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Sparrow, J. M., Grzeda, M. T., Frost, A., Liu, C., Johnston, R. L., Scanlon, P., Pithara-McKeown, C., Elliott, D., Donovan , J. L., Joseph-Williams, N., Holland-Hart, D., Donachie, P. HJ., Dixon, P. C., Kandiyali, R., Taylor, H., Breheny, K., Sterne, J. A. C., Hollingworth, W., Evans, D., ... Searle, J. (2022). Developing decision support tools incorporating personalised predictions of likely visual benefit versus harm for cataract surgery: research programme. *NIHR Open Research*, *10*(9). https://doi.org/10.3310/BAGA4188

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Programme Grants for Applied Research

Volume 10 • Issue 9 • October 2022

ISSN 2050-4322

Developing decision support tools incorporating personalised predictions of likely visual benefit versus harm for cataract surgery: research programme

John M Sparrow, Mariusz Grzeda, Andrew Frost, Christopher Liu, Robert L Johnston, Peter Scanlon, Christalla Pithara, Daisy Elliott, Jenny Donovan, Natalie Joseph-Williams, Daniella Holland-Hart, Paul HJ Donachie, Padraig Dixon, Rebecca Kandiyali, Hazel Taylor, Katie Breheny, Jonathan Sterne, William Hollingworth, David Evans, Fiona Fox, Sofia Theodoropoulou, Rachael Hughes, Matthew Quinn, Daniel Gray, Larry Benjamin, Abi Loose, Lara Edwards, Pippa Craggs, Frances Paget, Ketan Kapoor and Jason Searle

DOI 10.3310/BAGA4188

Developing decision support tools incorporating personalised predictions of likely visual benefit versus harm for cataract surgery: research programme

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Declared competing interests of authors: Robert L Johnston (deceased) was a director of the Electronic Medical Records company from which data on cataract surgery were extracted for analyses in work package 2. Paul HJ Donachie is the statistician for the Royal College of Ophthalmologists' National Ophthalmology Database and reports grants from the Healthcare Quality Improvement Partnership outside the submitted work. Jenny Donovan declares membership of National Institute for Health and Care Research (NIHR) Rapid Trials and Health Technology Assessment (HTA) Committee Boards. Jonathan Sterne was a member of the NIHR HTA Clinical Trials and Evaluation Board from 2012 to 2015. William Hollingworth was a member of the NIHR HTA Clinical Evaluation and Trials funding committee between 2016 and 2021.

Published October 2022
DOI: 10.3310/BAGA4188

This report should be referenced as follows:

Sparrow JM, Grzeda M, Frost A, Liu C, Johnston RL, Scanlon P, *et al*. Developing decision support tools incorporating personalised predictions of likely visual benefit versus harm for cataract surgery: research programme. *Programme Grants Appl Res* 2022;**10**(9). https://doi.org/10.3310/BAGA4188

Programme Grants for Applied Research

ISSN 2050-4322 (Print)

ISSN 2050-4330 (Online)

Programme Grants for Applied Research (PGfAR) was launched in 2013 and is indexed by Europe PMC, NCBI Bookshelf, DOAJ, Ulrichsweb™ (ProQuest LLC, Ann Arbor, MI, USA) and Scopus® (Elsevier, Amsterdam, Netherlands).

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This report

The research reported in this issue of the journal was funded by PGfAR as project number RP-PG-0611-20013. The contractual start date was in December 2013. The final report began editorial review in November 2019 and was accepted for publication in October 2021. As the funder, the PGfAR programme agreed the research questions and study designs in advance with the investigators. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The PGfAR editors and production house have tried to ensure the accuracy of the authors' report and would like to thank the reviewers for their constructive comments on the final report document. However, they do not accept liability for damages or losses arising from material published in this report.

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Abstract

Developing decision support tools incorporating personalised predictions of likely visual benefit versus harm for cataract surgery: research programme

John M Sparrow,[1,2*] Mariusz Grzeda,[1,2] Andrew Frost,[3] Christopher Liu,[4,5,6] Robert L Johnston,[7†] Peter Scanlon,[7] Christalla Pithara,[2,8] Daisy Elliott,[2] Jenny Donovan,[2] Natalie Joseph-Williams,[9] Daniella Holland-Hart,[9] Paul HJ Donachie,[7,10] Padraig Dixon,[2] Rebecca Kandiyali,[2] Hazel Taylor,[11] Katie Breheny,[2] Jonathan Sterne,[2] William Hollingworth,[2] David Evans,[12] Fiona Fox,[13] Sofia Theodoropoulou,[1] Rachael Hughes,[2] Matthew Quinn,[5] Daniel Gray,[14] Larry Benjamin,[15] Abi Loose,[1] Lara Edwards,[1,8] Pippa Craggs,[1] Frances Paget,[1] Ketan Kapoor[1] and Jason Searle[1]

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Background: Surgery for established cataract is highly cost-effective and uncontroversial, yet uncertainty remains for individuals about when to proceed and when to delay surgery during the earlier stages of cataract.

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Objective: We aimed to improve decision-making for cataract surgery through the development of evidence-based clinical tools that provide general information and personalised risk/benefit information.

Design: We used a mixed methodology consisting of four work packages. Work package 1 involved the development and psychometric validation of a brief, patient self-reported measure of visual difficulty from cataract and its relief from surgery, named Cataract Patient-Reported Outcome Measure, five items (Cat-PROM5). Work package 2 involved the review and refinement of risk models for adverse surgical events (posterior capsule rupture and visual acuity loss related to cataract surgery). Work package 3 involved the development of prediction models for the Cat-PROM5-based self-reported outcomes from a cohort study of 1500 patients; assessment of the validity of preference-based health economic indices for cataract surgery and the calibration of these to Cat-PROM5; assessment of patients' and health-care professionals' views on risk–benefit presentation formats, the perceived usefulness of Cat-PROM5, the value of personalised risk–benefit information, high-value information items and shared decision-making; development of cataract decision aid frequently asked questions, incorporation of personalised estimates of risks and benefits; and development of a cataract decision quality measure to assess the quality of decision-making. Work package 4 involved a mixed-methods feasibility study for a fully powered randomised controlled trial of the use of the cataract decision aid and a qualitative study of discordant or mismatching perceptions of outcome between patients and health-care professionals.

Setting: Four English NHS recruitment centres were involved: Bristol (lead centre), Brighton, Gloucestershire and Torbay. Multicentre NHS cataract surgery data were obtained from the National Ophthalmology Database.

Participants: Work package 1 – participants ($n = 822$) were from all four centres. Work package 2 – electronic medical record data were taken from the National Ophthalmology Database (final set > 1M operations). Work package 3 – cohort study participants were from Bristol ($n = 1200$) and Gloucestershire ($n = 300$); qualitative and development work was undertaken with patients and health-care professionals from all four centres. Work package 4 – Bristol, Brighton and Torbay participated in the recruitment of patients ($n = 42$) for the feasibility trial and recruitment of health-care professionals for the qualitative elements.

Interventions: For the feasibility trial, the intervention was the use of the cataract decision aid, incorporating frequently asked questions and personalised estimations of both adverse outcomes and self-reported benefit.

Main outcome measures: There was a range of quantitative and qualitative outcome measures: questionnaire psychometric performance metrics, risk indicators of adverse surgical events and visual outcome, predictors of self-reported outcome following cataract surgery, patient and health-care practitioner views, health economic calibration measures and randomised controlled trial feasibility measures.

Data sources: The data sources were patient self-reported questionnaire responses, study clinical data collection forms, recorded interviews with patients and health-care professionals, and anonymised National Ophthalmology Database data.

Results: Work package 1 – Cat-PROM5 was developed and validated with excellent to good psychometric properties (Rasch reliability 0.9, intraclass correlation repeatability 0.9, unidimensionality with residual eigenvalues ≤ 1.5) and excellent responsiveness to surgical intervention (Cohen delta −1.45). Work package 2 – earlier risk models for posterior capsule rupture and visual acuity loss were broadly affirmed (*C*-statistic for posterior capsule rupture 0.64; visual acuity loss 0.71). Work package 3 – the Cat-PROM5-based self-reported outcome regression models were derived based on 1181 participants with complete data ($R^2 \approx 30\%$ for each). Of the four preference-based health economic indices assessed, two demonstrated reasonable performance. Cat-PROM5 was successfully calibrated to health economic indices; adjusted limited dependent variable mixture models offered good to excellent fit (root-mean-square error 0.10–0.16). The personalised quantitative risk information was generally perceived as beneficial. A cataract decision aid and cataract decision quality measure were successfully developed based on the views of patients and health-care professionals. Work package 4 – data completeness was good for the feasibility study primary

and secondary variables both before and after intervention/surgery (data completeness range 100–88%). Considering ability to recruit, the sample size required, instrumentation and availability of necessary health economic data, a fully powered randomised controlled trial (patients, $n = 800$, effect size 0.2 standard deviations, power 80%; $p = 0.05$) of the cataract decision aid would be feasible following psychometric refinement of the primary outcome (the cataract decision quality measure). The cataract decision aid was generally well-received by patients and health-care professionals, with cautions raised regarding perceived time and workload barriers. Discordant outcomes mostly related to patient dissatisfaction, with no clinical problem found.

Limitations: The National Ophthalmology Database data are expected to include some errors (mitigated by large multicentre data aggregations). The feasibility randomised controlled trial primary outcome (the cataract decision quality measure) displayed psychometric imperfections requiring refinement. The clinical occurrence of discordant outcomes is uncommon and the study team experienced difficulty identifying patients in this situation.

Future work: Future work could include regular review of the risk models for adverse outcomes to ensure currency, and the technical precision of complex-numbers analysis of refractive outcome to invite opportunities to improve post-operative spectacle-free vision. In addition, a fully powered randomised controlled trial of the cataract decision aid would be feasible, following psychometric refinement of the primary outcome (the cataract decision quality measure); this would clarify its potential role in routine service delivery.

Conclusions: In this research programme, evidence-based clinical tools have been successfully developed to improve pre-operative decision-making in cataract surgery. These include a psychometrically robust, patient-reported outcome measure (Cat-PROM5); prediction models for patient self-reported outcomes using Cat-PROM5; prediction models for clinically adverse surgical events and adverse visual acuity outcomes; and a cataract decision aid with relevant general information and personalised risk/benefit predictions. In addition, the successful mapping of Cat-PROM5 to existing health economic indices was achieved and the performances of indices were assessed in patients undergoing cataract surgery. A future full-powered randomised controlled trial of the cataract decision aid would be feasible (patients, $n = 800$, effect size 0.2 standard deviations, power 80%; $p = 0.05$).

Trial registration: This trial is registered as ISRCTN11309852.

Funding: This project was funded by the National Institute for Health and Care Research (NIHR) Programme Grants for Applied Research programme and will be published in full in *Programme Grants for Applied Research*; Vol. 10, No. 9. See the NIHR Journals Library website for further project information.

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Report Supplementary Material 2 Stability through time of a Statistical Model for indicators of Posterior Capsule Rupture in Cataract Surgery

Report Supplementary Material 3 Clinical outcome and risk factors for posterior capsule rupture and visual acuity loss following cataract surgery in patients aged 90 years and older

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Supplementary material can be found on the NIHR Journals Library report page (https://doi.org/10.3310/BAGA4188).

Supplementary material has been provided by the authors to support the report and any files provided at submission will have been seen by peer reviewers, but not extensively reviewed. Any supplementary material provided at a later stage in the process may not have been peer reviewed.

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List of abbreviations

Cat-PROM5	Cataract Patient-Reported Outcome Measure, five items
Catquest-9SF	Cataract questionnaire 9-item Short Form
CDA	cataract decision aid
CDQM	cataract decision quality measure
CTT	classical test theory
DQM	decision quality measure
EMR	Electronic Medical Record
EQ-5D-3L	EuroQol-5 Dimensions, three-level version
EQ-5D-3L+VIS	EuroQol-5 Dimensions, three-level version, with vision 'bolt-on' domain
EQ-5D-5L	EuroQol-5 Dimensions, five-level version
EQ-5D-5L-VSE	EuroQol-5 Dimensions, five-level version, value set for England
EQ-5D-CW	EuroQol-5 Dimensions Crosswalk
ES	effect size
FAQ	frequently asked question
GHNHSFT	Gloucestershire Hospitals NHS Foundation Trust
HCP	health-care professional
HQIP	Health Quality Improvement Partnership
ICECAP-O	ICEpop CAPability measure for Older people
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health and Care Research
NOD	National Ophthalmology Database
OR	odds ratio
PAG	Patient Advisory Group
PCR	posterior capsule rupture
PPI	patient and public involvement
PROM	patient-reported outcome measure
PSSRU	Personal Social Services Research Unit
RCT	randomised controlled trial
ROC	receiver operating characteristic
SD	standard deviation
SDM	shared decision-making
URG	User Reference Group
VA	visual acuity
VCM1	Vision Core Measure 1
VRQoL	vision-related quality of life
VSQ	Visual Symptoms and Quality of life questionnaire
WP	work package

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Plain English summary

Decisions about whether to opt for cataract surgery right away or hold off are mostly based on a patient's ability to read letters on a test 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) that they have to wait longer, that is until their vision is deemed poor enough. For the decision-making process to be more patient friendly, we developed and tested a series of decision support 'tools' that give individual patients and their doctors a better understanding of how cataracts affect everyday vision.

To enable patients to express how their vision affects them day to day, we developed a short questionnaire, Cataract Patient-Reported Outcome Measure, five items (Cat-PROM5), which has been shown to work well. Cat-PROM5 can be completed by patients before they see their eye doctor and can then be considered alongside the letter test chart results. Cat-PROM5 can also be completed after surgery, which is useful for doctors to assess how much a patient has benefited 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 with it.

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 that also includes general cataract surgery information and frequently asked questions. This was tested and most of the patients and doctors thought it was useful, although the cataract decision aid and the way it is used could still be improved.

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Scientific summary

Background

Cataract surgery is the most frequently undertaken surgical procedure in the NHS, with around 450,000 operations performed annually. Understanding the impact of cataracts on a patient's perceptions of their own 'lived vision' in the complex, dynamic, everyday visual environment in which they live is key to establishing the need for surgery. Formal measurement of self-reported visual difficulty related to cataracts can provide important information that is complementary to the standard clinical parameters generally used to assess need for and benefit from surgery.

The programme was divided into four work packages (WPs).

Objectives

Work package 1

- To allow the patient's voice to be more clearly and systematically expressed regarding their visual difficulty through the development and validation of a brief cataract patient-reported outcome measure (PROM) of visual difficulty, named Cataract Patient-Reported Outcome Measure, five items (Cat-PROM5).
- To compare and contrast Cat-PROM5 with the current 'best-of-class', but longer, instrument for use in routine cataract surgical services.

Work package 2

- To validate or update existing risk models for adverse outcomes.
- To assess the stability through time of the risk model for posterior capsule rupture.
- To improve understanding of the rates of adverse outcomes in the growing very elderly population.

Work package 3

Quantitative

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

Qualitative

- To inform the development and refinement of a cataract decision aid (CDA) through qualitative research involving patients and health-care professionals (HCPs) to:
    - identify the most acceptable presentations of risk and benefit probabilities
    - explore the acceptability of the new measure, Cat-PROM5, to HCPs
    - identify specific frequently asked questions (FAQs) from cataract surgery
    - explore issues of informed shared decision-making (SDM) for patient counselling.
- To develop a CDA in a FAQ format in which the likelihood of self-reported benefit is set alongside risks of a possible adverse outcome to provide an integrated decision support tool with personalised outcomes prediction.
- To develop a cataract decision quality measure (CDQM) for the patient's cataract surgery decision.

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Health economic

- To evaluate the performance of existing and emerging health economic indices [the preference-based measures the EuroQol-5 Dimensions, three-level version (EQ-5D-3L); EuroQol-5 Dimensions, three-level version, with vision 'bolt-on' domain (EQ-5D-3L+VIS); EuroQol-5 Dimensions, five-level version (EQ-5D-5L); and ICEpop CAPability measure for Older people (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.

Work package 4

Quantitative

- To undertake a feasibility study for a future fully powered randomised controlled trial (RCT) of the use of the CDA.
- To estimate the sample size for a possible future fully powered RCT.
- To validate the self-reported outcomes and benefits prediction models.

Qualitative

- To explore how the CDA influences pre-operative SDM.
- To explore how patients and HCPs perceive the CDA in the context of routine care.
- To explore background and specific instances of discordance in which HCPs' and patients' perceptions of outcomes were at odds.

Health economic

- To estimate the implementation costs and potential savings of the use of the CDA.

Methods

Work package 1

Development of Cat-PROM5

Under the construct 'visual difficulty due to cataract', 21 candidate questions were harvested from two published questionnaires for administration to pre- and post-operative patients at four participating NHS centres: Bristol, Gloucestershire, Torbay and Brighton. Three iterative cycles (patients, $n = 200$, $n = 316$ and $n = 306$, respectively) of questionnaire administration, analysis (Rasch, factor analysis), item reduction and validation (precision, test–retest, responsiveness, discrimination, convergent validity) produced the final five-item set that was psychometrically and qualitatively compared in a head-to-head study with the existing, 'best of class', longer, 9-item questionnaire.

Work package 2

Models for adverse outcomes, the very elderly and refractive outcome

Three separate multicentre data extracts were obtained from the National Ophthalmology Database (NOD). The initial extract included $\approx$ 180,000 cataract surgery records, the second $\approx$ 600,000 and the third $\approx$ 1M operation records. Based on the first extract, two key cataract surgery adverse outcomes were modelled by logistic regression: operative posterior capsular rupture (PCR) of the lens and visual acuity (VA) loss in the surgical eye. Based on the second extract, updated models were derived, assessing stability of the PCR model through time and producing specific outcomes for the subgroup of patients aged $\geq$ 90 years. Based on the third extract, indicators of post-operative refractive outcome (spectacle requirement) were generated using a complex-numbers approach.

Work package 3

Quantitative: predictor models of self-reported outcomes

A cohort study with a target sample of 1500 people undergoing cataract surgery in Bristol and Gloucestershire was undertaken to phenotype participants for identification of pre-operative indicators of post-operative outcome. Logistic regression models were developed for both the self-reported Cat-PROM5 post-operative outcome and improvement from pre-operative baseline, each based on pre-operative parameters.

Qualitative: cataract surgery patient information, decision-making, a cataract decision aid and a cataract decision quality measure

Two focus groups and 15 semistructured interviews investigated patient and clinician views on aspects of cataract surgery decision-making at two centres.

The International Patient Decision Aid Standards Collaboration Checklist for the development and quality assessment of patient decision aids was used to guide the development of the CDA using an iterative, collaborative, multistage process, involving a user reference group of 16 key stakeholders and the Patient Advisory Group of five patients, followed by qualitative user testing interviews with a further 20 patients and six clinicians. A CDQM was developed as a trial outcome, drawing on experience from other clinical areas.

Health economic: performance of health utilities and calibration of Cat-PROM5

The Cat-PROM5 and ICECAP-O data were collected from 1181 cohort study participants, with collection of the other three health economic utilities (the EQ-5D-3L, EQ-5D-3L+VIS and EQ-5D-5L) on a 1 : 1 : 1 random allocation basis. Descriptive statistics, linear models and adjusted limited dependent variable mixture models were produced to calibrate utilities with Cat-PROM5. Separate models were estimated for pre- and post-operative Cat-PROM5 completions.

Work package 4

Quantitative: feasibility of a cataract decision aid randomised controlled trial

A two-arm feasibility RCT with a target sample of 40 participants was undertaken, with the CDQM being the primary outcome. Data from participants were used to validate the Cat-PROM5 benefits prediction models, derived in WP3, by comparing model predictions with self-reported parameters.

Qualitative: cataract decision aid, shared decision-making and mismatching outcomes

Perceptions of the intervention were investigated through analysis of anonymised recordings of 42 consultations in the feasibility trial, augmented by interviews with 15 patients and six clinicians.

Mismatching or discordant perceptions of outcome between patients and clinicians were investigated through thematic analysis of interviews with seven patients and nine HCPs.

Health economic

The additional resources incurred from implementation of the CDA compared with standard care in the feasibility trial were assessed based on appointment time costs obtained from the Personal Social Services Research Unit (PSSRU) and the cost per minute of clinician time.

Qualitative: immediately sequential bilateral cataract surgery

A thematic analysis of a meeting of 29 stakeholders exploring the ethical perspectives of immediately sequential bilateral cataract surgery (both eyes at 'one sitting') was undertaken.

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Results

Work package 1: Cat-PROM5 performance

A brief, psychometrically robust questionnaire was developed that performed as well as, or better than, the previous, 'best-of-class', longer nine-item alternative. The Cat-PROM5 questionnaire has excellent reliability (Rasch 0.9, person separation 2.98, low differential item functioning, Cronbach alpha 0.89), validity (strong correlation with existing measure, $R = 0.85$), repeatability (Rasch scale intraclass correlation coefficient 0.89) and responsiveness to surgery (baseline Cohen delta −1.45); it is unidimensional (infit–outfit 0.84–1.14, residual eigenvalues ≤ 1.5) and flexible, allowing patients to map their personal visual difficulties to the questions. With only five questions, it is sufficiently brief to make it feasible to implement in routine, high-volume cataract surgical services.

Work package 2: outcome models

Based on the initial anonymised data extract of 180,000 operations, logistic regression models for adverse outcomes had reasonable fit and were broadly similar to those we previously published (*C*-statistic for PCR 0.64; VA loss 0.71).

For PCR model stability, logistic regression analyses using an updated sample of 600,000 operations (*C*-statistics approximately 0.60) over a 10-year period from 2005 to 2014 indicated stability from 2005 to 2011; 2012 was an atypical year, and 2013 and 2014 were comparable.

The outcomes of 25,856 cataract operations undertaken between 2000 and 2014 in 19,166 people aged ≥ 90 years were analysed separately. PCR occurred in 2.7% of these operations. Post-operative VA was available for 61.8% of eyes, with VA being good enough to drive (6/12) in 74.4% overall, and reaching this level in 84.7% for those without visually significant comorbidity.

A refractive outcome analysis using complex numbers was undertaken on a further updated sample of 1,070,601 operations, with a refraction result available for 491,414 of these. Ocular comorbidities did not impact the refractive outcome to a clinically important extent, but the complex-numbers methodology revealed a greater spread of refractive outcomes than expected.

Work package 3: benefits prediction models, cataract decision aid presentation and content, and health economic utilities performance and mapping

The regression models for the Cat-PROM5 post-operative final outcome achieved moderate fit, with an R^2 of 29.1%; for improvement from pre to post operation the model had an R^2 of 31.2%. The models comprise data items that are readily accessible in the context of patient care.

The patient-preferred risk and benefit information presentation was '*n* out of 100 individuals' affected. Despite SDM being performed variably, Cat-PROM5 was generally viewed as being positive for SDM. Concerns were expressed regarding the clinician time needed.

These insights informed the iterative development of the CDA intervention by the user reference group of professionals and patients. Based on the modelling, personalised risk and benefit information was included for adverse outcomes and self-reported benefit. The prototype CDA was further refined by testing the usability, acceptability, utility and expected impact with patients and clinicians.

For health economic utilities 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. The EQ-5D-3L+VIS had a lower ceiling effect and better convergent validity with Cat-PROM5. The ICECAP-O also had a low ceiling effect, with some evidence of convergent validity with Cat-PROM5.

For health economic calibration/mapping, the adjusted limited dependent variable mixture models dominated linear models on all criteria. Separate pre- and post-mixture models offered good to excellent fit. Three component models, including sex, age and diabetic status, had superior performance (EQ-5D-5L and ICECAP-O root-mean-square errors 0.10–0.16).

Work package 4: randomised controlled trial feasibility, perceptions and costs of the cataract decision aid for shared decision-making, discordant outcomes and bilateral surgery

Of the 145 potentially eligible patients for the RCT feasibility study, 47 were recruited and attended an initial visit. Of these, one withdrew and three were clinically ineligible for surgery. A total of 43 patients were randomised, one of whom subsequently became clinically ineligible, leaving 42 patients across three centres. At the baseline visit, two patients failed to attend. Of the 40 patients who were followed up post operation, 15 participated in the qualitative substudy interviews.

Sample sizes for a fully powered trial were estimated. For independent groups, a small effect size (0.2 standard deviations) would be detectable at 80% power with 800 participants (400 per group), and a medium effect size (0.5 standard deviations) at 90% power with 200 participants (100 per group).

Regarding the choice of prediction model for a future trial, the performance of the prediction model for the final Cat-PROM5 post-operative outcome was superior to the model for pre- to post-operative change in score and would be the preferable model for a future trial.

Observer OPTION 5 Scores revealed clinicians' use of the CDA with patients resulted in more SDM behaviours. However, the key SDM tasks of introducing the choice and eliciting patient's preferences were not always carried out. Many patients had already decided that they wanted the surgery and consultants did not always perceive the choices of 'surgery, delay or decline' as useful. The CDA was effective at providing information to patients about their options, including their personalised risk, but did little to support the introduction of choice or elicitation of preferences. Overall, clinicians felt that, with some changes, the CDA could be integrated into routine clinical settings and form part of a larger trial.

As expected, the identification of patients with discordant outcomes was difficult as these are uncommon events. However, interviews with seven patients and nine HCPs revealed some insights. In most patients' experience, discordance was the result of unexpected changes in visual ability after surgery, highlighting the nuanced and multidimensional 'lived experience' of vision. Factors linked to medical practice were primarily the technologies used. Clinicians and patients believed there was a need for a more personalised approach to SDM on lens choice and refractive aims, and to address patient preferences and expectations and realign these with a more realistic understanding of the potential outcome. The barriers to changing practice included established ways of working and available time for in-depth personalised conversations with patients.

Based on the time taken for consultations in the two arms and additional data collected for the intervention arm, it was possible to collect relevant information to inform a costs analysis.

The pivotal issue under consideration in immediately sequential bilateral cataract surgery is the very low, but unquantifiable, risk of bilateral blindness from surgery with complications if undertaken on 'both eyes at the same sitting', versus patient convenience and service efficiency. Three overarching themes relating to the pros and cons of this were identified and divided into eight subthemes. The themes included beneficence and non-maleficence, autonomy, and distributive justice. The stakeholders concluded that a bilateral procedure was an ethical undertaking, provided patient autonomy was appropriately considered.

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Conclusions

- A brief, NHS-implementable, psychometrically robust cataract patient-reported outcome measure (PROM), named Cat-PROM5, was developed to capture visual difficulty due to cataracts and relief through surgery.
- Indicators of cataract surgery adverse outcomes and self-reported benefits were identified, statistically modelled and validated.
- A CDA was developed and refined.
- Health economic work evaluated the performance of established and emerging utilities in cataract surgery and these utilities were mapped to the Cat-PROM5 instrument.
- The feasibility RCT indicated that a future, medium-sized trial would be feasible, with minor refinements of instrumentation.
- Qualitative investigation of discordant or mismatching outcomes highlighted themes relating to patient expectations of surgery and lack of available clinician time for full explanations of the visual changes following surgery.

Implications for clinical practice and services

- Implementable instrumentation for structured measurement of the patient's view of their visual difficulty for both pre-operative assessment and post-operative outcome assessment was developed and is available for use in clinical services.
- Better communication between clinical staff and patients underpins patients having more realistic expectations of surgery.
- Utilising patient-centred metrics could facilitate improved SDM, with clinical tools for individualised estimates of likely self-reported benefits and adverse outcomes enhancing discussion and informing consent.
- The Cataract National Audit has piloted the use of Cat-PROM5 as a patient-focused outcome and intends to develop this further, thus incorporating the patient's voice in outcomes reporting. In the interests of gathering Cat-PROM5 data, both of the specialty-specific ophthalmology electronic medical record system providers of the NHS are developing enhanced functionality for collection of the required data.
- Acceptably low rates of both adverse surgical events and adverse visual outcomes have been found in the very elderly.
- Where there are surgical backlogs arising from the COVID-19 pandemic, we understand that:
    - A number of services are using Cat-PROM5 to prioritise early surgery for those whose self-reported vision is worst affected.
    - The question of operating on both eyes at a single sitting has taken on fresh relevance.

Research recommendations

- A fully powered RCT of the CDA with personalised risk and potential benefit estimates would clarify its potential role in routine care (subject to further refinements of the CDQM outcome measure and earlier use of the intervention in the patient pathway).
- Regular review and update of the risk models for adverse outcomes would ensure currency as these are used to adjust centre and surgeon results for case complexity in national audits.
- The Cat-PROM5 prediction models would benefit from further validation to better understand their performance.
- The technical precision of complex-numbers analysis of the refractive outcome invites opportunities to investigate causes of the spread of refractive outcomes with improvements in the achievement of post-operative spectacle-free vision in mind.
- Further research is needed to clarify the role of surgery on 'both eyes at a single sitting' in terms of safety. Damage to the vision of or even blindness in both eyes owing to, for example, contaminated fluids or infection is a potentially devastating outcome that could follow such bilateral surgery.

Trial registration

This trial is registered as ISRCTN11309852.

Ethics statement

Ethics approval was obtained for all relevant sections of this report.

Funding

This research programme was funded by the National Institute for Health and Care Research (NIHR) Programme Grants for Applied Research and will be published in full in *Programme Grants for Applied Research*; Vol. 10, No. 9. See the NIHR Journals Library website for further project information.

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SYNOPSIS

Background

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 the National Institute for Health and Care Excellence (NICE).[3] For individuals affected by a gradual onset and progression of visual difficulty from cataracts, 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 is evidence of unmet need and local variation in how referrals for cataract surgery were processed.[2] There are inevitable risks associated with the procedure, and these need to be considered in the context of visual requirements, visual difficulty and potential to benefit. Standard pre-operative assessment for cataract surgery currently relies heavily on measurement of visual acuity (VA),[3] a test conducted one eye at a time, in a darkened space, with self-reported visual difficulty all too frequently receiving secondary consideration at best.

Programme structure and interlinkage of work packages

The cataract research programme consisted of four interlinking mixed-methodology work packages (WPs) (*Figure 1*), with work from each WP feeding forward to contribute to and inform subsequent elements. The overarching theme throughout the programme was the development and assessment of clinical tools intended to support and enhance pre-operative decision-making by patients considering cataract surgery and health-care professionals (HCPs) delivering their care.

Work package 1 comprised the development, assessment and validation of a psychometrically robust cataract patient-reported outcome measure (PROM) for the measurement of visual difficulty from cataracts and its relief from surgical intervention. The resultant self-reported measure, Cataract Patient-Reported Outcome Measure, five items (Cat-PROM5), was taken forward to WP3, in which prediction models for the Cat-PROM5 outcome were developed to predict the likely patient self-reported post-surgery benefit. Occasionally, surgery can have adverse outcomes that are of importance to patients and HCPs. In WP2, existing prediction models for established adverse outcomes were reassessed on fresh, routinely collected NHS electronic medical record data for two important adverse outcomes: an intraoperative complication [posterior capsule rupture (PCR)] and VA loss affecting the eye that was operated on following surgery.

Using questionnaire data collected in WP3, a parallel health economics mapping exercise was undertaken to translate the Cat-PROM5 scores into established health economic utilities, thus facilitating future health economics research in cataract studies through reducing questionnaire burden on study participants. Qualitative work elements ran through each of the WPs to gain a rounded picture of the preferred formats for the development of clinical tools based on outputs of the prediction models and the information requirements of both patients and HCPs. Through this approach, a cataract decision aid (CDA) was developed, providing patients and HCPs with relevant information on cataracts and cataract surgery, including personalised predictions of both the likely post-operative self-reported visual benefit and possible adverse outcomes. In WP4, we assessed the feasibility of a future fully powered randomised controlled trial (RCT) with the CDA as an intervention.

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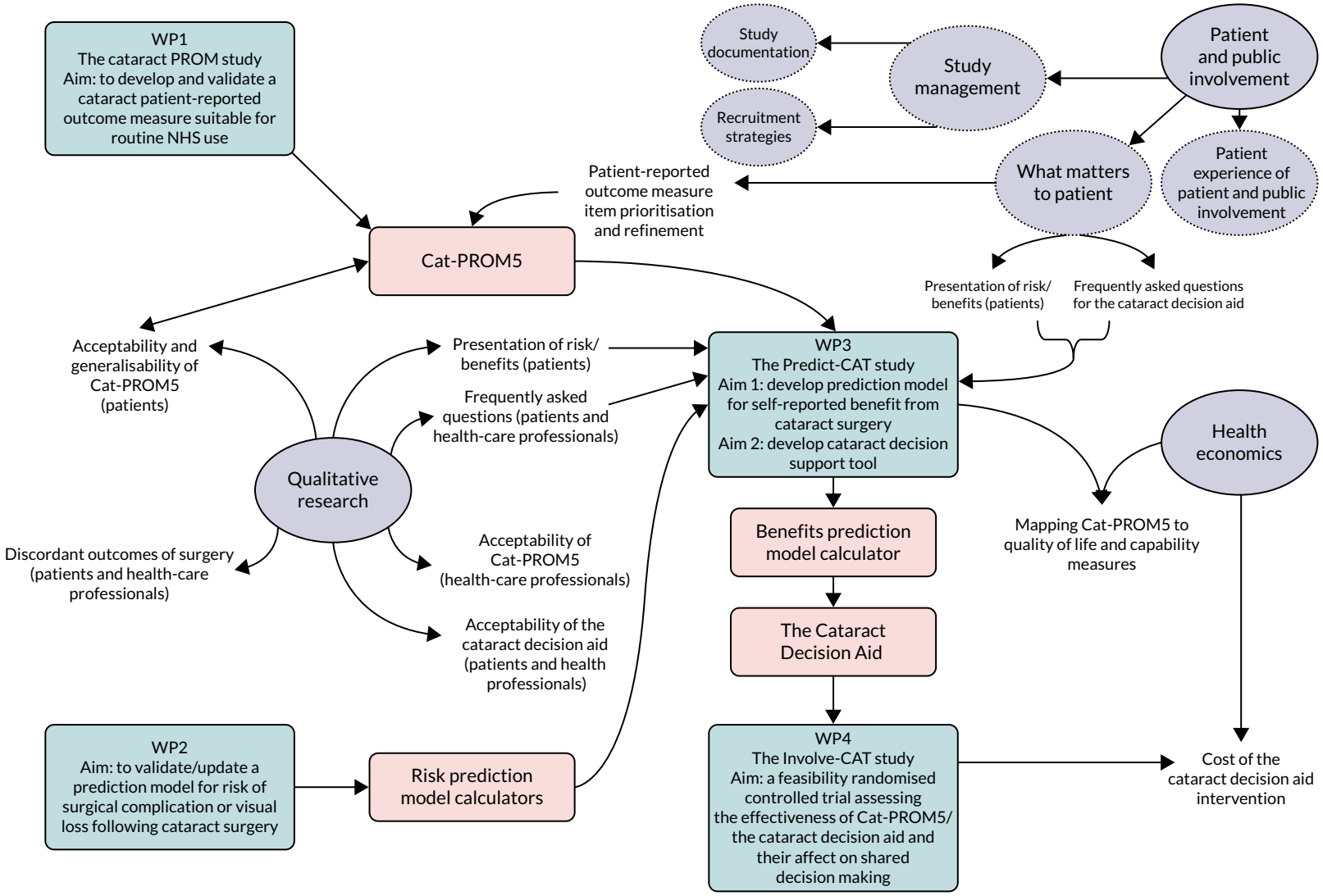

FIGURE 1 Research pathway diagram. Cat-PROM5, Cataract Patient-Reported Outcome Measure, five items; PROM, patient-reported outcome measure.

In addition to the four main WPs, a number of additional studies were opportunistically undertaken and these have provided 'added value' to the cataract research programme overall.

Patient and public involvement

The cataract research programme was supported by a Patient and Public Involvement (PPI) Patient Advisory Group (PAG) throughout the programme, from the grant development stage through to programme completion, with group sessions and comments from group members contributing positively and successfully to many aspects of the work.

The lead applicant established the PAG at the pre-application stage. The initial 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. Therefore, the patients were experts on their own experience, could meaningfully contribute their personal thoughts and understanding of their visual abilities and difficulties, and were ideally placed to advise the management team on a wide range of themes related 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.

Professor David Evans, who previously led People in Health West of England,[4] was the chairperson of the PAG, which met twice a year at the Bristol Eye Hospital ($n = 10$ meetings in total). At the inaugural meeting, 'ground rules' were established, with the aim of fostering a positive and supportive informal 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.

The PAG members who were unable to attend the meetings were invited to contribute remotely if they were able to and, between meetings, contributions were gathered from members by e-mail, over the telephone or by post, depending on their preferences and on the task involved. Where relevant, documents were shared prior to each meeting to allow members to have time to become familiar with the content and the 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 ethics 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 the font, layout, length and some of the wording to improve plain English.
    - PAG members suggested improvements to the promotional materials of the cohort study (named Predict-CAT) to promote 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 refer themselves to the study team. This improved the recruitment rate of the Predict-CAT study and contributed 15% of the overall participants.

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- Questionnaire item reduction
    - During the development cycles of the cataract PROM questionnaire, the PAG were invited to take part in a group exercise to help guide decisions on the relative priority of questions being considered for the final version of the Cat-PROM5 questionnaire (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 the theme or domain to which they thought the question related.

- Qualitative discussion
    - Members of the PAG were invited by e-mail to make comments on the drafted topic guides for the qualitative Predict-CAT substudy (Predict-CAT-Qual), specifically on whether or not the proposed questions were understandable.
    - The group were invited to discuss the acceptability of the presentation of risk during a face-to-face meeting.
    - Prior to the commencement of focus groups with study participants, and led by Christalla Pithara, PAG members discussed their experiences and thoughts on shared decision-making (SDM) and the use of decision aids. PAG members were also asked to comment on the type of information that is important for patients to receive in advance of their operation to inform the 'mismatching outcomes' element of the qualitative work.
    - Led by Natalie Joseph-Williams and Daniella Holland-Hart, the PAG members took part in a focus group that focused on the question of what matters to patients when deciding to have surgery [to inform the development of the frequently asked questions (FAQs) section of the CDA] and also provided feedback on the drafting of the CDA.

- 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,[5] patient members demonstrated their experience across four dimensions related to their perception of their involvement in research. The analysis of this exercise is under way at the time of writing and it is planned to share the findings of this and the group discussion at a later date. The programme team feel that the duration of PAG membership and the number of meetings that were held provided a unique experience and opportunity to elucidate what does and does not work well in PPI within ophthalmology services and, therefore, the team are of the view that 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 Vision Core Measure 1 (VCM1)[6] and Visual Symptoms and Quality of life questionnaire (VSQ),[7] which together formed the basis of Cat-PROM5 development, used patient interviews to identify themes and issues relevant to patients (with the VCM1 consulting visually impaired patients and the VSQ consulting cataract patients).
- A former patient of the Bristol Eye Hospital Cataract Care Service sits on the Programme Steering Committee and provided expert commentary, knowledge and guidance from a user perspective throughout the programme.
- A patient representative also sat on the User Reference Group (URG), which was established to discuss the developing versions of the CDA.

Work package 1: development of Cat-PROM5, a brief cataract patient-reported outcome measure

Aims

- To develop a short, psychometrically robust and responsive cataract PROM questionnaire measuring the construct 'visual difficulty related to cataract', which is suitable for use in high-volume surgical environments.
- To compare and contrast the newly developed PROM with the current 'best-of-class' instrument that is 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[6] and the VSQ[7] PROMs. Under the construct 'visual difficulty due to cataract', 21 questions were reoperationalised into the first developmental version of the questionnaire. Three 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 five questions was confirmed in the final cycle of independent data collection and analysis. Following confirmation of the psychometric performance of the five-item set, its performance was also compared in a head-to-head study with the existing, longer, 'best-of-class' 9-item questionnaire, the Cataract questionnaire 9-item Short Form (Catquest-9SF).[8,9] In a separate qualitative exercise, the final item set was evaluated in a group of patients that included people who had cataracts and other ocular comorbidities.

Data collection

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

The inclusion criteria were being aged $\geq$ 50 years, the ability to understand and complete development versions of the Cataract PROM and Catquest-9SF in English, and the willingness to participate and to provide informed consent. The exclusion criterion was visually significant ocular or systemic comorbidity.

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

Data analysis

Rasch analysis was the primary analytical method used,[10–12] supported by supplementary analyses. Among the many advantages of Rasch analysis are that it allows for the selection of unidimensional questions (items) that together measure an underlying latent trait (here, difficulty with vision due to cataracts),

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it assesses the performance of the individual items (disordering, 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. Supplementary analyses included principal components analysis and confirmatory factor analysis.[11,13–17]

Data were collected by participants completing developmental versions of the new Cataract PROM questionnaire, as well as the established Catquest-9SF for purposes of comparison.

Cataract patient-reported outcome measure development

Analysis of the 200 'cycle 0' completions resulted in the removal of 10 items based on a range of statistical techniques, including sequential Rasch (partial credit model) analyses (items were excluded if they had disordered thresholds, poor fit or category-average disordering, and the worse-performing item of an intentionally included pair of duplicate questions was excluded), principal components analysis and confirmatory factor analysis.

The resulting unidimensional 11-item set was taken forward to a development cycle, 'cycle 1', in which 316 patients completed questionnaires at both pre- and post-operative time points. Preliminary analysis revealed that the selection of fewer than five items resulted in a consistent and significant drop in psychometric performance (Rasch reliability) and it was decided to aim for a five-item final set. The two best performing items were selected for inclusion, followed by a systematic search for the 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 PPI PAG] and expert opinion, the remaining three items were chosen.

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

Comparison with Cataract questionnaire 9-item Short Form

Psychometric Rasch analysis confirmed that the five-item set performed at least as well or better than the previous, longer and more restrictive 'best-of-class' instrument, the Catquest-9SF.[18]

Qualitative element

A qualitative study on a separate small group of patients explored the face-validity and acceptability of both the Cat-PROM5 and Catquest-9SF questionnaires.[18,19] In this group, participants included people with visually significant comorbidities. Semistructured face-to-face interviews were guided by an interview schedule or topic guide, with new points added as analysis progressed to enable the exploration of emerging themes.[20] Transcribed data were coded using standard software for the collation, storage, analysis and management of qualitative data (NVivo; QSR International, Warrington, UK), and analysed using techniques of constant comparison derived from grounded theory methodology.[21,22] Emerging themes and codes in transcripts and across the data set were then compared to look for shared or disparate views among participants.[23] Data collection and analysis continued until the point of data saturation.

A total of 16 interviews were conducted with nine men and seven women: 11 of the patients were awaiting their cataract surgery and five had recently undergone surgery. Thirteen participants had other visual comorbidities. Overall, participants found both questionnaires acceptable, although patients with severe visual comorbidities noted that it was difficult to separate how the cataract and

their other conditions affected their quality of life. Most participants preferred the large-font format of Cat-PROM5. Some participants preferred questions with more response options, as in Cat-PROM5, whereas others preferred fewer response options, as in the Catquest-9SF. The specific scenarios of the Catquest-9SF created some uncertainty for those whose 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. By contrast, Cat-PROM5 enabled them to determine the individual vision-related factors that they perceived to be important and to respond to the questions easily.

Limitations

To develop Cat-PROM5 as an instrument that is specific to cataract-related visual difficulty, 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 within work package 3 that included people with visually significant comorbidities).

Key findings

A brief, psychometrically robust questionnaire was developed that performed at least as well or better than the previous, longer, 'best-of-class' alternative. The Cat-PROM5 questionnaire has excellent reliability (Rasch 0.9, person separation 2.98, low differential item functioning, Cronbach alpha 0.89), is unidimensional (infit–outfit 0.84–1.14, residual eigenvalues ≤ 1.5), is valid (strong correlation with existing longer measure, $R = 0.85$), is repeatable (Rasch scale intraclass correlation coefficient 0.89) and is responsive to surgery (baseline to follow-up Cohen delta −1.45). 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 Cat-PROM5 questionnaire is available for download as a supplementary online form at https://static-content.springer.com/esm/art%3A10.1038%2Feye.2018.1/MediaObjects/41433_2018_BFeye20181_MOESM134_ESM.pdf

Relationship with other work packages

Cat-PROM5 was established as the Cataract PROM for the programme and was taken forward to WP3, Predict-CAT (the development of benefits prediction models, presentation of risk information and development of a CDA), and WP4, the feasibility study for a future RCT (named Involve-CAT), as the measure of self-reported benefit.

Further information

Full details on the development of Cat-PROM5 have been published and are available as open access papers.[18,19]

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Work package 2: cataract surgery risk models for posterior capsule rupture and visual acuity loss

Aim

To validate or update existing risk models for PCR and monocular harm using multicentre data from 180,000 electronic medical records (EMRs) for cataract surgery.

Approach

We modelled two key outcomes that are of importance in cataract surgery. These are the two primary safety outcomes used in the National Ophthalmology Database (NOD) audit.[1]

Posterior capsular rupture is defined, for the purposes of the National Cataract Audit, as 'posterior capsule rupture with or without vitreous prolapse or zonule rupture with vitreous prolapse' and abbreviated as PCR.[24] It should be noted that the definition excludes zonule dehiscence where no vitreous prolapse has occurred. PCR is the most frequently arising intraoperative complication and is reported for 1.1% of operations in the National Audit; the next most frequently reported specific complication is recorded as arising in just 0.3% of operations.[24] When PCR, as defined above, occurs, there is an approximately sixfold-increased risk of vision loss, an approximately 40-fold-increased risk of post-cataract retinal detachment and an approximately eightfold-increased risk of endophthalmitis (serious post-operative infection in the eye).[25] PCR is regarded by NICE as an adverse and harmful event in cataract surgery[3] and is a key safety outcome in the National Cataract Audit, and avoidance of PCR has high validity with surgeons.[24]

Visual acuity loss in the eye undergoing surgery refers to vision that is significantly worse after the operation than it was before, as measured using the sight test letter reading chart. VA loss arises in 0.5% of operations and is the second key National Cataract Audit safety outcome, in which it is defined as a doubling (or worse) of the visual angle.[24]

Data collection

Multicentre data were obtained from the NOD[1] through a data-sharing agreement with the data controller, the Health Quality Improvement Partnership (HQIP). The data consisted of the patients' electronic medical records and covered cataract surgery undertaken by participating centres between 2006 and 2010. The anonymised sample consisted of 180,114 eyes from 127,685 patients (see *Report Supplementary Material 1* for further details of outcomes, exposures and distributions).

Data analysis

Known and suspected candidate predictors for PCR and VA loss were evaluated using a logistic regression analysis.

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Posterior capsule rupture

Posterior capsule rupture data were complete. In this sample, PCR arose in 3514 out of 180,114 (1.95%) eyes.

Visual acuity loss

There were some missing VA data. Of the 180,114 eyes in the sample, 147,962 had pre-operative VA readings. For 104,437 (70.6%) eyes, these were corrected VA readings; for 43,525 (29.4%) eyes, these were uncorrected readings. A further 1591 eyes had pre-operative pinhole readings only, but these were not used in this analysis. Of the 180,114 eyes in the sample, 116,038 had post-operative VA readings. For 74,887 (64.5%) eyes, these were corrected VA readings; for 28,678 (24.7%) eyes, these were uncorrected VA readings; and for 12,473 (10.8%) eyes, these were pinhole VA readings, which were accepted post operation. Of the 147,962 eyes with pre-operative VA readings, 95,561 (64.6%) had post-operative VA readings. For 60,578 (63.4%) eyes, they were corrected VA readings; for 24,460 (25.6%), they were uncorrected VA readings; and for 10,523 (11.0%), they were pinhole VA readings. In this sample of operations, undertaken between 2006 and 2010, the VA of 1455 out of 95,561 (1.52%) eyes deteriorated after cataract surgery, a proportion which has significantly reduced since these (early) data were collected.[24]

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). Having established the logistic regression model, the model statistics were reported (see *Report Supplementary Material 1*).

Key findings

Posterior capsule rupture

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 receiver operating characteristic (ROC) curve (*C*-stat) for this model was 0.64, indicating fair fit.

Visual acuity loss

The following variables entered into/remained in the logistic regression model: PCR, age, axial length, pupil size, gender and the following copathologies; 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 undertaken before and up to 2006,[26] suggesting that the models were reasonably stable prior to 2010.

Limitations

Overall, the main limitation of this work was the fact that the data that was obtained related to surgery undertaken between 2006 and 2010. In addition, some VA data were missing, with only 64.6% of eye operations having both a pre- and a post-operative VA measurement available for calculation of the VA loss measure.

Electronic patient data are recorded by clinical staff, including surgeons, and it is possible that not all adverse outcomes (PCR and VA) were accurately recorded.

To address the limitation of these surgeries being from a relatively early cohort of operations, fresh data were requested from the NOD through an updated 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.

Relationship with other work packages

Based on these approaches, calculators estimating the risk of PCR and VA loss were taken forward to WP3 for the determination of patients' preferred mode of presenting risk information and the identification of patients' concerns for the FAQs and development of the CDA. The CDA was subsequently tested in the WP4 feasibility RCT.

Added value: posterior capsule rupture model stability through time

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

Multicentre data were obtained from NOD[1] 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

Three approaches to candidate risk predictor selection for model building were used: (1) a clinically sound list of predictors; (2) the χ^2 p-value of < 0.10 was used for predictors to exclude those that, from the outset, appeared unlikely to be statistically important; and (3) a univariate effect size (ES) satisfying $0.9 >$ odds ratio (OR) > 1.20 was used to exclude small, and therefore clinically unimportant, effects.

Following these analyses, stability through time was considered. Early years were excluded, as the sample sizes were smaller and the number of 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 logistic regression model stability through time. The models derived from the three options for initial selection of candidate predictors were applied to each year separately, and were assessed for stability across the 10 years.

Key findings

The three candidate predictor selection options resulted in slightly different lists of predictors, indicating that the method of selection of candidate predictors (clinically sound, or χ^2 $p < 0.1$, or $0.9 >$ OR > 1.20) was important. Model fit was fair to moderate for all of the models, with *C*-statistics near or slightly above 0.6.

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The models, which were derived using the full set of data, were applied to each of the years separately and parameters examined for stability across the years. For a number of variables, statistical significance was not consistently achieved within years. Overall, for all of the initial candidate selection options, the models were stable for the period 2005–11. The year 2012 was an atypical year, not being consistent with earlier or later periods, whereas 2013 and 2014 were comparable.

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

Limitations

The data used in these analyses are ageing, 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 provided key information about the stability of the PCR risk model and the model-based risk calculator used in the CDA (WP4).

The wider implications of these findings include confirmation that the risk model, although stable across certain periods, is prone to shifts; this emphasises the need to review and revise the models that are being used in national audits to adjust for case complexity of centres and surgeons (see *Report Supplementary Material 2*).

Added value: cataract outcomes in people aged ≥ 90 years

Aim

To report operative complications (PCR) and VA outcomes for cataract surgery in people aged ≥ 90 years.

Approach

We performed an 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 in *Data collection*) was undertaken. We analysed the outcomes of 25,856 cataract operations undertaken in 19,166 people aged ≥ 90 years between the years 2000 and 2014.[27]

Key findings

A significant operative complication (PCR) occurred in 2.7% of all operations. Although this is higher than the rate found among younger patients, the surgical risk remains relatively low.[24]

Post-operative VA was available for 61.8% of eyes, with VA being good enough for the patient to drive (Snellen VA 6/12) in 74.4% overall, and 84.7% reaching this level out of those without a visually significant comorbidity.

Limitations

The main limitation of this study was the reduced proportion of patients with a post-operative VA recording.

Relationship with other work packages

This work was a standalone substudy offering added value to the programme overall.

This 'added value' analysis has been published.[27]

Added value: refractive outcomes of cataract surgery

Post-operative refraction (spectacle requirement) is determined by the 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.

Aim

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

Approach

The measurement of refraction consists of three variables (sphere, cylinder and axis), which makes the analysis and reporting of refraction problematic; 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.[28] 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 that, crucially, does not approximate or discard any of the information in the refractive result.

Data collection and analysis

A fresh third set of electronic medical record data was obtained from the NOD through an updated data-sharing agreement with HQIP. Data on 1,070,601 cataract operations were received. The primary refractive outcome of interest was available for 491,414 of these operations. The primary outcome was trivariate and was modelled using a multivariate, normal, multilevel model and four multilevel structures.[29]

Key findings

Despite the methodological complexity of the analytical approach, it was feasible to apply the method to refractive outcome data and rigorously model indicators of post-operative refraction. Analysis revealed that ocular comorbidities did not impact refractive outcome to a clinically important extent, but the complex-numbers methodology revealed a greater spread of refractive outcomes than expected. 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 of the information required for the analysis, potentially reducing the generalisability of the results. However, the purpose of the analysis was to demonstrate feasibility through a proof-of-concept analysis, which was achieved.

Relationship with other work packages

This analysis is a standalone item with regard to the other WPs, but post-operative refraction is highly relevant to patients' post-operative 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 (see *Work package 4, Qualitative element 2: mismatching outcomes*).

Further information

- *Report Supplementary Material 1* provides additional detail on the logistic regression analyses that were undertaken, based on 180,000 cataract procedures.
- *Report Supplementary Material 2* provides 'added value' to the programme through an analysis of the stability through time of the risk models, based on 600,000 cataract procedures.

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- *Report Supplementary Material 3* provides 'added value' to the programme through an analysis of outcomes for people aged ≥ 90 years, based on 25,000 cataract procedures.
- 'Added value' is provided to the programme through an analysis of indicators of refractive outcomes, using a novel approach to analysis of refraction data, based on a subgroup of 491,414 operations for which relevant pre- and post-operative refractive data were available.

Work package 3: Predict-CAT and the development of a cataract decision aid and cataract decision quality measure

Quantitative elements: the Predict-CAT cohort study

Aim

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

Approach

We conducted a cohort study of 1500 people undergoing cataract surgery to phenotype the participants, with a view to identify pre-operative indicators of post-operative self-reported benefit from surgery in terms of final post-operative outcome and improvement from pre-operative baseline.

Data collection

The cohort study took place at two sites: Bristol and Gloucestershire. Pre-operative patients approaching cataract surgery were invited to participate. The inclusion criteria were aged ≥ 50 years; approaching either first- or second-eye cataract surgery; willingness to participate and provide informed consent; and the ability to understand and complete the Cat-PROM5, EuroQol-5 Dimensions, three-level version, (EQ-5D-3L), EuroQol-5 Dimensions, three-level version, with vision 'bolt-on' domain (EQ-5D-3L+VIS), EuroQol-5 Dimensions, five-level version (EQ-5D-5L) and ICEpop CAPability measure for Older people (ICECAP-O) questionnaire instruments as required. Following recovery, postal questionnaire completions were made between 6 and 8 weeks after surgery. Full recruitment of 1506 participants was achieved, with 1204 patients recruited in Bristol and 302 in Gloucestershire. It is noteworthy that encouragement from our Patient Advisory Group to introduce a self-referral option resulted in 15% of Bristol's recruitment through this route. Following withdrawals, losses to follow-up and data cleaning, 1181 participants had complete data for analysis (*Figure 2*).

Data analysis

Among the 1181 participants with valid data, scattered missing data items remained. To preserve the sample from further attrition, these missing data items were imputed using multivariate imputation by chained equations (MICE) in which 20 data sets were created with missing data replaced by imputed values, each entailing 10 cycles of regression switching. This method relies on the missing at random (MAR) assumption. In parallel with the multiple imputation analyses, complete-case analyses were also undertaken (with missing values ignored). The complete-case analyses were based on 1089 complete cases.

Initial descriptive analyses of candidate predictor and outcome variables were undertaken, followed by linear regression modelling of two Cat-PROM5 Rasch-calibrated outcome variables. The final outcome was modelled in two forms: first, as the post-operative score and, second, as the improvement from baseline (the difference between the pre- and post-operative scores = delta approach). Potential predictors were categorised into blocks according to timeline order, from 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, variables were entered into the model in ordered blocks and an *F*-test was performed for each block as a whole. If the *p*-value for the block was > 0.05 then the whole block was rejected. If the *p*-value of the test for the block was < 0.05, the specific predictors were examined and

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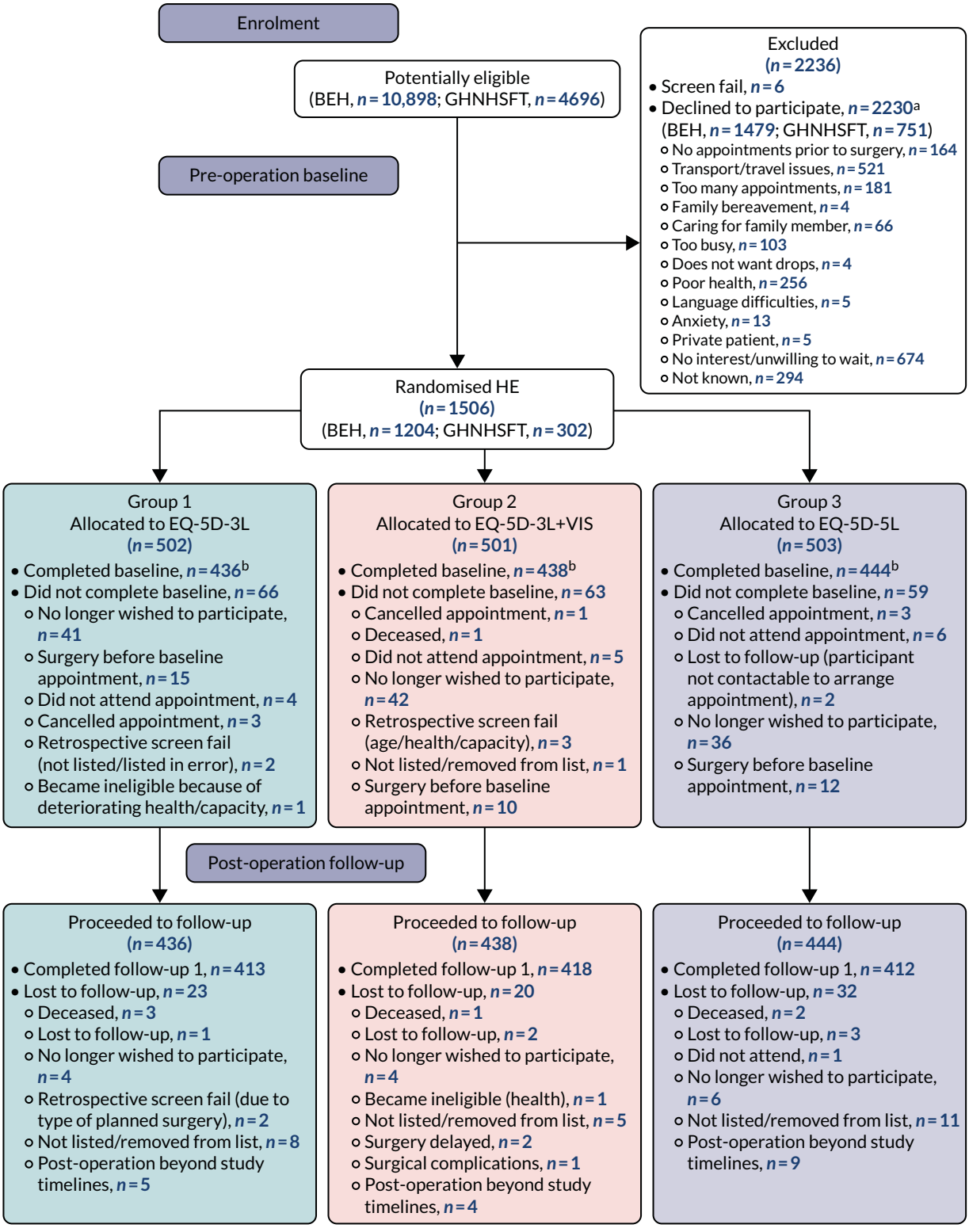

FIGURE 2 The Predict-CAT flow diagram. a, Some people gave more than one reason; b, the number analysed varies between reports because of data completeness. BEH, Bristol Eye Hospital; GHNHSFT, Gloucestershire Hospitals NHS Foundation Trust; HE, health economics questionnaire.

those with small effects were iteratively removed. After each stage, all of the predictors were reviewed by an experienced ophthalmologist for whether the list and the model made clinical sense, and predictors without plausible clinical meaning were removed. Following model construction, the model diagnostics were checked and acted on if necessary. (See *Report Supplementary Material 4* for further details.)

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 the Cat-PROM5 post-operative final outcome achieved an R^2 of 29.1%; for improvement in Cat-PROM5 from pre to post operation, the models achieved an R^2 of 31.2%. The final models with and without imputation, together with model diagnostics, are available in *Report Supplementary Material 4*.

Key findings

Full recruitment to the cohort study was achieved. The losses to follow-up were below the level of 20% for which we had planned. Some further losses arose because of 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 that are readily accessible in the context of patient care. The only indicator that is not routinely collected in pre-operative 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 $R^2 \approx 0.30$.

Although the two chosen analytical approaches produced very similar models, it is possible that data were not missing at random, which may have introduced bias in the results based on multiple imputation.

The performance of these models was further assessed using fresh data in WP4.

Relationship with other work packages

The self-reported benefits prediction models were set alongside the models predicting adverse outcome risk from WP2, with all of these models taken forward into the CDA developed in WP3, qualitative element 2. The CDA was, in turn, taken forward to the WP4 feasibility RCT.

Qualitative element 1: Predict-CAT-Qual – presentation, content and perceptions of usefulness of information for cataract patients

Aims

- To identify the most acceptable way of presenting risk and benefit probability information to patients as part of a CDA.
- To identify cataract surgery-specific FAQs from patients and HCPs to inform the development of a CDA.
- To explore the acceptability of Cat-PROM5 to health-care providers.
- To explore the perceived issues of shared and informed decision-making during cataract surgery patient counselling with patients and HCPs to inform the development and implementation of a CDA in routine practice.

Approach

The qualitative research elements ran alongside the quantitative research. The purpose of this work was to gather views and insights that could be used to inform the development of the decision support

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tools being developed in the programme. Recruitment was from patients attending the cataract services, with stratification where feasible, for example for gender. Interviews were guided by an interview schedule or topic guide, and were audio-recorded, transcribed verbatim and analysed using NVivo software.[20,22,23] Focus groups similarly followed a standard approach to methodology, data collection and analysis.[30,31]

This work included conducting:

- Focus groups and interviews with patients to inform
    - The presentation format of risk information for the development of a risk and benefit probability calculator.
    - The presentation, issues of concern, supporting information and FAQs for the development of a CDA.
- Interviews with HCPs to
    - Explore the acceptability of Cat-PROM5.
    - Inform content development and explore the usefulness of decision aids in clinical practice.
    - Consider the attitudes towards and practice of shared decision-making.

Data collection

Patients

Two focus groups and 15 one-to-one semistructured interviews were conducted with 33 individuals attending the Bristol clinics and two attending the Gloucestershire clinics. The mean age of patient participants was 77 years, with the youngest participant aged 55 years and the oldest aged 86 years. Of the 33 patient participants, 14 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, and most were suffering from other eye comorbidities. In addition to the formal qualitative approach, the interpretation of the findings was supported by the programme PPI PAG.

Health-care professional interviews

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

Results

Risk–benefit information

Patients participating in the study were shown four numerical ways of presenting risk and benefit information, each accompanied by a pictogram visually representing that probability: a percentage (%), *n* out of 100 individuals, the number of people treated for one person to experience a benefit/complication, and the probability as a decimal. Patient participants preferred '*n* out of 100 individuals' as it was the most easily understood format for presenting both risks and benefits, which corresponded with the preferred option of the PAG.

Information for frequently asked questions for a cataract decision aid: patients

Frequently asked questions were identified through patient participants' narratives discussing the information they found useful at the time, questions they would have asked now but did not ask then,

and emerging gaps in knowledge of surgery-specific issues. The items that were 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 intraocular lens 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 for a cataract decision aid: health-care professionals

Information that HCPs highlighted as being of perceived importance included:

- Risks and benefits.
- Providing information about refractive outcomes.
- About the surgery and surgery aftercare.
- Whether or not surgery is needed.
- Waiting times.

Cataract decision aid: health-care professionals views on Cat-PROM5

Overall participants thought that Cat-PROM5 captured how vision-related quality of life might be affected by cataracts. The majority thought that the outcome measure was short, simple and easy for patients to complete on their own. Participants thought that it captured information that was of importance to HCPs, but a few commented on the usefulness of knowing the specific areas affected by cataracts, something that was not directly captured by Cat-PROM5. Several believed Cat-PROM5 captured information that was already used to inform decision-making. Participants thought that having a structured way of capturing vision-related quality of life (VRQoL) information would make the discussions taking place during consultations more consistent, introduce the patient perspective in decision-making, standardise and formalise the way that VRQoL information is collected and recorded, and facilitate post-surgery assessment of surgery outcome.

Shared decision-making: health-care professionals

Shared decision-making appears to be inconsistently practised by HCPs. The majority of HCP participants thought there was variability in practice and inconsistencies in the kind of information discussed with patients, the way that this information is discussed and explained, and how decisions are made by individual clinicians. Some HCPs thought that this variability resulted in inequities regarding who was 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 would ensure that the VRQoL of each patient is taken into consideration and also formally reported in patients' health records, and the use of FAQs and decision support tools would enhance the information exchange process and support informed and shared decision-making.

Health-care professionals 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 these in routine practice and how well the decision support tool and its aims fit with current care pathways.

Key findings

Patients preferred '*n* out of 100', as it was the most easily understood format for risk presentation.

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Issues of perceived interest, concern or importance for cataract surgery were elicited from patients and HCPs. This knowledge informed the development of the FAQs section of the CDA (WP3, qualitative element 2).

Cat-PROM5, as part of a CDA, was seen as worthwhile by HCPs in terms of standardising the assessment of self-reported difficulty suffered by patients with cataracts.

A CDA and shared decision-making in cataract surgery were mostly seen as relevant and necessary by HCPs, with risk information considered to be an important aspect of a shared discussion.

Limitations

Moderate sample sizes from a small number of centres may limit the generalisability of these findings, although recruitment continued until saturation was achieved, which will ameliorate this potential risk.

Relationship with other work packages

The format for the presentation of the personalised risk/benefit information and the information content for the FAQs were taken forward to the CDA in WP3, qualitative element 2, the Predict-CAT instrument development stage.

Cat-PROM5's acceptability to HCPs and views on shared decision-making informed the approach to engagement with this service-critical group with regard to the set-up of the WP4 feasibility RCT.

Qualitative element 2: development of a cataract decision aid and a cataract decision quality measure

Aims

- To develop a CDA in a FAQ format in which the likelihood of the Cat-PROM5 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 (the feasibility trial).

Approach

The International Patient Decision Aid Standards (IPDAS) Collaboration Checklist[32] for the development and quality assessment of patient decision aids was used to guide the development of the CDA. We used a collaborative, multistage development process involving key stakeholders, and we conducted qualitative user testing interviews with patients and clinicians. Recruitment was from the cataract services, with purposive stratification where feasible [e.g. gender and professional group (surgeon, nurse, optometrist)]. Interviews were guided by an interview schedule or topic guide, and were audio-recorded, transcribed verbatim and analysed.[20,22,23] The focus group followed the standard approach to methodology, data collection and analysis.[30,31]

Development of the prototype cataract decision aid

The multistage, 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 HCPs 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.

  - A total of 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).

- A focus group was conducted with the cataract research programme PPI PAG members.

  - Five members of the PAG attended the focus group session. The audio-recorded focus group was transcribed and feedback gathered.

- To further inform the evidence-based content of the CDA, several sources of data/evidence were consulted:

  - Focus groups and patient interviews that were previously conducted as part of WP3, qualitative element 1.
  - The scoping review of published guidelines and literature.
  - Expert opinion.
  - Predicted harm models (WP2).

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

The prototype CDA comprised the following elements:

- Introduction page.
- Section A: FAQs.
- Section B: What matters to you? What questions do you have?
- Section C: personalised information about your likely outcomes.

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

User testing of the prototype cataract decision aid

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 6 weeks previously. User testing interviews were conducted with a total of 26 participants: 20 patient participants (10 male and 10 female) and six clinician participants (four ophthalmologists, one nurse and one optometrist). Clinician input was supplemented by the URG and the study management team.

Semistructured interview questions for the patient participants covered the following topics: views on the usefulness of the CDA; understanding of the content (including terminology, presentation of risks, etc.); views on the FAQs included, and the ranking of the candidate FAQs (to discover if any excluded FAQs should be included); and views on the different parts of the CDA (the personalised risk section, space for questions, etc.), the layout/design, readability, when/how they would like to receive the CDA and potential improvements.

Semistructured interview questions for the clinician participants covered the following topics: views on the usefulness of the CDA (for themselves and patients), the accuracy/comprehensiveness of the content, views on the different parts of the CDA (the personalised risk section, space for questions, etc.),

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fit within local clinical systems, potential influence on their behaviour, perceived barriers to and facilitators of use, and contextual factors that might impact future implementation.

Patient and clinician participants were sent a copy of the prototype CDA prior to the telephone interview. All patient and clinician audio-recordings 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 (usefulness, use in clinical practice, etc.) and the different components of the CDA (FAQs, personalised information section, etc.). New emerging themes that had not been captured by the initial framework 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: (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 and (5) implementation in a clinical setting. Two new categories were added to the framework during analysis: (6) information provision and preferences and (7) 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 cataract decision aid

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 pages in the booklet increased from seven to nine. Additional questions were added to section A (FAQs), and further clarification and details were added. Presentation 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.

Cataract decision quality measure

Decision quality measures (DQMs) are condition-specific instruments that have been developed to assess patients' understanding of available treatment options, their personal preferences, their perceived readiness to make a decision and the alignment between their preferences and preferred option. DQMs are made up of four key sections: (1) knowing your options (knowledge questions), (2) what is important to you? (preference questions), (3) thinking about the decision you face (readiness to decide, standard items that are not condition specific) and (4) choice of treatment (which assesses current treatment preference). We drew on our experience of developing DQMs for other clinical areas (breast cancer, tonsillectomy, etc.) as part of a SDM implementation programme.

We aimed to develop a 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 from the PAG focus group (about what 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 were able to ensure that input from patients and clinicians was 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 PAG highlighted the issues that matter the 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), and these were incorporated into the CDA. Evidence syntheses ensured that the information provided in the CDA was evidence-based, for example the FAQs in section A.

Incorporating the risk calculator element that was developed as part of WP2 (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.

The qualitative user-testing interviews found that patients and clinicians were generally positive about the CDA. Both patients and clinicians felt that the CDA would provide a trustworthy source of information, including adequate and accurate information. Clinicians felt that 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 the questions that they would want answered before making a decision. Patients and clinicians felt that the CDA would reinforce the idea that a 'choice' exists with regard to cataract surgery, would encourage better patient involvement in cataract surgery decisions, was easy to understand and 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 that their patients might want in terms of risk information and what patients said they wanted after reflecting on previous experiences in which they had not received this information. Overall, it was felt that the CDA would be feasible to use in routine clinical settings.

Limitations

Despite significant efforts to recruit clinicians from all four collaborating sites, it was not possible to recruit from one site. However, the clinical input was strong from the URG and the research programme team.

Relationship with other work packages

The Predict-CAT qualitative work (FAQs, etc.) fed directly into the development of the CDA. Both the CDA and the CDQM were taken forward as key instruments in the WP4 feasibility RCT.

Health economics: performance of health utilities and calibration of Cat-PROM5

Standard health economic indices of utility are known to be insensitive to mild to moderate vision loss.[33] In this health economic section, their performance in people with cataracts was evaluated and calibrated against Cat-PROM5 in accordance with International Society for Pharmacoeconomics and Outcomes Research (ISPOR) guidance.[34]

Aims

- To evaluate the performance of existing and emerging health economic indices (the preference-based measures EQ-5D-3L, EQ-5D-3L+VIS, EQ-5D-5L and 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 at two sites in England. The questionnaires were completed both pre and post operation for all participants, with questionnaire data available for 1315 participants. The Cat-PROM5 and ICECAP-O data were collected from all participants, with collection of the other health economic utilities (the EQ-5D-3L, EQ-5D-3L+VIS and EQ-5D-5L) undertaken on a 1 : 1 : 1 random allocation basis.

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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. Currently, there are two algorithms for generating EQ-5D-5L preference-based utilities for a UK sample: the Euro-Qol-5 Dimensions, five-level version, value set for England (EQ-5D-5L-VSE) and the EuroQol-5 Dimensions Crosswalk (EQ-5D-5L-CW).[35–37] Both algorithms were used here.

Calibration

Linear models and adjusted limited dependent variable mixture models were estimated. Full data were available for 1181 patients undergoing cataract surgery. Cat-PROM5 was mapped to two quality-of-life measures (the EQ-5D-3L and EQ-5D-5L) and one capability measure (the ICECAP-O). We did not map to the EQ-5D-3L+VIS questionnaire because of the infrequent use of the questionnaire and its unclear relevance to the calculation of quality-adjusted life-years. 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

Key findings

Performance

The EQ-5D-3L and EQ-5D-5L did not perform well across almost every measure of validity and responsiveness and they had the largest ceiling effects (*Table 1*); the EQ-5D-3L+VIS had a lower ceiling effect and better convergent validity with Cat-PROM5. The EQ-5D-3L+VIS 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 ESs 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 Cat-PROM5; it performed best on many measures of responsiveness.[38]

Calibration/mapping

The adjusted limited dependent variable mixture models dominated linear models on all performance criteria. The 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) that conditioned on some or all of these covariates (depending on the target measure and pre- and post-operative status) performed better than models with fewer components that did not condition on covariates (*Figure 3*). The models for EQ-5D-3L did not converge post surgery under any mixture model, possibly because of the large number of participants reporting perfect (EQ-5D-3L index score = 1) quality of life.[39]

Limitations

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

Relationship with other work packages

In addition to the links and dependencies within the Predict-CAT WP3 cohort study noted here, these health economic elements of the programme link Cat-PROM5, developed in WP1, to established and emerging health economic utilities that are preference-based measures. This work is indirectly linked to the WP4 feasibility RCT as it would inform the choice of a preference-based measure to be included in any future fully powered RCT. Furthermore, the calibration or mapping exercise would allow health

TABLE 1 Summary of preference-based measure performance against the criteria that were evaluated

Criterion	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]
VA correlation	✗	✗	✗	✗	✗
Known groups validity					
First-eye or second-eye surgery	✗	✗	✗	✗	✗
Habitual near VA in the operated eye (logMAR)	✓	✗	✗	✗	?[b]
Ocular comorbidities	✗	✗	✗	✗	✗
Responsiveness					
Change scores and ESs					
Visual quality of life	✗	✗	✗	✗	✓
Patient-perceived benefit of surgery	✗	✗	✗	✗	?[c]
Change in near VA in operated-on eye	✗	✗	✗	✗	✗

✓, present; ✗, absent; ?, conflicting results for EuroQol-5 Dimensions randomisation groups.
a EQ-5D-3L group correlation coefficient did not exceed 0.3.
b Between-group differences were significant ($p < 0.05$) for the EQ-5D-3L group only.
c There was no difference in change scores for the EQ-5D-3L group visual quality of life and patient-perceived benefit obtained from post-operative supplementary questionnaire.

Notes
Ceiling effect: > 15% scoring the maximum of 1.
First-eye or second-eye surgery: second-eye surgery patients were expected to report significantly better health-related quality of life.
Habitual near VA (usual spectacles if worn) in the operated eye (on the logMAR scale): patients with worse VA were expected to report significantly lower health-related quality of life.
Ocular comorbidities: patients with ocular comorbidities were expected to report lower health-related quality of life.
Floor effect: > 15% scoring the minimum possible score.

economic analyses to be undertaken based on the 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

- *Report Supplementary Material 4* provides further information on the Predict-CAT cohort study and the development of the self-reported outcomes and benefits models.
- *Report Supplementary Material 5* provides further information on the qualitative elements of WP3 relating to the format and content of information for patients based on input from patients and HCPs.
- *Report Supplementary Material 6* provides further information on the development of the CDA.
- *Report Supplementary Material 7* provides further information on the performance of existing and emerging health economic indices when used for cataract surgery.[38]
- *Report Supplementary Material 8* provides further information on calibration or mapping of Cat-PROM5 to emerging health economic indices.[39]

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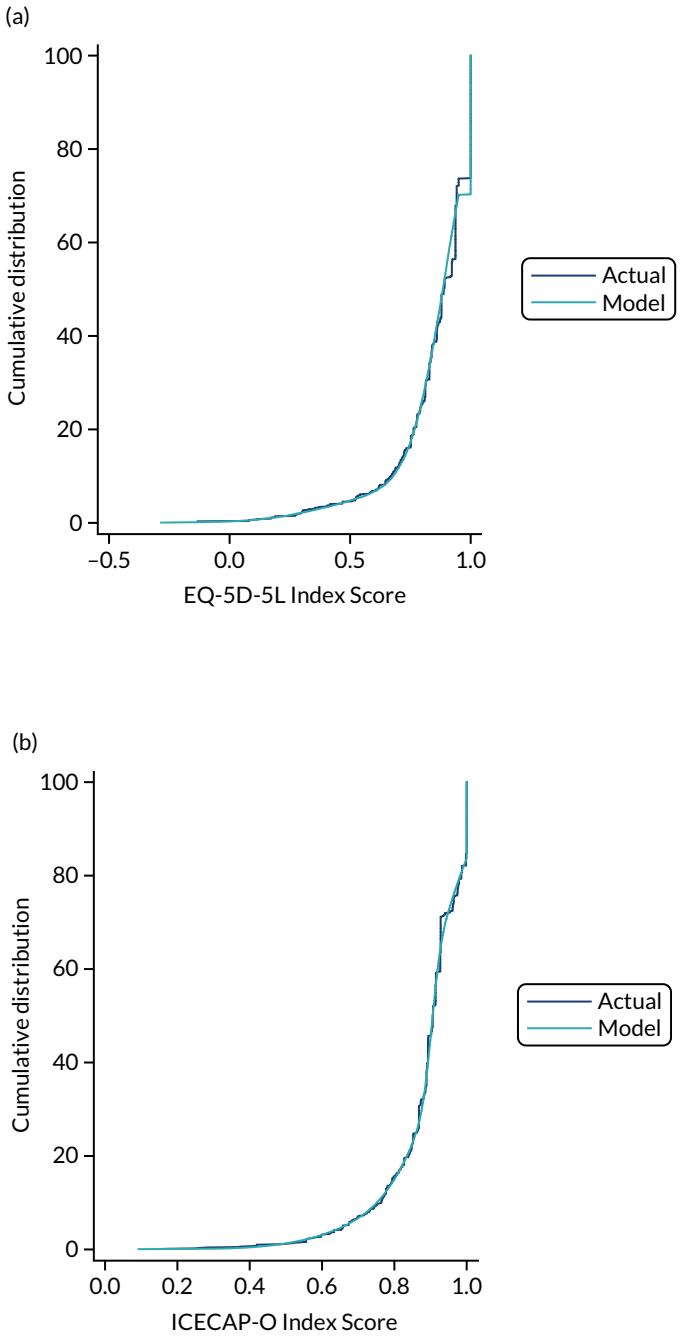

FIGURE 3 Calibration/mapping: comparison of actual and predicted follow-up distributions. (a) EQ-5D-5L; and (b) ICECAP-O.

Work package 4: feasibility study of the cataract decision aid trial and qualitative study of mismatching outcomes

Quantitative elements: feasibility of a cataract decision aid randomised controlled trial and validation of benefits prediction models

Aims

- To undertake a feasibility study for a possible future fully powered RCT of the use of a 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 the form of a two-arm RCT with the CDA as an intervention. The intervention group was defined as the group of patients in whom the CDA was used, while patients in the standard-care 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, five or six 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 CDQM developed as a part of WP3 was used to assess patients' decision quality. The CDQM is a measure intended to capture patients' 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.

Pre-operative parameters were used to predict the expected post-operative 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 and Gloucestershire), that is 10 patients per centre. During the study, however, it became clear that Gloucestershire would be unable to join the study owing to local capacity issues and Torbay would be able to join the study only later, owing to staff illness. This required over-recruitment by Bristol and Brighton; nonetheless, full recruitment of 42 completing patients was achieved (*Figure 4*).

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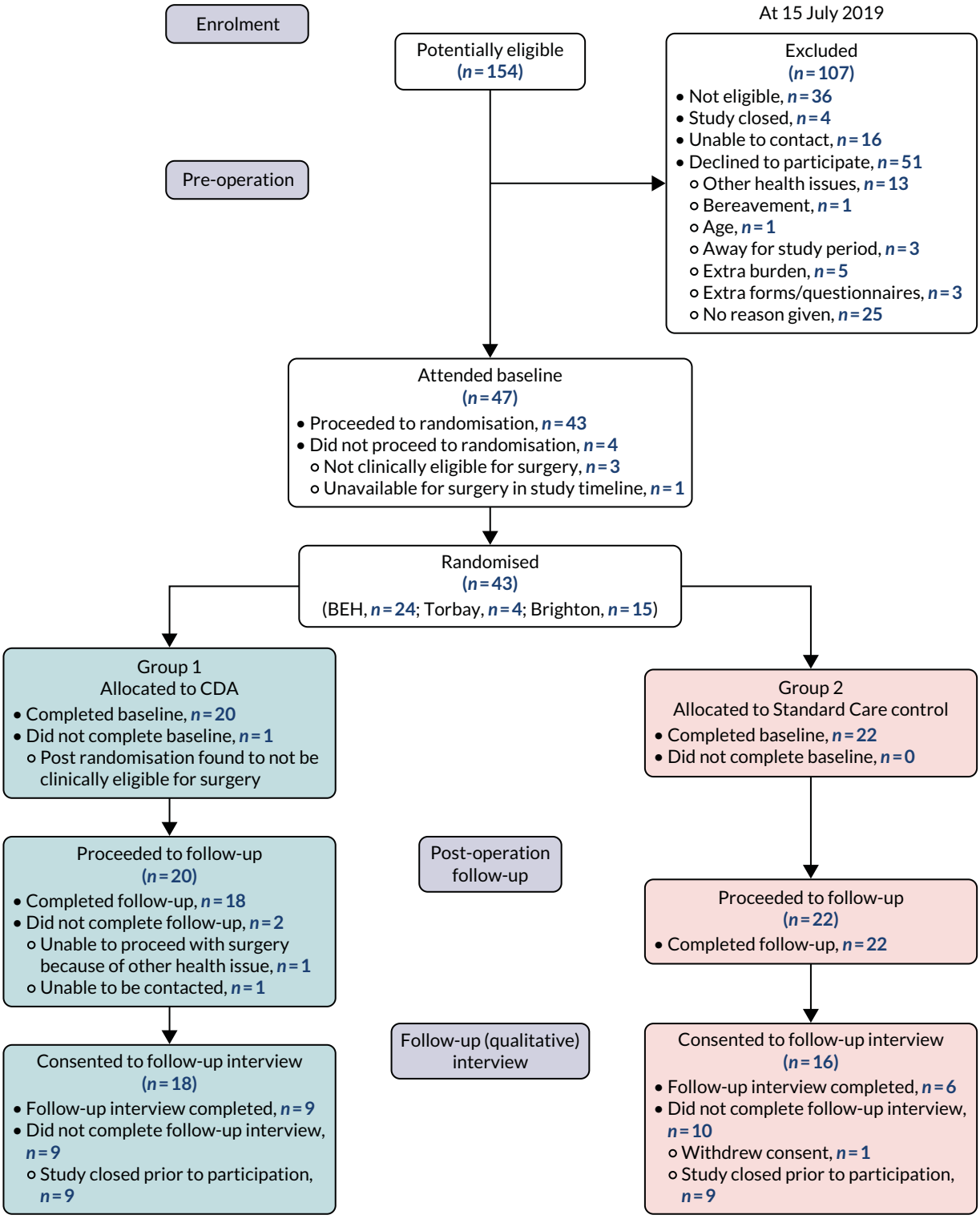

FIGURE 4 The Involve-CAT Consolidated Standards of Reporting Trials flow diagram. BEH, Bristol Eye Hospital.

Data analysis

The effects of the intervention were analysed in two ways. For the summary scores expressed by a single value [i.e. knowledge about cataract (section A), readiness for decision-making (section C) and Cat-PROM5], *t*-tests were undertaken for both dependent (paired) samples and independent samples. Tests for dependent samples were performed to assess the importance of the intraindividual changes in CDQM scores from before to after the consultation and in the Cat-PROM5 measures from before

to after surgery. 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 that compared reported preferences with the decisions actually made (sections B and D), Spearman's rho was calculated as a basic statistic capturing levels of concordance between what was reported as important for patients and what was actually chosen.

A power study was undertaken to inform a sample size estimate, providing calculations of the 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 the ESs were chosen according to Cohen's classification of standardised ESs[40] [standard deviation (SD) of unity].

Bland and Altman plots were used to compare predicted outcomes with observed outcomes for the two benefits prediction models (prediction of the final post-operative outcome and prediction of the improvement in score from pre to post operation).

Results

The level of data collection completeness was good for the feasibility study primary and secondary variables, both before and after intervention/surgery (range 100–88% complete). The intervention group and standard-care control group were similar across key variables at baseline, indicating successful randomisation. Although it is expected that, in a feasibility study, statistical power would be insufficient to arrive at any conclusions, standard analyses were undertaken on the collected data to confirm feasibility for such analyses and to gain insights into the likely future performance of the outcome measures.

Primary outcome: cataract decision quality measure

The tests (for independent samples) conducted after the consultation/operation showed no important differences between the CDA intervention group and the standard-care control group prior to the consultation (at baseline) or after the consultation (at follow-up) for knowledge (section A) or readiness to decide (section C). In this small sample, using the CDA did not improve the knowledge or readiness to decide about cataracts and their treatment.

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

Additional basic psychometric analyses were undertaken for questions in sections 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) revealed 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) showed 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 group and the standard-care control group at either pre-operative baseline or post-operative time points for the Cat-PROM5 scores. As expected, significant improvements in the Cat-PROM5 scores were observed between baseline and post-operative completions for both groups (paired *t*-tests). Despite there being no significant differences in the Cat-PROM5 scores post operation, the score improvement in the CDA intervention group (3.40) was almost half a logit larger than that in the standard-care control group (2.96).

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Sample size estimate

In the absence of a clear primary outcome ES emerging from the feasibility study, a standard power calculation approach was adopted for sample size estimation for a possible future RCT.[41] For the *t*-tests for independent groups, a small ES (0.2 SD) would be detectable with 80% power using a sample size of 800 (1 : 1 allocation, 400 in each group). A medium ES (0.5 SD) would be detectable with > 90% power using 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 ES and a 1 : 1 group allocation, a total sample size of 250 would be required for the detection of this effect with 80% power, and a sample size of 325 would be needed for 90% power.

Performance of the Cat-PROM5 benefits prediction models

The correlation coefficient between predicted outcome and actual outcome was 0.57 for the final post-operative 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 owing to lack of capacity to undertake the research, and the start of recruitment at another site being delayed owing to staff health.
- Data collection completeness for key variables was good and statistical analysis of the collected data was feasible.
- Analysis of the CDQM primary outcome revealed psychometric imperfections in the performance of the knowledge section, which would benefit from review and refinement in advance of a fully powered trial.
- For independent groups, a small ES (0.2 SD) would be detectable with 80% power using a sample size of 800 (1 : 1 allocation, 400 in each group) and a medium ES (0.5 SD) would be detectable with 90% power using a sample size of 200 (1 : 1 allocation, 100 in each group).
- The performance of the prediction model for the final Cat-PROM5 post-operative outcome was superior to the model for prediction of change in the Cat-PROM5 score from pre- to post-operative time points.

Limitations

One limitation of WP4 was related to the CDQM, the knowledge section of which would benefit from further development work prior to consideration of its use as an outcome in a fully powered RCT.

A further limitation was the fact that the prediction model (developed in the WP3 Predict-CAT cohort study) for a change in the 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-operative Cat-PROM5 score – pre-operative Cat-PROM5 score) has greater variance and is, therefore, subject to higher uncertainty. However, the final Cat-PROM5 prediction model was confirmed to have reasonable predictive power.

Relationship with other work packages

WP4 depended on the following outputs from each of 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, the CDA and the CDQM from WP3.

Qualitative element 1: perceptions of the cataract decision aid for shared decision-making

Aims

- To explore how a CDA incorporating personalised risk and benefit information influences pre-operative SDM for cataract patients and HCPs.
- To explore how patients and HCPs perceive the CDA in the context of routine care.

Approach

All audio recordings of consultations (CDA group and standard-care control group) in which the surgeon and patient discussed the treatment options for cataract surgery were transcribed verbatim, anonymised and analysed in NVivo.[21,23] This included scoring consultations using the Observer OPTION 5 instrument,[42] comparing appointments with the CDA (the intervention group) and without the CDA (the standard-care control group) of the feasibility RCT.[43,44] Sampling was both opportunistic (available HCPs) and purposive (a balance of HCP groups and genders for patients).

Recruitment

Patient consultations

All pre-operative consultations with the surgeon were audio-recorded and included in the qualitative assessment.

Post-consultation follow-up interviews

From among the participants in the main WP4 study, we aimed to recruit 10–12 patients (five or six of whom received the CDA, and five or six of whom did not receive the CDA) as well as one to three surgeons per participating site (who had used the CDA) to take part in audio-recorded follow-up interviews. The Cardiff University team were notified of participants (patients and surgeons) who had agreed to be contacted for a follow-up interview on the main WP4 study consent form.

Data collection and analysis

All audio-recordings of consultations (CDA and control groups) in which the surgeon and patient discussed the treatment options for cataract surgery were transcribed verbatim. Recordings of all 42 RCT appointments were scored in relation to SDM. Audio-recordings of the follow-up interviews were also transcribed verbatim and transcripts were entered into NVivo for analysis. A framework analysis approach[45] was used to analyse the data, based on the key topic areas covered by the interview guide (usefulness, use in clinical practice, experiences of the pre-operative decision-making process, etc.) and also the model of SDM in clinical practice.[46] This model outlines three key stages of the SDM process, characterised by different types of 'talk': choice, option and decision.

Post-consultation follow-up interviews with patients and surgeons qualitatively analysed their perceptions of the appointments and the CDA. Separate interview schedules (topic guides) were used for surgeon and patient follow-up interviews (see *Report Supplementary Material 11*).

A total of 15 patient follow-up interviews were undertaken: 10 in the CDA group and five in the standard-care control group (Brighton, $n = 5$; Bristol, $n = 7$; Torbay, $n = 3$).

Six clinician participants who participated in the CDA arm of the study participated in the post-consultation follow-up interviews across three participating sites (Brighton, $n = 1$; Bristol, $n = 4$; Torbay, $n = 1$). The clinician participants were surgeons (ophthalmologists), four of whom were male and two of whom were female.

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Key findings

Several key issues arose that would be likely to have an 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, the Observer OPTION 5 scores revealed that there was a significant difference in mean total scores between the CDA arm and standard-care control arm, with all five items scoring higher, on average, in the CDA consultations than in the standard-care control consultations. These results indicate that when clinicians use the CDA with patients, a greater number of 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 or not the CDA was used.
- Consultants did not consistently perceive the choices of 'surgery, delay or decline' as useful or legitimate and, therefore, some did not agree with the presentation of choices in the CDA.
- Many of the patients had strong prior preferences and had already decided that they wanted the surgery. Thus, it would be difficult to reintroduce the choice talk at the consultation stage. This indicated that the SDM discussion around having or declining cataract surgery might be better placed or at least initiated earlier in the clinical care pathway, 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. For example, more work could be undertaken in the consultation to reintroduce 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, for example with a community optometrist, an 'optician'.
- Overall, surgeons 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, with options including:

    - The CDA could be used as part of a two-stage process. It could be introduced to patients before the consultation, ideally being sent to patients with their appointment letters. In the consultation, the 'what matters to me' and 'personalised risks and benefits' sections could be elaborated and discussed.
    - The CDA could be introduced at an earlier point in the care pathway, such as prior to referral to the hospital.
    - More consistent and adequate clinician training in SDM could be provided to the wider team of HCPs who would deliver the CDA.
    - The risk calculators could be better integrated into the local clinical systems, with as much of the information pre-populated prior to the consultation as possible.

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

The earlier WPs all fed into this element of the work, which looks forward to a possible future RCT of the CDA that acknowledges the lessons learnt here.

Qualitative element 2: mismatching outcomes

Aim

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

We sought out patients with discordant or mismatching outcomes among the WP3 Predict-CAT study cohort participants, and consultants at the four collaborating centres were also separately asked to identify and recruit patients in their centre who had discordant outcomes. HCPs from the collaborating centres with experience of this relatively uncommon phenomenon were invited 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 outcomes, that is patients who are dissatisfied with the outcome of their surgery or perceive a negative outcome, despite there being no clear clinical explanation for experiencing a poor outcome. Examples might include dysphotopsia, reflections, glare or residual minor refractive error.
- Positive mismatching outcomes
    - The patient is happy with poor surgery or VA outcomes, that is patients who report satisfaction/positive outcomes when 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, intraocular lens subluxed or mild to moderate macular dysfunction.

Data collection

Data collection for this substudy was organised in two separate strands.

The first strand included semistructured one-to-one interviews with patients identified as falling within the mismatching outcomes definition, which were carried out face to face or over the telephone. The second strand of the study involved semistructured one-to-one interviews with HCPs who were involved in cataract care delivery and had experience with the phenomenon of discordant outcomes.[20]

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

Data analysis

All interviews were, with participants' consent, audio-recorded, fully transcribed and anonymised. Anonymised transcripts were analysed in NVivo 10, guided by principles of thematic analysis.[47]

Key findings

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

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- Patient narratives highlighted the nuanced and multidimensional 'lived experience' of vision, whereby patients might be happy with one aspect of vision, for example distance vision, but dissatisfied with another, perhaps more valued, aspect that determined their overall judgement on the outcome of the surgery.
- The factors raised by HCPs to explain the phenomenon were linked to medical practice, doctor–patient communication and patient-specific attributes. The factors linked to medical practice were primarily the technologies used, for example the choice of lens implant and unintended optical side effects resulting from individual lenses, and the use of measurement and testing devices that are able to capture the visual experiences of the patients.
- HCPs and patients thought that the quality of the doctor–patient relationship shaped patients' perceptions of the outcome. Both believed that there was a need for SDM 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 that were thought to exist between patients' and HCPs' understanding of what 'good vision' means; address patient preferences and expectations and realign these with a more realistic understanding of the potential outcome; and provide accurate and individualised information on what the patient should expect of 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 in 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-operative follow-up, and trust in the providers' abilities to carry out ophthalmological examinations and procedures.
- HCPs thought that it was important to understand the 'discordant outcomes' case profile to identify determinants of discordance and to target patients who might be more prone to dissatisfaction with their outcome so that they could receive more intensive patient counselling.
- HCPs thought that the presence of comorbidities and a more complex clinical profile, the patients' visual abilities before the surgery, and the patients' personality and social characteristics explained discordant outcomes.
- The participant recruited to the study who had the only positive mismatching outcome 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 (trust in HCPs, the quality of their relationship with the HCPs and being engaged in informed and shared decision making) shaped their post-operative experiences.
- However, several barriers to changing practice were identified, often linked to the challenges of changing current ways of working and the time HCPs had available to engage in such in-depth personalised conversations with patients.

Limitations

As this is a relatively uncommon phenomenon, it was 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; HCPs from the collaborating centres who had knowledge of the programme and its aims assisted in finding the patients and 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 SDM.

Health economic elements: implementation costs of a cataract decision aid

Aim

To estimate the implementation costs and potential savings of the use of a CDA.

Approach

This study compared the additional resources incurred as a result of implementing the CDA with those of standard care in the Involve-CAT pilot RCT study. The additional resource was the time taken to collect the data needed for the CDA and administer the CDA during the SDM discussion, and the subsequent impact on discussions in the remaining appointment. There is also 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 health-care use following surgery (accident and emergency visits, etc.).

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 appointments. Costs were obtained from the Personal Social Services Research Unit (PSSRU).[48] 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 CDA 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. The cost differences between study arms were assessed using two-sample *t*-tests.

Key findings

- The mean and median durations were longer in the CDA arm than in the standard-care control 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 assessments for the two assessors was 2.6 minutes.
- The mean total cost associated with NHS resource use in the primary analysis was £52.20 for the CDA arm and £37.80 for the standard-care control arm (difference £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; $p = 0.03$.
- As all patients in both arms progressed to surgery, only a small difference was observed for subsequent health-care resource use (single centre, $n = 23$).
- The use of a CDA was likely to moderately increase the pre-operative clinic cost as a result of a longer SDM consultation and the need for a near-vision test for the benefits calculator tool.
- To derive the quality-adjusted life-year data in a future fully powered RCT, the post-operative Cat-PROM5 scores could be mapped to health economic utilities for the CDA intervention and standard-care control groups using the mapping algorithms developed in this research programme.

Limitations

Despite the 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, WPs 1–3, fed into this cost analysis.

Added value: ethics perspectives of immediately sequential bilateral cataract surgery

The practice of immediately sequential bilateral cataract surgery is controversial in the UK. On the one hand, there is a low but unquantifiable risk of bilateral vision loss in the event of an adverse event (infection, contamination, etc.) arising that affects more than one operation on an operating list. On the other hand, there are potential efficiency savings and convenience for patients, who require only a single trip to the operating theatre when they have cataracts affecting both eyes.

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Aim

To undertake a thematic analysis of a stakeholder meeting exploring the ethics perspectives of immediately sequential bilateral cataract surgery.

Approach

A semistructured 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 chief investigator with a proposal to undertake transcription and qualitative analysis of the discussion that took place at the meeting.

Data collection and analysis

In total, 29 stakeholders attended the meeting; they were invited through purposive sampling. The professions of the stakeholders included but were not limited to ophthalmologists ($n = 9$), patients ($n = 5$), religious leaders ($n = 4$), ophthalmic nurses ($n = 3$), ethicists ($n = 2$), lawyers ($n = 2$) and commissioners ($n = 1$). Thematic qualitative analysis[47] was conducted on the resultant transcript of the discussion.

Key findings

Three overarching themes were identified, which were subdivided into eight subthemes. The themes included (1) beneficence and non-maleficence (patient benefits, patient risks, the uncertainties of risk and patient interpretation of the risk–benefit analysis), (2) autonomy (patient and surgeon choice, informed consent and the barriers to effective communication) and (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. Consequent cost savings to health care that may occur following the implementation of immediately sequential bilateral cataract surgery may be considered a secondary benefit; the primary benefit should be centred on potential (although not yet well defined) patient convenience factors.

Limitations

Although key ethics issues were identified and analysed, the 29 stakeholders who attended could not have included all of the relevant views. This analysis does, however, provide a reference point for the issues and ethics factors surrounding the practice of immediately sequential bilateral cataract surgery.

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

Further information

- *Report Supplementary Material 9* provides further information on the feasibility study for a possible future fully powered RCT.
- *Report Supplementary Material 10* provides further information on validation of the Cat-PROM5 outcome and benefit prediction models.
- *Report Supplementary Material 11* provides further information on patients' and HCPs' views and practice of SDM, and the potential role of the CDA.
- *Report Supplementary Material 12* provides further information on mismatching or discordant outcomes following cataract surgery.
- *Report Supplementary Material 13* provides further information on implementation costs of use of a CDA.
- *Report Supplementary Material 14* provides 'added value' to the programme through an analysis of ethics perspectives of immediately sequential bilateral cataract surgery.

Summary of changes to the programme

Changes to work package 3

Operational limitations at the lead site caused a delayed start to recruitment to Predict-CAT as the local trust was not able to provide a clinical examination room for the study in a timely manner. Combined with an initial slower than expected recruitment rate, this prompted the study team to take the following actions after consulting the Programme Steering Committee:

- An additional recruiting site was opened in Gloucestershire and it recruited 302 Predict-CAT cohort study participants.
- PAG members were consulted for their opinion and advice on improvement to study advertising material and implementation of a 'self-referral' mechanism for recruitment.
- We sought a 6-month no-cost extension to the programme, which was helpfully granted by the National Institute for Health and Care Research (NIHR).

Changes to work package 4

The feasibility RCT that constituted the WP4 had been planned to take place cross four collaborating sites. One site (Gloucestershire) did not have the capacity to join the study and another (Torbay) had a delayed start owing to staff illness. The recruitment target of 40 participants was, nonetheless, achieved as a result of over-recruitment at two of the sites.

Option Grid

At the time of the grant application, the intention was to develop a patient decision support tool in the format of an Option Grid© (EBSCO Health, Ipswich, MA, USA), in collaboration with co-applicant Professor Glyn Elwyn (previously of Cardiff University, Cardiff, UK). Following Professor Glyn's departure from Cardiff University and the commercialisation of the Option Grid©, the decision was taken with co-applicant Natalie Joseph-Williams of Cardiff University (who replaced Glyn Elwyn) to continue with the development of a CDA separately from the commercialised Option Grid© collaborative, using similar methodology and the knowledge of staff at Cardiff University (with the exception of the risk–benefit indicator models developed in WP3, which were developed at Bristol as intended). The resulting CDA, developed during WP3 and tested during WP4, remains the property of Cardiff University and will be made available for free use under a Creative Commons Licence.

Work package 1, added value

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

Work package 2, added value

(See *Report Supplementary Material 1–3* and Hughes *et al.*[49] for further details.)

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Additional analyses were undertaken to understand the:

- Stability of the risk model for the surgical complication of PCR.
- Cataract surgery outcomes in people aged $\geq$ 90 years.
- Indicators of refractive outcomes, using a novel analysis method.

Work package 4, added value

(See *Report Supplementary Material 4* for further details.)

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

Reflections on the programme: successes, impacts and issues

Cat-PROM5

Cat-PROM5 has attracted wide interest since its first presentation at the National PROMs Summit (London, UK) in 2016, as well as further interest from the international community since two development papers were published in the *Eye* journal.[18,19]

Cat-PROM5 has been prioritised for implementation by the NHS Wales *PROMs, PREMs and Effectiveness Programme.*[50] The programme has developed its own software platform for data collection, and Cat-PROM5 has also been translated into Welsh. 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 commissioned the Royal College of Ophthalmologists to undertake a feasibility pilot study of the use of Cat-PROM5 in the National Cataract Audit between 2017 and 2019.[51]

The Royal College of Ophthalmologists has prioritised development of the use of Cat-PROM5 as a patient-centred outcome in the National Cataract Audit.[1]

A web-based EMR data collection portal has been developed by the providers of the most widely used ophthalmology EMR system in the NHS. The portal allows for flexible data entry either in the hospital setting or by patients in their own home via a secure link e-mailed to them (which can be automated to arrive 2–3 months post operation if desired). The portal transfers data directly into the patient's EMR.

The providers of the second most widely used ophthalmology EMR system have likewise developed their software to include the functionality to collect Cat-PROM5 data.

The National Institute for Health and Care Excellence recently recommended that referral for cataract surgery should not be based on visual acuity alone, and went on to suggest Cat-PROM5 as a suitable self-reported outcome measure in their quality standards for serious eye disorders.[52]

Cat-PROM5 has been used as a quality-of-vision outcome measure in a recently published study comparing conventional cataract surgery with femtosecond laser-assisted surgery.[53]

Patients benefit from empowerment through an ability to formally document the visual difficulties they experience as a result of their cataracts.

Health-care providers and surgeons benefit through use of Cat-PROM5 to:

- Better understand a patient's visual burden from cataracts.
- Better support them in SDM pre operation.
- Demonstrate to patients, commissioners and the public the benefits provided to patients post operation through cataract surgery.

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Health utilities mapping tool

In this programme, we have confirmed that standard preference-based quality-of-life and capability measures, as used by NICE for cost-effectiveness analyses, perform relatively poorly in the context of mild to moderate vision loss from cataracts.[38] The mapping tool developed to convert the Cat-PROM5 data to more traditional preference-based quality-of-life and capability measures (the 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.[39]

Researchers and research patients benefit from the reduced need for completion of multiple quality-of-life questionnaires, many of which are not responsive to changes in vision.

Risk factor analysis

The statistical modelling approach for the construction of calculators for pre-operative assessment of the risk of surgical complications and loss of vision (validated here during the assessment of 180,000 cataract operations and updated since then) has been integrated in the most widely used ophthalmology EMR system.

Easy access to this risk information allows for better informed consenting of patients approaching cataract surgery and allows services to ensure that complex patients who are at an increased risk of surgical complications are exclusively operated on by highly experienced surgeons.

Pre-operative risk assessment facilitates appropriate case selection for training surgeons so that they perform only straightforward operations while they are gaining experience.

The National Cataract Audit has adopted the approach to adjust provider and individual surgeon outcomes based on case complexity.[24] Since first presenting surgeon's results back to them on a website in 2010, the PCR rate has declined by over 50% and VA loss rate by almost 40%:

- Without giving surgeons credit for the complexity of their work through adjustment for case complexity, participation in the audit (currently covering > 100 centres) would have been difficult to achieve. This approach has immeasurably enhanced the quality and surgeons' acceptance of the National Cataract Audit.
- Risk adjustment discourages risk-averse behaviours by surgeons who might otherwise wish to 'improve their statistics' by operating on the most straightforward cases only.
- The cost saving to the NHS from avoiding additional treatments that would have been necessary to deal with complications has been estimated at £2M annually.

Specific analysis of the risks and outcomes associated with operating on people aged ≥ 90 years were explored and published in the journal *Eye*,[27] and this work was previously awarded a prize at the European Society of Cataract and Refractive Surgery (ESCRS) conference (Lisbon, Portugal) in 2017.

Documenting acceptably low rates of both adverse surgical events and adverse visual outcomes in this elderly group, which is of increasing demographic importance, will guard against older people not being offered surgery when they would be very likely to benefit from it.

Benefit model

The Cat-PROM5 self-reported outcome prediction tool has not yet been published and, thus, has not attracted attention. However, it can be anticipated that this will be used for personalised prediction of

benefits for individual patients in a similar way to how the risk prediction models are currently being used. Making a calculator tool available to clinicians that allows them to predict the likely benefits for patients pre operation could further improve informed consent in future.

Cataract decision aid

The CDA was well received by patients and HCPs; the main perceived concern for the latter was the time required to use the CDA. The feasibility trial used the CDQM as a primary outcome, which produced confusing results. The review and refinement of this as the primary outcome measure would be required in preparation for a fully powered CDA RCT. Furthermore, use of the CDA earlier in the patient's pathway would enhance its ability to function as intended, as, by the time patients reach a pre-operative assessment, most have the expectation that surgery will be going ahead.

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 in the NHS and two researchers have gained prestigious academic promotions. We wish to give special thanks to NIHR for its financial support for continuing professional development and for facilitating the advancement of research capacity across the local region (South West England).

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Conclusions

In this mixed-methodology cataract research programme, the brief NHS-implementable psychometrically robust cataract PROM, Cat-PROM5, was developed to capture visual difficulty owing to cataract and its relief through surgery, thus bringing the patient's view of their vision and their voice to the heart of cataract care. Indicators of risks and self-reported benefits related to cataract surgery were identified, and statistically modelled and validated, allowing for the estimation of the risks and potential self-reported benefits for individual cataract patients who are considering surgery. Health economic work evaluated the performance of established and emerging utilities in cataract surgery and these have been mapped to the Cat-PROM5 instrument. Qualitative investigation of discordant or mismatching outcomes highlighted themes relating to patient expectations of surgery and the lack of available clinician time for full explanations of the visual changes and anticipated spectacle requirements following surgery. A CDA incorporating personalised risk and potential benefit information was qualitatively developed and iteratively refined. A feasibility RCT of the CDA as an intervention was undertaken to inform a possible future fully powered trial. Based on quantitative and qualitative evaluations, a future medium-sized trial would be feasible with minor refinements of instrumentation and use of the CDA intervention at an earlier stage in the patient pathway.

Several 'added value' projects were undertaken within the programme; these included assessment of the temporal stability of the risk models for adverse outcomes over 1 decade, analysis of the clinical outcomes of cataract surgery for people aged $\geq$ 90 years, analysis of the impact of ocular comorbidities on refractive outcome using complex numbers, and ethics considerations of cataract surgery on 'both eyes at the same sitting'.

This programme has added to the body of knowledge through the:

- Delivery of the brief psychometrically robust NHS-implementable cataract PROM, Cat-PROM5.
- Qualitative assessment of patients' and HCPs' perceptions of the potential value of Cat-PROM5 in routine clinical services.
- Mapping of Cat-PROM5 to established and emerging health economic indices to reduce questionnaire burden on participants in future cataract clinical trials evaluating the cost-effectiveness of novel interventions.
- Quantification of risk indicators for adverse clinical outcomes in cataract surgery and assessment of risk indicator stability through time.
- Documentation of the acceptably low rates of both adverse surgical events and adverse visual outcomes in very elderly patients aged $\geq$ 90 years.
- Assessment of refractive outcomes based on a comprehensive complex-numbers metric that includes all of the information contained in a refractive measurement.
- Exploration of the ethics issues surrounding the practice of bilateral simultaneous cataract surgery (operating on both eyes together) as opposed to the current practice of sequential surgery (operations on both eyes, separated in time).
- Quantification of pre-operative indicators of self-reported Cat-PROM5 benefit from surgery.
- Development of a CDA incorporating personalised predictions of benefit and risk (based on statistical models) for favourable and adverse outcomes.
- Qualitative assessment of patients' and HCPs' perceptions of the potential value of a CDA with personalised benefit and risk predictions in routine clinical services, and the perceived barriers to its implementation.
- Assessment of the feasibility of a possible future fully powered RCT of a CDA with personalised benefit and risk predictions.

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Limitations

The limitations of each of the substudies have been described in the relevant sections of the *Synopsis*.

Research recommendations

- A fully powered RCT of the CDA with personalised risk and potential benefit estimates would clarify its potential role in routine care (subject to further refinements of the outcome measure and use of the intervention earlier in the patient pathway).
- We recommend regular review and update of the risk models for adverse outcomes to ensure currency, as these models are used to adjust centre and surgeon results for case complexity in the National Cataract Audit.
- The Cat-PROM5 prediction models would benefit from further validation to better understand their performance.
- The technical precision of complex-numbers analysis of the refractive outcome invites opportunities to investigate causes of the spread of refractive outcomes, with improvements in the achievement of post-operative spectacle-free vision in mind.
- Further research is needed to clarify the role of surgery on 'both eyes at a single sitting' in terms of safety and the very small risk of bilateral blindness in the event of a common cause issue resulting in damage to the vision of or even blindness in both eyes.

Implications for health care

Implications for health care relate to opportunities to implement structured measurement of the patient's view of their visual difficulty to improve SDM for cataract surgery, tools for individualised estimates of likely self-reported benefits and adverse outcomes, and better communication between clinical staff and patients to facilitate patients having more realistic expectations of the outcome. The Royal College of Ophthalmologists has piloted the use of Cat-PROM5 as a patient-focused outcome in the National Cataract Audit[51] and has prioritised Cat-PROM5 for its future inclusion as a primary effectiveness outcome, thus imbedding the patient's voice in national audit outcomes assessment. Acceptably low rates of both adverse surgical events and adverse visual outcomes were found in the very elderly. The question of operating on both eyes at a single sitting has taken on fresh relevance where there are surgical backlogs, and we understand that a number of services are using Cat-PROM5 to prioritise early surgery for those whose self-reported vision is the worst affected.

Acknowledgements

The programme team would like to thank all the supporters, past and present, who collectively helped the programme team, both professionally and personally.

Professor John Sparrow was supported and advised by co-applicants Jenny Donovan, Jonathan Sterne, Alan Tennant, Andrew Frost, William Hollingworth, Hazel Taylor, Glyn Elwin, Katherine Brain and Claire Gilbert, who provided specialist professional advice for the planning of particular elements of the programme. We are appreciative of their support at this formative phase.

We are particularly grateful to our Patient Advisory Group (PAG) members: Clarence Nesbitt, Gemma Kennedy, Keith Price, Ilse Temple, Jonathan Kelly, Mary Davies, Robert Finnie, Sheila Tucker, Thomas Radford and David Malster.

We are exceptionally grateful for the tremendously generous support given to us by our PAG members, our Programme Steering Committee patient member and our URG patient 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 thank them all once again.

We would like to extend our gratitude to our study participants across all four centres for kindly donating their time and experiences to the programme.

To our Programme Steering Committee – Larry Benjamin, Catey Bunce, Nick Strong, Myra Higgins, Steve Hyde, Clara Eaglen and Matthew Winyard – thank you for your guidance and professional support and advice throughout the programme.

We are grateful to our sponsor, University Hospitals Bristol Research and Innovation Department, for its extensive support and guidance throughout the programme, in particular to staff members Mary Perkins, Diana Benton, Elinor Griffiths, Katherine Wale and Eleanor Hiscott. Thank you to Liz Wilkinson (University Hospitals Bristol and Weston NHS Foundation Trust research accountant) for their enduring patience over the years. In addition, lead applicant John Sparrow is grateful for the grant development protected time he received from University Hospitals Bristol Research and Innovation Department.

We are thankful to the Clinical Trials Evaluation Unit (University of Bristol) for its support in the design and maintenance of the study databases used in the cataract PROM, Predict-CAT and Involve-CAT.

Thank you to our NIHR programme managers Vasilis Kontogiannis, Elisabeth Aitkenhead and Michelle Edye.

We are grateful to our nursing teams at University Hospitals Bristol and Weston NHS Foundation Trust for welcoming us into their departments and allowing us to become part of the patient pathway, and to our bookings teams for training, advice and flexibility.

To Robert Elvin, Zameen Brar, Claire Buckland, Steve Chaffey, Lucinda Inman and Desiree Alabanza-Behard, we are incredibly grateful for all of your tremendous efforts in participant recruitment, data entry and administrative support at University Hospitals Bristol and Weston NHS Foundation Trust.

Thank you to our outstanding programme managers Lara Edwards, Pippa Craggs, Abi Loose, Andrew Turner and Frances Paget for their hard work and devotion to the programme.

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Thank you to our programme statistician, Mariusz Grzeda, whose hard work and extensive knowledge of statistics formed the basis of most of the qualitative work achieved in the programme (WPs 1–4).

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.

Thank you to optometrists Ketan Kapoor and Jason Searle, who clinically assessed 1200 patient participants in the Predict-CAT study; to ophthalmologists Venkata Avadhanam, Colin Chu, Samantha Hunt and Sofia Theodoropoulou, for their clinical support during the Involve-CAT study; and to Derek Tole and Sofia Theodoropoulou for their ideas and help with the analyses of patients aged ≥ 90 years.

Thank you to the clinical and administrative teams at our collaborating centres, led by co-applicant and principal investigator Andrew Frost in Torbay and co-applicant and principal investigator Christopher Liu in Brighton, for their substantial efforts in helping us to achieve our goals.

It is with deep regret that we note the loss of our friend, colleague, co-applicant and principal investigator 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 his support and local leadership in the Predict-CAT study and for taking over Robert Johnston's roles as co-applicant and principal investigator in Gloucestershire. Thanks also to the optometric research team in Gloucestershire, led by Sue Carter, who clinically assessed 300 patient participants.

Contributions of authors

John Sparrow (https://orcid.org/0000-0003-3704-0105) (Consultant Ophthalmic Surgeon, with a specialist interest in Cataract Surgery and Glaucoma; Honorary Professor of Ophthalmic Health Services Research and Applied Epidemiology, University of Bristol; Clinical Lead for the National Ophthalmology Database Cataract Audit) was the lead applicant and chief investigator. He was directly responsible for the conception, planning and delivery of all four WPs, and oversight of their analysis and interpretation. He provided leadership and support to study staff and researchers. Previously, he was co-developer of the VSQ and VCM1 questionnaires, which laid the groundwork for development of Cat-PROM5. He undertook statistical (Rasch) analysis during the pilot phase of the Cat-PROM5's development (WP1). He drafted the final report of the programme and authorised the final version for submission to NIHR. He is the corresponding author and guarantor of the work.

Mariusz Grzeda (https://orcid.org/0000-0003-2777-8763) (Research Programme Statistician) was the programme statistician. His substantial contribution was the analysis and interpretation of data across all four WPs. 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 (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 CDA and CDQMs and performed the preliminary validation of the Cat-PROM5 benefits prediction model (WP4).

Andrew Frost (https://orcid.org/0000-0002-3665-7878) (Consultant Ophthalmologist and Centre Principal Investigator) was a co-applicant, principal investigator and ophthalmologist centre lead for Torbay. He was closely involved in the item reduction and final development of Cat-PROM5 (WP1), qualitative elements (WPs 3–4) and direct care of Involve-CAT participants (WP4). Previously, Andrew was the lead developer of the VCM1 questionnaire, which (with the VSQ) formed the basis of the Cat-PROM5 item set.

Christopher Liu (https://orcid.org/0000-0002-1045-196X) (Professor of Ophthalmology and Centre Principal Investigator) was a co-applicant, principal investigator and ophthalmologist centre lead for Brighton. He was involved in the development of Cat-PROM5 (WP1), the qualitative elements (WPs 3 and 4), the strategic planning of the discordant outcome qualitative aims and direct care of Involve-CAT participants (WP4). Christopher initiated the project that undertook qualitative analysis of the stakeholder meeting on the ethics perspectives of immediately sequential bilateral cataract surgery.

Robert Johnston [Consultant Ophthalmology and Centre Principal Investigator (deceased)] was a co-applicant, principal investigator 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 Gloucestershire Hospitals NHS Foundation Trust (GHNHSFT) as a recruiting site for WP3. It is with deep regret that we note the passing of Robert, our good friend and colleague, in September 2016. Following his death, Robert's role was taken over by **Peter Scanlon**.

Peter Scanlon (https://orcid.org/0000-0001-8513-710X) (Professor of Ophthalmology and Centre Principal Investigator) was a co-applicant, principal investigator and ophthalmologist centre lead following the death of **Robert Johnston**. He facilitated and set up arrangements for the inclusion of GHNHSFT as a second recruitment site for WP3 with **Pippa Craggs (https://orcid.org/0000-0001-5705-741X)** as programme manager.

Christalla Pithara (https://orcid.org/0000-0003-2958-5201) (Senior Research Associate in Health Services Research) conducted qualitative research across WPs 3 and 4 on the presentation of risk and benefits, perceptions of Cat-PROM5 and the CDA, and discordant outcomes. She was involved in data collection, qualitative data analysis and preparation of the Predict-CAT qualitative study final reports.

Daisy Elliott (https://orcid.org/0000-0001-8143-9549) (Qualitative Medical Research Fellow) conducted the qualitative research on the acceptability and generalisability (to patients with visual comorbidities) of Cat-PROM5 in WP1, and provided planning, supervision and oversight of qualitative work in WP3.

Jenny Donovan (https://orcid.org/0000-0002-6488-5472) (Professor of Social Medicine) was a co-applicant, was responsible for qualitative research design and oversight (WPs 1 and 3–4) and was co-developer of the VCM1 and VSQ questionnaires that formed the basis of Cat-PROM5 development. She also contributed to the strategic planning of the feasibility RCT (WP4).

Natalie Joseph-Williams (https://orcid.org/0000-0002-8944-2969) (Lecturer, with specialist interest in SDM and improving patient care, Cardiff University School of Medicine) was a co-applicant and principal investigator for Involve-CAT (taking over from Glyn Elwyn, who emigrated to the USA and commercialised the Option Grid collaborative). Natalie led the development and user testing of the CDA and CDQMs used in the feasibility RCT (WPs 3–4).

Daniella Holland-Hart (https://orcid.org/0000-0002-1127-5152) (Research Associate) was responsible for co-ordinating the development and user testing of the CDA and CDQMs, and conducting the interviews and qualitative analyses of the feasibility RCT (WPs 3 and 4).

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Paul HJ Donachie (https://orcid.org/0000-0002-2989-8972) (Medical Statistician, Royal College of Ophthalmologists National Ophthalmology Database) is a collaborator on the programme. He provided extracted cataract surgery data through the data-sharing agreements (WP2).

Padraig Dixon (https://orcid.org/0000-0001-5285-409X) (Health Economist) produced the calibration-mapping tool to crosswalk to health economic utilities (capability and quality-of-life preference-based measures) from Cat-PROM5 (WP3).

Rebecca Kandiyali (https://orcid.org/0000-0001-8566-9536) (Health Economics Research Fellow) participated in and guided analysis of the performance of health economic utilities (capability and quality-of-life scores) in cataract patients (WP3).

Hazel Taylor (https://orcid.org/0000-0003-3430-5278) (Medical Research Statistician) was a co-applicant and responsible for the strategic planning of the risk-indicator analyses (WP2). She undertook the initial WP2 analyses to review and refine the risk models for PCR and VA loss.

Katie Breheny (https://orcid.org/0000-0001-6886-4049) (Health Economist) 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).

Jonathan Sterne (https://orcid.org/0000-0001-8496-6053) (Professor of Medical Statistics and Epidemiology) was a co-applicant and oversaw the planning of statistical work across all WPs.

William Hollingworth (https://orcid.org/0000-0002-0840-6254) (Professor of Health Economics) was a co-applicant and the health economics lead, responsible for the strategic planning of the health economics elements (WPs 3 and 4).

David Evans (https://orcid.org/0000-0001-6961-7031) (Professor in Health Services Research; previously led People in Health West of England, a collaborative initiative on public involvement in research) was a co-applicant, was chairperson of the PAG throughout the programme and will author a collaborative paper with the PAG members to jointly describe the experiences of the group.

Fiona Fox (https://orcid.org/0000-0001-7313-8105) (Senior Qualitative Research Associate) conducted and analysed the qualitative interviews of patients and HCPs in relation to the discordant outcomes aim (WPs 3 and 4).

Sofia Theodoropoulou (https://orcid.org/0000-0003-3038-5354) (Academic Clinical Lecturer in Ophthalmology) reported on the risk factors and clinical outcomes in the aged $\geq$ 90 years population (WP2). She was also involved in the direct care of Involve-CAT participants.

Rachael Hughes (https://orcid.org/0000-0003-0766-1410) (Statistician) performed analysis and interpretation of the refractive outcomes of records from the NOD (WP2).

Matthew Quinn (https://orcid.org/0000-0002-8877-5024) (Medical Student) undertook the transcription, coding, qualitative analysis and interpretation of a stakeholder meeting around the ethics implications of immediately sequential bilateral cataract surgery.

Daniel Gray (https://orcid.org/0000-0003-0233-113X) (Doctor of Philosophy Research Student in Sociology) oversaw the qualitative analysis and interpretation of the stakeholder meeting regarding the ethics implications of immediately sequential bilateral cataract surgery.

Larry Benjamin (https://orcid.org/0000-0003-3748-649X) (Consultant Ophthalmologist) provided oversight throughout the programme as chairperson of the Programme Steering Committee and made recommendations for final revisions prior to submission of the final report.

Abi Loose (https://orcid.org/0000-0002-9178-102X) (Research Programme Manager) was a senior trial co-ordinator, latterly the programme manager; and drafted the PPI, impact and limitations sections of the report. She assisted in the operational design of WPs 1 and 3–4, and provided management support at the conclusion of the programme. Alongside **David Evans**, she will co-author a collaborative paper with the PAG.

Lara Edwards (https://orcid.org/0000-0003-3018-5459) (Research Programme Manager) was the first research programme manager, was responsible for the operational design of WPs 1 and 3 and provided management and leadership during the first 2 years of the programme.

Pippa Craggs (https://orcid.org/0000-0001-5705-741X) (Research Programme Manager) was research programme manager from 2016 to 2018, and provided leadership, management and the operational design of WP4 and the qualitative studies in WP3. She also set up the second recruiting site for WP3 to expand recruitment.

Frances Paget (https://orcid.org/0000-0002-2423-2629) (Research Programme Manager) was a senior trial co-ordinator and interim programme manager, assisted in the operational planning for WP4 and provided management support during the programme's final year.

Ketan Kapoor (https://orcid.org/0000-0003-3135-7320) (Optometrist) 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 (https://orcid.org/0000-0002-7133-760X) (Optometrist) conducted clinical examinations of Predict-CAT participants at the lead site.

Publications

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* 2018;**32**:796–805. https://doi.org/10.1038/eye.2018.1

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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* 2019;**33**:1161–70. https://doi.org/10.1038/s41433-019-0389-z

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Ethics statement

Ethics approval was obtained for all relevant sections of this report.

Data-sharing statement

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

Patient data

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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This report presents independent research funded by the National Institute for Health and Care Research (NIHR). The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health and Social Care

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