Clinical Data Set

The Royal College of Ophthalmologists National Ophthalmology Database (NOD) Age-related Macular Degeneration (AMD) Audit Data Set

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1 Introduction and Funding

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 the Royal College of Ophthalmologists' National Ophthalmology Database (RCOphth NOD) age-related macular degeneration (AMD) audit. The data set has been composed by the AMD Audit Advisory Group and is a derivative of the main AMD Data Set published by The Royal College of Ophthalmologists' Informatics and Audit Sub-committee.

Funding

NOD AMD audit has been previously funded by hands off grants from industry partners with no involvement in the development or implementation of the project. The project is now funded purely by on-going support through subscription fees from participating centres.

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 the purposes of the RCOphth NOD AMD 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 in line with the Audit's specified objectives (see outcome measures below). 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

The RCOphth NOD AMD Audit's key outcome and process measures are:

- Percentage of eyes (or patients) for which treatment was offered or started (when appropriate) within 14 days of referral
- Percentage of eyes (or patients) completing the loading phase of 3 injections, within 10 weeks of the first injection
- Percentage of eyes for which follow-up was delayed by more than 14 days after the planned follow-up interval on at least one occasion in the first 12 months
- Median visual acuity changes from baseline to months 12 and 24 (adjusted for baseline age and visual acuity)
- Percentage of eyes with a good visual acuity state (≥70 ETDRS letters or ≤ 0.3 LogMAR) after 12 and 24 months
- Complications of treatment e.g. Presumed Infectious Endophthalmitis (PIE) or Intra Ocular Inflammation (IOI).

3 Scope

This data set applies to people with Late AMD only. (See NICE Guideline 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" form of Late AMD, or the "wet" inactive from of Late AMD (also known as disciform scar). Multiple forms of Late AMD may be present in an eye 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. The data set for the RCOphth NOD AMD audit may require some changes to existing electronic medical record (EMR) systems with the addition of a small number of new items, such as the date of receipt of referral from primary care, and mandatory entry of others, such as visual acuity at baseline and after 12 and 24 months of follow-up.

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

6 Age-related macular degeneration data set

Item	Description	Values/format
NOD-specific patient identifier	The RCOphth NOD does not **routinely** hold patient-identifiable data (PID), such as an NHS number or local hospital number. For organisations using an EMR system and submitting data without specific approval to provide patient-identifiable data, any link to patient identifiers must be removed during the extraction process and **before** the data are transferred to the RCOphth NOD. This ensures that patients cannot be re-identified from the data received by the NOD. An exception applies to participating centres **in England and Wales** that have signed an appropriate Data Sharing Agreement with the RCOphth and are covered by approval under Section 251 of the Health Service (Control of Patient Information) Regulations 2002, granted following advice from the Health Research Authority's Confidentiality Advisory Group (CAG). This Section 251 arrangement applies only to participating centres in England and Wales**.** Where this approval applies, those centres are permitted to submit the PID specified within the scope of the approval and Data Sharing Agreement to the RCOphth NOD for the approved purposes. Any collection, transfer, processing and use of PID under this arrangement must remain within the scope and conditions of the relevant Section 251 approval and Data Sharing Agreement.	INTEGER or STRING
Age (Date of birth)	The age of the patient in years at the time of presentation or at	DATE

	the time of an event or treatment. As the age will change, it will be derived from date of birth. However, the actual date of birth and all subsequent dates for a given patient will be perturbed by the same random number of dates to prevent patient identification prior to submission to the RCOphth NOD.	
Sex	The patient's biological sex	ENUM (Male, Female)
Provider Organisation e.g. NHS Trust, Health Board or equivalent organisation commissioned to provide the service	ODS CODE (England - allocated by NHS Digital) or equivalent for organisations in Northern Ireland, Scotland or Wales	Text and numbers
Site at which treatment took place	ODS CODE (England) or equivalent	Text and numbers
Ethnic category	The ethnicity of the patient using the classification used for the 2011 census.	ENUM A = White – British B = White – Irish C = Any other White background D = Mixed - White and Black Caribbean E = Mixed - White and Black African F = Mixed - White and Asian G = Any other mixed background H = Asian or British Asian – Indian J = Asian or British Asian – Pakistani K = Asian or British Asian – Bangladeshi L = Any other Asian or British Asian background M = Black or Black British – Caribbean

		N = Black or Black British – African P = Any other Black or Black British background R = Chinese S = Any other ethnic group Z = Not stated
Smoking status		ENUM (Never smoked, Ex-smoker, Current smoker)
Date of receipt of initial referral	Date of receipt of the original referral from primary care with suspected nAMD. This is vital to enable the Audit to report on starting treatment, when appropriate, within 14 days of receipt of the initial referral from primary care and in accordance with NICE guidance.	DATE

7 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, when appropriate, (if different to date of baseline assessment). This is vital to enable the audit to report starting treatment, when appropriate, within 14 days of receipt of referral from primary care and in accordance with NICE guidance.	DATE
*Baseline Distance Visual Acuity For visual acuity data, see the note at the end of this document.	Recorded on the day treatment started or within 14 days before treatment	FLOAT (LogMAR, ETDRS letter score)

*Date of Baseline Distance Visual Acuity		DATE
Eye laterality	Data for each eye needs to be recorded separately as the data may not the same for both eyes. The laterality is an important key in linking submitted data files together and not all patients will have both eyes treated.	ENUM (Right, Left)
Significant ocular co-morbidity (Yes/No) Select all that apply	Ocular disease, other than AMD, that may have an impact on visual acuity change after the initiation of treatment. 1. **Retinal disease** • Geographic atrophy • Subretinal fibrosis • Diabetic retinopathy/DMO • Retinal vascular disease • Epiretinal membrane • Vitreomacular traction/macular hole • Pathologic myopia • Inherited retinal dystrophy • Angioid streaks • Multifocal choroiditis **2. Optic nerve disease** • Glaucoma • Optic neuropathy/optic atrophy **3. Media abnormalities** • Significant cataract/PCO • Corneal pathology **4. Other** • Amblyopia • Previous vitrectomy	ENUM

	• Any other condition likely to limit visual acuity	
Retinal thickness on OCT imaging	Thickness of the ETDRS central 1mm subfield on OCT imaging	INTEGER
Treatment with intra-vitreal therapy		ENUM • None • Bevacizumab • Bevacizumab gamma • Ranibizumab • Ranibizumab biosimilar (Ongavia, Ximluci) • Aflibercept 2 mg • Aflibercept biosimilar • Aflibercept 8 mg • Faricimab • Brolucizumab • Other (please specify)
Type of professional administering treatment	Medical or Non-medical (Nurse, Optometrist, Orthoptist)	ENUM
Planned follow-up interval	Intended interval till next review in days or weeks. This is vital to enable the Audit to report on delays from the planned follow-up interval.	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)

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

Item	Description	Values/format
Assessment Date	Date of attendance and/or surgery	DATE
*Distance Visual Acuity	Recorded on the day, or within 7 days, of further treatment	FLOAT (LogMAR, ETDRS letter score)
*Date of Distance Visual Acuity	Date for the relevant Visual Acuity assessment	DATE
*Distance visual acuity at months 12 and 24 (-28/+84 days)	This data is vital to enable the Audit to report visual acuity outcomes after 12 and 24 months.	FLOAT (LogMAR, ETDRS letter score)
Eye laterality	Data for each eye needs to be recorded separately as the data may not the same for both eyes. The laterality is an important key in linking submitted data files together and not all patients will have both eyes treated.	ENUM (Right, Left)
*Distance visual acuity recorded at every visit	For visual acuity data, see the note at the end of this document.	FLOAT (LogMAR, ETDRS letter score)
New significant ocular pathology since baseline (Yes/No) If Yes – select from the same list above	Ocular disease, other than AMD, or surgery that may have an impact on visual acuity change after the initiation of treatment e.g. new geographic atrophy or sub-retinal fibrosis, cataract and/or vitrectomy surgery, other	ENUM

Retinal thickness on OCT imaging	Thickness of the ETDRS central 1mm subfield on OCT imaging	INTEGER
Treatment with intra-vitreal therapy		ENUM: • None • Bevacizumab • Bevacizumab gamma • Ranibizumab • Ranibizumab biosimilar (Ongavia, Ximluci) • Aflibercept 2 mg • Aflibercept biosimilar • Aflibercept 8 mg • Faricimab • Brolucizumab • Other (please specify)
Type of professional administering treatment	Medical or Non-medical	ENUM
Planned follow-up options	Plans for follow-up to include: - Ongoing follow-up with further review in provider eye clinic - Ongoing follow-up but involving shared care with community optometrists - Permanently stopping treatment and discharge - Permanently stop treatment but with continued follow up by provider	ENUM (Other – please specify)

Planned follow-up interval	Intended interval till next review in days or weeks when ongoing follow-up planned. This is vital to enable the Audit to report on delays from the planned follow-up interval.	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)
Ocular complications of intra-vitreal therapy	This is vital to enable the Audit to report on the safety of intra-vitreal therapy for AMD.	ENUM 1. None 2. Presumed infectious endophthalmitis (PIE) 3. Intra-ocular inflammation (IOI) 4. Retinal detachment 5. Traumatic cataract

*__Note:__ To allow flexibility in analysis time windows, all recorded VA measurements should be submitted as a separate file, linked to the main extract by the NOD patient identifier. The file requires one row per eye per VA assessment, with four fields: NOD patient ID, eye laterality, date of VA, and best VA at that assessment. An optional field for measurement type (corrected, pinhole or unaided) may be added, in which case all VA measurements for each eye can be included.

9 Authors

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