA arm. The mean duration of the two assessors was 2.6 minutes.
- The mean total costs associated with NHS resource use in the primary analysis was £52.20 for the CDA arm and £37.80 for standard care, the difference being £14.40, p=0.06, N=40.
- Inclusion of the additional test for near vision in the secondary analysis increased this difference to £16.87, p=0.03.
- Since all patients in both arms progressed to surgery with little difference observed for subsequent healthcare resource use (single centre, N=23).
- Use of a CDA is likely to moderately increase preoperative clinic cost as a result of a longer shared decision-making consultation and the need for a near vision test for the benefits calculator tool.

Limitations

Despite a relatively small sample size in this feasibility RCT it does appear that the introduction of a CDA would incur modest additional cost.

Relationship with other work packages

All previous elements of the programme, WP1, WP2 and WP3 fed directly into this cost analysis.

Work Package 4 Added value – Ethical Perspectives of Immediately Sequential Bilateral Cataract Surgery

The practice of Immediately Sequential Bilateral Cataract Surgery is controversial in the UK, opposing views relate on the one hand to the low but unquantifiable risk of bilateral vision loss in the event of an adverse event arising which affects more than a single operation on an operating list (e.g.

infection, contamination) and on the other hand to potential efficiency savings and convenience for patients only needing a single trip to the operating theatre where they have cataract affecting both eyes.

WP4 Added Value Aim

- To undertake a thematic analysis of a stakeholder meeting exploring the Ethical Perspectives of Immediately Sequential Bilateral Cataract Surgery

Approach

A semi-structured independent stakeholder meeting was held at the Royal College of Ophthalmologists London headquarters in June 2018. This event was convened separately from the Research Programme by one of the programme co-applicants (CL) who approached the CI with a proposal to undertake transcription and qualitative analysis of the discussion which took place at the meeting.

Data collection and analysis

In total, 29 stakeholders attended the meeting, invited through purposive sampling. The professional characteristics of stakeholders included but were not limited to: Ophthalmologists (9), patients (5), religious leaders (4), ophthalmic nurses (3), ethicists (2), lawyers (2) and commissioners (1). Thematic qualitative analysis was conducted on the resultant transcript of the discussion.

Key findings

Three overarching themes were identified, which were subdivided into eight subthemes. Themes included: (1) Beneficence and Non-maleficence (Patient Benefits, Patient Risks, The Uncertainties of Risk, Patient Interpretation of the Risk-benefit Analysis); (2) Autonomy (Patient and Surgeon Choice, Informed Consent, The Barriers to Effective Communication); (3) Distributive Justice (The Allocation of Resources: The Individual vs the Collective).

The stakeholders concluded that the procedure was an ethical undertaking provided patient autonomy was appropriately considered. This requires an individual interpretation of the risk-benefit balance, which must include an understanding of the low but unquantifiable risk of severe complications, including bilateral blindness. Cost savings to healthcare that may consequently occur following the implementation of ISBCS may be considered a secondary benefit, whereas the primary benefit should be centred on potential (though as yet not well defined) patient convenience factors.

Limitations

Although key ethical issues were identified and analysed, the 29 stakeholders attending could not have included all relevant views. This analysis does however provide a reference point for the issues and ethical factors surrounding the practice of Immediately Sequential Bilateral Cataract Surgery.

The true benefits to patients are as yet ill-defined as are the potential healthcare savings. Similarly, the risks of severe bilateral complications and loss of vision remain unquantified and unquantifiable in light of their rarity.

Further Information

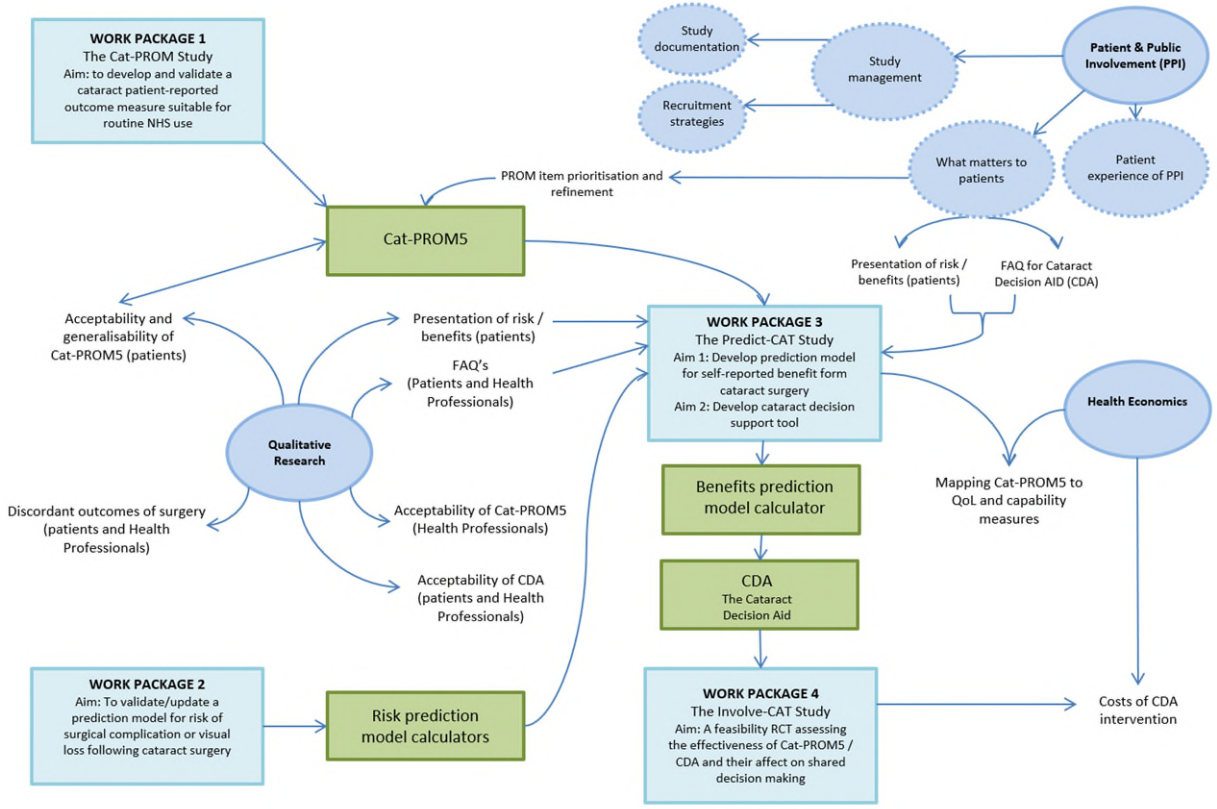
- **Appendix 11**. Provides further information on the Feasibility study for a possible future fully powered RCT
- **Appendix 12**. Provides further information on validation of the Cat-PROM5 outcome and benefit prediction models
- **Appendix 13**. Provides further information on patients' and healthcare professionals' views and practice of shared decision making and the potential role of the Cataract Decision Aid
- **Appendix 14**. Provides further information on mismatching or discordant outcomes following cataract surgery
- **Appendix 15**. Provides further information on implementation costs of use of a Cataract Decision Aid
- **Appendix 16**. Provides further information on ethical perspectives of immediately sequential bilateral cataract surgery

Conclusions

Cat-PROM5, a brief, NHS suitable patient centres outcome measure for visual difficulty related to cataract and its relief through surgery has been developed and validated quantitatively and qualitatively. A statistical model for preoperative prediction of likely postoperative self-reported Cat-PROM5 outcome has been derived and existing models for the index surgical complication and Visual Acuity Loss have been refined on independent data, and the stability through time of the PCR model has been assessed. Qualitative work, with patients and health professionals, has been used to construct and refine a frequently asked questions format cataract decision aid which incorporates general information about cataracts and cataract surgery, personalised predicted probabilities of likely self-reported Cat-PROM5 outcome (indication of potential benefit) and risks associated with surgery in terms of a surgical complication and vision loss (indication of potential harm). Health economic analyses have assessed the performance of established and emerging preference-based health-related quality of life indices in terms of validity and responsiveness to cataract surgery, and Cat-PROM5 has been mapped to these health economic utilities. A feasibility study for a possible future RCT has been undertaken to assess the potential for a future fully powered trial of the CDA developed in this programme.

(Synopsis word count 14,926)

Research Map



Patient and Public Involvement

The Cataract Research Programme has been supported by a Patient and Public Involvement (PPI) Patient Advisory Group (PAG) throughout the programme, from the Grant development and application stage, to programme completion, with group sessions and comments from individuals contributing positively and successfully to many aspects of the work.

The lead applicant established a Patient Advisory Group (PAG) at the pre-application stage. The group consisted of five patients who had attended the Cataract treatment service at the Bristol Eye Hospital who had received surgery on one or both eyes. The patients were therefore experts on their own experience and could meaningfully contribute their own thoughts and understanding of their visual ability and advise the management team on a wide range of themes relating to the programme. During the programme some group members left for personal reasons and were succeeded by new members recruited from the Hospital cataract service.

Chaired by Professor David Evans (who previously led People in Health West of England), the PAG met twice a year at the Bristol Eye Hospital (10 meetings in total). At the inaugural meeting, 'ground rules' were established with an aim to foster a positive and supportive environment to encourage open discussion. Meetings were formatted to include a programme overview and progress report, followed by a task, and concluded with feedback on the impact of their contributions to date. PAG members unable to attend the meetings were invited to contribute remotely if they were able to, and between meetings contributions were gathered from members via email, telephone or post, depending on their preferences and on the task involved. Where relevant documents were shared prior to each meeting to allow members time to become familiar with the content, and research methodology was explained to the group at a level commensurate with their prior knowledge and the requirements of the task.

The following is a summary of the main themes under which the PAG contributed to the running of the programme:

Pre-application stage

- Prior to submission of the application, patient representatives met to review the main aims of the research and discuss their own experiences and thoughts on patient decision support.

Prior to ethical approvals

- The group made suggestions for improvement of the format and content of Patient Information Sheets and Informed Consent Forms to ensure readability. This included changes to font, layout, length and some wording to plain English.
- PAG members suggested improvements to Predict-CAT study promotional material to improve interest in the study and highlight the potential benefits to participants.
- They discussed and supported the idea of a "self-referral" system whereby potential participants could be sent study information by post following their Hospital appointment and could refer themselves to the study team. This improved the recruitment rate of the Predict-CAT study and contributed 15% of overall participants.

Item reduction

- During the development cycles of the Cat-PROM questionnaire, the PAG were invited to take part in a group exercise to help guide decisions on which questions to put forward for the final version of the questionnaire (Cat-PROM5) where initial statistical analysis results were supportive. The exercise involved the PAG members commenting on how important they felt the question was to cataract patients and what theme or domain they thought the question related to.

Qualitative discussion

- The PAG were invited by email to make comments on the drafted Topic Guides for Predict-CAT-Qual, specifically whether the proposed questions were understandable.
- The group were invited to discuss the acceptability of presentation of risk during a face-to-face meeting.
- Led by Christalla Pithara, PAG members discussed their experiences and thoughts on shared decision making and the use of decision aids, prior to commencement of focus groups with study participants. PAG members were also asked to comment on what type of information is important to patients before their operation to inform the "mismatched outcomes" aim of the qualitative work.
- Led by Natalie Joseph-Williams and Daniella Holland-Hart, the PAG members took part in a focus group to discuss two themes: *What matters to patients when deciding to have surgery* (to inform the development of the 'Frequently Asked Questions' section of the BDA) and *to give feedback on Decision Aids*

PAG evaluation workshop

- At the final PAG meeting, Professor David Evans led a group exercise to map the experiences of the group members and management team and to collectively and individually reflect on their experiences of PAG participation. Using a modified version of

the 'cube' framework for PPI process evaluations[14], patient members demonstrated their experience across four dimensions related to their perception of their involvement in research. The analysis of this exercise is underway at the time of writing and it is planned to share the findings of this and group discussion at a later date. The programme team feel that the duration of PAG membership and number of meetings held has provided a unique experience and opportunity to elucidate what does and doesn't work well in PPI within Ophthalmology services and therefore consider our findings may benefit future research.

The Cataract Research Programme was also supported by PPI in the following ways

- Prior to the commencement of the Cataract Research Programme, developers of the host questionnaires VCM1[10] and VSQ[11], which together formed the basis of Cat-PROM5 development, used patient interviews to identify themes and issues relevant to patients (VCM1 consulting visually impaired patients, VSQ cataract patients).
- A former patient of the BEH Cataract Care Service sits on the Programme Steering Committee and provided expert commentary, knowledge and guidance from a user perspective throughout the duration of the programme.
- A patient representative also sat on the User Reference Group (URG) which was established to discuss the developing versions of the CDA.

We are exceptionally grateful for the tremendously generous support given to us by our PAG members, our Steering Committee patient member and our URG member. We are appreciative of the fact that they donated their time, and shared their experiences, contributing in an open and honest way, with significant positive impact on the successes of the programme. We take this opportunity to once again thank them all.

Summary

Successes and limitations

Changes to programme not anticipated in Grant application:

Work Package 3

Operational limitations at the lead site caused a delayed start to recruitment to Predict-CAT due to the local Trust not being able to provide a clinical examination room in a timely manner for the study. Combined with an initial slower-than expected rate of recruitment, this prompted the study team to take the following action, after consulting the PrSC:

- Open an additional recruiting site in Gloucestershire who recruited 302 Predict-CAT cohort study participants
- Consult the PAG for their opinion and advice on improvement to study advertising material and implementation of a 'self-referral' mechanism for recruitment
- Seek a 6-month no-cost extension to the programme – kindly granted by NIHR

Work Package 4

The feasibility randomised-controlled trial which constituted the fourth work package was planned to take place over four collaborating sites. One site did not have capacity to join the study (Gloucestershire) and another had a delayed start due to staff illness (Torbay). The recruitment target of 40 participants was none-the-less achieved as a result of over-recruitment at two of the sites.

Option Grid©

At the time of Grant application, the intention was to develop a patient decision support tool in the format of an Option Grid© in collaboration with co-applicant Glyn Elwyn (previously of Cardiff University (CU)). Following Professor Glyn's departure from CU and the commercialisation of the Option Grid©, the decision was taken with co-applicant Natalie Joseph-Williams of CU (who replaced Glyn Elwyn) to continue with the development of a Cataract Decision Aid (CDA) separately from the commercialised Option Grid© collaborative, using similar methodology and the know-how of staff within CU (with the exception of the risk-benefit indicator models developed in WP3 as intended at

Bristol). The resulting CDA, developed during WP3 and tested during WP4 remains the property of CU and will be made available for free use under a Creative Commons Licence.

The flexibility and support of the NIHR in allowing additional time for completion of the programme, enabled the study team to use their available resources to best effect and complete 'added value' work to enhance the programme's findings and to inform future work. Additional outputs, not anticipated in the Grant proposal, include the following elements of work:

Work Package 1

- Additional qualitative work to analyse the acceptability of the Cat-PROM5 questionnaire, and the coverage of patient concerns (language/accuracy/relevance of questionnaire), and to understand the generalisability of the questionnaire to patients with ocular co-morbidities

Work Package 2

- Additional analyses to understand:
    - Stability of the risk model for the surgical complication of Posterior Capsule Rupture (PCR)
    - Cataract Surgery Outcomes in people aged 90 years and over
    - Indicators of refractive outcomes using a novel analysis method

Work Package 4

- A supplementary qualitative analysis of a stakeholder meeting was undertaken to analyse the ethical implications of immediately sequential bilateral cataract surgery

Future research and future practice

Current and anticipated Programme Impact

Cat-PROM5

Cat-PROM5 has attracted wide interest since its first presentation at the National PROMs Summit (London, UK) in 2016, and further interest from the international community since two development papers were published in the journal Eye[4, 5].

- Cat-PROM5 has been prioritised for implementation by the *NHS Wales PROMs, PREMs and Effectiveness Programme.* They have developed their own software platform for data collection, and Cat-PROM5 has also been translated into the Welsh language. Utilisation of the questionnaire has begun in cataract surgical centres in Wales with a view to becoming part of routine cataract care for around 20,000 Welsh cataract patients annually.
- The Health Quality Improvement Partnership (HQIP) commissioned the Royal College of Ophthalmologists to undertake a feasibility pilot of the use of Cat-PROM5 in the National Cataract Audit between 2017 and 2019[6].
- A web based EMR data collection portal has been developed by the providers of the most widely used ophthalmology EMR in the NHS. The portal allows for flexible data entry either in the hospital setting or by patients in their own home via an emailed secure link sent to them (which can be automated to arrive 2-3 months postoperatively if desired). The portal will transfer data directly into the patient's EMR record.
- The providers of the second most widely used ophthalmology EMR system are currently developing their software to include functionality to collect Cat-PROM5.
- The UK National Institute for Health and Care Excellence (NICE) recently recommended that referral for cataract surgery should not be based on visual acuity alone and go on to suggest Cat-PROM5 as a suitable self-reported outcome measure in their Quality Standards for Serious Eye Disorders[7].
- Cat-PROM5 has been used as a quality of vision outcome measure in a recently published study comparing conventional cataract surgery versus femtosecond laser-assisted surgery[8].
- Benefits to patients from empowerment through an ability to formally document the visual difficulties they experience from their cataracts.
- Benefits to health care providers and surgeons through use of Cat-PROM5 to
    - Better understand a patient's visual burden from cataract
    - Better support them in shared decision making preoperatively
    - Demonstrate to patients, commissioners and the public the benefits provided to patients postoperatively through cataract surgery.

Health Utilities mapping tool

The mapping tool developed to convert Cat-PROM5 data to more traditionally used preference-based quality of life and capability measures (EQ-5D-3L, EQ-5D-5L and ICECAP-O) will enable vision-specific outcome data to be utilised in cost-effectiveness analysis of cataract care.

- Benefit to researchers and research patients through reduced need for completion of multiple quality of life questionnaires, many of which are not responsive to vision.

Risk factor analysis

- The statistical modelling approach for construction of calculators for preoperative assessment of risk of surgical complications and loss of vision (validated here during the assessment of 280,000 cataract operations and updated since) has been integrated in to the most widely used ophthalmology EMR.
- Easy access to this risk information allows for better informed consenting of patients approaching cataract surgery and allows services to ensure that complex patients are operated on exclusively by highly experienced surgeons.
- Pre-operative risk assessment facilitates appropriate case selection for training surgeons in order that they only perform straightforward operations while gaining experience.
- The National Cataract Audit has adopted the approach to adjust provider and individual surgeon outcomes based on case complexity[1]. Since first presenting surgeon's results back to them on a website in 2010 the PCR and Visual Acuity Loss rates have each declined by almost 40%.
    - Without giving surgeon's credit for the complexity of their work through adjustment for case complexity participation in the audit would have been difficult to achieve. This approach has immeasurably enhanced the quality and acceptance by surgeons of the national audit.
    - Risk adjustment discourages risk aversive behaviours by surgeons who might otherwise wish to 'improve their statistics' by only operating on the most straightforward cases.
    - The cost saving to the NHS from avoidance of additional treatments which would have been needed to deal with those complications has been estimated at £2m annually.
- Specific analysis of the risks and outcomes associated with operating on people aged 90 years and over were explored and published in the journal Eye[9] this work having previously been awarded a prize at European Society of Cataract and Refractive Surgery (ESCRS) conference in 2017. Clarifying outcomes in this elderly group of increasing demographic importance will guard against older people not being offered surgery when they would very likely benefit from surgery.

Benefit model

The Cat-PROM5 self-reported outcome prediction tool has not yet been published and as such has not attracted attention. It can however be anticipated that this will be used for personalised prediction of benefits for individual patients in a similar way in which the risk prediction models are now being used. Making available to clinicians a calculator tool which allows them to predict likely benefits for patients preoperatively could further improve informed consent in future.

Cataract Decision Aid (CDA)

The CDA was well received by patients and health professionals, the main concern for the latter being time to use the decision aid. The feasibility trial used the Cataract Decision Quality Measure as a primary outcome which produced confusing results, it may be that review and refinement of the primary outcome measure would provide fresh insights through clearer results.

Staff development

It is worthwhile to note the various personal achievements of research staff associated with the programme. Since the commencement of the programme, all administrative programme staff at the Sponsor site have received promotions within the NHS and two researchers have gained prestigious academic promotions. May we give special thanks to the NIHR for their financial support for continuing professional development and for facilitating the advancement of research capacity across the local (South West) region.

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Thank you to our Programme Statistician, Mariusz Grzeda, whose extensive knowledge of statistics and hard work formed the basis of most of the qualitative work achieved in the programme (WP1,2,3 & 4).

Thank you to our qualitative research collaborators, Daisy Elliott, Christalla Pithara and Fiona Fox, led by Jenny Donovan in Bristol and Daniella Holland-Hart led by Natalie Joseph-Williams in Cardiff.

Thank you to our health economics collaborators, Padraig Dixon, Katie Breheny and Rebecca Kandiyali led by William Hollingworth.

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Thank you to the clinical and administrative teams at our collaborating centres for your substantial efforts in helping us to achieve our goals, led by co-applicant and PI Andy Frost in Torbay and co-applicant and PI Christopher liu in Brighton. It is with deep regret that we note the loss of our friend, colleague co-applicant and PI Robert Johnston, who died in September 2016. Rob was instrumental in obtaining EMR data for the cataract surgery risk factor analyses. We thank Peter Scanlon for taking over Rob's roles as co-applicant and PI in Gloucestershire, and for Peter's support and local leadership in the Predict-CAT study. Thanks also to the optometric research team in Gloucestershire led by Sue Carter who together clinically assessed 300 patient participants.

Contributions of authors

Professor John Sparrow was the lead applicant for the Grant and Chief Investigator for the programme. John is a Consultant Ophthalmic Surgeon with a specialist interest in Cataract Surgery and Glaucoma and is Honorary Professor of Ophthalmic Health Services Research and Applied Epidemiology at the University of Bristol and Clinical Lead for the National Ophthalmology Database Cataract Audit. He was directly responsible for the conception, planning and delivery of all four work packages and oversight of their analysis and interpretation. He provided leadership and support to study staff and researchers. He was previously co-developer for the VSQ and VCM1 questionnaires which laid the groundwork for Cat-PROM5 development. He undertook statistical (Rasch) analysis during the pilot phase of Cat-PROM5 development (WP1). He drafted this final report on the programme and authorised the final version for submission to NIHR. He is the corresponding author and guarantor of the work.

Mariusz Grzeda was the programme statistician. His substantial contribution was the analysis and interpretation of data across all four work packages. His specialist area is Rasch analysis which provided the basis of item reduction for the development of Cat-PROM5 (WP1). In addition, he re-evaluated the statistical risk model for surgical complications (posterior capsule rupture - PCR) and assessed the stability of the model through time (WP2 added value). He developed the benefits prediction models for self-reported benefit from cataract surgery using Cat-PROM5 as the outcome measure (WP3). He undertook the quantitative analyses for the feasibility RCT of the Cataract

Decision Aid and Cataract Decision Quality Measures and performed the preliminary validation of the Cat-PROM5 benefits prediction model (WP4).

Dr Andrew Frost was a co-applicant, PI and Ophthalmologist centre Lead for Torbay. He was closely involved in the item reduction and final development of Cat-PROM5 (WP1), qualitative elements (WP3&4) and direct care of Involve-CAT participants (WP4). Andrew was previously the lead developer of the VCM1 questionnaire which (with VSQ) formed the basis of Cat-PROM5 item set.

Professor Christopher Liu was a co-applicant, PI and Ophthalmologist Centre Lead for Brighton. He was involved in the development of Cat-PROM5 (WP1), qualitative elements (WP3&4), strategic planning of the Discordant Outcomes qualitative aims and direct care of Involve-CAT participants (WP4). Christopher initiated the project which undertook qualitative analysis of the stakeholder meeting on the ethical perspectives of immediately sequential bilateral cataract surgery.

Mr Robert Johnston was a co-applicant, PI and Ophthalmologist Centre Lead for Gloucestershire. He was involved in the development of Cat-PROM5 (WP1), and the data aggregation and data sharing arrangements required for risk modelling (WP2). He was also involved in the strategic planning for the addition of GHNHSFT as a recruiting site for WP3. It is with deep regret that we note the passing of Rob, our good friend and colleague, in September 2016. Following his death, Rob's role was taken over by Peter Scanlon.

Professor Peter H Scanlon was a co-applicant, PI and ophthalmologist centre lead following the death of Rob Johnston. He facilitated and set up arrangements for inclusion of Gloucestershire as a 2nd recruitment site for WP3 together with Pippa Craggs as Programme Manager.

Dr Christalla Pithara is a senior research associate in health services research; she conducted qualitative research across WP3&4 on the presentation of risk and benefits, perceptions of Cat-PROM5 and the Cataract Decision Aid, and on Discordant Outcomes. She was involved in data collection, qualitative data analysis, and preparing of the Predict-CAT qualitative study final reports.

Dr Daisy Elliott conducted the qualitative research into the acceptability and generalisability (to patients with visual co-morbidities) of Cat-PROM5 in WP1 and provided planning, supervision and oversight of qualitative work in WP3.

Dr Fiona Fox conducted and analysed the qualitative interviews of patients and Health Professionals in respect to the Discordant Outcomes aim (WP3 & 4).

Professor Jenny Donovan was a co-applicant, responsible for Qualitative Research design and oversight (WP1, 3 & 4) and was co-developer of the VCM1 and VSQ questionnaires which formed the basis of Cat-PROM5 development. She also contributed to the strategic planning of the feasibility RCT (WP4).

Professor Jonathan Sterne was a co-applicant. Jonathan oversaw the planning of statistical work across all work packages.

Dr Natalie Joseph-Williams was a co-applicant and PI for Involve-CAT (taking over from Glyn Elwyn who emigrated to the US and commercialised the Option Grid collaborative). Natalie is a Lecturer at the Cardiff University School of Medicine with specialist interest in shared decision making and improving patient care. She led the development and user-testing of the Cataract Decision Aid and Cataract Decision Quality Measures used in the feasibility RCT (WP3&4).

Dr Daniella Holland-Hart is a research associate responsible for coordinating the development and user-testing of the Cataract Decision Aid and Cataract Decision Quality Measures, and conducting the interviews and qualitative analyses of the feasibility RCT (WP3&4).

Paul HJ Donachie is a Medical Statistician for the Royal College of Ophthalmologists National Ophthalmology Database and collaborator for the programme. He provided extracted cataract surgery data through the data sharing agreements (WP2).

Hazel Taylor was a co-applicant responsible for the strategic planning of risk indicator analyses (WP2). She undertook the initial WP2 analyses to review and refine the risk models for PCR and VA Loss.

Dr Padraig Dixon is a Health Economist who produced the calibration mapping tool to cross walk to health economic utilities (capability and quality of life preference-based measures) from Cat-PROM5 (WP3).

Katie Breheny is a Health Economist and analysed the performance of health economic utilities (capability and quality of life scores) in cataract patients (WP3) and undertook the health economics elements of the Involve-CAT feasibility study (WP4).

Dr Rebecca Kandiyali is a Health Economist and participated in the Cat-PROM5 calibration and the performance of health economic utilities analyses (WP3).

Professor William Hollingworth was a co-applicant. He was Health Economics lead and responsible for the Strategic planning of the health economics elements (WP3&4).

Professor David Evans was a co-applicant. He is Professor in Health Services Research and previously led People in Health West of England, a collaborative initiative on public involvement in research. David chaired the Patient Advisory Group (PAG) throughout the programme and will author a collaborative paper with the PAG members to describe jointly the experiences of the group.

Dr Sofia Theodoropoulou is Academic Clinical Lecturer in Ophthalmology and reported on the risk factors and clinical outcomes in the 90 years and over population (WP2). She was also involved in the direct care of Involve-CAT participants.

Dr Rachael Hughes is a statistician and performed analysis and interpretation of the refractive outcomes of records from the National Ophthalmology Database (WP2).
Matthew Quinn is a medical student and undertook the transcription, coding and qualitative analysis and interpretation of a stakeholder meeting around the ethical implications of immediately sequential bilateral cataract surgery.
Daniel Gray is a PhD research student in Sociology and oversaw the qualitative analysis and interpretation of the stakeholder meeting regarding the ethical implications of immediately sequential bilateral cataract surgery.
Mr Larry Benjamin is a Consultant Ophthalmologist and Chair of the Programme Steering Committee providing oversight throughout the programme. He made recommendations for final revisions prior to submission of the final report.
Abi Loose was Senior Trial Coordinator and latterly Programme Manager. Abi drafted the PPI, Impact and Limitations sections of the report. She assisted in the operational design of WP1, 3 & 4 and provided management support at the conclusion of the programme and with Professor David Evans will co-author a collaborative paper with the Patient Advisory Group.
Lara Edwards was the first Research Programme Manager and was responsible for the operational design of WP1 and WP3 and provided management and leadership during the first two years of the programme.
Pippa Craggs was Research Programme Manager from 2016-2018 and provided leadership, management and operational design of WP4 and qualitative studies under WP3. She also set up the second recruiting site for WP3 to expand recruitment.
Frances Paget was Senior Trial Coordinator and interim Programme Manager. She assisted in the operational planning for WP4 and provided management support during the programme's final year.
Ketan Kapoor is an Optometrist. He assisted in the operational design and clinician training for the Predict-CAT study and completed clinical examinations of Predict-CAT participants at the lead site.
Jason Searle is an Optometrist and conducted clinical examinations of Predict-CAT participants at the lead site.

Publications

1. Sparrow JM, Grzeda MT, Frost NA, Johnston RL, Liu CSC, Edwards L, et al. Cat-PROM5: a brief psychometrically robust self-report questionnaire instrument for cataract surgery. Eye (Lond). 2018;32(4):796-805.

2. Sparrow JM, Grzeda MT, Frost NA, Johnston RL, Liu CSC, Edwards L, et al. Cataract surgery patient-reported outcome measures: a head-to-head comparison of the psychometric performance and patient acceptability of the Cat-PROM5 and Catquest-9SF self-report questionnaires. Eye (Lond). 2018;32(4):788-95.
3. Roberts HW, Wagh VK, Sullivan DL, Hidzheva P, Detesan DI, Heemraz BS, et al. A randomized controlled trial comparing femtosecond laser-assisted cataract surgery versus conventional phacoemulsification surgery. J Cataract Refract Surg. 2019;45(1):11-20.
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(Several additional papers currently undergoing peer review)

Data sharing

Consent for the sharing of individual patient data was not obtained from participants involved in any study under the programme. Consent for sharing of summary-level data may be made on application of Professor John Sparrow.

NHS patient data used during this Programme

This work uses data provided by patients and collected by the NHS as part of their care and support. Using patient data is vital to improve health and care for everyone. There is huge potential to make better use of information from people's patient records, to understand more about disease, develop new treatments, monitor safety, and plan NHS services. Patient data should be kept safe and secure, to protect everyone's privacy, and it's important that there are safeguards to make sure that it is stored and used responsibly. Everyone should be able to find out about how patient data is used. #datasaveslives. You can find out more about the background to this citation here: https://understandingpatientdata.org.uk/data-citation.

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Appendices

Appendix 1. The Cat-PROM5 Questionnaire

Cat-PROM5

Cat-PROM5 Questionnaire

STRICTLY CONFIDENTIAL

Thank you for helping us to know more about your eyesight.

SOME OF THE QUESTIONS MAY SEEM SIMILAR BUT PLEASE ANSWER ALL

Full Name _____

Date of Birth (DD/MM/YY) _____

Address _____

_____

_____ Postcode _____

Please read the following information

Please think about your **eyesight** in the **past month.**

If you use **glasses** or **contact lenses** for some activities, please answer according to how you can see **when using them**.

If you have had an eye operation, an eyesight test, a change of glasses or a sudden change in the eyesight **in the past month** please inform us **now**.

Please ask for help if the questions are not clear

If you use **glasses** or **contact lenses** for some activities, please answer according to how you can see **when using them**.

Please think about your **eyesight** in the **past month.**

1. In the past month, have you felt that **your bad eye** is affecting or interfering with your vision overall?

No, never	☐	0
Yes, some of the time	☐	1
Yes, most of the time	☐	2
Yes, all of the time	☐	3

The rest of the questions are about your eyesight **overall**, **using both eyes together.** If you use **glasses** or **contact lenses** for some activities, please answer according to how you can see **when using them**.

Think about how your **eyesight** has made you **feel** in the **past month**.

2. In the past month,

   How much has your **eyesight** interfered with your **life in general**?

Not at all	☐	0
Hardly at all	☐	1
A little	☐	2
A fair amount	☐	3
A lot	☐	4
An extremely large amount	☐	5

If you use **glasses** or **contact lenses** for some activities, please answer according to how you can see **when using them**.
Please think about your **eyesight** in the **past month.**

3. How would you describe your vision **overall in the past month** - with both eyes open, wearing glasses or contact lenses if you usually do?

Excellent	☐	0
Very good	☐	1
Quite good	☐	2
Average	☐	3
Quite poor	☐	4
Very poor	☐	5
Appalling	☐	6

4. In the past month, how often has your **eyesight** prevented you from doing the things you would like to do?

Never	☐	0
Some of the time	☐	1
Most of the time	☐	2
All of the time	☐	3

If you use **glasses** or **contact lenses** for some activities, please answer according to how you can see **when using them**.

Please think about your **eyesight** in the **past month.**

5. In the past month, have you had difficulty reading normal print in books or newspapers **because of trouble with your eyesight?**

No difficulty	☐	0
Yes, a little difficulty	☐	1
Yes, some difficulty	☐	2
Yes, a great deal of difficulty	☐	3
I cannot read any more **because of my eyesight**	☐	4
I cannot read because of **other reasons**	☐	8

6. Please tell us who actually gave the answers to the questions and who wrote them down

I gave **all** the answers and wrote them down **myself**	☐	1
I gave **all** the answers and someone else wrote them down as I spoke	☐	2
A friend or relative gave some of the answers on my behalf	☐	3

Please write today's date here:

/	/	
DAY	MONTH	YEAR

NOW, PLEASE CHECK THAT YOU HAVE ANSWERED ALL THE QUESTIONS ON EVERY PAGE.

Please hand back to the person who provided you with this questionnaire or return in the envelope supplied to:

Thank you for completing this questionnaire about your eyesight.

Your answers will be **confidential**.

Appendix 2. Risk Models for Posterior Capsule Rupture and Visual Acuity Loss

Updating Risk Models

Risk Models for Posterior Capsule Rupture and Visual Acuity Loss
(Updating of models published on earlier data)

A quantitative analysis for Work Package 2 of a NIHR funded Cataract Research Programme.

Analysis by Hazel Taylor

Reviewed by John Sparrow and Rob Johnston

Report completed January 2015

Posterior Capsule Rupture (PCR)

Definition of PCR

Posterior capsular rupture (PCR) is defined for the purposes of the National Audit as "posterior capsule rupture with or without vitreous prolapse or zonule rupture with vitreous prolapse" and abbreviated simply as PCR. It should be noted that the definition excludes zonule dehiscence where no vitreous prolapse has occurred (https://www.nodaudit.org.uk/).

Data coding

1. **Surgeon Grade**

   This was coded into 4 categories; Consultant, Non-Consultant Career Grade, Senior Trainee, Junior Trainee. The categories were made up of the following grades:

   Consultant – Consultant.

   Non-Consultant Career Grade – Associate Specialist, Staff Grade, Trust Doctor.

   Senior Trainee – Fellow, Registrar, Specialty trainee (Year 4, 5 & 6), Specialist Registrar, Specialty Registrar.

   Junior Trainee – Senior House Office, Specialty trainee (Year 1, 2, 3)

2. **Co-Pathology**

Variables identifying presence (either prior to surgery or at surgery) or absence of the following co-pathologies or operations were created:

Glaucoma

'Previous Trabeculetomy' and 'previous surgery for glaucoma' included.

Age related macular degeneration.

Amblyopia

Brunescent / white cataract

Diabetic retinopathy

Those who had previous surgery for diabetes were included here.

Corneal Pathology

High myopia

Those who had ever had an axial length of >=28 prior to surgery were also included in this definition.

No fundal view / vitreous opacities

Previous vitrectomy.

Defined from the following 5 co-pathology codes;

'Previous vitrectomy for FTMH/ ERM' ,

'Previous vitrectomy for FTMH / ERM / other reason' and

'Previous retinal detachment surgery'.

'Retinal detachment'

'Vitrectomy'

Also included were those who had previous surgery ppv (ppv = 1 on the previous surgery file) and the inclusion of these increased considerably the number with 'previous vitrectomy.'

Pseudoexfoliation / phacodonesis

Uveitis / synaechiae.

Inherited Eye Disease

Optic nerve / CNS disease

Other

Other macular pathology

Those with the co-pathologies macular hole and epiretinal membrane were also included here.

Other retinal vascular pathology

The co-pathologies were defined using the definitions discussed with Paul using information from previous surgery and indication for current surgery, in addition to the information in the co-pathology dataset. {See Pauls definitions document for further details.}

3. Biometry

For the biometry data, namely axial length and anterior chamber depth, some eyes had multiple assessments made. For this analysis, the assessment, closest to the time of the cataract operation has been used.

Sample Used in the Analysis

The sample has been defined according the criteria outlined in the documentation written by Paul. The sample consisted of 180,114 eyes from 127,685 patients.

Characteristics of sample to be used in the analysis.

3514/180114 (1.95%) of eyes had PCR

Mean age of eyes 75.6 (standard deviation 10.35) (range 18.1 – 109.7)

Anterior Chamber length was only available for 31,105 eyes.

		N	%
Age	<60	14,232	7.90
	60-69	30,088	16.70
	70-79	67,399	37.42
	80-89	61,395	34.09
	90+	7,000	3.89
Gender	Male	71,950	39.95
	Female	107,662	59.77
	Not specified	502	0.28
Any alpha blocker (alfuzosin, doxazosin Indoramin, parazosin, tamsulosin, terazosin)	No	176,440	97.96
	Yes	3,674	2.04
Able to lie flat	No	2,136	1.19
	Yes	63,437	35.22
	Missing	114,541	63.59

Inability to co-operate	No	37,099	20.60
	Yes	1,572	0.87
	Missing	141,443	78.53
Axial length	<26	171,855	95.41
(will look at this in quintiles also)	>= 26	8,130	4.51
	Missing	129	0.07
Axial length in quintiles	<= 22.43	36,163	20.08
	22.44 – 23.01	36,256	20.13
	23.02 – 23.53	35,771	19.86
	23.54 – 24.24	35,918	19.94
	>= 24.25	35,877	19.92
	Missing	129	0.07
Axial length	>21.5	172,259	95.64
	≤ 21.5	7,726	4.29
	Missing	129	0.07
Glaucoma	No	165,704	92.00
	Yes	14,410	8.00
Age related macular degeneration	No	162,088	89.99
	Yes	18,026	10.01
Amblyopia	No	177,434	98.51
	Yes	2,680	1.49
Brunescent White Cataract	No	174,928	97.12
	Yes	5,186	2.88
Diabetic retinopathy	No	171,649	95.30
	Yes	8,465	4.70
Corneal Pathology	No	175,868	97.64
	Yes	4,246	2.36
High myopia	No	173,557	96.36
	Yes	6,557	3.64
No fundal view/ vitreous opacities	No	178,753	99.24
	Yes	1,361	0.76
Previous vitrectomy	No	177,196	98.38
	Yes	2,918	1.62
Pseudoexfoliation / phacodonesis	No	177,887	98.76
	Yes	2,227	1.24
Uveitis / synaechiae.	No	178,344	99.02
	Yes	1,770	0.98
Inherited Eye Disease	No	179,888	99.87
	Yes	226	0.13
Optic nerve / CNS disease	No	179,409	99.61
	Yes	705	0.39
Other	No	173,074	96.09
	Yes	7,040	3.91

Other macular pathology	No	178,567	99.14
	Yes	1,547	0.86
Other retinal vascular pathology	No	178,594	99.16
	Yes	1,520	0.84
Surgeon Grade	Consultant	105,116	58.36
	Non-consultant career grade	22,479	12.48
	Senior Trainee	43,724	24.28
	Junior Trainee	8,795	4.88
Pupil size	Large	155,302	86.22
	Medium	19,189	10.65
	Small	5,459	3.03
	Missing	164	0.09

Logistic regression model for outcome PCR

The following variables: age, gender, pupil size, surgeon grade, any alpha blocker, axial length and the following co-pathologies; glaucoma, age related macular degeneration, amblyopia, brunescent white cataract, diabetic retinopathy, corneal pathology, high myopia, no fundal view/ vitreous opacities, previous vitrectomy, pseudoexfoliation / phacodonesis, uveitis synaechaie, other, other macular pathology, other retinal vascular pathology were offered to the logistic regression model. Note the other co-pathologies and individual alpha blockers were not offered to this preliminary logistic regression model, as the numbers were relatively small.

The variables able to lie flat, inability to co-operative and anterior chamber length were not offered to the preliminary logistic regression model due to the large amount of missing data.

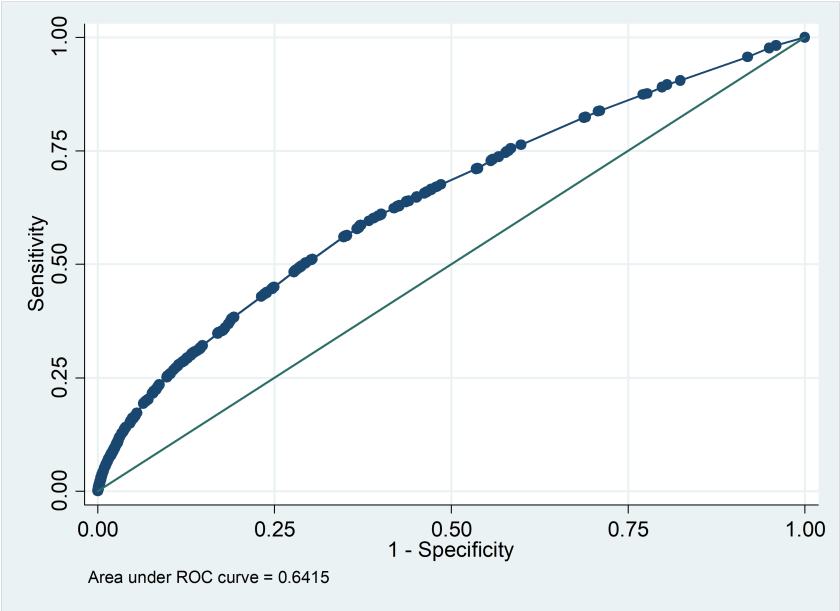
Backwards and forwards logistic regression was carried out, taking account of the clustered nature of the data (the fact that left and right eyes from the same patient are unlikely to be independent).

The following variables entered/ remained in the logistic regression model: age, surgeon grade, pupil size, glaucoma, brunescent white cataract, no fundal view/ vitreous opacities, previous vitrectomy, pseudoexfoliation/ phacodonesis and other.

Note n = 179,950 due to some missing data for pupil size.

		Odds Ratio	**95% CI**	**P-value**
Surgeon Grade	Consultant	1.00		<0.001
	Non-consultant career grade	1.07	[0.95, 1.20]	
	Senior Trainee	1.71	[1.59, 1.85]	
	Junior Trainee	2.85	[2.53, 3.20]	
Pupil Size	Large	1.00		<0.001
	Medium	1.21	[1.09, 1.34]	

	Small	1.72	[1.48, 1.99]	
Age	<60	1.00		<0.001
	60-69	0.87	[0.75, 1.02]	
	70-79	0.98	[0.86, 1.12]	
	80-89	1.15	[1.01, 1.32]	
	90+	1.56	[1.30, 1.88]	
Gender	Female /Not specified	1.00		0.007
	Male	1.10	[1.03, 1.18]	
Glaucoma	No	1.00		<0.001
	Yes	1.23	[1.10, 1.38]	
Brunescent white cataract	No	1.00		<0.001
	Yes	3.36	[2.95, 3.82]	
No fundal view/ vitreous opacities	No	1.00		<0.001
	Yes	1.72	[1.33, 2.22]	
Previous vitrectomy	No	1.00		0.007
	Yes	1.40	[1.10, 1.79]	
Pseudoexfoliation / phacodonesis	No	1.00		<0.001
	Yes	2.51	[2.07, 3.04]	
Other	No	1.00		<0.001
	Yes	1.83	[1.60, 2.10]	



The area under the ROC curve is 0.6415.

Monocular Visual Acuity (VA) Loss

Definitions for VA and VA Loss

Pre-op and post-op visual acuity has been derived using the definitions of the NOD (https://www.nodaudit.org.uk/). VA Loss is defined as a doubling or worse of the visual angle.

As so few pre-op visual acuity readings were by pin-hole only, it was decided not to use the pre-op pin-hole data.

Of the 180,114 eyes in the sample, 147,962 had pre-op visual acuity readings. For 104,437 (70.6%), they were corrected visual acuity readings and for 43,525 (29.4%), they were uncorrected readings. A further 1,591 eyes had preoperative pin hole readings only, but these were not used in this analysis.

Of the 180,114 eyes in the sample, 116,038 eyes had post-op visual acuity readings. For 74,887 (64.5%), they were corrected visual acuity readings, for 28,678 (24.7%), they were uncorrected visual acuity readings and for 12,473 (10.8%) they were pin-hole visual acuity readings, which were accepted postoperatively.

Of the 147,962 eyes with pre-op visual acuity readings, 95,561 (64.6%) had post-op visual acuity readings. For 60,578 (63.4%), they were corrected visual acuity readings, for 24,460 (25.6%), they were uncorrected visual acuity readings and for 10,523 (11.0%) they were pin-hole visual acuity readings.

For 1,455/95,561 (1.52%) eyes, the visual acuity got worse after cataract surgery.

This has been defined as [Pre-op visual acuity] – [Post-op visual acuity] ≤ -0.30 (With visual acuity rounded and analysed to two decimal places, so a change of -0.28 is NOT defined as getting worse).

Characteristics of sample to be used in the analysis (N= 95561).

Mean age of eyes 75.8 (standard deviation 10.01) (range 18.1 – 104.1)

The 95,561 eyes are from 76,640 patients.

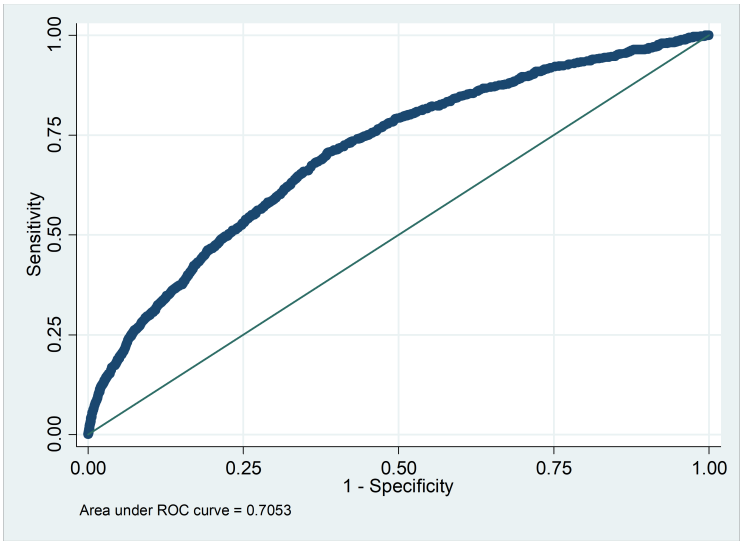
		N	%
PCR	No	94,219	98.60
	Yes	1,342	1.40
Age	<60	6,934	7.26
	60-69	15,980	16.72
	70-79	36,658	38.36
	80-89	32,519	34.03
	90+	3,470	3.63
Gender	Male	37,943	39.71
	Female	57,338	60.00
	Not specified	280	0.29

Any alpha blocker (alfuzosin, doxazosin Indoramin, parazosin, tamsulosin, terazosin)	No	93,587	97.93
	Yes	1,974	2.07
Able to lie flat	No	1,198	1.25
	Yes	38,906	40.71
	Missing	55,457	58.03
Inability to co-operate	No	23,809	24.91
	Yes	930	0.97
	Missing	70,822	74.11
Axial length	<26	91,340	95.58
(will look at this in quintiles also)	>= 26	4,153	4.35
	Missing	68	0.07
Axial length in quintiles	<= 22.43	18,877	19.75
	22.44 – 23.01	19,273	20.17
	23.02 – 23.53	19,067	19.95
	23.54 – 24.24	19,371	20.27
	>= 24.25	18,905	19.78
	Missing	68	0.07
Axial length	>21.5	91,557	95.81
	≤ 21.5	3,936	4.12
	Missing	68	0.07
Glaucoma	No	89,358	93.51
	Yes	6,203	6.49
Age related macular degeneration	No	85,700	89.68
	Yes	9,861	10.32
Amblyopia	No	94,216	98.59
	Yes	1,345	1.41
Brunescent White Cataract	No	93,171	97.50
	Yes	2,390	2.50
Diabetic retinopathy	No	91,611	95.87
	Yes	3,950	4.13
Corneal Pathology	No	93,605	97.95
	Yes	1,956	2.05
High myopia	No	92,069	96.35
	Yes	3,492	3.65
No fundal view/ vitreous opacities	No	94,904	99.31
	Yes	657	0.69
Previous vitrectomy	No	94,349	98.73
	Yes	1,212	1.27
Pseudoexfoliation / phacodonesis	No	94,485	98.87
	Yes	1,076	1.13
Uveitis / synaechiae.	No	94,883	99.29
	Yes	678	0.71

Inherited Eye Disease	No	95,455	99.89
	Yes	106	0.11
Optic nerve / CNS disease	No	95,243	99.67
	Yes	318	0.33
Other	No	91,905	96.17
	Yes	3,656	3.83
Other macular pathology	No	94,782	99.18
	Yes	779	0.82
Other retinal vascular pathology	No	94,830	99.24
	Yes	731	0.76
Surgeon Grade	Consultant	56,750	59.39
	Non-consultant career grade	11,419	11.95
	Senior Trainee	22,520	23.57
	Junior Trainee	4,872	5.10
Pupil size	Large	82,314	86.14
	Medium	10,498	10.99
	Small	2,653	2.78
	Missing	96	0.10

Logistic regression model for outcome VA Loss

In addition to the variables offered to the logistic regression model for the PCR outcome, a variable for PCR was also offered to the logistic regression and the model adjusted for pre-op visual acuity. The following variables entered/ remained in the logistic regression model, when the analysis was carried out **adjusting for pre-op visual acuity**: PCR, age, axial length, pupil size, gender and the co-pathologies; glaucoma, age-related macular degeneration, diabetic retinopathy, corneal pathology, brunescent white cataract, previous vitrectomy, other macular pathology, other retinal vascular pathology and other.



The area under the ROC curve for this model is 0.7053.

The adjusted odds ratios for this model, adjusting for all variables included in the model and pre-op visual acuity (N= 95400)

		Odds Ratio	**95% CI**	**P-value**
Pupil Size	Large	1.00		0.0062
	Medium	1.27	[1.10, 1.48]	
	Small	1.12	[0.85, 1.47]	
Age	<60	1.00		<0.001
	60-69	1.51	[1.12, 2.02]	
	70-79	1.28	[0.97, 1.69]	
	80-89	1.63	[1.23, 2.15]	
	90+	2.80	[2.00, 3.91]	
PCR	No	1.00		<0.001
	Yes	5.27	[4.21, 6.61]	
Axial length in quintiles	<= 21.50	1.91	[1.52, 2.39]	<0.001
	21.51- 22.43	1.27	[1.07, 1.50]	
	22.44 – 23.01	0.98	[0.83, 1.16]	
	23.02 – 23.53	1.00		
	23.54 – 24.24	0.83	[0.70, 0.99]	
	24.25 – 25.99	0.86	[0.71, 1.04]	
	>= 26	0.90	[0.65, 1.24]	
Gender	Female /Not specified	1.00		0.048
	Male	1.12	[1.00, 1.26]	
Age related macular degeneration	No	1.00		<0.001
	Yes	2.16	[1.88, 2.48]	
Other retinal vascular pathology	No	1.00		<0.001
	Yes	4.83	[3.50, 6.67]	

Diabetic retinopathy	No	1.00		<0.001
	Yes	2.21	[1.79, 2.72]	
Glaucoma	No	1.00		<0.001
	Yes	1.97	[1.67, 2.33]	
Corneal Pathology	No	1.00		<0.001
	Yes	2.37	[1.84, 3.05]	
Previous vitrectomy	No	1.00		<0.001
	Yes	2.79	[1.93, 4.05]	
Brunescent white cataract	No	1.00		<0.001
	Yes	1.96	[1.43, 2.70]	
Other macular pathology	No	1.00		<0.001
	Yes	3.35	[2.32, 4.84]	
Other	No	1.00		0.040
	Yes	1.28	[1.01, 1.62]	

(Appendix 2, word count 1994)

Appendix 3. Stability through time of a Statistical Model for indicators of Posterior Capsule Rupture in Cataract Surgery

Stability through time of a Statistical Model for indicators of Posterior Capsule Rupture in Cataract Surgery

Stability through time of the risk model for Posterior Capsule Rupture (PCR) during cataract surgery.

Background

Posterior capsular rupture (PCR) is defined for the purposes of the National Audit as “posterior capsule rupture with or without vitreous prolapse or zonule rupture with vitreous prolapse” and abbreviated simply as PCR. It should be noted that the definition excludes zonule dehiscence where no vitreous prolapse has occurred. PCR is the most frequent intraoperative complication and when it occurs as defined above there is an approximately 6-fold increased risk of vision loss, an approximately 40-fold increased risk of post cataract retinal detachment and an approximately 8-fold increased risk of endophthalmitis (serious postoperative infection in the eye).

A statistical risk model is used to adjust surgeon and centre results for case complexity in the National Cataract Audit in order to ensure that surgeons who take on difficult operations in patients who are likely to benefit from surgery, are not penalised for doing so. A clear understanding of the stability through time of the risk adjustment model is thus important to give confidence to surgeons that the model in use is relevant and applicable to current surgical practice.

Data

Data were obtained from the National Ophthalmology Database (NOD) through a data sharing agreement with the data controller, the Health Quality Improvement Partnership (HQIP). Data were cleaned prior to transfer with data available for analysis on 602,459 operations on 404,857 patients from 2000 to 2014. PCR data was available for all operations and was recorded as having occurred in 10,960 (1.82%) operations.

Analysis

Three approaches to candidate risk predictor selection for model building were used:
a) A clinically sound list of predictors; b) Chi-square p-value p<0.10 for predictors to exclude at the outset those unlikely to be statistically important; c) Univariate regression effect size satisfying 0.9>OR>1.20 to exclude small and therefore clinically unimportant effects. Table 1 provides a bivariate analysis of the data with regard to candidate risk indicators for PCR.

Table 1. Bivariate analysis of candidate risk indicators for PCR

Characteristic (%;n [in the whole sample of eyes])	Eyes with PCR: %;n [in given subgroup]	Chi-square;df;p	Odds-ratio*;p
PATIENT			
Gender			
Female (59.35%;357,555)	1.75%;6,241	26.781;1;<0.001	1.106;<0.001
Male (40.65%;244,904)	1.93%;4,719		
Age			
<70yo (25.11%;151,294)	1.59%;2,407	227.278;5;<0.001	Ref. category
70–74 years (15.72%;94,699)	1.73%;1,641		1.091;0.007
75–79 years (21.28%;128,188)	1.66%;2,133		1.047;0.128
80–84 years (20.94%;126,129)	1.93%;2,439		1.220;<0.001
85–89 years (12.66%;76,293)	2.17%;1,654		1.371;<0.001
≥90 years (4.29%;25,856)	2.65%;686		1.686;<0.001
Eye			
Right Eye (50.82%;306,144)	1.81%;5,545	0.222;1;0.638	1.009;0.638
Left Eye (49.18%;296,315)	1.83%;5,415		
First-second eye			
First eye operated (57.40%;345,837)	1.88%;6,517	19.325;1;<0.001	0.917;<0.001
Second eye operated (42.60%;256,622)	1.73%;4,443		
Socio-economic class (IMD)			
1st quintile (20.00%;120,519)	1.65%;1,990	165.771;4;<0.001	Ref. category
2nd quintile (20.00%;120, 492)	1.70%;2,045		1.028;0.379
3rd quintile (20.00%;120,481)	1.64%;1,972		0.991;0.781
4th quintile (20.00%;120,491)	1.89%;2,272		1.145;<0.001
5th quintile (20.00%;120,476)	2.23%;2,681		1.356;<0.001

Socio-economic class (IMD)- shortened			
1-3 quintile (60.00%;361,492)	1.66%;6,007	125.501;1;<0.001	1.242;<0.001
4-5 quintile (40.00%;240,967)	2.06%;4,953		
Patient is diabetic			
No (82.15%;494,921)	1.78%;8,807	24.510;1;<0.001	1.128;<0.001
Yes (17.85%;107,538)	2.00%;2,153		
Alpha-blockers			
No alpha-blockers (94.16%;567,294)	1.82%;10,328	0.101;1;<0.751	0.987;<0.751
Alpha-blockers (5.84%;35,165)	1.80%;632		
EYE/OCULAR CO-MORBIDITIES			
Patient has age-related macular degeneration			
No (90.08%;542,721)	1.82%;9,861	0.156;1;0.693	1.013;0.693
Yes (9.92%;59,738)	1.84%;1,099		
Patient has amblyopia			
No (98.46%;593,175)	1.81%;10,712	38.327;1;<0.001	1.492;<0.001
Yes (1.54%;9,284)	2.67%;248		
Patient has corneal pathology			
No (97.38%;586,681)	1.81%;10,647	2.457;1;0.117	1.095;0.117
Yes (2.62%;15,778)	1.98%;313		
Patient has diabetic retinopathy			
No (94.60%;569,914)	1.80%;10.272	16.738;1;<0.001	1.177;<0.001
Yes (5.40%;32,545)	2.11%;688		
Patient has glaucoma			
No (91.45%;550,921)	1.80%;9,902	17.225;1;<0.001	1.145;<0.001
Yes (8.55%;51,538)	2.05%;1,058		
Patient has high myopia			
No (96.16%;579,343)	1.81%;10,508	2.495;1;0.114	1.080;0.114
Yes (3.84%;23,116)	1.96%;452		
Patient has an inherited eye disease			
No (99.85%;601,543)	1.82%;10,948	1.332;1;0.249	0.716;0.251
Yes (0.15%;916)	1.31%;12		
Patient has optic nerve or central nervous system disease			

No (99.60%;600,062)	1.82%;10,927	2.638;1;0.104	0.753;0.105
Yes (0.40%;2,397)	1.38%;33		
Eye has uveitis / synechiae at the time of surgery			
No (99.04%;596,669)	1.81%;10,820	11.734;1;0.001	1.342;0.001
Yes (0.96%;5,790)	2.42%;140		
Eye has psuedoexfoliation / phacodonesis at the time of surgery			
No (98.89%;595,749)	1.78%;10,577	574,971;1;<0.001	3.349;>0.001
Yes (1.11%;6,710)	5.71%;383		
Eye has a brunescent / white mature cataract			
No (96.71%;582,631)	1.69%;9,842	1,674;1;<0.001	3.478;>0.001
Yes (3.29%;19,828)	5.64%;1,118		
Eye has no fundal view / vitreous opacities at the time of surgery			
No (99.09%;596,977)	1.78%;10,647	468,796;1;0.001	3.335;>0.001
Yes (0.91%;5,482)	5.71%;313		
Eye has other macular pathology at the time of surgery			
No (98.65%;594,298)	1.82%;10,836	4.163;1;0.041	0.831;0.042
Yes (1.35%;8,161)	1.52%;124		
Eye has other retinal pathology at the time of surgery			
No (99.03%;596,592)	1.82%;10,839	1.961;1;0.161	1.138;0.162
Yes (0.97%;5,867)	2.06%;121		
Eye has undergone vitrectomy surgery (Retinal detachment')			
No (98.24%;591,880)	1.82%;10,747	2.274;1;0.132	1.111;0.132
Yes (1.76%;10,579)	2.01%;213		
Eye has previously undergone trabeculectomy surgery			
No (99.49%;599,391)	1.81%;10,874	16.714;1;<0.001	1.561;<0.001
Yes (0.51%;3,068)	2.80%;86		
Eye has any other ocular co-pathology			
No (96.29%;580,137)	1.77%;10,264	218.926;1;<0.001	1.787;<0.001
Yes (3.71%;22,322)	3.12%;696		
Axial length measurement			
<21mm (0.17%;1,012)	3.06%;31	11.552;2;0.003	1.710;0.003
21-28mm (98.62%;594,123)	1.81%;10,777		Ref. category
>28mm (1.22%;7,324)	2.08%;152		1.147;0.096

Pre-op Visual Acuity			
<0.00 LogMAR (0.58%;2,924)	1.06%;31	1,182.480;5;<0.001	Ref. category
0.00–0.30 LogMAR (34.21%;171,910)	1.43%;2,463		1.356;0.093
0.31–0.60 LogMAR (35.32%;177,514)	1.61%;2,855		1.525;0.020
0.61–0.90 LogMAR (13.03%;65,494)	1.90%;1,246		1.810;0.001
0.91–1.20 LogMAR (7.04%;35,356)	2.08%;735		1.981;<0.001
>1.20 LogMAR (9.82%;49,361)	3.69%;1,823		3.579;<0.001
Pre-op Visual Acuity- shortened			
<=0.60 LogMAR (70.11%;352,348)	1.52%;5,349	605.978;1;<0.001	1.686;<0.001
>0.60 LogMAR (29.89%;150,211)	2.53%;3,804		
OPERATIVE ISSUES			
Bilateral operation			
Not bilateral operation (99.70%;600,545)	1.82%;10,926	0.020;1;0.888	0.976;0.888
Bilateral operation (0.30%;1,914)	1.78%;34		
Patient able to lie flat			
patient was able to lie flat (99.24%;597,887)	1.82%;10,855	5.787;1;0.015	1.271;0.016
patient was not able to lie flat (0.76%;4,572)	2.30%;105		
Patient was able to cooperate			
patient cooperated (99.35%;598,550)	1.82%;10,899	1.474;1;0.225	0.855;0.225
patient did not cooperate (0.65%;3,909)	1.56%;61		
Pupil size			
Large (81.18%;21,727)	1.72%;8,435	299.931;2;<0.001	Ref. Category
Medium (15.22%;91,668)	1.98%;1,815		1.152;<0.001
Small (3.61%;489,064)	3.29%;714		1.937;<0.001
SURGEON CHARACTERISTICS			
Surgeon grade			
Consultant (58.00%;349,421)	1.47%;5,144	1,122.430;3;<0.001	Ref. Category
Independent non-consultant (13.13%;79,127)	1.58%;1,250		1.074;0.024
Experienced trainee (24.84%;149,644)	2.43%;3,637		1.667;<0.001
Inexperienced trainee (4.03%;24,267)	3.83%;929		2.664;<0.001

In order to account for the structure of the data, four statistical approaches were initially used:

1. A naïve approach in which nesting of eyes within patients was ignored; 2. Robust standard errors; 3. Generalized estimating equations; and 4. Multilevel modelling. *Each of these resulted in the same set of candidate predictors so in order to simplify the analysis for the focus on stability through time, only the naïve approach (ignoring the data structure) was taken forward to the next stage*.

To ensure that sufficient data was present for each year to be included in the annual comparisons through time the number of operations and presence of the candidate predictors in each year was checked. It was found that the early years did not contain sufficient numbers for credible analysis and the most recent decade only, from 2005 to 2014 was therefore accepted for further analysis.

Model stability was assessed by several methods

- The consistency of inclusion of candidate predictors when offered to models for each year individually
    - assesses as the number of times individual candidate predictors showed up across all the years
- Comparison of performance measures across the years
    - Calibration:
        - linear intercept and slope of regressions of predicted probabilities vs. observed for each of the years
        - separate graphs for years depicted PCR rates per decile of estimated probability (horizontal axis) against both the average predicted PCR probability for the decile and the observed PCR rate for the decile (vertical axis)
    - Discrimination: c-statistics for individual years
- Assessment of stability of model parameters across years
    - explored by inclusion of year as a factor in the model
    - exploration of groupings of years to clarify regions of stability and instability across the decade

These methods were applied in turn to the three approaches to risk predictor selection: a) A clinically sound predictors; b) Chi-square p-value $p<0.10$; c) Univariate regression effect size satisfying $0.9>OR>1.20$.

Results

The stability through time findings from the three approaches (a,b,c) were similar. In order to avoid repetition of similar results, and in the interests of keeping this document a manageable size, only approach 'b' will be included in detail in this report.

Model based on the list of factors with univariate Chi-square p-value p<0.10

For years 2005-2014 this model took the form presented in Table 2. The model is relatively parsimonious with 14 predictors with reasonable fit, C-stat=0.62.

Table 2. Significant predictors at the P<0.05 level in the multivariable model.

PCR	Odds Ratio	Std. Err.	z	P>z	95% CI	
C-stat=0.62						
amblyopia	1.24	0.085	3.1	0.002	1.08	1.41
glaucoma	1.08	0.037	2.2	0.027	1.01	1.15
psuedophaco	2.32	0.134	14.6	0.000	2.08	2.60
brunescent	2.17	0.083	20.2	0.000	2.01	2.34
Nofund	1.29	0.087	3.8	0.000	1.13	1.48
Othmac	0.82	0.075	-2.2	0.027	0.68	0.98
othercopath	1.61	0.067	11.6	0.000	1.49	1.75
preVACAT_d1	1.10	0.029	3.6	0.000	1.04	1.16
preVACAT_d2	1.32	0.044	8.2	0.000	1.23	1.41
preVACAT_d3	1.43	0.058	8.8	0.000	1.32	1.55
preVACAT_d4	1.99	0.067	20.5	0.000	1.87	2.13
Gender	1.10	0.023	4.4	0.000	1.05	1.14
age_d1	1.18	0.040	4.9	0.000	1.10	1.26
age_d2	1.15	0.036	4.3	0.000	1.08	1.22
age_d3	1.34	0.041	9.4	0.000	1.26	1.42
age_d4	1.43	0.049	10.3	0.000	1.33	1.53
age_d5	1.66	0.077	10.9	0.000	1.52	1.82
1st or 2nd eye	0.95	0.020	-2.5	0.012	0.91	0.99
imd_d1	0.99	0.033	-0.3	0.804	0.93	1.06
imd_d2	0.96	0.032	-1.2	0.229	0.90	1.03
imd_d3	1.08	0.035	2.5	0.012	1.02	1.16
imd_d4	1.21	0.038	5.9	0.000	1.13	1.28
isdiabetic	1.12	0.028	4.4	0.000	1.06	1.18
pupil_d1	1.09	0.030	3.3	0.001	1.04	1.15
pupil_d2	1.45	0.062	8.6	0.000	1.33	1.58
cons	0.01	0.000	-121.5	0.000	0.01	0.01

Consistency of predictors across years

Indicators highlighted in red were not present reliably in all 10 years when these were separately modelled. Frequencies were, glaucoma 4/10, other macular degeneration 6/10, and 1st or 2nd eye operated 7/10. All the other predictors were consistently present in each year separately, 10/10.

Consistency of performance measures across the years

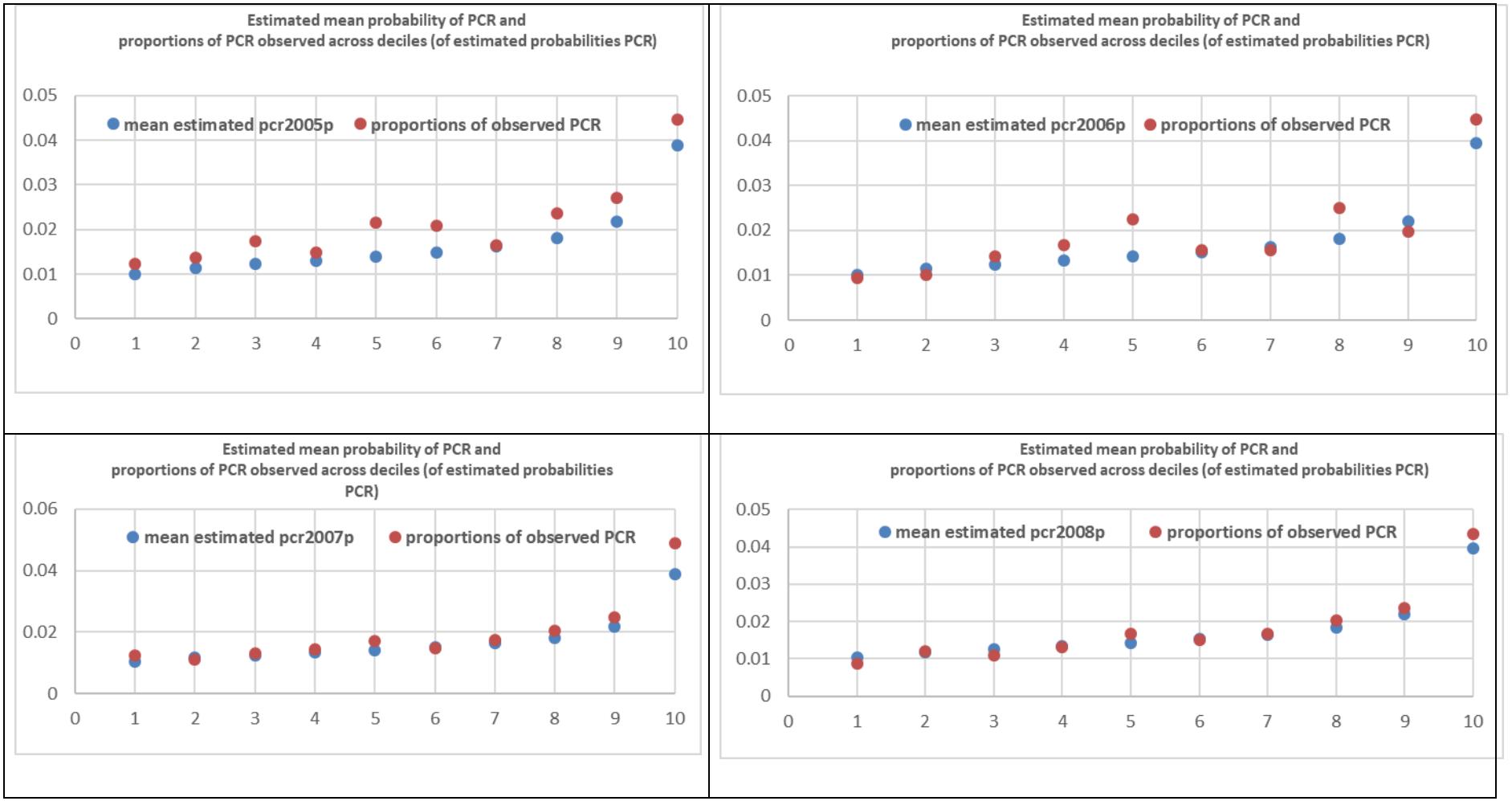
As seen in Table 3, a change in intercept arose in 2012, accentuated in 2013 and 2014 indicating a shift in calibration in later years. Slopes and C-statistics were consistent throughout.

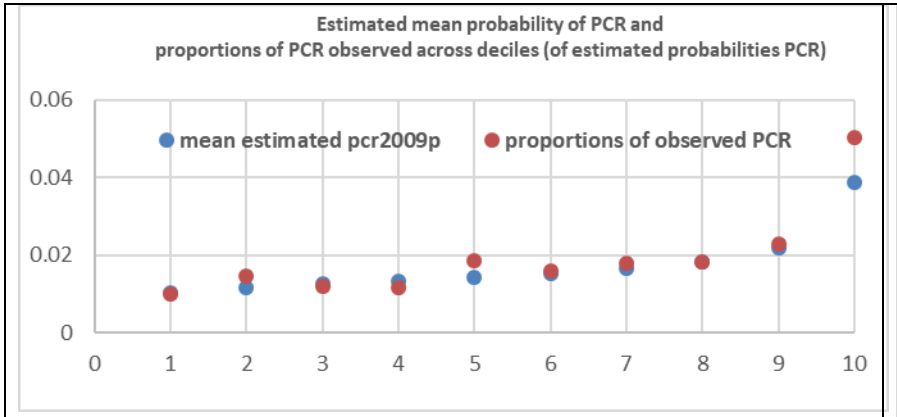
Table 3. Calibration and Discrimination: Linear intercept, slope and C-statistics for individual years

Year	Intercept (calibration)	Slope (calibration)		C-stat (discrimination)
2005	0.23	0.93		0.61
2006	0.12	0.98		0.62
2007	0.13	1.10		0.63
2008	0.04	1.05		0.63
2009	0.11	1.15		0.63
2010	0.12	0.92		0.61
2011	0.07	0.94		0.61
2012	-0.03	0.99		0.61
2013	-0.26	1.00		0.62
2014	-0.26	0.92		0.61
Mean	**0.03**	**1.00**		**0.62**
SD	**0.16**	**0.08**		**0.01**

Calibration plots are presented in Figure 1 showing the graphs for individual years of proportions of PCR vs. deciles of the estimated probabilities of PCR. Graphs show both predicted values and observed values. The proximity of the blue (estimated) and the red (observed) dots in each estimated probability of PCR indicates reasonably close agreement between model estimation and observed probabilities across the deciles of the estimated probabilities of PCR.

Figure 1. Calibration plots for each year showing proportions of PCR vs. deciles for both predicted values and observed values.




Estimated mean probability of PCR and
proportions of PCR observed across deciles (of estimated probabilities PCR)
mean estimated pcr2009p
proportions of observed PCR
0.06
0.04
0.02
0
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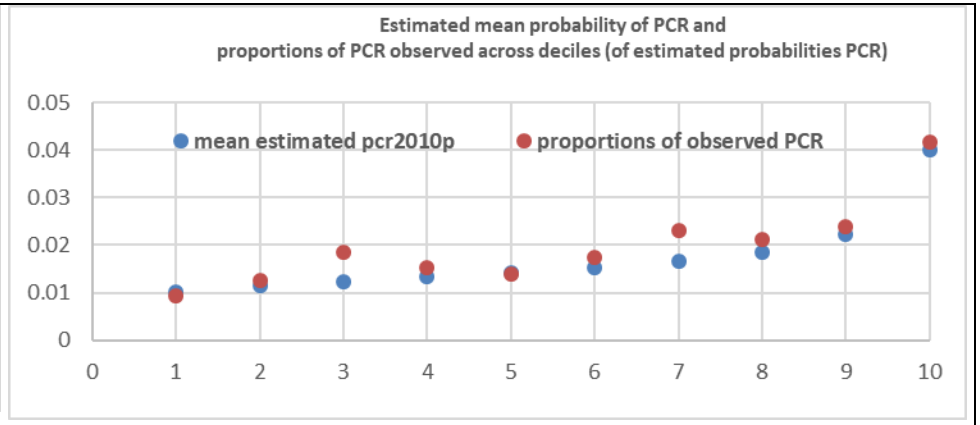
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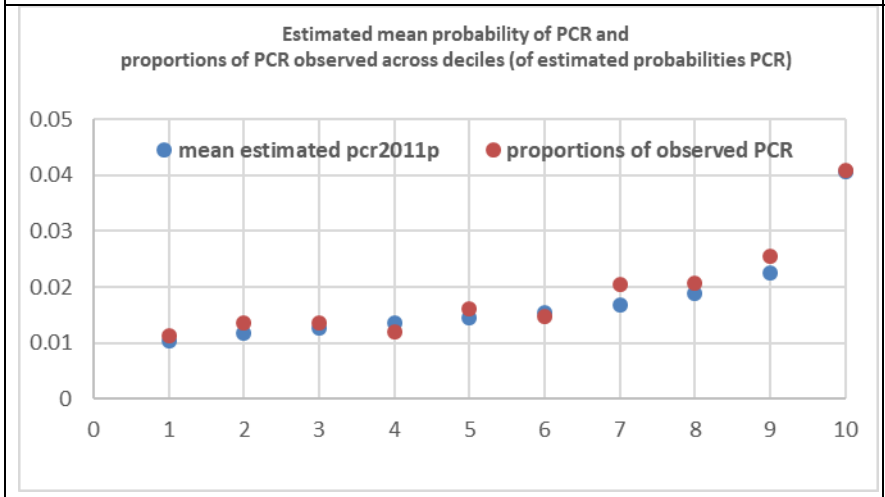
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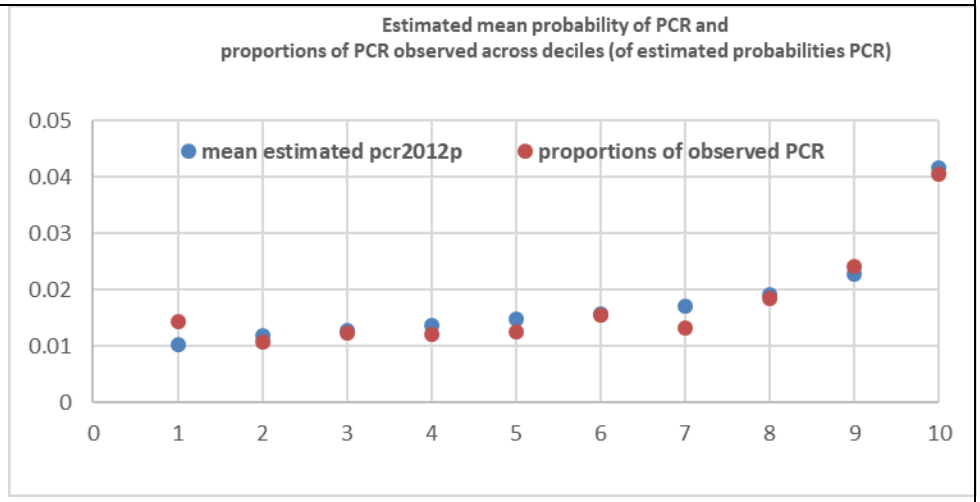
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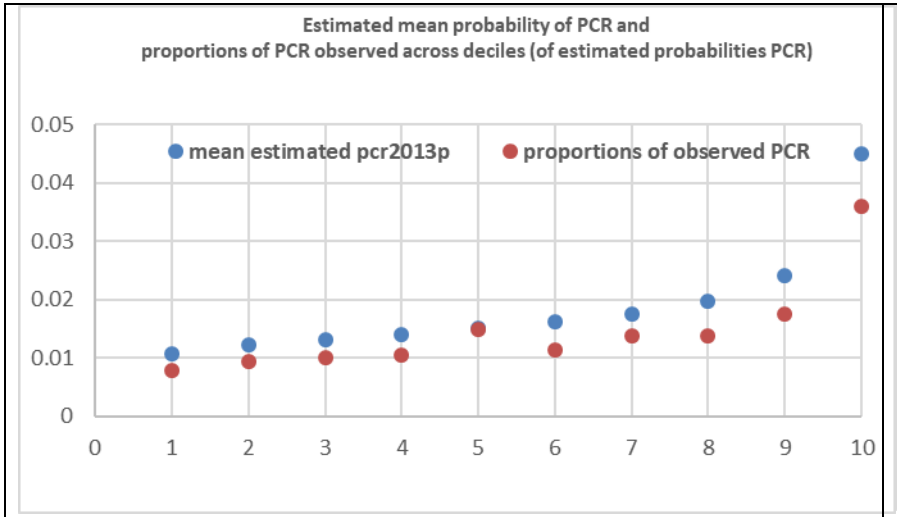
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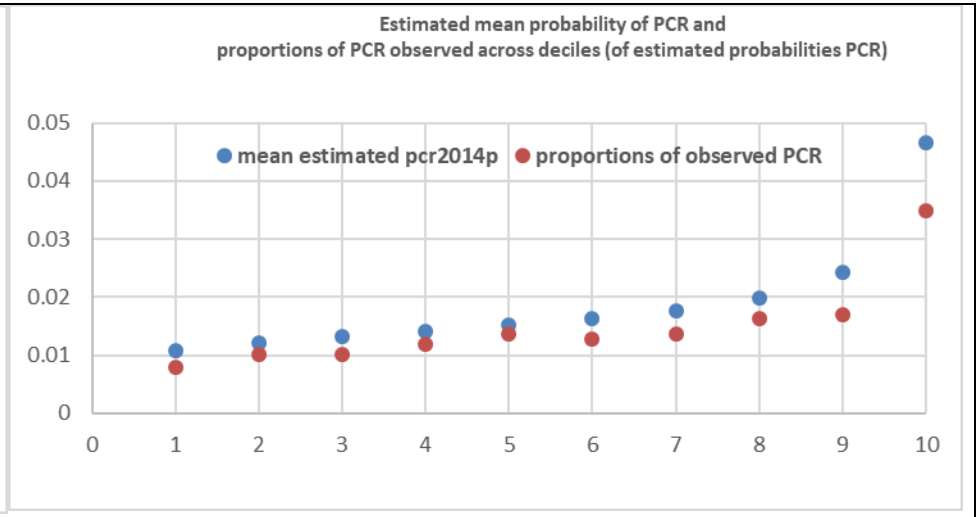
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proportions of PCR observed across deciles (of estimated probabilities PCR)
mean estimated pcr2014p
proportions of observed PCR
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0 1 2 3 4 5 6 7 8 9 10

Table 4. Significance of including year as a predictor in the model. Both global tests (LR & Wald) are highly significant indicating variation between years with individual year indices confirming that the discrepancy arises from the year 2012 onwards.

Year of Surgery	**OR**	**P**
2005	Reference category	
2006	0.90	0.079
2007	0.90	0.070
2008	0.84	0.001
2009	0.89	0.030
2010	0.90	0.038
2011	0.85	0.002
2012	0.78	0.000
2013	0.64	0.000
2014	0.64	0.000
LR chi2	**195.03**	
p	**<0.001**	
Wald chi2	**188.73**	
P	**<0.001**	

Table 5. Assessment of temporal stability through time by likelihood ratio tests for groupings of years. These tests illustrate a change in stability with 2012 manifesting as a 'rogue year', followed by establishment of a new (different) model stability of the final two years in 2013 and 2014.

2005	**2006**	**2007**	**2008**	**2009**	**2010**	**2011**	**2012**	**2013**	**2014**	**LR chi2**	**df**	**p**
x	x	x	x	x	x	x	x	x	x	472.71	234	<0,001
x	x									32.16	26	0,188
x	x	x								61.28	52	0,178
x	x	x	x							92.95	78	0,119
x	x	x	x	x						113.70	104	0,242
x	x	x	x	x	x					147.58	130	0,139
x	x	x	x	x	x	x				173.27	156	0,163
x	x	x	x	x	x	x	x			232.80	182	0,007
x	x	x	x	x	x	x	x	x		374.97	208	<0,001
								x	x	30.37	26	0,252
							x	x	x	93.97	52	<0,001

The other two approaches to selection of candidate predictors revealed broadly similar patterns of stability and instability through time with the pivot year at 2012.

Conclusions

These analyses have revealed that stability of the risk model for PCR existed from 2005-2011 with a 'rogue year' at 2012 followed by two stable years, 2013 and 2014. It will be interesting to undertake similar analyses on more recent data to assess stability forward of 2014. The importance of these analyses is that these insights provide guidance as to the frequency with which models for risk adjustment of surgeons' outcomes should be refreshed.

Analyses: Mariusz Grzeda
Written: John Sparrow
(Appendix 3, word count 1997)

Appendix 4. Clinical outcome and risk factors for posterior capsule rupture and visual acuity loss following cataract surgery in patients aged 90 years and older

Outcomes and Risk Indicators for People aged 90 years and older

This 'added value' analysis has been published:

Theodoropoulou S, Grzeda MT, Donachie PHJ, Johnston RL, Sparrow JM, Tole DM. The Royal College of Ophthalmologists' National Ophthalmology Database Study of cataract surgery. Report 5: Clinical outcome and risk factors for posterior capsule rupture and visual acuity loss following cataract surgery in patients aged 90 years and older. Eye (Lond). 2019;33(7):1161-70.

Full text available:

https://research-information.bris.ac.uk/files/187398573/2018.12.20_cataract_90_outcomes_manuscript_CORRECTED_CLEAN_FINAL_FOR_SUBMISSION.pdf

Refraction analysis using complex numbers

Analysis of cataract surgery refractive outcome and indicators for intended postoperative refraction using a composite complex numbers methodology

Added value to WP2 – Methodology and Initial Results

Methods

Refraction measurements

The analyses are based on data collected up to 30th September 2018. Refractive measurements with only a recorded sphere value were assumed to have a corresponding cylinder value of zero. All refractive measurements with a zero cylinder value were given a corresponding axis value of zero. A refractive measurement was classified as partially observed if: (i) the sphere value was missing, (ii) the cylinder value was missing but the sphere and axis values were recorded, and (iii) the axis value was missing but the recorded cylinder value was non-zero. I have assumed I have been given a clean dataset (i.e., any known data entries had been removed). In such a large dataset any remaining anomalies are usually accounted for by the statistical model.

All refraction measurements in the minus-cylinder format were converted to the plus-cylinder format. The pre-operative keratometry measurements, K1 and K2 (in dioptres) and K2 axis (in degrees), that were closest to the date of the operation were selected. The intended refraction measurement was calculated and any in minus-cylinder format converted to plus cylinder format (close to 0.5% of measures).

The intended refraction measurement and the post-operative refraction measurement from the sphero-cylinder scale were converted to the dioptric power matrix scale. On this dioptric power matrix scale, I calculated the difference between the post-operative and intended refraction measurement (i.e., post-operative – intended). *This difference was the primary outcome of interest*.

Modelling the multilevel structure

The primary outcome was trivariate (involving three components f_{11}, f_{12} and f_{22}) and was modelled using a multivariate normal multilevel model fitted in Stata and MLwiN via the runmlwin command.

Compared models with different multilevel structures. The following models were compared when the modelling each component separately (univariate models) and all 3 simultaneously (multivariate model):

- model 1: nested two-level model with eyes nested within surgeons
- model 2: nested two-level model with eyes nested within patients
- model 3: nested three-level model with eyes nested within patients nested within surgeons
- model 4: three-level cross-classified model

All models contained a fixed intercept and a random intercept at each level, and were fitted using Markov Chain Monte Carlo estimation with 500 burn-in iterations and 5000 iterations for the monitoring chain. The models were compared with respect to the Deviance Information Criterion (DIC) and the Mean Squared Error (MSE). DIC is a likelihood-based goodness of fit measure that penalises for model complexity and MSE indicates how well the model predicts the outcome [i.e., it is the mean of the squared differences between the observed outcome and the model predicted outcome]. Lower values of DIC and MSE indicate a better fit to the data.

Markov Chain Monte Carlo estimation

MCMC estimation produces a chain of estimates (for each parameter) which are random draws from the required stationary distribution. Diagnostic tools applied to these chains check for (i) convergence to the stationary distribution, (ii) serial correlation (also known as autocorrelation) of the draws within a chain. Ideally, we want to see convergence and independent (or weakly) correlated draws. I applied MCMC estimation with 500 burn-in iterations (period before convergence) and 5000 chain iterations (period after convergence). Also repeated this for 5000 burn in iterations and 50,000 chain iterations.

Selecting the covariates

Performed backward stepwise selection on the following covariates: diabetic retinopathy, glaucoma, high myopia, inherited eye disease, diseased optic nerve, uveitis/synaechaie, pseudoexfoliation/phacodenesis, no fundal view/vitreous opacities, other macular pathology, other retinal pathology, undergone vitrectomy surgery, undergone trabeculectomy surgery, other ocular co-pathology, brunescent/white mature cataract, and posterior capture rupture during cataract surgery. Stepwise selection was performed on the multivariate model (i.e., 3 outcomes modelled simultaneously) using the likelihood ratio test. The multilevel structure was a nested 3-level model because this model could be estimated using maximum likelihood (enabling the use of the likelihood ratio test) and the multilevel structure had no effect on the fixed effect estimates (n.b., the

covariates enter the model as fixed effects). To aid comparison of coefficients across the 3 outcome components, these outcomes were standardised prior to the stepwise selection procedure (n.b., all covariates were binary). A covariate was eliminated if the p-value from the likelihood ratio test was >0.01 and its 3 coefficients (one for each outcome) were all less than 0.1. Given the large sample size I set the cut-off p-value to the more stringent level of 0.01 as opposed to the usual 0.05.

Results

Refraction measurements

The dataset contains information on 1,070,601 cataract operations, where 198,047 operations have no refraction measurements. Among the remaining 872,554 cataract operations, 452,039 have fully observed pre-operative and post-operative measurements, 263,233 have only a fully observed pre-operative measurement, 151,851 have only a fully observed post-operative measurement, and 5,431 have neither a fully observed pre-operative nor post-operative measurement

Among the 603,890 operations with a fully observed post-operative measurement only 491,414 had fully observed pre-operative keratometry data and a "predicted post-operative" refraction. Therefore, the primary outcome of interest was only available for 491,414 operations.

352,110 patients had a total of 491,414. Of these 352,110 patients, 212,806 patients had a single eye operation, 95,770 patients had two operations by different surgeons and 43,534 patients had two operations by the same surgeon.

Table 1a shows the median, and lower and upper quartile values of the intended refraction data (based on preoperative keratometry data and surgeon's predicted sphere), post-operative refraction data, and their difference. Table 1b reports the estimated (unconditional) mean with 95% confidence interval of the intended refraction data, post-operative refraction data and their difference. The unconditional means were estimated using a multilevel model, containing only a constant fixed effect, which accounts for correlations within surgeon and correlations within patients.

Table 1a: Median [lower quartile, upper quartile] of post-operative and intended refraction measurements, and their difference, among 491,414 operations with both measurements. Quartiles calculated on the power matrix scale and back-transformed to the sphero-cylindrical scale.

	Lower quartile S/CXA	**Median S/CXA**	**Upper quartile S/CXA**
Post-operative refraction	-1.07/+0.66X21	-0.47/+0.47X180	-0.02/+0.56 X 166
Intended refraction	-0.79 / +0.36 X 41	-0.27 / +0.05 X 180	-0.06 / +0.35 X 140
Post - intended	-0.72 / +0.59 X 23	-0.19 / +0.44 X 4	+0.20 / +0.54 X 164

Table 1b: Estimated (unconditional) mean of post-operative and intended refraction measurements, and their difference [with lower and upper 95% confidence interval limits] among 491,414 operations with both measurements. Calculated on the power matrix scale and back-transformed to the sphero-cylindrical scale.

	Mean S/CXA	**Lower 95% CI limit S/CXA**	**Upper 95% CI limit S/CXA**
Post-operative refraction	-0.51/+0.50X5	-0.52/+0.50X5	-0.50/+0.50X4
Intended refraction	-0.25/+0.042X2	-0.26/+0.04X4	-0.25/+0.04X1
&Post - intended	-0.25/+0.46X5	-0.26/+0.46X5	-0.24/+0.46X4

&: A global p-test was calculated on the power matrix scale testing evidence against the null hypothesis that the mean differences [post – intended] of all three outcomes [f11, f12 and f22] equalled zero. Reported a p-value <0.00001.

Selecting the multilevel structure

For both the univariate and multivariate models, the patient-level variance of the outcome component f_{12} (and its patient-level covariances with f_{11} and f_{22}) were estimated to be close to zero. Therefore, to aid estimation these variances-covariances were constrained to be zero. Table 1 shows the DIC and MSE values across the four multivariate models with different multilevel structures. Both the DIC and MSE values indicate that the nested 3-level model was the best fit to the data. I have compared the parameter estimates from the nested 3-level model with the cross-classified model (results not shown). The results for the fixed effects and the surgeon-level variance-

covariances were very similar between the two models. However, there were noticeable differences in the results of the patient-level and eye-level variance-covariances (e.g., 0.35 (95% CI 0.34, 0.36) versus 0.26 (95% CI 0.25, 0.27)), although all results were in the same direction and of comparable magnitude. Note, the results from comparing the univariate models follow the same patterns as shown in table 2 (results not shown). I consulted Dr George Leckie (an expert in multilevel modelling) and he would expect the nested 3-level model to give a superior fit despite the cross-classified nature of the data. However, cautioned to fit the cross-classified model as the nested model could lead to under-estimated standard errors.

Table 2: Model fit statistics comparing multivariate models with different multilevel structures

Model	Deviance Information Criterion (DIC)	Mean Squared Error (MSE) of		
		f_{11}	f_{12}	f_{22}
Nested 2-level – eyes nested within surgeons	3,018,273	1.17	0.119	1.22
Nested 2-level – eyes nested within patients	3,007,341	0.723	0.125	0.753
Nested 3-level – eyes nested within patients within surgeons	2,957,923	0.589	0.119	0.639
3-level cross-classified model	2,970,921	0.731	0.119	0.766

MCMC diagnostics

The MCMC diagnostics indicated that after a burn-in of 5000 iterations, convergence had been achieved. Analysis of each chain of estimates reveals a substantial autocorrelation problem. A chain of 50,000 iterations produces 1957 independent estimates. George Leckie has recommended hierarchical centring to reduce the autocorrelation problem. Still awaiting the results from running this analysis.

Selecting the covariates

Table 3 shows the frequencies (and percentages) for all covariates considered for selection. Backward stepwise selection eliminated five covariates: other macular pathology, other ocular co-pathology, inherited eye disease, disease of the optic nerve, and no fundal view.

Table 3: Frequencies for covariates based on the 491,414 eye operations with intended and post-operative refraction measurements

Covariates under consideration	Number of operations (%)
Indication of diabetic retinopathy at time of surgery	27,098 (5.51%)
Indication of glaucoma at time of surgery	43,022 (8.75%)
Indication of high myopia at time of surgery	21,255 (4.33%)
Indication of inherited eye disease at time of surgery	530 (0.11%)
Indication of diseased optic nerve at time of surgery	1,690 (0.34%)
Indication of uveitis/synaechiae at time of surgery	3,412 (0.69%)
Indication of pseudoexfoliation/phacodonesis at time of surgery	4,652 (0.95%)
Indication of no fundal view/ vitreous opacities at time of surgery	5,855 (1.19%)
Indication of other macular pathology at time of surgery	11,363 (2.31%)
Indication of other retinal pathology at time of surgery	4,342 (0.88%)
Eye has previously undergone vitrectomy surgery	7,570 (1.54%)
Eye has previously undergone trabeculectomy surgery	1,957 (0.40%)
Indication of other ocular co-pathology at time of surgery	22,415 (4.56%)
Indication of brunescent/white mature cataract at time of surgery	19,155 (3.90%)
Indication if posterior capsular rupture occurred during surgery	4,574 (0.93%)

Table 4 shows the results from fitting the model with the remaining (selected) covariates. These results are from the nested 3 level model which gives near identical results (for the fixed effects) as that of the cross-classified model. The cross-classified model can only be fitted [with current software] using Bayesian estimation whilst the nested model can be fitted using maximum likelihood estimation. Since we wanted a global test of the null hypothesis that the three coefficients [for a covariate] are jointly zero, and this test is only available with maximum likelihood estimation, I have presented the nested results. I have converted the coefficient estimate and the limits of the 95% confidence interval from the power matrix scale back to the spherical-cylindrical scale.

Table 4: Fixed effects estimates from the final model of the stepwise procedure. All coefficients, standard errors and the limits of the 95% confidence intervals are reported as compound numbers; sphere / cylinder X axis. Note, the limits of the 95% confidence interval were calculated by back-transforming the confidence interval limits on the f11, f12 and f22 scale. The P-value is from a global test calculated on the f11, f12 and f22 scale in which the null hypothesis is that the three coefficients are jointly equal zero.

	Point estimate	**Standard error**	**95% CI**	**P-value**
Diabetic retinopathy	+0.10/+0.016X105	0.0093/0.0089X0.20	+0.091/+0.014X89, +0.11/+0.022X115	<0.00001
Glaucoma	-0.098/+0.067X96	0.0082/0.0082X0.030	-0.11/+0.066X93, -0.087/+0.068X99	<0.00001
High myopia	-0.12/+0.038X29	0.0095/0.0073X0.13	-0.14 /+0.046X32, -0.10/+0.031X24	<0.00001
Uveitis/synaechiae	-0.055/+0.076X11	0.026/0.025X0.10	-0.098/+0.088X19, -0.015/+0.071X2	<0.00001
Pseudoexfoliation/phacodonesis	+0.085/+0.023X112	0.021/0.018X0.39	+0.055/+0.018X83, +0.11/ +0.039X123	<0.00001
Other retinal pathology	+0.0048/+0.045X85	0.023/0.023X0.12	-0.032/+0.053X74, +0.037/0.046X99	0.0015
Previous vitrectomy surgery	-0.037/+0.040X24	0.016/0.014X0.18	-0.069/+ 0.053X30, -0.0072/+0.031X13	0.0001
Previous trabeculectomy surgery	-0.072/0.066X119	0.030/ 0.023X0.24	-0.11/0.043X108, -0.036/0.094X125	0.0006
Brunescent/white mature cataract	+0.011/+0.015X73	0.011/0.010X0.26	-0.0087/+0.023X62, +0.029/+0.012X94	0.0047
Posterior capsular rupture	-0.24/+0.041X80	0.022/0.022X0.15	-0.28/+0.052X70, -0.21/+0.038X95	<0.00001

(Appendix 5, word count 1994)

Appendix 6. Predict-CAT Cohort Study – Cat-PROM5 Outcomes Prediction

Predict-CAT Cohort Study

Cat-PROM5 Outcomes Prediction

The Predict-CAT Cohort Study:

Cat-PROM5 Outcomes Prediction

Background

As part of this programme a cataract patient reported outcome measure has been developed, Cat-PROM5. The psychometric properties of the instrument are good to excellent. Having confirmed robust performance of Cat-PROM5, the next step for the programme was to develop statistical models which provide for preoperative prediction of self-reported postoperative outcomes. Construction of two types of prediction models would be helpful to patients preoperatively to provide estimates of their likely postoperative benefits, should they choose to proceed with surgery. These two models would be designed to inform patients about

1. Their final self-reported outcome and
2. Their improvement in self-reported vision from before to after surgery.

Our earlier work, updated and validated as part of the programme, developed risk models for predicting the probability of a patient having an adverse even from cataract surgery. Two adverse events were modelled, the index operative complication (Posterior Capsule Rupture - PCR) and visual damage related to the surgery (Visual Acuity Loss - VA Loss). Our previous research demonstrated that the predicted probability of a surgical complication varies by as much as 50-fold, depending on the characteristics of the patient and the eye for surgery. When a PCR complication arises, there is a six-fold greater chance that vision will be significantly worse after surgery than before, i.e. VA Loss. Some of the reasons for this higher rate of vision loss following an operative complication include a 40-fold increased risk of a retinal detachment developing and an eight-fold increased risk of a serious and potentially blinding infection arising.

Personalising risks of adverse outcomes according to an individual patient's characteristics is important for a range of reasons, including for example, better informed consent preoperatively, and ensuring that complex surgical cases are operated on exclusively by highly experienced surgeons to optimise the chances of a good outcome. Similarly, personalising estimates of likely benefit is equally important, so that a patient approaching surgery can consider the likelihood of having visual

benefit, alongside the risks of coming to harm. An important aspect of the research programme is to address this information need.

Aim

- To develop a prediction model for personalised prediction of self-reported Cat-PROM5 outcome after cataract surgery
- To develop a benefits prediction model for personalised prediction of self-reported improvement in Cat-PROM5 score from before to after cataract surgery

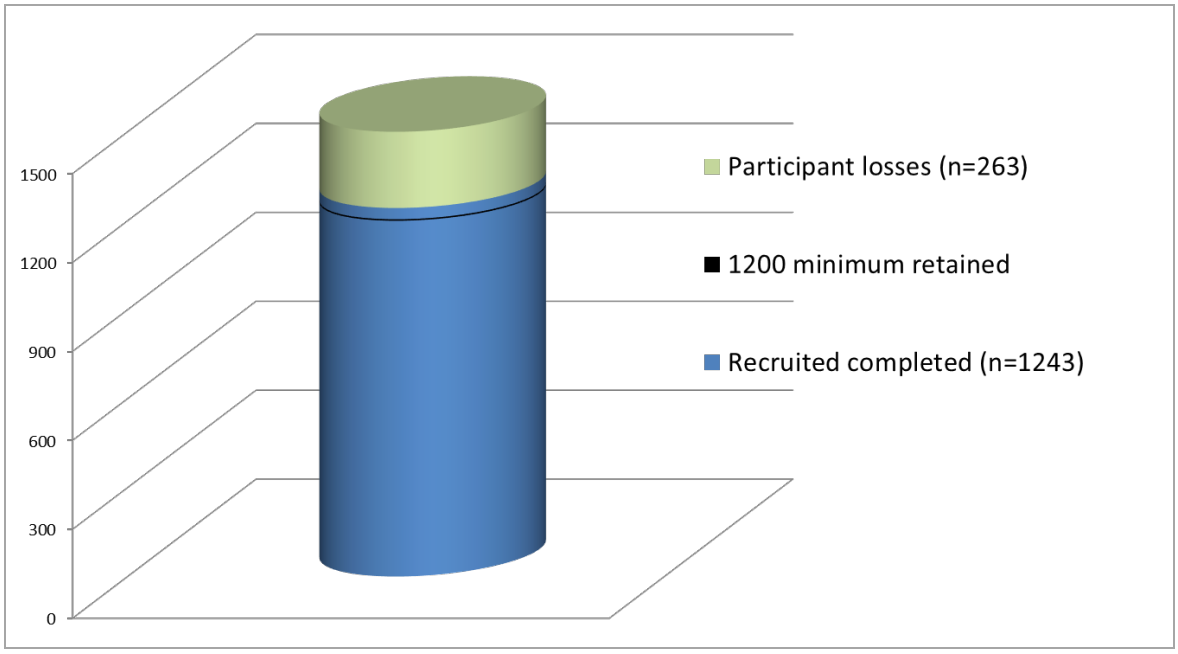
Method

As part of the programme, a cohort study named Predict-CAT was undertaken to profile patients preoperatively and to follow them through surgery and record their outcomes in detail postoperative. A target sample of 1500 patients was planned, anticipating a 20% loss to follow-up rate, the desired retained sample was 1200. Two centres took part in recruitment, Bristol and Gloucestershire. Patients were recruited at the preoperative stage, mostly in preoperative assessment clinics, and those wishing to participate were seen twice in research clinics, once before and once after their cataract surgery. A full general and ocular history was taken, along with a full eye examination preoperatively. A less intense postoperative assessment was undertaken, which included a full examination of the eye which had undergone surgery.

Participants

Full recruitment of 1506 participants was achieved, with 1204 patients recruited in Bristol and 302 in Gloucestershire. Figure 1 shows the final recruitment figures with 1243 participants completing the study. Following cleaning of data and accounting for missing data items there remained 1181 participants with valid data for analysis.

Figure 1. The final Predict-CAT recruitment status.



Statistical Analysis

Among the 1181 participants with valid data there remained scattered missing data items. In order to preserve the sample from further attrition these missing data items were imputed using multivariate imputation by chained equations (MICE) in which 20 datasets were created with missing data replaced by imputed values, each entailing ten cycles of regression switching. This method relies on the Missing at Random (MAR) assumption. In parallel with the analyses based on the multiple imputation routine, complete case analyses were also undertaken (missing values ignored). These were based on 1089 complete cases.

Initial descriptive analyses of candidate predictor and outcome variables was undertaken, followed by linear regression modelling of two Cat-PROM5 Rasch calibrated outcome variables. The final outcome was modelled as the postoperative score and the improvement from baseline as the difference between the pre- and postoperative scores (delta approach). Potential predictors were categorised into blocks according to a timeline order, earlier to later, and from the most general diseases to the most specific. All models included age, gender and the baseline Cat-PROM5 status as predictors regardless of their observed 'statistical importance'. Skewed distributions were transformed if necessary and variables were entered into the model in ordered blocks and an F test

performed for each block as a whole. If the p value for the block was above 0.05 then the whole block was rejected. Where the p value of the test for the block was less than 0.05, the specific predictors were examined and those with small effects iteratively removed. After each stage all the predictors were reviewed by an experienced ophthalmologist as to whether the list and the model made clinical sense and predictors without plausible clinical meaning removed. Following model construction, the model diagnostics were checked and acted upon if necessary.

Results

The results of the modeling are presented here in tables 1 to 4. All effects are statistically important except the patient's age. However, it was decided on theoretical/clinical grounds that age should be included in every model. All models explain around 30% of variance.

Final Cat-PROM5 Self-Reported Outcome

Models using imputed data and complete cases only are shown in Tables 1 & 2. The models are very similar. Model diagnostics (not shown) were satisfactory.

Pre- to Postoperative Cat-PROM5 Self-Reported Score Change

Models using imputed data and complete cases only are shown in Tables 3 & 4. Again, the models are very similar. Model diagnostics (not shown) were likewise satisfactory.

Conclusion

Based on the results of these analysis it will be possible to use these models to predict the likely final Cat-PROM5 outcome for individual patients as well as the change in score (typically an improvement with less self-reported visual difficulty) from before to after surgery. Simple spreadsheet calculators can be constructed which make prediction of outcomes easily accessible for surgeons. This personalised approach to information can provide patients with more realistic estimates of their likely benefit from surgery, and set alongside the risks of an adverse event, patients will be better placed to make well informed decisions about surgery.

Table 1. Linear regression model for postoperative Cat-PROM5 score using imputation

Model obtained from 20 datasets with missings replaced by Multiple Imputation	m=20	n=1,181			[95% Conf. Interval]	
Regressor approach. Predicted variable is the transformed score at follow-up:	Coef.	Std. Err.	t	P>t	Lo	Hi
Const.	3.726	0.019	198.840	0.000	3.689	3.763
Baseline Cat-PROM5	-0.010	0.001	-11.460	0.000	-0.012	-0.008
Age	-0.0003	0.000	-1.010	0.314	-0.001	0.000
Women	-0.010	0.004	-2.620	0.009	-0.018	-0.003
Patient is diabetic	-0.015	0.006	-2.410	0.016	-0.027	-0.003
Medical history: endocrine disease	0.017	0.005	3.360	0.001	0.007	0.026
Number of ocular pathological problems: (among glaucoma, diabetic retinopathy, age-related macular degeneration; other retinal vascular pathology; other macular pathology; ambylopia)						
One problem	-0.011	0.004	-2.520	0.012	-0.020	-0.002
Two or more problems	-0.019	0.007	-2.870	0.004	-0.033	-0.006
Other pathological history (different than those listed above)	-0.014	0.004	-3.390	0.001	-0.023	-0.006
ln(VA habitual distance + 0.31) in operated eye	0.034	0.007	5.290	0.000	0.022	0.047
VA unaided in better eye	-0.025	0.006	-4.260	0.000	-0.036	-0.013
VA corrected near in better eye	-0.040	0.011	-3.520	0.000	-0.063	-0.018
Previous cataract surgery	0.026	0.005	5.400	0.000	0.016	0.035
Interaction term: Previous cataract surgery # ln(VA habitual distance + 0.31) in worse eye						
1	-0.020	0.010	-2.020	0.043	-0.040	-0.001
R2	29.1%					

Table 2. Linear regression model for postoperative Cat-PROM5 score using complete cases only (no missing data items)

Model obtained from complete case analysis (missings ignored)		n=1,089			[95% Conf. Interval]	
Regressor approach. Predicted variable is the transformed score at follow-up :	Coef.	Std. Err.	t	P>t	Lo	Hi
Const.	3.721	0.019	192.410	0.000	3.684	3.759
Baseline Cat-PROM5	-0.010	0.001	-10.620	0.000	-0.011	-0.008
Age	0.0002	0.000	-0.580	0.559	-0.001	0.000
Women	-0.009	0.004	-2.340	0.020	-0.017	-0.001
Patient is diabetic	-0.017	0.006	-2.630	0.009	-0.029	-0.004
Medical history: endocrine disease	0.018	0.005	3.520	0.000	0.008	0.028
Number of ocular pathological problems: (among glaucoma, diabetic retinopathy, age-related macular degeneration; other retinal vascular pathology; other macular pathology; ambylopia)						
One problem	-0.011	0.005	-2.440	0.015	-0.020	-0.002
Two or more problems	-0.018	0.007	-2.620	0.009	-0.032	-0.005
Other pathological history (different than those listed above)	-0.014	0.004	-3.140	0.002	-0.022	-0.005
ln(VA habitual distance + 0.31) in operated eye	0.041	0.007	6.150	0.000	0.028	0.055
VA unaided in better eye	-0.026	0.006	-4.370	0.000	-0.037	-0.014
VA corrected near in better eye	-0.047	0.012	-4.030	0.000	-0.069	-0.024
Previous cataract surgery	0.023	0.005	4.610	0.000	0.013	0.032
Interaction term: Previous cataract surgery # ln(VA habitual distance + 0.31) in worse eye						
1	-0.029	0.010	-2.850	0.004	-0.049	-0.009
R2	29.2%					

Table 3. Linear regression model for pre- to postoperative Cat-PROM5 score change using imputation

Model obtained from 20 datasets with missings replaced by Multiple Imputation	m=20	n=1,181			[95% Conf. Interval]	
Delta approach. Predicted variable is the change score (as a difference between follow-up and baseline measurement):	Coef.	Std. Err.	t	P>t	Lo	Hi
Const.	-4.602	0.748	-6.150	0.000	-6.069	-3.134
Baseline Cat-PROM5	-0.591	0.035	-16.780	0.000	-0.660	-0.522
Age	0.007	0.010	0.700	0.486	-0.013	0.027
Women	0.348	0.154	2.260	0.024	0.046	0.650
Patient is diabetic	0.584	0.242	2.410	0.016	0.108	1.059
Medical history: endocrine disease	-0.650	0.196	-3.310	0.001	-1.034	-0.265
Number of ocular pathological problems: (among glaucoma, diabetic retinopathy, age-related macular degeneration; other retinal vascular pathology; other macular pathology; ambylopia)						
One problem	0.510	0.175	2.910	0.004	0.166	0.853
Two or more problems	0.917	0.270	3.390	0.001	0.387	1.447
Other pathological history (different than those listed above)	0.549	0.170	3.230	0.001	0.215	0.882
ln(VA habitual near + 0.31) in operated eye	-0.759	0.266	-2.860	0.004	-1.280	-0.238
VA unaided in better eye	0.961	0.232	4.150	0.000	0.507	1.416
VA corrected near in better eye	1.976	0.462	4.280	0.000	1.070	2.882
ln(VA habitual distance + 0.31) in worse eye	-1.215	0.298	-4.080	0.000	-1.799	-0.630
Previous cataract surgery	-1.028	0.182	-5.660	0.000	-1.384	-0.672
Interaction term: Previous cataract surgery # ln(VA habitual distance + 0.31) in worse eye						
1	1.271	0.384	3.310	0.001	0.517	2.025
R2	31.2%					

Table 4. Linear regression model for pre- to postoperative Cat-PROM5 score change using complete cases only (no missing data items)

Model obtained from complete case analysis (missings ignored)		n=1,089			[95% Conf. Interval]	
Delta approach. Predicted variable is the change score (as a difference between follow-up and baseline measurement):	Coef.	Std. Err.	T	P>t	Lo	Hi
Const.	-4.333	0.788	-5.500	0.000	-5.880	-2.786
Baseline Cat-PROM5	-0.613	0.037	-16.700	0.000	-0.685	-0.541
Age	0.002	0.011	0.200	0.841	-0.019	0.023
Women	0.293	0.159	1.840	0.066	-0.019	0.606
Patient is diabetic	0.617	0.253	2.440	0.015	0.121	1.113
Medical history: endocrine disease	-0.679	0.202	-3.370	0.001	-1.075	-0.284
Number of ocular pathological problems: (among glaucoma, diabetic retinopathy, age-related macular degeneration; other retinal vascular pathology; other macular pathology; ambylopia)						
One problem	0.573	0.183	3.130	0.002	0.214	0.932
Two or more problems	0.932	0.277	3.370	0.001	0.389	1.474
Other pathological history (different than those listed above)	0.475	0.175	2.710	0.007	0.131	0.819
ln(VA habitual near + 0.31) in operated eye	-0.878	0.271	-3.250	0.001	-1.409	-0.348
VA unaided in better eye	0.918	0.240	3.820	0.000	0.447	1.390
VA corrected near in better eye	2.393	0.474	5.050	0.000	1.463	3.323
ln(VA habitual distance + 0.31) in worse eye	-1.362	0.316	-4.310	0.000	-1.982	-0.742
Previous cataract surgery	-0.913	0.192	-4.770	0.000	-1.290	-0.537
Interaction term: Previous cataract surgery # ln(VA habitual distance + 0.31) in worse eye						
1	1.532	0.414	3.700	0.000	0.719	2.344
R2	31.9%					

(Appendix 6, word count 1979)

Appendix 7. Predict-CAT-QUAL - Information for Cataract Patients

Predict-CAT QUAL

Information for Cataract Patients: Presentation, Content and Perceptions of Usefulness of Information for Cataract Patients

Predict-CAT Qual: Presentation, Content and Perceptions of Usefulness of Information for Cataract Patients

Summary of key findings

Aims

- Explore the acceptability of the Cat-PROM5 questionnaire with healthcare professionals (developed and validity-tested in WP1 of the Cataract Research Programme)
- Identify the most acceptable way of presenting risk and benefit probability information to patients as part of a Cataract Decision Aid
- Identify cataract surgery specific Frequently Asked Questions to be included in a Cataract Decision Aid
- Explore issues of shared and informed decision-making during cataract surgery patient counselling to inform the development and implementation of a Cataract Decision Aid in routine practice

Methods

- Conduct focus groups and interviews **with patients** to inform development (presentation, format and additional information) of a risk and benefit probability calculator and Cataract Decision Aid
- Conduct interviews **with healthcare professionals (HCPs)** to explore the acceptability of Cat-PROM5 and the usefulness of decision aids in clinical practice

Participants

Patient focus groups and interviews

Two focus groups and 15 one-to-one semi-structured interviews were conducted with 33 individuals attending the BEH clinics and two attending the GHNHSFT clinics. The mean age of patient participants was 77, with the youngest participant being 55 years old and the oldest 86. Out of the 33 patient participants, fourteen were women, all but one were White British, English was the first language of all participants and the majority were from more affluent areas. Most were suffering from other eye co-morbidities.

Healthcare professional interviews

Eight interviews with clinicians based in the BEH and three with clinicians based in GHNHSFT were conducted between March 2017 and February 2018 (11 interviews in total). Eight of the HCP participants were female. Four HCP were ophthalmologists, three nurses, and four optometrists.

Findings

Acceptability of Cat-PROM5 to healthcare professionals

Interviews were conducted with 11 HCPs: eight based in the BEH and three in GHNHSFT. HCPs were asked to comment on each question of the Cat-RPOM5 individually, and on Cat-PROM5 as a whole. Overall HCPs thought Cat-PROM5 captures vision-related quality of life well and how it might be impacted on by cataracts. The majority thought the outcome measure was short, simple and easy for patients to complete on their own and thought it captured information of importance to HCPs, but a few commented on the usefulness of knowing the specific areas affected by cataract, something not captured by the Cat-PROM5. Several believed the Cat-PROM5 captured information already used to inform decision-making.

Participants thought having a structured way of capturing VRQoL information would make more consistent the discussions taking place during consultations, introduce the patient perspective in decision-making, standardise and formalise the way VRQoL information is collected and recorded, and facilitate post-surgery assessment of surgery outcome. Some challenges to implementation were raised: resources available i.e. time; relevance of Cat-PROM5 to the role and responsibilities of the HCP and the purpose of their contact with patients in different stages of the care pathways; whether responses to the questions are influenced by patients' and/or their family's wish to have

the surgery and their expectations from the surgery i.e. reliability of responses; and attitudes of HCPs towards the questionnaire e.g. the effectiveness and added value in clinical practice.

Identify the most acceptable way of presenting risk and benefit probability information as part of a cataract decision aid

Patients participating in the study were shown four different numerical ways of presenting risk and benefit information, each accompanied by a pictogram representing visually that probability: N out of 100 individuals; number of people treated for one to experience benefit/complication; and probability as a decimal. Patient participants preferred "N out of 100 individuals" as the most easily understood format to present both risks and benefits. In terms of the pictograms, there was no general agreement as to which was the most useful to aid understanding of probabilities, or indeed whether pictograms are needed at all for this information.

Identify cataract surgery-specific frequently asked questions to be included in a cataract decision aid

Patient reported FAQs

Frequently Asked Questions (FAQs) were identified through patient participants' narratives discussing the information they found useful at the time, questions they would have asked now but didn't ask then, and emerging gaps in knowledge of surgery-specific issues.

What the surgery will entail (dispelling myths and alleviating anxiety): The most common concern was about the actual cataract surgery and what it would involve, something that patient participants thought was not well explained before the surgery.

The potential risks in relation to the potential benefits from the surgery: Most patients could recall being given risk-related information during their pre-surgery appointments but not all could recall being given a description of the potential benefits. Patient participants expressed the need to have information about the benefits of surgery as well as the risks, preferably discussing one in relation to the other.

Post-surgery complications and self-care: Post-surgery complications and self-care was another topic of concern. Patients participating in the study were concerned about what to look out for after the operation, and even though a few pointed out that this was a topic covered by the information booklet, not all were aware of how their everyday lives might be impacted. Some patient participants reported not being informed of the possibility of experiencing the complications they had experienced after the surgery.

Information about the Intra Ocular Lens (IOL) options and refractive implications post-surgery: The type of IOL to choose from and making decisions on refractive corrections were discussed in both focus groups and in two individual interviews. One participant reported this choice was the only real choice they had to make when it came to cataract surgery. Patients reported these choices were not explained to them in previous encounters with clinicians and they were not given time to consider their options, causing anxiety prior to the surgery. Other related sources of dissatisfaction included not being made aware of the extent of visual ability differences pre- and post-surgery, or the refractive difference between the two eyes (anisometropia) that might result after surgery.

How long is it safe to wait to have the surgery before risks overtake benefits: Another concern was how long it was safe for people to wait before having the surgery, after they were alerted to the presence of cataracts. Patients raised the question of whether there is a point after which the risks involved increase and the surgery becomes more complex.

The impact of comorbidities on the risks and benefits: When having additional eye problems, patients reported to experience increased uncertainty as to how much or whether the surgery would benefit their eyesight. The importance of the level of expertise of the surgeon was discussed and whether an experienced surgeon should carry out the surgery because of increased risks.

Other people's experiences: Peers were a valued source of information about the cataract surgery process, the potential impact of cataracts and implications of having the surgery. Access to such stories was thought to be of importance to people who did not have the social networks to benefit from direct peer informational support.

HCP-reported FAQs

Risks and benefits. Even though all HCP participants reported going through the risks and benefits of the surgery with patients, most thought the majority of patients were not overly concerned about the risks, nor were they motivated to discuss benefits.

Providing information about refractive outcomes. Earlier data collection highlighted information about the new IOL and refractive outcomes of surgery to be of importance to patients. Some HCPs thought this was important information to discuss with patients to address expectations, and others were confident about the level of information given to patients. Others however raised concern about patients' understanding of the information and raised challenges involved in making accurate predictions of outcome and the uncertainty involved when advising patients on possible outcomes.

About the surgery and surgery after-care. HCP participants reported patients' main concerns to be around the surgery, e.g. addressing anxiety about the process of surgery, and post-operative self-care.

Whether surgery is needed. Some patients were reported to be uncertain about the surgery and asking professionals whether surgery was needed.

Waiting times. Some HCPs reported waiting times to be patients' main concern.

Explore issues of shared and informed decision-making during cataract surgery patient counselling to inform the development and implementation of cataract decision aid in routine practice

Patient perspectives

Patients reported they had received information about cataracts and cataract surgery from formal and informal sources. This was mainly through information booklets disseminated by the cataract service, friends and relatives, and only a minority used the internet as a source of information. Patients' decisions were shaped by a number of factors, most frequently patients' wish for improved vision and fear of losing eyesight because of the cataract. The main trigger to having the surgery was the recommendation made by eye specialists and cataract surgery was understood to be the only way of preventing further visual loss. Other triggers were friends' and family members' positive experiences with cataract surgery which raised expectations for improved eyesight. The main barrier to going ahead was fear of surgery. Overall patients participating in the study understood the risks of cataract surgery to be very low, particularly older patient participants who perceived they had more to gain by having the surgery since their vision was already compromised.

Patients did not appear to be actively engaged in the information exchange process and reasons for not engaging included high anxiety levels during the consultation, forgetting the questions they had in mind, not feeling comfortable asking questions, or not having enough time to ask questions. Many patients had already taken the decision to have the surgery before their pre-surgery appointment, therefore did not see the need to ask questions. Patients thought information should be given as early as possible in the care pathway, preferably by the optometrist or included in the referral letter for patients to have time to consider the information before making a decision.

Healthcare Provider perspectives

HCPs reported that not all patients were engaged during cataract counselling, particularly when discussing risks and benefits. Reasons HCPs thought explained the lack of engagement included the patients' expectations for experiencing benefit from the surgery, paternalistic understandings of the doctor-patient relationship, not feeling comfortable asking questions, already feeling informed, and experiencing stress and anxiety during the consultation. On the other hand, patients who were more engaged in the information exchange process were thought to be younger, with higher expectations of visual ability, having co-morbidities and higher risk for complications, and being more aware of the refractive potential of the surgery.

Shared-decision making appears to be inconsistently practiced by HCPs. The majority of HCPs thought there is variability in practice and inconsistencies in the kind of information discussed with patients, the way this information is discussed and explained, and how decisions are made by individual clinicians. For some, this variability can result in inequities in who is offered surgery. All HCPs agreed that the introduction of standardised and structured ways to support the information exchange process would enhance practice, for example through the introduction of Cat-PROM5 that would ensure VRQoL of each patient is taken into consideration but also formally reported in patients' health records, and the use of FAQs and decision support tools to enhance the information exchange process and support informed and shared decision-making.

HCPs were open to the use of decision-support tools in clinical practice, but several challenges to implementation were discussed, mainly the time needed to implement in routine practice and how well the decision support tool and its aims fit in with current care pathways. For some HCP participants, the need to discuss individualised information, such as the individualised risk and benefit probabilities, would introduce certain complexities in practice: it would require time, access to individualised patient information at the time of the consultation, and expertise on the part of the clinician seeing the patient that might not always be possible in the current care context. Implications for informed consent and the time available to patients to reflect on the information given in order to make informed decisions were raised.

(Appendix 7, word count 1998)

Appendix 8. Development of a Cataract Decision Aid

Development of a Cataract Decision Aid

Cardiff qualitative study report for WP3 Predict-CAT decision aid sub-study: Development & user testing of a personalised decision aid for cataract surgery

Report prepared by:

Dr Natalie Joseph-Williams, School of Medicine, Cardiff University (NJW)

Dr Daniella Holland-Hart, School of Medicine, Cardiff University (DHH)

REPORT PURPOSE

To outline the work and findings of the decision-aid sub-study component of WP3 (Predict CAT), which is part of the following NIHR Grant Funded Programme for Applied Research - 'Cataract Surgery: Measuring and Predicting Patient Level Vision Related Health Benefits and Harms'.

This report relates to Question 4 of the overarching Cataract Programme, outlined in the main study protocol:

> Q4. Decision Support: what information is helpful to assist shared decision making and how to present this?
>
> A4. Development of a brief decision aid containing personalised probability-based information.

This work specifically refers to the second component of WP3, outline in the Predict-CAT protocol:

Objective:

- Develop a brief decision aid in which the likelihood of self-reported benefit is set alongside risks of harm (surgical complications / VA loss) to provide an integrated decision-support tool for personalised prediction of outcomes
- Outcome:
- Integrated clinically relevant patient-clinician risk calculator tools providing evidence-based estimate of the potential to benefit from surgery and the risk of an adverse surgical outcome for individual patients
- A functional brief decision aid in Frequently Asked Questions (FAQ) format

Executive Summary

Using a multi-stage collaborative process between patients, clinicians and researchers, we developed and refined a personalised Cataract Decision Aid (CDA) to encourage shared decision making between patients and clinicians. The aid highlighted the choices of 'surgery, delay or decline' for patients and provided a space for patient's individualised risk and benefit calculations to be written down.

The process of developing the CDA involved:

- Input from a cataract Patient Advisory Group, which highlighted issues that matter most to patients when making the decision about cataract surgery (including likelihood of success / benefits, pain, what happens during the surgery, side effects / risks, eyesight changes, and post-surgery recovery). These issues were incorporated into the CDA.
- Input from clinicians which helped to ratify the accuracy of the CDA content.
- Qualitative user-testing interviews, which found that patients and clinicians were generally positive about the CDA, and they felt that it would be useful to both patients and clinicians when discussing cataract surgery.

User-testing revealed that participants felt that the Cataract Decision Aid would reinforce the idea that a 'choice' exists with regard to cataract surgery. It also would encourage better patient involvement in cataract surgery decisions, it was easy to understand and it could feasibly be integrated into clinical care pathways.

Patients and clinicians felt that it would provide a trustworthy source of information, including adequate and accurate information. Clinicians also felt it would act as a framework and a reminder to cover certain information that they might otherwise not cover and patients felt that the CDA provided them with answers to those questions they would want answered before making a decision. Although some patients and clinicians suggested alterative digital formats of the CDA, most felt that the most usable and feasible format would be a paper-based CDA.

The developed Cataract Decision Aid consisted of 4 sections:

- **Introduction page** - this page introduces the patient to the CDA, explaining the purpose of the tool, and outlines the structure / content. It reinforces that message that patient's preferences are important when making decisions about cataract surgery
- **Section A**: Frequently Asked Questions (FAQs) - this section uses general information to provide answers to some of the questions patients frequently ask about cataract surgery. It will help patients to think about the things that matter most to them.
- **Section B**: What matters to you? What questions do you have? - this section provides space for patients to write notes or any questions they have for their clinician during their upcoming appointment.
- **Section C**: Personalised information about your likely outcomes - the clinician will use this section with patients during their appointment to provide personalised information about their likely outcomes, and to discuss any issues that are specific to them personally.

Overall, it was felt that the CDA would be feasible to use in routine clinical settings, however, some key issues were raised during the user-testing interviews, including:

- Clinicians noted that many of their patients were not aware that there is a choice available, and they tended to presume that once they have been referred to the cataract clinic that surgery was the only option. This reflects patient's perceptions, as some tend to assume that the surgery will be done once they have been referred to the clinic. Therefore, participants felt that the CDA could play an important role in highlighting the existence of choice, and thus better preparing patients for a 'shared' discussion when they attend their appointment.
- Some clinicians reported a need to protect their patients from the risk information, especially if the patient was at relatively low risk of those outcomes occurring. Clinicians at times 'filtered' the information that they gave to patients depending on their

perception of how much information the patient would want. Thus, some clinicians queried the benefit of the personalised risk information element of the CDA for all patients. Some patients reported that they would have liked more detailed information about the likely outcomes, especially after they had viewed the CDA. As such, whilst tailoring the information is acceptable and sometimes necessary, it will be important to ensure that any tailoring is based on the patient's preference for information, and not based solely on the clinician's judgement of what information the patient wants.

- Concerns were expressed by clinicians regarding the time needed to complete the personalised risk element of the CDA in the consultation, and they had some reservations over how much information patients would want about their individualised risks. We recommended that the CDA is delivered to patients ahead of their appointment, to read in their own time, and then the personalised risk element could be completed together with the patient during the consultation.

(Appendix 8, word count 998)

The Cataract Decision Aid

NHS
University Hospitals Bristol
NHS Foundation Trust

Patient Name: .....

What choices are available if you have cataracts?

This **decision aid** is designed to help you and your clinician make a **shared decision** about how best to manage your cataract. Cataracts happen when the lens, a small clear disc inside your eye, develops cloudy patches. The options available to you are:

- **having cataract surgery** or
- **delaying or declining cataract surgery**

This decision aid has three parts to help you think about your options:

A. Frequently Asked Questions (FAQs)

This section (pages 2-6) uses **general information** to provide answers to some of the questions patients frequently ask about cataract surgery. It will help you to **compare the options** and think about the **things that matter most to you**.

B. What matters to you? What questions do you have?

This section (page 6) provides space for you to write **notes** or any **questions** you have for your clinician during your upcoming appointment. Try to think about how the treatment options might affect you personally.

C. Personalised information about your likely outcomes

Your clinician will use this section (page 7) **during your appointment** to provide **personalised information** about your likely outcomes, and to discuss any issues that are specific to you personally.

We want to know what's important to you

When deciding about cataract surgery, it is important for you to think about your own **personal preferences** and to **discuss these with your clinical team.** This will help you and your clinician to make a **shared decision** about what is **best for you.** If you have any questions about the options, please just ask a member of your clinical team.

Remember to bring this leaflet with you to your next appointment

Please turn over...

A. Frequently Asked Questions (FAQs)

FAQS	Have cataract surgery	Delay or decline having surgery
What are the treatments?	• If you choose to have surgery, the surgeon will remove the cataract. The cloudy lens will then be replaced with a clear artificial lens inside the eye. If this surgery is successful then the lens should last a lifetime. • The strength of the lens can be chosen to suit your eye and your individual needs. The choice of lens will determine the sort of glasses (distance or near) you would need after the operation. Dual focus lenses are not recommended by or available on the NHS. Your surgeon will discuss these options with you before surgery.	• If you delay or decline having surgery, you may need visual aids or adaptations to help you see better. This includes temporary solutions like using glasses, lenses or visiting a low vision service. • Other adaptations may include: using magnifying glasses, large print books or adjusting screens to make text larger.
What do the treatments involve?	• The surgery is usually done in one day with no overnight stay in hospital. It should last around 30 minutes, but you may be in hospital for a few hours. • Most people have a local anaesthetic. This involves having eye drops that numb the eye or an injection near the eye (but not in the eyeball itself). Sometimes people will have a general anaesthetic or sedation during the surgery, depending on their health. • You will usually be awake during surgery, but you will not be able to see the lens being removed. • During surgery, you should be able to communicate with the surgeon.	• You may need to visit an optician or clinic to receive appropriate visual aids and adaptations. They may also be able to provide advice on how to get the best out of your vision.
How long will it take me to recover?	• You may feel unwell for 24 hours. • If the vision in your other eye is poor, you may struggle with your overall vision for a few days. • Within 2 to 5 days, your eye should be feeling comfortable. It usually takes between 3 weeks and 3 months to heal completely.	• You will not need any recovery time. Apart from surgery, there is no other way to treat a cataract. So, over time the cataract is likely to get worse. This may affect your daily activities.

FAQS	Have cataract surgery	Delay or decline having surgery
Will I feel any pain?	• The surgery is usually pain free. The local anaesthetic might cause some discomfort. • Part of your face will be loosely covered by sterile drapes that are lifted off your face. Fresh air will blow gently underneath, and you will be able to breathe freely. You will be aware of the surgeon touching you around your eye and people are often aware of drops going onto the eye to keep the surface of the eye from drying. • Sometimes people feel a bit of pressure during the operation and are aware of noises from the machine being used by the surgeon.	• Cataracts themselves do not cause eye pain. Very advanced cataracts can however cause other eye problems which may become painful.
What are the potential improvements to my eyesight?	Over 95 out of 100 operations are successful. Information specific to you will be explained to you by a clinician, who will fill in Section C, before you make a choice. Generally, people experience improvements such as: • Improvement to long or short-distance vision (if you have strong glasses it is likely that you will need a weaker prescription) • Seeing brightness and colours better • Reduced glare in bright light or sunshine Most people will still need glasses for near, or distance or both.	• If you delay or decline surgery, visual aids and adaptations can increase the quality of your eyesight. However, if your cataract gets worse you may then need to be referred at a later date to reconsider surgery.
What are the potential improvements to my quality of life?	Improvements may include: • Seeing things more clearly (e.g. seeing who is coming) • More independence getting around (walking and driving) • Greater participation in social activities • Reading and viewing television more easily (glasses usually needed) • Reduced risk of falling	• Glasses, lenses or adaptations can help with reading, viewing television, and other daily tasks.

FAQS	Have cataract surgery	Delay or decline having surgery

What are the possible risks?	• The level of risk will depend on your eye and general health. Information specific to you will be explained to you by a clinician before you make a choice. Generally:
	  ○ Around 5 in 100 people who have surgery will have complications. Most of these are minor but may occasionally involve a second surgery or a delay in recovery. Around 95 in 100 operations go as planned, and no further surgery will be needed.
	  ○ Vision in around 1 in 100 people is significantly worse after surgery, compared with before surgery.
	  ○ Around 1 in 1000 people who have surgery suffer permanent blindness in the operated eye.
		• Most cataracts get worse over time but how quickly this happens varies between people. If the cataract gets worse, your eyesight will also deteriorate.
		• If your cataract gets worse you may no longer be able to carry out daily activities (e.g. driving and reading) which can lead to a loss of independence and you may have a higher risk of falling.
		• Leaving the cataract for too long may make it more difficult to operate on in future and may increase the risk of complications during future surgery.

What are the possible side-effects?	You may get some of the following early on after the surgery: • Blurry vision • Floaters (black shapes) • Greater sensitivity to sunlight • Eye infection (uncommon, but can be serious) • Unequal vision in your two eyes (you may just need new glasses) • Short-term double vision (up to 3 days post-surgery) • Swelling of the retina or cornea (which can cause reduced vision for up to 3 months or more) • Retinal detachment (layer of tissue at the back of eye pulls away from tissue around it) which might be accompanied by bright flashes of light	• Visual aids and adaptations rarely have any side-effects. • Having cataracts may increase your risk of falling.

FAQS	Have cataract surgery	Delay or decline having surgery
What are the practical considerations?	• You will need to wear an eye shield for 24 hours after the surgery. It should also be worn during the night for around 2 weeks. You will need to take eye drops for 4-6 weeks. • You should not do any bending for a few days, or heavy lifting for around 1 month. • You can shower normally after a few days, but you should take care not to let water run in your eyes until 1 month post-surgery. • You should avoid getting anything into your eye for a few weeks (such as soap, water, make-up). • A post-surgery eye assessment should take place 2-8 weeks after the operation. During this time, it is likely that you will have to use your old glasses prescription. It may be useful to buy cheap reading glasses during this time. You can also visit your optician or optometrist to have the old lens in your glasses removed or a clear lens inserted.. • If you need the help of a carer you may need extra help early on after surgery. If you provide caring support, you may need help doing so after the surgery. • If you work, you will need to take time off to recover after surgery (especially if your work involves manual handling or driving).	• If your cataracts get worse you may need help with daily activities such as driving, reading, getting around, or caring for others.
Will I be able to drive?	• You will not be able to drive home immediately after surgery. • If you have a general anaesthetic, you will not be able to drive for 48 hours. • A few days after surgery, if you feel well with comfortable eyes and are able to read a number plate at 20.5 metres, you should be able to drive.	• If your cataracts get worse, it might mean that you will not be able to drive. You should contact your opticians and the DVLA to find out more information.

Can I change my mind?	If you are unsure about your decision you can discuss this with your clinician at any time. They will ask you about your preferences and help you to make a decision that is best for you. If you decide to delay or decline, you can change your mind at any time in the future.
Where can I find out more information?	You can contact your optometrist, GP or the cataract service. You can find out more details about your local cataract service from your hospital. More information can also be found on the NHS website on the internet. This website includes a short animated video on how cataract surgery works: https://www.nhs.uk/video/Pages/Cataractanimation.aspx

B. What matters to you? What questions do you have?

Please use this space to make a note of anything you want to discuss with the clinician during your upcoming appointment. Please feel free to use an additional sheet if needed. You can also use this during your appointment to make notes.

Try to think about how the treatment options will affect you personally (your job, hobbies, caring duties, lifestyle, driving, other health conditions etc)

Please turn over...

C. Personalised information about your likely outcomes

Your **clinician** will complete this section **during your appointment** to provide **personalised information** about your own estimated risks of complications or benefits of having surgery, and to discuss any issues that are specific to you.

Date of appointment		**Clinician's Name**	

	Small	**Medium**	**Large**
What is the likelihood of improvements of at least a small, medium or large amount after surgery?	..... in 100 patients	..... in 100 patients	..... in 100 patients
How would surgery change my ability to see at distance and close up? **Would my need for glasses be different after surgery?**			
What is my risk of a serious surgical complication?	**Low** Less than 1 in 100 patients	**Medium** Between 1-3 in 100 patients	**High** More than 3 in 100 patients
What is my risk of losing vision as a result of the surgery? (vision in the operated eye notably worse after the surgery)	**Low** Less than 1 in 100 patients	**Medium** 1-3 in 100 patients	**High** More than 3 in 100 patients
Are there any other problems that are more likely in my case than normal?			

Other comments

Development of this decision aid

This decision aid has been developed by Cardiff University, Bristol Eye Hospital, and the University Hospitals Bristol NHS Foundation Trust. The development involved patients, clinicians and researchers. The work has been funded by the National Institute for Health Research as part of a Programme Grant for Applied Research: Cataract Surgery: Measuring and predicting patient level vision related health benefits and harms.

The predictions of reported benefits in Section C of the decision aid are based on statistical analysis of many patients' self-report benefit. Risk of adverse event information presented in Section C is supported by the National Ophthalmology Database Audit risk calculator. This is available at www.nodaudit.org.uk

The full list of references and authors credentials & details about the development process can be viewed at: link to a webpage will be available in final version.

CARDIFF UNIVERSITY
PRIFYSGOL CAERDYDD

NHS
University Hospitals Bristol
NHS Foundation Trust

Performance of Health Utilities in Cataract Surgery

Assessing the construct validity and responsiveness of Preference Based Measures (PBMs) in cataract surgery patients

Breheny K, Hollingworth W, Kandiyali R, Dixon P, Loose A, Craggs P, Grzeda M, Sparrow JM. Assessing the construct validity and responsiveness of Preference Based Measures (PBMs) in cataract surgery patients. Quality of Life Research (QOLR) 2020, doi: 10.1007/s11136-020-02443-3. [Epub ahead of print]

Open access available at

https://link.springer.com/article/10.1007/s11136-020-02443-3

Mapping to quality of life and capability measures in cataract surgery patients: From Cat-PROM5 to EQ-5D-3L, EQ-5D-5L and ICECAP-O

Mapping to quality of life and capability measures in cataract surgery patients: From Cat-PROM5 to EQ-5D-3L, EQ-5D-5L and ICECAP-O

Shortened paper for NIHR end of programme report

Padraig Dixon[1,2], William Hollingworth[1], John Sparrow[1,3]

1 Bristol Medical School, University of Bristol

2 MRC Integrative Epidemiology Unit, University of Bristol

3 Bristol Eye Hospital. Bristol

Paper accepted and will be released shortly:

Dixon P, Hollingworth W, Sparrow JM. Mapping to quality of life and capability measures in cataract surgery patients: From Cat-PROM5 to EQ-5D-3L, EQ-5D-5L and ICECAP-O.

In press: MDM Policy & Practice, Feb 2020.

Abstract

Objectives Cataract is a prevalent and potentially blinding eye condition. Cataract surgery is a very frequently undertaken procedure. The objective of this analysis was to develop a mapping algorithm that could be used to predict quality of life and capability scores from the Cat-PROM5, a newly developed, validated patient-reported outcome measure for patients undergoing cataract surgery.

Methods We estimated linear models and adjusted limited dependent variable mixture models. Data were taken from the Predict-CAT cohort of up to 1,181 patients undergoing cataract surgery at two sites in England. The Cat-PROM5 was mapped to two quality of life measures (EQ-5D-3L and EQ-5D-5L) and one capability measure (ICECAP-O). All patients reported ICECAP-O and one or other of the EQ5-5D measures before and after cataract surgery. Separate models were estimated for pre and post-operative outcomes. Model performance was assessed using likelihood statistics, graphical inspections of model fit and error measurements including mean square error.

Results Adjusted limited dependent variable mixture models dominated linear models on all performance criteria. Mixture models offered good to excellent fit. Three component models that allowed component membership to be a function of covariates (sex, age and diabetic status) and which conditioned on some or all of these covariates (depending on the target measure and pre- and post-operative status) had superior performance to models with fewer components and which did not condition on covariates. An exception was the EQ-5D-5L post-surgery measurement for which a two-component model was selected. Models for EQ-5D-3L did not converge post-surgery under any mixture model, possibly because of the high number of participants reporting perfect (EQ-5D-3L index score=1) quality of life.

Conclusions The newly developed Cat-PROM5 measure is a psychometrically validated measure of outcomes for patients undergoing cataract surgery. Mapping from Cat-PROM5 to quality of life and capability measures using adjusted limited dependent variable mixture models is feasible, and the estimates can be used to support cost-effectiveness analysis in relation to cataract care.

Key words: Cataract, quality of life, EQ-5D, mapping, ICECAP, Cat-PROM5 mixture models

Aim

The objective of this analysis was to develop a mapping algorithm that could be used to predict quality of life and capability scores from the Cat-PROM5, a newly developed, validated patient-reported outcome measure for patients undergoing cataract surgery.

Methodology

Good statistical practice in mapping

A critical rationale for mapping functions is to accurately predict, in a variety of datasets, health state utility values of the target instrument (30). The accuracy of predictions can be understood, in broad terms, as a measure of the "fit" between the model's predicted utility values and the utility values reported by respondents. It is plausible that no single model emerges as superior to others when assessed against various selection criteria. We therefore relied on a variety of criteria as follows. Summary measures of fit, such as the root mean squared error (RMSE), mean absolute error (MAE), and ranges of predictions are frequently reported in mapping analyses (31) and offer helpful but partial and potentially insensitive characterisations of model fit (12).

Covariate selection

A wide variety of patient-level data were collected as part of the Predict-CAT study. Wailoo et al (12) recommend that the inclusion of covariates in a mapping model should be justified a priori.

Exploratory data analysis and missing data

We undertook exploratory data analysis by calculating Spearman's correlation coefficient, calculating summary statistics, comparing ranges, and calculating EQ-5D and ICECAP-O measures at different levels of the CatPROM5 instrument.

Approach to model development

The dependent variable in all regressions is an EQ-5D index score (whether the EQ-5D-3L score or the EQ-5D-5L score) or the ICECAP-O index score. All models included the Cat-PROM5 summary index value. Initial modelling analyses indicated that model was fit and model convergence was not necessarily improved when including the components of the index itself. Moreover, including subcomponents of the index as separate variables may complicate the use of mapping algorithms in

contexts where only summary level data on the score is available. We focused on models that included only the Cat-PROM5 index value.

Mixture models with one component, implying a single latent class, were dominated by mixture models with more than one component. Mixture models with four components almost never converged. We therefore focused attention in all subsequent modelling on two- or three-class component models. We only considered mixture models for the EQ-5D questionnaires that explicitly incorporated the gap between perfect health and the next highest possible value.

Results

Complete data at both baseline and follow-up appointments was available from 1,181 different participants of whom 598 were women (51%), although complete data (both baseline and follow-up assessments) on target outcome measures (i.e. both EQ-5D measures and ICECAP-O) was not available for all of these individuals. Mean age at baseline was 73.8 years (standard deviation: 8.2). There were 226 (19%) diabetic participants at baseline.

Table 1 Summary statistics

	Baseline				Follow-up			
	EQ-5D-3L (n=396)	**EQ-5D-5L (n=383)**	**ICECAP-O (n=1,174)**	**CatPROM5 (n=1,181)**	**EQ-5D-3L (n=396)**	**EQ-5D-5L (n=383)**	**ICECAP-O (n=1,174)**	**CatPROM5 (n=1,181)**
Mean	0.76	0.83	0.86	-0.31	0.80	0.85	0.89	-3.20
SD	0.24	0.17	0.12	2.34	0.23	0.17	0.11	3.08
Minimum	-0.18	-0.1	0.16	-9.18	-0.08	-0.13	0.16	-9.18
Maximum	1.00	1.00	1.00	7.45	1.00	1.00	1.00	4.98
% of "best" values	26.5%	15.7%	9.7%	0.1%	38.6%	26.4%	15.4%	9.2%

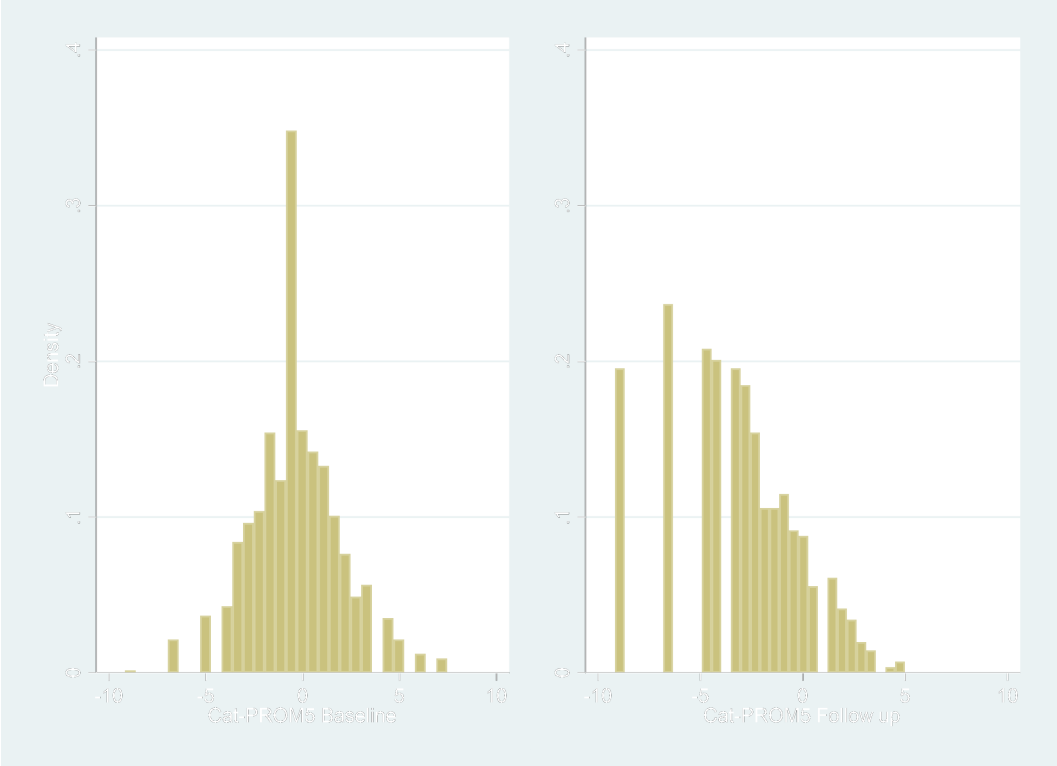
Table 2 Correlation between quality of life/capability and Cat-PROM5

	Baseline			Follow-up		
	EQ-5D-3L	EQ-5D-5L	ICECAP-O	EQ-5D-3L	EQ-5D-5L	ICECAP-O
Spearman's rho	-0.20	-0.30	-0.35	-0.20	-0.26	-0.29

Distributions of source and target instruments

Figure 1 summarises the distribution of Cat-PROM5 at baseline and follow-up (n=1,186 at each time point).

Figure 1 Responses to Cat-PROM5 at baseline and follow-up



This indicates an improvement in overall cataract-related outcomes, confirming the improvements reported in Table 1, with a leftward shift in the index value of Cat-PROM5 apparent at follow-up compared to baseline. Figures 2 and 3 summarise baseline and follow-up EQ-5D-3L (n=396) and EQ-5D-5L (n=383) index utilities.

Figure 2 Responses to EQ-5D-3L at baseline and follow-up

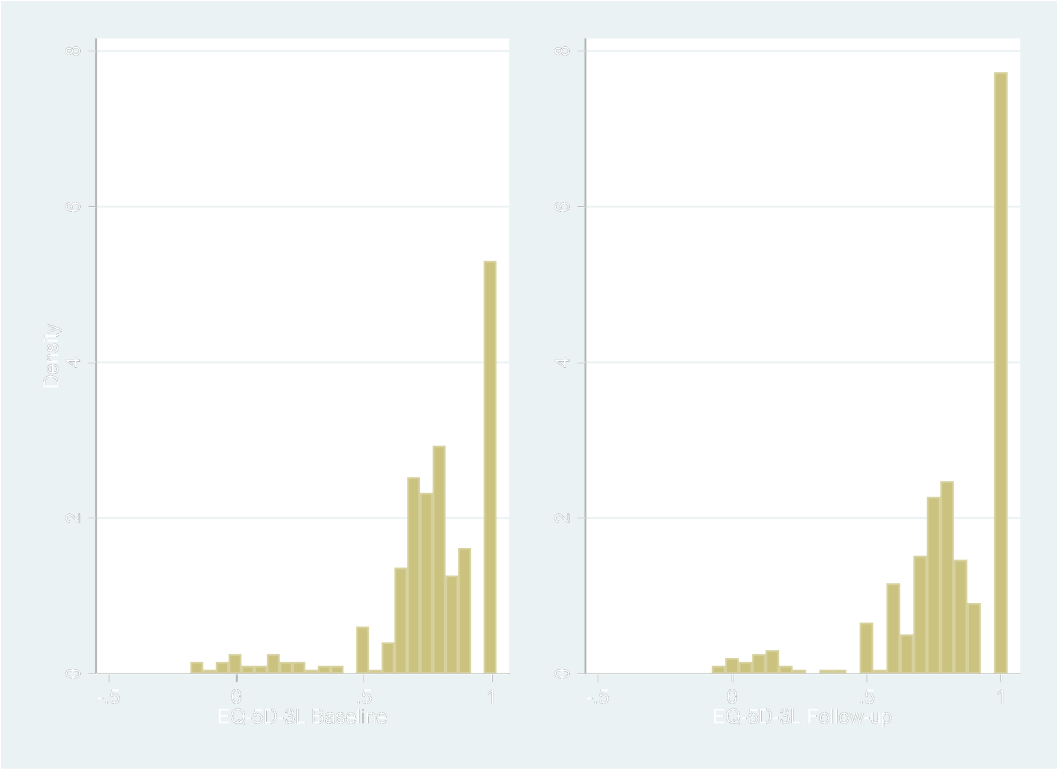
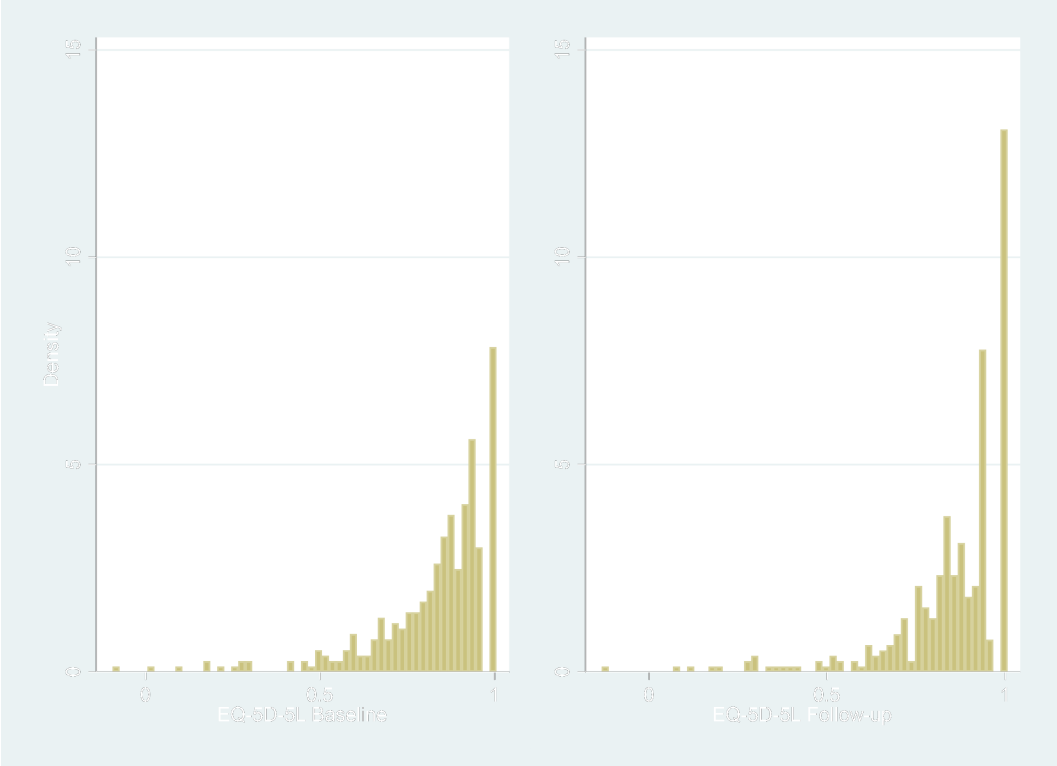


Figure 3 Responses to EQ-5D-5L at baseline and follow-up



Notable features of both the EQ-5D-3L and EQ-5D-5L distributions include:

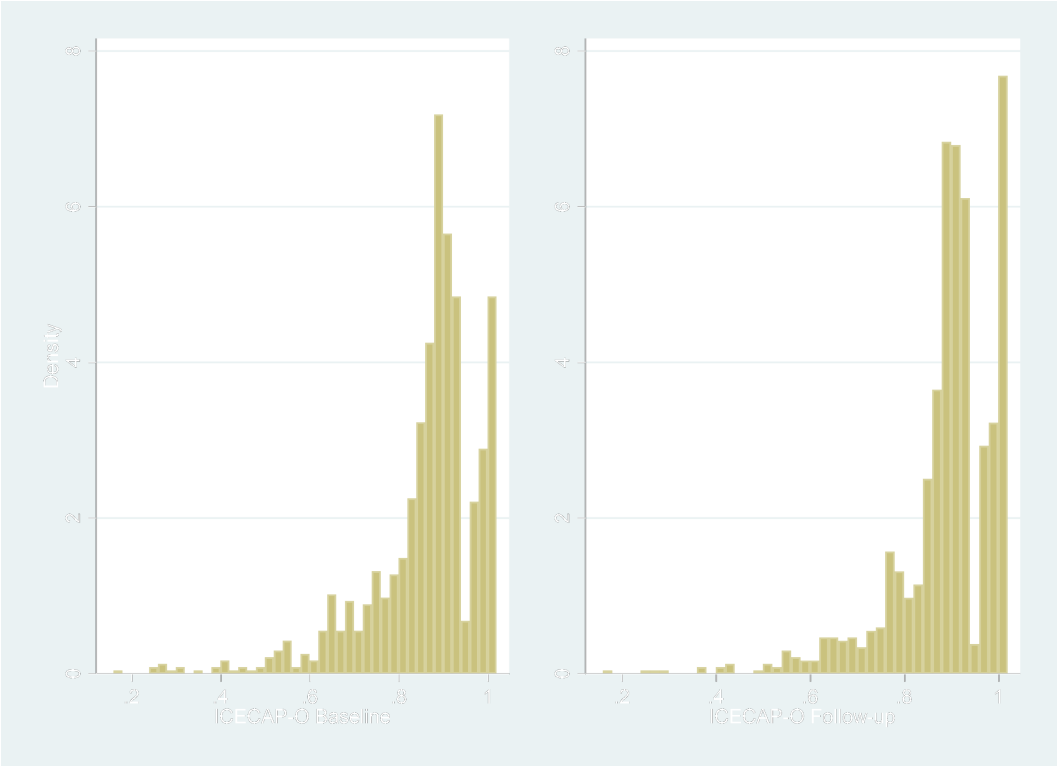
- EQ-5D scores are bounded: no observations may exceed 1 (the score for perfect health), and no patients report health below the permitted minimum for each instrument
- Mass of observations at perfect health: For example, for the EQ-5D-3L questionnaire 27% of observations at baseline report perfect health and 39% report this maximum value at follow-up.
- Skewness: more patients appear to be in relatively "good" health (left skewed distribution) than in "poor" health
- Gaps: there is a "gap" in the distribution between this maximum index value associated with perfect health and the next highest index score – this is a consequence of the valuation tariffs applied to value the "next best" health state
- Multimodality: there is more than one "peak" evident in each distribution. In both distributions there is evidence of a group of patients reporting relatively low health (e.g. EQ-5D-3L values between approximately 0.1 and 0.4) and a group of patients reporting higher health, as well as the mass of observations at perfect health (EQ-5D=1).

These are the classic features of EQ-5D distributions that have been reported for many different types of disease and health condition (e.g. (10, 22)). These features –alone or in combination –

present a challenge to the construction of mapping algorithms, but for which the adjusted limited dependent variable mixture models are well suited.

The distribution of the ICECAP-O index values (n=1,174) is similar to that of EQ-5D in some respects (Figure 4).

Figure 4 Responses to ICECAP-O at baseline and follow-up



Similarities with EQ-5D distributions include skewness, multimodality, mass of observations at the maximum permitted value, and the limited range. One difference with the EQ-5D distributions is the absence of a noticeable “gap” between the maximum value and the next highest value.

Table 3 presents models with the lowest RMSE, provided that these models had good face validity, and that at least one other criterion (AIC, BIC, mean absolute error) was better than the median performance (across all estimated models for the target outcome concerned) for that criterion.

Table 3 Model performance of selected specifications

	Baseline			Follow-up	
	EQ-5D-3L (n=396)	EQ-5D-5L (n=383)	ICECAP-O (n=1,174)	EQ-5D-5L (n=383)	ICECAP-O (n=1,174)
Specification: Covariates	Cat-PROM5, age, sex and diabetic status	Cat-PROM5, age, sex and diabetic status	Cat-PROM5, age, sex and diabetic status	Cat-PROM5, age and sex	Cat-PROM5, age and sex
Specification: Variables influencing component membership	Cat-PROM5, sex and diabetic status	Cat-PROM5, age, and diabetic status	Cat-PROM5, age and sex	Cat-PROM5, sex and diabetic status	Cat-PROM5, sex and diabetic status
Number of components	3	3	3	2	3
RMSE	0.229	0.154	0.106	0.161	0.104
MAE	0.160	0.111	0.073	0.112	0.072
AIC	-149.588	-296.507	-1447.194	-766.444	-1468.820
BIC	-81.904	-247.984	-1348.123	-717.198	-1391.635

Note: Convergent models could not be identified for EQ-5D-3L at follow-up. RMSE: Root mean square error. MAE: Mean absolute error. AIC: Akaike Information Criterion. BIC: Bayesian Information Criterion.

It is notable that specifications were similar in all models, with age and sex included as covariates, and likewise sex influences component membership probabilities in all models. All models make use of data on sex, age, and diabetic status alongside Cat-PROM5.

Table 4 Comparison of predictions to actual data

	Baseline			Follow-up	
	EQ-5D-3L (n=396)	EQ-5D-5L (n=383)	ICECAP-O (n=1,174)	EQ-5D-5L (n=383)	ICECAP-O (n=1,174)
Predicted mean outcome	0.76	0.83	0.86	0.85	0.89
Actual mean outcome	0.76	0.83	0.86	0.85	0.89
Predicted standard deviation of outcome	0.25	0.17	0.12	0.17	0.11
Actual standard deviation of outcome	0.24	0.17	0.12	0.17	0.11
Predicted proportion in perfect health	27.2%	18.1%	10.6%	30%	16.3%
Actual proportion in perfect health	26.5%	15.7%	9.7%	26.4%	15.3%
Predicted minimum outcome	-0.53	-0.24	0.00	-.013	0.09
Actual minimum outcome	-0.18	-0.1	0.16	-.013	0.16

Note: Convergent models were not obtained for EQ-5D-3L at follow-up.

The results indicate accurate prediction of the mean and standard deviation of all outcomes. There is some modest over-prediction at the tails of all outcome distributions, which can also be seen in conditional distribution functions for these models comparing predicted values from simulated data (using 1,000 simulated values from the estimated mixture models) to actual data on each target outcome variable. (Figures 5 and 6).

Figure 5 Comparison of actual and predicted baseline distributions

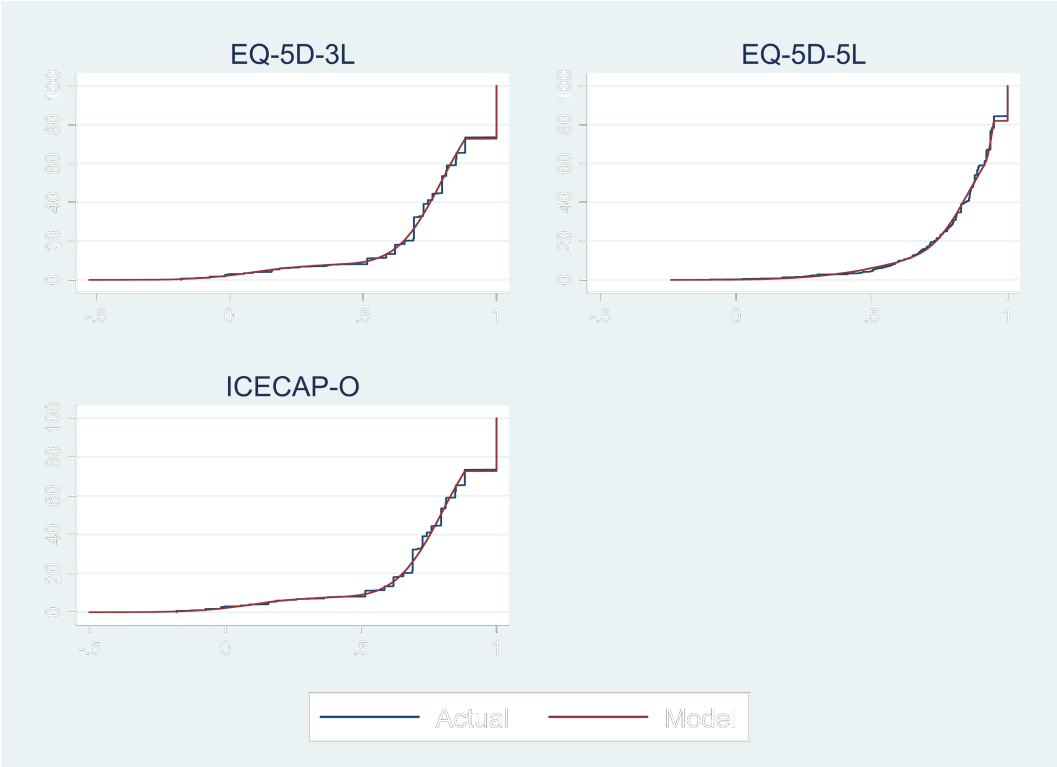
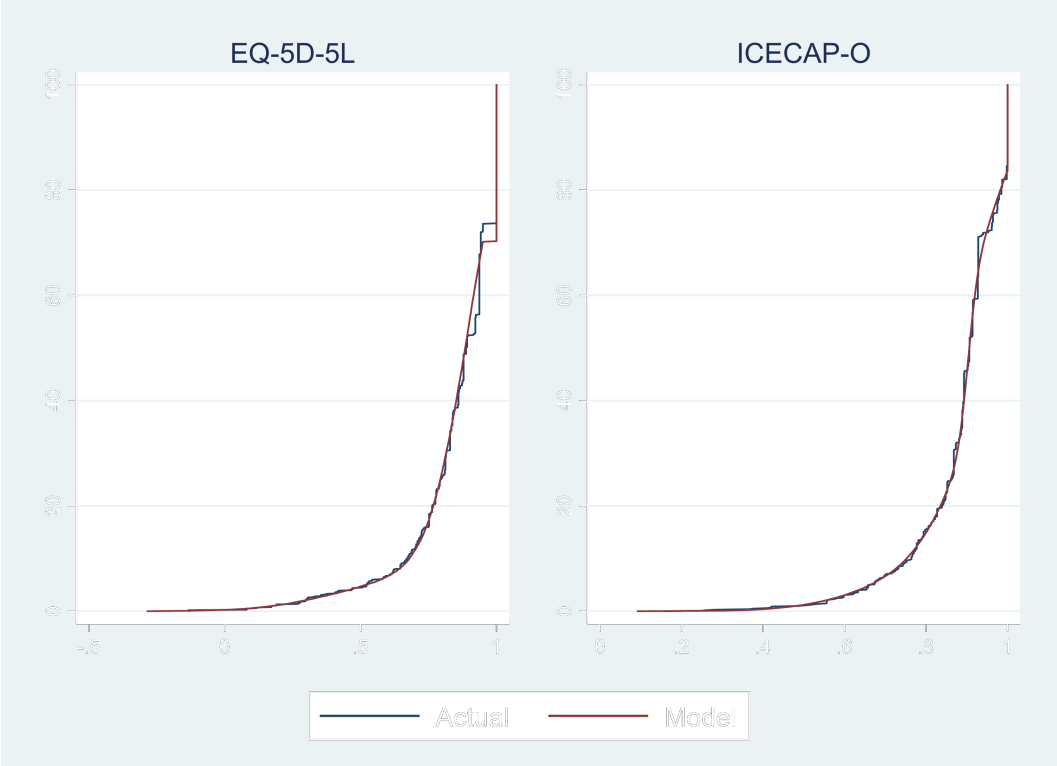


Figure 6 Comparison of actual and predicted follow-up distributions



Despite this modest overprediction at the extremes of the distribution, there is a good fit between the simulated data produced by each model and the actual data. This is also further evidence in favour of the face validity of these models. Finally, 95% confidence intervals by decile of the Cat-PROM5 overlap those of predicted values for all models (Figures 7 and 8).

Figure 7 Conditional Distribution Functions comparing observed versus simulated data at baseline

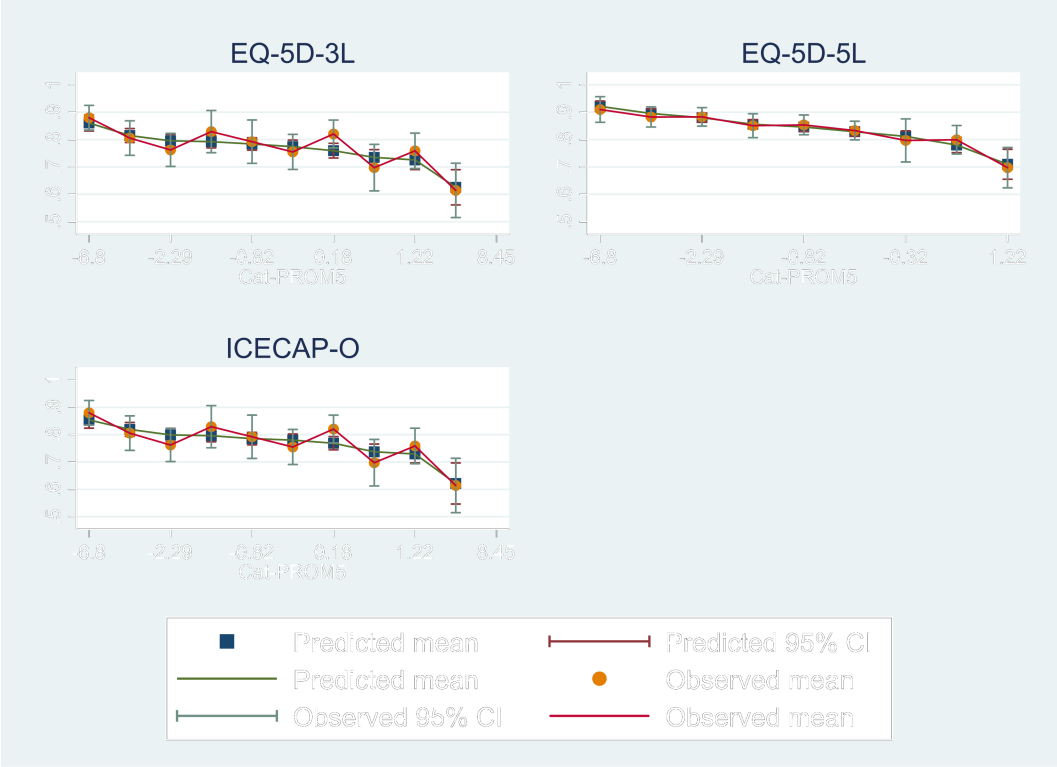
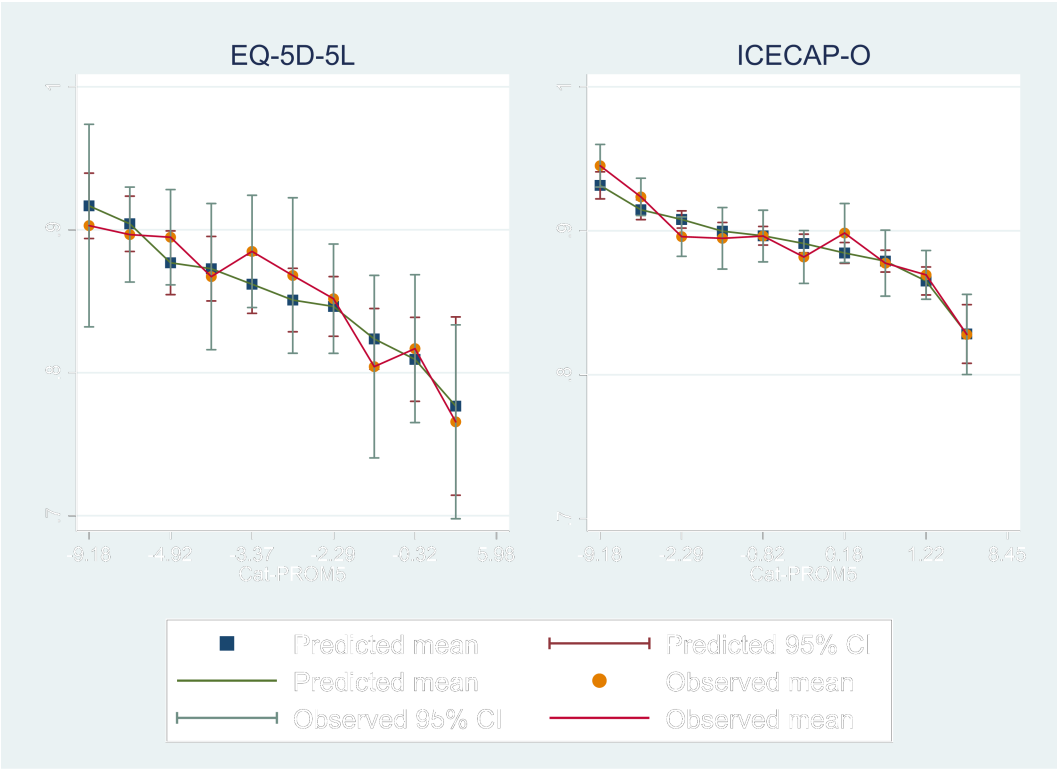


Figure 8 Conditional Distribution Functions comparing observed versus simulated data at follow-up



Conclusions

Overall, adjusted limited dependent variable mixture models offer a good to excellent fit. In this cohort, models including at least age and sex as covariates and which allowed probabilities of component membership to be a function of sex and other covariates reproduced important features of target outcome distributions. All models except one predicted the mean and standard deviation of target outcome measures to two decimal places (the exception predicted to one decimal place). The models reflected mean values by decile of Cat-PROM5, reproduced the skewness and multimodality of target outcome distributions, and did not predict any values outside feasible ranges. This performance was superior in all respects to that of adjusted and unadjusted linear models. Supplementary material contains Stata code to implement the mapping algorithm in other samples. (Appendix 10, word count 1994)

Appendix 11. Quantitative Analysis of the Feasibility of a Cataract Decision Aid RCT

Quantitative Analysis for Involve-CAT Feasibility of a Cataract Decision Aid Randomised Controlled Trial

Involve-CAT

A feasibility assessment for a possible future fully powered Randomised Controlled Trial of the use of a Cataract Decision Aid providing information on cataract surgery, including personalised risks and benefits.

A quantitative analysis as part of Work Package 4 of a NIHR funded Cataract Research Programme.

Analyses and first draft by Mariusz Grzeda

Writing completed by John Sparrow

Background

The overarching aim of the cataract research programme was to investigate possible ways to improve decision making processes for people approaching cataract surgery. In relation to this element of the work, the grant application assumed earlier development of statistical models predicting the outcome of surgery including occurrence of an operative surgical complication (significant breach of the lens-zonule barrier referred to as Posterior Capsule Rupture – PCR), vision loss related to surgery (Visual Acuity Loss or VA Loss) and self-reported benefit from surgery based on Cat-PROM5 scores (a Patient Reported Outcome Measure or PROM). Measures thus included both subjective and objective indices. During the first part of the programme (Work Package 1 or WP1) the PROM, Cat-PROM5 was developed and validated. The predictive models for PCR and VA Loss were developed and validated as a part of WP2. In the third work package (WP3) factors predicting self-reported benefits from a cataract operation were explored with regards to a change in the Cat-PROM5 measure between pre- and post-operation time-points. The aim of the final work package (WP4) was to incorporate the predictive models for risks and benefits into a decision aid and to assess how this influenced, and was perceived by patients approaching cataract surgery, and the clinicians delivering their care. Specifically, it was designed to reduce uncertainty and confusion in relation to a decision about whether or not to proceed with a cataract operation. Current practice is such that the possible benefits and risks of potential adverse outcomes are presented to patients in vague terms such as 'likely to see better after the operation' or as a list of possible complications that might happen along with average rates.

Aims of Involve-CAT (WP4)

The study took the form of a feasibility study exploring the possibility of establishing a future randomised controlled trial (RCT) using a cataract decision support aid as an intervention. The development of the Cataract Decision Aid (CDA) and the qualitative analysis of its performance are described in separate reports, this report will cover the analysis of the quantitative data arising from the feasibility trial. The key hypothesis considered in the study

was that the quality of the process of patient-clinician Shared Decision Making (SDM) in cataract surgery is improved through use of a Cataract Decision Aid (CDA) because it improves patient knowledge, encourages the patient's deliberation process and increases patient's 'readiness' for making an informed decision about the treatment. Information contained in the CDA (see Appendix 8) included general information about cataract surgery as well as specific individualized risk and benefit predictions based on the patient's eye and general health. The quantitative outcomes presented here were extensively supported by qualitative analyses of a Shared Decision Making (SDM) approach based on in-depth interviews reported separately.

Specific quantitative issues explored in WP4 included:

(1) Examination of the suitability of candidate quantitative outcome metrics for use in a possible future fully powered RCT, these metrics together forming the Cataract Decision Quality Measure, (CDQM - developed as a part of WP3).

(2) Consideration of the feasibility RCT effect sizes to inform sample size estimation for a possible future fully powered RCT designed to fully test possible benefits of using a CDA in clinical practice. The approach assumed standard levels of alpha (type-I) and beta (type-II) errors as described in the power study section of this report.

(3) A validation exercise for of the model predicting self-reported benefits from cataract surgery expressed as a change in the self-reported Cat-PROM5 measure between pre-operative and post-operative assessments. *This is the subject of a separate report – see Appendix 6.*

(4) The estimation of possible costs arising from potential wide scale implementation of the decision aid. *This is the subject of a separate report – see Appendix 15.*

Study design

The reported feasibility study took a form of a two-arm RCT with the CDA as an intervention. The intervention group was defined as a group of patients in which the CDA was used while patients in the control group underwent standard NHS care. The allocation of patients to groups was conducted through a 1:1 block randomisation process by centre. It was assumed that within each centre 5-6 participants should be allocated within each arm (receiving the CDA intervention vs. not receiving the intervention).

The research process was multistage, starting with pre-screening and proceeding through assessment of patient eligibility for the study, recruitment, obtaining consent, randomisation, baseline clinical and self-reported pre-operative vision assessment with Cat-PROM5, applying either the CDA intervention or defaulting to standard care, making a shared decision about surgery, and finally documenting the outcome of the operation, including a post-operative self-reported vision difficulty assessment with Cat-PROM5.

Participants

The current feasibility study assumed recruitment of 40 participants from 4 cataract research centres (Bristol, Torbay, Brighton, Cheltenham), 10 patients each per centre. During the study however it became clear that Cheltenham would be unable to join the study due to local capacity issues and Torbay only able to join late due to staff illness. This required over-recruitment by Bristol and Brighton, with full recruitment of 42 patients none-the-less being successfully achieved.

Outcome measures

The Cataract Decision Quality Measure (CDQM) developed as a part of WP3 was used to assess patients' decision quality. The CDQM is a measure intended to capture patient's knowledge about options, preferences and readiness to make a decision about the treatment. It was treated as a primary outcome in this study. The CDQM questionnaire was completed twice, first before the consultation at the baseline visit and then immediately following the consultation. It included several items that were grouped in four sections:
A assessed knowledge about cataracts, C readiness to make a decision, and B&D functioned

together as a tool in which patients first indicated what was important to them (B) and then actually decided on the treatment (D).

A secondary quantitative outcome was Cat-PROM5, a self-reported measure of vision quality developed and validated in WP1 of the grant programme. The Cat-PROM5 questionnaire was completed by patients twice, initially at the baseline pre-operative time-point and then at the post-operative follow-up visit.

Statistical analyses

Since the study was a feasibility study performed on a limited sample of 42 patients, statistical analyses were kept simple. Analysis included descriptive statistics with frequency analyses with chi-square tests. The effects of the intervention were analysed in two ways. For the summary scores expressed by a single value (knowledge about cataract (Section A), readiness for decision making (Section C) and Cat-PROM5) t-tests for both dependent (paired) samples and independent samples were undertaken. For the linked sections B&D, Spearman's Rho assessed concordance between what was reported as being important and what was subsequently chosen.

To inform a sample size estimate a power study was undertaken providing calculations of sample sizes needed for a possible future fully powered RCT to investigate the impact of the CDA on the quality of patient decisions. The magnitudes of effect sizes were chosen according to Cohen's classification of standardised effect sizes (standard deviation of unity).

Results

The intervention and standard care control groups were evenly matched at baseline.

Primary and secondary outcomes

This section summarises results of comparisons of primary and secondary outcomes across intervention and standard care groups, for before and after consultation / operation.

Independent t-tests showed no important differences between groups at follow up for knowledge or readiness to decide. Paired t-tests between baseline and post-consultation showed no change for knowledge in either group. Unexpectedly, readiness to make a decision declined after the consultation in the intervention group.

No significant differences were observed between the intervention and control groups at either baseline or post-operative points for Cat-PROM5 scores. As expected, significant improvements in Cat-PROM5 scores were observed between baseline and post-operative completions for both groups (paired t-tests). Despite there being no statistically significant differences in Cat-PROM5 scores post-operatively for this small sample, the score improvement in the CDA intervention group (3.40) was almost half a logit greater than in the control group (2.96).

Basic psychometric analyses were undertaken for questions in section A and C using classical test theory (CTT) to detect possibly malfunctioning questions (item to total correlations and Cronbach's alpha). These indicated that the scale of knowledge questions (Section A) would benefit from review and further refinement (low Cronbach's alphas and item to total correlations). Similar analyses on readiness to make a decision questions (Section C) were however encouraging.

A further aspect of the CDQM was investigation of whether using the CDA during the consultation improves the level of concordance between what is important for a patient and what they then actually choose in terms of their treatment decision. Spearman's rho computed for indicators from sections B (4 items) and D (1 item - Choice of the treatment) Were close to zero

Power study

One of the aims of this feasibility study was to provide sample size calculations for a possible future fully powered RCT of the decision aid. The analyses of statistical power presented were conducted by the analytical approach. All computions were performed in G*Power and summarized below in a form of a series of graphics.

For t-test for dependent samples (matched pairs) the standard deviation of the difference between measures at pre-consultation and post-consultation was standardised to 1.00 and effect sizes were set at 0.20SD as a minimum and increased in steps of 0.30SD. This enabled checking the assumed levels: minimal (0.20SD), moderate (0.50SD), and large effects (0.80SD) as recommended by Cohen, with an additional very large effect (1.10SD).

The graphic in Figure 1 indicates that for detection of a small effect (0.2SD - red line) from pre- to post-operatively a sample of 400 would provide >95% power for a two sided alpha of p=0.05. And sample 200 is needed to obtain 80% power for detection of this small effect.

The graphic in Figure 2 indicates that for t-tests for independent groups, a small effect size (0.2SD) would be detectable with 80% power by a sample size of 800 (1:1 allocation, 400 in each group). For 90% power 1050 cases in all would be needed. Larger effect sizes would be detectable with power >90% at a sample size of 200 in all.

Figure 1. Power for various sample sizes for differences between two dependent group means

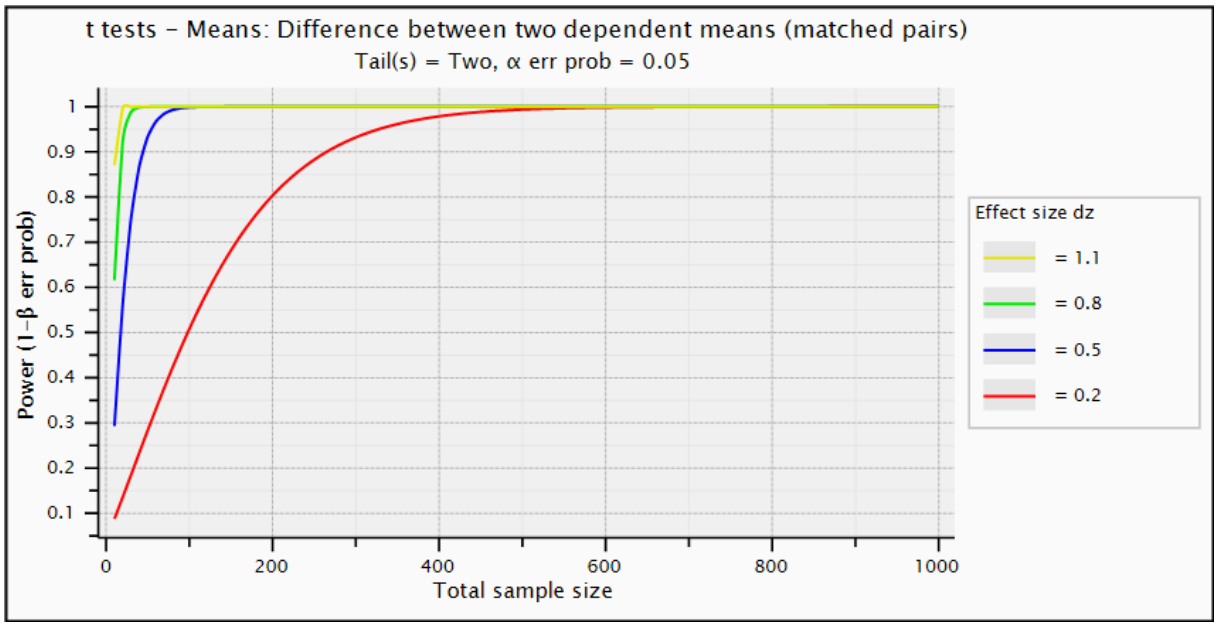
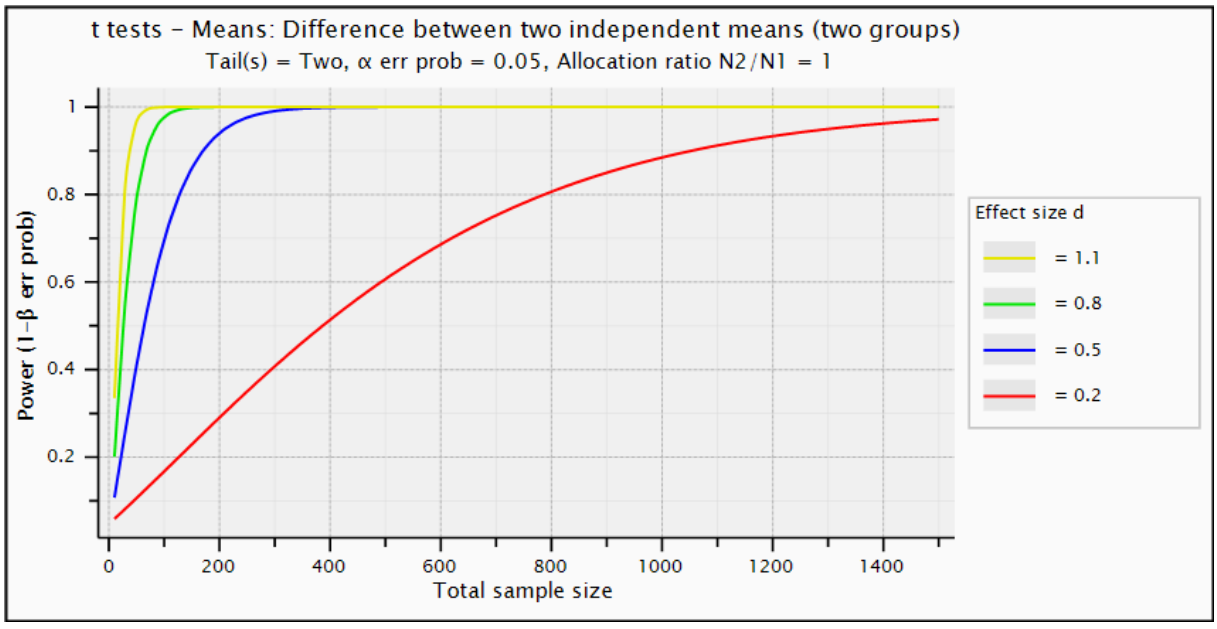


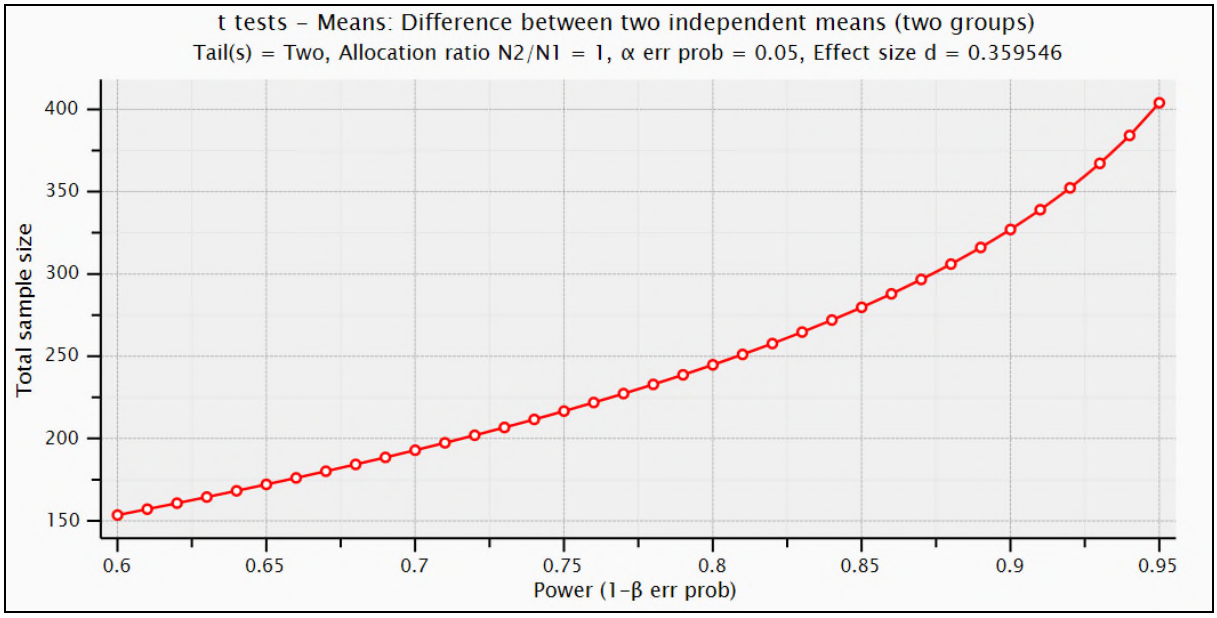
Figure 2. Power for various sample sizes for differences between two independent group means.



Based on a difference of around 0.72 Logits or 0.36SD, as observed for the secondary Cat-PROM5 outcome, the graphic in Figure 3 illustrates that for differences of this

magnitude between two independent group means a total sample of 250 would be required for detection of this effect with 80% power and 325 needed for 90% power.

Figure 3. Power for various sample sizes for small to medium differences of 0.36SD between two independent group means.



Conclusions

In conclusion this study has illustrated that a fully powered randomised controlled trial of the Cataract Decision Aid (CDA) would be feasible in terms of recruitment of centres, recruitment of patient participants and sample size. The primary outcome measure, the Cataract Decision Quality Measure (CDQM) would however require further refinement in advance of a full trial.

(Appendix 11, word count 1902)

Validation of Cat-PROM5 Benefits Prediction Models

Involve-CAT

Validation of predictive model for benefit from surgery

Analyses and first draft by Mariusz Grzeda

Writing completed by John Sparrow

Background

The overarching aim of the cataract research programme was to investigate possible ways to improve decision making processes for people approaching cataract surgery. During the first Work Package of the programme (WP1) the PROM, Cat-PROM5 was developed and validated. In WP2 predictive models for PCR and VA Loss were developed and validated. In WP3 factors predicting self-reported benefits from a cataract operation were explored with regards to a change in the Cat-PROM5 measure between pre- and post-operative time-points. Based on these factors predictive models were constructed to provide patients considering surgery with personalised information on their likelihood of self-reporting benefit from an operation. The developed prediction models were included in a cataract decision aid. The aim of the final work package (WP4) was to incorporate the predictive models for risks of harm and self-reported benefits into a decision aid and to assess how this was perceived by, and influenced patients approaching cataract surgery and the clinicians delivering their care. This final work package took the form of a feasibility study for a possible future fully powered RCT. The data from this feasibility study were analysed to assess the validity of the benefits prediction models on an independent group.

Data

The sample size of the feasibility trial was 42 participants from 3 collaborating centres (Bristol, Brighton, Torbay), full details of the participants are provided in the main WP4 Involve-CAT report. Data for the model validation analysis presented here were available for 27 cases with measurements on Cat-PROM5 both for pre- and postoperative time points as well as all the required risk predictors.

Results

Scatter plots comparing predicted and observed values are shown in Figures 1, and 2a&b. Plots indicate that the observed and predicted values are positively correlated. The correlation coefficient for the model predicting the change or self-reported Cat-PROM5 benefit (*delta approach*) is 0.215 while for the model predicting post-operative follow-up values it is substantially higher at 0.570 (after transforming back to original units this correlation was 0.578). The R squares from the linear regression models predicting observed values for outcome variables as a function of values obtained by the implementation of the predictive models developed in WP3, were 0.046, 0.325 and 0.334, for the delta, follow-up transformed, and follow-up back transformed approaches respectively.

The equation for the delta approach (Figure 1) has the following form

$$benefit\_observed=-1.624+0.310*predicted\_benefit,$$

for the follow-up approach (Figure 2a) is

$$transf\_follow\_up\_observed =-0.855 +1.234*predicted\_transf\_follow\_up$$

and for back transformed follow-up approach (Figure 2b) the regression equation is

$$follow\_up\_observed= 0.279+1.222*predicted\_transf\_back\_follow\_up$$

Figure 1. Scatter plot for predicting the change on Cat-PROM5.

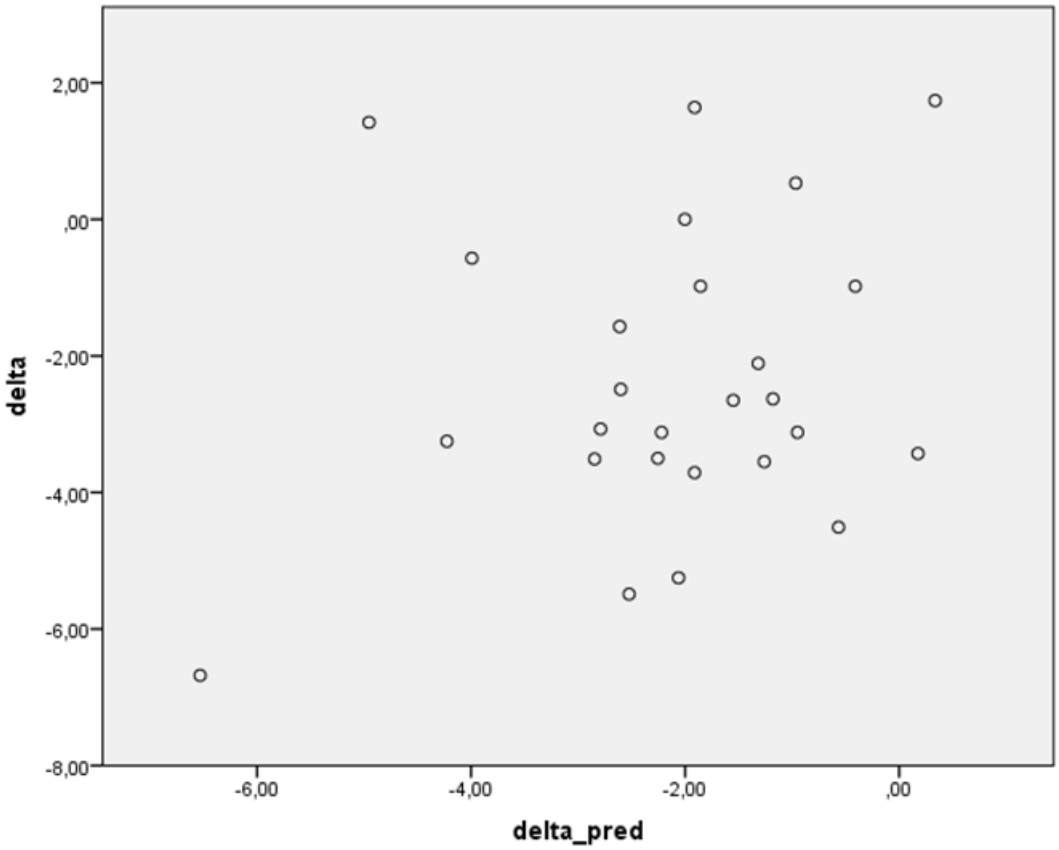


Figure 2a. Scatter plot for predicting the follow-up measure on Cat-PROM5 (transformed by the following operation Cat-PROM5_transformed=ln(-Cat-PROM5+36.826).

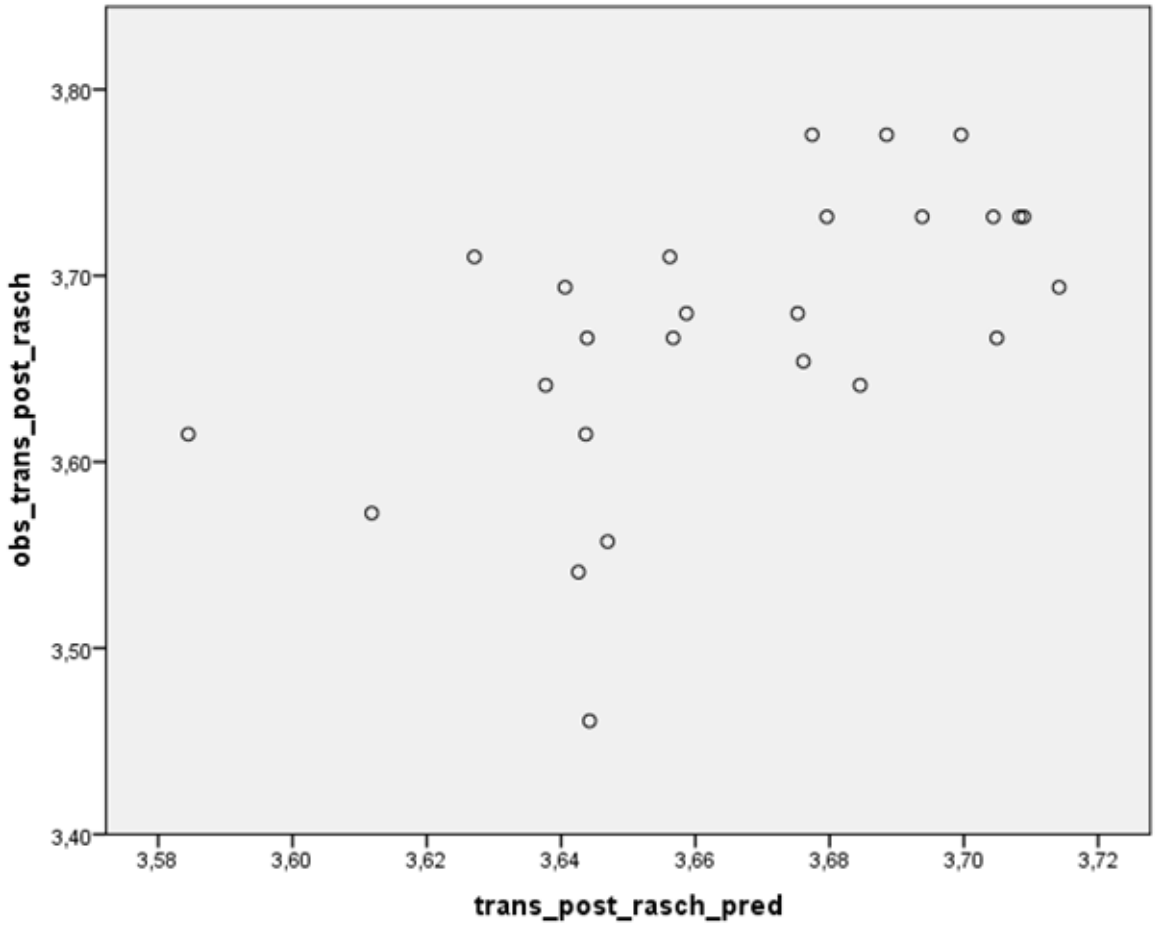
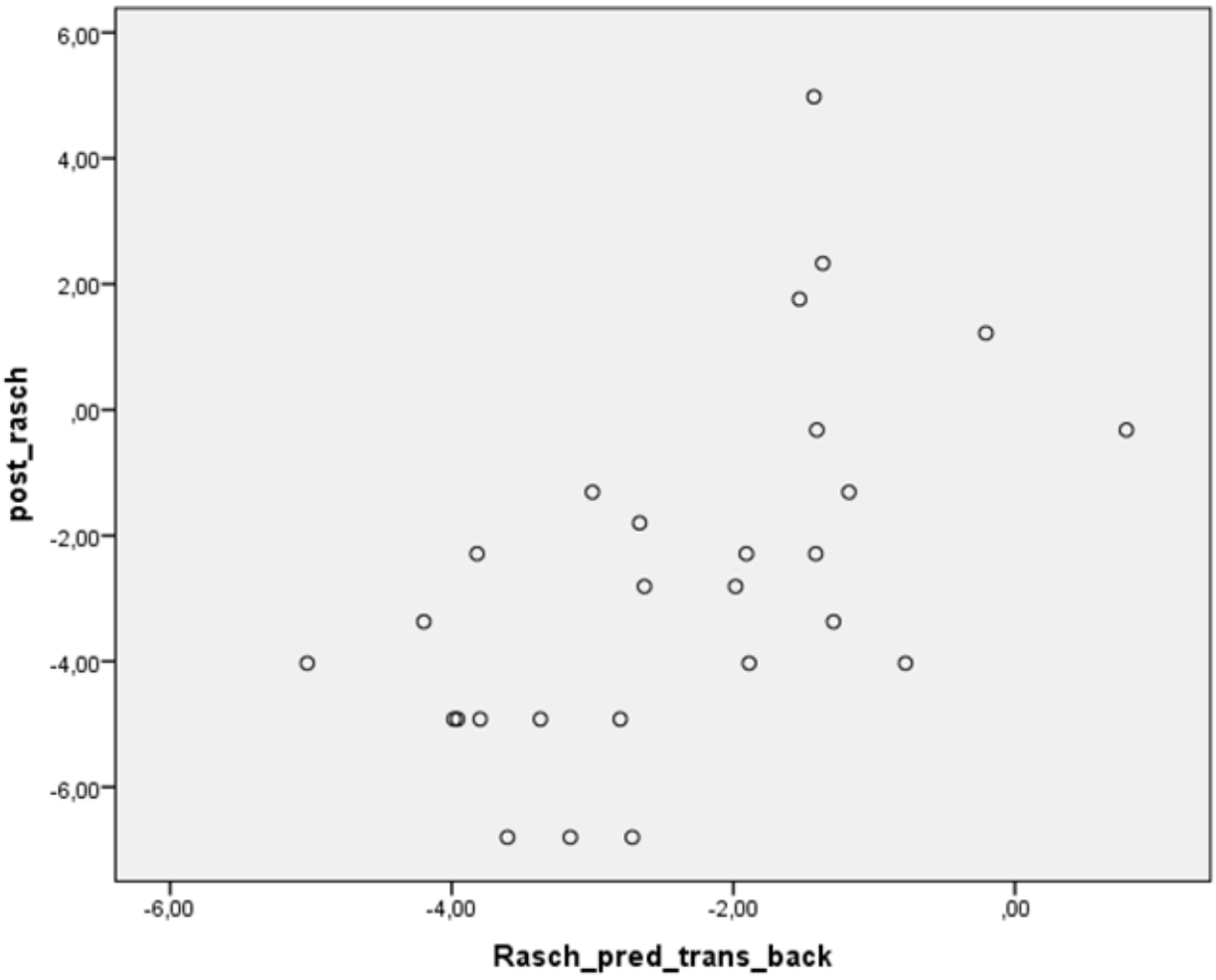


Figure 2b. Scatter plot for predicting the follow-up measure on Cat-PROM5 (back transformed to the original unit of Cat-PROM5: Rasch_pred_trans_back =-exp(Rasch_transformed_pred) + 36.821.



Discussion

Despite the reduced number of available cases the validation analyses have been possible and in general have confirmed that the models do predict self-reported benefit. These results illustrate that both approaches produce reasonably valid predictions, however the model for the follow-up approach is clearly superior. This reflects the fact that the delta approach models a *difference* between two Rasch measures and is therefore subject to a higher measurement error component than the follow-up approach. This is a consequence of the fact that with the delta approach errors from the two subtracted measures accumulate, producing a higher random component in the composite variable than in each of the contributing measurements singly. In terms of making predictions, and as observed here, predictions based on a variable created by the delta approach are subject to higher levels of uncertainty. For these reasons, for future implementation in wider clinical settings, we recommend the follow-up approach as the more robust option.

Conclusion

This exercise on independent data provide an assessment of the performance of the prediction models for self-reported Cat-PROM5 benefit from cataract surgery. Although predictions of both the final score are and improvement (delta approach) are possible, the former is prone to less uncertainty and is proposed as the preferable option.

(Appendix 12, word count 691)

Appendix 13. Qualitative Analysis of Perceptions of the Cataract Decision Aid for Shared Decision Making

Qualitative Analysis for Involve-CAT A feasibility randomised controlled trial of a Cataract Decision Aid

Cardiff Qualitative Report for Involve-CAT

A feasibility randomised controlled trial of a Cataract Decision Aid

Report prepared by:

Dr Natalie Joseph-Williams, School of Medicine, Cardiff University (NJW)

Dr Daniella Holland-Hart, School of Medicine, Cardiff University (DHH)

REPORT PURPOSE

This element of the programme will explore the feasibility of establishing a randomised controlled trial (RCT) using the Cataract Decision Aid (CDA) as an intervention. Embedded within the trial will be qualitative and cost elements and an exercise to validate the benefits prediction model developed earlier in the research programme. This report relates to Question 6 of the overarching Cataract Programme, outlined in the main study protocol:

> Q6. Implementation: how do patient decision support tools influence preoperative shared decision making; what are the implementation costs and potential savings; how feasible is a full-scale decision support RCT; how accurate is the benefits and prediction model; why unexplained poor outcomes?
> A6. A feasibility trial of a Cataract Decision Aid (CDA) with embedded qualitative assessments for a possible future fully powered RCT; evaluation of prediction model validity; qualitative investigations to include outcome mismatches (a continuation of qualitative aim commenced in WP3).

The report outlines the results and analyses that the Cardiff University team have completed with regard to WP4 (Involve-CAT). Specifically, this report outlines the qualitative elements of WP4:

- How does a decision aid influence preoperative shared decision making?
- How do patients and clinicians perceive the CDA in the context of routine care?

Executive Summary of Qualitative findings from Involve-Cat: a feasibility randomised controlled trial (RCT) of a cataract decision aid (CDA)

Background

Using a mixed-methods approach, we conducted qualitative and quantitative analysis of the decision aid. This included quantitatively scoring consultations using the OPTION 5 Observer instrument, comparing appointments with (CDA) and without the aid (Standard Care). We listened to recordings of the appointments and scored each of them in relation to shared decision making. Also, we analysed the 'used a framework' approach to qualitatively analyse the consultations. Additionally, we conducted interviews with patients and clinicians and qualitatively analysed their perceptions of the appointments and the decision aid.

We found that the Cataract Decision Aid (CDA) does have an effect on the quality and quantity of Shared Decision Making (SDM) that takes place during cataract consultations. We also found that the CDA was acceptable and perceived as helpful by both patients and clinicians and the CDA has the potential to be integrated into routine clinical settings.

However, several key issues arose that would likely impact on the effectiveness of the CDA and the extent to which it could be easily integrated. We highlight these key findings and outline recommendations for improving how and when the CDA is delivered within routine cataract care pathways, and as part of a future full-scale RCT.

Key Findings

- Observer OPTION5 scores revealed that there was a significant difference in mean total scores between the CDA and the Standard Care (SC) arm. We also found that there was a significant difference in OPTION5 scores at the item level, with all five items scoring higher on average in the CDA consultations compared to the SC consultations. These results suggest that when clinicians use the CDA with patients, more SDM behaviours are present, and they are carried out to a greater extent.

- The consultation observations and the OPTION5 analyses revealed that the key SDM tasks of introducing the choice and eliciting patient's preferences were not always carried out, regardless of whether the CDA was used.

- Consultants did not consistently perceive the choices of 'surgery, delay or decline' as useful or even legitimate and therefore some did not agree with the presentation of choices in the decision aid. For some consultants who believed that there was a choice available to patients, declining surgery was generally not perceived as an 'equal' choice. For other consultants, the options were to have surgery or delay surgery, but not to decline the surgery. This view was also reflected by some patients, with several patients stating that they felt the only route was to have the surgery and 'doing nothing was not an option'.

- For many of the patients, they had strong prior preferences and had already decided that they wanted the surgery. Thus, it would be difficult to re-introduce the choice talk at the consultation stage. This indicates that the shared decision making discussion around having or declining cataract surgery might be better placed earlier in the clinical care pathway or at least initiated earlier, before patients had formed strong prior preferences of what they wanted.

- The CDA was very effective at providing information to patients about their options, including their personalised risk, but it did little in the way of supporting the introduction of choice or the elicitation of patients' preferences, partly because of the patients' prior preferences.

- A number of approaches could help to rebalance the process towards SDM including: more work could be done in the consultation to re-introduce the concept of choice, emphasising that surgery is not a foregone conclusion, and providing a clear rationale for patient involvement in the decision making process; or, the introduction of choice could be initiated earlier in the care pathway (e.g. with an optician).

Recommendations

Overall, clinicians felt that the CDA could be integrated into routine clinical settings, and delivered as part of a larger RCT. However, changes would need to be made to the way in which the CDA is delivered so that it is feasible, including:

- The CDA should be used as part of a two-stage process. First, the CDA should be introduced to patients before the consultation, ideally being sent to patients with appointment letters. They will be asked to focus on using Section A (FAQs) and Section B (what matters to me) before the appointment, and they will be told that Section C (personalised risks) will be completed during the appointment. Then, the CDA will be used as a collaborative tool during the consultation.

- Possibly introduce the CDA at an earlier point in the care pathway. Generic elements of the CDA (Section A and Section B) would be better delivered prior to the referral to the consultant (e.g. with an optician), leaving the personalised element for the detailed discussion with the consultant after referral.

- Provide more consistent and adequate clinician training in SDM to the clinicians and the wider team who will be delivering the CDA. The skills training would help to ensure 'coherence' of the concept of SDM amongst the team members and it will explain how SDM is different to existing processes (e.g. informed consent). It will ensure that the way in which the CDA is introduced and delivered by the clinician maximises the potential effectiveness of the CDA.

- To improve future feasibility, the risk calculators should be better integrated into the local clinical systems, or a process should be put in place to pre-populate as much of the information as possible prior to the consultation.

(Appendix 13, word count 1145)

Appendix 14. Mismatching or Discordant Outcomes

Factors behind instances of discordance between clinician and patient cataract surgery outcome assessments

Factors behind instances of discordance between clinician and patient cataract surgery outcome assessments

Summary of key findings

Aims

- To explore, with healthcare professionals and patients, identified cases of mismatches or discordance between clinicians' and patients' perceptions of cataract surgery outcomes

Methods

- Semi-structured interviews with Healthcare professionals (HCPs) involved in cataract care delivery, who had experiences with the discordant outcomes phenomenon.
- Semi-structured interviews with patients falling within the mismatching outcomes definition.

Definition

Discordance could be either positive or negative.

Negative mismatching outcomes:

- The patient is unhappy with good surgery and VA outcome: Patients who are dissatisfied with the outcome of their surgery or perceive a negative outcome, even though there is no clear clinical explanation for experiencing a poor outcome. Examples might include dysphotopsia, reflections, glare, residual minor refractive error.

Positive mismatching outcomes:

- The patient is happy with poor surgery or VA outcome: Patients who are reporting satisfaction/positive outcomes where the VA or technical elements of the surgery appear to indicate that a normally symptomatic clinical problem exists of which the patient seems to be unaware. Examples might include reduced VA, IOL subluxed, mild to moderate macular dysfunction.

Recruitment

A discordant outcome is a relatively uncommon phenomenon. Affected patients were identified in two main ways.

- Predict-CAT study participants whose responses to the Cat-PROM5 questionnaire post-op (i.e. their self-reported of outcome of surgery) did not match their clinical assessment of outcome;

- Patients identified through routine clinics whose reported perceptions of outcome did not match their clinical assessment of outcome.

Participants

Patients

Interviews with seven patients took place. Three participants were identified through the Predict-CAT study, and four were identified by HCPs during clinics and using the mismatching outcomes definitions disseminated to each centre. Three participants were recruited from in Bristol and four from Torbay. Only one was recruited as a positive mismatching outcome case i.e. their perception of outcome was more positive than the healthcare professional's assessment. The majority were from areas of low social deprivation. Most patient participants had other visual co-morbidities, but none that could clinically explain their experiences of surgery outcome.

Healthcare professionals

Nine HCPs were interviewed. Three interviews were with members of the Cataract Research Programme team. One participant was an optometrist, and eight were ophthalmologists. Four were based in Bristol, one in Gloucestershire, two in Torbay, and two in Brighton. One participant was currently working in private practice.

Findings

Experiences of discordance among patient participants

Discordance in most patients' experience was the result of unexpected changes in visual ability after surgery, for example changed spectacle prescriptions, problems with peripheral vision, whilst two participants experienced unexpected symptoms such as floaters and dry eyes which they felt compromised their quality of life. Overall, it was the impact on the patients' everyday life and functional status that determined their perception of outcome, particularly if they were not expecting the particular outcome.

Factors explaining the phenomenon

Medical technologies. Explanations given by HCPs linked to medical practice were primarily the technologies used, for example the choice of IOL and unintended optical side effects resulting from individual lenses, and the use of measurement and testing devices able to capture the visual experiences of the patients. For example, many HCPs thought current measurement practices do not capture the full spectrum of dimensions of vision affected by cataract surgery, such as optical aberrations.

Doctor-patient relationship. Quality of the doctor-patient relationship was thought by both HCPs and patients to shape patients' perceptions of outcome. Both believed there was a need for a more personalised approach to patient counselling and shared decision-making when making decisions on lens choice and refractive aims of the surgery. For patients, trust towards the HCPs was also important, and this trust was found to be compromised through breakdowns in the process of care delivery, for example continuity of care, ease of access to post-op follow-up, and trust in the professionals' abilities to curry out ophthalmological examinations and procedures.

Patient-specific attributes. Presence of co-morbidities and a more complex clinical profile, the patients' visual abilities before the surgery, the patients' personality, and social characteristics were raised by HCPs and patients to explain discordant outcomes. All HCPs thought personality was a determinant of discordant outcomes, and a small minority of patients alluded to their personality to explain their decisions and actions. Ultimately however for these patients the quality of cataract surgery counselling received prior to their surgery shaped their post-operative experiences.

Conclusions

Ways to improve quality of care

There was agreement between HCPs and patients of the importance of supporting a personalised approach to shared and informed decision-making. Moving away from a generalised approach when providing risks and benefits information and towards adjusting the information to the individual patients' clinical and psychological profile was seen as important. Allowing more time for patients to consider their options and reflect on the information was also important. For some HCPs, ensuring there was a clinical need for cataract surgery and avoiding performing surgeries on individuals with good quality of vision; adopting new technologies; and allowing access to ophthalmologists after the surgery were also seen as important.

Barriers to improvement

Several barriers to changing practice were identified, more often linked to the challenges of changing current ways of working, and the time available to HCPs to engage in such in-depth personalised conversations with patients.

(Appendix 14, word count 875)

Implementation Costs of a Cataract Decision Aid

Implementation Costs of a Cataract Decision Aid

A health economic analysis of Involve-CAT

Implementing the clinical decision aid (CDA) to help patients decide whether to have cataract surgery could have resource implications for the NHS. The additional resource is the time taken to collect data needed for the CDA and administer it during the shared decision making (SDM) discussion and subsequent impact on discussions in the remaining appointment. There is also the potential for the CDA to impact the number of patients choosing to have surgery and, if it affects the risk profile of patients having surgery, the healthcare use following surgery (e.g. A&E visits). This analysis compares the additional resources incurred as a result of implementing the CDA compared to standard care in the INVOLVE-CAT pilot RCT study.

Methods

The aim was to estimate the difference in costs between participants receiving standard care and those receiving the CDA. Costs of the CDA intervention were assumed to comprise the clinician time spent conducting the clinic appointment and associated assessments.

Resource use

Clinic appointment

Data were obtained from participants' CRFs. The start and end time of each stage of the appointment were recorded on the CRF by the clinicians undertaking the research assessment and clinical assessment appointment. Figure 1 presents the times that were recorded, what each stage involved and the resulting durations that were calculated. The primary outcome of the analysis is highlighted in yellow. The CDA could impact the remaining appointment after the SDM, thus the primary analysis compares the difference in costs incurred from the start of the SDM to the end of the appointment. Costs were obtained from the Personal Social Services Research Unit (PSSRU). The cost per minute of the clinician's time was calculated and used to estimate the total resource use for each participant's clinic appointment. The clinical assessment and SDA were predominantly led by consultant ophthalmologists.

The CDA required an additional assessment of near vision. This was not recorded in CRFs. Two optometrists recorded how long the assessment of near vision took for a subset of patients in the CDA arm and calculated the mean time. Secondary analysis included the cost of this additional near vision assessment.

Additional resource use

Resource utilisation data was obtained from the hospital records of participants from one centre. Data included day case and inpatient admissions, post-operative appointments and location, A&E attendances and outpatient appointments.

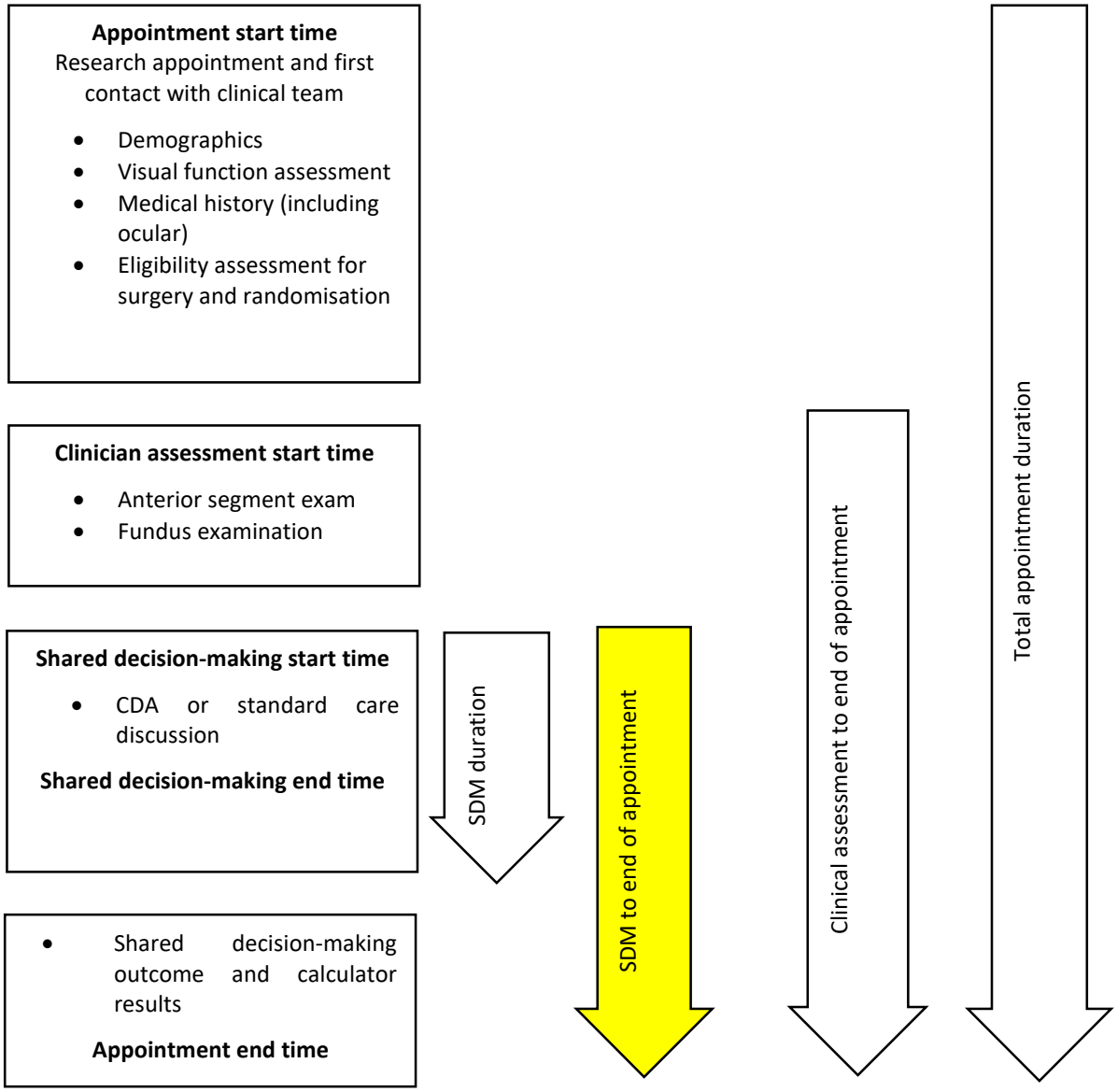


Figure 5 Recording of times and durations calculated

Analysis

Cost differences between study arms were assessed using two-sample t-tests. The primary analysis evaluated the cost of the CDA and impact on subsequent discussions only. Secondary analysis included an estimated cost of undertaking a near vision assessment in the CDA arm. Frequencies were calculated for the additional healthcare resource use. Although the CDA might influence the decision to have surgery, in fact all patients in both arms of the pilot study elected to have cataract surgery. We report healthcare use for the cataract procedure and subsequent healthcare by arm, but do not provide a comparison of costs.

Results

Appointment duration

Table 1 reports statistics describing the duration of selected stages of the appointment. The mean duration was longest in the CDA arm for all intervals reported. Standard deviations were larger in the CDA arm due to one SDM discussion lasting 80 minutes. Regardless, median times in the CDA arm were also longer. Data for SDM discussion duration was missing for two participants in the standard care arm.

Table 3 Appointment duration descriptive statistics

		Arm		
		CDA	***Standard Care***	***Total***
SDM to end of appointment (minutes)	*N*	*20*	*20*	*40*
	Mean (SD)	*29.0 (18.1)*	*21.0 (5.7)*	*25.0 (13.9)*
	Median	*29.5*	*20*	*21*
	Minimum	*5*	*12*	*5*
	Maximum	*88*	*31*	*88*
SDM duration (minutes)	*N*	*20*	*20*	*40*
	Mean (SD)	*16.9 (16.8)*	*8.6 (4.1)*	*12.7 (12.8)*
	Median	*12.5*	*8*	*9*
	Minimum	*4*	*3*	*3*
	Maximum	*80*	*18*	*80*
Clinical assessment to end (minutes)	*N*	*20*	*22*	*42*
	Mean (SD)	*46.3 (32.4)*	*27.4 (8.0)*	*36.4 (24.7)*
	Median	*41*	*26.5*	*30*
	Minimum	*11*	*15*	*11*
	Maximum	*155*	*50*	*155*

Two optometrists recorded how long the assessment of near vision took for a subset of patients in the CDA arm. The mean duration of the two assessors was 2.6 minutes (156 seconds) (Table 2).

Table 4 Assessment of near vision estimates

	Number of patients assessed	***Mean duration (seconds)***	***Minimum duration (seconds)***	***Maximum duration (seconds)***
Optometrist 1	*5*	*252*	*180*	*300*
Optometrist 2	*6*	*60*	*40*	*80*

Unit cost data

The duration of each appointment was combined with unit cost data to estimate the resource use for each participant. Unit costs are reported in Table 3. The assessment of near vision was conducted by a Band 7 optometrist. This assessment is not usually conducted in usual care, so costs were only applied to the CDA arm. A nurse assistant (Band 3) or nurse (Band 5/6) are also able to conduct this assessment.

Hospital optometrists are not included in the PSSRU costs. Cost per minute of a Band 7 radiographer's time is therefore used in its absence.

Table 5 Unit costs

Resource	***Cost per hour (£)***	***Cost per minute (£)***	***Notes***	***Source***
Consultant ophthalmologist	*108*	*1.80*	*Consultant medical hospital doctor*	*PSSRU, 2018*
Optometrist	*57*	*0.95*	*Cost of a Band 7 radiographer*	*PSSRU, 2018*

Analyses of costs

The mean total costs associated with NHS resource use and used in the primary analysis are reported in Table 4. Mean cost for the CDA arm was £52.20, which was not significantly different than standard care (mean £37.80, difference £14.40, p=0.06).

Table 6 Costs of healthcare resource use – Primary analysis

	Arm			95% confidence intervals		
	CDA (£) Mean (SD)	***Standard care (£) Mean (SD)***	***Difference (£)***	***Upper CI***	***Lower CI***	***p- value of t-test***
SDM start to end of appointment	*52.20 (32.63)*	*37.80 (10.19)*	*14.40*	*-1.06*	*29.88*	*0.06*

Table 5 reports secondary analysis which includes the estimated cost of the assessment of near vision. Total mean costs were significantly larger in the CDA arm (difference £16.87, p=0.03).

Table 7 Costs of healthcare resource use - Secondary analysis

	Arm			95% confidence intervals		
	CDA (£) Mean (SD)	***Standard care (£) Mean (SD)***	***Difference (£)***	***Upper CI***	***Lower CI***	***p- value of t-test***
SDM to end of appointment and near vision assessment	*54.67 (32.63)*	*37.8 (10.19)*	*16.87*	*1.39*	*32.35*	*0.03*

Additional resource use

Table 6 reports healthcare resource use following the clinical assessment appointment. Data was obtained from clinical records and pertains to 23 participants from one participating site. Data is summarised as the total number of healthcare contacts in each arm. One patient had surgery on both eyes within the duration of the study. Some patients had two post-operative visits and some post-operative appointment data was missing. One patient attended for surgery but was rescheduled, returning at a later date. The initial appointment is not included. There is little difference between study arms, although the CDA had fewer eye-related outpatient appointments.

Table 8 Subsequent healthcare resource use

	CDA N=11	***Standard Care N=12***	***Total N=23***
Cataract operations (total)	*11*	*13*	*24*
Community post-operative appointment (total)	*9*	*7*	*16*
HES post-operative appointment (total)	*3*	*4*	*7*
Outpatient optical appointments (total)	*2*	*5*	*7*
Outpatient other speciality (total)	*5*	*5*	*10*
A&E attendances (total)	*3*	*2*	*5*

Conclusion

Including the CDA in a cataract surgery SDM discussion does increase NHS costs, although costs were not significantly greater than standard care. Including an assessment of near vision conducted by an optometrist has the impact of making the CDA significantly more expensive, however. The estimated time to conduct the near vision assessment was widely disparate between the two assessors, therefore its accuracy is uncertain. Furthermore, in the Involve-CAT study optometrists conducted the assessment, whereas in practice nurses or nurse assistants could administer it.

(Appendix 15, word count 1278)

Appendix 16. A Stakeholder Meeting Exploring the Ethical Perspectives of Immediately Sequential Bilateral Cataract Surgery

A Stakeholder Meeting Exploring the Ethical Perspectives of Immediately Sequential Bilateral Cataract Surgery

A Stakeholder Meeting Exploring the Ethical Perspectives of Immediately Sequential Bilateral Cataract Surgery

Summary of findings

Authors: Matthew Quinn[1], Daniel Gray[2], Christopher Liu[1,3,4]

1 Brighton and Sussex Medical School, Brighton, UK

2 School of Social Sciences, Cardiff University, Cardiff, UK

3 Sussex Eye Hospital, Brighton and Sussex University Hospitals NHS Trust, Brighton, UK

4 Tongdean Eye Clinic, Hove, UK

ABSTRACT:

Background

Cataract surgery numbers are predicted to increase 50% by 2035. New efficiencies have therefore been sought to increase cataract surgical productivity. Recently, a modified approach to the standard cataract surgery pathway, known as immediately sequential bilateral cataract surgery (ISBCS) has been attracting interest. This approach consists of operating on both eyes at the same sitting.

The purported benefits of ISBCS have been argued in the literature, these include both direct patient and wider economic benefits. However, the surgical uptake of ISBCS remains low and the procedure is controversial among UK Ophthalmologists. As many of the controversies of ISBCS are underpinned by ethical dilemmas, the aim of this work was to explore the ethical perspectives of ISBCS from a variety of stakeholder viewpoints.

Method

A semi-structured independent stakeholder meeting was convened at the Royal College of Ophthalmologists London headquarters in June 2018. In total, 29 stakeholders attended the meeting, invited through purposive sampling. The professional characteristics of stakeholders included but were not limited to: Ophthalmologists (9), patients (5), religious leaders (4), ophthalmic nurses (3), ethicists (2), lawyers (2) and commissioners (1). Thematic qualitative analysis using methodology proposed by Braun & Clarke (2006) was conducted on the resultant transcript of the discussion.

Results

Thematic analysis identified 3 overarching themes, which were subdivided into 8 subthemes. Themes identified include: (1) Beneficence and Non-maleficence (Patient Benefits, Patient Risks, The Uncertainties of Risk, Patient Interpretation of the Risk-benefit Analysis); (2) Autonomy (Patient and Surgeon Choice, Informed Consent, The Barriers to Effective Communication); (3) Distributive Justice (The Allocation of Resources: The Individual vs the Collective).

Conclusion

This analysis provides a reference point for the issues and ethical factors surrounding ISBCS. The stakeholders concluded that the procedure was an ethical undertaking provided patient autonomy was appropriately considered. This requires an individual interpretation of the risk-benefit balance, which must include an understanding of the low but unquantifiable risk of severe complications. Cost savings to healthcare that may consequently occur following the implementation of ISBCS may be considered a secondary benefit, whereas the primary benefit is centred on patient convenience factors.

INTRODUCTION

In view of increasing demand, new surgical efficiencies have been sought to increase cataract productivity whilst maintaining excellent outcomes. The traditional approach for patients with bilateral symptomatic cataract is known as delayed sequential bilateral cataract surgery (DSBCS). This protocol consists of operating on one eye first, then returning to complete the second eye at a (predetermined) later date. More recently, an alternative approach to cataract surgery delivery known as immediately sequential bilateral cataract surgery (ISBCS) has been attracting attention. This procedure consists of operating on both symptomatic eyes, at the same sitting. Proponents of ISBCS suggest the approach has numerous benefits. However, critics have raised concerns regarding ISBCS. The rate that ISBCS is undertaken is variable worldwide.

The Ethical Aspects of Immediately Sequential Bilateral Cataract Surgery (ISBCS)

Medical ethics exists as an ever-evolving blend of variable ethical standards, with no underlying unified authority. Some critics believe that for an elective procedure, ISBCS should not be undertaken as the potential benefits do not outweigh the potential harms of the protocol. The concept of not inflicting harm (non-maleficence) and promoting good (beneficence) is an integral basis for many theoretical approaches in medical ethics. In 1979, American bioethicists Tom Beauchamp and James Childress drew on an existing combination of ethical theories to synthesise ‘principlism’, a proposed common moral framework for ethical decision making in medicine. The approach is based on four prima facie moral commitments: Respect for autonomy, beneficence, non-maleficence and justice.

Conflict within medical ethics occurs when any two ethical principles are at odds. This is often not the exception, but the norm within clinical practice. The principles are considered non-hierarchical, where no single principle tops another. Broadly, two arms of thought can be applied to ethical decision making: Deontological and utilitarian. Deontological ethics refers to the adherence to obligations, where the morality of an action is dependent on the intrinsic nature of that action. In contrast, the utilitarian approach makes a decision in view of its overall consequences, with the aim being the greatest benefit for society as a whole.

Aim

Despite increasing numbers of ISBCS carried out year on year, ISBCS remains a controversial topic within Ophthalmology. An independent stakeholder meeting was conducted to explore the key ethical aspects of ISBCS from a range of expertise. This paper does not attempt to describe in detail the arguments for and against ISBCS, as this process has been discussed elsewhere in the literature. Instead, we aim to develop an understanding of how stakeholders balance their personal ethical considerations of ISBCS, to provide holistic conclusions based on the current available evidence. Additionally, it is our hope that the representation of a variety of expert and patient ethical perspectives will guide the identification of future areas of research for ISBCS.

METHOD

Approach

The use of stakeholder meetings to evaluate perspectives on healthcare policy is a commonly undertaken practise within healthcare organisations. For this independent meeting, we have defined stakeholders as: Persons who may be directly or indirectly affected by a change in cataract surgery protocol. The stakeholders selected participated as a collective group of non-author contributors, to assist in the identification of their ethical perspectives of ISBCS.

To gain an understanding of the viewpoints raised during the meeting, qualitative thematic analysis was used to identify prominent ethical themes that arose. This paper will focus on the essentialist/realist approach, as examining individual's experiences will provide the narrative for their respective ethical positions. We employ the methodology introduced by Braune and Clark, which outlines a clear protocol consisting of a series of phases researchers must complete for analysis. No rigorously tested framework exists for the design of stakeholder meetings for use in such events. This report therefore adheres to the Consolidated criteria for Reporting Qualitative research (COREQ) guidelines.

Stakeholders

Stakeholders were invited via email through purposive sampling. Stakeholders contacted were colleagues, acquaintances or personal contacts of the principle organisers of the event. Where individual stakeholder's views of ISBCS were known a priori, attempts were made to select a mixture of participants both for and against the procedure. Once stakeholders had confirmed attendance, they were provided with the meeting agenda and a list of ethical questions to be discussed. A total of 29 stakeholders participated.

Table 9 Professional Characteristics of Stakeholders Present

Professional Capacity	Number of Attendees
Health Care Professionals	
Ophthalmologist	6
Ophthalmologist and Ethicist	1
Ophthalmologist of Muslim faith	1
Ophthalmologist and Public Health Ophthalmologist	1
Ophthalmic Nurse and Patient	3
Optometrist	1
Other Professionals	
Bioethicist	1
Bioethicist and political philosopher	1
Commissioner	1
Lawyer	2
Health Economist	1
Religious Persons	
Catholic Priest	1
Academic of Jewish Faith	1
Muslim Chaplain and Scholar	1
Rabbi	1
Lay Attendees	
Lay trustee of the RCOphth	1
Lay member of the RCOphth	1
Medical Student	1
Patient	2
Patient Advocate	1
Total	29

Data Analysis

The data were transcribed intelligent verbatim and imported into qualitative software organiser EnVivo12™. The analysis was conducted using a 'bottom up' or inductive approach, using an open coding technique in which the themes developed were data driven.

RESULTS

The ethical themes that emerged from the stakeholder meeting are described in table 2. The 3 primary themes echoed previously described principles of bioethics described by Beauchamp and Childress, these include: (1) Beneficence and non-maleficence; (2) Autonomy; and (3) Distributive Justice. The primary themes were formed of a total of 8 subthemes. The themes and their sub-themes are discussed below, substantiated by accompanying quotations from the meeting.

Table 10 Themes and subthemes identified at the stakeholder meeting

Theme	Subtheme
1. Beneficence and Non-Maleficence	1.1 Patient Benefits
	1.2 Patient Risks
	1.3 The Uncertainty of Risk
	1.4 Patient Interpretation of the Risk-benefit Analysis
2. Autonomy	2.1 Patient and Surgeon choice
	2.2 Informed Consent
	2.3 The Barriers to Effective Communication
3. Distributive Justice	3.1 The Allocation of Resources: The Individual vs the Collective

DISCUSSION

This meeting aimed to discuss the ethical challenges of the currently controversial procedure of ISBCS, as perceived by a group of 29 stakeholders. This meeting is unique, as there is currently no research that fully evaluates the ethical considerations of ISBCS, beyond a risk-benefit analysis. The thematic analysis drawn from these data produced primary themes that echoed the previously described "principles of bioethics" proposed by Beauchamp and Childress. These principles are claimed to be naturally intrinsic to medical ethics, permeating across differing personal philosophies, politics, religion and moral theories. Additionally, the ubiquitous application of these principles may explain the underlying utilisation of aspects of these principles by stakeholders. Maclin R argues that even if not stated explicitly, these principles are invoked in ethical justifications within the medical field. We have therefore reported the "four principle" approach for a case specific analysis of ISBCS.

The first ethical principle discussed was the consideration of beneficence and non-malificence. Although initially described as separate principles, they are often combined within ethical literature for the purpose of a risk-benefit analysis. The benefits and risks of ISBCS discussed by stakeholders, were similar to those described in literature. Stakeholders felt the direct benefits of ISBCS were centred on patient convenience factors, but the ethically important risk was for the potential for bilateral vision loss. Stakeholders stated that the risk of bilateral endophthalmitis was very low, and could not be accurately quantified based on existing data. The highly emotive nature of binocular blindness, combined with the inevitability of an occurrence based on high cataract incidence, may explain why stakeholders attributed weight to this complication.

Within medical practice, the principle of patient autonomy is often distilled within the obligation to obtain informed consent. The stakeholders identified that promoting patient autonomy to enable patient-centred decision making for ISBCS was a paramount undertaking. Shivasi A argues the most effective way to promote patient autonomy is to reduce the epistemic disparity between the patient and clinician. Therefore, the process of informed consent derives its moral value from reducing the inequalities of power associated

with the doctor-patient dynamic. Stakeholders stated that to achieve informed consent, clinicians must communicate effectively to ensure service users can understand complex information associated with any given procedure.

The ethical importance of distributive justice was an area of debate at the meeting. The discussion illustrated the conflict between utilitarian and deontological approaches to the distribution of healthcare resources. Some ophthalmologist felt the financial cost-saving to society the ISBCS protocol provided was an important consideration, given the finite health resources available. This consideration is in contrast to literature that describes medical practitioners as primarily morally deontological in nature. In contrast, many patient and religious stakeholders focused on the deontological approach, this reflects literature that argues many aspects of religious ethics are primarily deontological in nature. Applying moral theory to resource allocation requires the reconciliation of the contrasting deontological and utilitarian perspectives. Within medicine, this can be achieved by maintaining a deontological approach at the level of the patient-clinician interaction, and considering the utilitarian perspectives at a "higher level", such as NICE committee evaluation. Ethically, we can conclude that financial savings from ISBCS are to be currently considered a secondary benefit of the protocol.

CONCLUSION

This analysis provides a reference point for the ethical factors governing the controversial topic of ISBCS. The stakeholders concluded offering ISBCS to be an ethical undertaking when patient autonomy was appropriately considered. This requires a patient's individual interpretation of the risk-benefit analysis, which must include an understanding of the low but unquantifiable risk of severe complications. Based on current evidence, cost savings to healthcare that may occur following ISBCS may be considered a secondary benefit, whereas the primary benefit is centred on patient convenience factors.
(Appendix 16, word count 1988)

END OF APPENDICES