Patient Reported Outcomes Measures in Cataract Surgery:

The feasibility of electronically auditing self-reported

Outcomes using Cat-PROM5

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It is with deep regret that we note the death of our friend and colleague Robert Johnston, who sadly died in September 2016. Without his inspirational vision, determination and career long commitment to quality improvement in ophthalmology this work would not have been possible.

Table of Contents

Patient Reported Outcome Measures (PROMs) in Cataract surgery: The Feasibility of electronically auditing self-reported outcomes using Cat-PROM5

This feasibility study was commissioned by the Health Quality Improvement Partnership (HQIP) as part of a National Ophthalmology Audit with The Royal College of Ophthalmologists as the Audit Provider.

Executive Summary

Many people living into or beyond their seventh decade will develop cataract requiring surgical intervention within their lifetime. Surgery is the only known effective treatment for cataract, the primary purpose of surgery being to relieve visual difficulty and improve vision related quality of life for those affected. Cataract surgery is the most frequently undertaken surgical procedure on the NHS; in the 2017-2018 year there were approximately 435,000 NHS cataract operations performed in England and Wales. The annual cost of cataract surgery to the NHS is estimated at around £450 million.

The purpose of cataract surgery is to relieve affected individuals of the visual difficulties they experience, which in turn inhibit their quality of life and functioning. Despite the well-known limitations of Visual Acuity (VA), and its weak correlation with vision related quality of life, the need for, and benefit from cataract surgery is almost exclusively measured using VA letter charts. The 2017 NICE Cataract Surgery Clinical guideline [NG77], and the high level 2019 NICE Quality standard [QS180] each caution against over reliance on VA, e.g. Quality standard 2 recommends: “Adults with cataracts are not refused surgery based on visual acuity alone.” Furthermore, this NICE quality standard goes on to propose Cat-PROM5 as a suitable patient focussed outcome measure for “Health-related quality of life for adults with cataracts”.

In response to these changes in emphasis, and in the interests of empowering the patient voice, the Welsh Patient Reported Outcome Measures (PROMs) and Patient Reported Experience Measures (PREMs) programme have prioritised implementation of Cat-PROM5

into their cataract services across all of Wales. The questionnaire has been translated into Welsh and an electronic data collection platform has been developed for Wales.

This report assesses the feasibility of implementation of electronic data collection of Cat-PROM5 in three to five English NHS centres providing cataract surgery. Centres were chosen which delivered cataract surgery using the Medisoft Electronic Medical Record (EMR) system, this EMR provider having previously been selected to deliver electronic data collection tools for the HQIP commissioned National Ophthalmology Database (NOD) cataract audit. The EMR provider's contract was amended to include provision of electronic data collection functionality for capture of Cat-PROM5 data at both pre- and postoperative time points.

Set up

Following specification, building and preliminary testing of the Cat-PROM5 EMR data collection functionality, the data collection tools were 'road tested' at a single centre. Early testing and refinement of the tools was achieved iteratively prior to implementation into the hospital's Medisoft EMR system. Clinical staff in the preoperative assessment clinic of this centre were already familiar with a paper-based version of Cat-PROM5, and they were invited to trial data collection using the EMR electronic Cat-PROM5 data collection tool once implemented within the cataract care EMR.

The software allowed for different data capture options:

- Initial paper self-completion by the patient in the clinic, with subsequent transcription onto the EMR (pre- and/or postoperatively)
- Administration of the questionnaire by staff in the clinic, who entered the information directly into the EMR as the patient responded (pre- and/or postoperatively)
- Obtaining an email address for the patient and sending a secure link for the patient to complete the questionnaire electronically at home (here used postoperatively but could also be used preoperatively)
- Self-completion by the patient in the clinic on an iPad (trialled only preoperatively)

After successful implementation and testing at the first centre, a number of other centres were invited to join the feasibility study. The clinical leads at centres were contacted, permissions gained, and a local 'champion' sought to lead the project.

Data Collection

Patient data collection took place over a 14 month period between 16 May 2018 and 21 July 2019. All successful completions were made at a single site, this being the initial site (where the clinical lead was based). Timelines for all the centres appear in Appendix 4.

Successes

- Data collection was possible using any of the options
- The flexibility of data collection options allowed for local staff and patient preferences
- Data collection was quick, the median time for electronic completion was three minutes
- Patients completing at home responded promptly to the postoperative email they received which was sent out automatically by the EMR system at two months postoperatively

Challenges

- At some centres there was significant resistance to data collection from clinical and managerial staff concerned about interruptions to clinic flow
- There was failure on the part of some staff to understand the need for, and the value of patient-focused outcomes, with resistance to changing working practices (reliance on VA)
- Information Technology (IT) issues were encountered
    - One centre experienced intermittent 'IT glitches' related to firewall blocking of certain elements of the functionality of the data collection software on some clinic computers
    - At one candidate centre local IT staff were unwilling to make the requisite adjustments to their system to allow the software to be implemented
    - Set up times were considerably longer than expected due to a variety of delays relating to gaining relevant permissions, availability of local IT staff for facilitation of software implementation and troubleshooting

Patient Self-Reported Outcomes

Process considerations

Preoperative completions were made almost exclusively in the preoperative assessment clinic, either on paper and then transcribed onto the EMR, or questions were administered verbally by preoperative staff who entered the patient's responses directly into the EMR.

The median (Inter-Quartile Range - IQR) time for both pre- and postoperative electronic completion was 3 (2; 4) minutes. The median number of days (IQR) at which data collection took place preoperatively was 44 (26; 89) and postoperatively was 60 (60; 62), the tight postoperative timing being explained by the fact that many patients completed Cat-PROM5 promptly in response to a postoperative email automatically sent to them by the Medisoft EMR at two months postoperatively.

Outcomes

After exclusion of incomplete and duplicate completions there remained 280 valid Cat-PROM5 completions by 207 patients (3.3% of patients excluded). There were 179 completions related to first eye operations and 101 related to second eye operations. 202 completions were made at the preoperative time point and 78 postoperatively. The average difference in the Rasch calibrated visual difficulty score from before to after surgery was 2.82 logits, equivalent to a Cohen standardised effect (here a reduction in visual difficulty) of 1.27SD, i.e. a very large improvement in self-reported visual difficulty after surgery. As would be expected, the biggest group differences were observed between patients completing Cat-PROM5 who had 2 unoperated cataracts in situ with those who had had both their cataracts removed. The Cohen standardised difference in difficulty was 1.61SD, i.e. an exceptionally large improvement for those whose cataracts had both been removed.

Feasibility

It has been possible to develop user friendly EMR based electronic data collection tools for flexible completion of cataract patient self-reported outcomes with software having been successfully implemented at a number of sites. Implementation took longer than desirable for a variety of reasons and there were IT related teething problems which prevented implementation at one site. A lack of clinical leadership was encountered at one centre where staff were resistant to data collection for reasons of workload and patient flow. Nonetheless,

it has been feasible to collect patient self-reported outcomes electronically using the Cat-PROM5 questionnaire. Furthermore, patients are happy to provide their PROM responses, both in a clinical setting and at home in response to an email with a secure link to an electronic version of the Cat-PROM5 questionnaire.

Lessons Learnt

Senior managerial and clinical leadership may be necessary to overcome barriers and avoid delays to implementation of the electronic data collection tools.

Trust clinical and managerial staff may need to be educated as to the relevance and importance of bringing the patient's view into consideration to provide a more rounded and patient centred approach to care and outcomes assessment.

Patients had no difficulty responding to the questionnaire and did so quickly. Furthermore, patients were able to make postoperative completions promptly from home using their own device in response to an email request with a link to the questionnaire.

Conclusion

In conclusion, this study has demonstrated that inclusion of the patient's voice in the patient pathway is feasible in routine EMR based NHS cataract care and that extraction and analysis of the resulting data demonstrates powerfully the self-reported benefits reported by patients receiving cataract surgery. A number of barriers were encountered which meant that in the time available only the lead centre reached the point where data were successfully collected, extracted and analysed. Progress was delayed when repeated approaches to the IT department at the second centre failed to gain traction due to pressure of other priorities. IT implementation was however successful at two further centres, at one of which clinical and managerial staff were reluctant to use the software because of local service pressures. With appropriate local engagement and leadership however, it should be possible for these identified barriers to be overcome.

1. Introduction

In 2017 the Healthcare Quality Improvement Partnership (HQIP) commissioned a two-year extension of the previously commissioned National Ophthalmology Audit, this being primarily focused on cataract surgery. The contract extension included a commission to assess the feasibility of the use of Cat-PROM5, a Patient Reported Outcome Measure (PROM), as a patient focussed outcome measure for cataract surgery. In common with the three previously commissioned and successfully delivered feasibility studies (macular degeneration, glaucoma and retinal detachment surgery), the brief included an expectation that the PROM would be electronically collected as part of routine clinical care.

2. Background

Many people living into or beyond their seventh decade will develop cataract requiring surgical intervention within their lifetime. Cataract surgery is the most frequently undertaken surgical procedure on the NHS; in the 2017-2018 year there were approximately 435,000 NHS cataract operations performed in England and Wales. The annual cost of cataract surgery to the NHS is estimated at around £450 million.

The purpose of cataract surgery is to relieve affected individuals of visual difficulties they experience which inhibit their quality of life and functioning. Despite the well-known limitations of Visual Acuity (VA), the need for, and benefit from cataract surgery is almost exclusively measured using 100% contrast VA letter charts. The 2017 NICE Cataract Surgery Clinical guideline, and the high level 2019 NICE Quality Standard each caution against over reliance on VA, e.g. Quality Standard 2 recommends: “Adults with cataracts are not refused surgery based on visual acuity alone.” Furthermore, this NICE quality standard goes on to propose Cat-PROM5 as a suitable patient focussed outcome measure for “Health-related quality of life for adults with cataracts”.

Patient reported outcomes aim to place patients’ quality of life at the centre of care. Quality of life impairment and its relief from surgery is of primary concern in a symptomatic condition such as cataract. Furthermore, a clear understanding of patients’ self-perceived and self-

reported visual difficulty underpins value-based decision making for planners and commissioners of patient services in the NHS and beyond.

In response to these changes in emphasis, and in the interests of empowering the patient voice, the Welsh PROMs and Patient Reported Experience Measures (PREMs) programme have prioritised implementation of Cat-PROM5 into their cataract services across all of Wales (development too late for inclusion in feasibility study). The questionnaire has been translated into Welsh and an electronic data collection platform has been developed for Wales.

The current HQIP commissioned PROM feasibility study aligns to these shifts in emphasis. This report assesses the feasibility of implementation of electronic data collection of Cat-PROM5 in a number of English NHS centres providing cataract surgery. Centres delivering cataract surgery using the Medisoft Electronic Medical Record (EMR) system were invited to pilot the PROM collection tool. This EMR provider had previously been selected to deliver electronic data collection tools for the HQIP commissioned National Ophthalmology Database (NOD) cataract audit, the main component of the National Ophthalmology Audit. Following the extension of the HQIP commission for the National Ophthalmology Audit, the Medisoft contract was amended to include provision of functionality for collection of electronic Cat-PROM5 data at both pre- and postoperative time points.

Context of the PROM Feasibility Study

The National Ophthalmology Database Audit is primarily concerned with publishing comparative cataract surgical results for named surgeons (excluding trainees) and named centres (including trainees) and sat within the National Clinical Audit and Patient Outcomes Programme (NCAPOP) from 01 September 2014 until 31 August 2019. The main cataract surgical audit is based on routine clinical care data which is extracted from specialty specific ophthalmology Electronic Medical Record (EMR) systems. The most widely used system is the Medisoft EMR system, which in 2018 contributed data from 87 centres. Other contributing systems are the OpenEyes EMR system contributing from four centres, Epic from one centre and in-house bespoke local databases contributing from 10 centres. The remit of this feasibility study was to investigate the practicality of collection and reporting of exclusively EMR derived data to assess the potential for future inclusion of Cat-PROM5 as a patient focused outcome measure within the NOD Cataract Audit.

The national audit is overseen by a RCOphth based multi-professional steering committee with Patient and Public Involvement (PPI) which reports via the Informatics and Audit Sub-committee to the Professional Standards Committee and ultimately to the College Council. Regular contract review meetings were held with the audit commissioners, HQIP.

3.Aims

To assess the feasibility of:

1. Developing electronic tools for EMR based collection of Cat-PROM5 patient reported outcome data
2. Implementing data collection functionality into routine NHS cataract care in at least 3 and up to 5 NOD contributing EMR established centres
3. Including the capture of Cat-PROM5 data within the usual patient pathway of participating centres
4. Remotely extracting, aggregating, analysing and reporting Cat-PROM5 pre- and postoperative patient self-reported data
5. Inclusion of Cat-PROM5 as a patient focused outcome for cataract surgery in the NOD cataract surgery audit

4.Methodology

Data collection tools for Cat-PROM5

The NOD subcontractor, Medisoft, was approached and discussions initiated regarding specification of Cat-PROM5 data collection tools. Required functionality for the tools included a number of key features written into the subcontractor's contract (September 2017 to October 2017) covering the two-year HQIP cataract audit funding extension:

- Full Information Governance (IG) compliance with data protection legislation, the Data Protection Act 2018, which includes General Data Protection Regulation (GDPR)
- Ability to collect data in the hospital setting as well as by the patient at home using standard devices

- Secure storage of PROM data with ability to link Cat-PROM5 completions with a patient's full ophthalmology electronic record
- Ability to extract and aggregated data from multiple centres in formats suitable for statistical analysis

Testing at Initial Centre

Based on this specification electronic tools were developed (November 2017 to January 2018), and following permissions (November 2017 to January 2018) pre-tested (January 2018 to February 2018), implemented and 'road tested' (February 2018 to April 2018) at an initial site, Centre 1. After iterative refinements, the clinical staff in the preoperative assessment unit (who had previous experience of a paper-based version of the questionnaire for research) were trained on the software (April 2018) and invited to collect patient data in their routine clinics (May 2018 to July 2019). After consent by interested patients, preoperative data collection took place in the clinical setting for a trial period of approximately three months. A small number of patients were invited to trial Cat-PROM5 completion on an iPad which proved problematic and this option was abandoned. Following on from this trial phase, participating patients were also invited to provide an email address which allowed for an automated email to be sent out by the EMR at two months postoperatively, inviting patients to make a postoperative completion of Cat-PROM5 at home.

Recruitment of further Centres

On the basis of 'proof of concept' through development and refinement of the data collection systems at the initial site, four further potential sites were approached. Centre participation was affirmed by agreement from the Clinical Lead for Ophthalmology and the Trust Caldicott Guardian.

Although all sites agreed in principle to participate in the feasibility study, challenges arose resulting in variable success.

- Centre 2: Permissions were obtained (January 2018 to March 2018) but implementation (April 2018 to August 2018) raised issues with resident IT services and the local IT department were not sufficiently engaged to make the necessary

adjustments which would allow the data collection tools to function correctly. Despite enthusiasm by the clinical staff at this centre, implementation had to be abandoned (September 2018). Delays at this site had a knock-on effect which resulted in delays to implementation at subsequent sites.

- Centre 3: With permissions (June 2018 to August 2018), successful implementation of the data collection software was achieved (September 2018 to November 2018) and staff trained (December 2018). However, the clinical and managerial staff in the preoperative assessment unit failed to engage (January 2019 to May 2019) because they did not understand the value of using the PROM and were concerned that inclusion of the PROM into the patient pathway would cause delay in the clinic. In the absence of strong leadership, PROM data collection did not get off the ground at this centre and efforts to encourage data collection were abandoned (June 2019).
- Centre 4: With permissions (December 2018 to February 2019) successful implementation of the data collection software was achieved (March 2019 to May 2019), and data collection piloted at this centre. Due to various delays, including illness of key staff members (June 2019 to July 2019), collection of patient data began too late for their results to be included in this feasibility report. It is noteworthy however, that this site was fully engaged and keen to participate.
- Centre 5: Earlier delays meant that implementation at this site could not be completed in time for this report. However, permission was obtained (May 2019 to July 2019) and the implementation is proceeding, and it is expected that the site will be in a position to collect PROM data.

Extraction of Data

All Cat-PROM5 completions were anonymously extracted along with clinical information relevant to the cataract surgical event, including patient's approximate age at surgery (perturbed by +/- 6 months to maintain anonymity), date of surgery, side and first or second eye surgery. Anonymised data were transferred to the NOD audit provider for checking, cleaning and analysis. Since descriptive analysis only was envisaged, a simple Excel based format was adopted.

5. Findings

Set up time

Times to set up proved longer than expected. Gaining IG permissions took around 3 months, relevant trust staff are busy, and it is important for local trusts to be satisfied that IG arrangements are correct. This step was achieved for all the sites. Securing engagement from trust IT departments also took longer than anticipated, around 3 months for those centres where IT departments had the capacity to cooperate. Implementation at Site 2 had to be abandoned as a result of IT staff not having the ability or will to make the required adjustments to allow the software to be implemented. Training preoperative clinical staff was straightforward as all centres were established EMR users. There was however resistance at Site 3 to including use of the PROM in the preoperative environment due to pressure on time, and a failure on the part of the clinicians and managers to understand the importance of including the patient's voice in outcomes assessment. At Site 3 there was an absence of clinical leadership which might have overcome this resistance. Site 4 made good progress, but the earlier delays had a knock-on effect which meant that they were not able to start data collection in time for inclusion in the feasibility study. These timelines are provided in Appendix 4.

Data Collection

Timelines for the various stages at the test centres are provided in the Gantt chart in Appendix 4. Patient data collection took place over a 14.4 month period between 16 May 2018 and 21 July 2019. A total of 315 completions were extracted, all from Centre 1.

Clinic staff reported that patients were happy to provide the information for completion of Cat-PROM5. The median (IQR) time for electronic completion was 3 (2; 4) minutes. The median number of days (IQR) at which data collection took place preoperatively was 44 (26; 89) and postoperatively was 60 (60; 62), the tight postoperative timing being explained by the fact that many patients completed Cat-PROM5 promptly in response to a postoperative email automatically sent to them by the Medisoft EMR at two months postoperatively.

Patients and Eyes

214 patients made 315 completions either pre- or postoperatively or both. After exclusion of incomplete and duplicate completions there remained 280 valid completions by 207 patients (3.3% of patients excluded). The median age (range) at the time of completion was 78 (45; 95) years, 144 (51%) patients were male and 136 (49%) female. There were 179 completions related to first eye operations and 101 related to second eye operations. 135 were right eyes, 139 were left eyes, and the side for surgery was unavailable for six preoperative completions where eyes were yet to undergo surgery at the time of data extraction. 202 Cat-PROM5 completions were made at the preoperative time point and 78 postoperatively. 134 completions took place prior to first eye surgery, 113 completions between first and second eye surgery, and 33 completions after both cataracts had been removed. 9 patients made 3 completions (prior to first eye, between operations, after second eye); 55 patients made two completions (once prior to, and once after either first or second eye surgery); 143 patients made a single completion, either prior to or after either first or second eye surgery).

Understanding Cat-PROM5 Outcomes

A Cat-PROM5 completion of the five questions can be summarised into a single continuous measure of visual difficulty due to cataract through Rasch calibration. The calibrated 'single value' comprises a measurement on the underlying latent scale of visual difficulty and is measured in logit units. These units are presented here such that a more negative value represents less visual difficulty and a greater positive value greater visual difficulty. The calibrated scale is theoretically centred at zero. For Cat-PROM5, the full range of calibrated values is from -9.18 (no reported visual difficulty) to 7.45 (maximum reported visual difficulty), the slight asymmetry of this range being due to minor skewing of the original set of data upon which calibration was based. The outcomes are reported both in terms of logits and, in order to better illustrate differences between scores, these results are standardised according to Cohen's convention as a proportion of the baseline preoperative standard deviation (SD). Standardised group differences of around 0.2SD are regarded as small, 0.5SD medium, 0.8SD large and 1.0SD or more as very large differences. In summary, visual difficulty is measured on a scale of 'logits', a more positive number is worse vision, a more negative number is better vision. The size of a change (improvement) can be represented as SD with 0.2SD being small and 1.0SD or more being very large.

Patient's Self-Reported Outcomes

The mean (range) for Rasch calibrated preoperative scores was -0.22 (-6.80; +6.01) logits and for postoperative scores was -3.04 (-9.18; +2.93) logits, the average difference in visual difficulty from before to after surgery thus being -2.82 logits, equivalent to a Cohen standardised reduction of 1.27SD, i.e. a very large improvement in self-reported visual difficulty after surgery (group score distributions shown in Figure 1). For patients undergoing first eye surgery the standardised reduction in visual difficulty was 0.47SD (a moderate improvement reflecting the presence of an as yet unoperated second cataract) and for patients undergoing second eye surgery the standardised reduction was 1.14SD (a very large improvement after removal of the second cataract). The difference between preoperative patients who were due to undergo first eye surgery and postoperative patients who had completed second eye surgery (i.e. difference between having both cataracts in situ and having had both removed) was 1.61SD (an exceptionally large improvement) (group score distributions in Figure 2).

Figure 1. Distribution of Rasch Calibrated Cat-PROM5 Scores for Pre- and Postoperative questionnaire completions

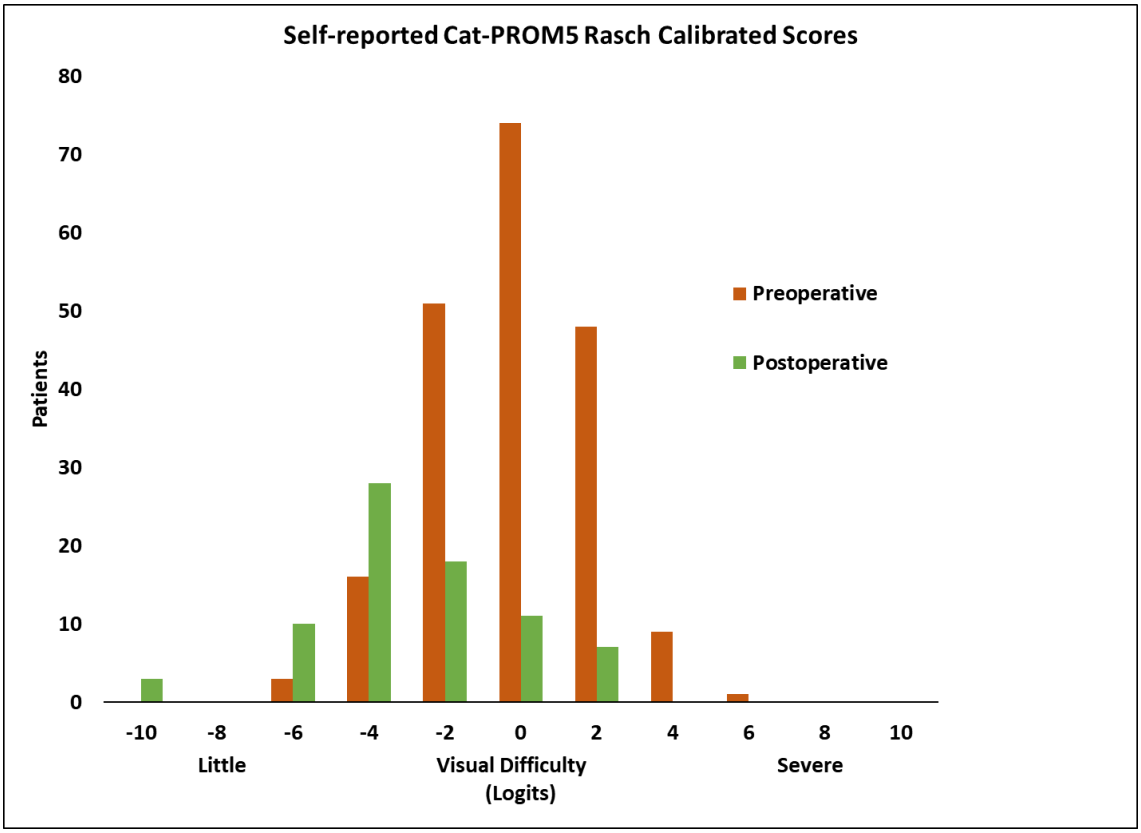
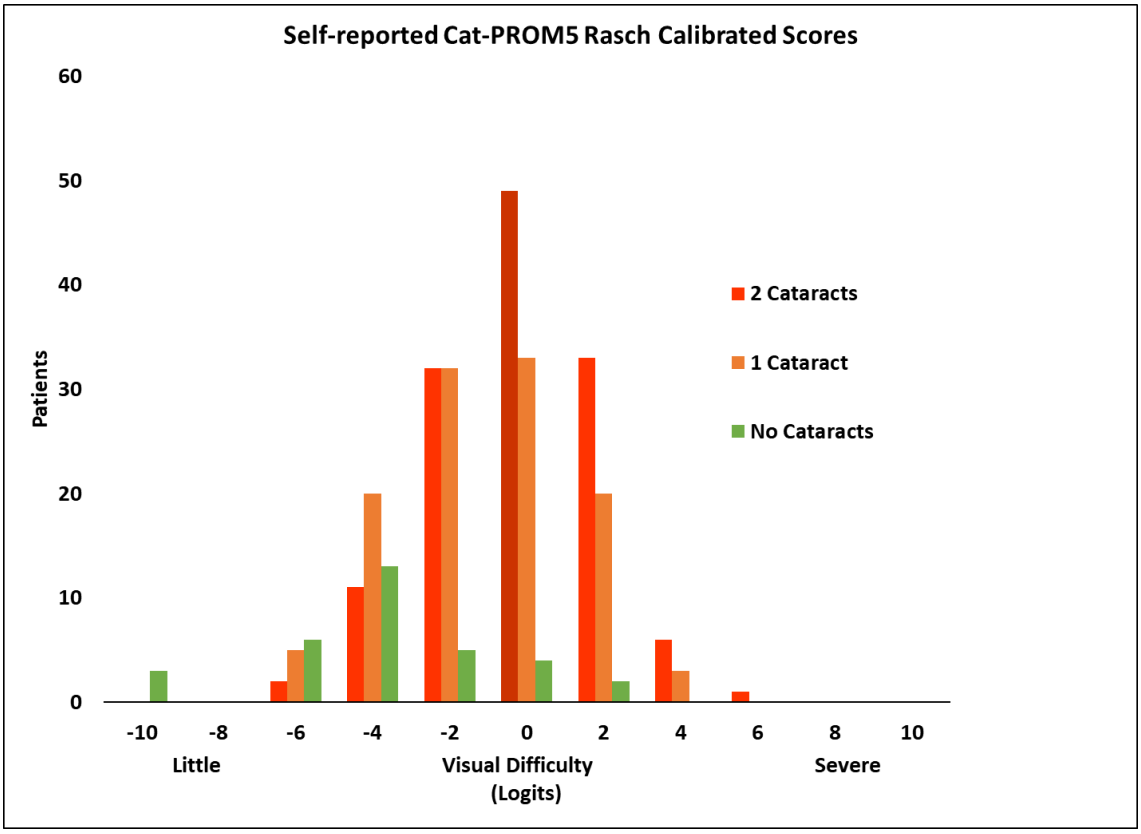


Figure 2. Distribution of Rasch Calibrated Cat-PROM5 Scores for patients with 2 cataracts in situ, 1 cataract in situ and after surgery on both eyes, with no cataracts



Successes in the process

- Data collection was possible using any of the options with staff and patients preferring some methods ahead of others
- The flexibility of data collection options allowed for preferences which were in part dependent on:
    - Physical layout of the clinic
    - Established patient pathways operating within a given clinic
    - At which point in the pathway the Cat-PROM5 data collection event was 'slotted in'
- Patients responded promptly to the automated postoperative email they received which was sent out by the EMR system at 2 months postoperatively

Challenges in the process

- Timelines on gaining permissions and implementation of software were longer than anticipated resulting in delays to progress
- At one centre there was significant resistance from clinical and managerial staff to data collection
    - Clinical staff cited pressure of time due to a high workload as a reason for being unwilling to include the data collection event into clinical care
    - Managerial staff cited the need for 'rapid processing' of (preoperative) clinic patients as a reason to not incorporate a PROM
    - Both groups were impervious to the suggestion that inclusion of a PROM would improve quality of care and introduce the patient voice into clinical assessments
- There was failure on the part of some clinical and managerial staff to understand the need for and the value of patient-focused outcomes, usually accompanied by a resistance to changing working practices (reliance on VA)
- IT issues were sufficient to completely prevent the implementation of the data collection software in one centre and 'IT glitches' arose at another centre where the trust software sometimes blocked the data collection functionality on some of the clinic computers

6. Summary of Key Points

EMR based electronic data collection

- *Data collection tools*
    - The successful development and implementation of Medisoft EMR based Cat-PROM5 data collection tools has been demonstrated, implementation of the software was however not straightforward for all centres
    - At one centre the local IT department was unwilling to make the necessary adjustments to their system, and software implementation was not achieved.
    - At another centre there were intermittent software malfunctions thought to be due to local firewall settings interfering with elements of the software functionality
    - Data collection tools for other EMRs have not yet been developed, however the Welsh PROMs and PREMs programme are developing their own Cat-PROM5 data collection platform for Wales and OpenEyes EMR have indicated that they wish to include Cat-PROM5 data collection functionality in their software
- *Engagement of clinical staff*
    - Clinical staff at most centres recognised the importance of integrating the patient's voice into the patient pathway and outcomes assessment
    - Disappointingly, at one centre clinical and managerial staff did not adequately recognise the value of including a PROM in their patient pathway and failed to engage with data collection on grounds of being concerned about workload and possible delays to the running of clinics

- *Engagement of patients*
    - Patients were happy to provide the necessary information and those who provided email addresses and undertook completions at home responded promptly upon receipt of the automated email at two months postoperatively
    - Completion times were short with a median of three minutes

Lessons Learned from the Feasibility Study

- *Trust specific IT issues and delays*
    - Timelines for implementation of the Cat-PROM5 data collection tools into the resident Medisoft programme were longer than desirable due to busy local IT staff needing significant time to approve and assist with the necessary arrangements
    - Lack of willingness on the part of local IT staff to make necessary adjustments to their IT systems resulted in a centre being excluded
    - Intermittent 'IT glitches' related to firewall blockages at one site reduced the volume of completions achieved

✓ The learning from this was that senior managerial and clinical leadership may be necessary to encourage IT staff to engage and address the IT issues in a timely manner.

- *Clinical and managerial engagement*
    - Lack of appreciation by clinical and managerial staff of the importance and value of including a patient focused outcome in the cataract service
    - Despite approvals and implementation of the software, clinical and managerial staff at one centre were reluctant to include collection of the PROM in their patient pathway citing concerns about workload and smooth

running of the clinic as reasons. This resulted in no data being collected for the study at this site

- ✓ The learning from this was that trust staff may need to be educated as to the relevance and importance of bringing the patient's view into consideration to provide a more rounded and patient centred approach to care and outcomes assessment.

- *Patient questionnaire completion*
    - Pleasingly, patients were happy to provide responses to Cat-PROM5
    - Completions were generally quickly achieved, the median completion time being just three minutes
    - Patients responded promptly to the automated email sent out at two months after surgery inviting them to make a postoperative completion of the questionnaire electronically in their own homes
    - A small group of patients who were asked to complete the questionnaire in the clinical setting using an iPad found this difficult as they were unfamiliar with a tablet format and function

- ✓ The learning from this was that patients had no difficulty responding to the questionnaire and did so quickly. Furthermore, patients were able to make postoperative completions promptly from home using their own device in response to an email request with a link to the questionnaire. The few patients who were invited to make completions on an iPad found this format difficult.
- ✓ Overall, these patient related learning points are encouraging, it may be that greater use of home completion would be beneficial in terms of reducing potential impact on clinic flows; the email invitation to complete Cat-PROM5 could be sent to a patient both before and after surgery.

Feasibility of inclusion of Cat-PROM5 as a patient centred outcome in the NOD Cataract Surgery Audit

This study has demonstrated that it is feasible to collect patient self-reported Cat-PROM5 questionnaire outcomes for cataract surgery using the EMR based data collection tools developed for this purpose. Centre specific IT issues can arise which require troubleshooting, but with adequate local engagement and a will, these should be resolvable. Patients are happy to provide their PROM responses, both in a clinical setting and at home in response to an email with a secure link to an electronic version of the Cat-PROM5 questionnaire.

In conclusion, this study has demonstrated that inclusion of the patient's voice in the patient pathway is feasible in routine EMR based NHS cataract care and that extraction and analysis of the resulting data demonstrates powerfully the self-reported benefits recorded by patients receiving cataract surgery.

Authorship

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Consultant Ophthalmologist and Clinical Lead for the National Ophthalmology Database Audit

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Appendix 1: The Cat-PROM5 Questionnaire

Cat-PROM5

References

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

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

Cat-PROM5 Questionnaire

STRICTLY CONFIDENTIAL

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

SOME OF THE QUESTIONS MAY SEEM SIMILAR BUT PLEASE ANSWER ALL

Full Name _____

Date of Birth (DD/MM/YY) _____

Address _____

_____

_____ Postcode _____

Please read the following information

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

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

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

Please ask for help if the questions are not clear

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

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

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

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

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

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

2. In the past month,

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

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

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

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

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

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

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

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

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

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

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

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

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

Please write today's date here:

/	/	
DAY	MONTH	YEAR

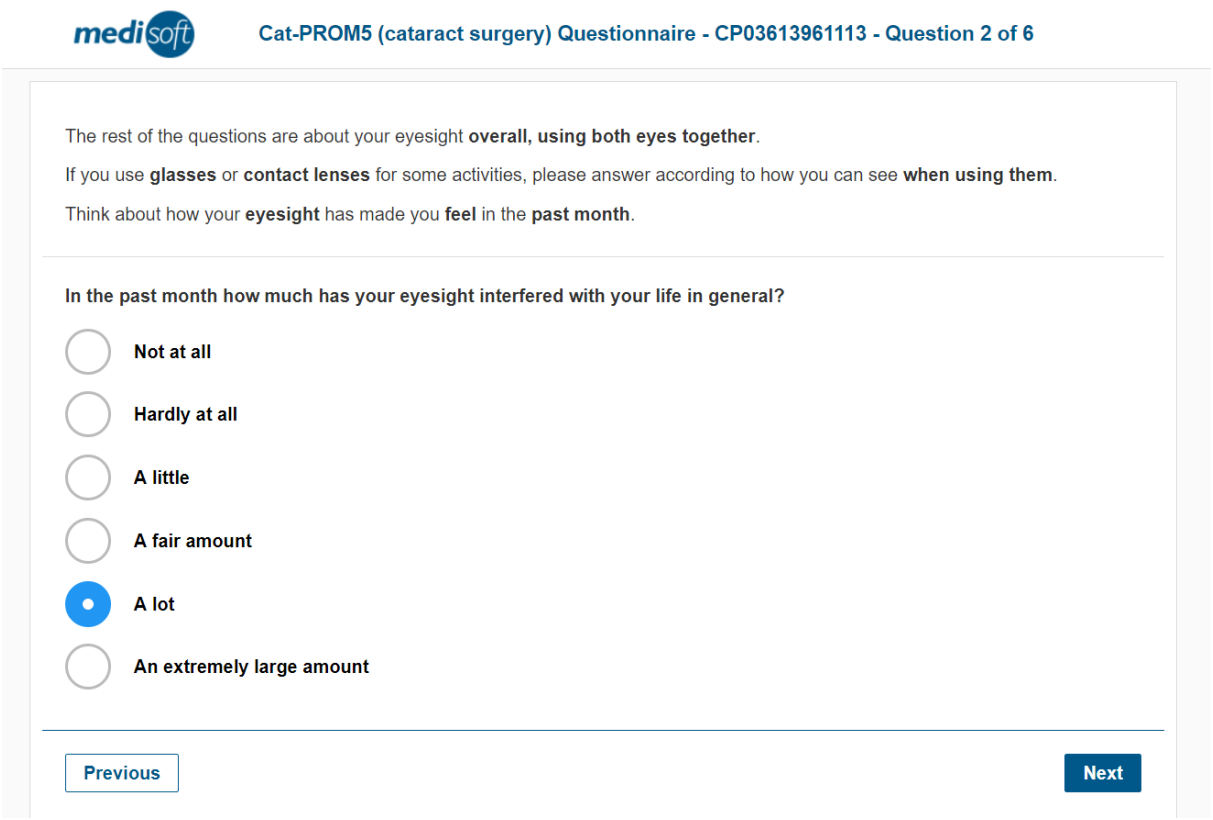
NOW, PLEASE CHECK THAT YOU HAVE ANSWERED ALL THE QUESTIONS ON EVERY PAGE.

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

Thank you for completing this questionnaire about your eyesight.

Your answers will be **confidential**.

Appendix 2: ‘Screen shot’ image of one of the Cat-PROM5 questions as seen on the EMR electronic data collection software



Appendix 3: Glossary

Abbreviation	Description
%	Percentage
EMR	Electronic Medical Record
Cat-PROM5	Cataract Patient Reported Outcome Measure
GDPR	General Data Protection Regulation
HQIP	Healthcare Quality Improvement Partnership
IQR	Inter Quartile Range
NCAPOP	National Clinical Audit and Patient Outcomes Programme
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NOD	National Ophthalmology Database
PPI	Patient and Public Involvement
PROMs	Patient Reported Outcome Measures
PREMs	Patient Reported Experience Measures
RCOphth	The Royal College of Ophthalmologists
SD	Standard Deviation
UK	United Kingdom
VA	Visual Acuity

Appendix 4: Gantt Chart for Cat-PROM5 feasibility study

Approximate timelines for PROMs feasibility study	Sep-17	Oct-17	Nov-17	Dec-17	Jan-18	Feb-18	Mar-18	Apr-18	May-18	Jun-18	Jul-18	Aug-18	Sep-18	Oct-18	Nov-18	Dec-18	Jan-19	Feb-19	Mar-19	Apr-19	May-19	Jun-19	Jul-19	Aug-19
Data Collection Software																								
Cat-PROM5 Data Collection Software Specification	■	■																						
Software writing			■	■	■																			
Pre-testing software functionality					■	■																		
Centre 1																								
Gaining permissions			■	■	■																			
Software implementation & trouble shooting						■	■	■																
Training staff on clinic computers								■																
PROM Data Collection									■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	
Centre 2																								
Gaining permissions					■	■	■																	
Attempted software installation								■	■	■	■	■												
Installation abandoned as local IT support unavailable													■											
Centre 3																								
Gaining permissions										■	■	■												
Software installation													■	■	■									
Training staff on clinic computers																■								
Failure of staff to engage with data collection																	■	■	■	■	■			
Attempted data collection abandoned																						■		
Centre 4																								
Gaining permissions																■	■	■						
Software installation																			■	■	■			
Training staff on clinic computers delayed due to illness																						■	■	
No data collected in time for feasibility study																								■
Centre 5																								
Gaining permissions																					■	■	■	
Software installation																								■
Reporting																								
Data extraction, analysis and report writing																							■	■