The ROYAL COLLEGE of OPHTHALMOLOGISTS

Ophthalmic Services Guidance

Electronic Medical Records: standards for UK ophthalmology services

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1. Introduction

The Royal College of Ophthalmologists (RCOphth) champions excellence in eye care. To provide the best care for patients, and to generate improvements in care, it is important to be able to measure the quality of clinical and supporting services provided and ensure minimum quality standards are met. Electronic Medical Records (EMRs)*† are increasingly helping clinical teams achieve this by recording clinical care in a legible and standardised manner to measure the quality of the services they provide (eg through more automated clinical audit). However, while EMRs have many potential benefits, their use is not without well-documented risks.[1]

This document, based on published evidence and consensus expert opinion, is designed to indicate how EMRs can support the aims of the RCOphth and its members in providing high quality ophthalmic care.

There are three components:
1. **Standards**: which specifically address, or are considered particularly pertinent to, ophthalmic care. They do not attempt to cover generic ground which has been comprehensively described or laid out in separate standards elsewhere.[2] Instead they aim to focus on a small number of key areas and standards which are important for the delivery of high-quality ophthalmic care. It is not expected most EMR vendors will comply with all the standards set out in this document, but the minimum standards are indicated by a "must".
2. **Datasets**: Datasets are being developed by the RCOphth for each of the ophthalmic sub-specialities. These datasets are designed to serve the breadth of eyecare, have gateway disease modules and contain components common across ophthalmic sub-specialities. It is anticipated the contents of these datasets are adopted by an EMR provider.
3. **Ophthalmic specific and Hospital Information Systems**: The document considers some of the pros and cons of an ophthalmic specific EMR compared to the use of a general electronic patient record the organisation uses for other specialties. These considerations should be useful when ensuring procurement decisions provide the greatest benefit for ophthalmic services and patients.

Please send feedback on the standards and how you have used them to Beth Barnes, Head of Professional Support beth.barnes@rcophth.ac.uk

[1†] An Electronic Health Record (HER) as defined by the International Organization for Standardisation (ISO) is a 'repository of information regarding the health of a subject of care, in computer processable from.' When you begin to read around the subject you will encounter both the terms electronic medical record (EMR) and electronic health record (EHR). These are often used synonymously however there are differences between what is meant by each term[11]. An EMR is an application which includes clinical data repository, clinical decision support, controlled medical vocabulary, order entry, computerized provider order entry, pharmacy, and clinical documentation applications which store the data about what happens to a patient during their encounter with a health care delivery organisation. An EHR on the other hand represents a summary of the information gathered in EMR's across multiple health care organisations which spans multiple episodes of care and is owned by the patient. An EHR can therefore only exist on the back of fully functioning EMRs which are developed to communicate with each other.

2. When planning an Electronic Medical Record for ophthalmic patients

Providers:

- Must involve clinicians in the procurement and implementation process of any EMR that is used for ophthalmology
- Must have a plan for transitioning from historic paper notes. The bulk upload of paper records as PDFs in an unstructured manner has poor responsiveness and is hard to appraise quickly. Details of the proposed interim/legacy document management system function should be fully explained to all staff. When transferring from one EMR to another there must be a plan for accessing historic records in a usable format
- Must ensure a realistic launch programme, with appropriate adjustment of clinical activity during implementation, and a backup records system should difficulties
- Must ensure robust data backup procedures are in place to ensure no large-scale loss of data due to single server failure. If stored locally, there must be provision of remote access (full access) to facilitate satellite clinics and reviewing records remotely. Where possible cloud-based storage that facilitates remote access is desirable
- Must have a clinical lead for the EMR who is responsible for managing the EMR including user records as well as liaising with the EMR provider to feedback problems and to co-ordinate updates/upgrades as required
- Should be able to present specific, detailed examples where the EMR has resulted in more sustainable healthcare as assessed by financial, social or environmental savings and demonstrate the EMR's effect on workflow and productivity.[3]

A good EMR for use with ophthalmic patients:

- Must be easy to learn and use ("intuitive") and have documented proof of usability assessment[4]. There should be minimisation of "clicks" and mandatory fields
- Must permit the capture of minimum structured data in line with agreed datasets[2] and permit the collection of unstructured, narrative data upon which much individual patient care often depends
- Must conform or map to vendor-neutral standard terminologies (for example SNOMED CT, ICD, NHS Data dictionary, DICOM, HL7) to provide problem lists, diagnoses, procedures, allergies, clinical findings and handle messages/communication between systems
- Must have the ability to import data recorded by networked diagnostic devices for example OCT and visual field machines) and should facilitate the capture of hand drawn notes / non networked images via personal devices (BYOD such as smartphone / digital ink devices) while complying with normal information governance standards
- Must allow visualisation of a summary of the patient's ophthalmic history, diagnosis list and current management plan in a single, rapidly accessible (responsive) view
- Must allow data viewing and entry, including viewing data/entries and images changing over time (such as IOP, visual fields, OCTs etc) easily in a

realistic time frame for a patient consultation. (This may feature graphical representation of trends eg field of vision / IOP / VA data or permit access to more detailed historic episode data)

- Must comply with national requirements for record retention and access and historical record destruction and ensure that this complies with differing requirements for patient groups (for example, those that have been recruited to clinical research studies)
- Must produce correspondence, which is customisable, automatically in a suitable format for the patient[5-7] and conforms to the national outpatient letter standards
- Must be able to send the correspondence to GPs and patients
- Must, if providing lens calculations, present the target outcome with sphere, cylinder and axis rather than just spherical equivalent
- Should be able to exchange the full set of useful and relevant ophthalmic clinical data with EMRs from other vendors if a user decides to change EMR provider
- Should have a transparent portal or mechanism for feedback, change requests and suggested improvements to the EMR and provide comprehensive real-time support
- Should have ophthalmic specific history, examination, investigation and surgical modules which contain accepted lists of ophthalmic symptoms, clinical parameters, investigations, and operative procedures *or* a suitably configurable multispecialty function adaptable to ophthalmic needs
- Should with appropriate permissions be able to send letters to the patient's optometrist
- Should be able to accept data from, and provide feedback to, multiple care locations – particularly community optometry services but also potentially school screening, general practice and patients at home, in order to support shared care pathways
- Should facilitate clinical audit:
    - Enable contribution to national audit programs
    - Enable collection of nationally and internationally agreed datasets
    - Support automated 'standard' audits on key quality and safety areas for ophthalmology recommended by NICE, RCOphth etc. (eg outcomes of cataract surgery, treatment for wet AMD, adherence to NICE guidelines for glaucoma: diagnosis and management, NICE guidelines for cataracts in adults: management etc) against recognised benchmarks and published standards for individual clinicians and departments
- Should support custom user defined clinical audits:
    - Support clinicians to provide evidence for revalidation
    - Facilitate reporting of performance
    - Present real time data on patients who are lost to follow up[8]
    - Present real time data on patients who have a delayed follow up appointment[9]
    - Record and easily display percentage of entries in structured format which can be broken down by specialty and individual with the aim of improving data entry quality
- Should facilitate research:

    - Enable the collection of enhanced datasets for research
    - Have the ability to flag patients who are likely to fit user specified inclusion criteria or who have a condition which is currently under British Ophthalmological Surveillance Unit (BOSU) surveillance (bosu@rcophth.ac.uk)
- Should support CVI registration:
    - Ability to flag patients who appear to be eligible for certification
    - Ability to collect the dataset required to complete and generate the CVI form
- Should ensure a system which permits and encourages up to date accountable and traceable user record administration with mandatory recording of GMC numbers for doctors, Nursing and Midwifery Council PIN for nurses, GOC number for optometrists and Health and Care Professionals Council registration number for other non-medical eye care professionals including orthoptists. Physician Associates (PAs) will soon be a part of the ophthalmic workforce – they are set to be regulated by the GMC by the end of 2024 and as such will have a GMC number by this time. A facility to set reminders to review the training grade of those expected to transition between roles, for example the training grade of an ophthalmologist in training is an important feature to ensure correct record keeping
- Could facilitate patient involvement by:
    - Enabling efficient collection of validated patient reported outcome and experience measures eg revalidation suitable patient feedback questionnaires, PREMS and PROMs[10]
    - Enabling patient access to their records and feedback forms through a patient portal

3. Ophthalmic datasets

Over time adopting the ophthalmic datasets as set out by the RCOphth will have huge benefits for standardisation of data recording and collection, audit, research and may facilitate the use of artificial intelligence to help deliver better care. The subspecialties for which the RCOphth have produced or are developing datasets for are:

- Cataract
- Urgent and emergency
- Cornea and external disease/ocular surface
- Refractive surgery
- Medical retina
- Vitreoretinal (surgical retina)
- Glaucoma
- Neuro-ophthalmology
- Paediatrics
- Strabismus/ocular motility
- Adnexal (oculoplastic, orbits and lacrimal)
- Inflammatory eye disease (incl uveitis)
- Genetics
- Oncology
- Community ophthalmology

4. Ophthalmic specific EMR and multi-specialty EPR

Whilst each ophthalmic specific EMR or multi-specialty EPR has different functionality there are some generic pros and cons associated with each. This section will assess these in relation to different areas of functionality so that when a provider is determining which approach to pursue, they can consider the complex trade-offs involved in the decision. We use the term Hospital Information System (HIS) to refer to EMR, document management and administration systems marketed as a solution for electronic working across most or all hospital specialties, rather than EMR solutions specialised for ophthalmology.

i) Usability and detailed functionality

Delivery of modern ophthalmology services requires high volume clinics; procedures and investigations in clinics and high-volume surgery and so requires the ability to access, review and input data rapidly. Functionality which supports the specific needs of ophthalmology includes 'clinic list' screens which organise the flow of patients through clinic, summary charts which plot key ophthalmic data together in a single view, 'defaults' for common procedures, exam findings and eye drops to reduce the amount of time spent keying in data and tools which make the creation of complex treatment plans possible with a minimum of clicks. In general, these features are more likely in an ophthalmic specific EMR.

Furthermore, ophthalmic EMRs support systems which allow the sharing of eye specific data with community optometrists. If done in a safe and IG compliant way, this is a key enabler for shared care schemes commissioned around the UK. This includes patient facing 'Patient Recorded Outcome Measurement' tools allowing subjective feedback to be combined with clinical data to better assess surgical outcomes.

Similarly, ophthalmic EMRs are developed to support virtual review pathways, so all key data and diagnostic information can be captured and accessed easily by clinicians working through subspecialty specific worklists.

The structured and detailed ophthalmology-specific assessment, treatment and management data collected by HIS software is often very limited. Some providers offer ophthalmic functionality and specific fields for (eg) visual acuity, refraction or diagnosis whilst some have developed more extensive ophthalmology modules. Discussions with users of these systems indicate the vast majority of data input lacks structure which limits the ability to collate information into dashboards for interfacing with third party devices and systems. Generic HIS systems also rarely cater for the needs of a multidisciplinary team which typically include ophthalmologists, ophthalmic nurses, orthoptists and optometrists.

Generic systems do however provide a range of other benefits which are either not possible or only partially possible with an ophthalmic specific EMR such as access to the full patient record and ward referrals within a single system. This reduces clinical risk created by users having to access multiple systems and the possibility of missing key information outside of the record they are reviewing. Another significant benefit is that functionality to help the clinical service operate smoothly is normally done within the HIS used by the trust such as appointment booking and pharmacy services. This reduces the risk of errors such as appointments not being booked through clerical

error. Several ophthalmology EMR's can exchange appointment related HL7 messages with the HIS, in real time, which ensures both systems remain synchronised but is often not as seamless and requires development work.

ii) Interfaces with ophthalmic diagnostic devices and image systems

Almost every ophthalmology outpatient visit requires diagnostic tests to provide measurements or image data to be reviewed by clinicians. Typically, these diagnostic tests involve a combination of images and measurements. Both of these are essential in assessing a patient's condition or treatment. The ophthalmic diagnostic device market is fast-moving, with dozens of new devices introduced each year. Although there is a move towards data standards such as DICOM, most of these devices require significant analysis and development before they can safely be integrated within an EMR. When multiplied across all specialties, it is generally not feasible for a HIS provider to provide rich integration with all diagnostic instruments, or to respond rapidly when new diagnostic devices are introduced.

Specialist EMR providers therefore are more likely to interface with ophthalmic instruments to bring the data to the patient record in real time to support clinical decision making. A generic DICOM or raw image viewing platform can help in some situations such as clinical triage but is unlikely to give enough detail to help a clinician make the following decisions, in contrast to specialist ophthalmology EMR providers:

- Calculate or display the lens options for Cataract surgery based on eye measurements
- Understand thickness trends with a patient's macula to decide treatment strategy
- Evaluate a patient's rate of visual field loss from glaucoma to determine whether changes in management are required

iii) Clinical governance, research and reporting

Ophthalmology EMRs often provide detailed and easy-to-use audits and reports which can be quickly generated and might otherwise take many days of trawling through paper notes or trying to work out clinical outcomes from free text fields in the general hospital HIS, or worse, scanned paper documents.

Data such as medical history, medications, visual acuity, refraction, intraocular pressure, eye examination findings, diagnoses and operations performed are all usually entered as structured data. Because the data entered is structured, detailed audit of medical and surgical treatment outcomes is possible. These systems have been used as the data source for many research projects and as the basis of numerous peer-reviewed publications. Outcomes can be reviewed by individual clinician, by department or by trust, showing complication rates and post-surgical outcomes against peers and national benchmarks. The National Ophthalmology Database (NOD) has benefited from the rich datasets which have been able to be generated by ophthalmology-specific EMR systems. These tools are also often part of the clinical appraisal and revalidation of ophthalmologists.

The most commonly performed operation in the UK is cataract surgery but without an electronic medical record system it is far more challenging from a time and cost perspective to accurately audit the results of cataract surgery. Wrong lens insertion is one of the most common never events and it seems possible that ophthalmic specific

EMRs linked to the biometry machines for the display of IOL power calculations are less likely to result in errors such as biometry from the wrong patient being uploaded to the patient record although we are not aware of any published evidence to support this. The most commonly performed ophthalmic procedure in the UK is anti-VEGF therapy for macular disease. Ophthalmic EMRs facilitate service redesign to increase the efficiency of retinal treatment clinics and allows commissioners to monitor the quality of care that is delivered. General HIS providers are in general not designed around the very specific needs of these care pathways or the treatment regimens that are required.

iv) Medical device regulations and nationally agreed datasets

Medical software is increasingly a regulated area, and software that offers clinical decision support, performs calculations or analyses trends is regulated under UK Medical Device Regulations. The burden of clinical validation, safety assessment and documentation to support these regulations is significant: each new software update must be documented and assessed against the regulations (sometimes with external audit) before it can be released to market.

The burden of these regulations is so significant that HIS providers may be forced to limit the functionality in their systems, omitting useful clinical tools because these would be classified as a medical device rather than 'clerical software'. In general, HIS solutions are less likely to support nationally agreed ophthalmic datasets making contribution to important research studies more challenging.

Lastly NHS trusts are required to comply with NICE guidance and increasingly purchasers of healthcare are likely to demand evidence of compliance. A specialised EMR can help the trust's ophthalmology department to follow NICE guidance for the use of intravitreal anti-VEGF drugs for example. Similarly, specific features relating to the care of glaucoma patients can help the trust's ophthalmology department to follow NICE guidance.

v) Clinical safety features and decision support tools

Ophthalmology EMRs typically include features that help ophthalmologists make well informed treatment decisions. For example, EMR systems can estimate the risk of a patient having cataract surgery suffering a posterior rupture of the capsule into which the artificial intraocular lens is implanted. High-risk patients can then be assigned to experienced surgeons. Other clinician decision support features include the structured grading of diabetic retinopathy based on various published national and international standards, charts showing the degree to which a patient's visual field is being lost, field validation which prevents the entry of unlikely values and alerts if a medication prescribed is contraindicated.

The use of multiple electronic records within the hospital does however increase the clinical risk that critical information is missed by the ophthalmology team. Furthermore, clinical teams not involved in eye care are unlikely to have access to an ophthalmic specific record or if they do would be unfamiliar with how important information is stored creating further clinical risk. In addition, communication between specialties such as cc'ing other clinicians involved in a patient's care is harder with two patient records making the care of patients under other specialties as well as ophthalmology more disjointed.

vi) Hospital quality accounts and revalidation of doctors

Detailed clinical outcome data should be delivered as part of meaningful hospital quality accounts. In general, ophthalmic specific EMRs can produce this in the form of standard reports and graphs generated as a by-product of routine clinical activity. Trusts using more than one data system to manage ophthalmology patients may find it harder to accurately code activity happening within ophthalmology. These issues can be mitigated with EMRs that send outcome related ophthalmology data via structured HL7 messages to HIS systems but again this may not be seamless and requires development work.

The RCOphth is currently developing clinical standards for all sub-specialties within ophthalmology. If implemented, every ophthalmologist will need to demonstrate their own clinical performance relative to these standards at each annual appraisal. Demonstrating compliance with these standards would likely be facilitated using an ophthalmic specific EMR thereby making the revalidation process easier.

vii) Integration with Hospital Information Systems

HL7 messaging is designed to support bidirectional data exchange between different information systems. The hospital wide EPR or HIS is typically regarded as the master patient record which feeds demographic and other data to downstream systems. Clinical colleagues in other specialties should therefore be able to review data, prescriptions, clinical notes and letters through the HIS (or EDMS). It is likely however the whole record is not transmitted and may be stored in areas tother clinicians are not used to viewing. The risk of missing important clinical data may be increased in cases where a dedicated ophthalmology EMR is linked to a hospital wide HIS. These risks highlight the importance of ensuring all encounters (including reports from devices, op notes, correspondence etc) and associated data, are made accessible (eg to a trust document management system via HL7 MDM messaging) within the HIS.

Improving adherence to open standards is supported by RCOphth and is an important principle for both ophthalmic specific EMR’s and generic HIS providers, and may mitigate this to a degree, but is unlikely to be as seamless for the trust as having a single HIS across all specialties.

Furthermore, integration increases workload for the trust IT department, additional cost from having to support both the generic EPR or HIS and the ophthalmic specific EMR and may run contrary to trust policies that all patient records are contained on a single platform as well as complicating issues such as prescribing.

viii) Clinic letters

At many hospitals copies of clinic letters to GPs and discharge summaries are saved to a hospital-wide electronic document management system (EDMS). This allows staff in other departments, or in primary care to have an overview of the patient’s care. Some EDMSs have the facility to transmit the automatically generated letters to GPs electronically, thereby speeding up communication with primary care, eliminating the cost of printing, postage, and packaging, and reducing the administrative workload on ophthalmic secretaries. While EDMSs can function well with an integrated ophthalmic specific EMR, this has not consistently been the case; and it is important this functionality is clearly specified in any contract.

5. Table comparing organisation wide HIS and ophthalmic specific EMR

Provider	Pros	Cons
Ophthalmic specific	• Permits rapid eye-specific data entry and review of previous records • Permits graphical display of data suited to ophthalmology • Device integration particularly biometry but also visual fields, high resolution images, auto-refraction and scans, compatibility with touch devices • Decision support tools which may enable clinical safety: for example, risk of PCR calculator, IOL Power calculations, Diabetic Retinopathy structured grading • Ease for eye-specific audits eg cataract surgery outcomes • Familiarity for ophthalmologists who have used elsewhere & ability to make (for example) intravitreal injection treatment plans quickly and easily • Community portals for optometrists, enabling shared care schemes • More customised for commonly used eye drugs e.g. anti-VEGF • Provides a robust mechanism for managing high volume surgery, clinic procedures and outpatient clinics • Facilitates service evaluation and re-design of retinal injection service • Easier to incorporate compliance with specific NICE guidance into the software • In some cases, able to integrate with Diabetic Eye Screening programmes (DESPs), enabling sharing of patient data and automated referral to ensure that patients are being cared for most appropriately • Drawing tools and templates allow for very accurate recording of clinical findings or procedure detail, using icons that are specific to ophthalmology	• Other teams may not be able to readily review eye notes presenting a potential clinical safety risk • Allergies, etc. often need to be manually re-entered rather than pulled from the generic trust HIS presenting another potential clinical safety risk • Siloed working means eye team not readily familiar with main HIS for ordering scans, prescribing, discharges and admission timeframes • If remote access is not offered at all trust sites, eye notes may not be available where the patient is eg during inpatient ward review in ITU. This is mitigated when all ophthalmic notes are sent to the trust EDMS • Patient bookings are decoupled from the EMR making booking clinics and operations more difficult with greater potential for lost to follow up however HL7 integration between respective systems can mitigate this to a degree • Although Ophthalmic EMRs cost significantly less than trust wide EMRs, the preposition for a trust to pay for two separate EMRs simultaneously may present a financial challenge when considering training, maintenance and the necessary IT resources required from the host organisation

Generic	• Potentially more cost-effective for the trust • Clearer for non-ophthalmology teams to see a patient's eye status • Generic markers like demographics and allergies stay with the patient • Booking patients is not decoupled from EMR • Better site wide and cross-site access of eye notes • Better access to ward referrals, full patient record in one place • Reduced clinical risk of having multiple clinical records with patient information stored in different locations • Prescribing is not decoupled from the ophthalmic EMR • Ophthalmologists are familiar with the trust electronic medical record facilitating discharge summaries, ward reviews, scan booking and prescribing	• Ophthalmic data input lacks structure thus limiting the ability to collate information into dashboards • Limited ability to interface with third party devices and systems e.g. automated data input from biometry machine with could potentially increase the chance of never events when switching from an ophthalmic EMR to HIS provider • Likely to make delivery of high-volume clinics, surgical and injection lists more challenging • Potential for reduced ability to support clinical research due to challenges with extracting meaningful structured ophthalmic data • Potential for relatively reduced provision of ophthalmic decision support tools: risk of PCR tool, IOL power calculations and DR structured grading calculator etc. which may be associated with improved patient safety • May lack integration with DESPs, and may not offer risk stratification systems within the product potentially resulting in a greater clinical safety risk for patients • Where a site already uses an Ophthalmic EMR, moving to a HIS the organisation is likely to lose much historically recorded data given the complexity of a data migration and lack of fields to map these data to

6. Useful links and documents

Standards for the clinical structure and content of patient records

- Royal College of Surgeons Dataset of Clinical Quality Indicators for use by all independent providers of cosmetic surgical procedures
- General Medical Council - Colleague and patient feedback for revalidation
- Professional Record Standards Body for Health and Social care – developing standards for outpatient letters
- Records Management Code of Practice for Health and Social Care 2016
- ISO Standards of relevance to these quality standards are as follows:
- ISO/IEC 90003 – Software engineering
- ISO/IEC 27000 family - Information security management systems
- British standards of relevance to these quality standards include:
- BS 10008 Evidential Weight and Legal Admissibility of Electronic Information

7. Abbreviations

AMD – Age related macular degeneration
BYOD – Bring your own device
CVI – Certificate of vision impairment
DICOM – Digital imaging and communications in medicine
EHR – Electronic Health Record
EMR – Electronic Medical Record
GMC – General Medical Council
HIS – Hospital Information System
HL7 – Health Level Seven
ICD10 - is the 10th revision of the International Statistical Classification of Diseases and Related Health Problems (ICD), a medical classification list by the World Health Organization (WHO)
IOP – Intraocular pressure
NICE – National Institute for Health and Care Excellence
PREM – Patient reported experience measure
PROM – Patient reported outcome measure
SNOMED CT - a structured clinical vocabulary for use in an electronic health record
VA – Visual Acuity

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