Beyond Visual Acuity: Patient-relevant Assessment Measures of Visual Function in Retinal Diseases

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Abstract:	Purpose: To identify patient-reported outcomes (PROs) and other clinical outcome measures (contrast sensitivity [CS], low-luminance visual acuity [LLVA] and reading acuity or reading speed [RA-RS]), relevant to patients with age-related macular degeneration (AMD) or diabetic retinopathy (DR), which would be recommended for use in clinical practice. Methods: The RAND/UCLA Appropriateness Method, based on the synthesis of the scientific evidence and the collective judgment of an expert panel using the two-round Delphi method, was applied. The evidence synthesis was performed by searching for articles on outcome measures for AMD and/or DR published between 2005 and 2018 in English or Spanish. The expert panel consisted of 14 Spanish ophthalmologists, who rated the recommendation degree for each outcome measure on a scale of 1 (extremely irrelevant) to 9 (maximum relevance). The recommended outcome measures were established according to the panel median score and the level of the panelists' agreement. Results: Through the evidence search, 33 PRO-specific questionnaires (21 for visual function, 6 for AMD, 3 for DR, 1 for AMD and DR) and 2 treatment satisfaction questionnaires (one on AMD and one on DR) were identified. In addition, 21 methods were found for measuring CS, 5 for LLVA, and 9 for RA-RS. According to the panel ratings, 11 of the 64 outcome measures evaluated for AMD, and 7 of the 61 evaluated for DR were recommended.

	Conclusions: The AMD and DR outcome measures recommended will help ophthalmologists choose the outcome measure most appropriate for their patients. Furthermore, the use of PROs will contribute to shifting clinical practice towards patient-centered medicine.

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INTRODUCTION

Age-related macular degeneration (AMD) and diabetic retinopathy (DR) are important retinal diseases. AMD produces central visual acuity (VA) loss, leading to severe and permanent vision impairment and blindness, with great impact on patients' quality of life. It is estimated that in Europe, 3.3% of people over 65 suffer from AMD [1], and about 200 million worldwide [2]. DR is the main cause of preventable blindness in working-age people. The estimated prevalence of DR is 40% in patients with type 2 diabetes and 86% in patients with type 1 diabetes [3].

Several objective measures can estimate the impairment degree in retinal pathologies, such as VA or optical coherence tomography (OCT), contrast sensitivity (CS), low-luminance visual acuity (LLVA), or reading acuity or reading speed (RA-RS). However, these objective measures do not necessarily reflect accurately the impact of their vision loss on patients' daily activities or quality of life. Therefore, instruments (questionnaires) known as *Patient-reported outcomes* (PROs) [4-6] have been developed, as well as methodology to ensure their scientific validity [6-10]. The PROs may be generic or specific [11]. Generic questionnaires measure health-related quality of life dimensions and may be applied to any type of patient or condition, e.g., the EuroQoL [12] or the *36-Item Short Form Health Survey* (SF-36) [13]. Specific questionnaires may be disease-specific (e.g., cardiac failure, glaucoma, AMD), population-specific (e.g., frail elderly, blind), function-specific (e.g., sleep, visual function), or problem-specific (e.g., pain, dyspnea).

In ophthalmology, numerous PRO measures have been developed [14]. A 2013 review identified 121 PROs for vision-related diseases [15]. In 117 clinical trials published between 2010 and 2013 on AMD interventions, 38 of the 858 outcome variables used were PROs [16]. In a 2017 review on retinal diseases, 110 PROs were identified, of which 62 were generic, 19 were ophthalmic-specific (e.g., the *National Eye Institute Visual Functioning Questionnaire* [NEI-VFQ]), and 29 were retinal-specific (e.g., the *Daily Living Tasks Dependent on Vision* [DLTV] for AMD and the *Retinopathy-Dependent Quality of Life Questionnaire* [RetDQoL] for DR) [17].

Given the plethora of PROs, the aim of this study is to identify PROs and other outcome measures (CS, LLVA, RA-RS) relevant to AMD or DR patients that could be recommended for use in clinical practice in Spain.

METHODS

The *RAND/UCLA Appropriateness Method* (RUAM) [18,19] was used to address the project aim. The RUAM is based on a synthesis of the scientific evidence and the collective judgment of an expert panel using the two-round Delphi method. With the RUAM, appropriateness criteria have been developed for numerous diagnostic and therapeutic procedures in different specialties [20-25], including ophthalmology [26-

28]. There is sufficient evidence regarding the sound methodology and the RUAM predictive validity on patient outcomes [22,29-35].

To apply the RUAM these steps were followed: 1) constitution of the expert panel; 2) creation of outcome measures list; 3) creation the first Delphi round questionnaire; 4) first Delphi round; 5) first round analysis and preparation of the second round questionnaires; 6) second Delphi round; and 7) second round analysis and proposal of the outcome measures to be recommended.

To assure the panel heterogeneity, the project Scientific Committee (SC) established the following criteria for the panel constitution: 1) Geography: regional distribution as ample as possible, 2) Experience: <10 years (2 panelists), 10-25 years (10 panelists), > 25 years (3 panelists); 3) Scientific production : At least 5 panelists with any publication on AMD or DR in the last 10 years; and 4) Gender: At least 5 panelist of each gender.

The SC proposed a list of 40 candidates, of which 15 were selected in such a way that would meet the desired distribution. Finally, the panel distribution was: gender (8 females, 7 males), location (from 8 Spanish regions), experience (<10, 10-25, and >25 years: 2, 10, and 3 panelists respectively), and scientific publications on AMD and/or DR in the past 10 years (7 had at least one publication). The method requires that each panelist must not know who the other panelists are.

To create the list of outcome measures for visual function, an evidence synthesis was performed (Annex 1). The bibliographic search was done on articles published from 2005 through 2018, in English or Spanish, using the Medline, Spanish Medical Index (IME), and Medicina en Español (MEDES) bibliography databases. Additionally, the bibliography of the last systematic review on the subject [17] was manually reviewed.

Thirty-three PRO questionnaires were identified in the evidence search, of which 21 were specific to visual function (e.g., NEI-VFQ-25), **6** to AMD (e.g., *Macular Disease Dependent Quality of Life Questionnaire* [MacDQoL]), **3** to DR (e.g., *Retinopathy-Dependent Quality of Life questionnaire* [RetDQoL]), **1** to AMD and DR (Low-Luminance Questionnaire (LLQ)), **1** to AMD treatment satisfaction (MacTSQ), and **1** to DR treatment satisfaction (RetTSQ).

Twenty-one methods were identified to measure CS; the most used was the Pelli-Robson, followed by the *Optec-Functional Vision Analyzer* (Optec-FVA). Five methods were identified to measure LLVA (*Electronic Visual Acuity tester*, *Early Treatment Diabetic Retinopathy Study* (ETDRS), *Smith-Kettlewell Low-Luminance Acuity Test* (SKILL), *Bailey-Lovie* charts, and Snellen lines). Of the **8** methods found to measure RA-RS, the most used was the *Minnesota Low-Vision Reading Test* (MNRead), followed by the *Radner* and the method used in the *Submacular Surgery Trials* (SST).

Finally, the list included 125 outcome measures, 64 for AMD and 61 for DR.

The evidence synthesis, the articles describing the PROs questionnaires and the first Delphi round questionnaire were sent to the panelists. They rated each of the 125 outcome measures using a scale of 1 to 9, where 1 means "extremely irrelevant" and 9 "maximum relevance" for use in Spain. Relevance was defined as the importance of each outcome measure in clinical practice for early diagnosis and outcomes follow-up. Ratings were received from 14 panelists (one panelist was unable to participate).

The panel's ratings were analyzed, and individualized questionnaires were created for each panelist for the second Delphi round. In this questionnaire, each panelist was able to see her/his own first round responses and the distribution of the other panelists' ratings with anonymized individual scores. With this anonymous feedback process, each panelist rated all the items, even if her/his score was the same as in the first round. All 14 panelists responded.

Establishing the recommended outcome measures

In the second-round panel ratings, since the number of panelists was not a multiple of 3, the IPRAS method (*Interpercentile Range Adjusted for Symmetry*) [18] was used to assess the level of agreement among the panelists. The disagreement measured with the IPRAS method gives a mathematical result equivalent to that which would occur in a panel multiple of three if, at least, a third of the panelists had scored in the range 1-3, and at least a third had scored in the range 7-9. As a result, the relevance of using each outcome measure was classified as with agreement (+) or disagreement (-).

The outcome measures with a median rating <4 with agreement were classified as "not recommended" (NR), and those with a median rating ≥7 with agreement were classified as "recommended" (RE). The category "may be recommended" (MR) was given to the rest: all those with a median ≥ 4 and <7, and to all those rated with disagreement, regardless of the median.

RESULTS

Table 1 shows the outcome measure in the left column. The columns labeled AMD and DR show the panel ratings median "M." Column "A" (Agreement) shows the agreement (+) or disagreement (-) among the panel ratings. The column labeled "R" (Recommendation) indicates the three recommendation categories: RE, MR, and NR. Of the 29 PRO questionnaires for AMD, 24 were rated with agreement and **5** with disagreement, resulting 8 RE, 10 MR and 11 NR. Of the 26 PRO questionnaires for DR, 20 were rated with agreement and **6** with disagreement, resulting 4 RE, 9 MR, and 13 NR (Table 1).

Twenty-one measures were identified for CS. For AMD, 20 were rated with agreement and **1** with disagreement, resulting 1 RE, 3 MR and 17 NR. For DR, all 21 were rated with agreement, resulting 1 RE, 2 MR and 18 NR (Table 2).

Five outcome measures were identified for LLVA. For AMD, 3 were rated with agreement and 2 with disagreement, resulting in 1 RE, 3 MR and 1 NR. For DR, 4 were rated with agreement and 1 with disagreement, resulting in 1 RE, 3 MR and 1 NR (Table 3).

Eight outcome measures were identified for RA-RS. Both for AMD and for DR, all 8 were rated with agreement, resulting 1 RE, 2 MR and 5 NR for both pathologies (Table 4).

Recommended outcome measures

The 11 outcome measures recommended for AMD and the 7 recommended for DR are shown in Table 5. By definition, all the recommended measures were rated with agreement. In the case of visual function PROs, the recommended measures have been listed according to the median value.

DISCUSSION

In clinical practice, health professionals face the challenge of classifying the patient's state or measuring the outcomes of an intervention. To that end, there are objective measures such as VA, perimetry, and OCT, as well as PROs, which capture the patient's experience, preference, or perception [4-6]. Thirty-three PRO questionnaires identified focused on AMD and DR (Annex 1). The PRO questionnaires differ in the areas they explore, the items they include and the way they are administered (e.g., self-administered, interviews, …), so they may present different complexities and require different resources (e.g., time, trained staff, …). A PRO that may be applicable in one clinical context might not be applicable in another.

The methodology is a key factor in projects to develop clinical practice recommendations. In this case, we used the RUAM, rather than a simple Delphi method, because the RUAM adds the robustness of the evidence synthesis. The RUAM was initially developed to make recommendations about the appropriateness of medical procedures [18,24]. A debated issue surrounding RUAM is the interpretation of indications rated as "uncertain," which in recent studies was renamed "may be appropriate" [36] and which, in this study, we named "may be recommended." When an outcome measure has been classified as MR with agreement, we interpret that the advantages and disadvantages of using the outcome measure are similar. When the MR category has been assigned with disagreement, it must be interpreted individually, as some panelists might have rated that outcome measure for use in a high-level hospital, and other panelists might have been thinking of hospitals with fewer resources. This classification offers the flexibility of using measures rated MR in some centers, depending on their specific characteristics.

Interestingly, only 11 outcome measures for AMD and seven for DR were deemed recommended. This might help ophthalmologists since they may focus on the recommendations instead of evaluating all other available outcome measures. Other studies have identified relevant outcome measures for AMD patients using the Delphi method, but they did not focus on PROs [37-39]. The only PRO recommended in one of the studies [37] was the *Impact of Vision Impairment Questionnaire (IVI)*, which is also recommended in our study.

The RUAM, like all methods, has limitations, such as the potencial familiarity bias. A test less known could be scored poorer than other more familiar that might result with a good score. For example, the panel ranked the ETDRS chart, a test that was design following the principles of Bailey-Lovie, better than the Bailey-Lovie chart itself. For this reason, to try to avoid this bias, the panel members have a variety of professional profiles in terms of gender, experience, geographic distribution and scientific production, in addition, the panelists were provided with the articles describing the PROs questionnaires. In any case, evidence exists on the method's validity in procedures of several specialties [29-35,40], including Ophthalmology [27,28]. The RUAM has shown that clinical outcomes are better when patients receive an appropriate procedure or when an inappropriate procedure is not performed [22,28].

Although the panelists rated each outcome measure's relevance within the context of Spanish Ophthalmology services, we believe the recommendations may be applicable in other contexts given the similarity in structure and process of Ophthalmology services in other healthcare systems.

In summary, we believe that the AMD and DR outcome measures recommended in this study will help ophthalmologists choose the most appropriate of the existing outcome measures for managing their patients. Furthermore, the use of PROs will contribute to shifting clinical practice towards patient-centered medicine.

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Table 1. AMD and DR patient-reported outcome measures

Patient-reported outcome measure	AMD			DR		
Visual function-specific:	**M**	**A**	**R**	**M**	**A**	**R**
Activity Inventory (AI)	3.0	+	NR	2.0	+	NR
Adaptation to Vision Loss Scale (AVL)	2.0	+	NR	1.5	+	NR
Daily Living Tasks Dependent on Vision (DLTV)	7.0	+	RE	2.0	+	NR
DLTV-11	5.0	-	MR	1.5	+	NR
Extended Mainz Questionnaire (EMQ)	2.5	+	NR	1.0	+	NR
Impact of Vision Impairment Questionnaire (IVI)	7.5	+	RE	7.0	+	RE
Low Vision Quality of Life Questionnaire (LVQOL)	7.0	+	RE	4.5	-	MR
Melbourne Low Vision Index (MLVI)	3.0	+	NR	1.0	+	NR
Manchester Low Vision Questionnaire (MLVQ)	2.0	+	NR	1.0	+	NR
National Eye Institute Visual Function Questionnaire-8 (NEI-VFQ-8)	4.5	-	MR	3.5	-	MR
NEI-VFQ-9	4.0	-	MR	3.0	-	MR
NEI-VFQ-17	2.5	-	MR	2.5	+	NR
NEI-VFQ-25	9.0	+	RE	9.0	+	RE
NEI-VFQ-39	7.0	+	RE	2.0	-	MR
NEI-VFQ-51	3.0	+	NR	2.5	+	NR
Visual Function Index (11 ítems) (VF-11)	5.5	-	MR	5.0	-	MR
VF-14	4.5	+	MR	5.0	+	MR
VF-4D	2.0	+	NR	1.0	+	NR
Visual Function Questionnaire Utility Index (VFQUI)	2.0	+	NR	2.0	+	NR
Vision and Quality of Life Index (VisQoL)	2.5	+	NR	2.5	+	NR
Vision Preference Value Scale (VPVS)	1.5	+	NR	1.5	+	NR
AMD-specific:	**M**	**A**	**R**			
Activity Limitation Questionnaire (ALQ)	4.5	+	MR			
AMD Health and Impact Questionnaire (AMD-HIQ)	3.0	+	NR			
AMD Self-Efficacy Questionnaire (AMD-SEQ)	4.0	+	MR			
Functional Reading Independence (FRI)	4.0	+	MR			
Macular disease Dependent Quality of Life questionnaire (MacDQoL)	7.0	+	RE			
Night Vision Questionnaire 10-item (NVQ-10)	4.0	+	MR			
DR-specific:				**M**	**A**	**R**
Quality of Life Item Banks (QoL-IB)				4.5	-	MR
Retinopathy-Dependent Quality of Life questionnaire (RetDQoL)				7.0	+	R
Vision-Related Functional Burden (VRFB)				5.0	+	MR
AMD and DR-specific:	**M**	**A**	**R**	**M**	**A**	**R**
Low-luminance questionnaire (LLQ)	7.0	+	R	6.0	+	MR
Treatment Satisfaction-specific:	**M**	**A**	**R**	**M**	**A**	**R**
Macular Disease Treatment Satisfaction Questionnaire (MacTSQ)	7.0	+	R			
Retinopathy treatment satisfaction questionnaire (RetTSQ)				7.0	+	R

AMD: Age-related macular degeneration; DR: Diabetic retinopathy; M: Median; A: Agreement level ("+": Agreement; "-": Disagreement.); R: Recommendation; RE: Recommended; MR: May Be Recommended; NR: Not recommended.

Table 2. Contrast sensitivity tests for AMD and DR

Contrast sensitivity test	AMD			DR		
	M	A	R	M	A	R
Cambridge low-contrast grating system	2.0	+	NR	3.0	+	NR
Contrast Glare Test (CGT)	2.5	+	NR	3.0	+	NR
Contraste de luminancia de escenas	2.0	+	NR	2.0	+	NR
ChromaTest	2.0	+	NR	2.0	+	NR
CSV-1000	5.5	+	MR	4.0	+	MR
Functional Acuity Contrast Test (FACT)	4.0	+	MR	3.5	+	NR
Innova Systems	2.0	+	NR	1.5	+	NR
Lea Numbers low contrast number test	1.5	+	NR	1.0	+	NR
Mars Letter Contrast Sensitivity Test	2.5	+	NR	1.5	+	NR
Maximum color contrast sensitivity test (MCCS)	2.5	+	NR	2.5	+	NR
Melbourne Edge Test (MET)	2.0	+	NR	2.5	+	NR
Macular Multi-Function Assessment (MMFA)	1.5	+	NR	1.5	+	NR
M&S Technologies Smart System (MSTSS)	1.0	+	NR	1.0	+	NR
Optec-Functional Vision Analyzer (Optec-FVA)	5.0	-	MR	5.0	+	MR
Pelli-Robson	9.0	+	RE	8.5	+	RE
QUEST	1.5	+	NR	1.5	+	NR
Quick contrast sensitivity function	2.5	+	NR	3.0	+	NR
Spaeth/Richman Contrast Sensitivity test (SPARCS)	2.0	+	NR	1.5	+	NR
Test 2000 PRO	2.0	+	NR	1.0	+	NR
Visual Capacity Analyzer (VCA)	1.0	+	NR	1.0	+	NR
Vistech	2.5	+	NR	3.0	+	NR

AMD: Age-related macular degeneration; DR: Diabetic retinopathy; M: Median; A: Agreement level ("+": Agreement; "-": Disagreement.); R: Recommendation; RE: Recommended; MR: May Be Recommended; NR: Not recommended.

Table 3. Low luminance visual acuity tests for AMD and DR.

Low luminance visual acuity tests:	AMD			DR		
	M	A	R	M	A	R
Bailey-Lovie	6.0	-	MR	5.0	-	MR
Electronic Visual Acuity tester	5.5	-	MR	5.0	+	MR
Early Treatment Diabetic Retinopathy Study (ETDRS)	8.0	+	RE	7.0	+	RE
Smith-Kettlewell low-luminance acuity test (SKILL)	4.5	+	MR	4.5	+	MR
Consecutive Snellen lines	3.0	+	NR	3.0	+	NR

AMD: Age-related macular degeneration; DR: Diabetic retinopathy; M: Median; A: Agreement level ("+": Agreement; "-": Disagreement.); R: Recommendation; RE: Recommended; MR: May Be Recommended; NR: Not recommended.

Table 4. Acuity/Speed Reading tests for AMD and DR.

Acuity/Speed Reading tests:	AMD			DR		
	M	**A**	**R**	**M**	**A**	**R**
Modified Bailey-Lovie	2.5	+	NR	2.5	+	NR
Belfast Reading Index	1.0	+	NR	1.0	+	NR
International Reading Speed Texts (IReST)	4.5	+	MR	4.0	+	MR
Minnesota Low-Vision Reading Test (MNRead)	7.0	+	RE	7.0	+	RE
Pepper Visual Skills for Reading Test	1.5	+	NR	2.0	+	NR
Radner	5.0	+	MR	4.0	+	MR
Reading Explorer test (REX)	2.5	+	NR	2.5	+	NR
Submacular Surgery Trials (SST)	3.0	+	NR	2.5	+	NR

AMD: Age-related macular degeneration; DR: Diabetic retinopathy; M: Median; A: Agreement level ("+": Agreement; "-": Disagreement.); R: Recommendation; RE: Recommended; MR: May Be Recommended; NR: Not recommended.

Table 5. Recommended outcome measures for AMD and DR.

Outcome measure	AMD	DR
PROM specific of visual function:	**M**	**M**
NEI-VFQ-25	9.0	9.0
Impact of Vision Impairment Questionnaire (IVI)	7.5	7.0
Daily Living Tasks Dependent on Vision (DLTV)	7.0	-
Low Vision Quality of Life Questionnaire (LVQOL)	7.0	-
NEI-VFQ-39	7.0	-
PROM specific of AMD:	**M**	**M**
Macular disease Dependent Quality of Life questionnaire (MacDQoL)	7.0	
PROM specific of DR:	**M**	**M**
Retinopathy-Dependent Quality of Life questionnaire (RetDQoL)		7.0
PROM specific of AMD and DR:	**M**	**M**
Low-luminance questionnaire (LLQ)	7.0	-
Specific for Treatment Satisfaction:	**M**	**M**
Macular Disease Treatment Satisfaction Questionnaire (MacTSQ)	7.0	
Retinopathy treatment satisfaction questionnaire (RetTSQ)		7.0
Contrast sensitivity test:	**M**	**M**
Pelli-Robson	9.0	8.5
Low luminance visual acuity test:	**M**	**M**
Early Treatment Diabetic Retinopathy Study (ETDRS)	8.0	7.0
Acuity/Speed Reading tests:	**M**	**M**
Minnesota Low-Vision Reading Test (MNRead)	7.0	7.0

AMD: Age-related macular degeneration; DR: Diabetic retinopathy; PROM: Patient-reported outcome measure; M: Median.