

# Implementation of European Cataract Community following International Consortium for Health Outcomes Measurements (ICHOM) standards: lessons learned at Araba Integrated Health Organization (IHO) (Vitoria-Gasteiz, Spain)

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## Introduction

Cataract is an opacity of the lens that reduces the amount of incoming light and results in visual function and quality of life deterioration. In Europe, the prevalence of cataract is 64% for the population over 70 years and it increases with age. In many countries, cataract surgery is one of the most commonly performed procedures and it has proven to be one of the most cost-effective health-care interventions. Despite this, outcomes assessment varies between ophthalmology departments and countries. This situation limits the benchmarking, the studies about best practices and the most adequate strategies to maximize value for patients. A European multi-site study involving 10 health institutions was created. It evaluated the results of cataract surgery following the International Consortium for Health Outcomes Measurements (ICHOM) cataract standard set characterizing the relationship between Patient-reported outcomes (PROMs) and Clinician-reported outcome measures (CROMs).

The purpose of the current abstract is to report the results of such study that corresponds to the ophthalmology clinic management unit of Araba Integrated Health Organization (Araba IHO) and to report the lessons learned.

## Methods

A prospective non interventional observational descriptive study was developed including patients from several centers from Finland, 4 centers from Spain, 2 centers from The Netherlands and 1 center from Germany, Italy and United Kingdom promoted by Johnson & Johnson Vision. The ICHOM Cataract Standard Set version 2.0.1 was followed to register the clinical data and the CATQUEST-9SF questionnaire to register the patient reported outcomes. The data were collected using a web platform developed by Quodem and was based on the timeline established by ICHOM (Figure 1).

The study was adhered to the tenets of the Declaration of Helsinki and was approved by the ethics committee of each participating center.

Descriptive statistical analyses and inferential analyses by multiple regression for quantitative outcomes were performed.

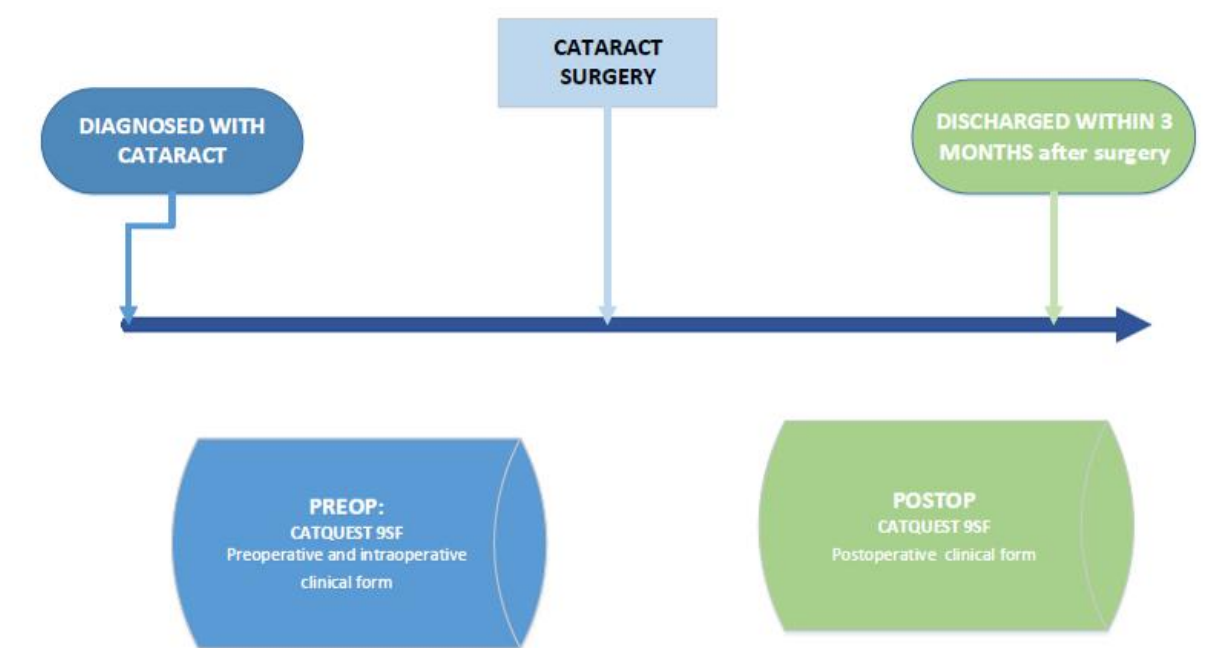


Figure 1. Process timeline

## Results

The multi-site study included 3799 cases and the results were reported by Zijlmans et al (2021). The main results were that in 88.7% of eyes, a postoperative corrected distance visual acuity (CDVA) equal or better than 0.3 logMAR was achieved and, a visual function improvement after surgery was reported by 91.5% of patients. In addition, a weak statistical correlation of postoperative CDVA with postoperative refraction, PROMs and complications were found ( $0.133 \leq r \leq 0.289$ ,  $p < 0.001$ ). A predictive model ( $R^2 : 0.254$ ) of postoperative CDVA considering 10 variables was obtained.

At Araba IHO, we collected 513 eye's data, but 4 were excluded. Table 1 shows the descriptive statistical analysis from this cohort: median age was 76 years (interquartile range: 71-82), 54.22% were female and 53.24% were left eyes. Eye comorbidity was present in 32.81% of the patients: 11.59% glaucoma, 8.84% macular degeneration, 3.73% diabetic retinopathy, 2.36% amblyopia and 12.18% other kind of ocular pathologies. The surgical procedure performed in all cases was phacoemulsification and 91.35% of them were performed mostly by an independent surgeon. The rate of intraoperative complications was 3.54%, being the most frequent complication the posterior capsule rupture (2.16%). The last follow-up visit was performed at a median time of 60 days (interquartile range 52-70 days). A postoperative corrected distance visual acuity (CDVA) of 0.3 and 0.0 LogMAR or better was achieved by 94.5% and 55.6% of eyes, respectively. No endophthalmitis were described and 4 patients (0.78%) required a new surgery. The preoperative and postoperative CATQUEST 9SF was answered by 99.21% 98.92% of the patients, respectively. Eighty six percent of the patients improved the mean result of the questionnaire ( $p < 0.000$ ). Finally, a list of lessons learned was collected during the study (table 2).

Table 1. Descriptive statistical analysis

VARIABLES	Total patients	Median	Interquartile range
Age (years),	509	76	71-82
Gender, n (%)	509		
Male	233, 45.78%		
Female	271, 54.22%		
Eye, n (%)	509		
Right	237, 46.76%		
Left	271, 53.24%		
Preoperative VA			
UDVA (Snellen)	509	0.3	0.15-0.4
CDVA (Snellen)	509	0.4	0.3-0.5
Fellow eye UDVA	508	0.5	0.3-0.7
Fellow eye CDVA	508	0.7	0.5-1
Target	509	-0.22	-0.32- -0.12
Comorbidity	167, 32.81%		
Glaucoma	59, 11.59%		
ARMD	45, 8.84%		
Diabetic Retinopathy	19, 3.73%		
Amblyopia	12, 2.36%		
Others	62, 12.18%		
Second eye surgery	219, 43.02%		
Previous eye surgery	39, 7.66%		
Corneal surgery	3, 0.59%		
Vitrectomy	16, 3.14%		
Others	23, 4.52%		
Intraoperative observations	88, 17.29%		
Brown/White cataract	36, 7.07%		
Corneal leucoma	10, 1.96%		
Pseudoexfoliation	9, 1.77%		
Pupil disorders	51, 10.02%		

VARIABLES	Total patients	Median	Interquartile range
Time to surgery (days)	509	82	35-104
Phacoemulsification technic	509, 100%		
Surgeon experience	509		
Independent surgeon	465, 91.35%		
Trainee	44, 8.65%		
Intraoperative complications	18, 3.54%		
PCR	11, 2.16%		
Zonular dehiscence	1, 0.2%		
Vitreous loss	7, 1.37%		
Dropped nucleus	0		
Others	9, 1.77%		
Time to last follow-up visit (days)	509	60	52-70
Postoperative VA			
UDVA (Snellen)	509	0.7	0.5-0.91
CDVA (Snellen)	509	1.0	0.81-1.00
Fellow eye UDVA	508	0.6	0.37-0.8
Fellow eye CDVA	508	0.85	0.6-1.00
Postoperative spherical equivalent	509	-0.25	-0.5-0.00
Refractive error	509	0.00	-0.31-0.23
Postoperative complications	13, 2.55%		
New surgery	4, 0.78%		
Endophthalmitis	0		
Corneal edema	3, 0.59%		
Others	6, 1.18%		
CATQUEST 9SF			
Valid preoperatively	99.21%		
Valid postoperatively	98.92%		

VA, Visual Acuity; UDVA, Uncorrected distance visual acuity; CDVA, Corrected distance visual acuity; ARMD, Age-related macular degeneration; PCR, Posterior capsule rupture

Table 2. Lessons learned

Leadership	the hospital manager must <b>actively promote</b> the project,
Human resources	+ because the project needs involved different human resources dedicated to the implementation (time-consuming project) and must be the same group during the project development:
Information and Communication Technologies (ICT) technician	- a ICT technician is needed to <b>stabilish and introduce</b> the CROM and PROM forms in the electronic medical record and to design and implement the data dashboards. The <b>data must be automatically entered</b> in the forms to avoid errors and in case this was not completely possible, a data manager is required.
Quality and safety coordinator	- a quality and safety coordinator is needed to <b>analyze the process, visualize the gaps</b> between the ICHOM's standard set/process and the hospital's process and to <b>coordinate the process</b> .
Leader in the medical condition	- an ophthalmologist leader in the medical condition is needed to <b>coordinate the medical team, to adapt the ICHOM's standards, to perform the continuous improvement and to communicate the project in science forums</b> .
Case manager	- an optician or nurse is needed to <b>follow-up</b> the patients and careers and their needs during the process.
Patients	- the patients and their careers and patients' associations must be involved in the project
Material resources	+ because the project needs standard and updated <b>devices and explorations rooms</b> .
Time	+ because the project implementation <b>requires more than six months</b> to get ready to start.
Economic resources	+ because all the previous items require <b>money directly or indirectly</b> .

## Conclusions

This abstract reports the implementation of the ICHOM standard set for cataracts in Araba IHO and confirms that **cataract surgery provides excellent visual outcomes and a positive impact on patients' quality of life**, with minimal complications in most of the patients. The lessons learned constitute a valuable resource to the management of these patients.

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