The ROYAL COLLEGE of OPHTHALMOLOGISTS

Clinical data set

Age-related Macular Degeneration Data Set

July 2019

18 Stephenson Way, London, NW1 2HD T. 020 7935 0702
contact@rcophth.ac.uk rcophth.ac.uk @RCOphth

Contents

Date of review: July 2022

1 Introduction

A data set comprises a set of defined variables representing clinical information about a patient with a given condition. Data sets already exist for cataract, retinal detachment, macular hole surgery and corneal cross-linking. Collection of agreed data sets allows comparison of outcomes across different platforms, including paper notes, proprietary electronic patient records and open source databases. The benefits of this approach have already been seen in the national cataract data set.

This document describes a proposed data set for age-related macular degeneration (AMD). The data set has been composed by a subcommittee of The Royal College of Ophthalmologists Informatics and Audit Sub-committee, comprising a representative selection of experts in medical retina, working in different healthcare environments across the UK. The authors have a great deal of experience not only in the diagnosis and management of AMD, but also in audit, electronic data collection, and research. Collection of this data set would allow comparison of outcomes between sites, using, for example, the International Consortium for Health Outcomes Measurement (ICHOM) https://www.ichom.org/ Standard Set for Macular Degeneration.

2 Application

The purpose of this data set is to represent an agreed set of clinical information which can be collected on patients with late AMD (geographic atrophy or neovascular disease) for purposes of clinical audit. As well as defining the items to be collected, the data set also describes the format for each item. The data set can be used as a basis for clinical care, outcome analysis, clinical audit, revalidation, and research. Common use of the data set will ensure that information collected by different clinicians, using different paper or electronic systems in different locations, is easily transferable, and can therefore form the basis of large, anonymised databases for audit and outcomes research. Each data item is colour coded according to the following scheme;

Category	
Mandatory	Data items which are essential for all applications, and must be collected
Desirable	Advised as valuable for audit or knowledge extraction purposes
Optional	Data items which are required for some applications, and may be collected

3 Scope

This data set applies to people with Late AMD only. (See NICE Guideline NG82 https://www.nice.org.uk/guidance/ng82- Age-related macular degeneration February 2018 for definitions of Early and Late AMD). Visual loss in Late AMD is usually a consequence of either the "dry" form of Late AMD (also known as geographic atrophy), the "wet" active form of Late AMD (also known as choroidal neovascularisation or neovascular AMD), the "indeterminate" from of Late AMD, or the "wet" inactive from of Late AMD (also known as disciform scar). Multiple forms of Late AMD may be present at the same time.

4 Principles

The data set is designed to comply with the following principles

1. **The data set should be a subset of information routinely collected**

The intention is not to burden already busy clinicians with additional work, so the data set should be constructed of items that are, or should be, recorded as part of the routine clinical management of the patient.

2. **Items not required for likely analysis should be excluded**

The collection of data requires time and effort, and therefore the total number of items should be kept to a minimum. The range of analyses likely to be conducted on the data is largely predictable, and items not required for these analyses should be excluded.

3. **Items in common with other College data sets should be congruent**

A number of data items (for example visual acuity, IOP) will be common to other ophthalmic data sets. It makes sense to ensure that only one definition for each item is used throughout all data sets, particularly within a subspecialty. This data set is therefore closely related to the existing macular hole and retinal detachment data sets.

4. **The data set should be capable of implementation in an electronic patient record**

It is likely that the maximum benefit of the data set will only be achieved when information is being routinely collected using electronic patient record systems. It is therefore essential that it is capable of being implemented electronically.

5 Data types

Each item of the data set has a data type, from the list below. These correspond to data types available in most relational database management systems (RDMS), which generally form the core of EPR systems.

Type	Description
NULL	A special entity representing an uncertain or unassigned value
INTEGER	An integer value, normally unsigned (i.e. zero or positive values)
FLOAT	A floating point value, positive or negative
BOOL	A value representing true or false
STRING	A value containing text (alphanumeric data) of unspecified length
ENUM	A value which represents one of a limited range of values
DATE	A value representing a date
DATETIME	A value representing a date and time

5 Age-related macular degeneration data set

Item	Description	Values/format
Patient ID	An identifier which will uniquely identify the patient. This could be the NHS number or a local patient identifier. This would be removed in anonymised data sets.	INTEGER or STRING
Age (Date of birth)	The age of the patient in years at the time of presentation or at the time of an event or treatment. As the age will change, it will be derived from date of birth.	DATE
Sex	The patient's gender	ENUM (Male, Female)
Consultant	Identifier for consultant in charge of patient (to allow individual audits) GMC Number	INTEGER
Ethnic category	The ethnicity of the patient using the classification used for the 2011 census.	ENUM (British, Irish, Any other White background, White and Black Caribbean, White and Black African, White and Asian, Any other mixed background, Indian, Pakistani, Bangladeshi, Any other Asian background, Caribbean, African, Any other Black background, Chinese, Any other ethnic group, Not stated
Smoking status		ENUM (Never smoked, Ex-smoker, Current smoker)
Route of referral	Route by which patient arrived in the ophthalmic department, based on who	ENUM (Optometrist, GP, Ophthalmologist from other Trust, Ophthalmologist from

	made the initial diagnosis (e.g. if an Optometrist sends a patient via the GP with a suspected diagnosis of AMD, this item would have a value of 'Optometrist')	same Trust, Ophthalmic A&E, New diagnosis in clinic, Other)
Date of initial referral	Date of receiving referral from primary or secondary care of first presentation to secondary care	DATE

6 Baseline assessment/start of treatment (to be recorded for each eye)

Item	Description	Values/format
Assessment date	Date of this assessment	DATE
Date of start of treatment	Date on which first treatment given following referral (if different to date of baseline assessment)	DATE
Blurred vision	Symptoms of blurred vision present, either for near or distance	BOOL
Metamorphopsia	Symptoms of distortion present	BOOL
Scotoma	Presence of a visual field defect	BOOL
Date of onset of symptoms	Date when patient first noticed any symptoms, or NULL if no symptoms	DATE or NULL
Distance Visual Acuity Measurement Standard	To allow comparison and conversion of Visual Acuity measurements recorded using different standards.	ENUM (Snellen, Log MAR, LogMAR single letter scoring, Decimal)

Distance Visual Acuity Measurement Method	To enable identification of alternative procedures for measuring Distance Visual Acuity in order to understand likely accuracy of measurements. More than one method may be employed on a given occasion.	ENUM (Best corrected distance visual acuity, Habitual distance visual acuity, Pinhole distance visual acuity, Unaided distance visual acuity)
Baseline Distance Visual Acuity		FLOAT
Near Visual Acuity Measurement Standard	To allow comparison and conversion of Near Vision measurements recorded using different standards	ENUM (Reduced log MAR, Reduced Snellen, Faculty of Ophthalmologists reading chart 'N' Score, Jaeger reading chart 'J' Score)
Near Visual Acuity Measurement Method	To enable grouping of the methods for measuring Near Visual Acuity in order to consider accuracy of measurements	ENUM (Best corrected near visual acuity, Habitual near visual acuity, Unaided near visual acuity)
Baseline Near Visual Acuity		FLOAT
Eye laterality	Affected eye	ENUM (Right, Left, Both)
Refraction	Refractive error as spherical equivalent	FLOAT
IOP	Intraocular pressure in mmHg	INTEGER
Vitreous	Attached or detached on clinical examination (definition of PVD is at the discretion of examining ophthalmologist)	ENUM (Uncertain, PVD, No PVD, Vitrectomised eye)
Significant ocular co-morbidity	Ocular disease, other than AMD, that may have an impact on visual acuity change after the initiation of treatment	

Choroidal neovascularisation	Present or absent	ENUM (No CNV, Sub-type not specific, RAP lesion (type 3 CNV), Classic only CNV (type 2 CNV), Mixed classic and occult CNV, Occult only CNV (Type 1 CNV) or Polypoidal choroidal vasculopathy)
Location of choroidal neovascularisation		ENUM (Sub-foveal, juxta-foveal, extra-foveal, peri-papillary and peripheral)
Geographic atrophy	Present or absent	ENUM (No geographic atrophy, Geographic atrophy)
Location of geographic atrophy		ENUM (Atrophy involving the foveal centre, Atrophy not involving the foveal centre)
Subretinal fibrosis	Present or absent under fovea	ENUM (No subretinal fibrosis, possible subretinal fibrosis, definite subretinal fibrosis involving fovea)
Retinal thickness on OCT imaging	Thickness of the ETDRS central 1mm subfield on OCT imaging	INTEGER
OCT imaging abnormalities		ENUM (Pigment epithelial detachment, Sub-retinal fluid, Intra-retinal cysts, Sub-retinal hyper-reflective material)
Treatment with intra-vitreal therapy		ENUM (None, Ranibizumab, Aflibercept, Bevacizumab)
Operative complications	Complications at the time of treatment	ENUM (None, Lens touch, Visual acuity loss to NPL, Other – please specify)
Significant post-operative complications	Complications since the last treatment	ENUM (None, Traumatic cataract, Retinal tear or detachment, Vitreous haemorrhage, Presumed

		infectious endophthalmitis, Other – please specify)
Planned follow-up interval	Intended interval till next review in days or weeks	INTEGER
Treatment with laser		ENUM (None, PDT / thermal / other laser)
Treatment with stereotactic radiotherapy		BOOL
Surgeon	Name and/or other identifier for primary surgeon to allow individual audits e.g. GMC number, NMC number	STRING and/or INTEGER
CVI offered or completed	Offer of certification as having Sight or Severe Sight Impairment, if appropriate	ENUM (Not appropriate, SI certification offered or completed, SSI certification offered or completed)
Provision of written information about AMD	Offered written information about AMD, such as that available from The Royal College of Ophthalmologists or national charities	ENUM (Offered or not offered)
Visual function Quality of life assessment or PROM	Intended for collection at baseline and after 12 and 24 months of follow-up. Options include the Impact of Visual Impairment (IVI) questionnaire (PMID: 27558785)	INTEGER

7 Follow-up assessment (to be recorded for each eye and at each visit)

Item	Description	Values/format
Date	Date of attendance and/or surgery	DATE
Delay in follow-up	Difference between intended and actual follow-up interval in days or weeks	INTEGER
Non-attendance	Reason for non-attendance, if known, to be recorded at months 12 and 24	ENUM (Not known, Treatment failure, Co-morbidity, Death)
Visual Acuity	Best-corrected distance visual acuity (Converted into standard format for analysis)	INTEGER
Distance Visual Acuity Measurement Standard	To allow comparison and conversion of Visual Acuity measurements recorded using different standards	ENUM (Snellen, Log MAR, LogMAR single letter scoring, Decimal)
Distance Visual Acuity Measurement Method	To enable identification of alternative procedures for measuring Distance Visual Acuity in order to understand likely accuracy of measurements. More than one method may be employed on a given occasion	ENUM (Best corrected distance visual acuity, Habitual distance visual acuity, Pinhole distance visual acuity, Unaided distance visual acuity)
Follow-up Distance Visual Acuity		FLOAT
Near Visual Acuity Measurement Standard	To allow comparison and conversion of Near Vision measurements recorded using different standards	ENUM (Reduced log MAR, Reduced Snellen, Faculty of Ophthalmologists reading chart 'N' Score, Jaeger reading chart 'J' Score)

Near Visual Acuity Measurement Method	To enable grouping of the methods for measuring Near Visual Acuity in order to consider accuracy of measurements.	ENUM (Best corrected near visual acuity, Habitual near visual acuity, Unaided near visual acuity)
Baseline Near Visual Acuity		FLOAT
Choroidal neovascularisation	Present or absent	ENUM (Sub-type not specific, RAP lesion (type 3 CNV), Classic only CNV (type 2 CNV), Mixed classic and occult CNV, Occult only CNV (Type 1 CNV) or Polypoidal choroidal vasculopathy)
Geographic atrophy	Present or absent and whether the atrophy involves the foveal centre or is away from the fovea	ENUM (No geographic atrophy, Atrophy involving the foveal centre, Atrophy not involving the foveal centre)
Subretinal fibrosis	Present or absent under fovea	ENUM (No subretinal fibrosis, possible subretinal fibrosis, definite subretinal fibrosis involving fovea)
Retinal thickness on OCT imaging	Thickness of the ETDRS central 1mm subfield on OCT imaging	INTEGER
OCT imaging abnormalities		ENUM (Pigment epithelial detachment, Sub-retinal fluid, Intra-retinal cysts, Sub-retinal hyper-reflective material, RPE TEAR/RIP)
Treatment with intra-vitreal therapy		ENUM (None, Ranibizumab, Aflibercept, Bevacizumab, Other – please specify)
Treatment with laser		ENUM (None, PDT / thermal /other laser)
Treatment with stereotactic radiotherapy		BOOL

Surgeon	Name and/or identifier for primary surgeon to allow individual audits e.g. GMC number, NMC number	INTEGER
Operative complications	Complications at the time of treatment	ENUM (None, Lens touch, Visual acuity loss to NPL, Other – please specify)
Significant post-operative complications	Complications since the last treatment	ENUM (None, Traumatic cataract, Retinal tear or detachment, Vitreous haemorrhage, presumed infectious endophthalmitis, Other – please specify)
Planned follow-up interval	Intended interval till next review in days or weeks	INTEGER
Visual function Quality of life assessment or PROM	Intended for collection at baseline and after 12 and 24 months of follow-up. Options include the Impact of Visual Impairment (IVI) questionnaire (PMID: 27558785)	
CVI offered or completed	Offer of certification as having Sight or Severe Sight Impairment, if appropriate	ENUM (Not appropriate, SI certification offered or completed, SSI certification offered or completed)

8 Authors

Mr. Martin McKibbin, St James's University Hospital, Leeds.

Mr. Adrian Tufail, Moorfields Eye Hospital, London.