

<a href="#">NHS Connecting for Health</a> <a href="#">Office of the Chief Clinical Officer</a> <a href="#">and Royal College of Ophthalmologists</a>	<b>The Cataract National Data set</b>			
	<b>Sponsors</b>	Connecting for Health Royal College of Ophthalmologists	<b>Version Number</b>	<b>0.4</b>
	<b>Developer</b>	John Sparrow CFH National Clinical Lead for Ophthalmology	<b>Version Date</b>	<b>7 April 2010</b>

## The Cataract National Data set

Inherited Information Standard

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**Amendment History:**

Version	Date	Amendment History
0.1	8 January 2010	First draft for comment
0.2	15 January 2010	Comments on first draft from Anne Casey
0.3	5 February 2010	Revised draft addressing issues raised by Anne Casey
0.4	7 April 2010	Revised submission addressing issues raised by appraisers Paul Budgen, Ian Shepherd, Nick Strong and Elizabeth Hunter

**Related Documents:**

These documents will provide additional information.

Reference Number	Title	Version
Appendix 1	<i>2010.04.07 Cataract National Data set v3.1.xls</i>	
Appendix 2	<i>Cataract Data Set Hazard Log v0.1.xls</i>	
	See also embedded documents	

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# 1. Standard Demographics

## 1.1. Name of Standard

*The Cataract National Data Set*

## 1.2. Sponsors

### *Departmental*

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## 1.3. Developers

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(Previously CFH Do Once And Share (DOAS) Cataract Team)

### *Ongoing owner of the standard*

Jointly owned by the sponsors identified in 1.2 above.

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## 1.4. Commercial Issues

There are no commercial, licensing or Intellectual Property Rights issues relating to the use of this standard within the NHS.

In future, the standard will include SNOMED-CT coding - the intellectual property rights of SNOMED-CT lie with the International Health Terminology Standards Development Organisation (IHTSDO). NHS Suppliers require a license from NHS Connecting for Health for this to be implemented in systems.

## 1.5. Background and Customer Need

Cataract surgery is the most frequently performed surgical procedure in the NHS with over 300,000 operations annually in England alone. Clinical systems to support the management of patients undergoing cataract surgery are in place or in development but there is no approved standard for the data that is recorded to support the cataract care pathway and provide data for secondary purposes. The cataract national data set has already been implemented in an electronic cataract care record (Medisoft) which is in use in ~40% of NHS cataract units in England. Given this extent of implementation, the data set is proposed as the national information standard. A second specialty system developer, (OpenEyes – an open source developer wishing to enter the market) has expressed an interest in the data set although the CFH LSP's (Cerner Millennium and I-Soft Lorenzo) and a third specific developer, VersaSuit, have thus far failed to express any interest despite repeated attempts at establishing a dialogue with each of them. The existing system at Moorfields Eye Hospital (E-Patient) is no longer supported though has been used to collect largely compliant data for around a decade in that hospital (see embedded report in the form of a poster presentation under 2.5 below).

Customers for / beneficiaries of the proposed standard are:

- Patients with cataract requiring assessment and treatment
- Cataract surgical units which deliver cataract care.
- Healthcare professionals delivering care to cataract patients.
- Surgeons for quality assurance: audit, appraisal, revalidation.
- Commissioners to support quality based purchasing.
- Acute trust managers and Care Quality Commission (CQC) for quality accounts.
- DH to support 18 week pathway and for quality indicators for cataract services.
- System developers to deliver cataract care records.
- Royal College of Ophthalmologists in setting benchmark standards for surgical practice.
- Royal College of Anaesthetists in setting benchmark standards for anaesthetic practice.
- Royal College of Nursing in setting benchmark standards for cataract care.
- College of Optometrists in setting benchmark standards for cataract care.
- Clinical and epidemiological researchers.

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## 2. Purpose and Scope

### 2.1. Standard Overview – describe the standard and refer to specification

The proposed standard defines data elements and values to meet information needs for the management of patients undergoing cataract surgery. This covers the full care pathway, from referral to discharge. All information items necessary for cataract assessment and treatment are included.

The cataract national data set specification covers all aspects of the care pathway and is available as Appendix 1 formatted as an Excel workbook. Separate sheets cover patient details and demographics, preoperative assessment, ocular biometry, anaesthesia, surgery and follow up (Excel workbook also embedded at 3.8).

A 'gap analysis' has also been undertaken by CFH which deals with the requirements for cataract care and maps these against those specified in the supplier Outline Base Specification (OBS).

### 2.2. Purpose

The primary purpose is to provide a data set to cater for the information needs of health care professionals caring for patients with cataract. The full cataract care pathway is covered, including information required at referral (level of vision, co-morbidity, medications), ophthalmological clinical assessment (details of ocular examination), preoperative assessment (ocular biometry, fitness for anaesthesia, fitness for surgery), anaesthesia (type of anaesthetic), surgery (details of procedure, any complications), postoperative treatments and recovery (eye drops, postoperative events) and visual rehabilitation (refractive and visual outcomes).

Indirect benefits will accrue due to the ability of electronic systems to automatically analyse the routinely collected data to risk assess individual patients in terms of the likelihood of a surgical complication. This risk stratification process will facilitate the process whereby the most complex and highest risk surgery is performed by the most experienced surgeons, a strategy which can minimise the absolute numbers of patients who experience a surgical complication.

Standardisation of the data items collected will ensure that information acquired by different centres is recorded consistently and hence is fit to be employed for the secondary purposes.

Service quality and professional benefits arise from the use of large volumes of electronically collected data for benchmarking, research and revalidation.

### 2.3. Scope

#### 2.3.1. What is the proposed standard to be used for?

Cataract care from referral into secondary care to discharge back to primary care. The data set is a by product of the clinical process but the richness of the contained data will support a variety of secondary uses.

Steps in the cataract pathway include: Initial optometric assessment with referral information for the hospital eye service, general practitioner information on general health and medications (in future some of this information may be derived from the summary care record), initial outpatient assessment and pre-operative assessment for those for whom it is appropriate to proceed to surgery, on the day preparation for surgery, anaesthesia and surgery, post-operative follow-up

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and outcome assessment. Knowledge support within software will allow pre-operative case mix stratification for surgical risk to ensure that surgery is delivered by the most skilled surgeons when the complication risk is highest.

Secondary uses for the standard will include benchmarking of outcomes for services as a whole and for individual surgeons. These form important clinical governance components in terms of quality assurance at institutional and surgeon levels. Future 'Trust Quality Accounts' and revalidation for surgeons would be greatly facilitated by standardised data being collected routinely as a by product of clinical care.

### **2.3.2. Who is the subject?**

Adults undergoing routine cataract surgery.

### **2.3.3. Who uses it?**

Suppliers:

Organisations designing and deploying electronic care record systems for cataract units. Other supplier organisations may use elements of the data set, for example, to support referral from primary care. Certain software products e.g. Choose & Book are 'customisable' with features which may be adjusted locally for improvement of referrals to secondary care.

Health care providers:

Carers of patients with cataract would directly collect, enter and use the information contained in the data set. Such individuals who are involved in direct clinical care consist of clinicians and support staff: ophthalmologists, general practitioners, nurses, optometrists, health care assistants, service managers, administrative staff.

Secondary users:

The data set will support quality assurance (clinical governance, clinical audit, benchmarking), commissioning, appraisal and revalidation of professionals, managers responsible for running services, local and national aggregation of data, clinical and epidemiological researchers. Overall these activities will serve to drive up standards of clinical care by informing and empowering users.

### **2.3.4. How is it used in routine existing working practices? Scenarios for use by different user groups**

The data set is currently collected in a variety of ways and cataract units vary from being fully electronic (in house) to fully paper based. From the perspective of the care pathway as a whole no settings are fully electronic because information transferred between GP's, optometrists and secondary care rely to a greater or lesser extent on paper based systems.

Data are collected by a multi-professional team of health care practitioners along the patient pathway (see end to end scenario below). Collected data accumulates in the electronic or paper or hybrid record as the patient moves along the pathway. At each point previous information is required by the carer. The amount of detail required at each point varies from all previous detail (e.g. for the surgeon when undertaking the operation) to a brief summary (e.g. for the optometrist undertaking the post-operative refraction).

Secondary use of the data becomes appropriate once the patient exits the pathway. Secondary uses include local audit of activity and outcomes (provider units & commissioners), local, regional and national aggregation of activity and outcomes (information used by a wide range of local,

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regional and national users including acute trusts, primary care trusts, strategic health authorities, the NHS Information Centre), benchmarking for surgeons (clinical governance, audit, appraisal & revalidation), benchmarking for services (quality accounts for acute trusts & service quality information for commissioners). Please also refer to data flows under section 3.1.

By way of examples three detailed scenarios for use are described. The scenarios are idealised situations which illustrate what will be possible once interoperable electronic working has been established. These scenarios can be interpreted in a paper world where the data transfers all occur manually or as already exists, hybrid situations where both electronic and paper systems sit side by side.

- Primary data set use: End to end scenario – The Patient Pathway
- Secondary data user: Appraisal and audit scenario – The Consultant Surgeon
- Patient safety: Case mix stratification scenario – The System Developer

*Scenario 1. The 'end to end' patient pathway – primary data collection*

Mrs Misty visits her GP having been referred to him by her community optometrist with cataracts. The GP agrees to refer Mrs Misty to the local eye hospital for consideration for cataract surgery. The receptionist arranges an appointment in the cataract clinic through choose and book and passes on the information regarding visual symptoms, refraction, distance visual acuity, reading acuity, general health, allergies and medications. In anticipation of her visit to the eye hospital her demographic records have been uploaded into the cataract electronic care record system via the hospital patient administration system (PAS). After confirming her arrival with the reception clerk she is met by a nurse who takes a history, checks her Snellen distance acuity and enters these details, and those from the GP and optometrist, into the electronic care record. Next she waits to be called in to see the consultant. When she enters the consulting room the consultant has her record open on the computer screen and is aware of the problem which is bothering her, and knows about her general health. Following introductions the consultant asks her a few more questions and examines her eyes, with a short break part way through, to allow the pupil dilating drops to work. The consultant records clinical information during the consultation on the computer by the side of the eye examination equipment. The consultant explains that Mrs Misty has cataracts affecting her vision and that otherwise her eyes are healthy. Mrs Misty is keen to have her vision improved and takes up the offer of cataract surgery for her right eye in the first instance, with a view to possible second eye surgery later. The consultant completes the electronic record, and letters are sent to her GP and optometrist. The nurse then directs her to the preoperative assessment area where she has further medical details taken from her of relevance to local anaesthesia, mobility and posturing. Eye biometry readings from a machine are transmitted directly to her electronic care record. The nurse discusses the risks and potential benefits of cataract surgery with her, obtains her consent for the operation, and she is given written information about cataract and cataract surgery to take home, as well as an appointment for her surgery in a few weeks time.

On the day of surgery Mrs Misty arrives early and the nurse prepares her for surgery. The nurse checks with her that nothing significant has changed since her assessment. She is made comfortable, reminded of the procedure for the day, information on allergies is checked and drops are instilled into her eye for surgery according to the prescription on her record. The consultant surgeon comes to the theatre lounge and confirms her consent to surgery with her and gives her the opportunity to ask any further questions regarding the surgery. The anaesthetist likewise comes to speak with her and gives her the opportunity to ask questions. When she goes through to the anaesthetic room the anaesthetist records the details of her local anaesthetic directly onto her electronic record. The surgeon checks the information on her record and confirms the strength of the prosthetic lens implant required according to the record of her eye biometry. She is taken through to the theatre and her operation is performed, following which she is escorted back to the theatre lounge while the surgeon records details of her surgery on her electronic record and sends a letter regarding her surgery to her GP. The nurses once again make her comfortable and after a period of recovery she is provided with postoperative information, eye

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drops, a hospital outpatient follow up appointment and discharged. She returns home with her accompanying person.

As instructed by the nurse, and in accordance with the written information received, she has visited her optometrist 4 weeks after her operation for a check on her glasses. Her optometrist has ordered a change in her right spectacle lens and has sent this refraction result to the hospital. Five weeks after her surgery she attends the clinic for her postoperative visit where her vision is checked by the nurse on arrival and she proceeds to see the consultant in the clinic. The consultant already has the information sent by the optometrist which has been transferred into the electronic record. Following a discussion regarding her recovery and her level of satisfaction with her vision the consultant examines her eyes. All is well and her postoperative records are completed. Mrs Misty indicates that she would like to 'try out' her new vision once she has received her new glasses from the optometrist and it is agreed that she will be sent a questionnaire asking about her visual symptoms and vision related quality of life at 3 months post operatively. Depending on her views at that time she may or may not wish to proceed with a second operation. She leaves the consulting room and the consultant notes the clinical findings on the electronic care record and the fact that she should be sent a questionnaire in due course. Summary letters are sent to her GP and optometrist.

#### *Scenario 2. The Consultant – secondary data use*

The consultant ophthalmologist has an appraisal due soon and wishes to include information on his cataract surgery complication rate for posterior capsule rupture, for visual acuity outcome, and for biometric and refractive accuracy over the past year. He logs into the cataract electronic care record and enters the audit section. He identifies the period for which he wants a report generated and the type of surgery. The report takes a couple of minutes to process and he is pleased to note that he has done 230 cataract operation in the past year and that his operative complication rate for capsule rupture is a very acceptable 1.3% (95% CI: 0.4% to 4.0%), in keeping with the recently published UK benchmark rate from an analysis of over 55,000 electronically recorded operations which was 1.92% overall and 1.41% for independent surgeons. He notes that in terms of corrected visual acuity outcome, 92% of his patients achieved 6/12 or better, similar to the published figure of 91%. He is less pleased with the accuracy of his refractive outcomes and notes that the average of his results is shifted by 0.75 dioptres towards a long sighted outcome. Reflecting on this result he decides to raise the question of customization of the departmental biometric "A constant" as this is now being recommended on the basis of published studies for improved precision of postoperative refractive outcomes. He will bring this up during his appraisal and should the results of the department as a whole reflect his own, then refining the biometry constant will improve outcomes for all the patients undergoing cataract surgery in the hospital.

#### *Scenario 3. System development – enhanced patient safety imbedded in the care record:*

The system supplier has implemented cataract care records in ~40% of NHS eye units in England. Analysis of anonymous electronic data extractions from early adopter sites have allowed preoperative risk indicators for surgical complications to be identified in a large and detailed set of over 55,000 cataract surgery records. These data indicate that the risk of a complication of surgery varies by up to 100 fold depending on preoperative case complexity variables. The supplier has been asked by consultant ophthalmologists to include a risk calculator in the cataract care record to automatically traffic light individual patients into high, medium or low risk categories, in order to ensure that the most experienced surgeons are scheduled to perform the most challenging cases, an approach which minimises overall complication risk for patients. The supplier is keen to oblige since providing a better product will provide safer patient care and enhance the marketability of the cataract electronic care record. The supplier is able to identify all the relevant risk indicator variables from the cataract national data set. These data items are all available for collection preoperatively and by ensuring that they are collected prior to surgery it is possible to risk stratify the surgical case mix. Following a cycle of software improvement the cataract care record is able to provide appropriate preoperative case complexity alerts to carers

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who are thus in a better position to ensure that the risk of a complication is minimised by scheduling the most difficult cases for the most skilled surgeons.

### 2.3.5. Where is it used? (locations)

Potentially all locations involved in the patient care pathway for cataract: The referring optometrist in a high street optometric practice, the GP in a practice, the PCT, the acute trust / cottage hospital / treatment centre (and back to optometrist for postoperative refraction).

## 2.4. Out of Scope

Complex cataract or crystalline lens problems requiring non-standard or complex combined treatments are excluded because the data requirements for such treatments frequently extend well beyond those for standard cataract surgery.

Infants and children with cataract are excluded as the care pathway, diagnostic needs, pre-operative care, surgery and post-operative care are all significantly different from those for adults.

## 2.5. Performance Characteristics – measurable criteria against which the standard can be judged as safe, interoperable, implementable and fit for purpose

Use of the Cataract National Data set in cataract care record systems – confirmation of acceptability, usability and safety by users.

Peer reviewed published papers provide strong evidence of the fact that the data set is judged as safe, implementable and fit for purpose. These published reports have been accepted and embraced by the clinical community. There is a wealth of information in the published reports which can be used for specific performance criteria. For example, numerous benchmarks appear in these reports, many of which would lend themselves to performance checking for new implementations. In terms of interoperability the data set should be SNOMED-CT coded in order to enhance this aspect and these codes would then need to be incorporated into existing and new applications.

Data can be extracted and used for secondary purposes by stakeholders as has been noted above.

Outputs based on the data set:

Jaycock P, Johnston RL, Taylor H, Adams M, Tole DM, Galloway P, Canning C, Sparrow JM and the UK EPR user group.

The Cataract National Data set Electronic Multi-centre Audit of 55,567 Operations: Updating Benchmark Standards of Care in the UK and Internationally. *Eye* 2009;23:38-49.

Narendran N, Jaycock P, Johnston RL, Taylor H, Adams M, Tole DM, Asaria RH, Galloway P, Sparrow JM and the UK EPR user group.

The Cataract National Data set Electronic Multi-centre Audit of 55,567 Operations: Risk stratification for posterior capsule rupture and vitreous loss. *Eye* 2009;23:31-37.

El-Hindy N, Johnston RL, Jaycock P, Eke T, Braga AJ, Tole DM, Galloway P, Sparrow JM, and the UK EPR user group.

The Cataract National Data set Electronic Multi-centre Audit of 55,567 Operations: Anaesthetic techniques and complications. *Eye* 2009;23:50-55.

Benzimra JD, Johnston RL, Jaycock P, Galloway P, Lambert G, Chung A, Eke T, Sparrow JM and the UK EPR user group.

The Cataract National Data set Electronic Multi-centre Audit of 55,567 Operations: Antiplatelet & Anticoagulant Medication. *Eye* 2009;23:10-16.

Most read paper by US Ophthalmologists when published ([www.medscape.com](http://www.medscape.com)).

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Johnston RL, Taylor H, Smith R, Sparrow JM.

The Cataract National Data set Electronic Multi-centre Audit of 55,567 Operations: variation in posterior capsule rupture (PCR) rates between surgeons. In press. Eye advance online publication, 14 August 2009; doi:10.1038/eye.2009.195

Knox Cartwright N, Johnston RL, Jaycock PD, Tole DM, Sparrow JM.

The Cataract National Data set electronic multicentre audit of 55,567 operations: When should IOL Master biometric measurements be rechecked? In press. Eye advance online publication, 14 August 2009; doi:10.1038/eye.2009.196.

Aristodemou P, Knox Cartwright N, Sparrow JM, Johnston RL.

Refractive outcome for 8109 eyes following cataract surgery: Impact of customisation of formula constants on prediction error for IOL Master Biometry. To customise by method of measurement or surgeon? Submitted to JCRS Jan 2010.

Aristodemou P, Knox Cartwright N, Sparrow JM, Johnston RL.

Refractive outcome for 8109 eyes following cataract surgery: Impact of formula choice between customised Hoffer Q, Holladay 1 and SRK/T. Which formula for which axial length interval? Submitted to JCRS Jan 2010.

N Patel, D Hildebrand, R Khan, A Ionides, O Findl.

Electronic Operative Patient Recording of Complications in Cataract Surgery.

Poster presentation from the Cataract Service, Moorfields Eye Hospital, London City Rd, London.

#### Published papers imbedded:



Adobe Acrobat Document



Adobe Acrobat Document



Adobe Acrobat Document



Adobe Acrobat Document



Adobe Acrobat Document



Adobe Acrobat Document



2009 Poster from Moorfields - NP Oxfor

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## 3. Business Justification

### 3.1. Strategic Fit

#### 3.1.1. Criteria under which the proposed information standard is submitted

It will be possible for the information standard to be used by the Department of Health as part of public scrutiny of NHS services. The NHS information centre (IC) already provides aggregate data on cataract surgery but this is process data lacks any measure of quality. The IC has provided a supporting statement for this data set. Implementation of the dataset will make it possible to monitor services in terms of pre-operative, operative and outcomes data. For example surgical complication rates and visual acuity outcomes will be extractable from centres routinely using electronic care records. Thus it will be possible for the standard to be used to audit or assess NHS and social care organisations on an ongoing basis by organisations such as Monitor and / or the Care Quality Commission for the NHS. In terms of revalidation of surgeons the Royal College of Ophthalmologists is fully signed up to use of the data set for this purpose. There currently exists a project (funded by the Academy of Medical Royal Colleges) whereby data extractions based on the data set are being used to develop risk based standards for cataract surgery (with a view to this methodology being extended to other high volume surgical specialties in the future). Connecting for Health are strongly supportive of content development generally and specifically for this data set and in addition to acting as the departmental sponsor have provided a letter of support for the data set. The submitter has been told that the ISB will obtain the necessary statement of support from the Technical Office of CfH.

A gap analysis has been undertaken by CFH based around the cataract care pathway and collection of the cataract national data set. The final report document from this project “Cataract Surgery Requirements / NHS CRS Contract Gap Analysis Version 1.0” received CFH approval on 5th March 2009:

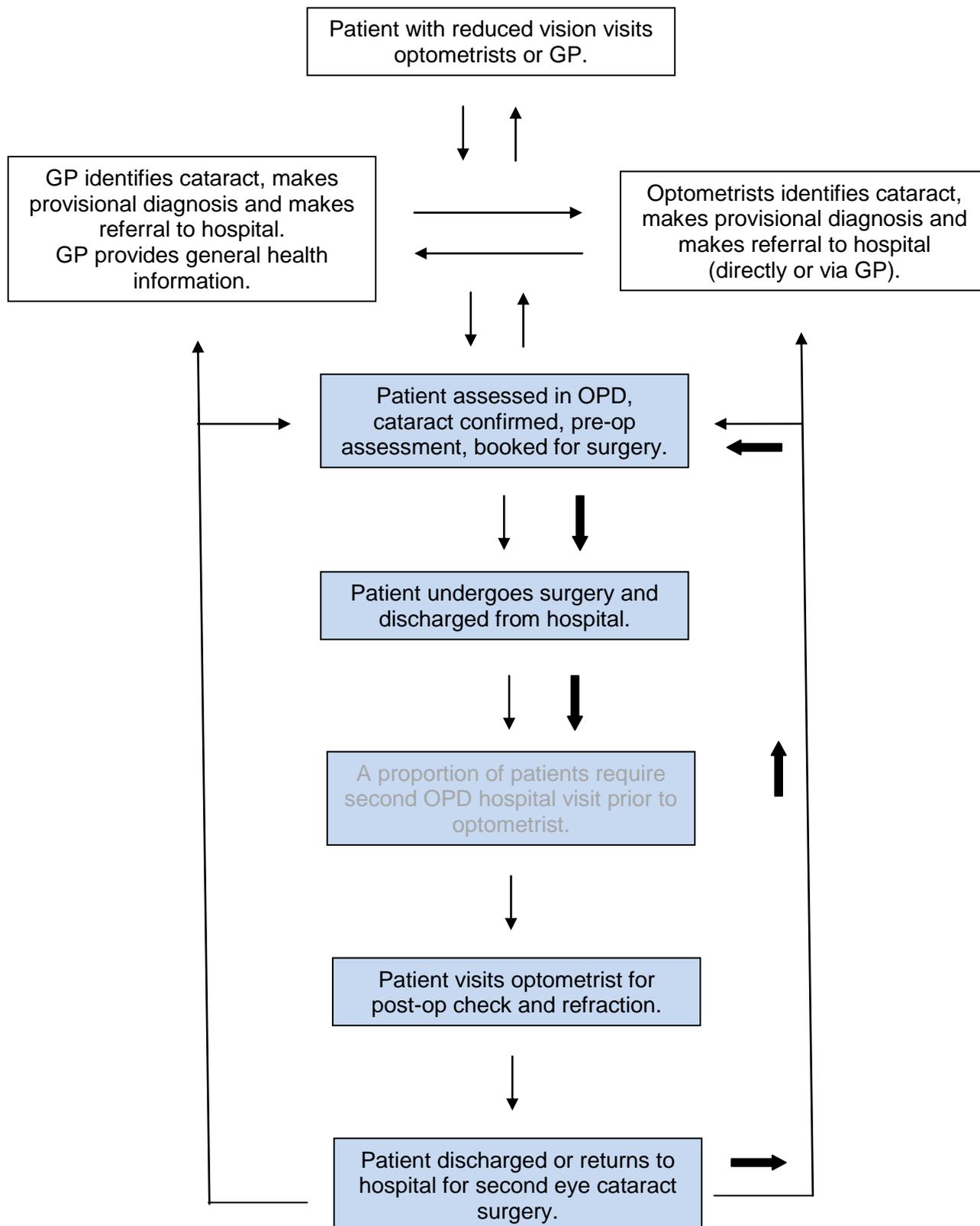


Microsoft Office  
Word 97 - 2003 Docu

Although LSP's are still a considerable distance away from catering for the clinical content and functionality needs of specialties the data set and functionality project noted above in 3.1.1 would provide a secure framework for this to develop over time. The current cataract care record market leader in the NHS is already 90+% compliant with the cataract national data set. There is a recognition by CFH that existing specialty systems have value and a role to play in developing the IT strategy. See <http://www.connectingforhealth.nhs.uk/systemsandservices/specialty>.

### 3.2. Implementation Architecture

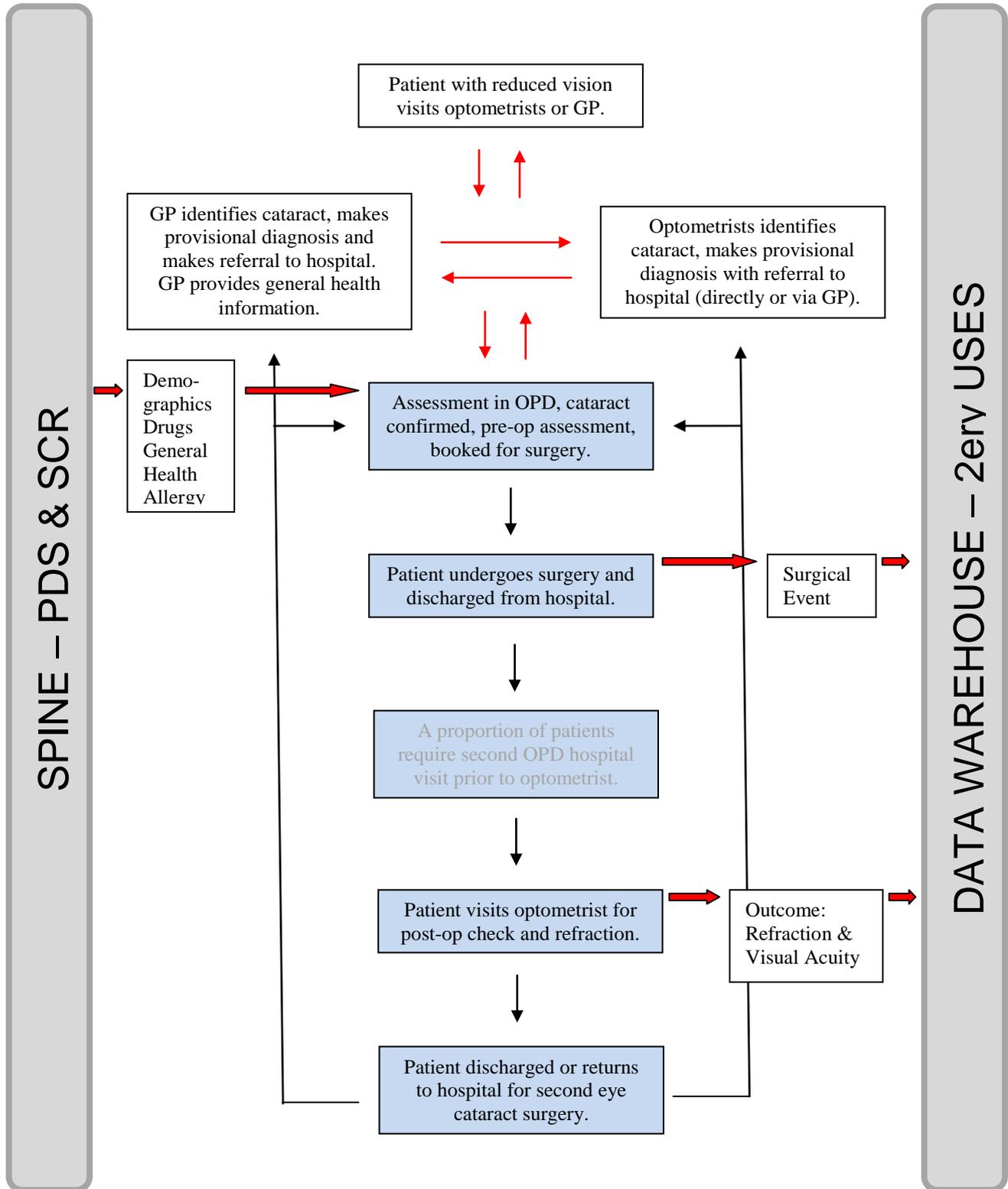
#### CURRENT HYBRID DATA FLOWS (NARROW ARROWS - PAPER; BOLD ARROWS - ELECTRONIC FOR UNITS WITH ELECTRONIC CARE RECORDS)



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The above diagram illustrates the current position for cataract surgical units (blue text boxes) without electronic care records (narrow arrows) and for those 40% of units with 'in house' electronic care record systems (bold arrows). Coding of surgical procedure is currently undertaken manually by 'coding clerks' through a separate, labour intensive and error prone process based on looking at the paper records and entering codes following surgery. These data are utilised for local secondary uses and also submitted to the NHS information centre for aggregate performance statistics.

**ENVISAGED FUTURE FULLY ELECTRONIC INTERNAL (BLACK) AND EXTERNAL (RED) DATA FLOWS**



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The above diagram illustrates future transfers of data, all of which will occur electronically. Key elements include the use of an electronic care record within the cataract unit (blue text boxes) which is able to draw demographic data from the acute trust's PAS (originating in the external personal demographics service or PDS), draw data from electronic referral (C&B) including information from the patient's GP on general health and data received from the optometrist regarding preoperative visual and refractive status, and draw data from the summary care record on current medications and allergies. General health data held in the summary care record may not be complete in the early stages of SCR implementation so these data will need to be confirmed by the referring GP. Receiving these data reliably and directly into the ophthalmic electronic care record will significantly decrease the workload of the acute trust whose staff currently obtain these data by a combination of scrutiny of the paper referral details and direct questioning of the patient.

Data transferred into the 'data warehouse' environment, i.e. outside the direct care environments of acute and primary care, will be pseudonymised in accordance with standard information governance and data protection requirements.

Over the coming few years the data set will need to be further developed to complete SNOMED-CT coding of all relevant terms. This will facilitate messaging along the lines indicated above in the text and diagrams. In the wider CFH arena full implementation of the SCR with inclusion of important SMOMED-CT coded general health information as well as standard messaging protocols will facilitate these data flows and ensure retention of the validity of transferred data. The current inefficient and costly system of manual data coding for secondary purposes will be avoided with enhanced accuracy and massively reduced salary costs associated with clinical data coders (who currently manually code over 300,000 NHS cataract operations a year in England alone).

### **3.3. Operational Fit**

#### **3.3.1. Concept of Operation. Paper / systems / scenarios for use in different technical contexts.**

The cataract national data set is currently used to varying degrees across a range of care settings which include paper, electronic and hybrid systems. The primary objective would be to provide a stable data framework for clinicians, commissioners, managers and developers. Within this framework electronic systems would be used by healthcare professionals to collect routine data as part of patient management. Initial patient and demographic information would be drawn from a hospital PAS system. Referral information (from GP or optometrist), where electronic, would be fed directly into the care record. A significant proportion of data entry would be direct clinician input as part of the clinical process. Certain types of data would be electronically transferred, for example ocular biometry devices already function in this way for the current market leading cataract care system. Thus, depending on the clinical and technical context, data fields would be populated as appropriate. It would be expected that confidentiality and security would be in accordance with the IG policies of CfH and the wider NHS whether electronic or paper based systems were in use.

SNOMED-CT coding of the data set would form a 'next step' to ensure retention of data validity in the context of large volume data extractions across different locations and systems. Coding of the data set is outside the scope of the current application.

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## 3.4. Impact and Implications

### 3.4.1. Implications to stakeholders of the standard being approved / not approved

*Approval:* This would signal stability of the data set as a framework for stakeholders. System suppliers would have a benchmark to work to and the existing CFH functionality project or 'Gap analysis' would be strengthened and more securely underpinned. Approval would thus provide a 'green light' to stakeholders who are currently held up and frustrated by the lack of certainty regarding data requirements for cataract surgery. A data benchmark would improve standardisation across organisations and facilitate meaningful comparative analyses of clinical services and outcomes. Ultimately this would impact positively on patient care.

The current market leader which provides electronic care record systems to ~40% of English trusts is already well aligned with the data set. Clinical data extracted from this system has been analysed and published in peer reviewed clinical science journal outputs. The electronic care record (no longer supported) at Moorfields Eye Hospital is likewise largely data set compliant with a poster presentation recently having been made at an academic meeting. These outputs have informed practice and updated practice benchmarks for cataract surgery in the UK and beyond (see imbedded documents at 2.5). Mandation of the standard would not create major difficulties for this system developer. There is one other departmental system in current use in England which is broadly aligned with the data set. Minor changes only would therefore be needed on the part of current system developers and new entrants into this market would have the standard to work to prior to implementation. Paper based systems would be an issue as the amount of data to be collected would be an issue. Realistically conformity with a data set such as this is only really possible within the context of an electronic care record.

Clinical staff collecting data using an electronic care record are already familiar with the data in the data set as these are the data needed to care for a patient within the standard cataract care pathway. Those staff currently working in paper based systems would require training in the use of the implemented care record system upon installation but the vast majority of data being collected would be familiar. Educational requirements for staff in regard to the data set itself would therefore be minimal.

There would be some local costs to implementation of electronic systems. This shift to electronic working is however directly aligned with current CfH and wider NHS policy. Offset against the increased cost would be savings associated with reduced labour and storage costs of paper records. It is acknowledged that electronic recording would take a little longer in many circumstances, especially in the early stages while staff were becoming familiar with software. There would however be savings in data collection time once the summary care record (SCR) was available as up to date medications information would be available for direct download from the SCR. The rollout of the SRC is current with well over a million such records already having been uploaded automatically from GP software. It is expected that this rollout will proceed rapidly to completion within the coming months.

*Non-approval:* The current 'planning blight' would continue with stakeholders feeling uncertain about detailed data standards and lacking confidence to invest time, energy or money into an activity which may later be undermined by approval of a standard different from the one which they may have chosen to adopt. This would create a climate conducive to yet further delay of LSP system delivery for patients requiring cataract care. From a stakeholder perspective non-approval would be disappointing in view of the considerable time and effort which has so far gone into development of the data set and the support which this work has received over 8 years from the Royal College of Ophthalmologists. Such an outcome would cause

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'reputational damage' by further eroding the credibility of current structures to move forward the vision of electronic working in the NHS.

### 3.4.2. Analysis of replacement of existing standards

The cataract national data set was initially developed under the auspices of the Royal College of Ophthalmologists and subsequently the Cataract Do Once And Share (DOAS) project. As such this data set has become the 'de-facto' standard and approval would have no adverse effects in terms of replacement of an existing standard. Approval would strengthen and provide legitimacy and stability to the cataract national data set as 'The Standard'.

## 3.5. Known Standards

### 3.5.1. Existing standards with a related purpose and scope (originally and since development)

As noted in 3.4.2 the cataract national data set is the 'de-facto' standard for cataract care in the NHS. The CFH functionality gap analysis was based on this data set.

The Royal College of Ophthalmologists Cataract Guidelines published in 2004 are currently being updated. Both the existing version and the version under development are consistent with the data set (JMS is a member of the current guideline development working party). The Royal College of Ophthalmologists revalidation working party is using the data set content to define standards for surgical practice and case mix adjustment of surgeon's outcomes.

The DH cataract care pathway and 18 week pathway are likewise each consistent with the content of the data set.

### 3.5.2. Assessment to include or eliminate – if relevant

Not relevant.

## 3.6. Interdependencies

### 3.6.1. Existing or planned standards

A range of ophthalmic data sets are at various stages of development. The diabetic retinopathy screening data set for example has full ISB approval and has been in use for a couple of years. The intention is to harmonise the ophthalmic data sets in a way which facilitates their interoperability. For example, visual acuity is collected in virtually all ophthalmic care contexts and should be done in a consistent manner throughout. It is planned to develop templates or 'archetypes' to ensure consistency across related standards. In the first instance the cataract and diabetic retinopathy screening data sets will be aligned where appropriate.

The NHS CFH National Clinical Lead has developed the present application for the cataract data set. The applicant has funded time for such work which is seen as important from a CFH clinical content perspective. With continued support further work on this and other ophthalmic data sets will be undertaken by the applicant in the same manner in which he has undertaken the work required for the present submission. Timelines will depend upon progress, once the cataract data set has been approved the applicant will move on to working on the next of the ophthalmic data sets.

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The existing diabetic retinopathy screening standard provides an ophthalmic exemplar for development of not only the current data set, but also for a spectrum of ophthalmic data sets. As part of the development process a 'library of archetypes' will become available from data sets which have received approval as standards. Specific data standards will thus evolve in line with both ophthalmic and generic information governance standards.

### **3.6.2. Projects, programmes or organisations**

The completed CFH functionality gap analysis noted above in 3.1.1 is dependent upon the cataract national data set.

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### 3.7. Consultation and Support – initial development and ongoing (may be related to governance in 3.9.1 below)

As noted above the cataract national data set was initially developed under the auspices of the Royal College of Ophthalmologists and subsequently the CFH Cataract DOAS project. During these phases of development the data set underwent wide consultation and received strong support from the Royal College of Ophthalmologists and from other relevant stakeholders. At closure of the DOAS project the data set had achieved ISB approval at the requirement stage and conditional approval was being worked up when the project funding ran out. Following this period the data set formed the basis of the 2008-2009 CFH cataract functionality gap analysis.

There exists broad support from relevant stakeholders (see Appendix A).

### 3.8. Standard Specification – refer to standard specification document

The cataract national data set specification covers all aspects of the care pathway and is formatted as an Excel workbook with sheets laid out as:

- Front Cover with development history
- Patient details and demographics (7 data items)
- Preoperative assessment (31 data items)
- Ocular biometry (19 data items)
- Anaesthesia (9 data items)
- Surgery (22 data items)
- Follow up (29 data items)
- 3 Appendices
  - 28 Footnotes
  - Selection of relevant OPCS 4.3 codes & sub-codes followed by all 460 eye codes
  - 12 Technical guidance notes

Data item sheets contain these 15 columns

- DI no. (DI=Data Item)
- Data Item Name
- Data Item Description
- Source
- Algorithm
- DD Element name (DD=Data Dictionary – incomplete, awaiting DD review)
- DD Note (DD=Data Dictionary – incomplete, awaiting DD review)
- Purpose
- Permissible Values
- Collection Status
- Implementation Priority
- Footnote
- 5 Byte Read Code (coding for future development)
- ICD10 / OPCS4.3 (coding for future development)
- SNOMED CT (coding for future development)

Full details are available in the Excel Workbook: *2010.04.07 Cataract National Dataset v3.1.xls* (also provided as Appendix 1).



2010.04.07 Cataract  
National Dataset v3.1

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## 3.9. Governance

### 3.9.1 Of the standard and its maintenance

The cataract national data set is intended as a public resource available to all. Maintenance of the content through regular review will be by one of the sponsors: The Royal College of Ophthalmologists. The data set working group of the College IT Committee is able to undertake this regular review work which could be usefully linked to relevant College Guideline reviews. Previous work by current members of the College IT group have involved SNOMED-CT coding of the glaucoma data set and partial coding of the diabetic retinopathy screening data set. Some consultative guidance from the UK Terminology Centre may be required for future coding exercises as occurred with the earlier work, but the detailed clinical knowledge required for coding of data set terms is already available. The resource required for undertaking this work would remain with the CFH NCL for Ophthalmology supported by clinical colleagues on an ad hoc voluntary basis. The fact that there are several data sets at various stages of development bear testament to the fact that it is possible for development to occur on this basis. Greater resource allocation for clinical content development would accelerate this process.

### 3.9.2 Information governance considerations

Normal information governance and consent rules will apply to the data collected when the fields of the data set are populated through clinical use and used for local /regional / national audits and analyses. Where multicentre data extracts occur the Royal College of Ophthalmologists will act as data controller. These extracts will be of high value in terms of setting of clinical benchmark standards for care of patients with cataract.

The Royal College of Ophthalmologists has a long and strong tradition of hosting national audit projects over two decades. The college is currently in the process of setting up an evaluation project of diabetic retinopathy for people who have been identified in screening as requiring referral to the Hospital Eye Service for diabetic retinopathy. Data will be extracted from multiple primary and secondary care sites, pseudonymised and analysed. The method of pseudonymisation is in line with DH guidance and the work has received Caldicott Guardian approval. True patient ID will not leave the acute trust as the locally applied pseudo-codes will remain on the local electronic care record database within the trust firewall. Data handling and analysis will be undertaken strictly in accordance with the data protection act.

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## 4. Development and Implementation

### 4.1. Summary of Approach to Development and Implementation to date

#### *Development*

Initial development under the auspices of the Royal College of Ophthalmologists began in 2002. Subsequently the CFH cataract DOAS project developed the data set further and obtained ISB approval at the requirement stage in 2006. Updating of the data set by the CFH NCL for Ophthalmology took place in 2008 as a preparatory step in the CFH functionality gap analysis project as detailed above in 3.1.

#### *Implementation*

The data set has already been implemented to a significant extent (90+%) by a system developer whose cataract care record is used in ~40% of English NHS cataract units. Data extracts have been undertaken, the largest under the auspices of the cataract DOAS project. This data extract has yielded across the board cataract surgery benchmark updates for the UK and beyond. Several reports have been published and others remain under development. The reports are listed at 2.5 above along with imbedded published documents.

### 4.2. Implementation Evaluation Report – how extensive; issues and lessons

Implementation has progressed organically because clinicians and acute trusts recognise the value of electronic working and the benefits of having access to the information in the cataract national data set. Ophthalmologists have provided informal feedback on the value of data items which can be used and compared across care settings. Collection of the same data items through electronic care record systems has allowed clinicians to compare their own outcomes with national benchmarks derived from multicentre data extraction and analysis. Clinicians have welcomed the ability to use standard data items for purposes of personal audit, reflective practice, appraisal and in future revalidation. At a recent clinical meeting where audit results were presented a senior consultant ophthalmologist commented that “The development of the cataract national data set and its electronic collection have revolutionised care in cataract surgery”. From a trust perspective the use of standard data items will provide an ability to inform quality accounts for cataract services.

Following publication of a pilot project data extraction of data set items an editorial written by an internationally renowned American academic ophthalmologist wrote: “*The study by Johnston and colleagues, entitled Pilot National Electronic Cataract Surgery Survey, published in this month's edition is as unassuming in its title as it is revolutionary in its implications. To the best of my knowledge, this work represents the first demonstration of potential for pooling the surgical results from an entire region or country in an on-line database in order to learn how best to care for patients.*” (Eye 2005:19;727–728.)

The data set has been under development since 2002. This has been an iterative process which has built the data set up from scratch on the basis of positive and negative feedback from review groups both within the Royal College of Ophthalmologists and subsequently through the CFH Do Once and Share (DOAS) cataract project. A further round of peer reviewing and updating took place in preparation for the CFH functionality gap analysis noted above.

Clinical benefits of the data set arise mainly through its use in electronic care records. The dominant electronic care record system for cataract surgery in the English NHS is closely aligned with the data set. From analysis of recent data extractions it is now possible for a bespoke risk calculation to be undertaken for individual patients using preoperative data items within the dataset. High risk cases can thus be automatically identified as an integral part of the care pathway in order to ensure that such cases are only operated on by the most experienced surgeons. This approach can dramatically reduce the

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absolute numbers of patients who experience a surgical complication. From the risk model the predicted probability of a complication arising varies by 100 fold between 0.75% and 75% depending on the preoperative risk profile of the individual patient. An ability to accurately identify high risk cases in advance has clear advantages for quality of service delivery. Armed with this information future work will be directed towards quantification of the benefits which arise from appropriate utilisation of these data to improve patient safety.

### **4.3. Implementation Roll Out Plans – if relevant**

Once approved, system developers will have access to a stable data standard to which they are able to work. Developers will see this as an opportunity and in view of the fact that cataract surgery is the commonest surgical procedure on the NHS there are substantial gains to be made from electronic working in this field. The data set cannot be implemented in its full form across the NHS immediately. Full implementation will only be possible within a context of electronic working. For this reason implementation will need to be via the route of a staged mandation for system developers. Eventually the entire NHS will work electronically, at which point implementation and mandation will apply universally across the NHS (and beyond for private providers).

### **4.4. Migration Plans – if relevant**

Apart from some 'home grown' person databases there are only 2 systems in use in the English NHS. One of these systems is currently implemented in a single hospital but is in the process of being phased out (personal communication, Medical Director, Moorfields Eye Hospital). The other cataract electronic care record system in use is implemented in ~40% of English NHS cataract units. This system is highly aligned with the data set and has already formed the basis of extremely valuable multicentre data extractions (see embedded publications).

Future development of the data set with SNOMED-CT coding would facilitate the use of coded terms within the care record system. This process would probably take a number of years to unfold in terms of firstly coding of the data set and then incorporation of the SNOMED-CT terms into the existing care record systems.

New electronic systems under development would be expected to enter the market in a compliant form. Depending on their time of entry this may or may not include the SNOMED-CT terms.

Mandation of the data set with a view to future incorporation of SNOMED-CT coded terms would drive the process of systems migration because in the future compliance with the data set would become a requirement for system procurement within the NHS. This data set cannot be mandated for full implementation in paper based systems as this would be impractical. With regard to existing systems a staged mandation would be proposed. For example, implementation of high priority items should occur 'at the next system upgrade', and lower priority items 'at the next major system upgrade'. Since there is effectively only one system in current use, and this system is already 90+% compliant, this should not create particular difficulties. Future entrants would have a standard to which they were able to work. Legacy data are not a particular issue for the same reasons noted above (the de facto in use system is already highly compliant) and also because where inconsistencies did exist in legacy data the high volume of activity would soon provide plenty of fresh data in the required format.

### **4.5. Human Behavioural, Organisational and Technical User Implementation Guidance**

This is a data set for use by ophthalmologists, nurses and optometrists, so knowledge of cataract terminology and processes is assumed. Context will also be apparent from the presentation of the data set in software. For those healthcare professionals who work in cataract care settings the information contained in the data set will be 'business as usual'. These are highly trained and skilled individuals who

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would not be doing the work which they do if they did not have an intimate understanding of the content and terms used in the data set. The layout and supporting notes which can be found within the data set spreadsheet (see imbedded file) will make the content unambiguous to the intended clinical audience.

Fields are presented in the current market dominant software according to the patient pathway. This Human-Computer Interface presentation makes the data items being collected context relevant to the clinical circumstance in which they are being used. The software has been in increasing use in NHS cataract units over a 7+ year period and previous multicentre data extractions have demonstrated consistency of use across multiple sites. This informal testing of conformance provides evidence that the data set content is consistently understood by system users. The software developers provide extensive hands on training at the time of initial system delivery and implementation as well as refresher and update training when software upgrades are supplied. In addition they operate a helpdesk for users with queries. The data set has been developed over an extended period with iterative interactions between clinical users, software developers, and the developers of the data set.

Human and organisational behaviour are already observable in regard to the perceived value and use of the data set. ~40% of English NHS trusts are already using this data set through their adoption of an electronic care record system for cataract surgery. The Royal College of Ophthalmologists has consistently supported and endorsed this data set since 2002 through its various developmental stages noted above. The clinical research community has embraced the data set as evidenced by the numerous published outputs arising from collection and analysis of collected data for purposes of benchmarking, audit, risk management, clinical governance, and service improvement.

Technical user implementation is already well established as exemplified by the 40% of cataract surgery units who use the data set within their electronic care record system. Further systems development will be facilitated through reassurance of systems developers that the data set is an approved and stable standard for the NHS.

#### **4.6. Safety – what risks accompany the use of the standard and how are these monitored / mitigated?**

The data set has been extensively and iteratively reviewed. Initially this took place within an expert working group of the Royal College of Ophthalmologists and subsequently as part of the CFH cataract Do Once and Share project. Iterative review included review by one of the directors of the current market dominant software development house, who is himself an ophthalmologist. A final round of updating and reviewing took place in advance of the CFH cataract functionality project. Repeated iterative cycles of review have thus mitigated against missing, ambiguous or erroneous data elements. Future review of the data set alongside the scheduled reviews of the Royal College of Ophthalmologists cataract guideline will ensure that data elements remain relevant and up to date.

There remains a responsibility of suppliers and deploying organisations to ensure that the content of the data set is correctly used in line with NHS information governance, conformance testing and risk management policies.

The cataract national data set is not yet SMOMED coded. This could represent a risk in terms loss of validity upon transfer of data between different electronic care systems. As more system developers adopt the data set this risk may increase. It is therefore important for the data set to be SNOMED-CT coded within a reasonable timeframe in order to mitigate this risk.

Hazard Log embedded in Excel Workbook: *Cataract Data Set Hazard Log v0.1.xls* (also provided as Appendix 2).



Cataract Data Set  
Hazard Log v0.1.xls

#### **4.7. Maintenance and Update Process Plans**

The Royal College of Ophthalmologists will undertake to review the data set every 3-4 years alongside the updating of its cataract surgery guideline. Where changes are required these will be fed through the ISB data set change process. Suppliers and end users will be able to contact the Royal College of Ophthalmologists (there will be a dedicated and monitored email address) whose IT committee will be responsible for receiving, logging and risk assessing requests for change. Lower risk requests will be considered at the next scheduled review as part of the expert review process linked with review of the college cataract guideline. High risk requests (where patient safety is at issue) will be acted upon without delay through chairman's action. The committee chair (personally or by delegation) will be responsible for ensuring that any reported high risk issues are considered and acted upon promptly without awaiting a scheduled review. Where the expert group considers that change is necessary a change notice will be initiated as usual according to established practice.

#### **4.8. Conformance Test Specification – what checks are done / should be done to demonstrate that the standard has been deployed as intended?**

To guard against implementation errors by suppliers all relevant data items related to the clinical process which are collected by an application should be listed and mapped to the data set. Following SNOMED-CT coding of the data set all clinical terminology should likewise be mapped to the relevant future SNOMED-CT codes in the data set.

Applications should be structured around the patient journey in a way which ensures that data collected as part of the clinical process is context relevant. Prior to full implementation piloting should be undertaken in a controlled clinical environment with normal data capture running alongside the new application. The pilot stage should confirm that the data collected by the new application can be extracted and that the extracted variables accord with expectation according to the input information. Checks should include 1:1 input – output agreement for smaller pilot samples as well as range and distribution checks for larger pilot samples.

The current market dominant system has been developed alongside the data set with involvement of the software developers in the development of the data set. This iterative process has resulted in adjustments of both the software and the data set, a process which has brought them into close alignment. Large multicentre data extractions have been undertaken from this system and these have been subjected to extensive analysis with multiple resultant publications (several of these peer reviewed outputs are listed at 2.5 and imbedded in this submission). There exists therefore a high level of confidence that this supplier's product is already well aligned with the data set.

In addition to these specific checks both suppliers and deploying organisations are required to undertake risk management according to NSH system safety risk management standards.

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## APPENDIX A

### Sponsor Statement(s)

(Insert copy of statement from sponsor(s) here)

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Statements of support from:

#### The Royal College of Ophthalmologists

- Mr John Lee, President, Royal College of Ophthalmologists and Consultant Ophthalmologist Moorfields Eye Hospital.
- Mrs Kathy Evans, Chief Executive, Royal College of Ophthalmologists.
- Mr Bill Aylward, Chair Royal College of Ophthalmologists IT Committee and Consultant Ophthalmologist Moorfields Eye Hospital.
- Mr Richard Smith, Vice President, Chair Royal College of Ophthalmologists Professional Standards Committee, and Consultant Ophthalmologist.
- Mr Winfried Amoaku, Vice President, Royal College of Ophthalmologists, Chair of the Scientific Committee and Consultant Senior Lecturer in Ophthalmology, Nottingham.



M Severs College Supporting statement  
M Severs re cataract dataset 220210 - RiclDataset ISB letter - W  
M Severs re Cataract Dataset ISB letter - W

#### CFH's Office of the Chief Clinical Officer (OCCO)

- Dr Simon Eccles, Medical Director, CFH OCCO.



M Severs re MD  
letter of endorsement

#### The NHS Information Centre

- Miss Parul Desai, Director of Population Health, The NHS Information Centre.



M Severs - Cataract  
Dataset ISB - Informa

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### End users of an existing cataract electronic care record system

- Mr Derek Tole, Consultant Ophthalmologist and Lead Clinician for the Bristol Eye Hospital.
- Mr Nathaniel Knox Cartwright, Specialist Registrar in Ophthalmology, South West Region.



M Severs - Letter of support from Mr Tole.  
M Severs re CND support statement N2

### A system developer

- Mr David Johnston, Managing Director, Medisoft LTD.



M Severs re Supplier support for CND.pdf

### Failed attempts to interest other suppliers including VersaSuite, Cerner Millennium & I-Soft Lorenzo:



Email strings to suppliers.rtf

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## APPENDIX B

### **NHS Connecting for Health - Technology Office Statement**

(Insert copy of statement from NHS CFH - Technology Office here)

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Statement from the CFH Technology Office to be provided through the ISB.