



National Ophthalmology Database UK AMD Audit Data Privacy Impact Assessment

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Introduction

The audit of Age-related Macular Degeneration (AMD) treatment aims prospectively to collect, collate and analyse a standardized, nationally agreed dataset from all providers of treatment for the wet or neovascular form of AMD (NvAMD) in the UK, subject to local Caldicott Guardian approvals. The audit aims to provide benchmarks for the standards of care and a powerful quality improvement tool to improve patient care and outcomes. Building on the existing achievements of the RCOphth NOD Project, the audit will utilize validated measures of quality that can discriminate between provider organisations. These will be presented on the RCOphth NOD website, allowing organisations to compare their performance against their local and national peers and giving patients a basis for making an informed choice about their preferred treatment location. Aggregate data will be included in annual reports, available for public scrutiny on the RCOphth NOD website, and certain elements and outcomes of the audit will be submitted for peer reviewed publication in the medical literature.

The [AMD Dataset](#) includes all the data associated with the initiation, delivery and outcomes of treatment for NvAMD including demographic details, ocular co-pathology and systemic co-morbidities, time from referral to the start of treatment, visual acuity in both eyes, number of injections, follow-up delays and complications of treatment. This data is routinely collected within electronic medical records as part of ongoing clinical care.

Key goals

The audit will provide real-world benchmarks for the standard of care given to patients with NvAMD, both for visual acuity outcomes and key clinical care processes. This will enable providers and commissioners to compare local clinical outcomes and care processes with those achieved in other sites. Key benefits of the audit include:

- Empowering patients to make an informed choice about their preferred treatment location.
- Highlighting and disseminating best practice,
- Eradicating variation in the NvAMD treatment outcomes.

Data Protection Impact Assessment

Section		Yes / No / N/A	Comments
<p>1. Does your project involve any automated decision making, evaluation or scoring including profiling and predicting using information about a person? Does the outcome from your project decide who gets access to services?</p>		No	<p>The project will collect data to enable providers and commissioners to:</p> <ul style="list-style-type: none"> • Compare treatment outcomes for the “wet” or neovascular form of AMD, after taking account of differences in baseline characteristics • Identify and disseminate best practice to improve key clinical care processes. • Please note, the outcome of this audit will not affect access to AMD treatment.
<p>2. Does your project involve any sensitive information or information of a highly personal nature?</p>		No	
<p>3. Does the proposal involve any data concerning vulnerable individuals who may be unable to easily consent or oppose the processing, or exercise their rights? This group may include children, employees, mentally ill persons, asylum seekers, or the elderly, patients and cases where there is an imbalance in the relationship between the position of the individual and the controller.</p>		Yes	<p>Patients eligible for inclusion in the audit may include employees, mentally ill persons, asylum seekers, or vulnerable, elderly patients. However, the data to be extracted will be anonymised and so individual patient consent is not required. Caldicott Guardian and/or local Information Governance lead approval will be obtained at each site.</p>

4. Does your project involve any innovative use or applying new technological or organisational solutions? This could include biometric or genetic data, the tracking of individuals' location or behaviour?		No	
5. Does your project match data or combine datasets from different sources?		Yes	Data will be extracted from existing Electronic Medical Record (EMR) Systems at participating centres. These include the Medisoft, MediSight and OpenEyes systems. Data will be anonymised prior to submission to the RCOphth NOD.
6. Does your project collect personal data from a source other than the individual without providing them with a privacy notice ('invisible processing')?		Yes	The data being collected is limited to that contained in the Royal College of Ophthalmologists AMD audit dataset and does not include identifiable information. Data is anonymised prior to submission to the RCOphth NOD. See Data Categories below.
7. Does your project process data that might endanger the individual's physical health or safety in the event of a security breach?		No	
8. Is this a new project? Or have the requirements for your project changed since its initiation? Are you sharing new information or linking to new datasets that were not part of the original project specification. Have you added any new audit streams to your project?		Yes	The UK AMD audit is a new clinical audit introduced by The Royal College of Ophthalmologists in 2021 as part of the National Ophthalmology Database. The NOD has been run by the RCOphth since 2009, with a focus on cataract surgery to date.

DPIA methodology and project information

Question	Answer
<p>1. At what stage in the project did you conduct this DPIA? e.g. planning stage, changes to the existing project, in retrospect.</p>	<p>This DPIA was originally completed in May 2021, before the formal launch of the UK AMD audit and has not been updated since.</p>
<p>2. Describe the overall aim of the project and the data processing you carry out</p>	<p>Age-related macular degeneration (AMD) remains a leading cause of sight impairment certification in England and Wales despite new treatment options. AMD is estimated to affect 600,000 people in the UK with an estimated 39,800 people developing the “wet” or neovascular form of AMD each year. The number of new cases of NvAMD is expected to rise by 60% by 2035.</p> <p>The UK AMD audit will collect data to enable providers to compare treatment outcomes for NvAMD, considering differences in baseline characteristics, to identify and disseminate best practice and to improve key clinical care processes. It will provide real-world benchmarks and enable patients, providers and commissioners to compare clinical outcomes and key processes at different sites. Additional benefits include:</p> <ul style="list-style-type: none"> • Enabling informed decision-making and patient choice • Highlighting and disseminating best practice, with the potential to eradicate variation in NvAMD treatment outcomes • Recording visual acuity change after implementing a robust method of adjusting visual acuity outcomes to take account of difference in baseline characteristics, especially starting visual acuity and age • Identifying variation in treatment pathways and key clinical care processes that drive best outcomes and implementing changes as part of the Getting it Right First Time (GIRFT) and the National Outpatients Transformation Programme • Identifying factors that are associated with compliance with treatment to 12 months and beyond • Facilitating the development of a NvAMD Patient Reported Outcome (PROM) tool and the collection of additional metrics that are important to patients

Data processing

Data from providers collected on the Medisoft or MediSight EMR systems is extracted by the EMR system supplier and transferred via Health and Social Care Network (HSCN)/N3 to a secure FTP server at Gloucestershire Hospitals NHS Foundation Trust (GHNHSFT). Data from other providers collected on the Open Eyes EMR system is extracted by the provider and transferred via the HSCN to a secure FTP server at GHNHSFT, or via the RCOphth NOD audit website (www.nodaudit.org.uk). Data from providers collecting data compliant for the audit on other systems, if acceptable, would be transferred via the RCOphth NOD audit website, downloaded and then deleted by the RCOphth NOD Team. Data files uploaded to the RCOphth NOD website must be password protected by the user and the password is made known to the RCOphth NOD statistician via a phone call or text message. Files are deleted from the RCOphth NOD website once downloaded onto the secure server at GHNHSFT where all data will be stored, which the RCOphth NOD statistician will analyse to produce reports. No patient identifiable data will be visible or derivable from any report.

The RCOphth NOD website is hosted on a secure server with an interfacing capability to allow for data to be received electronically from Hospital Eye Services across the UK.

The Data Processors are (i) EMR suppliers engaged to extract EMR data from participating centres using EMR systems and (ii) Gloucestershire Hospitals NHS Foundation Trust. All personnel responsible for transferring the data and initial data analysis are covered under Trust Information Security policies and/or specific contracts making express provision for the responsibilities of Data Processors. Specific data sharing projects will be possible via the RCOphth Data Access Request mechanism which allows for data access by other interested parties. The Data Processors noted here are in addition to the local trust / provider who are responsible for the management of their own PID.

Retention of data

Each data extract received by the RCOphth NOD is retained for 5 years. It is deleted at the end of this 5-year period, provided analyses have been fully completed and published. The data extract includes raw data at patient level. Processed data is reported for the relevant analysis period for specific analyses, which may be shorter or longer than 5 years.

Yearly data extraction: Participating RCOphth NOD centres can use the annual data submission as an opportunity to re-extract and re-submit data from previous audit years. There are advantages to re-extracting data each year and this is automatic for centres using the Medisoft EMR, but as noted above, no single data extract is retained for longer than 5 years.

DPIA consultation

- Approved by Kathy Evans, DPO for The Royal College of Ophthalmologists has approved this DPIA (08 June 2021).

Stakeholder group consultation

The Macular Society is a UK charity that aims to support people with AMD, to raise awareness of the impact of AMD and to encourage research into novel therapies for people with AMD. The Macular Society has provided financial support to the Royal College of Ophthalmologists for the RCOphth NOD NvAMD audit. The views of members of the Society were obtained in March and April 2021 through an online webinar and a subsequent member survey. As well as providing evidence of support for the concept of a national audit of NvAMD treatment, these engagement events were also vital in selecting key, provider level outcomes that were important to both clinicians and to patients. An introduction to the planned UK AMD audit will also be published in the summer 2021 edition of Sideview, the quarterly Society magazine

Publishing your DPIA report

<https://www.nodaudit.org.uk/>

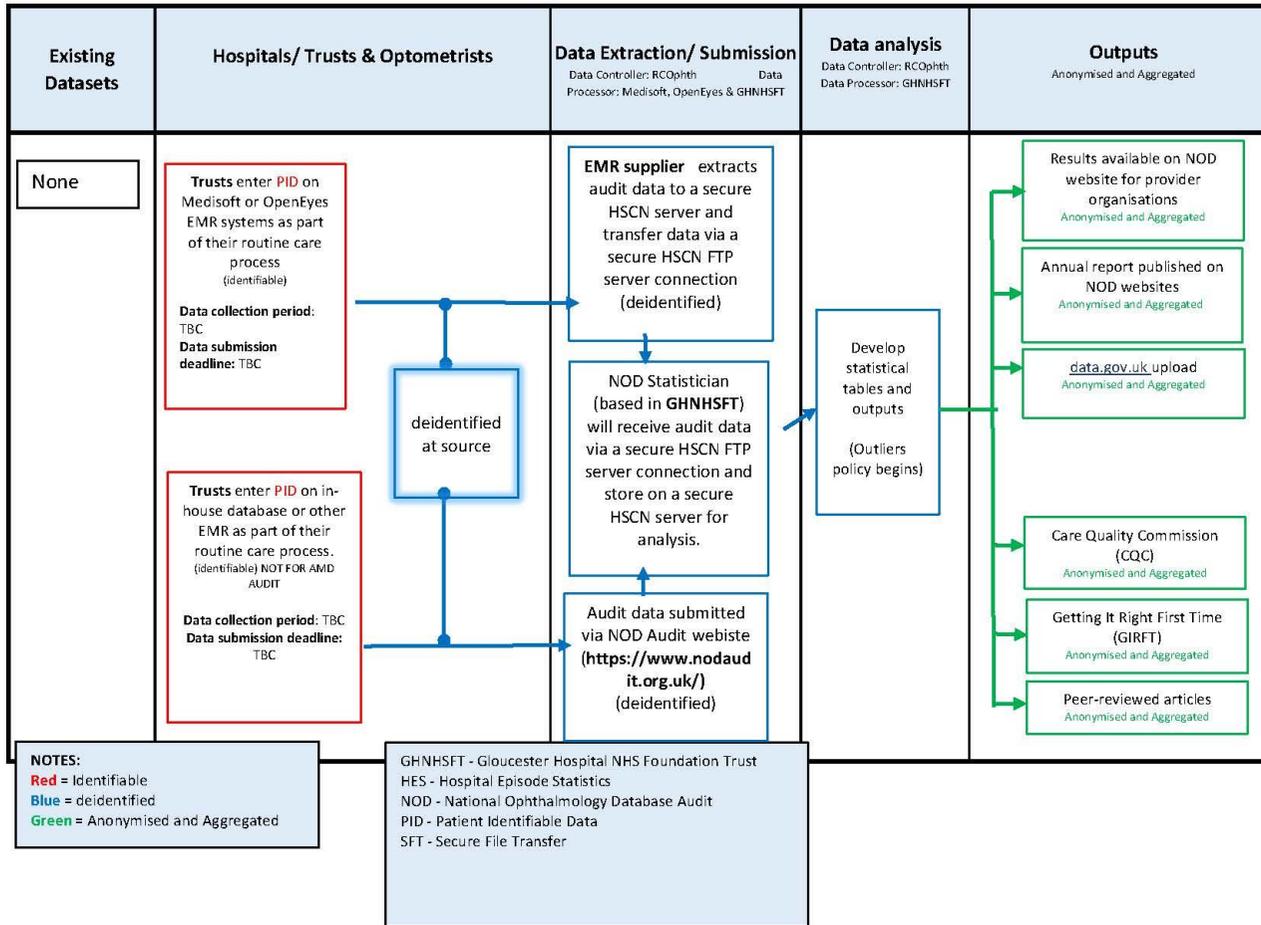
Data Information Flows

Providers using the Medisoft or MediSight EMR system: Data are extracted from the Hospital Eye Services EMR server by the EMR system supplier and transferred via HSCN/N3 to a secure FTP server at GHNHSFT. All data is stored on a secure server at GHNHSFT which the RCOphth NOD statistician will analyse to produce reports. No patient identifiable data will be visible or derivable from any report.

Providers using the Open Eyes EMR system: Data are extracted from the EMR system by the provider and transferred via the HSCN to a secure FTP server at GHNHSFT, or via the RCOphth NOD audit website.

Data from providers collecting data compliant for the audit on other systems, if acceptable, is transferred to the RCOphth NOD audit website. Data files uploaded to the RCOphth NOD website must be password protected by the user and the password made known to the RCOphth NOD statistician via a phone call or text message.

National Ophthalmology Database Audit - Data Flow



Transferring personal data outside the European Economic Area (EEA)

- No personal data is being transferred outside of the EEA.

Privacy Risk Register

Justification for collecting personal data

Data categories (Information relating to the individual's)	Is this field used/?	N/A	Justifications (there must be justifications for collecting the data items. Consider which items you could remove, without compromising the needs of the project.)
Personal Data			
Name	No		The de-identification of all patient identifiable data submitted to the RCOphth NOD is achieved through the application of a unique identifier to each patient's data at the time of data extraction and before the data is transferred from a contributing centre to the RCOphth NOD. The relationship between the RCOphth NOD identifier and the patient identifiers on the centre's EMR system is not recorded within the submitting EMR system and is not visible to clinicians at those centres. Only the source centres and the EMR providers (both of which have access to all the identifiable data, with appropriate governance controls in place) can re-identify patients, regardless of any data linkage that can be applied downstream within the same data source. Therefore, no identifiers leave the EMR systems in the contributing centres and the NOD identifier can link records within the RCOphth NOD but cannot support linkage to any external dataset.
NHS Number (England and Wales)/CHI number (Scotland)	No		The data once sent to and stored within the RCOphth NOD contains a unique identifier that cannot be de-referenced by any Data Processor to identify a patient but can be used to match new data extractions with the appropriate patient in the future.
Address	No		

Postcode	No		
Date of birth	Yes		Dates of birth and death will be anonymised by the addition of a random number of days from -180 to +180.
Date of death	Yes		Dates of birth and death will be anonymised by the addition of a random number of days from -180 to +180. Date of death is required to account for loss to follow-up at the key milestones of month 12 and month 24 after the start of treatment.
Age	No		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.
Sex	Yes		See gender
Marital status	No		
Gender	Yes		Gender of patient required to identify risk factors for successful treatment and inequalities.
Living habits	Yes		Smoking habits – smoking status is associated with earlier disease presentation and a high treatment burden
Professional training/awards	No		
Income/Financial/Tax Status	No		
Email address	No		
Physical description	No		
Gender identifier e.g. Hospital; No.	No		
Home Phone Number	No		
Other identified e.g. IP address/event logs	No		
Mobile Phone/Device	No		
Device Mobile Phone/Device IMEI No	No		
Location Data (travel/GPS/GMS Data)	No		
Device MAC address (wireless	No		

network interface)			
Sensitive personal data			
Physical/Mental Health of Condition	No		
Sexual Life/orientation	No		
Family/lifestyle/social circumstance	No		
Offences committed/ alleged to have committed	No		
Criminal proceedings/outcomes/sentence	No		
Education/Professional training	No		
Employment/career	No		
Financial affairs	No		
Religion or other beliefs	No		
Trade union membership	No		
Racial/ethnic origin	Yes		The racial / ethnic origin of individual patients will be collected from the EMRs. This data is extracted from provider Patient Administration Systems (PAS). Current evidence suggests that the AMD phenotype differs between racial groups.
Biometric data (fingerprints/facial recognition)	No		
Genetic data	No		

Data quality standards for personal data

No personal data is being extracted or stored for the RCOphth NOD AMD audit

The RCOphth NOD database consists of a database hosted on a secure server. Interfacing standards are open and available for any supplier of EMR systems to adopt. Establishment of the system and the processes for assuring IG processes has been undertaken in consultation with the GHNHSFT IG officers and The Royal College of Ophthalmologists.

Data exported to the RCOphth NOD statistical support officers is stored on a secure server hosted by GHNHSFT. This server can only be accessed by the RCOphth NOD team in GHNHSFT and the data is stored on a restricted access sever that only the RCOphth NOD statisticians can access, with the submitted data stored on separate disc space to all other files. No raw data are or will be stored on any other system (other than the source data collection systems, which in the case of EMR systems are regulated by contract between the EMR provider and each contributing Hospital Eye Service) except where the release of data is approved through the RCOphth data release process.

GHNHSFT Data Security and Protection Toolkit (DSPT) information: organisation code is RTE.

Data held on the RCOphth NOD website is managed by Hypergram and hosted by Nimbus Hosting Ltd which uses VIRTUS Data Centres LTD. data centre in London. The hosting provider complies with current International Organisation for Standardisation standards (ISO27001:2013) for Data Centre management. ISO27001 covers the management activities and physical security standards for maintaining and provisioning services in data centres. As such it provides a level of guarantees in relation to hosted services and provides the RCOphth NOD project with a high level of confidence in relation to physical data security.

Individual's rights

Individual's rights (where relevant)	Describe how you ensure individuals are aware of these rights	Describe how you would do this	Please copy and paste section of document that states individual's rights
<p>Individuals are clear about how their personal data is being used.</p>	<p>A patient information leaflet (PIL) will be available on the RCOphth NOD website</p>	<p>The PIL will be available on the RCOphth NOD website and centres contributing data to the RCOphth NOD audits will be asked to help local treatment centres.</p> <p>The project delivery team AMD audit will also work with Macular Society to distribute the PIL and to raise awareness of the audit.</p> <p>It is not felt to be necessary to consent individual patients as no personal data is collected by the RCOphth NOD.</p>	<p>'What information is collected for the AMD audit?</p> <p>Information can be submitted to the audit by your hospital if you had AMD treatment in England, Wales, Scotland, Northern Ireland or Guernsey. We cannot identify any individual patient from this information. The information collected, as part of your patient record for AMD treatment, and used by the RCOphth NOD includes:</p> <ul style="list-style-type: none"> • Visual acuity (your ability to discern the shapes and details of the things you see) • The change in visual acuity over time (adjusted for other variables which might affect this) • Treatment within 14 days of diagnosis (as recommended in NICE AMD clinical guidelines: www.nice.org.uk/guidance/ng82) <p>Anonymised data submitted to the RCOphth NOD shows us if you have had AMD treatment on one or both eyes. The hospital responsible for your AMD treatment can identify an individual patient from this information as it is part of your care record. However, we do not see any information which identifies</p>

			<p>individual patients. Information submitted into the audit will be retained for the duration of the audit.</p> <p>How is the information used? The information is analysed, and the audit report will help hospitals and consultants to benchmark, improve and balance care across the country. Although the risk of AMD treatment is on average quite low, the RCOphth NOD AMD audit aims to further improve the quality of care and patient outcomes. The report is made available to the public, and surgeon and centre reports are published on the RCOphth NOD website, www.nodaudit.org.uk. We emphasise that no individual patient can be identified from any audit report.'</p>
Individuals can access information held about them	N/A - the RCOphth NOD cannot identify patients based on the information submitted.		<p>Your right to access may be limited as the information submitted by participating hospitals is anonymous to the audit team. However, you can contact the hospital that provided your AMD treatment if you wish to access your information.</p> <p>If you have concerns about the way your information is being handled, you have the right to make a complaint with the ICO (Information Commissioner's Office (ICO), the</p>

			independent authority in the UK responsible for upholding information rights in the public interest via telephone on 0303 123 1113 or their website: https://ico.org.uk/make-a-complaint/
Request erasure (right to be forgotten) in certain circumstances, making clear that it does not apply to an individual's health or care record, or for public health or scientific research purposes	N/A - the RCOphth NOD cannot identify patients based on the information submitted.		
Rectification of inaccurate information	N/A - the RCOphth NOD cannot identify patients based on the information submitted.		
Restriction of some processing	N/A - the RCOphth NOD cannot identify patients based on the information submitted.		
Object to processing undertaken on some legal bases	N/A - the RCOphth NOD cannot identify patients based on the information submitted.		
Complain to the Information Commissioner's Office	N/A - the RCOphth NOD cannot identify patients based on the information submitted.		
Withdraw consent at any time (if processing is based on consent)	N/A - the RCOphth NOD cannot identify patients based on the information submitted.		
Data portability (if relevant)	N/A - the RCOphth NOD cannot identify patients based on the information submitted.		
Individual knows the identity	This information will be		

<p>and contact details of the data controller and the data controller's data protection officer</p>	<p>available in the Patient Information Leaflet and made available on the RCOphth NOD website.</p>		
<p>In which countries the data controller is processing their personal data. For data transfers outside the EU, a description of how the data will be protected (e.g. the recipient is in an 'adequate' country / how a copy of the safeguards can be obtained.</p>	<p>N/A</p>		
<p>To know the legal basis under which their information is processed. Is there a clear legal basis for the processing of personal data? If so, what is the legal basis?</p>	<p>This information will be available in the Patient Information Leaflet and made available on the RCOphth NOD website.</p>		<p>Legal basis for processing your data The audit is covered under General Data Protection Regulation (GDPR) by the following legal basis for processing your data:</p> <ul style="list-style-type: none"> • processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller {Article 6 (1) (e)} • processing is necessary for reasons of public interest in the area of public health, such as protecting against serious cross-border threats to health or ensuring high standards of quality and safety of health care and of medicinal products or medical devices, on the basis of Union or Member State law which provides for suitable and

			specific measures to safeguard the rights and freedoms of the data subject, in particular professional secrecy. {Article 9 (2) (i)}
Whether the provision of personal data is part of a statutory obligation and possible consequences of failing to provide the personal data.	N/A		
The source of the data (where the data were not collected from the data subject)	N/A		
Categories of data being processed	N/A		
Recipients or categories of recipients	N/A		
The source of the personal data	N/A		
To know the period for which their data will be stored (or the criteria used to determine that period)	N/A		
The existence of, and an explanation of the logic involved in, any automated processing that has a significant effect on data subjects (if applicable)	N/A		

Privacy Risks

Risks affecting individuals

N/A

Privacy Risks and Actions Table

What are the potential risks to the individuals whose personal data you hold?	Likelihood of this happening 1 Very unlikely 2 Unlikely 3 Possible 4 Likely 5 Very Likely (See guidance below for definition)	Impact 1 -Insignificant 2-Minor 3-Moderate 4-Major 5-Catastrophic (See guidance below for definition)	Overall risk score (likelihood x impact = score)	Will risk be accepted, reduced or eliminated?	Mitigating action to reduce or eliminate each risk OR Where risk is accepted give justification.	Explain how this action eliminates or reduces	Expected completion date	Responsible owner
Illegitimate access	1	2	2	Accepted	No personal identifiable patient data is received or stored by the RCOphth NOD. Access to raw data is restricted to the RCOphth NOD statisticians.	Data is de-identified by EMR providers at source before submission to the RCOphth NOD.	Data extraction date	Beth Barnes, Head of Professional Support
Undesired modification								
Disappearance of data	1	5	5	Accepted	Adherence to the GHNHSFT IT Security	GHNHSFT IT systems back-ups.	In-place	GHNHSFT IT department

					policy	Providers could be contacted and asked to re-submit data.		
Network failure	1	2	2	Accepted	Adherence to the GHNHSFT IT Security policy	GHNHSFT IT policies.	In-place	GHNHSFT IT department
Sub-contractor network failure or cyber-attack	1	5	5	Accepted	Adherence to the GHNHSFT IT Security policy	GHNHSFT IT policies.	In-place	GHNHSFT IT department
Corporate risks & compliance risks section								
National Data Opt-out risk (England only)	1	3	3	Accepted	The NOD does not collect PID.	N/A	N/A	Beth Barnes, Head of Professional Support