The ROYAL COLLEGE of OPHTHALMOLOGISTS

Corneal Cross-Linking Data Set

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1. Introduction

A data set comprises a set of defined variables representing clinical information about a patient with a given condition. A formal Royal College interest in ophthalmic data sets began in 2002 with the initiation of work on the cataract national data set. Under the umbrella of the NSF for diabetes a diabetic retinopathy screening data set was developed and subsequently the Do Once And Share (DOAS) programme supported further data set work on cataract, glaucoma and diabetic eye care. The widespread use of the cataract national data set has facilitated useful national audits.[1]

This document describes a proposed data set for corneal cross-linking (CXL). The data set has been composed by a working group of the UK CXL Consortium, comprising a representative selection of experts in the management of keratoconus and related corneal ectasias working in a variety of healthcare and academic environments across the UK.

2. Application

The purpose of this data set is to represent an agreed set of clinical information which can be collected on patients being considered for corneal cross-linking. 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	
Revalidation	Required for revalidation purposes
Mandatory	Data items which are essential for all applications, and must be collected
Optional	Data items which are required for some applications, and may be collected

NB. Selection of red items to be confirmed by the revalidation committee of the College.

3. Scope

This data set applies only to patients with corneal ectasia who may be suitable for corneal collagen cross-linking. In this context, corneal ectasia encompasses keratoconus, pellucid marginal degeneration and post-excimer ectasia.

4. Principles

The data set is designed to comply with the following principles;[2]

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 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 the minimum required to ensure patient safety. 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.

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 type determined from table 1 below. These correspond to data types available in most relational database management systems (RDMS), which generally form the core of real EPR systems.

Table 1

Type	Description
NULL	A special entity representing an uncertain or unassigned value
INTEGER	An integer value, normally unsigned (i.e. zero or positive values only)
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. Components of Data Set

The data set is divided into 4 sections;

1. Demographics – demographic data about the patient
2. History – previous relevant medical & surgical history
3. CXL operation – details of CXL surgery
4. Assessments – initial assessment and all follow-up assessment

1. DEMOGRAPHICS

The elements in this section will be common to all ophthalmic data sets.

Item	Description	Value/format
Patient ID	An identifier which will uniquely identify the patient. In England and Wales this could be the NHS number. Alphanumeric hospital numbers could also be used. This would be removed in anonymised data sets	INTEGER/STRING
Age	The age of the patient in years. Age provides sufficient information for analysis, without also being patient identifiable data (PID), unlike date of birth	INTEGER
Sex	The patient's gender	ENUM (Male, Female)
Postcode	The postcode district (outward code). This is the first part of a postcode, and generally corresponds to a post town. It gives useful information for demographic analysis, without being PID	STRING
Consultant	Identifier for consultant in charge of patient (to allow individual audits)	INTEGER
Ethnic category	The ethnicity of the patient using the classification used for the 2011 census[3]	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)
Route of referral	Referred by whom?	ENUM (Optometrist, GP, ophthalmologist)

2. HISTORY

Item	Description	Value/format
Eye	Eye	ENUM (Right, Left)
CXL	Previous CXL	BOOL (Yes, No)
Refractive surgery	Previous refractive surgery	ENUM (None, LASIK, PRK, SMILE, RK, ICRS, phakic IOL) 1 or more
Ocular surface disease	Previous diseases of the ocular surface	ENUM (None, HSK, bacterial keratitis, marginal keratitis, RCES, allergic eye disease) 1 or more
Atopy	Does the patient have atopic conditions?	ENUM (None, Asthma, eczema, hayfever) 1 or more

The history can be taken at the first consultation and thereafter merely updated as necessary.

3. ASSESSMENTS

Item	Description	Value/format
Vision/refraction		
Date	Date of visit	DATE
Eye	Eye	ENUM (Right, Left)
Reason for visit		ENUM (new patient, follow-up)
Current correction	Vision correction used by patient	ENUM (unaided, spectacles, SCL, RGP, hybrid, scleral)
Visual acuity chart	Chart used to record patients visual acuity	ENUM (Snellen, EDTRS)
UDVA	Uncorrected distance visual acuity	ENUM (Values determined by chart type)
CDVA	Corrected distance visual acuity	ENUM (Values determined by chart type)
Sphere	Refractive spherical error	FLOAT
Cylinder	Refractive cylinder	FLOAT
Axis	Axis of cylinder	FLOAT
Topography		
Kmax	Steepest keratometry over the whole cornea	FLOAT
Front k1	Flattest front curvature in the 3 mm zone	FLOAT
Front k2	Steepest front curvature in the 3 mm zone	FLOAT
Back k1	Flattest back curvature in the 3 mm zone	FLOAT
Back k2	Steepest back curvature in the 3 mm zone	FLOAT
Thinnest pachymetry		INTEGER
Belin Ambrosio	Enhanced ectasia score	FLOAT
Quality score	Quality score front	ENUM (OK, Borderline yellow, Poor red)
Quality score	Quality score back	ENUM (OK, Borderline yellow, Poor red)
CL removed prior to scan?		ENUM (Not applicable, Today, 1 week, 2 or more week)

Item	Description	Value/format
Specular microscopy		
Endothelial cell density	/mm2	FLOAT
Coefficient of variation		FLOAT
Slit-lamp		
Ocular surface inflammation		ENUM (None, controlled, uncontrolled, other)
Ocular surface inflammation = other		STRING
Cornea	Any other relevant signs?	ENUM (clear, scarring, other)
Cornea = other		STRING
Outcome		
Diagnosis	The diagnosis reached at the end of the assessment.	ENUM (Not ectasia, keratoconus, post-laser ectasia, pellucid marginal degeneration)
Status	Is the ectasia stable or has it progressed	ENUM (stable, progressed, uncertain)
Reason for deciding status		ENUM (keratometry, pachymetry, refraction, acuity) 1 or more
Outcome	What decision is made at the end of each assessment	ENUM (follow-up, CXL, Discharge)
Comments	Additional assessment comments not otherwise appearing in the data set.	STRING

4. CORNEAL CROSS LINKING SURGERY

Item	Description	Value/format
Date	Date of surgery	DATE
Operator	Grade of person performing CXL	ENUM (Optometrist, nurse, consultant, fellow, ST)
Device	UVA device used	ENUM (IROC UVX-1000, IROC UVX 2000, Avedro KXL I, Avedro KXL II, Peschke CCL-Vario, other)
Epithelial status	Was the epithelium removed?	ENUM (On, off, partial disruption)
Epithelial debridement	How was the epithelium removed	ENUM (manual, ETOH-assisted, transPTK, transPRK)
Debridement size	Diameter of epithelial defect	INTEGER (mm)
Iontophoresis	Was iontophoresis used?	BOOL (Yes, No)
Iontophoresis current	Iontophoresis settings	INTEGER (mA)
Iontophoresis duration	Iontophoresis settings	INTERGER (minutes)
Riboflavin preparation	Name of solution	STRING
Riboflavin duration	Total riboflavin soak time	INTERGER (minutes)
UV irradiance	UV power	INTEGER (mW/cm2)
UV duration	Duration of UV exposure	INTEGER (minutes)
UV continuous or pulsed	Continuous or on/off phase of pulsed exposure (seconds)	ENUM (continuous, 0.5, 1, 1.5, 2)
Topography guided?	Topography-guided devices available soon	BOOL (Yes, No)
UV total energy	(Energy (J/cm2) = power (W/cm2) x duration (seconds)	INTEGER (J/cm2)
Duration of BCL wear	How many days?	ENUM (Not used, 1,2,3,4,5,6,7 or more)
Post-operative therapy	Drops used following CXL	ENUM (antibiotics, steroids, NSAIDs, lubricants). 1 or more
Steroids before epithelium healed	Were steroid drops used before epithelialisation complete?	BOOL (Yes, No)
Complications	Complications following CXL	ENUM (none, sterile infiltrate, infective infiltrate, melt, delayed epithelial healing, HSK re-activation, RCES, haze). 1 or more
Comments	Additional surgery comments	STRING

7. References

1. Cataract National Data set V1.2 – Royal College of Ophthalmologists.
2. Dataset Guidelines Authors: The Informatics and Audit Committee, Royal College of Ophthalmologists. V1.0 2013
3. 2011 Census Ethnicity Coding. www.england.nhs.uk

8. Authors

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