

**Electronic Medical Records in paediatric ophthalmology:**

**A study of potential users and uses to inform design**

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## **Declaration**

I, Maria Cross confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

## **Abstract**

Electronic medical records are at the core of an advancing movement toward information-driven healthcare. By enhancing abilities to capture, store, and analyse vast amounts of health data, the routine use of electronic medical records is advocated as a means to improve the efficiency and quality of care provision, advance population health, empower patients, and reduce healthcare costs. However, the delivery of any benefits is threatened by a failure to understand the unique care environments of different clinical specialties, and to appropriately customise system design. This has prompted a move to the user-centred design process of health information technology.

Paediatric ophthalmology is a unique field that faces particular challenges in electronic medical record adoption. As with other ophthalmic specialties, the heavy use of imaging and diagrammatic documentation is difficult to replicate electronically. As is the flexibility required to meet the demands incurred by the varying ages, developmental stages, and visual needs of each patient, reflecting a unique interface between the ophthalmic and paediatric requirements.

The consideration of such requirements is essential throughout the user-centred design of effective health information technology systems. However, paucity in the evidence base surrounding electronic medical record design methodologies and system usage hinders technological development and application within paediatric ophthalmology.

This research was centred on a user-centred design process, to provide an understanding of the users of electronic medical records in paediatric ophthalmology, and their requirements. Taking a mixed methods approach, this

research initially explored the landscape of medical record use – gathering user-centred requirements – and concluded with the development and testing of three prototype data collection forms, for specific use cases within paediatric ophthalmology. Overall, this work articulates the specific challenges and requirements in this area, and provides the foundation for future design and adoption strategies of electronic medical record systems within paediatric ophthalmology.

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## **Table of Supplementary Materials**

**Case study 1**.....Retinopathy of prematurity screening web application.

**Case study 2**.....Infant visual acuity plots Microsoft Access database.

**Case study 3**.....Pedigree drawing web application.

All supplementary materials are available on a CD-ROM, included with this thesis.

## List of abbreviations

<b>Abbreviation</b>	<b>Meaning</b>
AAO	American Academy of Ophthalmology
AP-ROP	aggressive posterior retinopathy of prematurity
BCVIS2	British Childhood Visual Impairment Study 2
CDSS	clinical decision support systems
CI	confidence interval
CUI	common user interface
EBM	evidence-based medicine
EDM	electronic document management system
EDT	electrodiagnostic test
EHR	electronic health record
EMR	electronic medical record
EPR	electronic patient record
FHIR	Fast Healthcare Interoperability Resource
GOSH	Great Ormond Street Hospital
HES	Hospital Episode Statistics
HITECH	Health Information Technology for Economic and Clinical Health
HSCIC	Health and Social Care Information Centre
HIT	health information technology
ICD-10	International Classification of Disease 10 <sup>th</sup> Revision
ICH	UCL Great Ormond Street Institute of Child Health
ICROP	International Classification of Retinopathy of Prematurity
indel	Insertion or deletion
ISO	International Organization for Standardisation

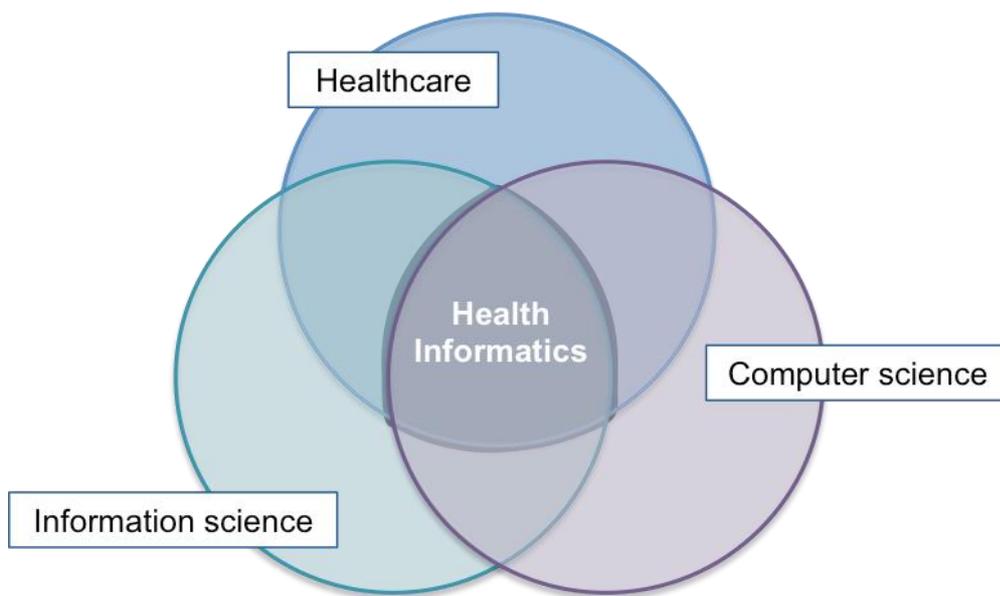
KAC	Keeler acuity cards
logMAR	logarithm of the minimum angle of resolution
LHS	learning health system
LVA	low vision assessment
MEH	Moorfields eye hospital
MeSH	Medical Subject Headings
NAO	National Audit Office
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NPEx	National Pathology Exchange
NPfIT	National Programme for Information Technology
OPCS-5	Office of Population Censuses and Survey 5 <sup>th</sup> Revision
PDP	perfectly drawable pedigrees
PIMS	patient information management system
ROP	retinopathy of prematurity
SCAMP	Standardized Clinical Assessment and Management Plan
SMART	Substitutable Medical Applications, Reusable Technologies
SNOMED-CT	Systematized Nomenclature of Medicine Clinical Terms
SUS	Secondary Uses Service
SPSS	Statistical Package for the Social Sciences
TAC	Teller acuity cards
UCD	User-centred design
UK	United Kingdom
VBA	Visual Basic for Applications
VMSP	vertical mining of maximal sequential patterns

# Chapter 1 Introduction

## 1.1 Background

### 1.1.1 Health informatics

Health informatics – the methods, resources and tools used for information management in healthcare – is a diverse and evolving field. It lies at the intersection between healthcare, information science and computer science (Figure 1)<sup>1</sup>, encompassing the many components of health information technology (HIT) including both software and hardware.



**Figure 1: A diagrammatic representation of the knowledge domains that interact within the field of health informatics.**

Diagram adapted from the United Kingdom Council of Health Informatics Professions<sup>1</sup>.

In this doctoral research, the role of medical records in health information management and use – to support both clinical care and research – has been explored for paediatric ophthalmology. A focus was placed on the software design

of electronic medical records (EMRs), considering the data and interface requirements from the perspective of the user.

### ***Electronic medical records***

EMRs are one form of HIT. The International Organization of Standardization (ISO) defines an EMR as ‘a repository of patient data in digital form, stored and exchanged securely, and accessible by multiple authorized users. It contains retrospective, concurrent and prospective information and its primary purpose is to support continuing efficient and quality integrated health care.’<sup>2</sup>

EMRs – as with paper-based medical records – contain a record of all information relevant to the care provision for an individual patient. The term EMR is often used interchangeably with electronic health record (EHR) and electronic patient record (EPR). While the terms EMR and EPR are often considered synonymous in the literature, a distinction is drawn between EMR and EHR, based on the completeness of the record and who owns it<sup>3, 4</sup>. An EMR is owned by a single healthcare organization, and describes only the information relevant to the care provided there. EHR is an umbrella term that incorporates EMRs and all of the data contained within an EMR system. An EHR refers to an aggregate record that contains the complete health history of a patient – i.e. all of the data from all of the health centres that have ever involved in the care of a patient – and lies beyond the focus of this work.

### **Paper- versus electronic-based documentation**

Comparisons of paper-based and electronic working have a long history outside of the healthcare domain. Noyes and Garland reviewed the relevant literature for reading, information processing, and writing tasks, considering measures of task accuracy and completion speeds<sup>5</sup>. While the authors concluded that electronic

working does not equate to paper-based methods for the outcome measures considered, they commented on the task specific nature of these findings and that such comparisons are limited by considering only tasks designed for paper-based working<sup>5</sup>.

Within healthcare, limited in vitro studies have reported that the electronic documentation of clinical patient data was more accurate<sup>6</sup> and quicker<sup>7</sup> than paper-based methods. However, in vivo studies did not always replicate these results. Improvements in the data completeness, accuracy and documentation times have been reported<sup>8-10</sup> in clinical settings, as has the opposite<sup>9, 11, 12</sup>. It is not surprising that there have been mixed results given the wide range of documentation software, settings and tasks encountered in medical care, in addition to variations between individual users.

In addition to reproducing paper-based noting tasks, electronic methods facilitate data management and analyses, which is becoming increasingly important as medical care becomes more data intensive. EMRs can serve a wide range of tasks such as clinical decision support, clinic flow management, and assisted audits. These features are cited as one of the major attractions of electronic-working in healthcare<sup>13</sup>.

### **1.1.2 Health information technology and the National Health Service**

Early large scale, electronic information systems were developed in the 1980's to facilitate the administration and management of the National Health Service (NHS), as recommended by a steering group chaired by Dame Körner<sup>14</sup>.

The eighties also saw the popularisation of HIT across primary care in the NHS, although the first general practice to implement EMRs and operate paperless working was established in 1975<sup>15</sup>. The United Kingdom (UK) has been at the forefront of HIT adoption in primary care. In 2009, it was reported that 96% of UK general practitioners used EMRs, the highest rate in a comparison of ten countries including the United States (46%)<sup>16</sup>. Conversely, in secondary care the NHS reputedly lags behind the States in terms of EMR adoption<sup>17</sup>. Benson attributed two factors to the discrepancy of HIT uptake in NHS primary and secondary care: a lack of economic incentives<sup>18</sup>, and the variety of tasks and environments encountered in secondary care (“scalability”)<sup>19</sup>.

In 2002, as part of a wider attempt to transform and modernise the entire NHS in England<sup>20</sup>, the government established the National Programme for Information Technology (NPfIT)<sup>21</sup>. The Programme promised to deliver seamless data flows across the entire health service by implementing a single comprehensive EHR for each patient. Some components were successful, including a national email and directory service (NHS mail) and NHS medical imaging software / picture archiving and communication system. However, overall, the NPfIT encountered severe difficulties, especially in delivering the “cradle-to-grave” EHR, and was abandoned in 2011<sup>21, 22</sup>.

Many factors have been postulated to be associated with the NPfIT failure<sup>23-25</sup>. The National Audit Office (NAO) notably blamed constant delays in delivery, a subsequent resistance from NHS staff, and increasing project costs that reached a total of £11.4 billion<sup>21</sup>. They attributed these factors to an unanticipated workload required to adapt the generic HIT systems to the differing needs of individual Trusts<sup>21</sup>.

The termination of the NPfIT left a disjointed information infrastructure across the NHS in England. While subsequent governments remained committed to the “information revolution”<sup>26</sup>, individual NHS Trusts became responsible for their own EMR deployments<sup>27</sup>. In 2013, the then Health Secretary Jeremy Hunt clarified, “what works ... is local solutions, local decisions and local leadership” before setting a new target for a paperless NHS by 2018<sup>28</sup>. Despite an extension of this deadline to 2020<sup>13</sup>, it was met with criticism. In the government commissioned review, the ‘digital doctor’ Professor Robert Watcher concluded that the timeline was “unrealistic”, and suggested 2023 was more probable<sup>29</sup>, while other evidence indicates a paperless NHS will not be achieved until 2027<sup>30</sup>.

### ***Secondary data uses***

In the UK, the permitted use of health information is strictly limited to medical purposes<sup>31</sup>. However, as enacted by the 1998 Data Protection Act, medical purposes also include medical research and the management of healthcare services<sup>31</sup>. This extends the uses and users of health data beyond those found in clinical environments.

To be reimbursed for care provision, regional NHS Trusts must submit data to the Secondary Uses Service (SUS) on a monthly basis. These data concern each individual NHS admission, outpatient appointment and Accident and Emergency visit<sup>32</sup>. SUS data feed into several NHS Digital – previously the Health and Social Care Information Centre (HSCIC) – databases that can be accessed by authorised secondary users to support healthcare planning, public health research, clinical audit and governance, and national policy development<sup>33</sup>. NHS Digital only disclose anonymised SUS data to secondary users, in keeping with the Common Law Duty of Confidentiality that prevents the sharing patient data without authorisation from

the individual concerned<sup>32</sup>. Definitions of anonymised data and other relevant privacy terms can be found in Table 1.

**Table 1: Data privacy terms and definitions.**

Term	Definition
Personal data	Data concerning a living individual who may be identified from the data, or from the data and other accessible information (as defined in the Data Protection Act <sup>31</sup> ).
Pseudonymised data	Data where all personal data have been removed; a pseudonym identifier is used so that the data may be re-identified.
Anonymised data	All personal data are removed; the data cannot be re-identified.

### Hospital Episode Statistics

The Hospital Episode Statistics (HES) data warehouse is one of the SUS databases; it contains a patient-level record of all ‘episodes’ of admitted, outpatient and accident and emergency care provided by NHS England. HES data have been collected nationally since 1987 to improve the use of hospital activity information and resource allocation<sup>14</sup>. Each episode details clinical (e.g. diagnoses, procedures), patient (e.g. age group, gender, ethnic category), and administrative (e.g. date of discharge) data.

Increasingly, HES data are used as a data source for research studies. However, the data quality of HES has been criticised in terms of the completeness<sup>34,35</sup> and the accuracy<sup>36</sup>.

### **Information standards**

As a wide variety of HIT systems are used across the NHS, vendor-neutral information standards are required to standardise the representation of clinical data

across different NHS Trusts and the spectrum of services involved in health and care. In the 2012 Health and Social Care Act, an information standard is defined as ‘a document containing standards that relate to the processing of information’<sup>33</sup>; standardised representations of data facilitate the accurate sharing, mining and analysis of health data.

### Coding terminologies

Structured clinical terminologies map the variable natural language and concepts used by clinicians into computer-readable, coded data. To ensure an accurate representation of clinical data within HIT systems, the terminology used should be both comprehensive, with a complete coverage of all concepts used to describe a patient, and reproducible, ensuring the same codes are always applied to the same concepts across the healthcare system.

Typically, specialist administrative staff within each NHS Trust manually code clinical data. For all episodes of care, the information captured within medical records is used to ascribe the reason for admission using International Classification of Disease 10<sup>th</sup> Revision (ICD-10) codes, and the procedures and interventions undertaken using the Office of Population Censuses and Survey 5<sup>th</sup> Revision (OPCS-5)<sup>32</sup>. Therefore, some coding terminologies are well implemented within the NHS information infrastructure. However, the ICD-10 and OPCS-5 coding terminologies are not fully comprehensive for all possible diagnoses or treatments for many medical specialties<sup>34, 37</sup> including ophthalmology<sup>38, 39</sup>, limiting their suitability and usefulness.

In 2014, the National Information Board proposed a single, comprehensive coding terminology – the Systematized Nomenclature of Medicine Clinical Terms (SNOMED-CT) – should be used as the sole strategic terminology for NHS England, to be fully implemented by 2020<sup>40</sup>. SNOMED-CT is an internationally

accepted terminology that was created by merging the College of American Pathologists' SNOMED Reference Terminology with the NHS' Clinical Terms version 3 (Read Codes). It provides a comprehensive coverage of medical concepts including both procedural and diagnostic codes, in addition to symptoms, observations, family history, medical devices, body structures and so forth<sup>41</sup>. However, there have been several reports of poor inter- and intra-coder reliability, often attributed to the vast size of the terminology<sup>42-45</sup>.

### Data models

To ensure clinical coding is carried out consistently throughout the entire healthcare system, the standardised application of individual codes from the terminology must be defined and encouraged through data models.

Coiera defines a model as both a representation of an object or phenomenon and a template used to construct that object or phenomenon<sup>46</sup>. An EMR data model will therefore describe the way clinical information should be collected, in what format, and how it is coded and stored within an EMR; it binds the data set to the clinical terminology. As there can be many ways to map clinical data to clinical codes, many different data models can exist. The universal adoption of a standard data model will help achieve semantic interoperability between care settings – as patients use different health services, and also between the clinical and research environments by ensuring data are computable and can be aggregated on a national scale<sup>40</sup>.

Some such standards are in development. One example, openEHR, is an open specification that models individual components of the medical record as 'archetypes'<sup>47</sup>. Archetypes – typically developed by clinical experts as opposed to system developers – define and constrain the semantics and structure of clinical concepts, including the application of the coding terminology<sup>47</sup>. This work takes a maximum data set approach to archetype definition, with the intention of

comprehensively covering clinical content, and, thus, is not complete. In 2015, when considering the application of openEHR archetypes for a diabetic retinopathy screening service, Eguzkiza *et al.* reported that 10 new archetypes had to be defined by the authors, in addition to using 22 existing archetypes available within the openEHR Clinical Knowledge Manager<sup>48</sup>.

NHS England also provides a Data Model and Dictionary Service that defines the nationally agreed set of standards for data collection, representation and interpretation<sup>49</sup>. However, the Dictionary only contains a limited collection of variables that are commonly used across the breadth of NHS care and in national audits to facilitate semantic interoperability; it does not provide a national standard for specialty specific data models.

#### A common user interface

In addition to data set requirements, users also have requirements for the design of HIT systems. Often, clinicians must review a wide range of information quickly to facilitate efficient care decisions. The HSCIC – precursor to NHS Digital – developed a series of design guidelines as part of the Common User Interface (CUI) programme<sup>50</sup>. The use of the guidelines is encouraged to standardise user interfaces of systems used within NHS England and minimise the learning curve associated with new HIT system adoption<sup>50</sup>.

The CUI guidelines define how a user should input and review standard medical record data variables, including the NHS number, patient sex, current medication lists, and adverse drug reactions. Additional layout guidance is provided for common EMR features such as a patient banner and patient list views<sup>50</sup>. As with the Data Dictionary, there is little specialty specific EMR interface design guidance, although, the Royal College of Ophthalmologists has endorsed<sup>51</sup> the use of the formal set of standards that were developed from the guidelines, following extensive

consultation with the Professional Record Standards Body and representatives from across medicine<sup>52</sup>.

### **1.1.3 Learning health systems**

#### ***Big data***

Big data is a term that has been used in analytics in many domains since the 1990's<sup>53</sup>. The data sets that are analysed are both deep – containing a large volume of data from many individuals – and wide – comprising a wide variety of many different data fields for each individual in the set. Volume and variety are two of the three dimensions ascribed to big data, known as the “three V's”<sup>54</sup>. Velocity, that is data that are rapidly inputted and used, is the third<sup>54</sup>.

Big data has had much success in the field of genomics, where large data sets are vital to identify meaningful associations<sup>55</sup>. Developments in data record linkage techniques – to combine data sets from within biomedicine and with other domains such as education, socioeconomics, and politics – are augmenting the data sets for analyses and expanding the applications of big data within healthcare<sup>56-58</sup>.

The NHS collects data on a national scale from across the spectrum of health and disease. With such a comprehensive health service, the United Kingdom is uniquely positioned to further the application of big data research to biomedicine. In March 2017, NHS England published a report reinforcing their commitment to a “digital contribution to research”<sup>59</sup>. The report highlighted the importance of big data, but also of the routine use of HIT systems that will support data aggregation through semantic interoperability through information standards<sup>59</sup>.

### ***Clinical decision support***

An increase in big data studies has the potential to vastly enhance medical knowledge and consequently practice, through the application of evidence-based medicine (EBM). EBM emphasises the integration of research evidence with clinician expertise, and patient values and expectations. Any new insights gained from harnessing EMR data need to feed back into the healthcare system, to support point-of-care decisions and promote high quality care.

Computerised clinical decision support systems (CDSS) present actionable, evidence-based recommendations that systematically consider relevant best practice protocols, aggregated population-level data, and the individual patient's condition and medical history. A CDSS may be standalone software, however, increasingly CDSS are being integrated with EMRs to provide guidance at the point of decision-making.

A variety of methods have been used to present recommendations to clinical users including alerts, reminders, and prompts<sup>60, 61</sup>. The systems may provide a means to incorporate relevant clinical guidelines and best practice advice from organisations such as the National Institute for Health and Care Excellence (NICE)<sup>62</sup>, or to integrate risk models that identify the likelihood of disease and intervention outcomes based on the individual patients' symptoms and medical history<sup>63</sup>.

The evidence on the impact of CDSS use has been assessed in numerous systematic reviews of the literature. The majority have found an overall benefit through improved guideline adherence or patient outcomes<sup>60, 64-66</sup>, although the differences were often small and the size and quality of published studies has been questioned<sup>67</sup>. It can be concluded that there is a great variation in CDSS design and usage but, if implemented correctly, the systems could improve patient care.

There has been a mixed reception of CDSS amongst clinicians. In general, studies in differing medical specialties have found clinicians were positive about the promise of CDSS but had difficulty integrating the systems with routine workflows<sup>68-70</sup>. Indeed, in a meta-analysis of 162 randomised trials, Roshanov *et al.* identified integration within an EMR or documenting system to be the largest predictor of CDSS success in influencing clinical decisions<sup>71</sup>. Additional user-reported challenges in adoption include alert fatigue, cost and disagreements with the systems' logic or recommendation<sup>68, 72</sup>.

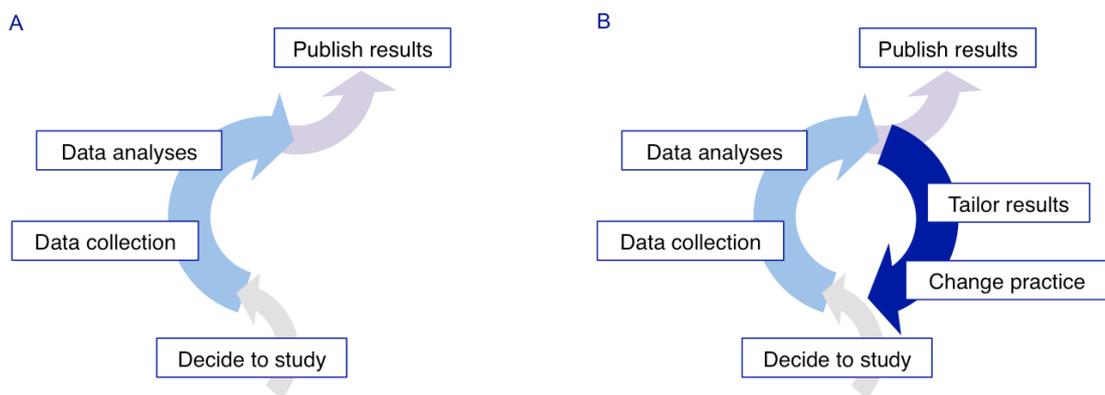
As HIT increases in complexity and assumes a greater role within clinical consultations, additional regulations are needed to govern usage. In 2010, the European Medical Devices Directive was amended accordingly. The definition of a medical device now includes software used for diagnostic and therapeutic purposes<sup>73</sup>. Therefore, while EMRs that simply capture, store and retrieve medical data are not considered medical devices, standalone CDSS or EMRs integrated with CDSS are elevated to medical device status and must operate within the stricter regulations.

In order to reduce the risk associated with extant CDSS, the Health Informatics department at Boston Children's Hospital are developing a series of Standardized Clinical Assessment and Management Plans (SCAMPs)<sup>74</sup>. While still aiming to assist clinical decision-making, SCAMPs, unlike CDSS, take a user-centred approach to continuously assess and improve the system's suitability for the clinical environment<sup>74</sup>. When SCAMP recommendations are not followed, the user is asked to provide a reason for deviation<sup>74</sup>. All deviations are frequently reviewed, allowing user feedback to drive HIT developments<sup>74</sup>.

### ***The learning health system***

Initiatives such as SCAMPs and personalised risk stratification are redefining the way data collected at the point-of-care are used to guide health innovation. “Learning health systems” will develop, with continuous knowledge cycles between medical practice and biomedical research<sup>75, 76</sup>.

The learning health system (LHS) is a concept that initially became popular in the United States at the beginning of this decade<sup>75</sup>. It provides a platform to innovate medical practice and the supporting technological systems, such as EMRs. In an LHS, each individual patient’s experience is available for study and will contribute to the institutional level learning and future practice.



**Figure 2: Medical knowledge flows.**

**A:** Typical knowledge flows. **B:** The continuous knowledge cycle in the learning health system. Diagram adapted from Friedman and Macy (2014)<sup>77</sup>.

In order to transition to a LHS, HIT systems must begin to capture and feedback user opinions and behaviours (Figure 2), making every interaction an opportunity for system learning and improvement. This – in combination with the new insights gained from harnessing big data from EMRs – is believed to promote high quality care through the application of EBM.

#### 1.1.4 Electronic medical records in ophthalmology

Internationally, EMR adoption has differed by clinical specialty<sup>78, 79</sup>. In 2013, two cross-sectional surveys – both from the United States, but using different data sources – reported the uptake of EMRs in ophthalmology significantly lagged behind other medical specialties<sup>78, 79</sup>. Their findings and estimates of usage aligned with those reported in a national survey conducted at the same time by the American Academy of Ophthalmologists (AAO), who found only 32% of ophthalmic practices routinely used an EMR<sup>80</sup>. This was in contrast to other medical specialties such as urology (67.5%), general practice (64.2%) and oncology (62.4%)<sup>78</sup>.

Chiang *et al.* have described the specific clinical features of ophthalmology that impose unique EMR design requirements, and therefore challenge system adoption within the field<sup>81</sup>. These include the heavy reliance on imaging – both hand drawn and formal imaging studies, the high volume nature of ophthalmology clinics, and the involvement of multiple care providers in the workflow for individual patients<sup>81</sup>. Given these challenges, it is not surprising that the AAO survey also found users of EMRs in ophthalmology to be less satisfied than in other medical specialities<sup>80, 82</sup>.

Largely, the published literature that explores the impact of EMR adoption within ophthalmology comes from a single academic medical centre in the United States, the Oregon Health and Science University Casey Eye Institute, who implemented the Epic EMR in 2006. Following their EMR implementation, it was reported that – in comparison to paper-based documentation – they saw four percent fewer patients overall, and the appointments took over forty percent longer<sup>83</sup>.

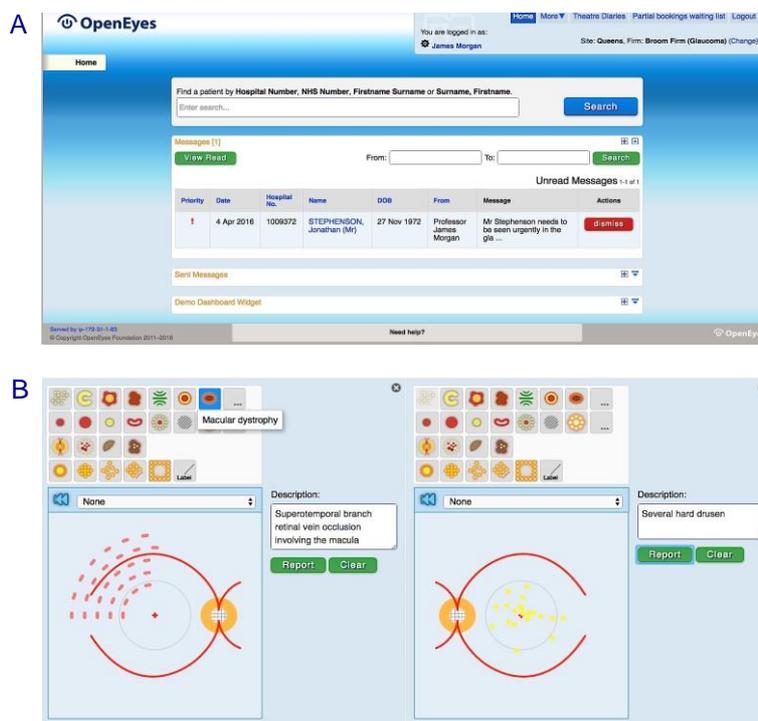
There is a paucity of literature describing EMR use in the UK. The only national evidence – a survey published in 2017 – found 45.3% of UK eye units use an EMR, with 79.1% of those being an ophthalmic specific system<sup>84</sup>. Medisoft was the most widely reported EMR in use, followed by OpenEyes<sup>84</sup>.

## ***The OpenEyes Foundation***

OpenEyes is an open source EMR, initially developed at Moorfields Eye Hospital (MEH) in response to a dissatisfaction with the commercial systems available at the time<sup>85</sup>. Aylward and Palmer set out the founding design principles of the system in 1999, when they published a study describing the usage of a precursor system in the MEH vitreoretinal service<sup>85</sup>.

The founding principles were defined as<sup>85</sup>:

- (i) Data ownership: clinicians were the intended user, and should enter the data into the system directly.
- (ii) No duplication: the system was to completely replace paper-based documentation, with all data entered into the electronic system instead of (not as well as) paper notes.
- (iii) No 'big bang': introduction of the system was not to disrupt the existing workflows, and thus, should be carried out incrementally.



**Figure 3: Screen captures of the OpenEyes medical record system.**

**A:** The home page dashboard. **B:** The posterior pole drawing tool. Screen captures are taken from the OpenEyes Foundation website<sup>86</sup>.

In 2015 it became the responsibility of the OpenEyes Foundation to manage the development of the system. Screen captures of the web-based OpenEyes EMR system can be seen in Figure 3.

This doctoral research concluded with the development of data capture forms for three paediatric ophthalmic use cases (Chapter 4, pp.139-178); the development of these forms utilised the OpenEyes Foundation's open source drawing package – EyeDraw, a core component of the OpenEyes EMR<sup>87</sup>.

EyeDraw is a web-based JavaScript application that uses HTML form and canvas objects. Individual drawing elements – displayed as icons to be added to the drawing canvas, as seen in Figure 3.B – are linked to SNOMED-CT codes, capturing the data contained within the drawing in a structured format. Data variables for the drawing components can also be bound to HTML form elements to give the user flexibility and choice over the data input method (drawing-based versus more formal form elements).

In 2014, at the beginning of this doctoral research, OpenEyes did not contain a paediatric specific module and, therefore, EyeDraw was lacking some of the relevant drawing elements.

### ***Electronic medical records in paediatric ophthalmology***

Paediatric ophthalmology, as a subspecialty of ophthalmology, is anticipated to encounter all of the challenges associated with EMR adoption described above, in addition to specific difficulties that reflect its interface with paediatrics and child health. In paediatrics, users have highlighted the importance an EMR system that facilitates monitoring the health and development of the patient, in addition to understanding and supporting the family context<sup>88</sup>.

Lim *et al.* found EMR usage varied by ophthalmic subspecialty within eye units, with paediatric ophthalmology seeing the least extensive usage<sup>84</sup>. While this evidence supports the notion that ophthalmic subspecialties have differing EMR requirements, their survey did not include any eye units within paediatric-specific centres<sup>84</sup> and, thus, little is known about EMR use within paediatric ophthalmology specifically in the UK.

Research from the paediatric practice at the Casey Eye Institute (4 clinicians) reported an eleven percent decrease in clinical volume<sup>89</sup> providing cautionary evidence of the negative impact of EMR use within paediatric ophthalmology, but more work is needed in this area to fully understand the impact of EMRs and further explore users requirements.

### ***Secondary data uses in ophthalmology***

The NHS SUS does not capture any ophthalmic outcomes. However, since 2010, the Royal College of Ophthalmologists has collected pseudonymised data in the National Ophthalmology Database for use in audit and research<sup>51</sup>. Primarily, the audit is of adult NHS cataract surgery conducted in England and Wales, although pilot studies were also undertaken for glaucoma, retinal detachment and wet age related macular degeneration<sup>90</sup>.

To standardise audit data submissions and also care provision, the College has defined a series of minimum clinical data sets<sup>91</sup>. A minimum data set is a series of data items listed alongside the format in which they should be captured. Generally, these data are to be collected as part of routine care, and so do not create additional work for clinicians. The minimum data sets are a subset of routinely collected data; they can be considered a starting point for EMR system design, to be augmented to fully support clinical care.

There are no minimum data sets specific to paediatric ophthalmology, and therefore no national agreement on which data to collect and which format the data should take. Although documentation guidelines do exist for specific diseases, for example retinopathy of prematurity<sup>92</sup>, more generally, there is no guidance for EMR data requirements within paediatric ophthalmology.

Without a national audit, there is also no database to support the secondary uses of data within the field. In the UK, visual impairment is relatively rare in childhood, with a great heterogeneity of underlying disorders<sup>93</sup>. Large scale research studies have been imperative in understanding the burden of visual impairment on the individual and on society, informing the provision of national eye care services<sup>93-95</sup>. It is therefore extremely important to have a means of aggregating and analysing data on a national scale, beginning with standardised data capture.

### **1.1.5 User-centred design**

Early HIT design was restricted by the limitations of technology. However, recent advances mean that HIT systems can now adapt to the needs of the user; design strategies are shifting towards a user-centred design (UCD), to create products that are useful.

In UCD, the “usefulness” of a system is determined by both its utility and usability<sup>96</sup>. Grudin explains ‘a potentially useful system can be unusable. A usable system ... can be useless, serving no recognizable purpose’<sup>97</sup>. The ISO defines usability as the ‘extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use’<sup>98</sup>.

A user-centred design must, therefore, be driven by the both the needs of the user and the intended environment of use.

The ISO standard on ergonomics of human system interaction (ISO 9241) describes six principles that underpin a successful, user-centred approach<sup>99</sup>:

- (i) The design is based upon an explicit understanding of users, tasks and environments.
- (ii) Users are involved throughout design and development.
- (iii) The design is driven and refined by user-centered evaluation.
- (iv) The process is iterative.
- (v) The design addresses the whole user experience.
- (vi) The design team draws upon multidisciplinary skills and perspectives.

This notion has become a precedent within modern health informatics, as summarised by Van der Lei's First Law<sup>100</sup>:

'Data shall be used only for the purpose for which they were created. If no purpose was defined prior to the collection of data, then the data should not be used.'

And thus, the UCD principles are being increasingly applied to HIT design<sup>101-103</sup>. In the United States, the Office of the National Coordinator of Health Information Technology now require all certified EMRs to have been developed with a UCD approach and undergone usability testing<sup>104</sup>. However, a recent study found variability in vendor UCD processes, with specific challenges in participant recruitment and the conduct of sufficiently in depth research into clinical workflows<sup>105</sup>. This is particularly problematic in UCD; it has been suggested that no design task should begin without first understanding the users and their tasks and needs<sup>106</sup>.

The user, as defined by ISO, is any 'person who interacts with the product'<sup>99</sup>. Within this work – to satisfy the fifth UCD principle and ensure the whole user experience is appropriately addressed – both the EMR system and the health data it contains are considered part of the product. The definition of an EMR-user is therefore extended to include any person who interacts with the technology or with the resulting health data.

Although standards have defined the principles of UCD, there is little guidance or agreement on which methods to use to define users and achieve a UCD – both within healthcare<sup>107</sup> and more generally<sup>108</sup>. Thus, a range of UCD techniques are commonly practised<sup>109</sup>.

For the design of HIT, UCD methods have included focus groups, domain expert interviews, in situ observational studies, artifact analyses or a mix of several of these methods<sup>110-113</sup>. These techniques are discussed in more detail in Chapters 3 (pp.77-137) and 4 (pp.139-178).

### **1.1.6 Summary**

EMRs hold great promise to facilitate EBM and harness the potential for meaningful information from the vast quantities of data collected routinely. However, usage of data and HIT systems for purposes other than which they were intended may introduce clinical errors. Systems therefore should be designed with a complete understanding of the intended users and uses. A range of UCD techniques can be applied to gain an in depth, holistic understanding of medical record use and, in the context of paediatric ophthalmology, are likely needed to engage the wide range of potential EMR users. The process should take into account the primary clinical

usage of data, in addition to secondary uses and the data standards that facilitate this. Should an evidence-base on medical record use in paediatric ophthalmology be built, it will form the starting point for future EMR design and adoption strategies within a field where, currently, there is little evidence to guide development.

## **1.2 Research outline**

### **1.2.1 Aims and objectives**

Broadly, this doctoral research aimed to provide an evidence base to inform a user-centred approach to HIT development within paediatric ophthalmology in the UK.

The specific objectives were to:

- (i) Assess the current landscape of medical record and medical record data usage within clinical and academic paediatric ophthalmology.
- (ii) Define the data and EMR design requirements imposed by the different users, uses and use environments encountered within paediatric ophthalmology clinical care and research in the UK.
- (iii) Develop and test exemplar data capture tools that address the identified requirements in specific paediatric ophthalmic use cases.

### **1.2.2 Research approach and setting**

As discussed in the background section of this chapter (specifically, see pp.36-38), to provide a complete and in depth understanding of user requirements, UCD methods often utilise a range of research techniques. The combination of qualitative and quantitative studies is termed a mixed methods approach<sup>114</sup>, and is the methodology that was followed in this doctoral research.

The following thesis is divided into six chapters, with Chapters 2 to 4 each addressing one of the main research objectives.

Having set out the background context and provided an overview of the literature in Chapter 1, Chapter 2 addresses the first objective of this research, exploring the existing information flows and HIT usage within NHS paediatric ophthalmology. A

national survey of clinicians working in paediatric ophthalmology and a literature review of the data sources of research recently published within the field are triangulated with semi-structured interviews. The barriers and facilitators – or pull factors – of EMR adoption are also considered in the context of the paperless NHS ideal described in the Background section (p.21).

As the UCD principles state, “an explicit understanding of users, tasks and environments” is required<sup>99</sup>. Therefore, to address the second research objective, in Chapter 3, a focus was placed upon a single use environment: the GOSH department of clinical and academic ophthalmology. GOSH provides tertiary care as the UK’s specialist children’s hospital and, therefore, this research captured the most complex use cases encountered in paediatric ophthalmology. An observational time-motion study and a medical record review were completed at GOSH to identify the clinical users of medical records and elicit their requirements – both of the user interface and the data set. Using the medical records written in GOSH ophthalmology outpatient clinics, a maximal set of routinely collected data was defined. The suitability of this data set to support research was assessed through a comparison to the data items captured as part of a national epidemiological study of childhood visual impairment and blindness undertaken at the UCL Great Ormond Street Institute of Child Health (ICH) at the time of this research.

In Chapter 4, the insights gained into the users of EMRs in paediatric ophthalmology were applied to develop a series of electronic data capture forms. Three clinical use cases were selected for development, to demonstrate the variety of scenarios and users encountered in paediatric ophthalmic care, and to meet clinical needs at GOSH. For each individual use case, a UCD approach was followed to develop and test the software. Two of the case studies were then

implemented in the GOSH ophthalmology outpatient clinics, as part of a new clinical research database.

The final study of this research, presented in Chapter 5, was an assessment of the completeness and accuracy of SNOMED-CT for paediatric ophthalmology, in the context of the same national epidemiological study that was considered in Chapter 3.

Finally, the findings of this work have been drawn together in Chapter 6, in which the implications for design and usage of a specific paediatric ophthalmic EMR are considered in the wider context of technological innovation.

### ***Research setting – the GOSH Transformation Programme***

Predominantly, this research was set in the ophthalmology department at the Great Ormond Street Hospital for Children NHS Foundation Trust (GOSH).

In 2015, GOSH announced a £50M, 20-year long digital strategy and clinical transformation programme, centering on the implementation of a new EMR system. Procurement for the EMR and a separate clinical / business intelligence and research platform commenced in January 2016. In early 2017, contracts were confirmed with Aridhia Informatics to deploy the research platform, and with the Epic EMR, including the ophthalmic specific module, Kaleidoscope.

The Epic “go live” phase was planned for the summer of 2019. In the interim period, while this doctoral research was taking place, the hospital began analysing clinic flows and gathering the system requirements of individual clinical departments. This influenced the direction of this doctoral research to focus on the study of the potential uses of an EMR system by the GOSH ophthalmology department, and to

generate user-defined requirements that may facilitate the adoption and customisation of their Epic system.

### **1.2.3 Research ethics**

The ICH and GOSH joint research and development office deemed this work a service development project. Therefore, no ethics approval was necessary to undertake the research.

## Chapter 2 “Use-scape” Exploration

### 2.1 Chapter aims

As set out in Chapter 1 (p.32), there is little published literature that describes the landscape of use (the “use-scape”) for EMRs and HIT within paediatric ophthalmology in the UK. This dearth of literature spans both the use of EMRs in clinical care, and the re-use of medical record data for research within the field.

In this chapter, a mix of methods were applied to explore the current landscape of HIT use within paediatric ophthalmology in the UK; both the clinical and research applications of medical record data were considered, with three overarching aims:

- (i) To assess the current status of EMR adoption within NHS paediatric ophthalmology.
- (ii) To explore existing data flows between clinical and academic communities within paediatric ophthalmology.
- (iii) To explore the perceptions of routine EMR usage by potential system users and identify barriers to paperless working in the field.

From this initial broad, exploratory work, an understanding was sought of the different factors influencing EMR adoption – the “pull” factors encouraging routine use, and any associated deterrents –that would form a foundation to guide further research in understanding the user-centred requirements of an EMR for paediatric ophthalmology.

## **2.2 Methods**

### **2.2.1 Study design**

In this study, the overall conclusions were drawn from the triangulation of three methods: an online national survey, literature review, and semi-structured interviews.

The online survey and literature review were conducted in parallel; the survey targeted clinicians working in paediatric ophthalmology in the UK, whereas the literature review considered the current methods of participant identification and data acquisition within academic research in the field. The initial findings from these two methods informed the development of a topic guide for the third method: interviews with both clinical and academics operating within paediatric ophthalmology. The qualitative interview data provided context and enriched the final conclusions drawn.

Below, the data collection and analysis techniques employed in each method have been expanded upon individually. The findings are then presented and discussed together in the subsequent sections of this chapter.

### **2.2.2 A national online survey of paediatric ophthalmic clinicians**

#### ***Instrument Design***

The survey was designed to capture data on current clinical documentation practices, and the perceived benefits and the perceived barriers associated with routine EMR use. An optional extension section – for those with prior experience

using an EMR – explored the impact of electronic documentation on routine clinical practice and competencies using health information technology.

Survey questions included multiple choice, short text and multiple response answers. Pre-defined answer options were based on existing literature,<sup>6-8, 10, 11</sup> and were informed by discussions with clinical colleagues. No personal demographic data were collected.

The questionnaire was piloted with five clinicians at GOSH and refined before final administration. The full survey and cover letter can be found in Appendix A (pp.231-238).

### ***Participant sample and survey administration***

As there is no UK database of clinicians practising in paediatric ophthalmology that would have provided the target population and sampling frame, participants were identified from an email listserve. The PAED-OPHTH-STRABISMUS Listserve is an established email group based in the UK. All consultant ophthalmologists and other ophthalmic clinicians (orthoptists and optometrists) of equivalent seniority who have exclusively or predominantly paediatric practices are able to join the group. It serves as a forum for clinical, service and policy discussions, and was therefore an appropriate target audience for the survey. At the time of survey administration, the listserve had 189 members.

All relevant clinical colleagues within GOSH and Moorfields Eye Hospitals' paediatric ophthalmology departments were also specifically invited, as members of the core research study group.

Potential participants were invited to complete the survey via email. The invitation provided an overview of the research project and a web link to the online survey.

Individual reminders were not possible, but two reminder emails were sent through the listserv three weeks apart. Responses were collected between June and August 2015.

### ***Data Analyses***

Univariate statistical analyses were completed using the Statistical Package for the Social Sciences (SPSS) version 23.0.0.0. For multiple response questions, all answer options were considered individually and grouped into broader categories apparent to the respondent during survey completion via question subheadings. Free text 'other' responses to these questions were coded into discrete concepts, and categorised and analysed as above. There were no required questions. Missing data were excluded from analyses via listwise deletion.

Statistical comparisons between groups were made considering the respondents' role, and previous experience using an EMR. The Chi-square test was used to compare nominal variables and the independent t test or ANOVA for continuous variables, as appropriate. All assumptions for statistical tests were met.

### **2.2.3 Literature review**

#### ***Search strategy and analyses***

The PubMed online database was searched to identify all papers coded under the medical subject headings (MeSH) Eye; Ophthalmology; Vision, Ocular; or Eye diseases. MeSH terms were combined with the 'or' operator. Pubmed filters were applied to limit the results to include only human participants in the child age range

(birth to eighteen years). A date filter was also applied to limit the publication date between 2010/01/01 and 2015/12/31, in addition to a filter that excluded articles that were not original research (e.g. reviews, study protocols, comments) or that were retrospective case reports.

From the search results, as this work was focused on the data use of NHS patients, all items that did not originate within the UK were removed. All remaining abstracts were then reviewed; items were excluded in line with the filters above (no human participants, no participants from the UK, no ophthalmic outcomes, no paediatric participants, not original research, and service development studies).

Next a full text review was performed of the remaining items; publications where the abstract was not available in Pubmed and so could not be reviewed were included in this stage. For each full text article, data were collected on the how participants were recruited, if the study had a paediatric focus or also included adults, and if routinely collected data were analysed as part of the research. Frequencies were analysed using Microsoft Excel for Mac 2011 (version 14.4.8).

A flow chart for this process, including how many items were excluded at each stage, can be found in Appendix B (p.240).

#### **2.2.4 Interviews**

##### ***Participant sample***

Purposive sampling was employed, to ensure a range of experiences and opinions were included. Individuals were invited with varying experiences using EMRs routinely, from different sub-specialties of paediatric ophthalmology, and different clinical roles or research domains and focuses.

Individuals were identified from the core study group including colleagues from GOSH, Moorfields Eye Hospital, and the associated academic institutions within University College London. Additional clinical participants were identified from respondents of the online survey who provided contact details to contribute further to research in the field.

A breakdown of individual participant characteristics can be found in Appendix C (p.241). The participants were classified as either a clinician ( $n=6$ ) or a researcher ( $n=5$ ); interview questions differed slightly depending on this grouping, although the same overarching themes were explored.

### ***Topic guide development***

Interviews were semi-structured; a topic guide was used to focus discussions. Topics were developed from the initial results of the online survey and literature review, and included experiences with EMRs, the uses of medical record for research, perceptions on the current information system and the adoption and impact of EMRs. Appendix D (pp.241-243) details the full topic guide used for both clinical and research groups.

### ***Data capture and analysis***

Interviews were conducted face-to-face ( $n=9$ ) or by telephone ( $n=2$ ), and were scheduled to take 45 minutes. All participants verbally consented to the process. Interviews were recorded digitally and manually transcribed verbatim, with one exception where the setting resulted in too poor a recording quality. Notes were additionally taken during and immediately after the interviews, and included in the analyses.

Using the NVivo 11 software package<sup>115</sup>, interview data were thematically analysed. Themes were predefined prior to the analysis as the perceived benefits and barriers of routine EMR use identified in the online survey, plus an additional theme coding methods of data acquisition and data sharing. Where appropriate, sub themes were created during the coding process to further explore these findings.

## **2.3 Results**

### **2.3.1 Survey participants**

90 individuals from 42 different NHS Trusts responded to the survey (location missing,  $n=7$ ). Using as the denominator 189 members on the email list at the time, this gives a crude participation rate of 47.6%. Given the nature of the listserve, it was not possible to compare participants and non-participants formally.

From those who provided their clinical role ( $n=68$ ), 41.2% ( $n=28$ ) identified themselves as ophthalmologists and 57.3% ( $n=39$ ) as orthoptists, with the remaining 1.5% ( $n=1$ ) optometrists. No significant differences were observed in the main method of documentation used, or the selection of individual benefits or barriers by the ophthalmologist and orthoptist groups. There was not sufficient data to assess differences for the optometrists grouping.

28 individuals completed the optional extension, including questions on experiences using an EMR and computer competency. The mean computer competency score for these respondents was 4.21 out of 5 (95% confidence interval, 3.89-4.53), with only one respondent rating their computer skills as below average ( $<3$ ). Those completing the extra questions may have done so because they had a greater interest in informatics and were more technically able. However no significant differences were found between this group and other respondents' answers to the main questions, and so the groups were not differentiated further.

### **2.3.2 The current landscape**

Only 7.8% of the survey respondents ( $n=7$ ) reported using an EMR routinely for the majority of their paediatric practice, while 10.0% ( $n=9$ ) used electronic document management systems – or scanned notes – and 82.2% ( $n=74$ ) used fully paper-

based methods. However, 64.4% of all respondents ( $n=58$ ) reported some experience using an EMR, with 60.3% ( $n=35$ ) of those including paediatric patients and the remaining 39.7% ( $n=23$ ) with adult patients only.

Interview participants also reported a range of experiences using EMRs. One clinician explained that high throughput and busy clinics discouraged the implementation of new working methods:

“There was a really big push to start using [the system], so we all did, but we still had the paper notes. And if the notes are there and you’re in a really busy - my clinics are so busy – and you just default to keep writing in the notes. But if you just had a clipboard or something with the basic information and a big sticker that says ‘patient now in EMR’ then you would have to use it. I mean you could still have the notes at the desk or something, but we had them in the clinic with us with patients and it was just easier to continue writing in them. So there was this big push, but no one really uses it.” **(Interview participant C1).**

Others explained that the systems available did not suit their needs:

“When I looked at the actual system and some of the data we were being asked to input, I didn’t understand some of the terms and some of the information that was there. So we actually print out the forms and write what we need to on them and then the hospital scans them. It’s like the EPR has actually increased the amount of paper that we use!” **(Interview participant C3).**

“In paediatrics we are still paper-based. There isn’t really a paediatric module in [the EMR]. Or I think there is, but I think it’s for A&E really, so I don’t use it, it doesn’t suit my purposes.” **(Interview participant C4).**

Only one interviewee routinely used an EMR; she described two different experiences with system adoption: the first system was chosen by the clinicians in the department to assist with audit processes, and the second was a top-down, Trust-wide initiative that replaced the ophthalmic-specific EMR.

“Well we, the department, bought [an ophthalmic EMR], mainly to do audit – it’s one of the most important things for us. And we did very well with that. You could just fill it up and click a couple of keys and it does what it was designed to do

...

But then everything was imposed upon us. They wanted everyone to use the same system; there was absolutely no consultation. They said that from this day everything would have to be done in [this EMR] and that was it. And now we can’t even audit.” **(Interview participant C2).**

### ***Using medical records for research***

All researchers and clinicians within the interview sample intentionally had experience using clinical databases or medical records to identify research study participants, or using the medical records as a data source for a research projects. Using medical record data was perceived to be beneficial to research, in terms of including a wider, more representative range of participants, and reduce the time burden associated with completing tests in a research setting for both participants and researchers on a one off and a longitudinal scale.

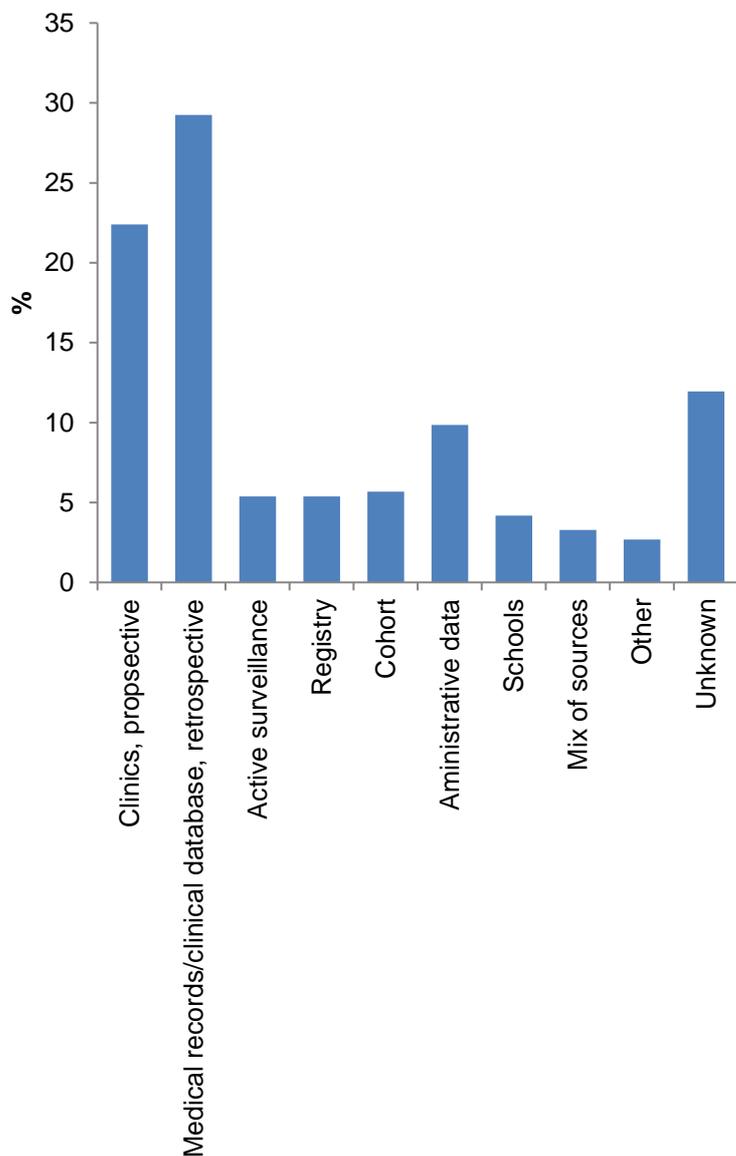
“Persuading families to come in and do extra tests for us is sometimes a challenge. I mean, patients are usually keen to help but I think fitting it around school, and parents’ jobs and siblings and everything certainly limits the sample. If you could reliably use data from clinics it would help – even if it just reduced how much we had to do in a research setting.” **(Interview participant R2).**

“It’s a national epidemiological study ... if we didn’t collect data from medical records I can’t imagine we’d ever be able to answer our research question as I don’t think we’d get a representative sample.” **(Interview participant R4).**

“It’s an incredibly useful way of identifying appropriate patients for inclusion in a research study, and often these studies go on for a long

time. Routine clinic assessments are a good way of monitoring outcomes over a number of years.” (Interview participant C6).

The literature search identified 335 original research articles from the UK that were recently published (within the five years of this research) and relate to paediatric ophthalmology. Of these, 6.3% ( $n=21$ ) described intervention studies and the remaining 93.7% ( $n=314$ ) were observational, with 21.0% ( $n=66$ ) of those describing genotype-phenotype associations. There was a relatively even mix of studies specific to paediatrics (49.6%,  $n=166$ ) and those including both adult and child participants (50.4%,  $n=166$ ).



**Figure 4: Methods of participant identification cited in published research studies.**

Other options include advertising through charities, newspapers, and social media, and recruiting siblings and friends of staff and participants.

When considering how participants were recruited to the published studies, a range of methods were identified (Figure 4); the majority did utilise clinical data.

49.3% of all citations assessed routinely collected data as part of the analyses. Often, this was in combination with data generated within the research study, as explained by interview participants:

“It’s important to have a confirmed diagnosis and a clinical phenotype, and to know the participants history, so the clinical data is really useful for that before we do our testing.” **(Interview participant R5).**

A need for standardised, comparable data was raised as a concern, as was the importance of control subjects in many research studies, for whom very little clinical data exists.

“We quite often need control participants to generate comparative, normative data, so we’d always have to do some clinical tests ourselves anyway. And for research, I think it’s best to have the tests like visual acuity done using the same test, in the same environment and by the same person – that can be so variable in clinics, and actually, so can how it’s recorded ... confidence in the testing methods and standardisation are both really important for a reliable comparison.” **(Interview participant R2).**

Access to medical records and patient data was also a problem encountered by many participants in the interview sample.

“We are doing a project here at the moment, and accessing the historical notes is a problem. If you want them pulled we have got to give money to the medical records staff, or their budget rather, from our departmental budget, because it is seen as extra work to have them to do it. So it is a real draw back ... it is an extra expense of we’ve got to think of” **(Interview participant C3).**

“Well, confirming the phenotypic data is a problem, and discussing the findings. We have to coordinate with clinicians, and quite often they will email me about one of their patients in our study but we have to try and

communicate without using patient identifiers because I don't have permission to access that data. I wish there was a better way of linking our database with the clinical systems so we could all access the information we need to." **(Interview participant R5).**

"I can't bring the data around with me on my laptop, it has to be encrypted on a desktop in a locked office, which means it's difficult to access and limits where I can work." **(Interview participant R1).**

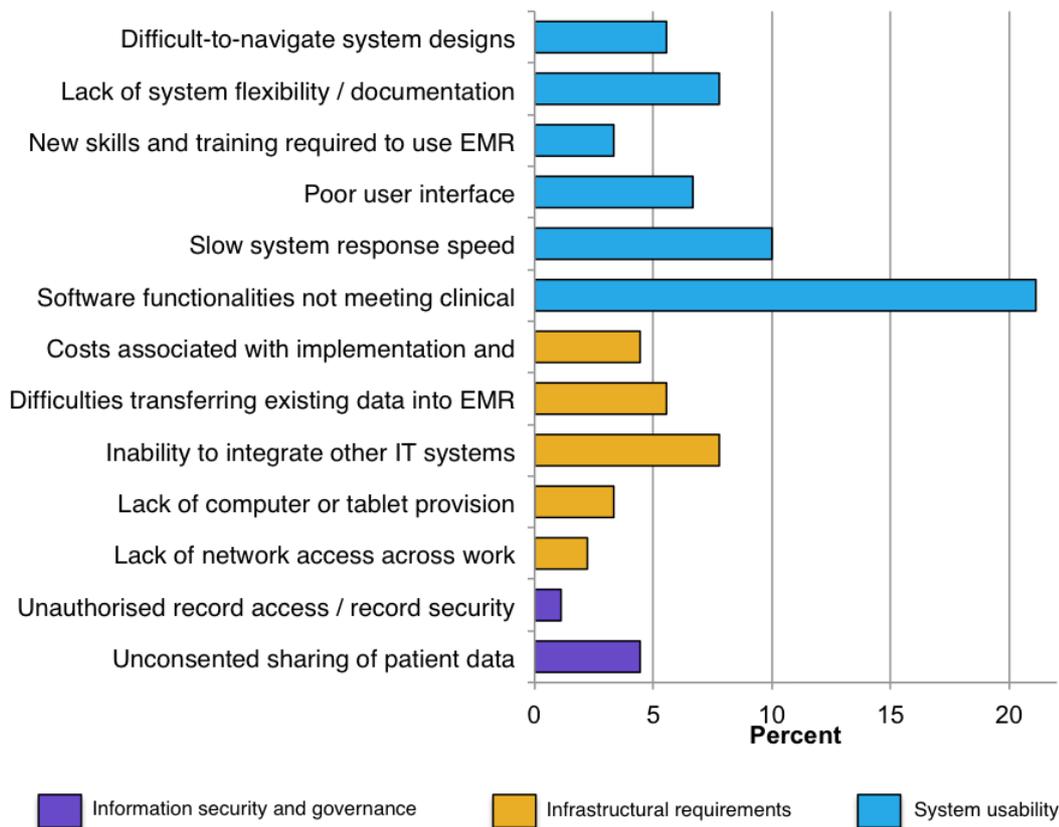
Other cited problems encountered when using routinely collected data in the current information system included incomplete data, legibility, and time required to clean and reformat data so it is usable.

"... it took a while to get used to finding the data in the notes, and at the start I did have to have a bit of help making sure I recorded the correct things, it can be really difficult to read and understand, and there are so many different acronyms or abbreviations used that I think you have to have some clinical knowledge before you can confidently interpret any routinely collected data." **(Interview participant R4).**

"To put it bluntly, the quality is very poor ... There's so many images that I can't use ... so mainly it is just the boring day to day data handling that I spend my time doing, and that's a bit upsetting, given that I came here to do the analysis. But it's necessary with the clinical images." **(Interview participant R1).**

### **2.3.3 The perceived barriers to routine EMR use**

From the online survey, the majority of items perceived to be the biggest barrier preventing or challenging routine EMR use could be classified as system usability issues (Figure 5).



**Figure 5: The major barrier to routine EMR use identified by paediatric ophthalmic clinicians.**

Barriers are sorted by type into three categories. Respondents could provide only one answer.

Respondents most commonly identified 'software functionalities not meeting clinical need' (70.0% of all respondents), 'slow system response speed' (66.7%) and 'lack of system flexibility / decreased documentation freedom' (65.6%) as barriers. These items were also the three most frequently reported as the single biggest barrier to routine EMR use (Figure 5), although 'software functionalities not meeting clinical need' was identified as the greatest barrier by over twice as many participants (21.1%) than those who selected the second most common, 'slow system response speed' (10.0%). Below, these issues are considered in more detail.

### ***Clinical needs – data capture***

'Software functionalities not meeting clinical need' was the most commonly identified barrier in the survey (Figure 5). When this topic was explored with clinical interviewees, the primary requirement of a medical record system – electronic or paper-based – was a record of clinical care provision.

One individual identified the data set as the foundation for EMR development, and that identifying all the required fields should be the priority:

“The first part should be getting the data set, then you do the aesthetics, the usability and reducing the click click click. That is annoying, and it is important. I guess you do think about it as you go through the dataset, you do go through the flow and how it should be presented in your head but you need to make sure you can record all the data you want to first.” **(Interview participant C1).**

Although, there were also concerns that too many data items would reduce efficiency and discourage use. The individual who had used an EMR acknowledged that, although structured data is useful, in the real world clinical environment speed became the priority and a simple, single free text box offered the most useful solution.

“You have to keep it simple. Although we need it to be comprehensive, it can't be prohibitively complicated. If I'm working with a child with uveitis I don't want to be presented with all the fields from all of ophthalmology, I just need the relevant bits – that's important. We really are under a lot of pressure in clinics. It has to be comprehensive but not so much that just the thought of entering data puts you off using it.” **(Interview participant C6).**

“I just find it takes so much longer so I usually end up writing a lot in the free text comment bit ... I don't really have that data for audit and I can't use any of the graphs and the things that are actually helpful. But I can get through a clinic and record everything that I need to that way, that's what's important when push comes to shove.” **(Interview participant C4).**

### ***System navigation and design***

As some of the previous quotes indicated, there is a perception that documenting using an EMR is slower than with paper. In the online survey, one participant commented “typing or 'clicking' is much slower than pens!”. The excess of mouse clicks was cited as a source of frustration, due to both poor page flow design and difficult data entry methods:

“Well it just slows everyone down, often you have to click through multiple things, and it takes a lot more time.” **(Interview participant C4).**

“I think it takes longer because you have to click to open a drop down and then click to select the answer you want. And you have to do that every time. With paper I'd usually just 'right and left' or something like that instead of writing all of the data out again.” **(Interview participant C5).**

Participants also felt that electronic systems did not suitably support diagrammatic data capture, and that the alternatives contributed to slower documentation in clinics:

“I like to have my own drawings that I can annotate, but I don't think you'd ever achieve that in an EMR. I think you're better off just putting a picture in there. It's certainly quicker than any electronic drawing tool, and looks better.” **(Interview participant C2).**

“... drawing your observations is really quick with paper, and it's what we've always done in clinics. Trying to describe what you see in a drop down or text box takes longer and is much more difficult to give an accurate picture. And I think it makes it slower when you're reviewing a patient's record too. Your eye is instantly drawn to a drawing – it gives a really quick summary of previous observations, but finding all that information in text is not so easy.” **(Interview participant C5).**

### ***User involvement in system design***

A sub-theme identified from the interview data was the difficulty for prospective users to participate in EMR design, which lead to usability problems. Unsurprisingly given the purposive sample, all clinical interviewees acknowledged the importance and expressed an interest in being involved in the development of EMRs, however, there was a belief that, more generally, clinicians are reluctant to engage with EMR development:

“I don’t think that clinicians do really want to engage in this sort of thing, but clinicians are the best ones to do it! ... We know what we need and what works. If you could make it happen, it would make using the EMR easier” **(Interview participant C1)**.

“It is a time commitment, you have to have individuals who care. But most people just get on with things as they are and don’t get involved with changes like this.” **(Interview participant C2)**.

All interviewees identified difficulties engaging with HIT development, often describing a communication barrier between clinicians and developers. In some cases, this came from prior experience working on HIT projects:

“I don’t think other clinicians think the way programmers do – it’s been really interesting working on this project ... Some of the concepts that [the developer] has explained to me, like how patients have to always have a state and always exist in the IT system – that’s just not something I’d thought about before! You know? It’s not how we do things. And I think clinicians can just end up losing their patients with all this. People who programme think about things in a very interesting way.” **(Interview participant C4)**.

“There’s a big disconnect between what clinicians tell the bosses of guys who do the coding what they want and what they eventually see. It’s best to have a one-to-one, face-to-face meeting with the actual guy doing the coding, or everything just gets lost in translation ... It’s hard to engage if you think you won’t get what you want in the end” **(Interview participant C1)**.

And again, a frustration was identified with the perception that individual clinicians have little influence on top-down HIT projects:

“I think that sometimes you can be a little bit cynical ... you might engage but it is difficult on a Trust level to change people’s opinions about things and alter what is going to happen to you.” **(Interview participant C2).**

#### Engaging other stakeholders

Clinical interviewees were receptive to the idea of other stakeholders, such as researchers, also being involved with EMR design. When asked about challenges they perceived, the focus was on the practicality of establishing a discourse more than a conflict of interests:

“Well you’d have to find a way of incorporating everyone’s opinions, but research and service planning and things are incredibly important to medicine, so, yes, I do think it is worth trying. And it’d probably helpful for them too, for when you’re designing a study or something, so you know what is realistic.” **(Interview participant C6).**

“I think it would be valuable, to everybody really. It’s better to make these administrative or other extra things part of the system to begin with than to add it on later when they realise some data they need is missing. But I think it’s best to do these things face-to-face, to sit down and discuss what everyone needs, and I don’t see that happening with clinicians and researchers and managers and policy makers and everyone!” **(Interview participant C3).**

This, however, was observed in the research sample. Participants were often surprised by the question, and were mindful that research was not the primary use of medical records and so should not be a priority in design.

“That’s funny, if you asked me who the users of medical records are, I would never have said me, I’d just think about all of the doctors and clinical things. But then all of our participants’ clinical data does come from notes, so I suppose, thinking about it that way, I am.” **(Interview participant R5).**

“I don’t know that I’d have much to say about the design – I’d worry I’d say something that a clinician wouldn’t like or agree with. I think the systems should be designed for them, really.” **(Interview participant R1).**

### ***System flexibility and customisation***

Survey respondents identified a lack of system flexibility in the available EMR systems as one of the biggest barriers preventing routine EMR use (Figure 5). In the interviews, this challenge was believed to be more prominent in paediatric ophthalmology compared to adults and other subspecialties:

“For cataract surgery, [the EMR] was really, really good – really straightforward. And for AMD, and things like that that are very consistent and reproducible – where you do the same thing with it each time and it prepopulates a lot of data. It doesn’t work like that in paediatrics” **(Interview participant C4).**

“... adults are more straightforward but paediatric phenotyping is a little more complex. There’s a big spectrum of phenotypes and sometimes you can’t accurately describe the patient in a strict IT system. I mean, for something that you think would be really simple like the diagnosis, they just didn’t get it right.” **(Interview participant C1).**

Individual system customisations for different users or patient pathways were discussed as a way of providing system flexibility. While a positive idea, the time required to achieve this was found to be discouraging:

“Something like Google with intelligent text entry that remembers what I’ve written before and it learns the way I work. If you’re learning to use a new system, I think it would be difficult finding the time to programming what your customisable options are – I’d love a system that just learnt from how I use it.” **(Interview participant C5).**

This difficulty in customising an EMR to suit the variable clinic flows was found to cause difficulties when implementing an EMR into an outpatient clinic:

“[Patients] need to be seen by orthoptists and have vision assessments and oculomotor, or they go to visual fields and have visual field tests, or they might go and have retinal photography or something like that, or they might need dilating. So at any one point lots of patients are doing different things – there are different courses through the consultation and not everybody has the same thing. So with an EMR it’s very easy to lose patients, very easy! Instead of having notes that – the [paper] notes followed the patients round and you knew where they were. [With EMRs] there is nothing telling you that actually that patient has been parked there for two hours and nobody has done anything with them at all!” **(Interview participant C2).**

This quote highlights how the uses of medical records extend beyond documenting clinical care provision; workflow management is an additional requirement of the system, and is particularly challenging within paediatric ophthalmology.

### ***Changing workflows and learning new skills***

Although this was not a major concern highlighted in the survey, changing workflows was a theme that emerged from the interview data. One participant described the difficulty in having to change their working practice from dictating letters to typing:

“You had to type letters – and well, I’m not a typist. I guess in future generations that will change. But the letters didn’t look very good. In paediatrics we write really long, detailed clinic letters. I think it’s important for the patients and for GPs to receive something that looks good and really, that they can read.” **(Interview participant C4).**

The interruption of existing clinic processes was believed to be particularly problematic in paediatrics, where patients need to be kept engaged with the assessment and technologies might be distracting. Four survey participants

described concerns about having to turn away from paediatric patients; this was also evident in the interview data:

“I do tend to move the paper notes around the room with me, sometimes children won’t sit still so you have to follow them and complete tests sitting on the floor and you and I like to jot things down as I do it. I think it would be hard to be chained to a computer” **(Interview participant C6).**

“With kids, you can’t have your back to kids! So what I end up doing is, I take a little notepad and I am writing all my refractions and everything down on there and I am putting it into [the EMR] when they have gone, in between patients. I’d usually have [the notes] on my lap, and you write as you go along and then have like three minutes admin time for patients, and now I am ten.” **(Interview participant C2).**

In fact, when asked what the ideal EMR system would be like, ignoring any technical limitations, one individual described an intelligent system that would simply allow them to replicate the freehand, paper-based methods:

“My ideal scenario would actually be to have a projector or something that projects the notes onto your desk like paper and you could still hand write into them and it just recognises your handwriting and it gets all the data. So it would have to be something that is intelligent. I want them to capture the data, but I also want to handwrite my notes.” **(Interview participant C4).**

In general, the sample responded to this question with fairly narrow answers that focused on improving existing systems, as described above. The only answer that deviated from the traditional description of medical records was the suggestion of using dictation to capture all data.

“I suppose just being able to dictate everything as I went would be good, like an electronic scribe.” **(Interview participant C6).**

### ***System interoperability***

Several survey respondents anecdotally highlighted the pragmatic problem of non-interoperable systems. One commented “We have been trying to establish [an EMR] for ophthalmology in our trust for the last 15 years and the single biggest obstacle has been our IT department complaining that it would not be compatible with their archaic system”.

Indeed, respondents with prior EMR experience were significantly more likely to select ‘inability to integrate EMR with other clinical IT systems’ ( $p=0.000$ ), suggesting this is a bona fide barrier experienced when implementing systems within NHS paediatric ophthalmology, as experienced by interview participant C2:

“So, this was a big issue, and required extra money to network the computers and things. All of the imaging stuff – OCT, retinal photography, visual fields, they all had to be networked into forum. ... We had to kick up a real fuss before we could get it. And now it opens within [the EMR], which is a big step forward, so having everything in one place. Because otherwise, we actually used to just have to go to the camera, which is ridiculous! **(Interview participant C2).**”

Multiple HIT systems was also identified as a challenge when working with clinical data for research:

“We started off collecting clinical data on our participants from their medical records. So, we’d request their paper notes, but then some bits would be in the patient computer system like the demographic details and all the previous appointments, and if you wanted to check what imaging had been done you’d have to use lots of different computer programmes ... in the end we had to rely more on self-reported histories and for what investigations they’d had and things, it simply came down to time.” **(Interview participant R3).**

### 2.3.4 The perceived benefits of routine EMR use

Overall, survey participants identified between 0 and 18 benefits, mean 8.59 items per participant (95% confidence interval, 7.64-9.54). The total number of benefits identified by each respondent was normally distributed (skewness -0.017, standard error 0.254; kurtosis -0.730, standard error 0.503), suggesting the list of answer options presented was comprehensive. An additional two benefits were highlighted by respondents using the *other* option: an improved record accessibility, both across care settings and out of hours ( $n=4$ ), and a reduction in lost notes ( $n=8$ ).

These priorities were also prominent in the interview data:

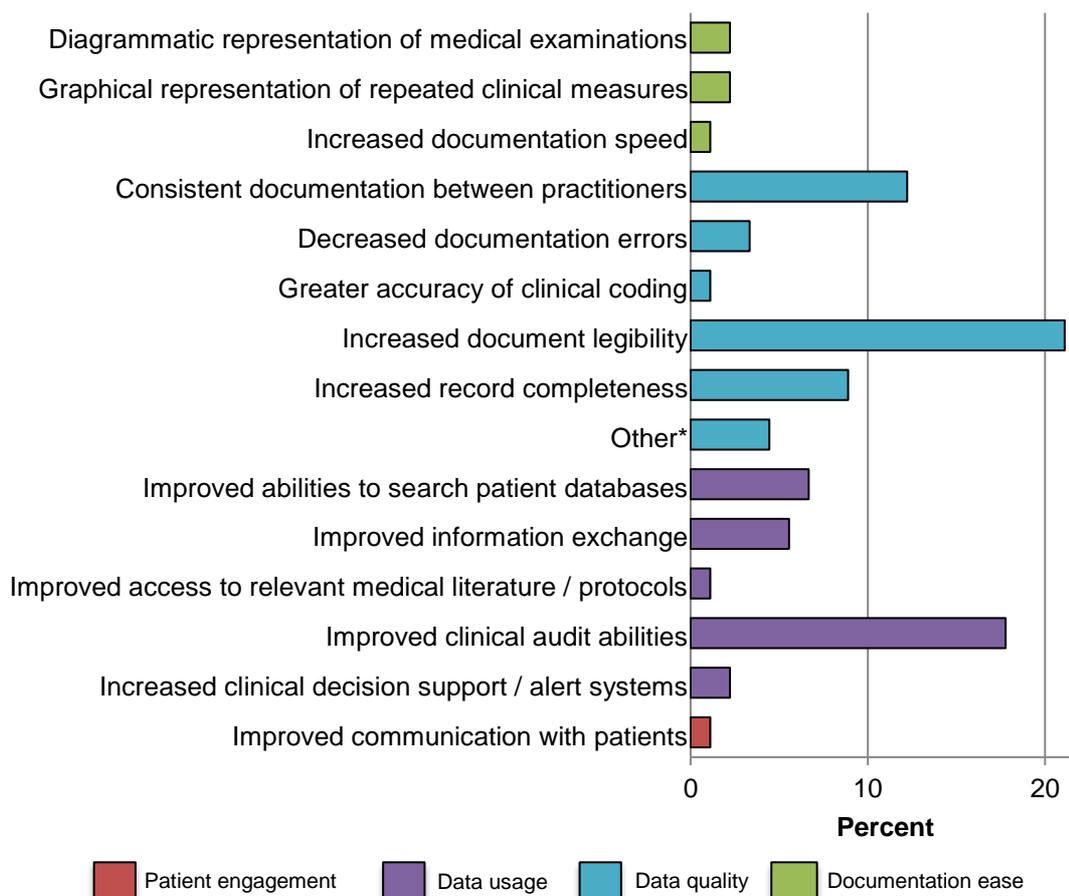
“I do think medical records are the way forward, they are so easily accessible. If I go to another hospital I would want all my notes to be there, and I would want the clinicians there to be able to see them.”  
**(Interview participant C4).**

“If it works, it would be so much easier for accepting referrals from many different agencies or well, just to help with patient care as well, so that all of the information relevant to a patient is accessible by all staff who are dealing with that patient.” **(Interview participant C3).**

“It would make notes more permanent and long term, so it’s harder to lose sets of notes, which does happen with paper.” **(Interview participant C6).**

Three survey respondents – two of whom worked within the same NHS Trust – did not identify a single benefit of routine EMR use, with one reasoning, “[an EMR] turns a clinician into a secretary and a data entry clerk”.

When considering the single biggest benefit of routine EMR use, the majority of survey respondents identified items associated with either improved data quality or enhanced data usage (Figure 6).



**Figure 6: The major benefit of routine EMR use identified by paediatric ophthalmic clinicians.**

Benefits are sorted by type into four categories. Respondents could provide only one answer. \* All “other” responses related to a reduction in lost paper notes.

Very few individuals focused on improved data capture processes, revealing clinicians’ perceptions that electronic documentation is not better than paper-based methods in terms of clinical productivity, as was reflected in one respondents’ comments “[an EMR] is about data retrieval – it is usually more difficult to get data in, but worth it.”

### ***Facilitating secondary data usage***

'Improved audit abilities' was identified as a benefit of routine EMR use by 71.1% of survey participants. The automation of processes was the main driver of this perception amongst the interview sample:

"I want to use EPR so I can run audits at the click of the button; all of the data will be in the system already and you just select what you want to look at and click, that's it! ... I don't see the point of EPR if you can't audit." **(Interview participant C4).**

"It would automatically churn out all the patients who have got those certain qualities that you are interested in, so yes, I do think it's a real advantage, not with the day to day clinic stuff but for auditing. With paper notes all that can take so much time." **(Interview participant C3).**

For research, interviewees focused more on the identification of suitable participants as a benefit of EMRs rather than use of clinical data for analyses:

"We did have quite strict inclusion criteria. If we could have build a complex query and search a database of patients that included all of the clinical that would have saved some time" **(Interview participant R2).**

"A lot of my recruitment is done through clinics, prospectively. ... It would be great to be alerted in advance, so an algorithm that looks at the patient list and age and diagnosis and things, and tells me when to be there. Or actually, something that alerts the clinician who has opened the patient's record that they should be recruited and gives them the study details would be cool." **(Interview participant R2).**

### **2.3.5 Previous EMR experience**

Comparisons were made between survey respondents with prior experience using an EMR system (in adult or paediatric care, or both;  $n=58$ ) and those with no prior

experience ( $n=32$ ). Overall, no significant differences were found in the mean number of items selected by those with prior experience ( $M_{\text{prior}}$ ) and those without ( $M_0$ ) for both the perceived benefits of routine EMR usage ( $p=0.866$ ;  $M_{\text{prior}}=8.52$ , 95% confidence interval (CI) 7.29-9.74;  $M_0=8.69$ , 95% CI 7.09-10.28), and the barriers ( $p=0.371$ ;  $M_{\text{prior}}=7.12$ , 95% CI 6.27-7.97;  $M_0=6.45$ , 95% CI 5.16-7.74).

As previously indicated (p.66), the survey participants with prior experience using an EMR system were significantly more likely to identify an 'inability to integrate EMRs with other clinical IT systems' as a barrier to routine usage. However, after adjusting for multiple testing using the Bonferroni correction ( $p \leq 0.002$ ), no other significant differences were found between the responses of those participants with previous experience and those without.

## 2.4 Discussion

### 2.4.1 Study strengths and limitations

This study included the first assessment, to the author's knowledge, of the experiences and perceptions of EMR use specifically within UK paediatric ophthalmology. In combining a mix of methods, a broad overview of the current landscape across the UK was achieved, whilst gaining in depth insights into specific issues and personal experiences with a range of potential users.

The findings reported in the current work, however, are limited by the sample population and by the assessment of reported experiences and opinions rather than direct observations of practice. The participation rate in the online survey was 47.6%. Whilst a higher participation rate would have provided a larger sample for analysis, the achieved rate was considerably higher than that reported in other published surveys of clinical practice through this source<sup>116</sup>. Since this was a novel exploratory study without a hypothesis based on a specific association or a prespecified effect size, formal power calculations could not be undertaken.

Participation in this survey, notably, was on a par with prior similar surveys in general ophthalmology<sup>80</sup> and in paediatrics<sup>117</sup>, and it is likely to have shared the same selection bias, i.e. respondents having a greater interest in the topic area than non-responders, as suggested by the high levels of self-reported computer competency. This would also be the case with the purposive interview sample. The effect of this, however, would be to allow for a more informed (rather than less informed) perspective through personal experience of HIT use; such biases would provide more 'extreme' views – both favourable and unfavourable – and thus more meaningful data to inform future user-centred design of EMR. There are no directly comparable studies against which these findings can be assessed.

Within both the survey and interviews, ophthalmic clinicians other than ophthalmologists were deliberately included so as to reflect the broader user group within NHS paediatric ophthalmology hospital-based services. There were no differences found in the survey responses of these clinical user groups. However, the size of our study sample may have precluded identification of meaningful variations, as was also the case in relation to the influence of workplace locality.

It is interesting that two of the three survey respondents who did not identify a single benefit of EMR use reported that they worked within the same NHS Trust. Shared local experiences and discussions may have influenced participant perceptions. An association between levels of EMR adoption and ophthalmic practice characteristics has previously been reported<sup>80</sup>. Further work is therefore needed to understand how local professional cultures influence perceptions and adoption of EMRs within NHS paediatric ophthalmology.

#### **2.4.2 EMR adoption in NHS paediatric ophthalmology**

The results suggest that, although there are EMR systems in use within the NHS – indicated by participants reporting some prior experience using an EMR, implementation is far from universal within paediatric ophthalmology, with fewer than one in ten participants using an EMR for the majority of their patients. Considering the limited literature on this topic, this low use rate is not unexpected and may be mirrored in other countries. It is also consistent with usage rates of fully functional, speciality specific paediatric EMRs by reported by paediatricians<sup>117, 118</sup>.

However, the identified EMR implementation rate is lower than that reported in general ophthalmology previously in the UK and internationally. In 2011, a national

survey by the AAO found 32% of practices routinely used an EMR<sup>80</sup>. This figure had almost doubled over the four years following the financial incentivisation of EMR 'meaningful use' in the 2009 Health Information Technology for Economic and Clinical Health Act (HITECH)<sup>119, 120</sup>. In the UK, although at the time of this research there was a national target of a paperless NHS by 2020, there was no equivalent direct incentivisation of EMR implementation, nor a financial driver related to billing for services. Both clinician-driven and top-down influences were identified as drivers for EMR adoption in the survey data. This was not assessed in the online survey and therefore general conclusions cannot be drawn on the role of organisational or socio-political pushes as drivers of EMR adoption; clearly these are potentially very important in driving and shaping EMR content and uptake.

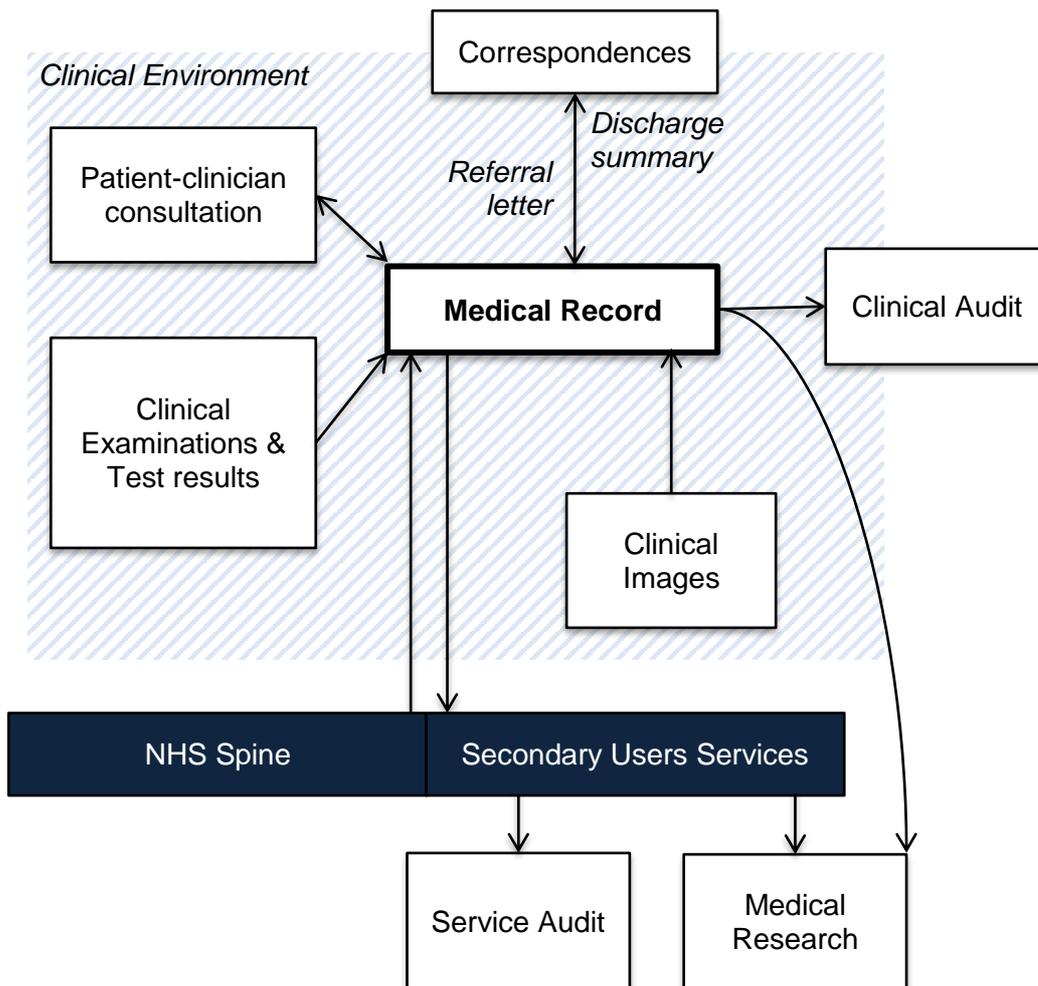
A usage rate of 45.3% of all UK eye units has been reported; however, this work also indicated that the majority of eye units did not use their EMR within paediatric specific clinics<sup>84</sup>, and so the lower estimate reported in this study is not surprising. A range of barriers that spanned the entire EMR adoption process were identified and were likely to account, at least in part, for the low usage rates.

Paediatric ophthalmic clinicians perceived system usability as the biggest challenge preventing EMR adoption. The interviews with clinicians highlighted how a paediatric ophthalmic EMR must cover all aspects of ophthalmic care without overburdening the system user, and be suitably flexible to meet the demands incurred by the patients' varying ages and developmental stages, and clinical needs. A failure to incorporate this into the system design was reported by one individual as a serious risk encountered during an EMR implementation, and was, more generally, likely to contribute to the finding that a majority of respondents identified 'software not meeting clinical needs' as the biggest barrier to EMR adoption.

The costs and availability of technology that integrates with other IT systems were also identified as barriers. The challenge of interoperability is particularly important in ophthalmology, considering the heavy use of diverse imaging and other testing<sup>81</sup>. In the online survey, participants with previous EMR experience were significantly more likely than those without to identify interoperability as a barrier preventing routine use, in contrast to US ophthalmologists for whom the reverse has been reported<sup>80</sup>. This discordance may reflect the differing healthcare systems, with variations in the wider framework of HIT adoption. Implementing suitable technologies and information systems that support full workflow integration requires a good understanding of local workflows and the other technologies in use. User engagement is therefore critical not only throughout system design, but also in the decisions made during the planning and implementation stages of EMR adoption, to ensure local requirements are met.

### **2.4.3 Medical record users and uses**

From the results of the current study and the review of the relevant literature presented in Chapter 1.1 of this thesis (pp.19-38), a wide range of uses was identified for the information stored within medical records that extend beyond the clinical environment (Figure 7).



**Figure 7: Information flows to and from medical records.**

The findings of this study did indicate a consensus that the primary use of medical records is to provide a record of care provision, and users believe this should be the focus of EMR design. However, the impact of EMRs on less obvious clinical uses of medical records – for example the management of patient flows – were identified also as challenges in EMR adoption. The importance of this and any other potential uses required further exploration, and became a priority of the next phase of this PhD research, presented in Chapter 3 (pp.77-137).

### **Secondary data uses**

In addition to considering the barriers clinicians face during EMR adoption, others have called for the use of “facilitators” – i.e. the perceived benefits – to encourage clinical use<sup>79, 121, 122</sup>. The improved data quality, search abilities and analysis of medical record data were seen as the biggest benefits of EMR use within paediatric ophthalmology. This desire for the meaningful use of routinely captured health data aligns with the benefits advertised by the initiatives promoting EMR adoption both internationally and in the NHS<sup>40, 119, 123</sup>, as discussed in Chapter 1 (pp.20-21, 28-32).

The findings of the literature review indicate that medical records do act as a data source for secondary uses in the current information system, forming an important part of both participation recruitment and data collection for some studies. However, both clinical and research users believe the adoption of EMRs would facilitate and improve data re-use.

Process automation was highlighted as a major priority for users. Many research studies still involve paper-based working. Aylward and Parmer reported that a computer programme processed an audit of ophthalmic EMR surgical outcomes in 45 seconds; it took a clinician a total of sixteen hours to complete the same audit manually<sup>85</sup>. However, following the introduction of HIT, process automation, data pre-population and additional copy and paste abilities are believed to contribute to documenting errors<sup>124</sup>.

Ahmed *et al.* compared a generic EMR with a custom-designed interface focused on the specialised tasks and actions clinicians completed in a tertiary care setting, and found the user-centred system decreased the number of data errors and also the time spent documenting<sup>125</sup>. Should this be achieved for NHS paediatric ophthalmology, it may remove the usability barriers identified in this work. First,

however, an understanding must be gained of what tasks clinicians undertake with an EMR and in what context.

Others within ophthalmology have commented upon the problem of the prominence of narrative documentation in a clinical setting, in comparison to the desire for more discrete data capture for research<sup>126</sup>. This theme was not identified in the findings of this study. With audit being a strong priority of clinical users, discrete data capture was recognised as a requirement. Users believed system usability inhibits structured data captured, and should, therefore, be a focus in order for systems to support both audit and research purposes.

#### **2.4.4 Conclusions**

The online survey indicated that, at the time of this research, there was a low rate of routine EMR usage within paediatric ophthalmology in the NHS. The barriers identified by participants highlight the need for a user-centred approach that considers not only the needs and workflows of clinical users, but also the wider IT framework and context of use.

An understanding of the specific tasks and environment in which medical records are used is needed to inform the design of a system that will be suitably flexible to meet the demands of paediatric care, whilst not overburdening users.

## Chapter 3 User analysis

### 3.1 Introduction

#### 3.1.1 User analysis in UCD

The first ISO<sup>99</sup> principle of UCD states that ‘the design is based upon an explicit understanding of users, tasks and environments’ (defined in Chapter 1, p.37). As such, when Johnson *et al.*<sup>127</sup> proposed a user-centred framework for HIT development, user analysis formed the first stage – the authors explained, ‘one of the most important issues in the design of usable applications is to learn about the people who will be using the application’<sup>127</sup>.

User analysis is the process of identifying potential system users, their actions, needs of the technology, and characteristics or attributes that may influence the system design. Following the analysis, users are often grouped and characterised using personas. Personas – initially described by Cooper<sup>128</sup> – are used to generalise groups of users according to the tasks or actions they need to complete using the system, their skills or expertise, and demographic data. Personas are then used to inform the initial system design proposal in an iterative UCD process.

#### ***Contextual design***

Within UCD, many strategies can be used to generate the insights for a user analysis. Contextual design is one user-centred methodology – developed by Beyer and Holtzblatt<sup>129</sup> – that emphasises ethnographic methods of data collection.

Ethnography is an immersive technique that aims to explore and understand the actions of individuals; it is based upon early anthropological researchers’ beliefs that

cultural experience and immersion is key to understanding people<sup>130</sup>. There is, however, no standard definition of an ethnographic approach, only that it encompasses a mix of methods, often including prolonged observational fieldwork<sup>131</sup>.

The contextual design methodology, although derived from ethnography, follows a more formally defined structure. The process begins with a contextual inquiry, in which users are observed and interviewed in context (i.e. in their place of work)<sup>132</sup>. Observations, including analyses of the artifacts in use – as discussed in greater detail in the next section of this chapter (p.79), focus on defining exactly what users do. The interviews, also conducted while the user works, are centred on the observations and aim to explore, with user input, why tasks are performed and in certain manners.

To achieve a structured interpretation of the qualitative data, Beyer and Holtzblatt define several different modeling approaches to consider different aspects of users work and, therefore, provide a holistic view of the factors influencing system usage<sup>132</sup>. Their “work models” include the ‘flow model’ to identify communications and interactions between users, the ‘sequence model’ to break actions down into common sequential tasks, the ‘artifact model’ to explore how users conceptualise and organise their work, and the ‘physical model’ that considers how users are limited or facilitated by their physical environment<sup>132</sup>. Diagrams are typically used to visualise the different work models and facilitate the identification of core design requirements and influencers<sup>132</sup>.

### **3.1.2 Defining the structure and contents of EMRs**

As discussed in Chapter 1 (p.27), recommendations are available to inform the best practice for the design and structuring of the medical records used within the NHS. In the 'Standards for the clinical structure and content of medical records', generic guidance is given for medical record section headings and the child data items to be entered under each heading<sup>52</sup>. Examples of headings include the family history, social history, and examination findings. In this standard, however, it is noted that users and system providers should agree upon the inclusion or exclusion of specific headings, and the order in which they appear within the EMR to ensure the system is appropriate for the specific care settings and circumstances of use<sup>52</sup>.

To engage with this process, EMR system designers require an understanding of how medical records are commonly constructed and formatted. However, it can be difficult for designers with little domain knowledge to efficiently gain user insights in highly specialised fields, such as medicine.

#### ***Sequential data mining techniques***

Artifact analysis – the study of how objects are used and conceptualised by end users – can, by providing an insight into existing information systems, contribute to the contextual inquiry and user analyses<sup>129</sup>. Unsupervised data mining techniques – if applied to the data collected during an artifact analysis of medical records – offer a means to provide insights into clinical documentation patterns, without the need for expert medical knowledge.

Sequence mining is a technique that can be used to compare linear sequences, defined in this work as a set of entities that occur together in a specific order. There are two general aims of a sequence analysis: to identify structural similarities

between sequences, and to identify patterns of items contained within sequences<sup>133</sup>.

A paper-based medical record contains a series of individual data items that, using the order in which they appear on the page, can be considered a sequence. In highlighting common documentation patterns, sequence mining could prove a useful and novel technique for the design of EMR page layouts.

### Sequence alignment

Sequence alignment techniques have been utilised and greatly developed within bioinformatics to understand important features and relationships within groups of DNA and protein sequences<sup>134</sup>. The technique has also been applied to other domains, including marketing and the social sciences, for example in the analysis of life course patterns and trends<sup>135</sup>.

To perform a sequence alignment, first, pairwise comparisons of all sequences within the set are made, to generate a score defining how similar each pair of sequences is. The score represents the minimum sum of transformations required to transform one sequence into the other. Two dimensions are considered when scoring sequence alignments: the state (i.e. if an item occurs in both sequences), and the order (i.e. if the item occurs at the same point in the sequence). A substitution transformation prioritises order, whereas insertions or deletions of items (indels) prioritise the sequence state. The transformations can be given different weightings in the scoring system, depending on the focus of the analysis.

There are often many possible ways of aligning two sequences; these can be visualised using a scoring matrix. Figure 8 provides a worked example of a sequence alignment matrix and similarity score calculation.

Starting in the top left hand corner, the score for each matrix cell is computed. Each cell has three potential values, derived from moving either to the right, down (both of which indicate an indel transformations), or diagonally (a match or substitution). The move that gives the largest or most positive overall score is applied and noted in the cell. The final alignment score is given in the bottom, right hand cell. Trace-back algorithms then work backwards through the matrix to calculate the optimal alignment for the two sequences, with as many like sequence items aligned as possible.

Sequence 1: A B C D  
 Sequence 2: B C A D E  
 Scoring system: +1 match  
 -1 mismatch (substitution)  
 -1 indel

	B	C	A	D	E	
	0	-1	-2	-3	-4	-5
A	-1	-1	-2	-1	-2	-3
B	-2	0	-1	-2	-2	-3
C	-3	-1	1	0	-1	-2
D	-4	-2	0	0	1	0

Alignment output: A B C - D -  
 - B C A D E  
 -1 +1 +1 -1 +1 -1 = 0

Alignment score: 0

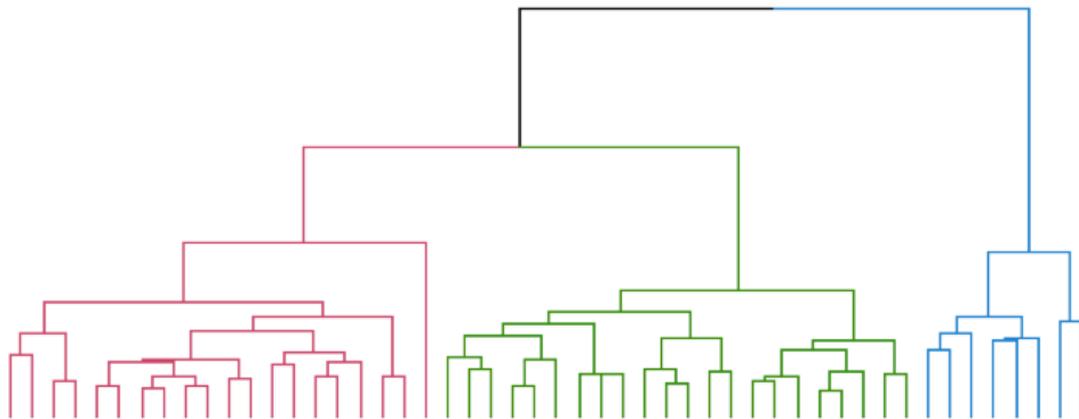
**Figure 8: An example of a sequence alignment matrix using the Needleman-Wunsch algorithm<sup>136</sup>.**

Blue cells indicate the final alignment path, arrows show the trace-back direction and thus the transformation type.

Having assessed the similarity between individual sequences, clustering algorithms can then be used to identify subgroups within the data that share similar sequences, and, often, other predictive variables.

One approach, agglomerative hierarchical clustering, incrementally joins the most similar sequences, as defined by the alignment, to form clusters. This process

repeats, joining similar clusters, until eventually one large cluster is produced. The output of hierarchical clustering can be visualised as a tree diagram, also called a dendrogram. An example dendrogram containing three clusters can be seen in Figure 9.



**Figure 9: An example dendrogram plot produced by hierarchical clustering.**

Example taken from Galili (2017)<sup>137</sup>. Individual sequence sets are spaced along the x-axis, and a measure of sequence similarity along the Y. A horizontal line represents the merger of two clusters; the higher the merger on the y-axis, the greater the dissimilarity of the two clusters. The height of merger links (i.e. level of similarity) should be consistent within distinct clusters. Three clusters (colour coded) can be seen in the example data.

### Sequential pattern mining

A second, complementary data mining technique that is commonly applied within sequence analyses is sequential pattern mining. Here, the aim is to identify frequently occurring subsequences within a set of sequences, which can also be considered as duplication transformations that aren't handled by sequence alignment methods.

In sequential pattern mining, the frequency of a subsequence – termed the support in data mining literature, or the relative support when presented as a ratio or percentage<sup>138</sup> – is given by the total number of sequences that contain the

subsequence of interest within the set. When the support is above a user-defined minimum threshold value (the minsup), the subsequence is considered to be a frequent pattern.

Many frequent sequential pattern mining algorithms are available<sup>139</sup>. As identifying all of the frequently occurring subsequences within a large sequence set can produce a great many solutions, sub-groups of algorithms aim to overcome this limitation and produce a more manageable solution set. Maximal sequential pattern matching algorithms output only the subsequences that, in addition to meeting the minsup criteria, are not contained within any of the other frequent sequential patterns for the sequence set<sup>140</sup>.

As with sequence alignments, the mining of maximal frequent sequential patterns has been applied in many domains including bioinformatics for DNA analysis<sup>141</sup>, and within healthcare to assess patterns in the temporal order of coded procedures undertaken for diabetic patients<sup>142</sup>.

### **3.1.3 Chapter aims and objectives**

A contextual inquiry was undertaken in an outpatient setting at GOSH to address three aims:

- (i) Identify the medical record uses and users, and the common information flows between these users.
- (ii) Define a data set of items routinely captured in outpatient paediatric ophthalmology, and assess its suitability as a data source for research studies.

- (iii) Explore variations in clinical documentation in terms of the timing, physical location, and contents (i.e. the individual data items captured by different users, and the order in which they were recorded).

It was hypothesised that, in combination with qualitative observational data, the application of unsupervised sequence mining techniques to medical record data could provide an EMR designer with an understanding of common documentation behaviours, and inform the structural and content design requirements of medical records.

## **3.2 Methods**

### **3.2.1 Research design**

In this work, the contextual design methodology was followed, employing the recommended mix of methods<sup>132</sup>: an observational time-motion study with informal interviews, and an artifact analysis in the form of a retrospective medical record review. Using these data, the two sequence mining techniques described above were applied.

As in Chapter 2 (see methods on p.45), the data collection and analyses for the various methods were performed in parallel. The findings were then triangulated to inform the research conclusions.

### **3.2.2 Research setting**

This research considered the end users and workflows within the GOSH ophthalmology department. GOSH provides tertiary care for children and, therefore, this research captured the most complex use cases encountered within paediatric ophthalmic clinical care.

Table 2 details the staffing in the GOSH ophthalmology department at the time of this research. As has been described for other hospital eye services within the UK<sup>143</sup>, the optometrists had an extended clinical role: in addition to optometric services (refraction, glasses and contact lens, and low vision assessments), they would also complete other aspects of the eye examination that would traditionally be undertaken by ophthalmologists.

**Table 2: Staffing in the GOSH department of ophthalmology.**

Role	N
Consultant ophthalmologist	11
Junior medical staff (ophthalmology fellow)	4
Consultant electrophysiologist	2
Vision scientist	3
Optometrist	6
Dispensing optician	2
Orthoptist	7
Community link team	1
Clinical nurse specialist	2

Additionally, health care assistants were present in the clinics to assist with dilation prior to clinical examinations, and with managing patient flows.

### **3.2.3 Time-motion study**

#### ***Participant sample***

To recruit participants, a method of ‘snowball sampling’<sup>144</sup> was employed, in which existing participants recommended successive colleagues to be observed who met criteria specified by the observer (MSC). Efforts were made to ensure the sample covered the range of clinical roles and patient groups encountered within the GOSH ophthalmology clinics. Additionally, by reflexively adapting the criteria as the study progressed, the snowball approach ensured any themes identified during data collection could be fully explored with the most knowledgeable participants.

Having discussed the research aims and data collection techniques prior to observation, verbal consent was obtained for all participants.

### **Data collection**

The observational sessions were conducted between February and June 2016, and lasted for half a day. Each session followed the workflow of a single clinician.

#### Timing data

Timing data were collected to identify when, in relation to the patient consultation, clinicians complete their documentation in the medical record.

During clinical observations, the start and end timestamps for predefined events were recorded, as has been described in other published time-motion studies in clinical environments<sup>83, 145, 146</sup>. However, unlike in other studies, to maintain a focus on clinical documentation, only the duration of patient consultations and time spent writing in the medical record were recorded, as defined in Table 3. Additionally, observations were ‘interrupted’ – indicated by recording the timing of a *Session interruption* event – if the clinician left the outpatient environment, to consult with a patient on a ward, for example.

**Table 3: Actions recorded during time-motion observations.**

Event name	Criteria / Description
Patient consultation	Patient within consultation room, even if observed clinician leaves room
Session interruption	Subject leaves the outpatient environment
Write notes	All times the pen is touching the paper record, or the clinician is typing an electronic note for a patient

#### Observational notes and informal interviews

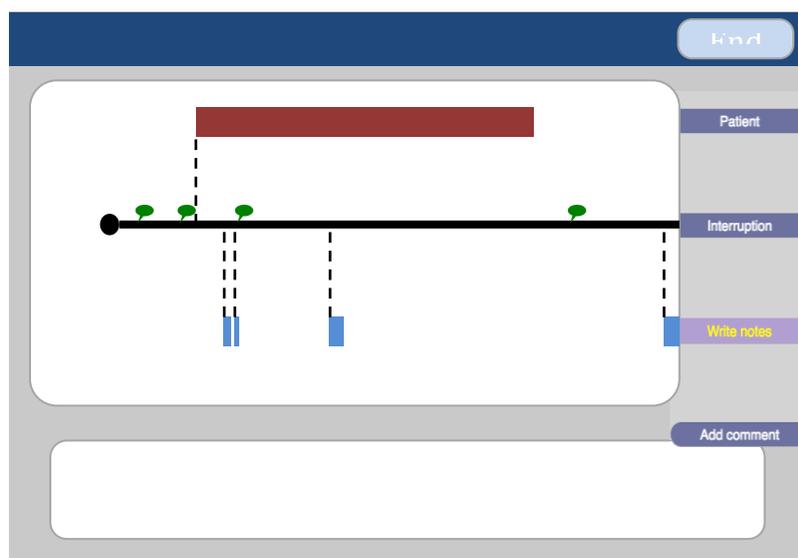
Observations were made and qualitatively noted regarding all interactions with medical records. When the participant wrote in the medical record, observations focused on identifying the note content, the timing of the documentation in relation to the patient’s consultation, and the location the task was completed (e.g. at the desk, on the clinician’s lap, in another clinician’s room).

Additionally, opportunistic, naturalistic interviews were conducted with the participants during observational settings. These interviews aimed to clarify and provide a more in depth understanding of observations, and so were conducted as time permitted, without interrupting the clinic flow. Notes were taken during the interview discussions and recorded alongside the observational notes; these data were captured and processed as a single source.

### Data collection tool

All observational data (quantitative and qualitative) were collected electronically using a handheld tablet device (Microsoft Surface Pro 4). Specialised web-based software was written to capture and visualise these data during observational sessions; Figure 10 provides a screenshot of the software in use.

Initially, before observations began, data describing the session were recorded, including a pseudonym for the observed clinician, their clinical role, and the clinic code. Then, when ready to start recording observations, a button would be pressed to store the date and time that the session commenced, and allow the recording of other observations using the software.



**Figure 10: Screenshot of the software used to collect observational data in use.**

The start and end timing of a clinical event was recorded by pressing the appropriate button, and submitted to a MySQL database using PHP. Active events were indicated through the use of different button stylings and visualised on a scrolling Gantt chart, created using the OpenEyes' EyeDraw framework<sup>87</sup>. Qualitative notes were captured using the textbox located at the bottom of the screen (Figure 10), and their chronology also visualised on the chart, once the comment was submitted to the MySQL database by pressing the *Add comment* event button.

At the end of each session, all patient consultation events could be reviewed and linked when necessary (i.e. if two consultations were observed for a single patient), submitting the unique patients as rows in a Patients data table within the MySQL database. Then, anonymised data describing each of the observed patients (age, gender, clinical problem list) were entered. The database schema is provided in Appendix E (p.245).

### ***Data cleaning and analyses***

Following each session, the qualitative notes were reviewed and corrected for typing errors and clarity; any retrospective changes were enclosed in square brackets for identification. The clean data were then imported into a Microsoft Access database (2013 version), using the same schema as that of the MySQL database (Appendix E, p.245).

#### Qualitative analyses

From the Access database, a report was generated for each session detailing all of the events and qualitative comments recorded. The reports were imported into nVivo<sup>115</sup> in portable document format. Using nVivo, thematic analyses were performed using the notes describing both observations and discussions with

participants. For each clinician observed, the thematic coding process continued until a saturation point was reached, when no additional themes were identified within the data.

Initially, the uses of medical records were coded, with a focus on those uses additional to the recording of a clinician's observations and impressions. Codes were reviewed and grouped into hierarchical themes, producing an affinity diagram, as described by Holtzblatt and Beyer<sup>147</sup>.

Secondly, thematic coding considered the documentation behaviours within three broad themes: the timing of clinical documentation, the location that the documentation took place, and the structure and content of documentation. Once the coding was complete for all sessions, the identified codes were reviewed for synonyms and as before, the prevalent themes identified. These were then considered in relation to the findings from the other methods utilised in this work, to derive models of how medical records are used in the GOSH ophthalmology outpatient clinics.

#### Quantitative analyses

All timing data were summed by patient within Microsoft Access to give the total duration of the patient consultation, the total time spent documenting notes during the consultation, the total time spent documenting before the consultation and the total time spent documenting after the consultation. These timings were considered using both the raw data and as a ratio, using the total patient consultation duration as the denominator.

To assess for a possible association and differences in the timing of clinical documentation between user groups, the summed timing data were imported into SPSS (version 24.0.0.0.) with the clinical role of the documenting clinician, and a Mann-Whitney U test was performed.

### **3.2.4 Artifact analysis – a retrospective medical record review**

#### ***Data source***

Data were obtained from the medical records written in the ophthalmology outpatient clinics at GOSH during a three-week period (October-November 2016). The hospital's patient information management system (PIMS) was used to identify all of the clinic appointments attended during this time; duplicate or double-booked appointments were removed.

The patients' medical records were accessed and reviewed using the electronic document management system (EDM) in use at GOSH. The majority of records were documented using pen and paper and scanned into EDM. However, it was also possible for clinicians to write free text electronic notes directly into the EDM system; both sources were reviewed and included in this study.

#### ***Data collection***

The medical record review was completed chronologically, in the order of PIMS appointments. The individual data items that were documented within the patient's record for the specified appointment date were identified.

Patient demographic data (hospital number, NHS number, names, date of birth, and gender) were not included as data items as they were either attached to the paper record using a generic patient label or were part of the page header for the electronic notes, and so, generally, were not recorded by the documenting clinician. Diagrams were recorded as a single data item, for example 'fundus diagram'. Any items documented multiple times, including for each eye, were recorded as sequential items.

The data items were grouped into item sets that represented the list of fields documented by a single clinician for one patient during a clinic visit. Items were ordered within each set as they appeared in the medical notes, reading from left to right and down the page.

The item sets were also grouped by patient and by date to form clinic visits. One patient may have been associated with multiple sets from a single clinic visit, if they saw multiple clinicians in one day. If a patient consulted with the same clinician multiple times during the visit, the data items were grouped within a single set, however, the different consultations and the order in which they occurred were noted.

For each set, the following data were recorded: the type of consultation (electrodiagnostic tests (EDTs), orthoptics, dilation, imaging, optometry, low vision assessment (LVA), fellow, or consultant), a pseudonym for the documenting clinician, and their clinical role as listed in Table 2 (p.86). A consultation rank value was also assigned to represent the chronological position of the consultation within the clinic visit.

Additional patient data were collected for each medical record reviewed, including the age at the time of the review in full years, gender, the clinical problem list as stated in the most recent clinic letter or referral documents, and whether it was a new or follow up visit. The new patient indicator was manually identified from previous clinic letters in EDM. If a patient had been seen in the department before but was discharged and re-referred, or was referred to another consultant, the patient was considered new for that clinic visit.

All data were stored using a Microsoft Access relational database (2013 version); all personal patient data were pseudonymised prior to being entered into the database.

The database schema, including a description of all of the data variables that were captured during this study, can be found in Appendix F (p.246).

### ***Data validation***

To assess the suitability of a non-clinical reviewer in collecting data from medical records or the first six sets of medical records, a consultant ophthalmologist (CE) repeated the data extraction process for the first six clinic visits identified in PIMS. In duplication, CE reviewed and extracted the data from six sets of medical records. The sets produced were reviewed and compared to highlight any subjectivity or initial errors in data collection; these were discussed and corrected before proceeding with the study.

### ***Data cleaning and analyses***

**Table 4: Diagnostic categories assigned to patients included in the medical record review.**

<b>Category name</b>
Adnexal / globe malformation
Anterior segment (cornea, cataract)
Uveitis
Neuro-ophthalmology
Retina
Strabismus, amblyopia and refractive error
Glaucoma
Craniofacial
Multi-system

The patients' clinical problem lists were found to be extremely heterogeneous and variable in length, and so a new variable was created: the patient's "diagnostic category". The problem list for each patient was reviewed by a consultant paediatric

ophthalmologist and assigned a primary diagnostic category from a predefined list (Table 4).

#### Missing data

Missing data were considered at the clinic visit level. The PIMS appointments where no consultation record was found in the EDM notes were grouped by patient and appointment date, to form single clinic visits.

At GOSH, the report for EDTs is created electronically and saved as an investigation result in the medical record, separate to the clinical notes in EDM. Unless the clinician additionally wrote in the medical record, it is possible these appointments were missed during the record review process. Therefore, once the record review was complete, the investigation reports for patients with a missing EDT appointment were also reviewed. If a report was found, the EDTs were entered into the database as the first consultation for the patient (as was the typical clinic flow), and the visits were not classed as missing, although no item sets were generated for these consultations.

The remaining visits with no corresponding consultations were defined as the missing data. These data were compared to the captured data using descriptive statistics, performed with SPSS version 24.0.0.0.

#### Consultation analyses and information flows

Using a query within the Microsoft Access database, the median number of consultations per clinic visit was calculated, and the frequency of each type of consultation and the order that they appear within clinic visits were considered. The SPSS software (version 24.0.0.0.) was used to test for an association between the type of consultation and its chronological ranking within the clinic visit; the Fisher's exact test was used.

Next, the information flows within the clinic were considered using the transitions between consultation types to represent transitions between medical record users. Within the Access database, all consultations were ordered chronologically according to the consultation rank variable, and by clinic visit. A Visual Basic for Applications (VBA) module was written to transpose these data to a new data table within Microsoft Access that described the transitions between each consultations and the start and end of the each clinic visit. An example of the data generated can be seen in Table 5 for a patient who, in a single clinic visit, consulted with an orthoptist, was dilated by a HCA, and then saw a consultant.

**Table 5: Example of consultation transition data.**

Clinic visit ID	From	To
1	Start visit	Orthoptics
1	Orthoptics	Dilation
1	Dilation	Consultant
1	Consultant	End visit

Within Microsoft Access, frequencies of the distinct transition types were calculated. To identify common information flows, transition data were then exported and visualised as a directed network graph using Cytoscape, version 3.5.1 for Mac OS X<sup>148</sup>. The graph was qualitatively assessed.

#### Maximal data set definition

After the data collection period, all of the data items identified from medical records were manually reviewed. Synonyms were removed from the data set and, where appropriate, data items were renamed in line with the standardised guidance<sup>52</sup>. The list of unique data items then provided the definition for the maximal set of routinely collected data items in the GOSH ophthalmology outpatient clinics.

To assess the suitability of these routinely collected items as a data source for research, a cross mapping was performed: the maximal data set identified in this

work was compared to the data set collected as part of a national epidemiological study – the British Childhood Visual Impairment Study 2 (BCVIS2).

BCVIS2 aimed to determine the incidence, context of detection, causes, management and short-term health and social outcomes of all-cause childhood visual disability. Therefore, the data that were collected in the study spanned the breadth and depth of paediatric ophthalmic care. Both ophthalmologists and paediatricians submitted data to the study; to maintain a focus on paediatric ophthalmic EMRs, the research data set for this analysis was identified from the initial BCVIS2 data collection form for ophthalmologists only.

All questions within the data collection form were reviewed and rephrased to form clinical data items. A simple mapping between the sets was performed manually, primarily to identify exact data item matches. However, when an exact match could not be found, research items were mapped to items in the maximal clinical set that included the variable of interest in addition to other information (i.e. a broader, parent item).

#### Documentation patterns

Using a Microsoft Access query, all data items were mapped to numerical keys, grouped by consultation and exported from the database. This produced a list containing sequences of numbers; one sequence – termed a consultation item set – represented all of the data items recorded for a single consultation in the order that the data appeared on the page within the medical record.

It was hypothesised that the design requirements for an EMR interface would differ based on the clinical role of the user, as to reflect the various clinical examinations performed within consultations of different types and, therefore, the different data item sets that each user group would need to capture. The following analyses aimed to identify if there were any trends associated with the data items written

within medical records and the type of consultation or the individual patient concerned. Analyses focused upon the sequential order in which items were recorded within consultation sets, in order to inform page layout designs.

Initially, using descriptive statistics, the lengths of the consultation item set sequences were considered. A Kruskal-Wallis test was performed using SPSS (version 24.0.0.0), to test for evidence of an association between the sequence length (i.e. the amount of data that was recorded) and the consultation type.

Then, sequence mining techniques were used to identify patterns in the order in which data items were recorded. An adaptation of the Needleman-Wunsch algorithm<sup>136</sup> was written in perl and used to calculate pairwise similarity scores between all sets, based on the data item sequence. A crude scoring algorithm was used: a data item match scored +1, and both a mismatch (substitution) and a gap scored -1 (indel). Using the resulting similarity scores, an agglomerative hierarchical clustering was performed to identify subgroups of consultation sets that contain similar sequences of data items. MATLAB 9.2 R2017b for Mac<sup>149</sup> was used to complete the cluster analysis employing the average linkage function, and to produce a dendrogram to visualise the results. The accuracy of the dendrogram in reflecting the underlying data (the pairwise distances) was measured in MATLAB using the cophenetic correlation coefficient<sup>150</sup>.

Clusters within the dendrogram were qualitatively assessed and defined. For each consultation item set, a nominal cluster membership variable was assigned to represent its placement within the dendrogram. To identify any if any consultation or patient-level variables influenced the clustering and, therefore, the sequential structure of the consultation items sets, SPSS (version 24.0.0.0) was used to test the evidence of any associations between cluster membership and those variables listed in Table 6. As appropriate, the chi-square, Fisher's exact, or Mann-Whitney U

tests were performed to compare the major clusters identified within the sequence data.

**Table 6: The variables considered when assessing potential influences driving the clustering of consultation item set sequences.**

Variable
Patient age
Patient gender
Patient diagnostic category
New patient visit
Clinic visit date
Clinic code
Consultation type
Chronological consultation rank within visit

Finally, pattern mining techniques were applied to identify short sequences of data items that were commonly recorded together within and between consultation item sets. The vertical mining of maximal sequential patterns (VMSP) algorithm<sup>151</sup> was used, using the SPMF open-source data mining library (version 2.21)<sup>139</sup>, to identify maximal frequent patterns of sequential data items.

During the pattern analysis, a minsup value of 0.05 was used, meaning that the sequential patterns had to occur in a minimum of 5% of the consultation item sets. The patterns were also limited to those that contained three or more items with no gaps; no maximum pattern length was defined. The resulting frequent sequential patterns were manually reviewed in comparison to the observational notes from the time motion study to identify distinct clinical tasks. When necessary, the sequences were subdivided to ensure each frequent pattern represented a single clinical task.

### 3.3 Results

#### 3.3.1 Data overview

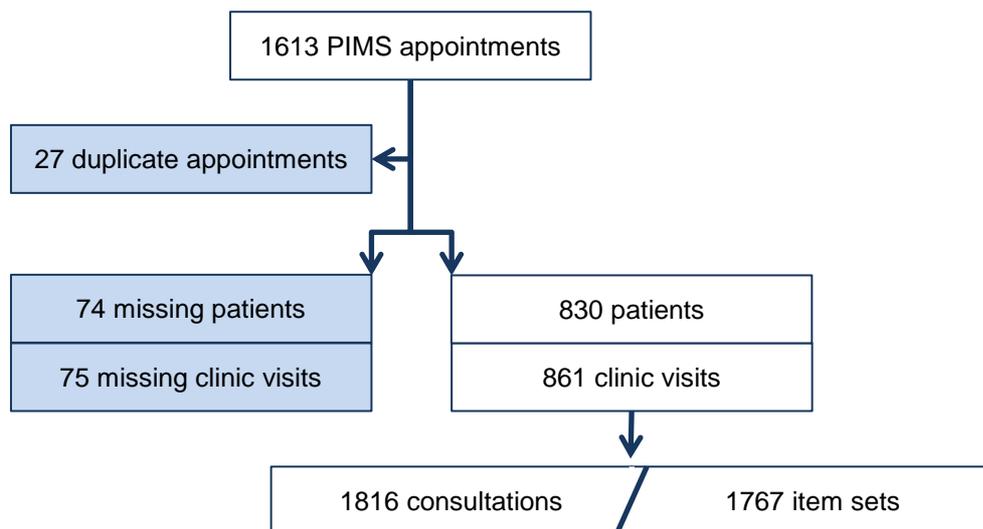
##### *Time motion study*

A total of 135.9 hours, spread over 39 sessions, were spent observing the GOSH ophthalmology outpatient clinics. Eleven clinicians, including a mix of consultants, optometrists, and orthoptists, participated in the study (Table 7).

**Table 7: Characteristics of observational sessions undertaken during a time-motion study of the GOSH ophthalmology outpatient clinics.**

Participant role	N participants	N sessions	N patients
Consultant	5	20	159
Optometrist	3	10	52
Orthoptist	3	9	38
<b>Totals</b>	<b>11</b>	<b>39</b>	<b>249</b>

##### *Medical record review*



**Figure 11: Flow chart of the data obtained from the GOSH PIMS database and the subsequent record review.**

Data excluded from the analyses are indicated in blue.

As seen in Figure 11, 1613 appointments (27 duplicates, 1586 unique) were identified in the GOSH PIMS database as having been “attended” during the three-week period of interest. From these appointments, 830 patients’ records were found and reviewed, giving 861 clinic visits. Thirty patients visited the clinic on multiple dates; one patient had three clinic visits and the remaining 29 had two.

Table 8 provides a summary for all of the attended clinic visits. Individuals with multiple clinic visits were counted multiple times, once for each visit they attended. For three of these patients, the additional visits were not recorded in PIMS – explaining the minimum value of zero for the number of booked PIMS appointments per clinic visit seen in Table 8 – but were identified whilst reviewing the patients’ record and included in this study.

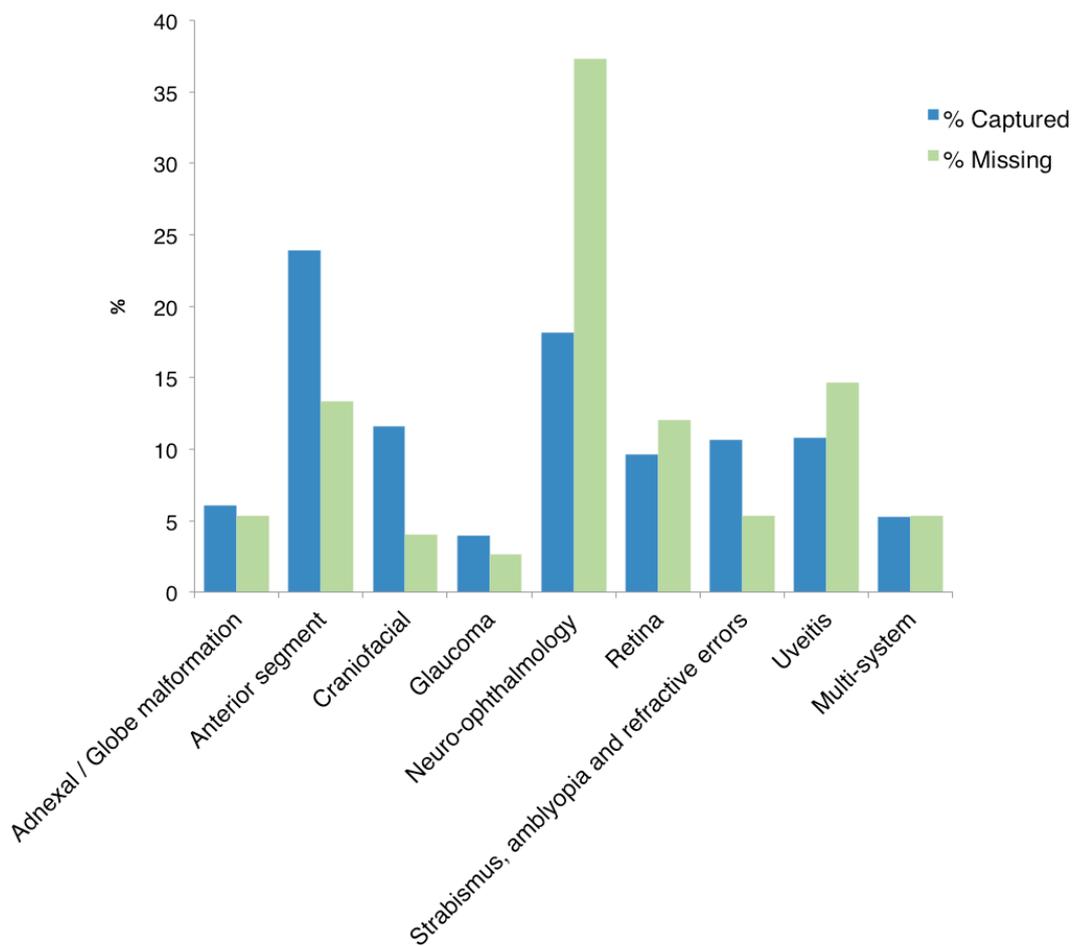
**Table 8: Summary of clinic visit characteristics, comparing captured and missing data.**

P values were calculated using the Mann-Whitney U test for continuous variables (age and number of PIMS appointments), and the Chi square test for categorical (gender and new patients). Applying the Bonferroni correction,  $p \leq 0.0125$  was used as the threshold for statistical significance.

	Captured	Missing	P value
<i>n</i>	861	75	
Median age in years (range)	6 (0-19)	7 (1-18)	0.530
Female (%)	428 (49.7)	39 (52)	0.704
New patient (%)	113 (13.1)	16 (21.3)	0.048
Median number of booked PIMS appointments per visit (range)	2 (0-4)	2 (1-3)	0.849
Median number of identified consultations per visit (range)	2 (1-5)		

The patient diagnostic categories in the sample did not have an even distribution. The majority (23.9%) had disorders of the anterior segment, followed by neuro-ophthalmology (18.1%). Only 3.9% of clinic visits were for patients with glaucoma, 6.0% adnexal and 5.2% had multiple systems involved. However, in addition to a

primary diagnostic category, a further 3.1% were classified as having other systems involved.



**Figure 12: Patient diagnostic categories as a percentage of total clinic visits for captured and missing data.**

#### Missing data

75 of the total 936 clinic visits identified were missing (8.01%). For 26.7% of these ( $n=20$ , 2.1% of the total number of clinic visits), no record of care was found – either in the clinic notes or a clinic letter – despite someone having entered that the patient was in attendance in PIMS.

When comparing the captured and missing clinic visits, the patient demographic data were similar (Table 8). However, the distribution of the diagnostic categories varied greatly. 37.3% of the missing patients were assigned a primary diagnostic category of neuro-ophthalmology, in contrast to 18.1% of patients in the captured clinic visits group. The proportions of patients with uveitis and retinal disorders were also increased in the missing visits, whereas those with craniofacial and anterior segment related disorders were greatly decreased (Figure 12).

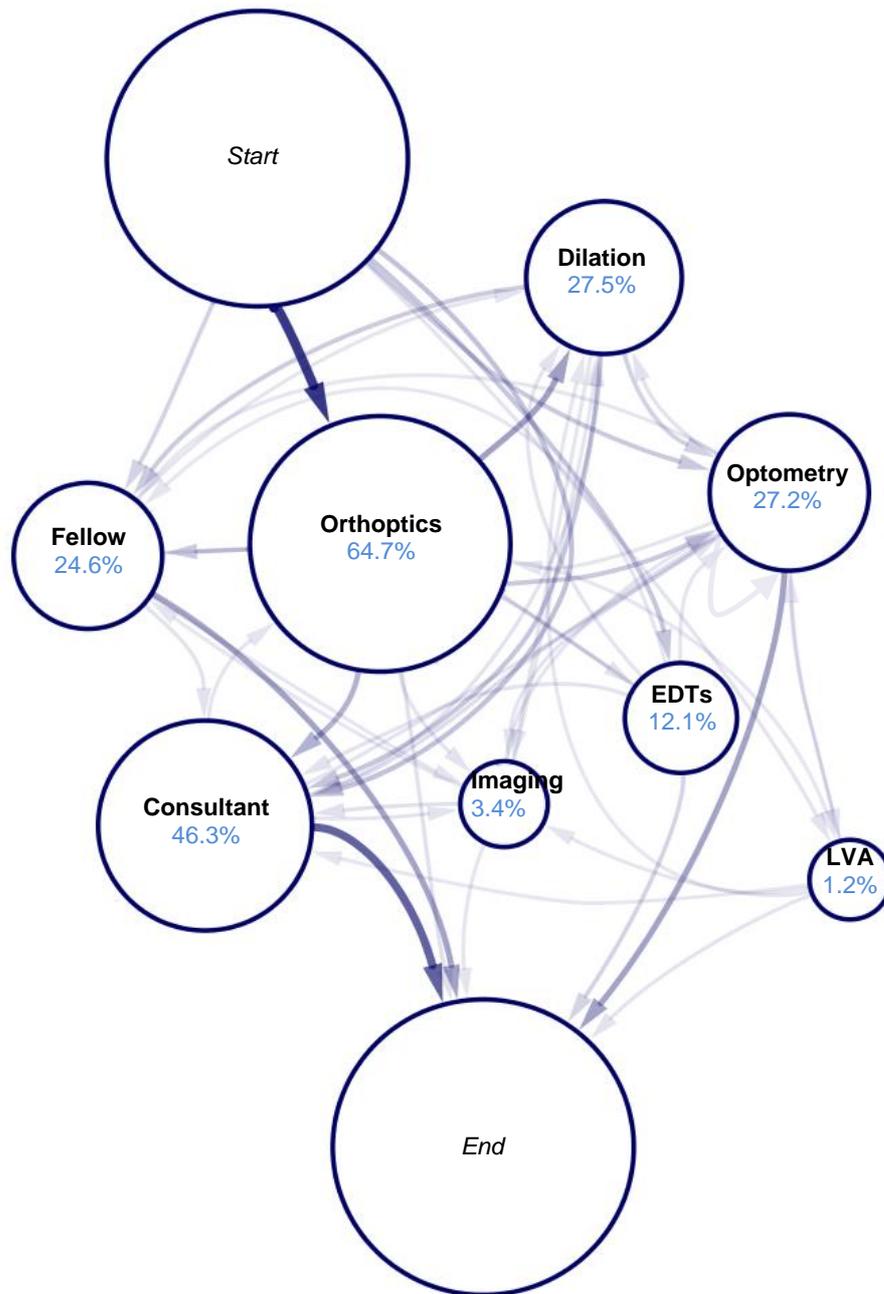
### **3.3.2 Clinical consultations**

#### ***Consultation characteristics and transitions***

As indicated in Table 8, patients encountered between one and five clinical consultations during their clinic visit (median 2). 64.7% of clinic visits included an orthoptic consultation. This was the most frequently observed consultation type, followed by the consultant (46.3%, Figure 13).

In 34 of the clinic visits, a patient had two consultations of the same type. 47.1% of these consultations were with a consultant ( $n=16$ ), 41.2% an optometrist ( $n=14$ ), and 11.8% with a fellow ( $n=4$ ). In one instance, the two optometry consultations were sequential, producing the looping arrow seen in Figure 13. The patient had a clinic appointment with an optometrist and was then seen by a different optometrist for a contact lens assessment. In the other 33 cases, the two repeated consultations were divided by another consultation type, for example dilation or imaging.

More generally, there were no obvious, common pathways identified between consultations within clinic visits (Figure 13).



**Figure 13: The user flow model<sup>132</sup>: transitions between outpatient consultations, as mapped from medical record data.**

Node size is proportional to the number of consultations of each type, the edge width and transparency are proportional to number of transitions between the linking nodes, and the arrows specify transition direction. Percentages indicate the percentage of clinic visits that that included the consultation type.

54 distinct transitions were identified between the different consultation types. Similarly to the most common consultation types, the most frequent transitions were from the start of the clinic visit to orthoptics (19.1%,  $n=511$ ) and from a consultant to the end of the clinic visit (14.5%,  $n=387$ ). Each of the other transition types represented less than 7.6% of the total number.

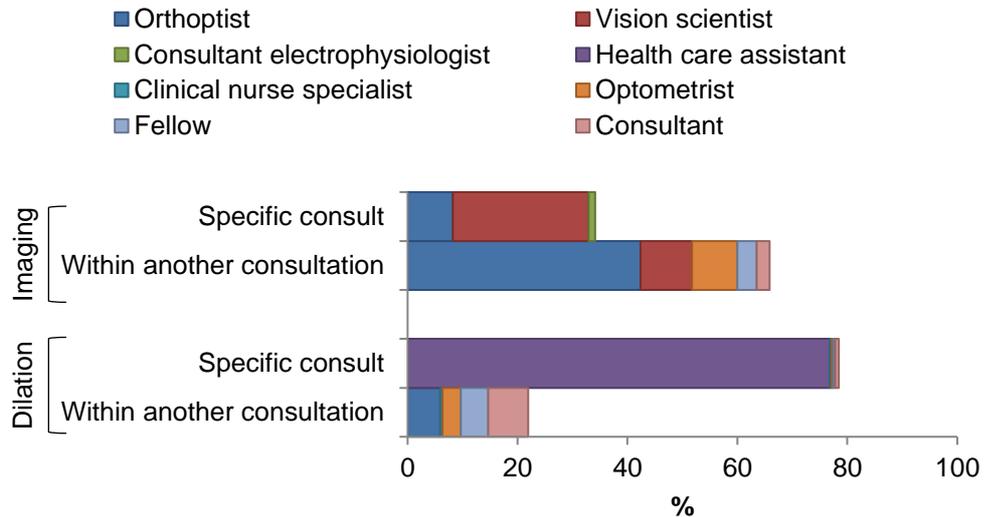
Despite the range in the number of consultations identified and also, therefore, the maximal consultation rank per clinic visit, a statistically significant association was found between the consultation type and the chronological consultation rank ( $p<0.005$ ) using the Fisher's exact test. EDTs, orthoptics and LVA consultations commonly occurred early on during the clinic visit, most frequently first, whereas dilation and imaging were unlikely to be the first consultation type (Table 9). Optometry, consultant or fellow consultations were often the last consultation in the visit, but could also occur early on in the visit.

**Table 9: Consultation type and rank cross-tabulation.**

		Consultation rank					Total
		1	2	3	4	5	
% within consultation type	EDTs	95.2	4.8	0.0	0.0	0.0	100
	Orthoptics	92.1	7.9	0.0	0.0	0.0	100
	LVA	70.0	30.0	0.0	0.0	0.0	100
	Optometry	33.9	34.7	26.6	4.8	0.0	100
	Consultant	26.7	38.1	24.8	9.2	1.2	100
	Fellow	25.9	32.4	38.0	2.8	0.9	100
	Dilation	0.4	85.2	13.5	0.8	0.0	100
	Imaging	0.0	48.3	34.5	17.2	0.0	100

For imaging and dilation events, the clinical role of the documenting clinician is not explicit and was found to vary (Figure 14). The majority of dilation events (76.8%) were documented by a health care assistant as part of a specific dilation consultation. However, consultants (0.66%), optometrists (0.33%), fellows (0.33%) and clinical nurse specialists (0.33%) were also found to have noted a dilation

specific consultation. This was rare within the data set, but if the clinician also undertook other clinical assessments the consultation would not have been classified as a dilation, as observed in 22.0% of all dilation events (Figure 14).



**Figure 14: Proportions of clinicians undertaking imaging studies and dilation, comparing specific consultations and other consultation types.**

Percentages indicate the proportion from all events observed, whether during a specific consult or another consultation type.

Imaging studies were more frequently undertaken as part of another consultation (65.9%) instead of within a specific imaging event (34.1%). In both cases, the most common role of the documenting clinician was an orthoptist or a vision scientist. Within the specific imaging consultations, 72.4% were completed by a vision scientist, 24.1% an orthoptists and 3.4% a consultant electrophysiologist. Imaging studies were also documented by orthoptists (64.3%) and vision scientists (14.3%) within the other types of consultation, in addition to optometrists (12.5%), fellows (5.4%), and consultants (3.6%).

Observational data indicate that, in some cases, the clinic flows may have been more complex than the medical record data suggests. Figure 15 depicts a case-matched comparison of the two data sources. Although the two cases do not represent the same clinic visit and so may have differed, the example shows how some consultations – in this case, one with a consultant – may not have been recorded in the medical records if no observations were noted by the individual.

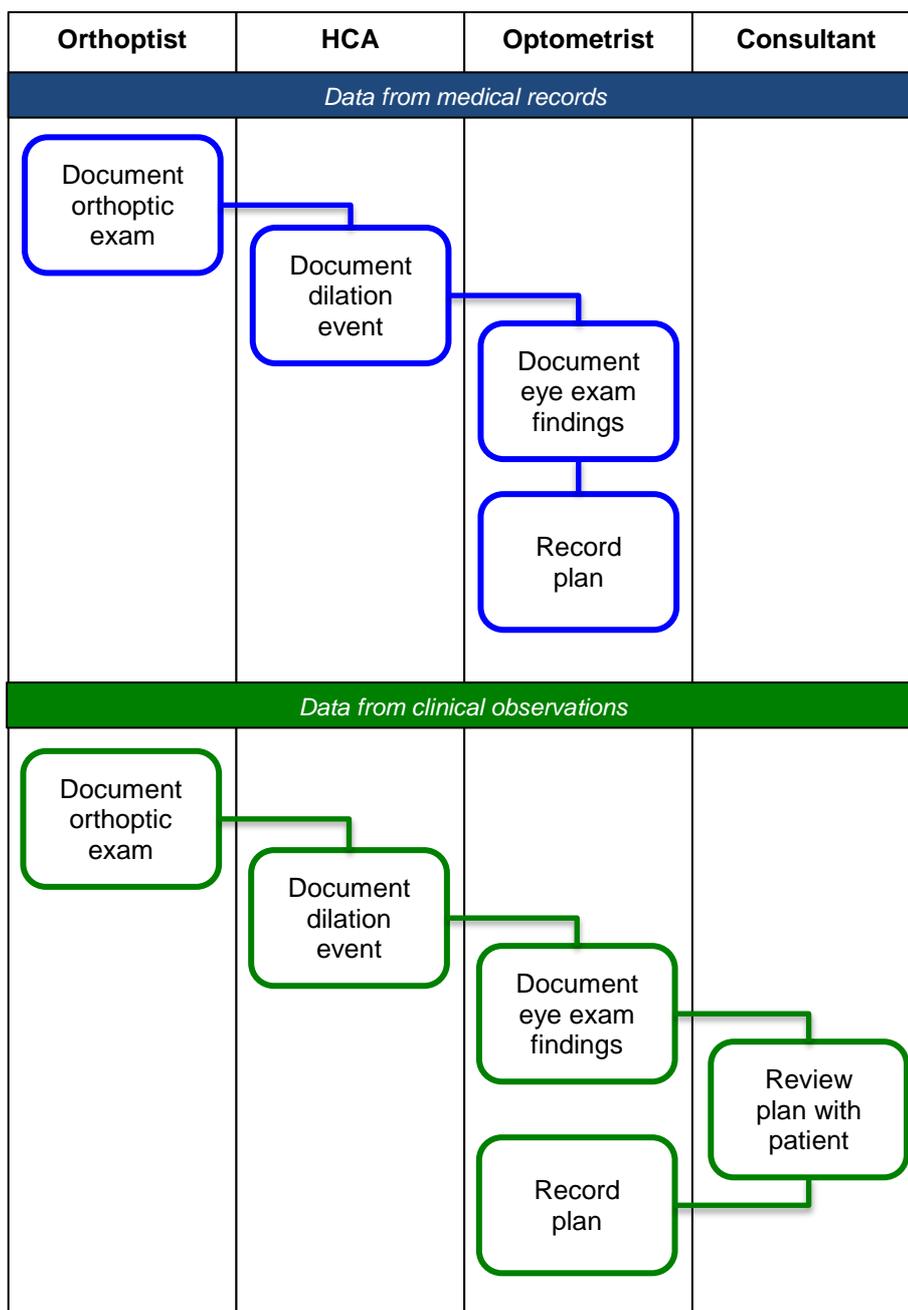


Figure 15: A comparison of consultation flows identified from different data sources.

In such cases, the clinician who undertook the main eye examination was often seen to document that the patient was 'seen by [X]', or 'discussed with [Y]' within their clinic note.

### ***The uses of medical records***

In addition to documenting the events and findings of the clinical consultations – the specific aspects of which are expanded upon in greater detail later in this chapter (pp.110-128), medical records were observed to play a key role in the transitions between clinical consultations. An affinity diagram detailing these uses can be seen in Figure 16.

One key theme was the role that the physical artifacts – regardless of the content of the medical record – had in managing patient flows, specific examples of which can be seen in Figure 16. Cases were also observed in which the file containing a patient's medical record was missing and, although single sheets of paper were used for documenting the findings of the visit, it was not obvious that the patient was waiting to be seen, resulting in delays in the patient's clinic visit.

The medical record was also used as a tool to communicate findings, both with patients and with colleagues, aiding management. The portability of paper notes was also seen to be an advantage here. Often, clinicians would take a medical record to the consultation room of a colleague, to accurately share their findings and to prompt discussions surrounding the patient's history and management plans, for example if the patient had previously had genetic testing or was certified. Users would record these discussions and plans in the medical record, often whilst away from their desk.

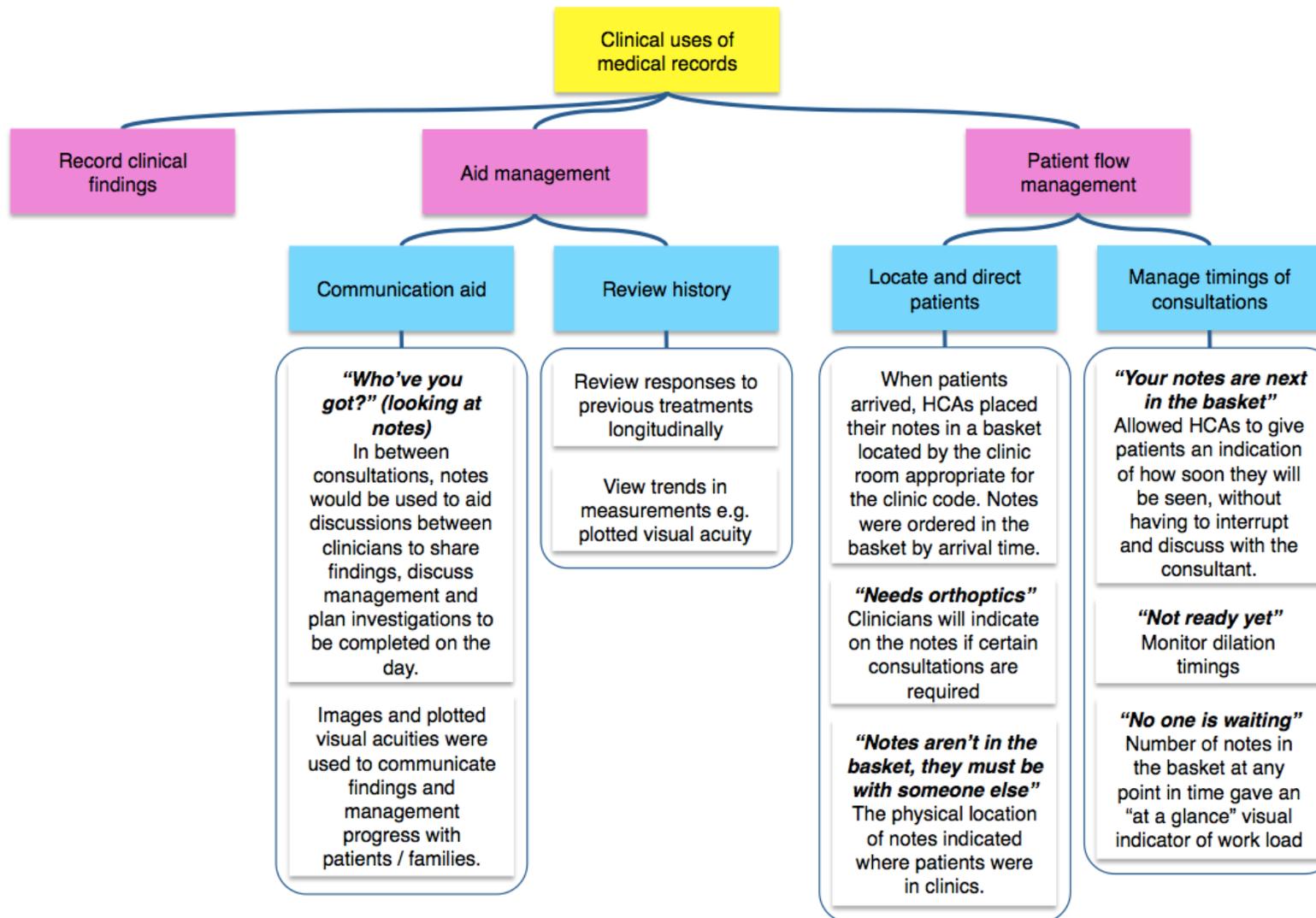


Figure 16: An affinity diagram derived from a contextual inquiry of medical record usage in the outpatient setting.

Items in the lowest hierarchy (white cards) are examples of the data and codes used to generate the higher-level themes.

### 3.3.3 Using medical records to record clinical findings – the maximal set of routinely collected data

274 unique data items were identified during the medical record review. The documentation frequency of the individual data items within this maximal set varied greatly; Table 10 lists the most frequently observed items within medical records.

**Table 10: The most frequently documented items within the maximal set.**

When ordering items by frequency, the top 5% are listed. The frequency is the number of times an item was identified when reviewing all outpatient medical records written over a three-week period.

Data Item	Frequency
Visual acuity (distance)	1857
Cover test findings	996
Symptoms	878
Optic disc drawing	864
Management plan	809
Testing method (distance acuity)	722
Intraocular pressure	696
Testing conditions (distance acuity)	664
Optic disc comments	658
Visual acuity (near)	648
Retinoscopy power cross drawing	597
Timing of follow up appointment	571
Patient's age	564

Some data items were only observed once within the maximal set. These included a contact address for a social worker and a visual impairment teacher, a recent travel history, and some specific orthoptic findings that did not form part of the routine examination, such as the Bielschowsky head tilt test.

### ***Research support***

57 items were identified in the BCVIS2 data collection form, seven of which were classed as demographic data and excluded from the mapping. Of the remaining 50 items, 31 exact matches (62.0%) were identified from the maximal set of routinely collected data.

Six additional items were partially matched with a routinely collected data item as the meaning could be inferred or computed from another field. Five of these were specific event dates, for example the *date of first eye examination* or the *date of visual field assessment*, which could be inferred from the date of an appointment or corresponding date for the medical record entry. The sixth – the *best-achieved visual acuity*, could also be computed to be the lowest value recorded.

For 6 research items (12%), there were no corresponding or similar items within the routinely collected maximal set, and therefore were not routinely collected in the GOSH outpatient clinics. These included the reason why a patient had not been certified as having sight impairment, and the main cause of sight impairment.

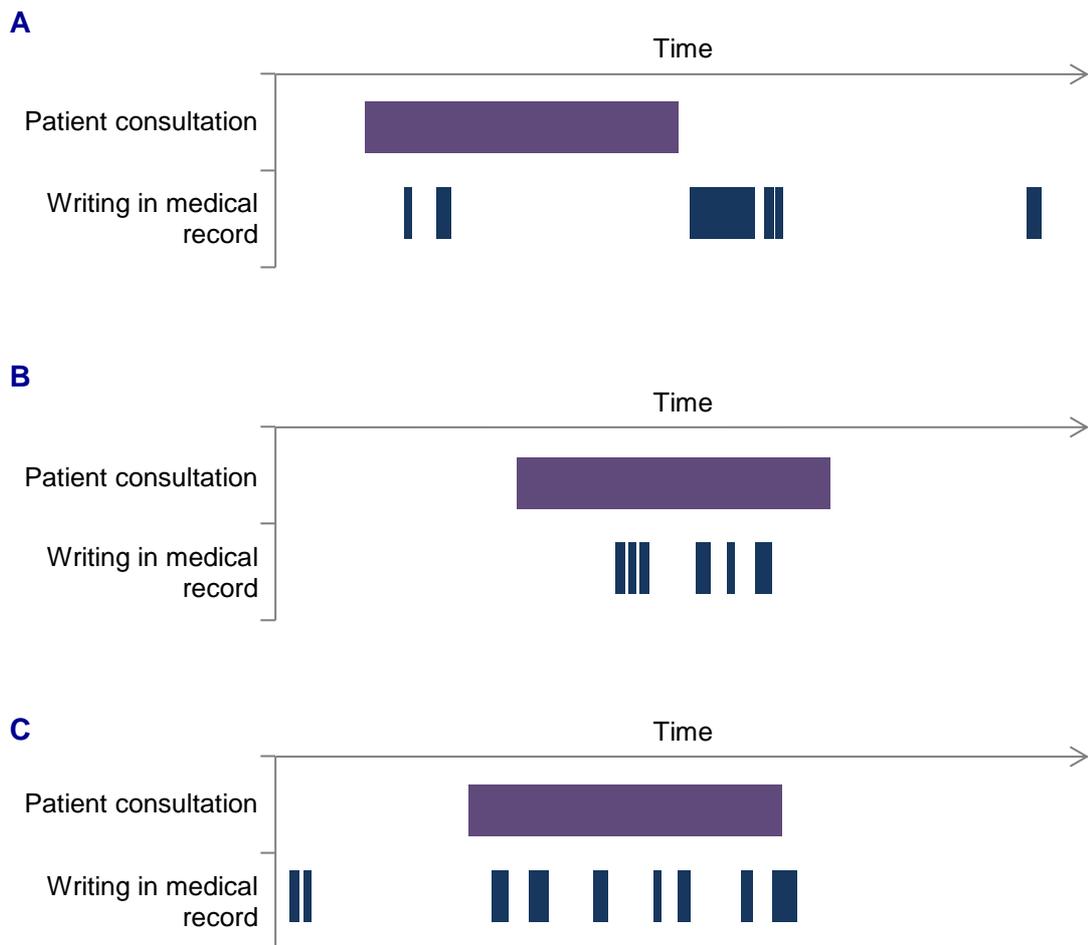
### **3.3.4 Variations in clinical documentation**

#### ***Documentation behaviours***

##### The timing of clinical documentation

When considering the timing of clinical documentation, three different behaviours were identified from the time-motion study; an example of each behaviour can be seen in Figure 17. In general, clinicians tended to either complete the majority of the clinic note after the patient consultation (Figure 17.A), or they would write the clinic note during the consultation (Figure 17.B). Often, with orthoptists, the note was

completed once they had discussed their findings with the consultant who was also due to see the patient; an example of this behaviour can be seen in Figure 17.A, where a discussion between clinicians resulted in a time delay before the final entry into the medical record was written.



**Figure 17: Different documentation behaviours.**

In all three examples, timing data have been normalized using the patient consultation durations to allow for comparisons of behaviours.

**A:** Writing the majority of the clinic note after the patient consultation. **B:** Writing the majority of the clinic note during the clinic visit, as observations are made. **C:** Summarising relevant historical data before the consultation begins, and then continuing with the documenting behaviour as seen in (B).

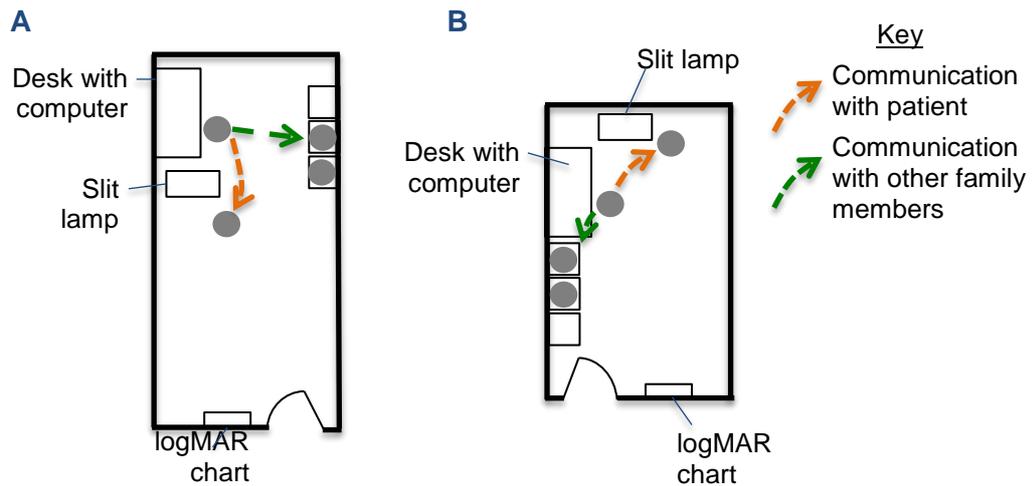
In one user, an additional behaviour was observed: prior to seeing a patient, the clinician spent time reviewing the patient's medication history and writing a summary table in the medical record (Figure 17.C). The rest of the documentation was then completed following behaviour (B).

There was no evidence of an association between the proportion of time spent documenting the medical record during a patient consultation and the clinical role of the observed clinician ( $p=0.861$ ). It can be assumed that the timing of clinical documentation was, generally, a preference of individual users, although other influencing factors such as the room layout and accuracy required for specific data items are in subsequent sections of this chapter.

#### The location of clinical documentation

Variations in how and where clinicians completed their clinic note were also observed. Some users tended to complete their clinic note in their laps whereas others wrote in the medical record at their desk. These behaviours were not unrelated to the different timings of documentation, discussed above. For example, if a clinician wrote the majority of their note during a consultation they may not use their desk as, for some users, turning to use a desk was considered off putting. Users explained that they didn't want to interrupt the consultation to write in the medical record, with concerns regarding patient waiting times and needing to maintain the attention of young children.

Different room layouts in the GOSH ophthalmology outpatient clinic did lend themselves to different behaviours, as modeled in Figure 18, highlighting the importance of the environment in medical record usage.



**Figure 18: The physical model<sup>132</sup>: schematic diagrams of different consultation spaces, indicating the influence of room layout on communication.**

**A:** An example clinic room in which a user would have to turn away from the patient and family to use the desk, and so had the notes in their lap whilst documenting. **B:** An example clinic room in which the clinician could use the desk and still communicate with the patient or their family.

Currently, the computer already plays a role in consultations where the clinician wants to discuss the findings of imaging with the patient. The ability to do so was limited to certain clinic rooms at GOSH; in other cases, a print out of the imaging would have been used. Therefore, even with the paper-based medical record, some users had experience including a computer in their workflow, although this was variable depending on where they conducted the majority of their consultations.

### ***Structural patterns within the medical record***

When discussing the order of the documentation with users, the majority indicated that medical records should have a logical structure, reflective of the order in which clinical assessments are performed. One consultant explained that, for the eye

examination, the order should move posteriorly through the eye, from the lids to the retina.

Upon clinical observation, however, it was clear that the order in which assessments were completed did vary between consultations. This was often due to the temperament of the patient but other reasons were also noted, such as a consultant suggesting a fellow undertakes an additional test with the patient.

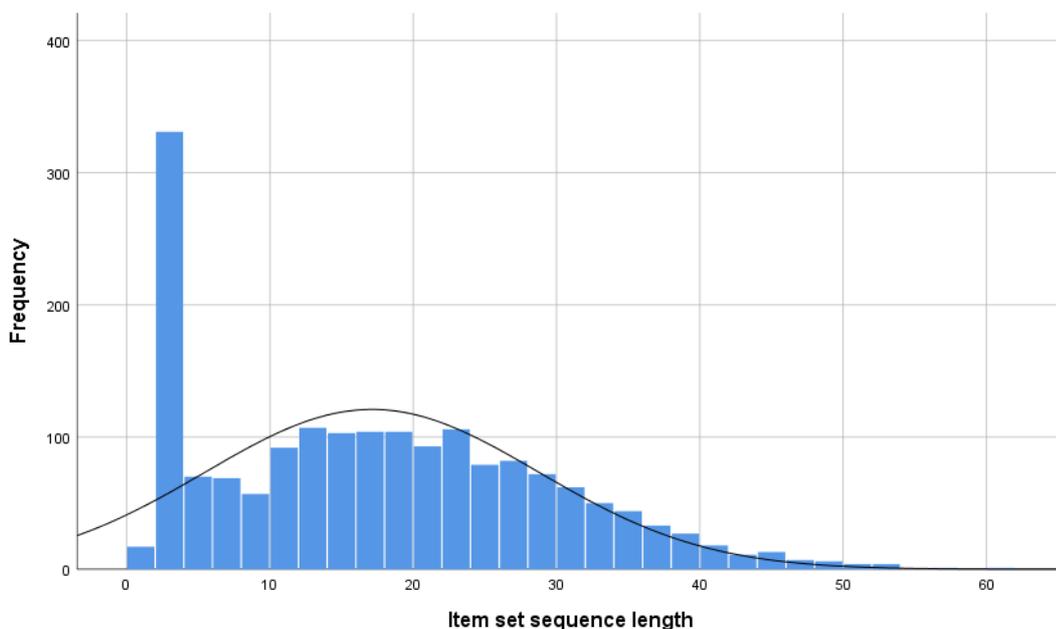
Despite these variations in the order in which clinical assessments were made, clinicians still tended to document their findings in the expected, logical order on the page. For the users who completed their clinic note during the consultation, this often meant subsequently inserting items in the desired location on the page so, in addition to not reflecting the order the tests were completed, they also did not necessarily reflect the order in which they were written. The users explained that this behaviour enabled other clinicians to easily locate the relevant information contained in the medical record at subsequent visits or consultations; users, therefore, prioritised the long-term readability when structuring the medical record.

Another situation in which clinicians documented their findings in a different order to the final reading order on page was observed only in those users that tended to complete their clinic notes after the patient consultation has ended. To ensure accuracy of the medical record, often the numerical findings – such as the intraocular pressure or a glasses prescription following a refraction – were noted as they were measured. This behaviour means that even though the majority of the note is written outside of the consultation, some time spent writing was nearly always observed during the consultation too, as exemplified in Figure 17.A. In these cases, users would often place the numerical data items on the page in the expected space, for example the intraocular pressure would be placed approximately halfway down the page. Then, once the patient has left the

consultation room, the clinician would document their other findings and observations above and below those noted during the examination, maintaining the desired page order and readability whilst also considering the record accuracy.

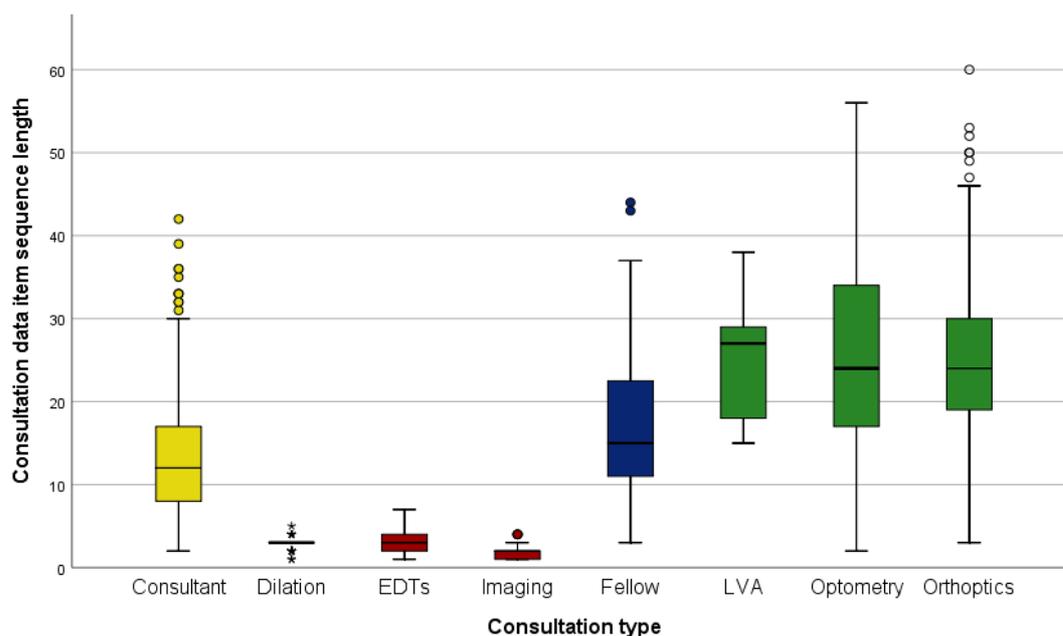
### Sequence lengths

As discussed above, some items from the maximal set of routinely collected data were documented more frequently than others (Table 10). Variations were also found in the number of items documented from the maximal set for individual consultations (i.e. the sequence length). Consultation item sets contained between 2 and 60 items, with a median of 16 (standard deviation 11.5). The distribution of sequence lengths had a positive skew (skewness 0.511, standard error 0.058; kurtosis -0.413, standard error 0.116). As indicated in Figure 19, there was a peak of sequences that were three or four items in length. This group of sequences included consultations of all types, excluding LVA. The majority were dilation consultations (70.6%,  $n=221$ ), 14.7% were from EDT consultations ( $n=46$ ), and 9.9% from consultations with consultants ( $n=31$ ).



**Figure 19: The skewed distribution of the sequence lengths for consultation item sets.**

Although a range of sequence lengths was observed within each consultation type (Figure 20), a significant association ( $p < 0.001$ ) was found between the consultation type and the sequence length. Dunn's pairwise tests indicated that consultation types could be grouped according to sequence length (Figure 20). One group – imaging, dilation, and EDT consultations – tended to be shorter in length, with a median of three data items, whereas orthoptics, optometry and LVA, when grouped, tended to be longer, with a median of 24 items. There was evidence of a significant difference ( $p < 0.001$ , adjusted using the Bonferroni correction) in the sequence lengths between groups, and between consultant consultations and all other types, and fellow consultations and all other types, excluding LVAs ( $p = 0.689$ , adjusted using the Bonferroni correction).



**Figure 20: Box plots for consultation item set sequence lengths, by consultation type.**

Colours indicate groupings of consultation types according to sequence length.

### Sequence alignment

When analysing the 1767 consultation sets from the medical record review, 1,560,261 pairwise sequence alignments and comparisons were made. A

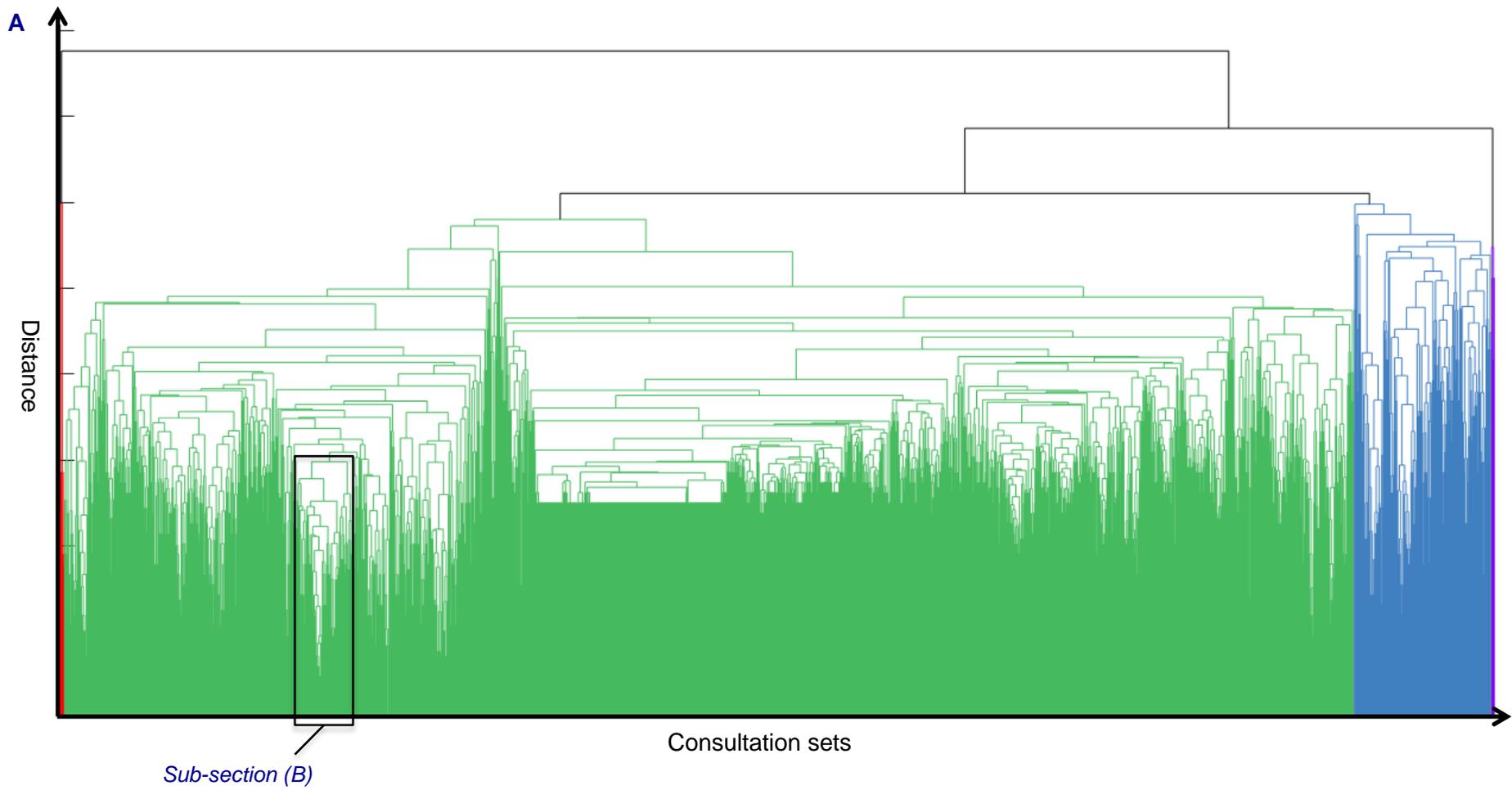
dendrogram of the output can be seen in Figure 21.A. The cophenetic correlation coefficient – a measure of the degree of congruence between the dendrogram and the original pairwise distance measures – was calculated to be 0.7835 out of a maximum value of 1.000. This indicated that a good agreement was achieved and the clustering solution reflected the underlying data with good accuracy.

Upon inspection of the data item sequences in closely aligned sets, it could be seen that the alignment was successful: closely clustered sets did have similar sequences of data items (see Figure 21.B and C for an example).

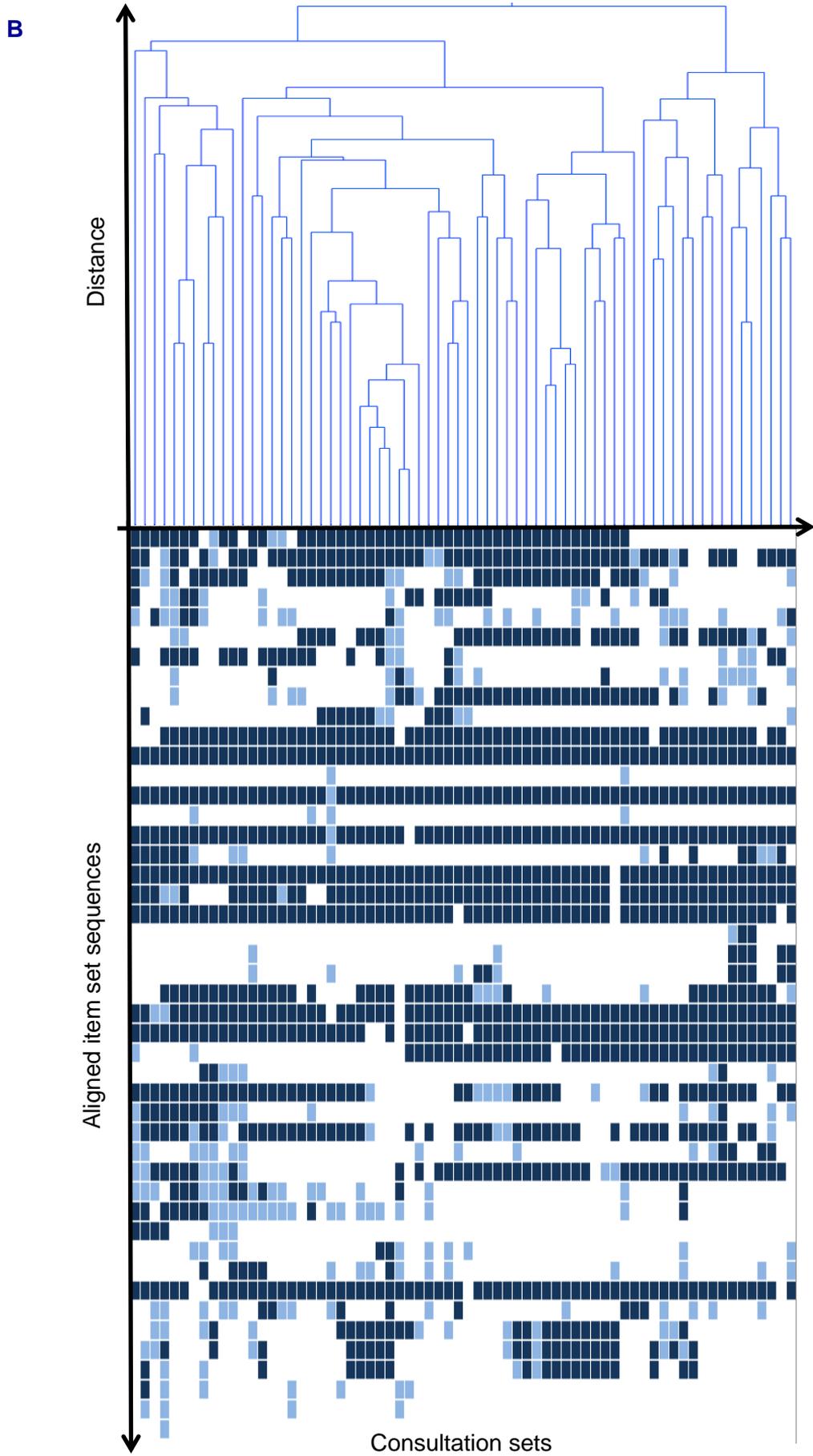
Two main clusters containing similar consultation item set sequences – as defined by the pairwise alignment – were identified within the data. These clusters were unequal in size: cluster B consisted of 1,589 members and Cluster C 169 (Figure 21.A). Within these two main clusters all sequences gradually decreased in similarity, giving no other informative groupings. There were, however, significant differences in the characteristics between the members of the two major clusters.

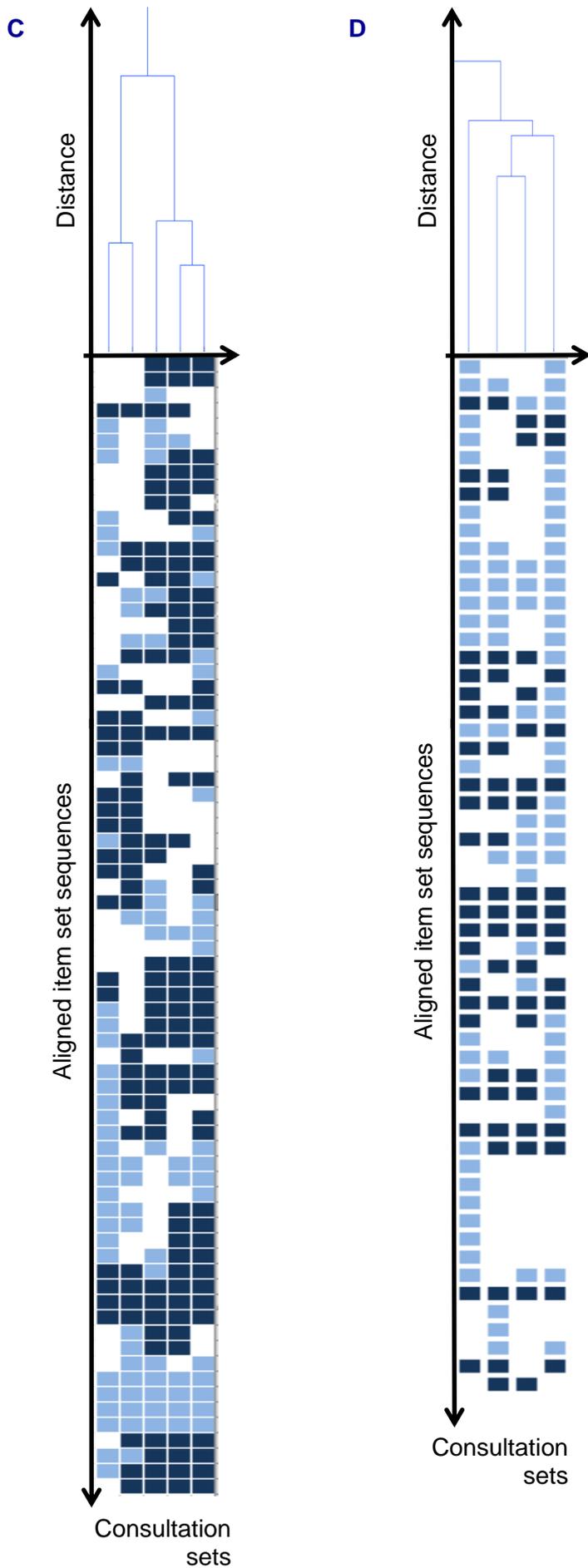
**Table 11: A comparison of the consultation types found in clusters B and C, defined using by a hierarchical sequence alignment of medical record data.**

<b>Consultation type</b>	<b>Cluster B (%)</b>	<b>Cluster C (%)</b>
EDTs	5.1	2.4
Orthoptics	32.7	18.9
LVA	0.6	0.6
Optometry	11.2	34.3
Consultant	23.3	16.6
Fellow	11.5	16.6
Dilation	13.8	10.1
Imaging	1.7	0.6
<b>Totals</b>	<b>100.0</b>	<b>100.0</b>



Cluster A   
 Cluster B   
 Cluster C   
 Cluster D





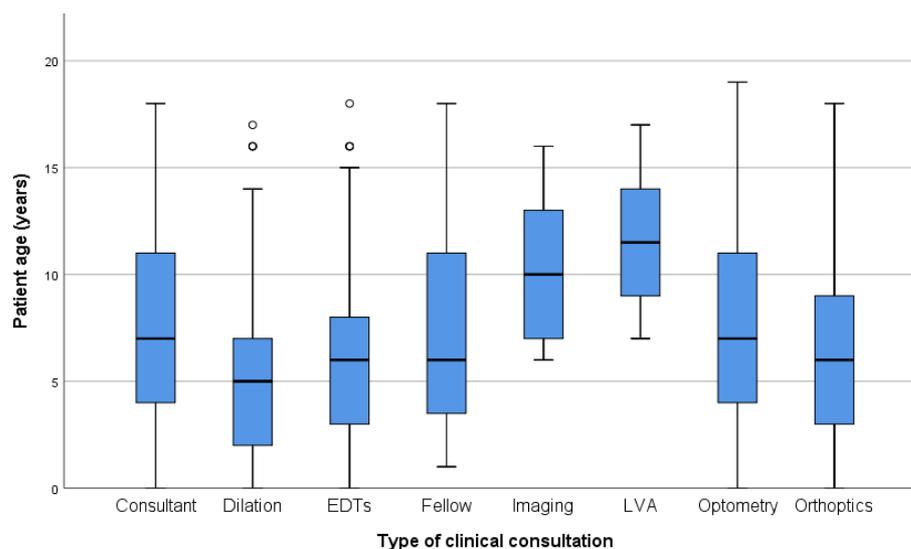
**Figure 21: An agglomerative hierarchical sequence clustering of data item sets identified from medical records.**

**A:** A dendrogram of the sequence clustering.

**B-D:** Sub-sections of the dendrogram in (A), also indicating the item set sequences for individual consultations within each sub-sample. **B:** Sub-section (B) as indicated in (A). **C:** Cluster A. **D:** Cluster D. Sequences have been aligned within the sub-samples. Squares represent individual data items within each sequence: navy blue squares indicate an item match with the sequence above, blue a mismatch, and white a gap insertion.

An association was found between the cluster membership and the type of consultation ( $p < 0.001$  using Fisher's exact test). Higher proportions of fellow and optometry consultations were found in cluster C, whereas cluster B had a greater proportion of EDT, orthoptist, consultant, dilation, and imaging consultations (Table 11). This pattern was not dissimilar to that observed when grouping consultation types by the lengths of item set sequences (Figure 20, p.116), except for, in this case, orthoptic consultations did not cluster with optometry.

There was also a significant difference ( $U = 148094$ ,  $p = 0.027$ ) between the ages of patients in clusters B and C. However, this was likely an artefact of an association between the patient's age and type of consultation ( $U = 77.4$ ,  $p < 0.001$ ): younger patients tended to see an orthoptist, and be dilated, whereas only the older patients would have a low vision assessment and undertake imaging (Figure 22). These findings were also reflected in the observational data: consultants were seen to assess the visual acuity for older patients themselves, whereas younger patients would be seen by an orthoptist, and imaging required patients to sit still throughout the process and therefore was, generally, not completed for the youngest patients.



**Figure 22: Box plots indicating an association between the patient age and consultation type.**

No significant associations were found between the cluster membership and patient gender ( $p=0.607$ ), diagnostic category ( $p=0.128$ ), new or follow up status ( $p=0.935$ ), the consultation rank ( $p=0.265$ ) and date of the clinic visit ( $p=0.222$ ).

Two additional “outlier” clusters were also produced (clusters A and D in Figure 21.A). An overview of the cluster membership and characteristics for each of these outlier groups is provided in Appendix G (p.247).

Cluster A contained five sequence sets, which were all documented during orthoptic consultations by two different clinicians. Figure 21.C indicates that there were regions of structural similarity within this group of sequences. The lengths of the sets ranged from 42 to 60 items, and, therefore, the sequences were longer than average (median 16). Indeed, all of the consultation sets within this group were in the top 1.5% of all set lengths within the sample.

The final cluster, although consisting of only four consultation item sets, displayed a low degree of sequence similarity, with a higher frequency of mismatched data items than was identified for other sub-sections of the dendrogram (Figure 21.D, in comparison to Figure 21.B and C). These sequences – two of which were documented by consultants and two by optometrists – were also longer than average, ranging from 31 to 49 items.

#### Frequent sequential pattern mining

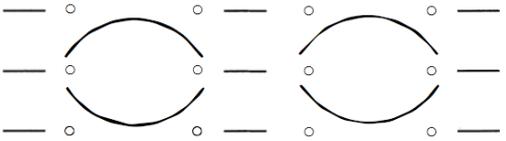
Eleven frequent patterns were identified within the consultation item sets that met the inclusion criteria (three or more items long, and supported by 5% or more of the data set). All eleven patterns could be mapped to clinical tasks. However, upon manual review of these patterns, three were subdivided into two distinct but commonly sequential tasks: reviewing the patient’s symptoms and assessing the distance visual acuity; the ocular motility and cover test; and the orthoptic summary

and dilation prescription. The final thirteen tasks and the patterns of data items are listed in

Table 12, including example data values or templates for the items that represent a drawing element.

**Table 12: Data items within the frequent maximal sequential patterns identified from medical record consultation sets.**

Example values have been provided for fields that would not be free text / comment-based. Examples are not an exhaustive list.

Data item	Example values
<b>Clinical task: Symptoms</b>	
Symptoms	
<b>Clinical task: Distance visual acuity</b>	
Testing conditions	Uncorrected With glasses With contact lens With pinhole
Visual acuity	0.10 logMAR 2.4 cpd Perception of light
Visual acuity	<i>As above</i>
Test method	Keeler acuity cards Kay pictures logMAR chart
Testing distance	4m 3m
<b>Clinical task: Near visual acuity</b>	
Visual acuity	N10 N4.5 <sup>-1</sup>
Visual acuity	<i>As above</i>
Test method	Reduced letters
<b>Clinical task: Ocular motility</b>	
Motility diagram (both eyes)	Template from Vivian and Morris <sup>152</sup> : 
Ocular motility comments	
<b>Clinical task: Cover test</b>	
Testing conditions	With glasses

	Uncorrected
Target distance	Near Distance
Cover test findings	
Data item	Example values
Clinical task: Orthoptic summary	
Orthoptic impression	
Discussed patient with another clinician	<i>Named clinician</i>
Clinical task: Dilating drop prescription	
Dilating drops prescribed	1.0% cyclopentolate 2.5% phenylephrine 1.0% tropicamide
Dilation laterality prescribed	Right and left eyes Right eye Left eye
Clinical task: Dilation	
Dilating drop given	1.0% cyclopentolate 2.5% phenylephrine 1.0% tropicamide
Dilation laterality given	Right and left eyes Right eye Left eye
Dilation time given	<i>Specific time value</i>
Clinical task: Anterior segment examination	
Anterior segment drawing	Template from EyeDraw (OpenEyes) <sup>87</sup> : 
Anterior segment comments	
Anterior segment drawing	<i>As above</i>
Clinical task: Intraocular pressure	
Test method	iCare tonometer Goldmann applanation tonometer Digital palpation
Intraocular pressure	21 Soft
Intraocular pressure	<i>As above</i>
Clinical task: Refraction	
Retinoscopy power cross drawing	Template from EyeDraw <sup>87</sup> :

Working distance	1/2m 2/3m
<b>Data item</b>	<b>Example values</b>
<b>Clinical task: Optic disc observations</b>	
Optic disc drawing	Template from EyeDraw <sup>87</sup> : 
Optic disc drawing	<i>As above</i>
Optic disc comments	
<b>Clinical task: Management</b>	
Impression	
Management plan	
Timing of follow up appointment	2 weeks 6 months 12 months

The sequential patterns identified through data mining techniques were typically short, ranging between five and three items. The manual subdivision of some of these patterns resulted in even shorter patterns, including a single-item task (Symptoms) and two tasks that contained only two data items (Ocular motility and Orthoptic summary).

Six of the identified frequent sequential patterns contained a repeated data item (Distance visual acuity, Near visual acuity, Anterior segment examination, Intraocular pressure, Refraction, Optic disc observations; Table 12). For the majority of clinical tasks, it can be assumed that these repeats represented observations for the right and left eyes. However, observational data also indicated that in some

circumstances repeats could also represent a repeated measure for the same eye; this was often observed when clinicians measured a patient's intraocular pressure.

It is not surprising that many of the individual data items contained within each pattern (Table 12) were also identified to be the most frequently documented items within the maximal set (Table 10). For the sequential patterns, the support within the entire set ranged from 5.0% to 13.9%, and 49.7% for the single-item pattern, symptoms (Table 13).

**Table 13: The clinical tasks associated with the maximal frequent sequential patterns of data items identified from within medical record item sets.**

The total pattern frequency was calculated as the number of times the pattern occurred within the entire data set, including repeats within a single item set.

Clinical task	Percentage of item sets containing pattern ( <i>n</i> )	Total pattern frequency
Symptoms	49.7 (878)	878
Distance visual acuity	5.0 (89)	89
Near visual acuity	11.0 (195)	195
Ocular motility	6.7 (119)	119
Cover test	11.8 (209)	231
Orthoptic summary	8.7 (154)	154
Dilating drop prescription	13.9 (245)	245
Dilation	9.2 (162)	162
Anterior segment examination	5.7 (101)	101
Intraocular pressure	9.3 (164)	169
Refraction	6.5 (114)	117
Optic disc observations	11.7 (206)	206
Management	7.9 (139)	139

From observational data, it was clear that many clinical tasks could be completed multiple times by a clinician during a single consultation. This was also indicated in the frequency data described in Table 13: in some cases, a discrepancy was identified between the number of consultation item sets that contain the pattern and the pattern frequency. This observation was most prominent with the cover test task that was identified within 209 item sets but had a total frequency of 231. Observational data indicated that this task – typically completed by an orthoptist –

may be repeated with and without correction and, therefore, the whole pattern is duplicated within an item set.

Many other clinical tasks were seen to repeat within a consultation, from observations; a notable example was the distance visual acuity. Although this was the most frequently identified single data item (Table 10), this observation was not, however, reflected in the frequency data (Table 13). The sequential pattern of data items associated with this clinical task was the longest identified (five items, Table 12). Observations suggested that, although the distance visual acuity was often repeated, subsequent assessments might have used the same test and testing distance but was performed under different testing conditions, for example with the addition of a pinhole. In these cases, users explained that, in order to minimise duplicate documentation, it is likely that only the testing conditions and additional acuity values would have been recorded; the entire sequence of data items would not have been repeated within the item set and therefore does not appear as a repeat within the frequency data.

## 3.4 Discussion

In this exploratory work, an in depth ethnographic study was performed following a contextual design approach, to consider the different uses and users of medical records in a clinical outpatient setting. A particular focus was placed on the identification of the common documenting behaviours, and structural patterns within the paper-based medical record, to inform the design of a user-centred, paediatric ophthalmic EMR.

### 3.4.1 Study strengths and limitations

#### Methodological approach

In this study, the contextual design methodology was followed. A core assumption of contextual design is that, while people are experts at what they do, often this knowledge is tacit and difficult for individuals to articulate<sup>129</sup>. In combining multiple methods, this limitation of many qualitative methods has been overcome; the conclusions of this work have been drawn from a comparison of what users say they do and their observed behaviours.

Furthermore, the application of the different work models originally defined by Holtzblatt and Beyer<sup>129</sup> ensured all facets of medical record usage were considered, including the specific contents, interactions between users, and the influence of the physical environment.

Unsupervised data mining techniques were additionally applied to the data generated by an artifact analysis, to gain insights into the structural patterns of medical record contents. No explicit design insights were gained from the sequence analysis of medical record data items. The sequence length appeared to influence

the clusters produced, particularly in expelling the longest sequences as outliers. Alternative scoring systems could be tested so that extended gap regions are not penalised as harshly as mismatched data items or single insertions.

#### Sample representativeness

There are no data available to compare the samples achieved in this study to the demographics of the patient attending the GOSH ophthalmology outpatient clinics, and, therefore, the representativeness of the sample could not be formally assessed.

The snowball sampling method employed for the time motion study was selected to flexibly gather data as required to ensure the breadth of use cases encountered within the GOSH ophthalmology outpatient were observed. User input into the participant selection was a key element of this method, and ensured the coverage was not biased by the limited experiences of the researcher.

For the medical record review, a saturation point when no new data fields were identified was reached after day 11 of data collection (73.3% of the total period). It can therefore be assumed that the maximum data set identified was complete for the study context, and that these data are representative of the medical records written in the GOSH ophthalmology outpatient clinics.

A small, but not insignificant amount of data was missing from these analyses. This may have been for a variety of reasons: (1) the medical records may have been lost before the file was scanned into EDM, (2) the file may not have been scanned, (3) the clinic visit was not documented in the medical record, or (4) the clinic visit did not take place. As someone indicated in PIMS that the patient attended, it has been assumed that the fourth reason was unlikely. However, it is possible that the entry into PIMS was a mistake, or that the patient attended and checked in but was subsequently not seen. To assess this assumption, an alternative data source – the

clinic outcomes data – would delineate if these clinic visits actually occurred. However, these data were not available for this study.

When studying the clinic transitions, any note documented in the medical record was considered a consultation. In some cases, the clinician may not have directly consulted with the patient, for example a consultant may have prescribed cycloplegic drops which were then delivered by a health care assistant and a fellow subsequently completed the clinical assessment. On the other hand – as found with EDT appointments but also a possibility in other consultation types such as imaging – a clinician may have seen a patient and not indicated this in the notes. These consultations will have been missed in the record review methods used in this study. The results, therefore, will not directly correlate with patient flows through the clinic. This was, however, appropriate for this study as the research focused on the users and uses of medical records, and it was important to include the non-patient facing tasks. In analysing observational data in parallel, such limitations of the data did not bias the conclusions drawn.

Finally, this work only represents a single point in time. It is expected that the proportions of patients consulting with, for example, a consultant or fellow will vary throughout the duration of the trainee's fellowship, as she gains more experience. As a result, a focus has been placed on the identification of different patterns and behaviours in the conclusions drawn below, as opposed to the specific frequencies of these events.

### Generalisability

Much of the UCD methodology, including contextual design, places an importance on defining the users' actions as they occur in the environment of system usage<sup>99</sup>. Therefore, it is not the intention of such research to be generalised to other settings. In this work a maximal data set of routinely collected data has been defined, and

documenting behaviours explored to inform the design of an EMR appropriate for use by the GOSH department of ophthalmology. Additional studies would be required to assess the suitability of the data set and design requirements for other NHS paediatric ophthalmic settings, in addition to other settings within GOSH, such as for the documentation of inpatient procedures.

### **3.4.2 Medical record design requirements**

#### ***The contents of the medical record***

In this work, a maximal set of data items routinely collected within the GOSH ophthalmology outpatient clinics has been defined. As discussed in the background section (Chapter 1, pp.26-27), in addition to defining a data set, care must also be taken to model the data in the context of the wider information system. Defining exactly how data are to be captured (i.e. the format and potential data values), in alignment with existing standards – such as those defined by the Royal College of Ophthalmologists and NHS England – would form the next phase of EMR design.

As indicated earlier in this thesis (Chapter 1, pp.32-33), others have cited the highly diagrammatic nature of ophthalmic documentation as a barrier that challenges EMR adoption within general ophthalmology<sup>81</sup>. It was also a concern perceived by paediatric ophthalmic users (Chapter 2, pp.59-60). This work validates that documentation within paediatric ophthalmology is highly diagrammatic: four of the thirteen identified clinical tasks with frequently documented sequential patterns of data items included one or more drawing elements. The inclusion of drawing tools within EMR system design is, therefore, vital if the system is to support current documentation methods of paediatric ophthalmic clinicians within GOSH.

Additionally, for infants, users were seen to visualise visual acuity data in a longitudinal graph, and compare their measurements to age-matched normative data. Spooner also discussed the importance of the graphical representation of paediatric patients' development over time within the EMR<sup>88</sup>. He recommends that the plots are placed at the highest level of a patient's record within the EMR system, as to promote accessibility and efficiency for clinical users<sup>88</sup>. This would also be good practice for a paediatric ophthalmic EMR.

One clinician, within a uveitis clinic, was noted to summarise other patient data longitudinally prior to seeing the patient. Paediatric uveitis is a chronic inflammatory eye disease that requires the observation of many signs and symptoms, has a variety of treatment options, and can be associated with systemic disease<sup>153</sup>. Therefore, the management of uveitis in children can be complex and require the coordination with other specialties. It is not surprising that reviewing and summarizing historical data within the medical record was a prominent user behaviour associated with this patient group.

As discussed with visual acuity data above, an EMR could support the summary and visualization of longitudinal data. It is currently time consuming for clinicians to summarise patients' data from the paper-based medical records in use within the GOSH ophthalmology clinics. This may explain why the behaviour was only observed in one user. Published studies suggest that the use of an EMR improves the efficiency of information retrieval, in comparison to paper-based methods<sup>154</sup>. The inclusion of such tools may be beneficial to the wider user group if they are easily accessible, as recommended above.

### ***Patient flow management***

The findings of this research indicated that the patient flows within the GOSH ophthalmology department were complex, without clearly defined pathways. Research from other domains indicates that undirected structures can result in the most efficient systems overall, for example when boarding an aeroplane<sup>155</sup>. It is not, however, the purpose of this research to assess the efficiency of the organisation within the GOSH ophthalmology clinics. Instead, this discussion focuses upon how it would translate into an electronic system, and which tools would be required to facilitate the identified work patterns.

As the pathway of the patient was typically not defined prior to the clinic visit, the paper notes were used to direct patient flows; this features must be replicated in the electronic system. Previously discussed anecdotal evidence (Chapter 2, p.62) suggested that, if attention is not paid to the uses of medical records in workflow management during system design, EMR implementation can disrupt existing flows and increase patient wait times. The inclusion of workflow management tools – such as the ability to track a patient's progress through a clinic and calculate wait times – would ease the adoption of an EMR into the GOSH ophthalmology clinics.

### ***Secondary data uses***

The primary focus of the work presented in this chapter was the identification of system requirements for EMR use in the clinical context. This was in line with the preferences that users expressed in a previous study (Chapter 2, p.68), in which researchers did not prioritise direct engagement with EMR design. As such, no specific research design requirements have been gathered in the present work.

However, as data re-use is a priority for the NHS in England<sup>13</sup>, the suitability of the maximal set of routinely collected data defined in this work has been considered as a source for research, in order to inform future work on this topic.

The coverage of the clinical and research concepts did have a good overlap, with 74.0% of research items being included in the maximal clinical set. It is anticipated that this coverage would be increased in an EPR that was interoperable with systems in use in other specialties, for example to identify a complete birth and social history of the patient. This could be achieved through interoperable clinical systems<sup>156</sup>, or the use record linkage research techniques<sup>157</sup>.

The findings do suggest that, at present, there are some differences in how researchers and clinicians structure data: researchers included more complex ideas than clinicians, such as specific time frames. The automated calculation of some fields may help resolve this disagreement, and should be supported when designing interfaces that allow researchers to access EMR data. This theme has been explored in more detail in the final study presented in this thesis (Chapter 5, pp.180-201).

It should also be noted that BCVIS2 – the research study considered in this work – had very broad research aims. More specific studies, with more focused research questions, might require a greater specificity or granularity of data than the BCVIS2. Further comparisons, in which a wider range of research studies are considered, are needed to reach a general conclusion on the suitability of the defined maximal set of routinely collected data for research purposes and make fully informed design recommendations.

### 3.4.3 Transitioning to electronic working

#### ***Structured documentation***

The use of unstructured paper notes allowed for a great variation in the structure and contents of the medical records in the GOSH ophthalmology outpatient clinics. Moving to electronic working, with structured data capture, would transform clinical documentation from a process of inclusion to one of omission.

Wright argued that structuring medical records enhances a clinician's ability to interpret the information and, therefore, limits medical errors<sup>158</sup>. This notion was reflected in this study – in the perceptions of the observed clinicians, who said they prioritised structure when writing their clinic notes in order to maintain the readability of the record.

The use of data mining techniques did not identify any patterns in the overall structure of the clinic notes written for individual consultations. This does not imply that the records were without structure; indeed, pattern mining methods identified several repeating motifs of data items that were commonly recorded together.

It is interesting that the frequent sequential patterns identified in this work highlighted a range of documenting behaviours. For example, the pattern for the anterior segment followed the form *drawing – comments – drawing*, whereas for the optic disc the pattern *drawing – drawing – comments* was observed. These small structural differences are likely insignificant to the overall medical record; however, if both forms were present for a single task within the analysed data set, they would have had an effect on the pattern mining results. As such, the list of clinical tasks identified within this work is not complete.

More sophisticated pattern mining techniques are available that can handle greater variability within the data set, accounting for gaps and small changes in order of

items within patterns<sup>138</sup>. An inclusion of more flexible patterns within the results would have been less informative for page design, which was the focus of this study. However, the analysis could be repeated using alternative algorithms to comprehensively identify the clinical tasks completed in the GOSH ophthalmology outpatient clinics and the associated item sets. This would likely increase the support for patterns within the data set and so yield more results.

Further analyses of clinical tasks is likely to be the most informative next step during the design of an EMR for the GOSH ophthalmology department. Further work is required to draw any final conclusions from the sequence alignment. However, the initial results and observational evidence suggest that – although it was hypothesized that the structure of the medical record would be dependent upon the consultation type – there is in fact a great deal of overlap in the tasks that were undertaken in the different consultation types, and therefore in the data items recorded. As such, no distinct clusters consisting of similar sequence structures were identified within the data.

The organisation of the GOSH ophthalmology department likely contributed to these findings, with no imaging technicians and the extended role of the optometrists. Conclusions regarding the structural requirements of medical records are, therefore, routed in the study context, highlighting the merits of the contextual approach for EMR design work.

### ***The role of super users***

A variety of behaviours surrounding medical record and computer usage were identified in this study, many of which varied by individual preference alone. In particular, some users completed their documentation at a desk and used the

computer during patient consultations. For these users, the impact of adopting electronic working is likely to be less disruptive in comparison to other users.

HIT-implementation research suggests that “super users” can act as a clinical role model for technological acceptance, and positively influence the adoption of HIT into clinical environments<sup>159-161</sup>. This suggests that the adoption of EMRs would, in addition to a user-centred design approach, also require an implementation strategy centred around the users within the department.

For some of the observed behaviours, however, care could be taken when designing the system to ensure existing work processes are not disrupted. For example, the portability of paper-notes could be reproduced using a cross-platform design that is suitable for tablet or mobile devices. In 2016, a survey reported that clinicians using tablet devices for documentation and medical record access believed that they improved communication with both patients and colleagues, and simplified clinical workflows<sup>162</sup>. Portable technologies are therefore worth considering for the GOSH ophthalmology department, to ease clinicians concerns regarding the interruption of patient consultations and the need to coordinate and communicate examinations with other clinicians in the clinic.

#### **3.4.4 Implications for UCD: Next steps**

Typically, having completed the initial user research, many UCD approaches, including contextual design, focus on the generalisation of user characteristics and derivation of personas<sup>128, 129</sup>. However, the findings of this research would imply such techniques are not appropriate for the study context; users in the GOSH ophthalmology department cannot be easily be grouped according to their documentation behaviours.

Challenges surrounding user heterogeneity have been described in other hospital settings in which care involves multiple providers<sup>163</sup>. One solution would be a

modular approach to system design, considering each clinical task in isolation. This approach has proved successful in the design of other ophthalmic specific EMRs such as OpenEyes<sup>86</sup>.

To achieve this, the clinical tasks undertaken within GOSH ophthalmology clinics need to be comprehensively defined. As discussed above, sequential pattern mining techniques, in combination with the insights gained through clinical observations, could be employed to identify the underlying data item sets that support each task. Then to complete the design process, the data item sets need to be fully defined for each task, considering the format and potential values of each item. And finally, the interface can be iteratively designed to capture these data.

In UCD, the division of users' work into specific, individual tasks is called a task analysis<sup>164</sup>. This use of this method as a base for system design has been explored in more detail in Chapter 4 (pp.139-178).

# Chapter 4 Applying the user-centred approach

## 4.1 Introduction

### 4.1.1 UCD techniques

Following the initial user research, the next phases of UCD aim to identify specific design requirements, and develop and test software to meet these requirements. The participation of end-users throughout these design and development processes allows users to ensure the system will meet their requirements, and is believed to relieve implementation challenges, such as user engagement or inefficiencies introduced by users having to learn how to use a new system<sup>165</sup>.

As indicated in Chapter 1 (p.36), a variety of UCD methods and techniques have been employed to develop useful HIT systems. In addition to the methods described in Chapter 3 (pp.77-137), three UCD techniques have been utilised in this chapter: focus groups, task analysis and use case scenarios.

Focus groups: During focus groups, users discuss experiences and expectations of a system.

Task analysis: Task analysis is defined as the process of 'identifying the procedures and actions to be carried out as well as the information to be processed to achieve task goals'<sup>164</sup>; the technique helps designers to understand what the users' goals are, how users achieve their goals, and task workflow. A range of techniques have been used to obtain data for task analysis, although, in defining a user-centred framework for HIT development, Johnson *et al.* propose that observational studies provide the richest data<sup>127</sup>. Following the task analysis, the findings can be visualised as archetypes, tables, flow diagrams, or sequence diagrams.

Use case scenarios: By describing example use cases, scenarios – often represented using fictional stories – can be used to provide context and explore requirements during the design of systems. Scenarios can also be used during task-based usability testing, to create realistic tests for users.

Small-scale usability studies are also a promoted means of validating design decisions during the user-centred development of HIT interfaces<sup>127</sup>. While the data from such studies are often not sufficient to verify the final usability of the system, qualitative data captured using audio or visual recordings can help designers gauge how the will the system will be used by end users and identify any design flaws<sup>166</sup>.

#### **4.1.2 Chapter aims and overview**

In the following chapter, a user-centred method to software design is applied and tested using three case studies. The cases studies are first presented separately, followed by a general discussion that considers the user-centred methods applied. Cases were selected to meet clinical needs that were identified by the GOSH ophthalmology department, and to address a range of different contexts and issues for HIT development within paediatric ophthalmology. Two of these cases were then implemented within a new clinical-research database at GOSH.

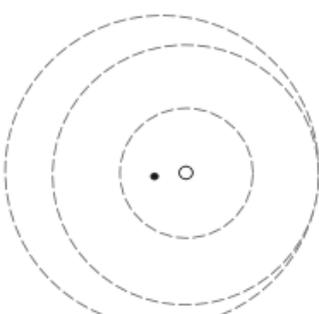
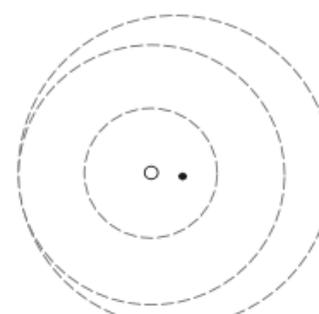
The product of each case study can be found in the supplementary material included with this thesis.

## 4.2 Development case studies

### 4.2.1 Case study 1: Retinopathy of prematurity screening

Retinopathy of prematurity (ROP) is a potentially sight-threatening disease caused by abnormal development of the vasculature in an immature retina. All ‘at risk’ babies – those born before 32 weeks of gestation or weighing less than 1.5 kilograms – are regularly screened for ROP by an ophthalmologist.

National screening protocols have been defined by the Royal College of Ophthalmologists and the Royal College of Paediatrics and Child Health<sup>92</sup>. These guidelines, in line with the International Classification of Retinopathy of Prematurity (ICROP)<sup>167</sup>, include recommendations for the data that should be captured to support screening, and in what format; a template paper data collection form is available (Figure 23).

<b>Stage 1:</b> —	<b>Stage 2:</b> =	<b>Stage 3:</b> ▬▬▬	<b>Stage 4/5:</b> ••••	<b>Laser:</b> x <sup>x</sup> x <sup>x</sup> x <sup>x</sup> x <sup>x</sup>	<b>AP-ROP:</b> AAA	
<b>Date:</b>	<b>R</b> 	<b>L</b> 				
<b>Postmenstrual Age:</b>						
<b>Follow-up:</b>						
<b>Examiner:</b>	<b>Zone:</b>	<b>Stage:</b>	<b>Preplus: Y / N</b>	<b>Zone:</b>	<b>Stage:</b>	<b>Preplus: Y / N</b>
			<b>Plus: Y / N</b>			<b>Plus: Y / N</b>
<b>Comments:</b>						

**Figure 23: Template form for retinopathy of prematurity screening.**

Template is as provided by the Royal College of Ophthalmologists<sup>92</sup>.

As seen in Figure 23, ROP is classified according to the disease severity – the stage, ranging from 0 / no ROP to 5 / severe disease – and the proximity of the boundary between the vascular and avascular retina to the optic disc (zones 1 to 3). The presence of dilated, tortuous vessels – plus disease – is indicative of disease worsening and therefore is also documented.

At the time of this research, no ophthalmic EMRs included specific tools for ROP screening. The aim of this case study was, therefore, to provide a suitable tool that could capture the standardised information required as part of the national ROP screening programme.

## ***Materials and methods***

### Task analysis

ROP screening ward rounds with two consultant ophthalmologists were observed to identify screening processes; qualitative notes were collected electronically during observations using a Surface Pro 4 tablet. Notes were reviewed and, using NVivo<sup>115</sup>, coded to identify the tasks the consultant completed during ROP screening. These tasks were used to construct a process flow diagram, revealing the user goals and system requirements.

### Software development

Initially, the College's template paper form (Figure 23) was used to guide software development. A web-based application was created, utilising HTML5 form and canvas objects. As in the paper template, the application included drawing tools; these were developed using the EyeDraw drawing package from the OpenEyes Foundation<sup>87</sup> (Chapter 1.1.4, p.33). New drawing elements were coded in JavaScript using canvas commands.

A focus group of potential users were involved throughout the development cycle. In addition to the vitreoretinal consultants at GOSH, four other consultant paediatric ophthalmologists were invited to participate in an expert user group; all participants were involved with the management of ROP patients within the UK. An iterative feedback process developed, using an online testing instance of the application and a mix of email and telephone correspondence to provide feedback. All feedback was shared between all group members to facilitate discussion and reach a consensus in design decisions.

#### Application testing

Application testing was completed during August-September 2017. Initial testing was completed at GOSH to ensure the application would be suitable for the intended use environment.

During a ROP screening ward round, a single consultant paediatric ophthalmologist – who was involved with the previous application development process – used the application to record screening consultations. The software was used in parallel to the current documentation practice at GOSH: the guideline paper template. For each patient seen during the ward round, the consultant first completed the paper form and then repeated the documentation using the electronic application and a screenshot was taken of the form once he had completed documenting. Timing data were collected for the total time spent with each patient and time spent documenting with both paper and electronic methods, using the tool and approach described in Chapter 3 (see methods on p.86). Observer notes were collected during this study for reference; however, they were not subject to any analyses. Timing data were imported into a Microsoft Excel spreadsheet, and totals and averages calculated.

To assess the suitability of the application for the range of disease states encountered during ROP screening, further testing was completed outside of the

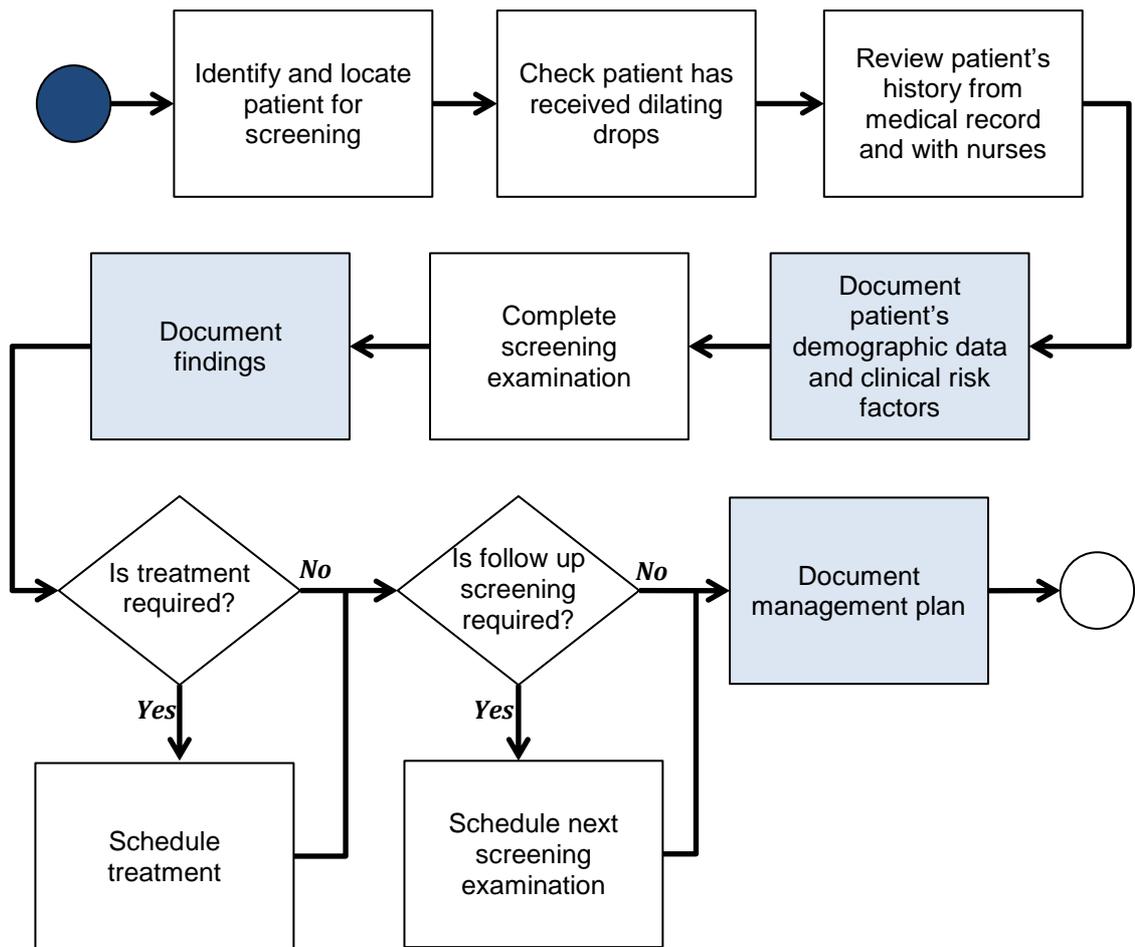
clinical environment. Eight fundus photographs were used to illustrate the different stages of ROP development, as defined by the International Classification of Retinopathy of Prematurity<sup>167</sup>. Clinical users (one consultant paediatric ophthalmologist and one ophthalmology fellow, both based at GOSH at the time of testing) were asked to record their observations from the images using the application. Before completing the task, users could practise using the software. The images were then presented in order of disease severity and, when required, assistance was provided with identifying clinical features within the images. The users would then click a button to begin testing and reveal the first image and, when they had completed a drawing, to move onto the next image.

Throughout the process, the position and timing of all mouse clicks on the webpage were recorded, and screenshots were taken by MSC of each drawing once it was completed. Mouse click flow data were used to reconstruct and compare the documentation behaviours of the different users. The total time to complete the documentation for each image was calculated to be the time between first revealing an image and the last mouse click for that image.

## **Results**

### Task analysis

During the screening process, the ophthalmologist was found to complete nine distinct tasks, three of which were classified as the primary documentation activities (Figure 24).



**Figure 24: ROP screening process flow diagram.**

The diagram represents the tasks completed by an ophthalmologist when screening a single patient. Tasks highlighted in blue became the primary focus for this case study.

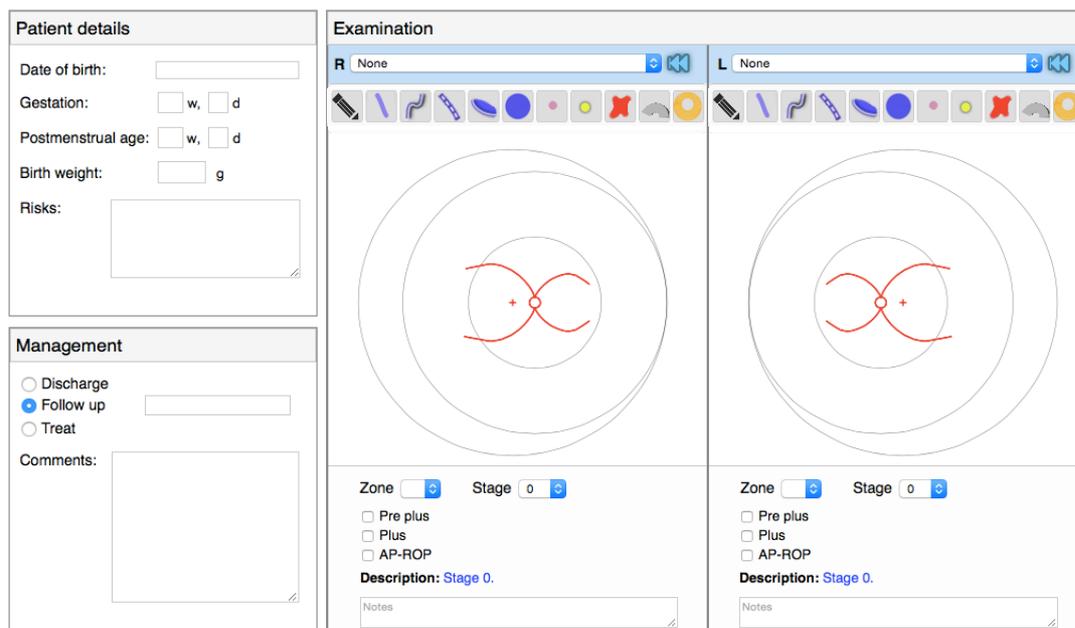
At GOSH, screening can take place in a number of wards within the hospital. While computers are available at the bedside on the majority of wards, the consultants being observed expressed a preference for software that would be suitable for a portable device to carry on the ward rounds and review the patient's history before arriving at the bedside.

Given the time constraints of this case study, designing an interface to capture the three documenting tasks (highlighted in Figure 24) became the priority for development work. The remaining tasks all required an interface with existing information systems in use within GOSH, for example to identify which bed and

ward the patient is in, or how long ago dilating drops were distilled. At the time of this research, these were a mix of electronic and paper-based systems, and so an efficient interface was not feasible.

### The application and usability feedback

The web-based application had three sections representing the three documenting tasks: patient details, examination findings, and management plan (Figure 25). As in the paper template, a tool was provided for drawings. Prognostic features could be added to the drawing by clicking on the icon and interacting with the controls to change the size and position.



**Figure 25: A screenshot of the web-based ROP screening application, designed for a tablet device.**

The drawing elements were designed to follow the key used in the Royal College of Ophthalmologists' template for stages 1-3 (Figure 23). More representative depictions of retinal detachments (stage 4/5), laser burns and aggressive posterior

ROP (AP-ROP) were chosen, in alignment with existing work in the EyeDraw repository.

Following user feedback, the drawing tools were refined and additional icons were added to document other relevant observations, including haemorrhages, exudate, and popcorn. A freehand tool was also created to allow users to draw more complex shapes, annotate features, or document observations not present in the icon list.

To prevent documentation duplication, the use of the drawing tools would autocomplete some form elements. For example, the zone and stage fields changed depending on the location of different elements within the drawing. Reciprocally, as some members of the user group preferred not to use the drawing tools for all patients, use of the form elements would automatically edit the drawing; the user could override this behaviour in the drawing, if desired.

As speed was identified to be a priority of users, in the patient details section, the postmenstrual age was also set as an auto-calculated field, based on the entered date of birth and duration of gestation.

### Test cases

The application was used during an ROP ward round in which two babies were screened; a screenshot of one of the examination findings can be seen in Figure 26. The screening process took 15 minutes and 5.2 seconds for the first patient observed, and 16 minutes and 3.2 seconds for the second. For the first patient 1 minute and 34.1 seconds were spent documenting using paper, and 40.0 seconds using the application. In the second patient, the paper-based method took 1 minute 42.1 seconds, in comparison to 1 minute 46.1 seconds with the application.

A

Date:	R		L	
Postmenstrual Age:	34+2			
Follow-up:	Y52			
Examined:	Zone: 2	Stage: 2	Zone: 2	Stage: 1
	Preplus: Y/N	Plus: Y/N	Preplus: Y/N	Plus: Y/N
Comments:	CT to well Y52 ? of regress ip		regress ip	

B

Assessment: exam 1

R None

Zone 2 Stage 2

Pre plus disease  
 Superotemporal  Superonasal  
 Inferotemporal  Inferonasal  
 Plus disease  
 APROP  
**Description:** Zone 2. Stage 2. Pre plus disease. Elevated ridge

L None

Zone 2 Stage 1

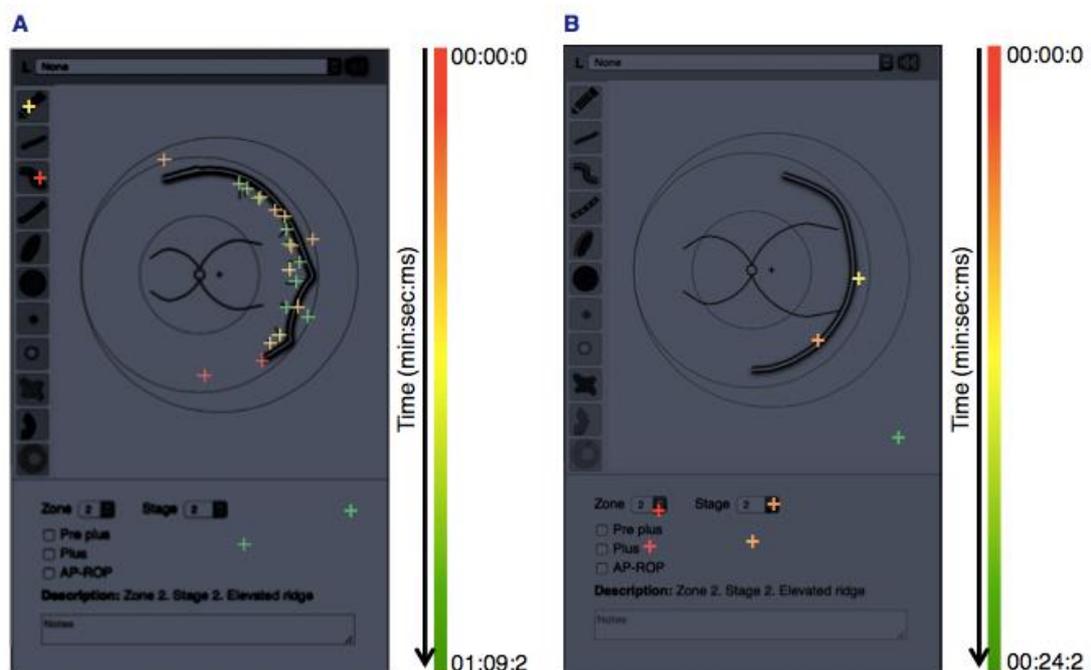
Pre plus disease  
 Plus disease  
 APROP  
**Description:** Zone 2. Stage 1. Demarcation line

**Figure 26: A comparison of an ROP screening assessment completed on a ward for paper-based (A) and electronic (B) documentation methods.**

Both figures were completed during a ward round, when assessing the same patient; the paper form was completed before repeating with the electronic application. The date has been removed to fully anonymise the patient.

During this process, the user provided feedback and requested a modification to increase the efficiency: when the zone is set using the drop down controls, the arcades should automatically move to the middle of the appropriate zone on the drawing. This development was added before the next image-based tests were completed.

When asked to record observations from images of ROP, the two test users could document all eight cases; however, different drawing behaviours were observed. An example can be observed in Figure 27: when drawing the same ROP image, one test user primarily used the form controls and subsequently edited the drawing (Figure 27.B), whereas the other used only the drawing tools (Figure 27.A), which took almost three times as long to complete.



**Figure 27: Electronic drawing behaviours identified through mouse click mappings.**

**A:** Use of only the drawing tools. **B:** Use of drop down form controls prior to editing the drawing. Both individuals were drawing the same ROP image (zone 2, stage 2).

Crosses indicate mouse clicks, colour coded by time (red: start of drawing, green: drawing completed), as indicated in the scales in the figure.

**Table 14: Documenting completion times, comparing two users recording their observations from images of ROP.**

Images are listed in the order that they were presented to the test user. User 2 was more experienced using the application in comparison to user 1.

ROP image classification	Time taken to complete task (min:sec)	
	Test user 1	Test user 2
Zone 2, stage 0 with plus disease	00:37.6	00:06.6
Zone 2, stage 1	01:01.3	00:37.8
Zone 2, stage 2	01:09.2	00:24.2
Zone 2, stage 3 with plus disease	01:30.3	00:08.5
Zone 2, stage 4a	00:48.2	00:57.0
Zone 1, stage 4b	01:43.4	00:50.0
Zone 1, stage 5 with plus disease	00:36.8	00:28.5
AP-ROP	00:19.3	00:02.4

Indeed, in general, the first user took longer to complete each task (median 54.8 seconds) in comparison to the second (median 18.9 seconds). However, a range of times was also observed for each user between images (Table 14). Both users took least time to document the first and last images; for these images, both test users chose to use the checkboxes on the form in preference to manually modifying the drawing.

### ***Discussion***

In this case study, the design of an application for ROP screening has been proposed, to replace the existing paper-based methods in use at GOSH.

The application could be used in the intended clinical environment: during a ROP screening ward round. The efficiency of the software was considered in comparison to paper-based methods for two patients during an ROP screening ward round, and was found to be comparable in one case and quicker in the other. However, in this study, the consultant ophthalmologist first completed the paper documentation and

repeated the process electronically; the time spent using the application may not have been representative of using only the software during the ward round. Although the qualitative feedback from users suggested the design was usable, further testing with more users would be required to robustly assess the usability of the software in terms of efficiency.

Through recording clinical observations from images of the different stages of ROP, users found the application to be capable of documenting the necessary range of disease states encountered during ROP screening. The drawing element was a major focus of this work. Initially, only features described within the international classification of ROP were included in the drawing tool. However, following user feedback, several other drawing elements were added, suggesting that – for ROP at least – medical drawings play a role in capturing those details that are not considered within the standardised grading classification.

At GOSH, imaging studies were not one of the main tasks identified within the screening process, and so was not included within this work. In other settings, however, imaging can form an important part of the ROP screening, and is increasingly discussed in the context of remote screening or “telemedicine”<sup>168, 169</sup>. While imaging can add important detail to the medical record, it does not duplicate drawing, which is a process used to indicate which features the clinician believes to be significant. Therefore, the ROP drawing tools developed within this work will remain of significant utility as a stand-alone tool or when combined with imaging systems.

Other tasks identified from the observational work were also excluded from this case study. Furthermore, only the role of the ophthalmologist was considered, omitting important steps, such as the identification of babies to be entered into the screening pathway and the delivery of dilating drops prior to the screening event.

Should the application be implemented within routine screening practices at GOSH, a process would need to be devised to identify which baby's records to open and complete within the application. However, EMR implementation is beyond the scope of this doctoral research; the focus on the screening process and the interface design of the data collection application was appropriate for the current case study.

#### 4.2.2 Case study 2: Infant visual acuity plots

Functional vision is clinically estimated using the visual acuity: an individual's ability to perceive spatial detail. In children, measuring the visual acuity can be challenging, as testing typically relies upon a good understanding of the assessment task and an ability to report an answer. A wide range of tests has therefore been developed to assess the acuity of children at different developmental stages (Table 15).

**Table 15: Clinical tests used to assess visual acuity in children.**

Table adapted from Speedwell *et al.*<sup>170</sup>.

Test	Corrected age range
Keeler acuity cards (preferential looking)	Birth – 9 months
Teller acuity cards (preferential looking)	Birth – 9 months
Cardiff cards (preferential looking)	6 – 18 months
Kay pictures	2 – 3 years
Snellen	≥ 4 years
LogMAR	≥ 4 years

##### Preferential-looking procedures

In infants, the functional vision is typically estimated using a preferential-looking technique<sup>171</sup>. In this method, a child is presented with two stimuli of equal average luminance: one blank target and one with a grating pattern. The infant will preferentially fixate upon the patterned stimulus. As the spatial frequency of the pattern increases, it becomes more difficult to resolve; eventually the child will not show a preference for either target, indicating their acuity in cycles per degree of the visual angle.

At this age, it is particularly important to assess acuity in comparison to age-matched normative data. Visual development is most rapid during infancy, thus interventions are believed to be most effective if undertaken at this time<sup>172, 173</sup>.

Normative data are available for a variety of preferential-looking tests for children up to the age of eight years<sup>174-176</sup>.

### Case study aims

At GOSH, several preferential-looking methods are used during the clinical assessment of infants: the Cardiff, Keeler (KAC) and the Teller acuity card (TAC) procedures. Both KAC and TAC methods are routinely plotted against normative data.

At the time of this research, the hospital was transitioning to paperless working and all paper notes were removed and scanned after each clinic. This meant that clinicians could no longer add to or maintain the longitudinal graphs of visual acuity measures. The aim of this work, therefore, was to provide a tool that could be used in the GOSH ophthalmology clinics to capture and graphically represent visual acuity data in comparison to the age norms, primarily for the KAC and TAC measures. A secondary aim was to extend the age range of the plotted graphs, to facilitate the longitudinal assessment of interventions.

## ***Materials and methods***

### Development and testing

Insights gained during the previous clinical observations and the medical record review (Chapter 3, pp.77-137) formed the evidence base for this case study. More specifically, the frequent pattern of data items associated with documenting the distance visual acuity (Table 12, p.123) provided the data set to be captured. Additionally, the binocular visual acuity – a field also observed within the maximal set of routinely collected items, but with a lesser frequency – was included for completeness.

Using Microsoft Access (2013 version), a relational database was developed. Information on the date of testing, test measure, testing distance, and acuity achieved for the right, left and both eyes together could be inputted into the database by patient, using the hospital number as the identifier.

Acuity graphs were plotted within the database using a Microsoft Access report. Binocular and monocular data were plotted on individual graphs, differentiating the right and left eye through a coloured key. Normative TAC graphs were reproduced using published data from Mayer *et al.*<sup>177</sup>, as recommended in the TAC manual<sup>178</sup>. For the KAC procedure, no normative data could be identified within the literature or from clinical colleagues; data for the KAC norms were extrapolated from the template in use within the GOSH ophthalmology clinics at the time.

For older children, an additional graph that displayed all of the different acuity measures could be plotted. For this graph, all acuity data were converted to the logarithm of the minimum angle of resolution (logMAR scale). The recommended Snellen equivalents<sup>178</sup> and standard Snellen to logMAR conversions were used for the KAC and TAC procedures. An additional correction of  $+0.30\log\text{MAR}$  per meter was applied for distance recognition acuity tests (logMAR or Snellen) not completed at the calibrated testing distance of the chart. For example, a test completed at two meters using a four meter chart was plotted as the recorded logMAR value plus  $0.6\log\text{MAR}$ . The different tests were distinguished on the graph through the use of different symbols.

To test the tool, the longitudinal data for 12 patients were retrospectively entered into the database by MSC. These data were retrieved from medical records using EDM, as described in Chapter 3 (see methods on p.91). If available, the best corrected visual acuity for the right eye, left eye, and with both eyes open for all

previous clinic visits of each patient were entered. The KAC, TAC or all acuities were then plotted, as appropriate.

#### Implementation and use

The Microsoft Access tool was made available to clinical staff within the GOSH ophthalmology department in October 2017. It was integrated with a new Access database used by the department to record basic demographic, diagnostic and procedural data. Clinicians could view the plotted acuities within the Access database, or export and print a report to be included in the patient's medical record (see Appendix H for an anonymised example of the report produced, p.248). All users of the database were encouraged to provide feedback on the tool and any additional features that may be required for use.

### **Results**

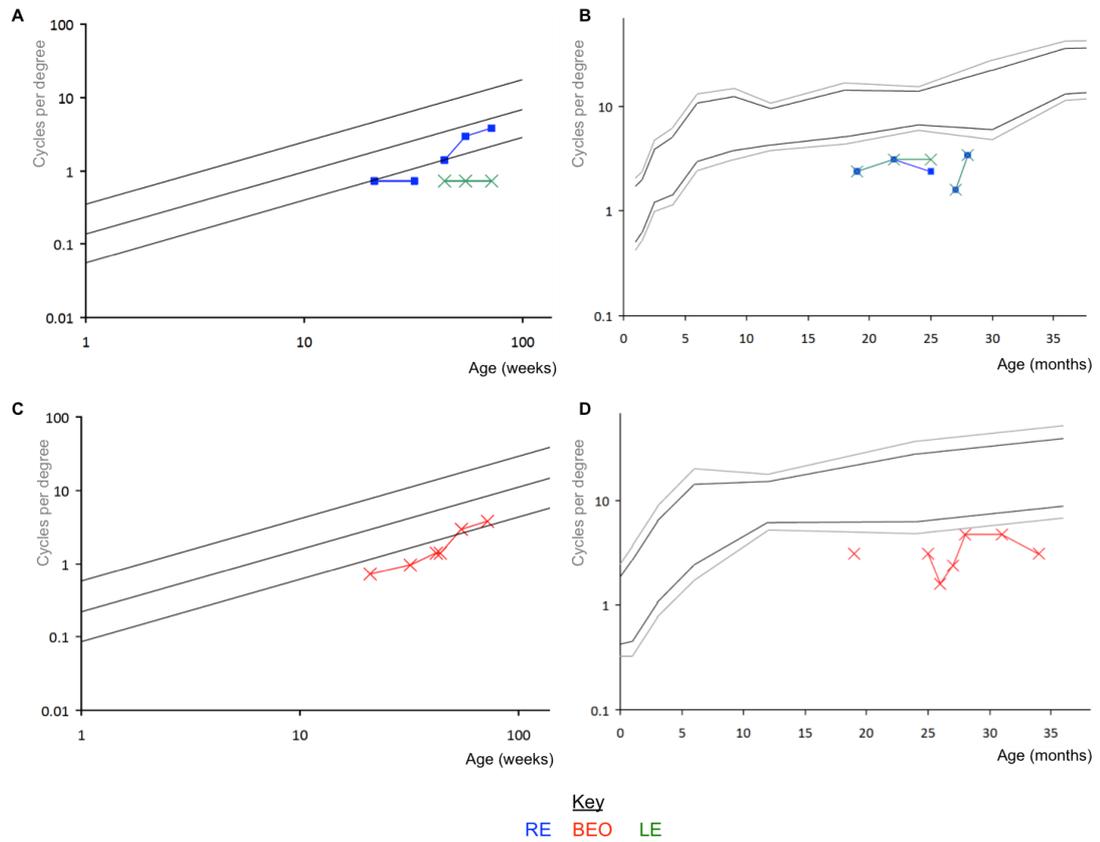
#### Retrospective test data

Examples of plots for the KAC and TAC procedures can be seen in Figure 28; in both patients, plotting the measured acuities against the normative data indicated the functional vision was below that expected. Figure 29 provides an example of an older patient (aged 8 years) who has had multiple acuity measures using different testing modalities.

#### Application use in GOSH clinics

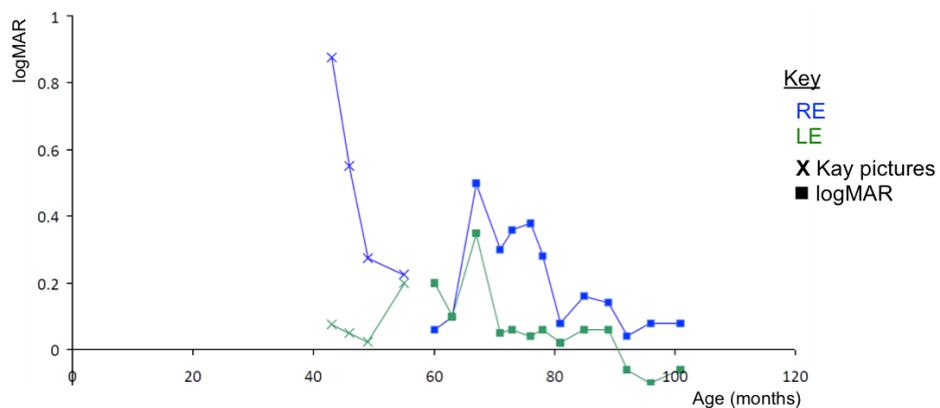
During a three-month period in 2017, a total of 330 acuity testing events for 68 unique patients (aged between 0 and 14 years, median 2 years) were entered into the GOSH ophthalmology departmental database. 28.2% of testing events were for KAC procedures ( $n=93$ ) and 7.3% for TAC ( $n=24$ ). Both orthoptic and medical clinicians had used the database to enter these data; no changes or additional

developments were requested by users following the implementation into GOSH clinics.



**Figure 28: Examples of Keeler and Teller visual acuities plotted with normative data.**

**A:** Monocular, Keeler acuity cards. **B:** Monocular, Teller acuity cards. **C:** Binocular, Keeler acuity cards. **D:** Binocular, Teller acuity cards.



**Figure 29: Longitudinal monocular visual acuities plotted for a patient undergoing occlusion therapy.**

## Discussion

An application was developed that could be used clinically to plot longitudinal visual acuity data for a range of paediatric patients. The focus of this work was to enable end users to plot the data against age matched norms, as it was identified as a key requirement by colleagues within the GOSH ophthalmology department and from clinical observations (Chapter 3, p.131). The importance of graphical representations of patients' development has also been highlighted by EMR users in other paediatric fields<sup>88</sup>.

In this study, published normative data could not be found for the KAC procedure and so data were taken from a normative graph in use within the GOSH clinics, of which the source of the original data was not known. Research indicates that the KAC and TAC tests produce comparable results in children aged between 24 and 90 months<sup>179</sup>, and normative TAC data have been used in place of KAC in published literature<sup>180</sup>. The KAC and TAC normative data used in this work were also found to overlap (Figure 30), and so the extrapolated KAC data were deemed acceptable and included within the Access database.

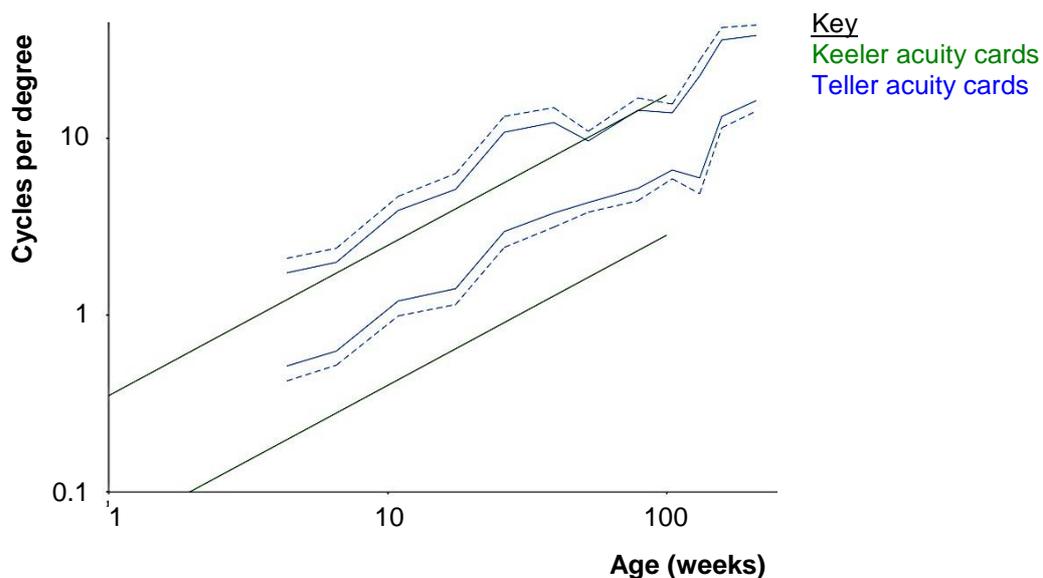


Figure 30: A comparison of normative data for Keeler and Teller acuity cards.

Microsoft Access was used to develop the database, as it was readily available for use by GOSH staff in the outpatient clinics, facilitating implementation. The application developed was suited to its purpose, and users did not request any changes; however, the software may not be suited for any further developments that require additional functionality. As we move into an era where patients are encouraged to access and interact with their health data online<sup>13</sup>, it is easy to envisage how similar visualisations of acuity data may be useful if made available to patients and their families. For example, in a tool that allows patients to document treatment compliance at home (e.g. with occlusion therapy) and visualise the changes in acuity following clinical assessments. Such a tool would require the use of interoperable software that can be accessed from outside of the Trust's network, and so Microsoft Access would no longer be suitable. However, the data set definition and data collection form designed within this case study would form a good platform upon which to base future work.

### 4.2.3 Case study 3: Pedigree drawing

Genetics are playing an increasing role in modern healthcare, with the rise of precision medicine. As such, pedigree drawing is becoming a vital part of medical history taking within clinical consultations.

In paediatric ophthalmology, many blinding diseases have a genetic cause. These include a number of disorders such as inherited dystrophies, optic neuropathies and cataract. Indeed, in Chapter 3, (pp.77-137) it was noted that pedigree drawings were a part of the routinely collected data set in the GOSH ophthalmology outpatient clinics. Thus, a requirement of a paediatric ophthalmic EMR for this context is the integration or inclusion of pedigree drawing software.

#### Algorithmic approaches to pedigree drawing

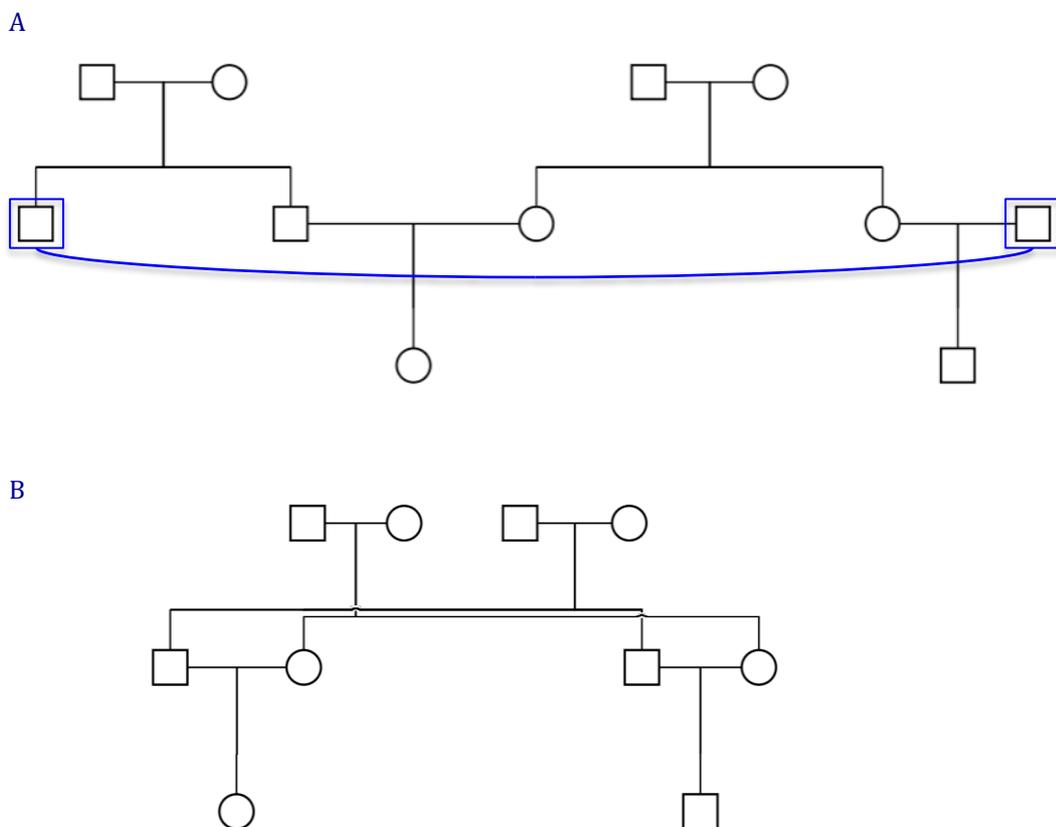
Tores and Barillot outlined five criteria of the “perfectly drawable pedigree” (PDP)<sup>181</sup>:

- (i) Individual family members must not overlap.
- (ii) Mates must be adjacent.
- (iii) Sibs must be adjacent, although an “orphan” spouse (i.e. one with no parents indicated on the graph) may be inserted into the sibship with their mate.
- (iv) Parents must lie above their child sibship.
- (v) Relationship lines must not cross.

A variety of approaches have been applied in pedigree drawing algorithms. Interval graph theory has been successful for PDP graphs<sup>181, 182</sup>. However, Tores and Barillot noted that divergence from PDP occurs when the pedigree contains more than two individuals with non-orphan mates in a single sibship, an individual has three or more mates, or the graphs are cyclic (i.e. consanguineous)<sup>181</sup>. Such

complexities are encountered in “real world” clinical pedigrees and therefore the problem remains non-trivial.

Some have focused efforts on transforming pedigrees into acyclic PDP graphs prior to visualisation. In this method, individual family members are duplicated so they appear twice in the pedigree, removing cycles from the graph and the need for line crossing<sup>183</sup> (Figure 31). The resulting graphs are more aesthetically pleasing but have reduced information content.



**Figure 31: Pedigree drawing solutions.**

Both images depict the same pedigree. **A:** A duplication transformation, removing all line crossing but a family member appears twice within the pedigree. **B:** A cyclic graph in which line crossing is indicated through the use of bridges.

The majority of open source, freely available pedigree drawing software (Table 16) are based on either Tores and Barillot’s interval graph method<sup>181</sup> or the duplication

transformation approach, derived from an algorithm originally published by Mäkinen *et al.*<sup>183</sup> Hybrid approaches are also available that will draw cyclic graphs when possible but, in the case of line crossing, duplication transformations may still be applied<sup>184</sup>.

**Table 16: Open source pedigree drawing software.**

Program (year published)	Approach	Interactive
Pediquery <sup>185</sup> (2004)	Interval acyclic graphs	No
CraneFoot <sup>183</sup> (2005)	Duplication transformation	No
HaploPainter <sup>186</sup> (2005)	Duplication transformation	No
kinship <sup>182</sup> (2006)	Interval acyclic graphs	No
Madeline 2.0 Pedigree Drawing Engine <sup>184</sup> (2007)	Hybrid	Yes
PedWiz <sup>187</sup> (2013)	Interval acyclic graphs	No
kinship2 <sup>188</sup> (2015)	Duplication transformation	No

When designing pedigree drawing tools for the clinical environment, the need for interactive software that can draw a pedigree in real time, as the patient reports their family history, poses an additional challenge. Six of the seven open source tools are only capable of producing pedigrees from a data file or command line input (Table 16), and are therefore not appropriate for clinical uses.

#### Force-directed graphs

Force-directed graph drawing algorithms aim to produce graphs in two- or three-dimensional space that are aesthetically pleasing. A popular force-directed method, known as spring-embedding, applies repulsive forces between all graph nodes and attractive forces between edges<sup>189</sup>. Spring-embedder models physically simulate force exertion and node movement until the system reaches a state of mechanical equilibrium. The resulting layouts typically have little line crossing and high degrees of symmetry.

The force-directed layout offers a solution to optimally space the components of a pedigree. In the current study, a force-directed approach was applied and tested

during the development of an interactive pedigree drawing tool that was suitable for use during clinical consultations.

## ***Materials and methods***

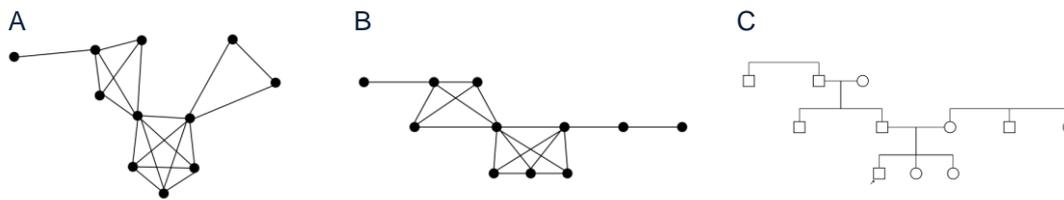
### Requirements analysis – Use case scenarios

Qualitative data collected during observations of the GOSH ophthalmology outpatient clinics (see Chapter 3 for detailed methods, pp.76-137) were reviewed for descriptions of family history taking and pedigree drawing processes. These data were used to construct three use case scenarios that describe different examples of family histories, including a range of situations and family structures. The scenarios (detailed in Appendix I, pp.249-250) were used to identify user goals and system requirements.

### Software development

Initially, pedigree features described in the Standardised Human Pedigree Nomenclature<sup>190</sup> were built. As with the previous ROP case study, components were developed using the OpenEyes EyeDraw framework and HTML web page elements. This was an iterative process, integrating user feedback throughout to ensure requirements were met and the resulting tool was appropriate for clinical use.

An additional algorithm was written in JavaScript to optimally space the pedigree components within the graph. A force-directed approach was applied in a three-stage algorithm (Figure 32). The first two stages space the family members within the graph, first by force application (Figure 32.A), and then according to pedigree drawing norms (Figure 32.B).



**Figure 32: Stages of the algorithm used to space pedigree members.**

**A:** Nodes optimally spaced via force application. All nodes are marked as black dots, the straight lines between node center points indicate the spring-like connections representing relationships. **B:** Node placement following coordinate normalisation according to pedigree drawing norms. **C:** Nodes and edges drawn according to the US Genetics Working Group's standardised pedigree representation<sup>191</sup>.

During the force application stage, all family members (nodes) are simulated as particles of the same charge, repelling one another as in Coulombs Law. Spring-like attractive forces based on Hooke's Law then pull directly related individuals towards one another. Through varying the spring strength for the different types of relationship, the algorithm adheres to pedigree-drawing norms. For example, a stiffer spring between two mates compared to that between two siblings encourages mates to be adjacent, even within sibships. Additional springs were used to preferably align male mates to the left of their partners, and to attract all members to the canvas midpoint, centering the pedigree. A final attractive force is applied between nodes and their start position at the point of running the algorithm; this ensures the pedigree layout is conserved between each algorithm application.

Stages (A) and (B) (Figure 32) are repeated iteratively until either all node movement is less than a minimum threshold distance, or a maximum number of iterations has been reached. Both termination points are defined as parameters of the algorithm and were optimised during the development and testing processes. Once all nodes are spaced, the pedigree is drawn according to the standardised representation (Figure 32.C).

### Software performance testing

Two consultant paediatric ophthalmologists were asked to test the software. From clinical observations, both participants were identified as clinicians who draw pedigrees as part of their routine practice; however, one individual (RH) was more involved with the development of the software than the other. Using the three use case scenarios, the two participants were separately asked to work through and record the relevant family history of each patient, as they would clinically, and draw the pedigree using the software. The participants were blind to the scenarios during the tests; MSC acted as a family member and, guided by questions from the clinician, reported the family history. During each test, data were collected on the timing of the user's mouse clicks, in addition to an audio recording of the session. Using the ELAN software (version 5.0)<sup>192</sup>, the audio data were transcribed and annotated to indicate who was speaking and whether they were asking a question, answering a question, or making other comments (e.g. to request help with the software). Using these data, the clinician's pedigree processes and use of the software were reviewed; annotated audio and mouse click timing data were then aligned, to assess if using the software resulted in pauses during the verbal history taking.

MSC also tested the software using pedigrees that were identified from medical records during the retrospective review (described in Chapter 3, see methods on pp.91-96). Only unique pedigrees were included, i.e. in cases where pedigrees were identified in the medical records of siblings or other relatives, only one pedigree for each family was tested. Any features that could not be drawn were discussed with users and added to the tool if required.

Finally, the performance of the software was compared to several other freely available pedigree drawing tools, using an assessment originally made by the developers of Madeline PDE 2.0<sup>184</sup> from the University of Michigan in 2007. Five

pedigrees from within the Madeline PDE 2.0 test data were used to compare their software to several others (Madeline 2.0 PDE, CraneFoot, HaploPainter, kinship2 package in R, and PedigreeQuery)<sup>193</sup>. Each test pedigree demonstrated a complex family feature (consanguinity, multiple partners, and multiple descent trees); the authors of the original work stated that the pedigrees are representative of complex pedigrees encountered in family-based clinical and genetic studies. Using the pedigree drawing tool, the test pedigrees were recreated and compared to the output from the other software in terms of the overall pedigree layout and component positioning, the order of individuals within groups such as siblings and mates, and the amount of line crossing.

#### Implementation and use

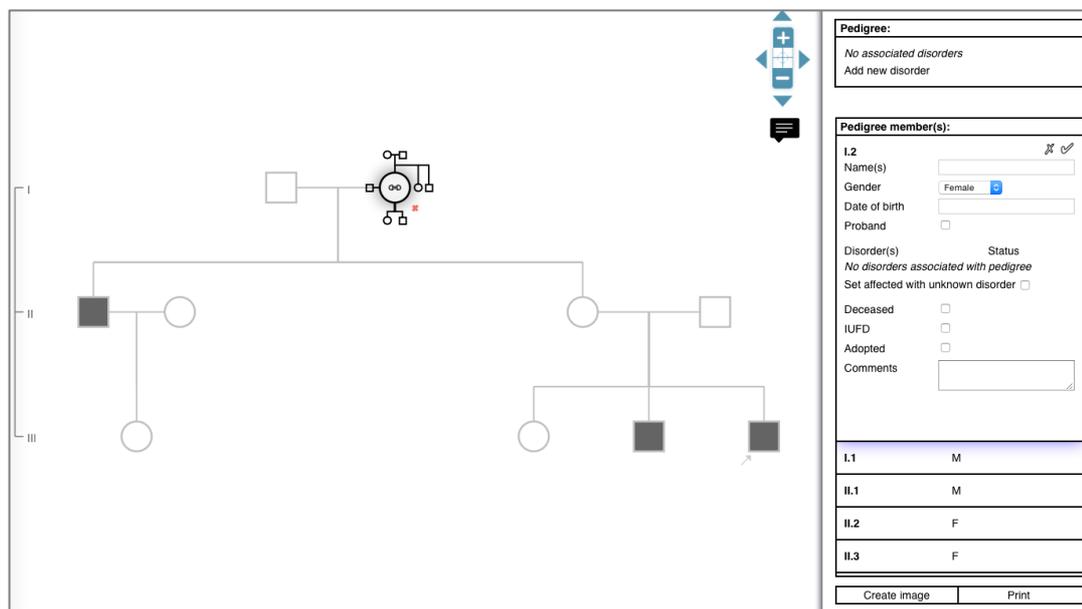
From March 2017, the pedigree drawing software was made available online for use by the ophthalmology department at GOSH. No pedigree data were stored; users could use the software to draw clinical pedigrees and either print or save the output as part of routine documentation. The saved pedigree images could be imported into the patient records within a Microsoft Access database in use by the GOSH ophthalmology department, as described for the visual acuity case study. The addition of pedigrees into the database was implemented as part of the introduction of a new workflow for genetic testing.

Users were encouraged to provide feedback regarding the suitability of the tool and its use within the clinical environment. All pedigrees drawn by clinical users and saved within the Access database were reviewed in November 2017 by MSC, to identify additional requirements and or challenges encountered when drawing pedigrees in real time as opposed to the retrospective method assessed with the record review process.

## Results

### The application

A screenshot of the web-based application produced can be seen in Figure 33. Using the interactive drawing tool, users were able to add and remove family members and set basic, commonly used parameters, such as an affected or deceased status. The sidebar, where all pedigree members were listed, was used to input more detailed demographic, phenotypic or genotypic information.



**Figure 33: A screenshot of the pedigree drawing software in use.**

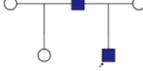
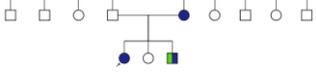
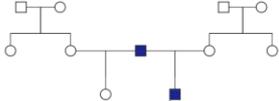
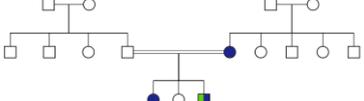
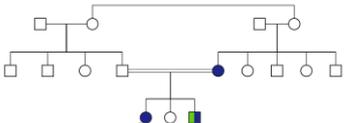
Eighteen required features of standardised pedigree representation were identified from the United States Genetics Working Group<sup>191</sup>. Twelve of these features were included in this software as a predefined icon, as was deemed appropriate by the clinical users involved in the development. An additional two features could be visualised using the software but were not specific icons; instead, the user was required to annotate family members manually with the desired feature (a summary of all features can be found in Appendix J, p.252).

Following iterative feedback from users, several additional drawing features were developed. These included the ability to indicate that a family member may have been affected with a disorder ('query affected'), an annotated symbol for intrauterine fetal demise, and the numbering of generations down the left hand side of the drawing. Also, the ability to annotate the pedigree was added: using the speech box icon (shown in Figure 33), users were able to select which features they would like to be annotated for all family members from the individual's name, age, phenotype, an auto-calculated identifier indicating the generation, or any free text using the comments field.

Use case scenarios

**Table 17: The construction of scenario pedigrees by clinical test users.**

Clinicians constructed pedigrees in reverse chronology; examples of the questions they asked the test patient are provided.

Scenario 1	Questions asked by clinicians	Scenario 3
	Do you have any brothers or sisters?	
	Mum / dad, do you have any brothers or sisters? Do they have any children?	
	Mum / dad, are your parents fit and well?	
	Mum / dad, are you related at all?	

When working through the use case scenarios (Appendix I, pp.249-250), both clinicians were able to draw all three pedigrees using the software. In constructing the pedigrees, both clinicians started with the youngest generation and logically

worked backwards in time until the history was no longer relevant, or no additional information could be recalled. Examples of this workflow and the questions asked by the clinicians can be found in Table 17 for the two more complex scenarios (scenarios one and three).

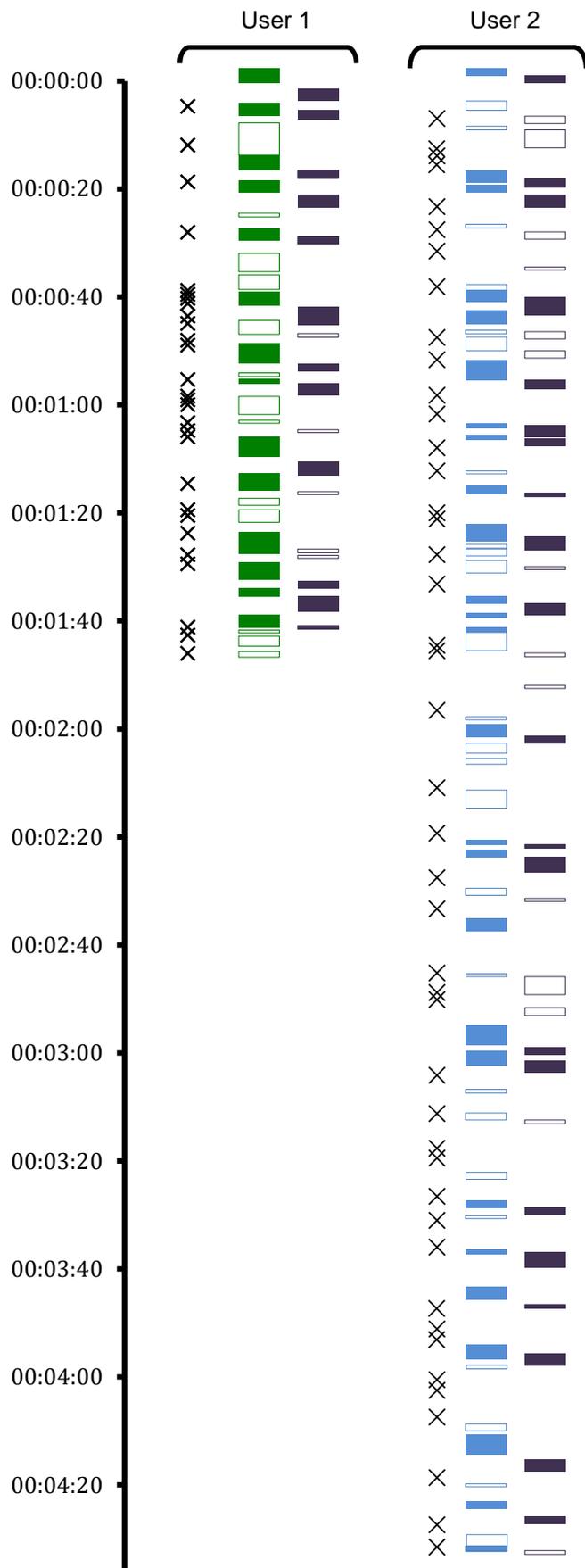
It was difficult to compare or generalise the performance of the two clinicians, as their documentation behaviours were quite different. The second clinician tended to include more information in each pedigree, such as the names and ages of the extended family; overall, this test user spent longer on each scenario, and made a greater number of mouse clicks (Table 18).

**Table 18: Summary statistics for pedigree drawing scenarios.**

User 1 was more experienced using the software in comparison to user 2.

		User 1	User 2
Scenario 1	Total time spent on scenario (min:sec)	1:46.2	4:28.7
	Proportion of time clinician spent asking questions (%)	35.8	20.7
	Proportion of time spent making other comments (%)	25.6	13.5
	Total number of mouse clicks	28	45
Scenario 2	Total time spent on scenario (min:sec)	1:21.0	3:57.1
	Proportion of time clinician spent asking questions (%)	24.8	18.6
	Proportion of time spent making other comments (%)	14.2	12.9
	Total number of mouse clicks	27	39
Scenario 3	Total time spent on scenario (min:sec)	2:04.4	6:11.9
	Proportion of time clinician spent asking questions (%)	25.0	22.3
	Proportion of time spent making other comments (%)	13.9	16.8
	Total number of mouse clicks	49	63

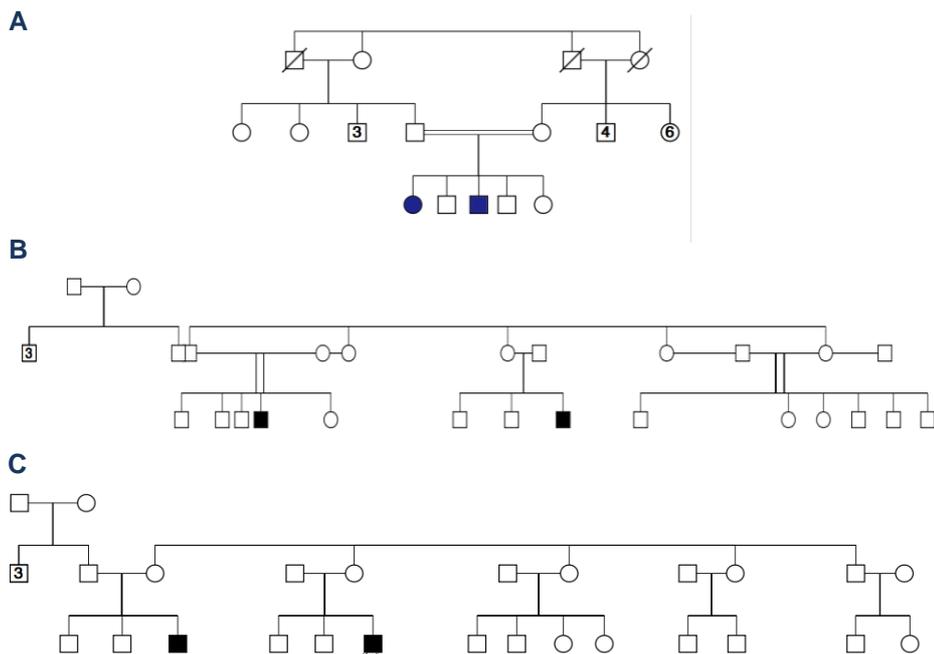
For both clinicians, the use of the software resulted in pauses in the conversation, as indicated through the timing of mouse clicks primarily in times when the clinician was talking but not asking the patient questions or in silent gaps (an example is visualised in Figure 34). In these cases, however, the first clinician with more experience tended to rearticulate the patient's history whilst he was drawing, whereas the second clinician asked questions about the software.



**Figure 34: Use case scenario one: timing data comparing two clinical test users.**

Filled bars represent time spent taking the patient's history: green for user 1 (experienced user), purple for the test patient (MSC), and blue for user two. Bars not filled with a colour represent speech not directly related with the history taking (e.g. asking how to use the software, or clarifying what is being drawn). Crosses indicate the user's mouse clicks.





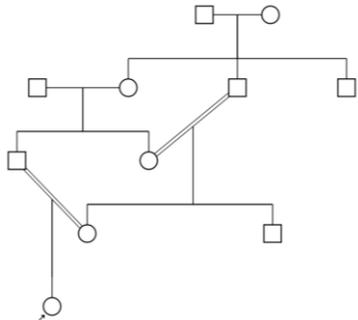
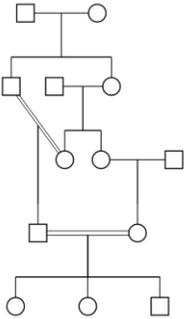
**Figure 36: Un-drawable pedigrees identified by clinical users.**

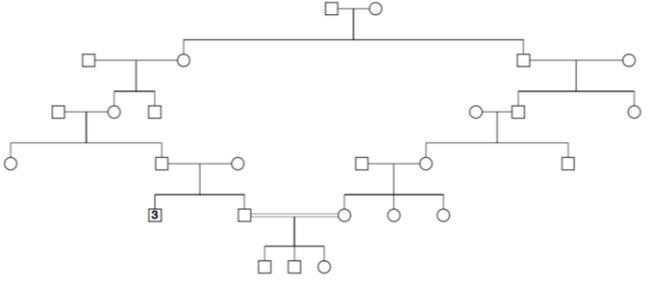
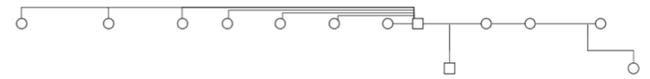
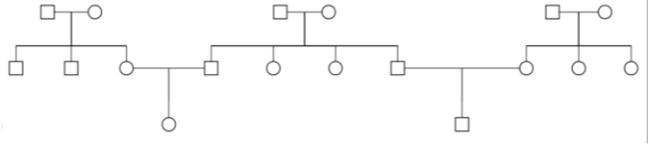
**A:** Two pairs of siblings mated, resulting in line crossing. **B:** With many individuals in a single generation, the algorithm did not reach equilibrium. **C:** Pedigree (B) re-rendered with the user manually overriding the layout.

Another challenge was encountered in calculating the layout of larger pedigrees. Examples were identified in which the layout was not resolved – as seen in Figure 36.B, resulting in a high degree of line crossing and an unreadable pedigree. To overcome this limitation, the ability for users to move family members within the pedigree was added, and so the algorithm can be overridden and the layout manually corrected (Figure 36.C). On occasion, however, this required family members to be added to the pedigree in an order that deviated from the patient’s verbatim description, and was found to be too time consuming during a consultation.

**Table 19: A comparison of open-source pedigree drawing tools.**

The software comparison was originally made by Khanna *et al.*; their findings (highlighted in purple) are presented in comparison to the performance of the software developed within this case study<sup>193</sup>. All pedigrees are depicted in the layout rendered by the algorithm, without any user input.

Force-directed approach	Madeline 2.0 PDE	CraneFoot	HaploPainter	kinship2	PedigreeQuery
			Pedigree rendered using non-standard notation and poor readability	Required duplication transformations	Could not render pedigree
		Required duplication transformations	Pedigree rendered using non-standard notation and poor readability	Required duplication transformations	Could not render pedigree

		<p>Required a duplication transformation</p>		<p>Pedigree layout correct, but consanguinity not indicated with a double line</p>	<p>Pedigree layout correct, but consanguinity not indicated with a double line and one case of bridged line crossing</p>
 <p>Could not render full pedigree: a high degree of line crossing occurred and the repulsive forces between individuals were too strong.</p>		<p>Required duplication transformations</p>	<p>Could not render pedigree</p>	<p>Could not render pedigree</p>	
		<p>Required duplication transformations</p>	<p>High degree of line crossing and incorrectly depicted relationships as consanguineous</p>		<p>With one case of bridged line crossing</p>

### Software comparison

The performance of the force-directed approach utilized in this case study was found to be comparable to other open-source pedigree drawing tools (Table 19). The software was able to render four of the five test pedigrees identified by Khanna *et al.*<sup>193</sup>, outperforming four of the other tools considered that often relied upon duplication transformations in order to render the pedigree.

One pedigree could not be visualised. Here, one male had eleven mates, each with several children. The software is limited to visualising a maximum of six mates for a single individual, beyond which line crossing occurs. Furthermore, as identified by the test users, the system does not reach equilibrium for pedigrees with many individuals in the same generation as the repulsive forces are too strong, resulting in an unsatisfactory layout. Only two of the other five tools could render this pedigree.

### **Discussion**

In this study, a clinical pedigree drawing application was developed that, following an iterative design process, was suited to draw the majority of the pedigrees identified and tested. Two clinicians were able to use the software when taking the history of test patients using scenarios, and it has been implemented within GOSH outpatient clinics.

However, the software was found to have some limitations that resulted in a failure to render larger pedigrees. This problem was only encountered by those clinical users that tested the software during GOSH ophthalmology clinics. A number of reasons may explain this: in contrast to the test pedigrees identified from medical records, the users were not as familiar with the software, and, as identified in the worked scenarios, the clinicians had to draw the family tree in the order and at the

speed dictated by the patient, which may have resulted in sub-optimal layouts. The pedigrees saved to the GOSH database were also generally larger. These patients were primarily on a pathway for genetic testing and, therefore, may represent the most genetically complex cases. Such clinical genetics applications would, however, form a major use for the tool in clinics, and so additional work is required to ensure the software is suitable for use.

Others have explored force-directed methods for larger graphs and found it necessary to identify sub-systems within the graph in which the forces are applied locally<sup>194</sup>. In the current application, large numbers of individuals in a single generation with the same fixed Y coordinate meant individual nodes tended to spread too widely across the X-axis following repulsive force simulation. The construction of smaller sub-pedigrees – consisting of closely related individuals – would minimise the number of family members with the same Y coordinate. Then, an application of only local forces within these sub-systems might facilitate the layout calculation for larger pedigrees.

Despite this limitation with the layout, the performance of the software was found to be comparable to other open-source tools. While, as noted by the original authors<sup>193</sup>, this comparison did not consider several pedigree features including multiple births, several phenotypes, or an ability to annotate individual family members. The software developed in this work contains all of these features, as indicated by the test pedigrees.

All of the other tools compared were either not able to render cyclic graphs, or made use of duplication transformations. Madeline 2.0 PDE – developed by the authors of the original comparison who selected the examples pedigrees – did not require the transformation of any of the test pedigrees considered; however, the documentation for the tool clarifies this is a technique that may be applied when line crossing

cannot be resolved<sup>184</sup>. The use of duplication transformations can improve the aesthetic criteria of complex pedigrees, so they adhere to the rules of PDP<sup>183</sup>. This may be preferable in the research context, for use in published figures and so forth. However, duplicating family members within a pedigree can introduce ambiguities and reduce the ability of clinicians to rapidly review the information during a consultation. The clinical users involved with this development case study expressed a preference for bridged line crossings as opposed to duplication transformations. This ability was only implemented within one other tool reviewed (PedigreeQuery<sup>195</sup>), but is feasible and a focus for future development work.

### 4.3 Conclusions

In this chapter, a UCD approach was applied to develop and test software for three clinical use cases. Some areas for future developments were identified; however, testing indicated all three case studies produced useful tools. As defined in Chapter 1.1 (p.36), the “usefulness” of a system considers both the utility and usability. In the three case studies included in this work, the majority of the tests assessed the utility of the tools developed.

During the design processes, different UCD methods were useful in ensuring the utility of the tools, and so the breadth of the clinical data encountered in each use case could be captured.

When developing the pedigree drawing tool – as also found by others involved with the development of clinical genetics applications<sup>196</sup> – the use of scenarios provided a means of understanding user behaviours and identifying requirements. Establishing a discourse between HIT designers and clinical end users was a concern identified by clinicians in Chapter 2 (pp.44-76); scenarios proved to be useful in overcoming this hurdle by providing background and context upon which discussions could be based.

In ROP, the breadth of cases expected was defined within an international classification system and therefore was known prior to the commencement of the UCD process. As such, task analysis techniques based on observational studies had a greater utility in this case study. This method provided a broader understanding of the context in which the application would be used, and a realistic whole-system view of additional work that would be required before implementing such an application into routine practice.

Both the ROP and pedigree drawing cases studies followed a highly iterative development process that continued whilst testing the systems. This was in contrast

to the process achieved in the visual acuity case study. In this instance, development was based upon an in depth ethnographic study of clinical documentation (Chapter 3, pp.77-137) and, as visual acuity assessments were found to be one of the most common tasks undertaken by a range of clinical users, there was a wealth of evidence to initially guide the design. An ethnographic study is a costly process when considering the total time spent on data collection and analyses. This should be considered prior to selected UCD techniques, especially when developing focused, single-purpose applications as presented in each of these case studies.

When considering the usability of each of the three case studies, qualitative data derived from focus groups and test user feedback formed the primary means of assessment. Although two of the use cases were implemented and used within the GOSH ophthalmology clinical workflow, it has been widely acknowledged within UCD literature that usage is not evidence of a usable system<sup>197</sup>.

Some preliminary quantitative assessments of system usability were undertaken in this work. As has been found with other HIT systems<sup>198, 199</sup>, the timing data obtained for both the pedigree drawing and ROP tools suggested there was a learning effect associated with use, where novice users spent longer completing the tasks. However, it was also noted in both cases that timing data might have been influenced by variations in documenting behaviours. Tests involving a larger number of end users would be required to make any conclusions about the usability of the tools, likely necessitating the engagement of clinicians from outside of GOSH. However, while the usability conclusions from this work may be limited, the initial findings suggest that the testing methods used would be appropriate for further usability studies.

## Chapter 5 The suitability of SNOMED-CT

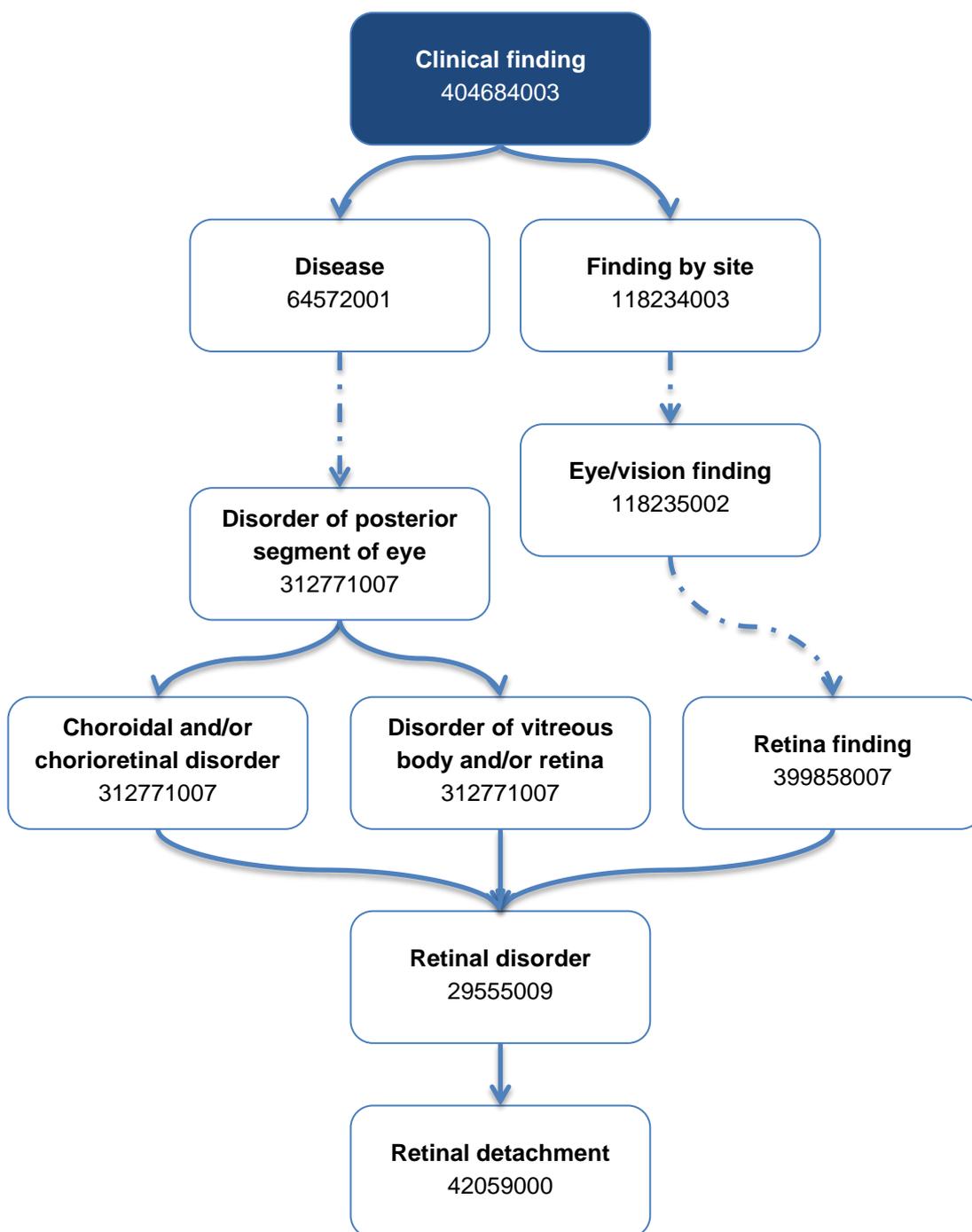
### 5.1 Introduction

SNOMED-CT is to be universally adopted as the standard coding terminology across NHS England by 2020, as previously discussed (p.25). The National Information Board endorsed the use of SNOMED-CT – believed to be the most comprehensive and accurate clinical terminology system – to ensure information is captured clearly and consistently across the healthcare system<sup>40</sup>.

As a structured terminology, the use of SNOMED-CT will facilitate data sharing within and across clinical environments, and also for secondary purposes. Through the standardised representation of clinical information, abilities to aggregate and analyse data will be enhanced at the point-of-care, for example within decision support systems, and for audit and research<sup>200</sup>.

#### 5.1.1 SNOMED-CT structure

SNOMED-CT is a collection of clinical concepts, each with a computer-readable, numerical identifier and associated human-readable textual descriptions. The concepts cover the entirety of the health and care of an individual, including all diagnoses, procedures, symptoms, drugs, body structures, and so forth. These differing domains provide the top-level concepts of SNOMED-CT, each with child concepts, giving a hierarchical structure. Concepts within domains are linked by *is a* relationships and increase in specificity with hierarchy depth. An example of several concepts linked by parent-child *is a* relationships within a single hierarchy can be found in Figure 37.



**Figure 37: Examples of SNOMED-CT concepts linked by parent-child *is a* relationships within the Clinical Finding domain for the Retinal detachment concept.**

Solid lines indicate a direct parent-child relationship, whereas, for dashed lines, some generations have not been visualised.

Other relationships are used to link SNOMED-CT concepts, providing the logical definitions. Here, SNOMED-CT concepts are often linked to a specific concept set – termed qualifiers – that lie within the Qualifying Value domain of SNOMED-CT and are used to refine the meanings of other codes. Unilateral, left, known absent, and in the past are all qualifiers. Examples of the linking relationships include finding site, severity, and laterality. The combination of multiple concepts is called post-coordination; a concept that is encoded using a single SNOMED-CT identifier is said to be ‘pre-coordinated’.

### **5.1.2 SNOMED-CT for ophthalmology**

The international ophthalmic community has been an active participant in the development of SNOMED-CT. In 2007, the terminology was officially endorsed by the American Academy of Ophthalmology; they have since made efforts to model ophthalmic concepts as SNOMED terms and evaluate their usage<sup>201</sup>.

In comparison to other clinical terminologies, SNOMED-CT has been found to have the best coverage of ophthalmic clinical concepts<sup>39, 43</sup>. This research, however, was conducted over ten years ago, when SNOMED-CT (January 2005 version) contained approximately 360,000 unique concepts<sup>39, 42</sup>, in comparison to the 535,886 concepts within the July 2016 release<sup>202</sup>. There is no up-to-date assessment on the suitability of SNOMED-CT for ophthalmology, and also no literature that considers the paediatric ophthalmology specifically, or the application of the coding system within ophthalmic research.

### **5.1.3 Study aim**

This was an exploratory study to identify the challenges that will follow the widespread adoption of SNOMED-CT within paediatric ophthalmology. The coverage, accuracy, and reproducibility of the terminology were considered when coding the data concepts identified within a national epidemiological study of childhood visual impairment and blindness.

## 5.2 Methods

The methods employed were similar to those described in the literature for similar studies that assessed the suitability and usability of clinical terminologies<sup>39, 43, 203, 204</sup>.

### 5.2.1 Study context

This study considered the suitability of SNOMED-CT in the context of a national epidemiological study, BCVIS2. An overview of the BCVIS2 study and its aims can be found in Chapter 3 (p.95). Data items from the initial BCVIS2 ophthalmology data collection form were used to identify expressions to be coded using SNOMED-CT.

### 5.2.2 Expression identification

The data collection form was parsed for discrete clinical expressions. The expressions may have been simple (consisting of a single concept) or complex (multifaceted, compound concepts). In Chapter 3, the BCVIS2 questions or data headings from the initial ophthalmology data collection form were considered (p.95); in this study, the answer options or potential data values were used. Each unique answer option gave a single clinical expression. Both high level concepts (e.g. *Disorder of the lens*) and lower level (e.g. *Cataract*) were included, as they appeared in the study design. Open-ended free text questions were excluded; however, “other” list items (e.g. *Other disorder of the lens*) were included.

### **5.2.3 Expression coding**

#### ***Expert reviewers***

In April 2017, two reviewers (MSC and GWA) – both with a high understanding of SNOMED-CT – individually selected codes for each of the unique expressions using the SNOMED-CT UK extension (20170401 release). To complete the process, both reviewers used the same online SNOMED-CT browser from the National Pathology Exchange (NPEX). For each code identified, the reviewers rated their confidence with the selection (1 – certain, 2 – somewhat certain, 3 – uncertain), and how accurate they thought it was (1 – complete match, 2 – partial match, 3 – no match) with explanations where necessary.

The two reviewers met in June 2017 to compare and harmonise the code selections. Here, the NHS England data model and dictionary (version 3)<sup>205</sup> was used, where appropriate, to align SNOMED-CT code choices with NHS data standards. Any discrepancies in code selection were discussed and, if possible, resolved. The remaining disagreements between the two reviewers formed the basis of a questionnaire that was to be completed by individuals practising in clinical ophthalmology, with the aim of reaching a final consensus for code selections.

#### ***Email questionnaire***

The questionnaire contained two parts: an initial section to assess the level of agreement across the participants, and a second section considering the unresolved disagreements between reviewers.

For the first section, a subset of the clinical expressions was randomly selected (approximately 5% of the total number identified), including only expressions where

the two reviewers where in complete agreement upon an appropriate SNOMED-CT code and how accurate it was for the given clinical expression.

For each of the selected items, participants were presented with the expression as it appears in the BCVIS2 data collection form with the corresponding question number, the readable English text for the chosen SNOMED-CT code and its destination parent concept (the supertype). Participants were asked how accurate they think the code choice was using five point Likert-type questions. The five possible answers were: 1 – complete match, 2 – partial match (too broad), 3 – partial match (too narrow), 4 – partial match (slightly different meaning), 5 – no match.

In the second section, for each of the unresolved disagreements, the chosen SNOMED-CT codes of the two reviewers were randomly assigned to be option A or option B, and presented as described for the first section. Participants were asked whether they would use option A, option B, both coding options, or neither to identify the appropriate data in an EMR, and were encouraged to explain their reasoning using a free text box. For questions where one reviewer did not think there was a suitable SNOMED-CT code available, participants were presented with only two options: option A – the single code selection, or no appropriate SNOMED-CT code.

The questionnaire was disseminated in September 2017 by email to the PAED-OPHTH-STRABISMUS Listserve, as described in Chapter 2 (p.46). The email included a cover letter outlining the aims of the study, an overview of SNOMED-CT and it's use, and the survey as a Microsoft Word document; the questionnaire could be completed electronically or printed and filled out by hand. A reminder email was sent to the group four weeks after the initial invitation; responses were collated until November 2017.

All questionnaire materials, including the cover letter, SNOMED-CT overview and questions, are available in Appendix K (pp.254-262).

#### **5.2.4 Data analyses**

All data were entered into Microsoft Excel spreadsheets, which were also used to compute frequencies. The frequency of exact code matching was calculated to assess the initial inter-coder agreement between the two expert reviewers. A dummy Boolean variable (true if match) was created and used in a chi-square test to test for an association between the complexity of the question and reviewer agreement.

Responses to the first questionnaire section that assessed the accuracy of chosen SNOMED-CT codes were collapsed from five categories to three for analyses: complete match, partial match and no match. For all questionnaire items, the modal average was used to indicate overall sample preference and the chi-square goodness-of-fit or Fisher's exact test was used to test for significance, as appropriate. All statistical analyses were completed using SPSS version 24.0.0.

## 5.3 Results

### 5.3.1 BCVIS2 clinical expressions

255 unique expressions were identified from the BCVIS2 data collection form, including both expressions common to all healthcare domains (e.g. *NHS number, ethnicity, family structure*) and expressions specific to ophthalmology (e.g. *Keeler acuity cards; Perception of light, right eye; Certified as Sight Impaired*).

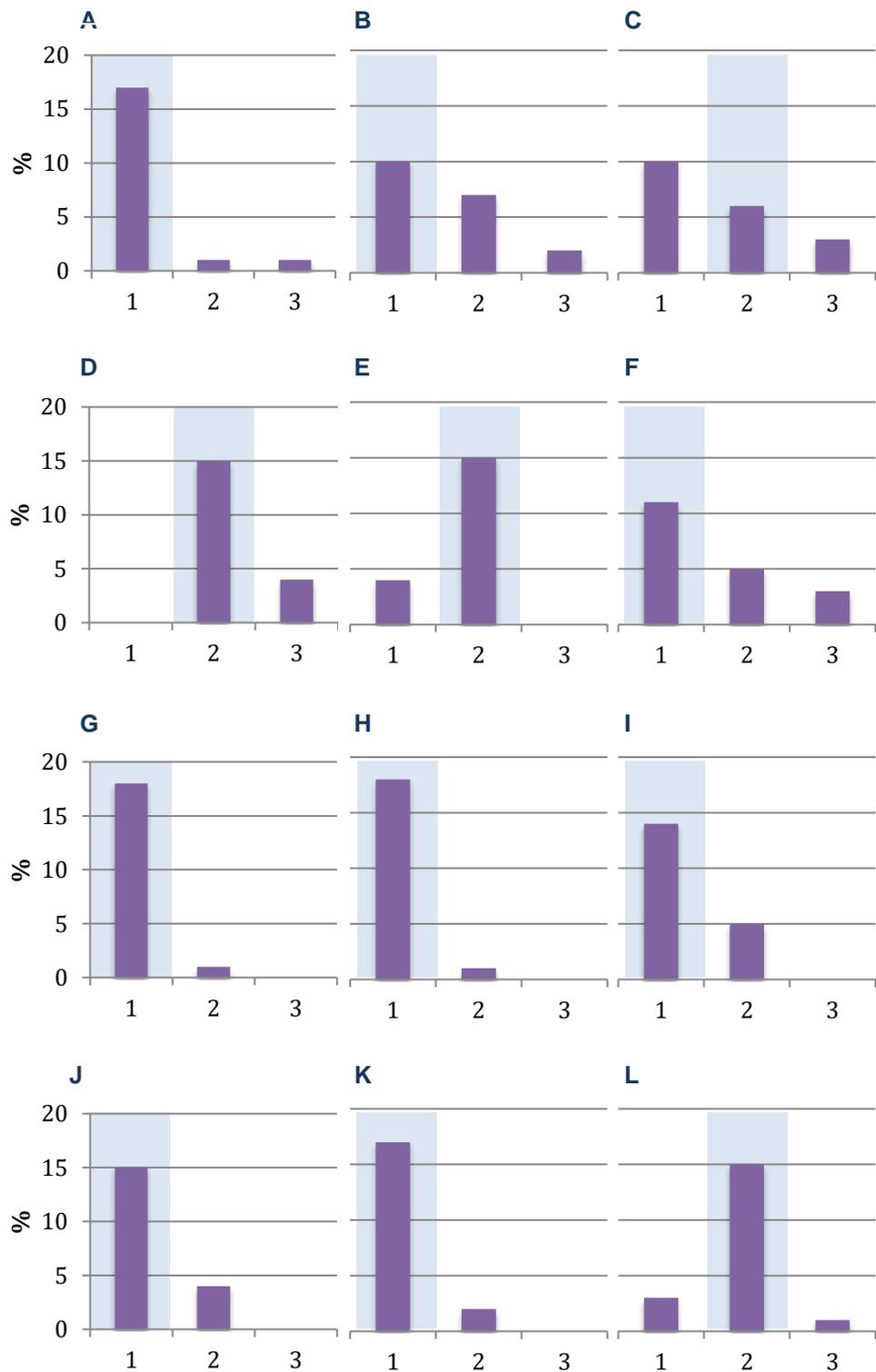
43.1% ( $n=110$ ) of the identified expressions included more than one clinical concept, and were classified as complex. A variety of complexities was observed, including specifying the laterality of a finding, indicating causation (e.g. *Retinal dystrophy resulting in visual impairment*), and temporal qualifiers such as the specific date of an event (e.g. *Date of visual field assessment*) or the chronology (e.g. *First referred by GP*).

### 5.3.2 Expression coding with SNOMED-CT

#### *Inter-reviewer differences*

When comparing the code selections for the two reviewers, 62 initial disagreements were identified (24.3%). The majority of the discrepancies (69.3%,  $n=43$ ) were over simple expressions, a statistically significant association ( $X^2(1)=5.212$ ,  $p=0.022$ ).

Six disagreements were not resolved by the reviewers, and thus formed the second section of the email questionnaire (see Appendix F for final questions, pp.247-261).



**Figure 38: Variations in the perceived accuracy of SNOMED-CT codes, comparing two expert reviewers and paediatric ophthalmic clinicians.**

Graphs A-L correspond to questionnaire items 1.1-1.12 (Appendix F). Categories along the x-axis represent (1) complete match, (2) partial match, and (3) no match. Blue shading indicates the expected value, identified by two expert reviewers.

### **Questionnaire findings**

Nineteen individuals completed the questionnaire, with no missing data. The first section of questions was designed to assess the agreement within the participant sample. All questions achieved over 50% agreement, with eight of the twelve questions achieving over 75% agreement (Figure 38).

In general, the sample agreed with the expected values that were identified by the expert reviewers. Individual participants agreed with the experts between 50.0 and 91.7% of the time (mean 76.8%, median 83.3%).

For one expression – *Ethnic group not stated or unknown*, the majority of respondents disagreed with the experts (Figure 38.C). This complex expression combined two ideas: an ethnicity that is unknown, and an ethnicity that has not been provided. In SNOMED-CT, these ideas are captured as two distinct concepts, whereas the reviewers' chosen code only specified that the ethnicity was not stated (Ethnic category not stated - 2001 census, 92531000000104) and therefore the reviewers rated it as a partial match. The modal survey response for this expression was '1 – Complete match' ( $n=10$ ). However, a chi-square goodness-of-fit test indicated that this majority was not statistically significant ( $X^2(2)=3.895$ ,  $p=0.143$ ) and there was no overall consensus within the sample for the accuracy of this SNOMED-CT code.

No consensus was achieved for a further two questions within the first section of the survey. For the first (Figure 38.B,  $X^2(2)=5.158$ ,  $p=0.076$ ), the concept Bangladeshi or British Bangladeshi - ethnic category 2001 census (92471000000103) was selected to represent the expression *Bangladeshi ethnicity*. And for the second (Figure 38.F,  $X^2(2)=5.474$ ,  $p=0.065$ ) – *Referral date*, post-coordination was used to combine three concepts: date of procedure, associated procedure and patient referral (439272007|:363589002|=3457005|). The p-values calculated for these two

questions were, however, close to the threshold value for statistical significance ( $p \leq 0.05$ ) and, in both cases, the mode was in agreement with the expert opinion.

Given this variability between participants, it was not surprising that complete agreement was not observed for items in the second questionnaire section, where the two reviewers were also not in agreement; consensus was achieved within the sample for three questions.

For *logMAR visual acuity, both eyes open* (question 2.1, Figure 39.A), the majority of participants ( $n=18$ ,  $X^2(1)=15.211$ ,  $p < 0.0005$ ) selected 'B – no suitable SNOMED CT code', reasoning that the code presented did not represent the idea of *both eyes open*, which was an important detail but it could not be coded using SNOMED-CT concepts. Only one individual was in disagreement.

In the fourth question (Figure 39.D) – *Hearing impairment*, respondents were asked to indicate a preference between two child concepts Hearing finding: Hearing problem (finding, 300228004) and Hearing disorder (finding, 128540005). The majority of respondents stated that both codes would be necessary to fully represent the expression ( $n=10$ ); this was statistically significant ( $p=0.045$ ), as assessed by Fisher's exact test.

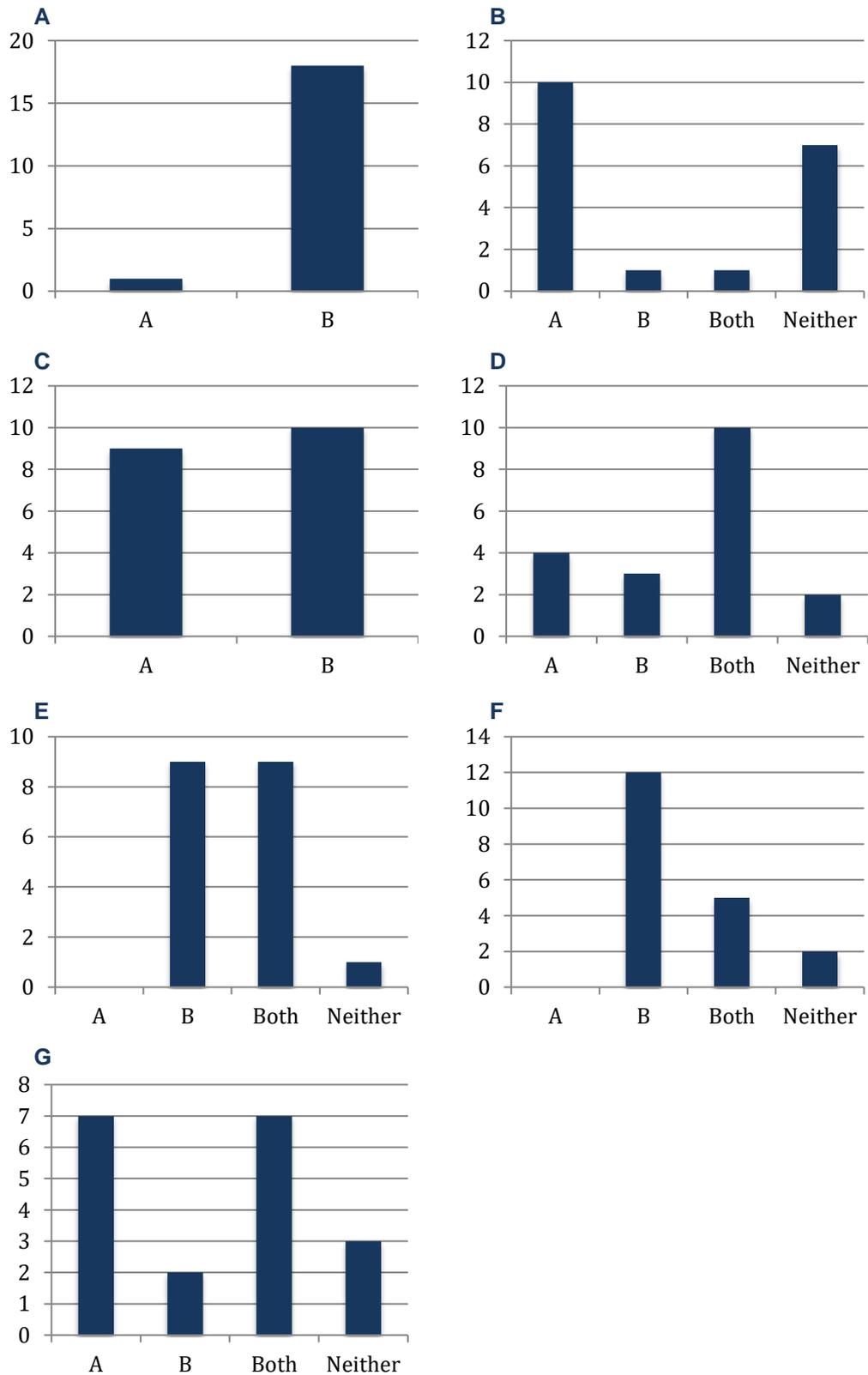
Questions five and six (Figure 39.E and F) assessed similar expressions to question 4: *Learning impairment*, and *Speech/language impairment*. For each of these three questions, the codes chosen by the reviewers had different relationships within the SNOMED-CT hierarchies. For *Learning impairment* (question 2.5), one reviewer (MSC) selected the broader, parent concept of that identified by the second reviewer (GWA). The relationship between the two codes was recognised and discussed by survey participants in the free text comments, with most reasoning that the parent concept chosen by MSC was too broad. Overall, however, the number of participants that reported that both codes were necessary was equal to

the number that selected only the second option ( $n=9$ ). Therefore, no SNOMED-CT code was identified to represent this expression.

For *Speech/language impairment* (question 2.6), the codes chosen by the two reviewers did not have a close relationship within the SNOMED-CT hierarchies. GWA selected Disturbance in speech (finding, 29164008) and MSC selected Speech and language disorder (finding, 231543005); the most common ancestor of these two concepts was the supertype – Clinical finding. The majority of survey participants selected the second code option – Speech and language disorder ( $n=12$ ,  $p=0.014$ , Figure 39.F).

There was no consensus for question 2.7, *Assessment by psychologist*. Here, the reviewers selected SNOMED-CT concepts with differing supertypes: Psychological assessment (procedure, 405783006) and Seen by psychologist (finding, 310348003). There were other, similar expressions identified within the BCVIS2 data set, however, inconsistencies within SNOMED-CT meant that this disagreement between the reviewers only arose on this one occasion. For example, for *Assessment by geneticist* the reviewers agreed Seen by geneticist (finding, 305674005) was appropriate, as there was no relevant procedure for this expression within the terminology.

The preferred SNOMED-CT codes for questions 2.4 (*Hearing impairment*) and 2.6 (*Speech/language impairment*) were added to the final code set identified by the two reviewers; the remaining four expressions were recorded as no suitable SNOMED-CT code.



**Figure 39: The SNOMED-CT code preference of paediatric ophthalmic clinicians.**

Graphs A-G correspond to questionnaire items 2.1-2.7 (Appendix F). Categories indicate a preference for different SNOMED-CT codes (A and B), both or neither.

### **The final SNOMED-CT code set**

In the final code set, a suitable SNOMED-CT code was not identified for 71 expressions (27.8%). For an additional 48 expressions (18.8%), a SNOMED-CT code that was only a partial match was identified. There was a statistically significant association between the accuracy of the SNOMED-CT code and the complexity ( $X^2(2)=7.643$ ,  $p=0.022$ ), with more complete matches identified for simple expressions than complex (Table 20).

**Table 20: The association between the accuracy of SNOMED-CT coding and expression complexity.**

Accuracy	Number of expressions (% within category)		
	Complex expressions	Simple expressions	Total
Complete match	49 (44.5)	87 (60.0)	136 (53.3)
Partial match	28 (25.5)	20 (13.8)	48 (18.8)
No code	33 (30.0)	38 (26.2)	71 (27.8)
Total	110 (100.0)	145 (100.0)	255 (100.0)

Within the subset where no appropriate codes were identified, there were several examples of subjective expressions that would have required further human input to qualify values for inclusion. For example, to define which illnesses were relevant for *History of other relevant illness as neonate*.

For 44.0% of the 184 coded expressions ( $n=81$ ), the post-coordination of SNOMED-CT concepts was required. Not all post-coordinated items were classified as complex: 29.2% ( $n=22$ ) of all post-coordinated items were for simple expressions. For the majority of these cases ( $n=17$ ), post-co-ordination was used to indicate the absence of a finding or event, or that the value was unknown.

The application of post-coordination was found to be inconsistent within the code set. For example, the post-coordination of three concepts was required to represent the expression *Normal electroretinogram* within SNOMED-CT: electroretinographic finding (finding) has interpretation (attribute) normal (qualifier value),

251589008|:363713009|=17621005|. However, *Electroretinogram abnormal* was a pre-coordinated concept (274524001, finding), as were both *Normal visual evoked potential* (102967008, finding) and *Abnormal visual evoked potential* (102968003, finding). Overall, 76.6% of the 77 complex expressions for which a code was identified required post-co-ordination.

## 5.4 Discussion

### 5.4.1 Study strengths and limitations

In this study, a small sample size was achieved and, therefore, the statistical power was insufficient to fully support some conclusions. The presence of outliers may also have biased the results from such a small sample. It is, however, important to acknowledge and highlight such edge cases during system design, and therefore the findings are still informative.

The estimated response rate was only 10.1%, assuming the email list used to recruit participants contained 189 members. This was much lower than that achieved with a previous survey (49.6%) that employed the same recruitment methods (Chapter 2, pp.44-76). While this may be a reflection of a general lack of interest in clinical coding amongst UK paediatric ophthalmic clinicians, the fact that, at the time of this work, SNOMED-CT was not widely used within the NHS may have made the exercise seem quite abstract and therefore unappealing to busy clinicians.

### 5.4.2 Suitability of SNOMED-CT for paediatric ophthalmology

In this study, exact SNOMED-CT matches were found for 53.3% of all expressions identified within the BCVIS2 data collection form. Chiang *et al.* reported exact matches for approximately 75% for ophthalmic concepts within SNOMED-CT<sup>39</sup>. However, the expressions considered within their study were identified from clinical case reports, and may have been less complex than the research-focused expressions considered in this work. They also achieved a lower agreement rate between three coders with expertise in both ophthalmology and SNOMED-CT

(53%)<sup>42</sup>; an inclusion of additional reviewers would likely reduce the rate achieved in this study (85.7%).

When considering the usability of SNOMED-CT, the inconsistencies identified within the final code set and the need for post-coordination were of concern. Guidelines and national standards were required to inform final code selections, which took time and may not be immediately available to SNOMED-CT users.

One issue of importance in ophthalmology is indicating the eye of interest. When qualifying the laterality, the NHS Digital guidance states that there are 'no general cases for the coding of pre-coordinated laterality in system processes – there is no compelling evidence that this approach is superior to using free text or system functionality to represent the laterality ... The current policy is therefore not to allow the pre-coordination of laterality.'<sup>206</sup> An exception to this rule was observed with observable entities that cannot be combined with the laterality attribute. For example, LogMAR visual acuity right eye (observable entity, 413078003) and LogMAR visual acuity left eye (observable entity, 413077008) exist as distinct concepts. It is, however, the data coded as a finding that would be of interest; for this, following the guidelines, post-coordination of the laterality attribute and left and right qualifiers should be used. Despite this, examples of Clinical finding codes pre-coordinated with a specific laterality were identified (e.g. On examination – right eye sees hand movements, finding 308082007).

NHS Digital acknowledge that not all existing content conforms to the guidelines<sup>206</sup>. Processes do exist that allow users to request the addition of new codes to both the international terminology and the UK extension<sup>206</sup>. All new codes must conform to the current guidance, offering a means of improving the content coverage and the inconsistencies identified within the code set. However, users should be aware that

both the terminology and the guidance is still developing, and will likely continue to require alterations and additions as medicine evolves.

### **5.4.3 Electronic coding**

With paper-based systems, clinical coding is typically a retrospective process undertaken by non-medical staff. One study suggested in the context of NHS ophthalmology suggested relying on coding staff interpreting medical records introduced inaccuracies<sup>207</sup>. With the intention of facilitating immediate data reuse and decision support systems, integrating coding with EMRs would transform clinical coding into a point-of-care process.

Guidance on how to implement point-of-care SNOMED-CT coding within an EMR environment is available from the NHS CUI project (p.27). It was suggested that only SNOMED-CT codes appropriate for the clinical context should be presented to the user<sup>208</sup>. Ambiguities in the intended contexts of the different SNOMED-CT domains have been criticised in other works<sup>209, 210</sup>, and was problematic in this study, as seen with the use of the procedural code, Keeler acuity cards, to encode the expression *Keeler visual acuity*. An IT system designed to confine code selections to only those appropriate for the context could eliminate these coding challenges and enhance coding accuracy.

The CUI suggestions focused on single-concept matching, i.e. searching for suitable SNOMED-CT concepts through text entry. In a single-center study in Germany, the introduction of an EMR system with a text-searchable diagnostic catalogue significantly increased the range and number of ICD-10 diagnostic codes applied to emergency and outpatient ophthalmic patients per case<sup>211</sup>. One can

imagine how this would be exaggerated with the use of a broader terminology such as SNOMED-CT.

Single-concept matching was the process initially undertaken in the current study by the two reviewers. However, this process is not always implemented within an EMR. For example, in OpenEyes, the coding process is hidden from the user. Such automated encoding – using pre-selected codes based on, for example, forced-choice drop down values, is used to standardise entries and eliminate problems arising from the inter-coder variation.

In order for SNOMED-CT to facilitate interoperability, the implementation of the terminology must be standardised across EMR platforms, in addition to individual system users. This relies upon EMR software being kept up to date with SNOMED-CT releases and extensions, and the implementation of SNOMED-CT being standardised across platforms. Although those with expertise in SNOMED-CT will likely guide the implementation of the terminology during EMR development, this study and other works have provided evidence of coding variations between expert users<sup>39, 204, 212</sup>.

Mapping guidelines have been shown to increase the consistency in SNOMED-CT code application within EMRs<sup>213</sup>. The previously described NHS-wide efforts (pp.24-27) will aid in the standardisation of SNOMED-CT applications for concepts common to all NHS patients. However, no guidance could be identified that directs the use of SNOMED-CT within ophthalmology.

#### 5.4.4 Research applications of SNOMED-CT

This work was conducted in the context of a national epidemiological study. Researchers are more likely to use single-concept matching than clinical users, to construct a database query to retrieve relevant information or identify study participants. Here, the contextual constraints will not be present and, therefore, the low reproducibility may still present problems in the usage of the SNOMED-CT. This is a great concern in the context of research, where the reproducibility of results and findings are vital.

A published survey of SNOMED-CT users indicated more research users were unsatisfied with the coverage of SNOMED-CT compared to clinical users<sup>214</sup>. In this study, the application of post-coordination was found to improve the ability of SNOMED-CT in capturing the granularity and contextual information encountered within research data sets. This finding is not unique to paediatric ophthalmology; in a study that considered vasculitis research, the application of post-coordination increased the exact match coverage from 23% to 88%<sup>215</sup>.

Others have raised concerns over the applicability of post-coordinated concepts to clinical data; while it is possible to represent the desired concepts for research studies, non-clinical qualifiers such as temporal states may not be applied to clinical data which are typically modeled as current or in the present<sup>204</sup>.

In this study, the use of post-coordination was also required to indicate an absent finding, for example *Not born in the UK*. Absent findings are not likely to be captured within medical records in this manner, as identified in the maximal data set defined in Chapter 3 (pp.77-137). In some cases, one might have to infer the absence of a finding from the absence of a finding code or any documentation of that finding. For example, if an individual is not registered as having a sight impairment, it is not likely to be documented if it is not relevant to their care or they are not eligible.

In other cases, the parent concept could be used to identify the desired data. For example Country of birth would be used to identify whether an individual was from the UK or not; classification into the two groups would be completed at the analysis stage, if required. A move to using structured EMR data as a source for epidemiological research would therefore likely require users to adapt questionnaire designs and analysis methods.

#### **5.4.5 Conclusions**

The coverage of SNOMED-CT for paediatric ophthalmic concepts was found to be incomplete. The identified coverage rate was lower than that reported by another study that considered the application of SNOMED-CT within general ophthalmology, possibly reflecting the research-focus of this study and the differences between the modeling of routinely collected data and data in research studies.

Many of the challenges identified when matching SNOMED-CT concepts to research items mirror the findings from the comparison of a research data set to the set of routinely collected data (Chapter 3, p.110) – an increased use of temporal qualifiers being one example. This is likely a reflection of the primary focus of SNOMED-CT development: the creation of a comprehensive terminology for clinical care. This would, however, imply that SNOMED-CT would be a terminology when coding the maximal set of routinely collected data items, although this has not been specifically assessed within this study.

Further work is required to ensure SNOMED-CT is suitable for use across paediatric ophthalmic care and research and will be applied in a standardised manner. An

increased awareness of the structure and applications of SNOMED-CT would be beneficial to users, particularly to inform research study designs.

## **Chapter 6 Conclusions and future work**

### **6.1 The landscape of EMR use in paediatric ophthalmology**

This research began with a broad scoping exercise, to explore of the landscape of HIT use within NHS paediatric ophthalmology. At the time – which was just before the target was announced to have a paperless NHS by 2020 – few examples of routine EMR usage were identified in the field. Subsequent aspects of this work centred on the GOSH department of ophthalmology, which entered into the early stages of a transformation programme to adopt a hospital-wide EMR system. As this work concluded, it was unknown if paediatric ophthalmic users in other NHS Trusts are experiencing similar developments. A second, follow-up survey should be conducted to assess changes in the landscape of use, and consider if political pushes are a driver of HIT adoption within the field.

When considering how EMR adoption and the movement towards a learning health system might impact researchers, the findings of the work conducted for this thesis indicated that adaptations would be required. This was primarily in the way that questionnaires are formed: changes would be required to match the stricter, more structured data models used in HIT systems. Researchers were considered within the scope of this work, but as indirect users, and so were not a focus of the contextual inquiry or subsequent design case studies. However, the findings will be informative for future work. When designing the specific interfaces that allow researchers to interact with routinely collected data, tools should be provided to support users to construct search queries that match the clinical data models in use.

## 6.2 Comments on the user-centred approach

In the national survey, paediatric ophthalmic clinicians highlighted the inability of EMR systems to meet clinical needs as the main barrier to routine EMR usage (see Chapter 2, pp.58-59), justifying the focus of this research on a user-centred approach to system design.

The contextual design methodology was chosen to increase the literacy of the designer in the subject area, and facilitate relationships with the users to aid the subsequent design processes. Although not all UCD techniques were found to be appropriate for this context, such as the characterisation of user groups as personas, the design and testing of a series of different tools demonstrated that the methodology could be successfully applied within a NHS paediatric ophthalmology setting.

The initial contextual inquiry was, however, labour intensive, and the data collection and familiarisation stages took a great deal of time. The appropriateness of the approach should, therefore, be deliberated for subsequent work, with a consideration of the rapid life cycle of technologies.

Participatory design, also termed co-design<sup>216</sup>, is an alternative user-centred approach in which the users are facilitated by designers to design the product themselves. Others have described successes in applying a participatory methodology to HIT development<sup>101, 217</sup>, including with the development of ophthalmic specific EMR systems such as OpenEyes. In contrast to the contextual approach, in which a designer first aims to build a sufficient level of domain knowledge to effectively design and communicate ideas with clinicians, participatory design eliminates the need for such preparatory work, but does rely on clinicians being sufficiently literate in informatics.

Difficulties in communicating with developers were described by paediatric ophthalmic users at the start of this research, and so user engagement in a participatory project may have been difficult to achieve at the time of this work.

In 2017, Wachter recommended that the successful digitization of the NHS would require a greater degree of literacy in clinical informatics amongst the NHS workforce<sup>29</sup>. In response, the NHS England has committed to “building a digital ready workforce” and have launched the NHS Digital Academy<sup>218</sup>. Thus, in the future, a participatory design approach may provide a better solution for the user-centred development of HIT.

### **6.3 Disruptive innovation**

The majority of the work presented in this thesis focused upon electronically replicating existing paper-based information systems. Wachter described this to be the first of four stages of HIT innovation<sup>219</sup>:

- (i) Medical record digitization
- (ii) HIT system interoperability
- (iii) Harnessing health data to gain new knowledge
- (iv) Conversion of new knowledge into actions at the bedside

Only once the technology is in place can disruptive changes to clinical work processes and care provision be achieved, for example through decision support systems (stage four). Wachter said, “in the beginning ... we put in the technology

and replicate the way we did the thing when we were using paper ... Then we reimagine the work. We say, 'well now that we have these new tools, why are we doing it the old way? Let's do it a brand new way' ... that's when you start seeing the massive advantages" <sup>219</sup>.

In this research, examples were identified in which the use of electronic systems may facilitate alternative ways of working. One example was the ability to document medical data in a different form to how it is reviewed, removing existing limitations in the order and format in which data must be recorded, and therefore overall design of the medical record.

Carroll *et al.* proposed that adopting an artifact is a cycle that will never reach an optimum state<sup>220</sup>: developments in the artifact – in this case the design of a medical record system – will lead to changes in the users' workflows that need to continuously be reassessed and accounted for in the design of the artifact. Therefore, the user-centric analysis of HIT should not end once a system has been implemented, to allow for future disruptive changes. Building the task-artifact feedback cycle into the design of HIT – as has been achieved with the SCAMP decision support systems (described on p.30) – would ensure that, once the technology has been implemented, it is continuously evaluated against the users' needs and reformed.

#### **6.4 The single-purpose application model**

A user analysis indicated that, although it is difficult to characterise different user groups within the GOSH ophthalmology department, distinctive clinical tasks could

be identified. Further work is required to fully specify each of the tasks, their supporting data sets, and design requirements. However, this work demonstrated that task specification could form the basis of system design for a paediatric ophthalmic EMR (see case studies in Chapter 4, pp.139-178).

The need for HIT system flexibility has been acknowledged more generally within healthcare, to support variable workflows and future medical innovations<sup>221</sup>. In 2009, Mandl and Kohane proposed a platform based solution<sup>221</sup> in which – much like a smartphone – the functionality of an EMR is derived from substitutable applications that can be modularly added or removed.

In addition to enabling system flexibility, this model is proposed to accelerate innovation – in both application functionality and usability – by fostering competition<sup>221</sup>. The Substitutable Medical Applications, Reusable Technologies (SMART) platform has been in development by Mandl and colleagues at the Boston Children's Hospital Computational Health Informatics Program and Harvard Medical School Department of Biomedical Informatics since 2010<sup>222, 223</sup>; there are now 49 SMART applications available<sup>224</sup>.

Three software applications were developed as part of the user-centric research presented in this thesis (Chapter 4, pp.139-178); each case study could form the basis of a single-purpose SMART application. To achieve this, the data captured in each application would need to be modeled in line with the standardised Fast Healthcare Interoperability Resource (FHIR) API and resource definitions<sup>222</sup>. Also, as discussed for the ROP screening application (pp.141-153), considerations will need to be made to ensure the applications are launched in the correct context (i.e. identifying the appropriate patient), in addition to ensuring the user is authorised to use the application to securely access and exchange data with the underlying EMR.

While the substitutable application model is promising to meet the complexity and flexibility required of a paediatric ophthalmic EMR, as the specialty consists of such a large number of clinical tasks, having to sequentially launch each application individually from within the EMR might become cumbersome for clinicians. Therefore, while each individual application may be considered usable, overall, the usability of the system will be limited.

Acknowledging that there is a problem with users knowing which substitutable application to use and when, and actively having to launch different systems to utilise all of the available tools, the authors of the SMART protocol are developing a complimentary technology – CDS hooks – that enables CDSS to run automatically and seamlessly within an EMR<sup>225</sup>. Notifications indicating which actions the user is currently completing within the EMR (e.g. a specific component of a clinical examination, or prescribing a medication) trigger the CDS hook and invoke an external CDSS application. If appropriate, relevant information or recommendations from the CDSS application will be shown to the user within the EMR, or an access link can be provided to direct the user to the external application. While the CDS hooks technology is still in its infancy, it is hoped that it will improve the integration of multiple applications with EMR workflows.

Outside of the healthcare domain, other substitutable systems such as smartphones are beginning to explore alternative interfaces to manage the growing number of single-purpose applications that are used. One example is a voice user interface – such as Amazon's Alexa<sup>226</sup> – that aims to create a more natural, speech-based interface that will initiate individual underlying applications and processes.

When speaking to users as part of this research, it became clear that their perception of a usable interface was heavily influenced by the technologies used in their day-to-day lives: participants would often use examples such as Google when

describing how they would want a HIT system to look and behave (Chapter 2, pp. 62-63). It is likely that a user-centric perception of system usability will be difficult to achieve if the technology employed feels outdated.

Technological innovation within hospital information management has reputedly lagged behind other domains. Multiple, non-interoperable systems; a lack of WiFi networks and other hardware; and data access and privacy concerns were all challenges identified by paediatric ophthalmic clinicians (Chapter 2, pp.44-76). However, building on the recommendations of the Wachter review, NHS England have committed to facilitating an interoperable HIT eco-system, including a NHS Digital Apps Library for patient facing applications<sup>59</sup>.

With this infrastructure and support in place, once systems have been designed around the individual clinical tasks completed within paediatric ophthalmology, the interface used to integrate these applications should be carefully considered, taking into account developments from outside of HIT and the medical domain to meet users' perceptions of usability.

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## Appendices

## Appendix A: National survey question items

### Paediatric Ophthalmology: Electronic Patient Records

#### 1.1

##### **Clinical role:**

- Consultant
- Orthoptist
- Optometrist
- Other, please specify \_\_\_\_\_

##### **How do you document clinical information for the majority of your patients?**

- Paper-based records
- Electronic document management system\*
- Electronic patient record system (EPR)

Please name the system or provider \_\_\_\_\_

\*Defined as a system in which medical notes are documented on paper and scanned into a computer or recreated digitally, and stored in an electronic database.

##### **Have you had any experience using an EPR?**

- No
- Yes, for paediatric ophthalmology only
- Yes, for adult ophthalmology only

- Yes, in paediatric and adult ophthalmology

## 1.2

**How would an EPR benefit your routine clinical work?** Select all that apply.

### Documentation Ease

- Data auto-complete or 'copy and paste' abilities
- Diagrammatic representation of medical examinations e.g. Slit lamps, Ocular motility
- Dictation and transcription tools
- Graphical representation of repeated clinical measure e.g. Visual acuity
- Increased documentation speed

### Data quality

- Consistent documentation practices between practitioners
- Decreased documentation errors
- Greater accuracy of clinical coding
- Increased document legibility
- Increased record completeness

### Data Usage

- Improved abilities to search patient databases
- Improved information exchange with other care professionals

- Improved access to relevant medical literature and protocols
- Improved clinical audit abilities
- Increased clinical decision support and alert systems

**Patient Engagement**

- Improved communication with patients
- Increased patient and / or carer access and contribution to medical records

**Other**

Please describe the other benefits you perceive.

---

---

**In your opinion, which is the single biggest benefit of EPR use?**

[Selected from checked answers above using drop down]

1.3

**Which obstacles prevent or challenge EPR-use within your routine clinical work? Select all that apply.**

**System Usability**

- Difficult to navigate system designs
- Lack of system flexibility / decreased documentation freedom

- New skills and training required to use EPR systems
- Poor user interface
- Slow system response speed
- Software functionalities not meeting clinical need
- Software may become obsolete

**Infrastructural requirements**

- Costs associated with EPR implementation and maintenance
- Difficulties transferring existing patient records into EPR
- Inability to integrate EPR with other clinical IT systems
- Lack of computer or tablet provision
- Lack of network or Wi-Fi access across the whole work department

**Information Security and Governance**

- Unauthorised record access / record security
- Unconsented sharing of patient data

**Other**

Please describe the other barriers you perceive.

---

---

**Which is the biggest obstacle you associate with EPR use?**

[Selected from checked answers above using drop down]

*Thank you for completing the first part of the survey.*

2.1

**For how long have you used your electronic system? \_\_\_\_\_**

**Please describe which clinical tasks you use your EPR for?**

---

---

---

2.2

**Did you receive any user training before adopting your electronic system?**

- Yes       No

**Did you receive any user support while first using your electronic system in routine clinical practice?**

- Yes       No

**How competent are you using a computer?** Please rate your skill level from 1-5  
(5 = Excellent, 1 = Poor).

- 5       4       3       2       1

2.3

**Did your clinical productivity change whilst first implementing your electronic system?**

- Increased       No change       Decreased

**Compared with using paper-notes, was your clinical productivity different 6 months after first implementing your electronic system?**

- Increased       No change       Decreased

**Please describe the factors affecting your clinical productivity?**

---

---

2.4

**Did you observe any benefits in your routine clinical work after implementing your electronic system?** Select all that apply

### **Documentation Ease**

- Increased documentation speed
- Reduced repetition and duplication of data entry

### **Data quality**

- Consistent documentation practices between practitioners
- Decreased documentation errors
- Greater accuracy of clinical coding
- Increased document legibility
- Increased record completeness

### **Data Usage**

- Improved abilities to search patient databases
- Improved information exchange with other care professionals
- Improved access to relevant medical literature and protocols
- Improved clinical audit abilities
- Increased clinical decision support and alert systems

### **Patient Engagement**

- Improved communication with patients
- Increased patient and / or carer access and contribution to medical records

- Other**

Please describe the other benefits you experienced.

---

---

**No benefit**

*End of survey.*

**Please name the Trust(s) you work for:** \_\_\_\_\_

**Please provide your contact details if you would like to contribute to our collaborative group, and be kept informed of our research developments within this area.**

Name: \_\_\_\_\_

Email address: \_\_\_\_\_

**Use this space if you would like to add any additional comments, or expand on any of the above answers.**

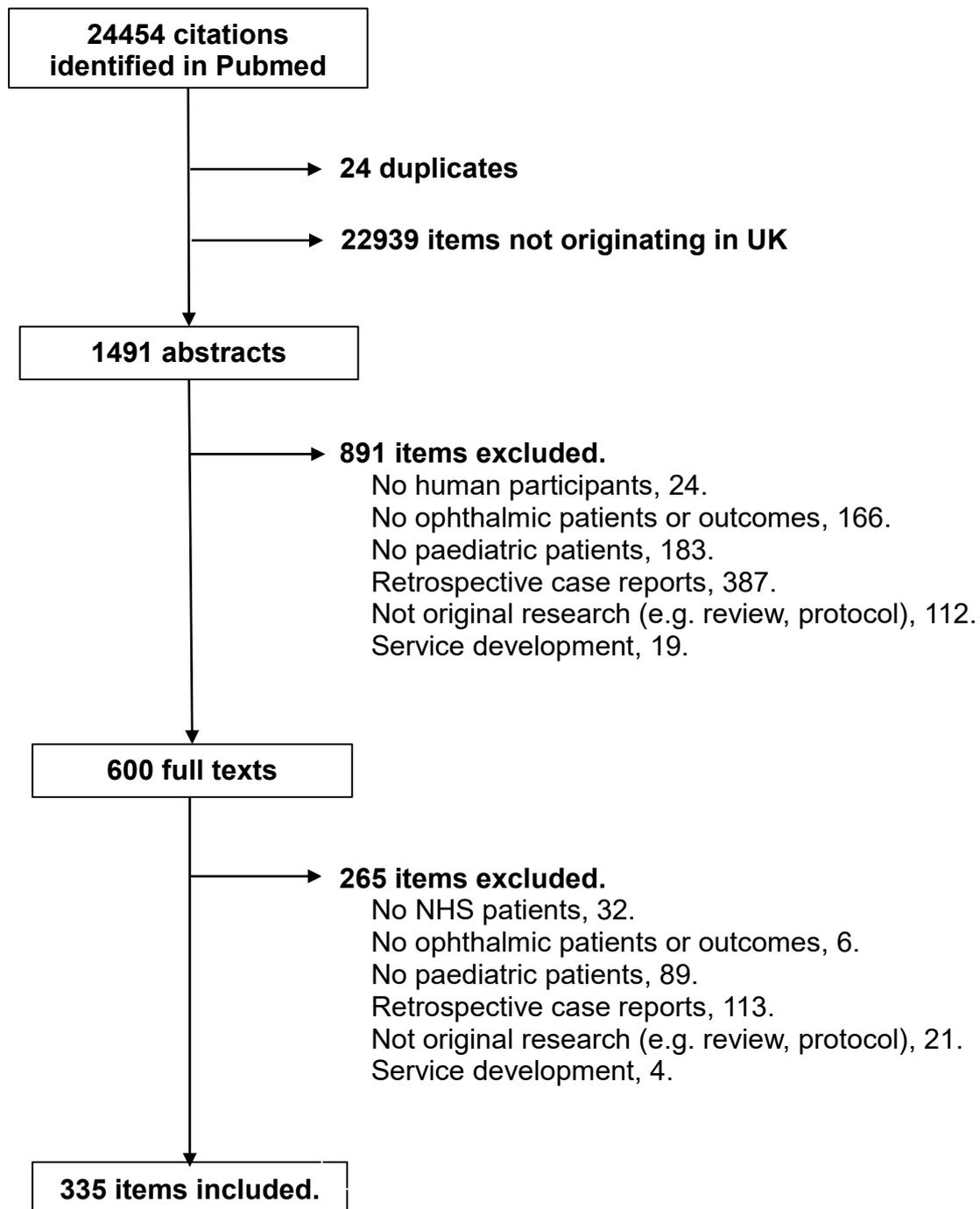
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## Appendix B: Flowchart of the Pubmed literature search.



## Appendix C: Interview participant characteristics

Participant ID	Role	Gender	Location (city)
C1	Consultant	F	London
C2	Consultant	F	Cambridge
C3	Head orthoptist	F	Sussex
C4	Consultant	F	Southampton
C5	Optometrist	F	London
C6	Consultant	M	London
R1	PhD student	M	London
R2	Post-doctoral researcher	M	London
R3	Post-doctoral researcher	M	London
R4	Research assistant	F	London
R5	PhD student	F	London

Participant identifiers with the prefix *C* were classed as clinicians, whereas those with the prefix *R* were classed as researchers.

## Appendix D: Topic guide for semi-structured interviews

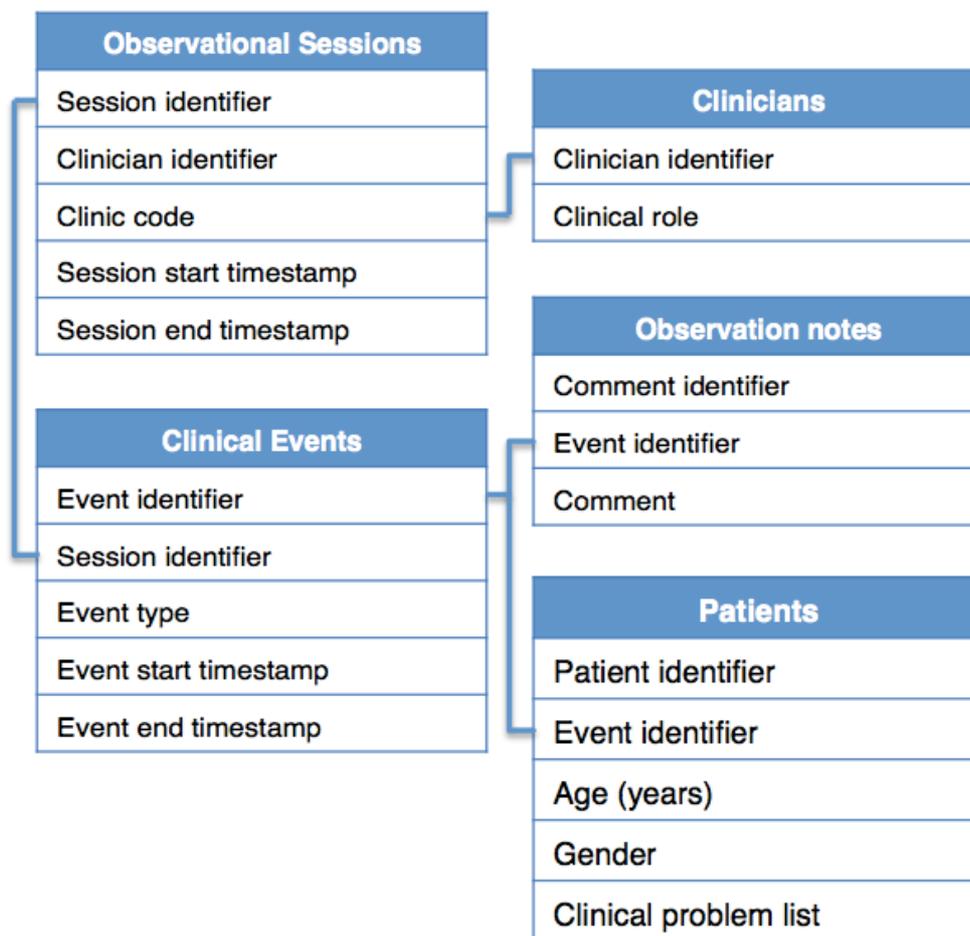
Clinical questions	Research questions
Background	
<ul style="list-style-type: none"> <li>- Sub-specialty, if appropriate</li> <li>- Do you also treat adult patients?</li> </ul>	<ul style="list-style-type: none"> <li>- Aims of your current research project</li> <li>- Ethics &amp; consent for current project, and participant recruitment processes</li> <li>- Other experiences within paediatric ophthalmic research</li> </ul>
Existing information system and HIT use	
<ul style="list-style-type: none"> <li>- How do you document medical records for the majority of your paediatric patients?</li> <li>- What works well with your current documentation practices?</li> <li>- What could be improved?</li> <li>- Have you ever used an EMR? Why / why not?</li> <li>- Do you think routinely using an EMR is beneficial?</li> <li>- What are the challenges of routine EMR use?</li> <li>- Quite a lot of people say systems aren't user-friendly, do you agree? What does a user-friendly system mean to you?</li> </ul>	<ul style="list-style-type: none"> <li>- What types of data do you use in your research?</li> <li>- How do you access the data and where do you store it?</li> <li>- What works well with your methods?</li> <li>- Has working with patients or patient data ever created any challenges?</li> <li>- Would you make any changes to the way you acquire and work with your data?</li> </ul>
Special requirements in paediatric ophthalmology	
<ul style="list-style-type: none"> <li>- Are your opinions specific to paediatric ophthalmology?</li> <li>- When working with paediatric patients, what do you do differently compared to when working with adults?</li> <li>- Do you think there are different EMR requirements for</li> </ul>	<ul style="list-style-type: none"> <li>- Are your opinions specific to paediatric ophthalmology?</li> <li>- Do you think there are any differences working with children patients and their data, compared to adults?</li> <li>- Have you had any experience researching in another field?</li> </ul>

<p>systems used in paediatrics to other ophthalmic subspecialties?</p>	<p>Were there any differences?</p>
<p>Re-using routinely collected data for research</p>	
<ul style="list-style-type: none"> <li>- Do you use medical records to complete audits? How do you do this? What are the challenges?</li> <li>- Are you involved in research projects using patient data? How do you identify participants and collect data? What are the challenges? What works well?</li> <li>- Do you think research and clinical care have different requirements of routinely collected data?</li> <li>- Do you think routinely collected data are suitable for research uses?</li> <li>- Whose responsibility do you think it is to consent patients for research?</li> </ul>	<ul style="list-style-type: none"> <li>- Do you think routinely collected data are suitable for research uses?</li> <li>- How do you find the quality of routinely collected data?</li> <li>- What data requirements do you have?</li> <li>- Whose responsibility do you think it is to consent patients for research?</li> </ul>
<p>Engaging in health IT development</p>	
<ul style="list-style-type: none"> <li>- Have you ever been involved in the development of a HIT system?</li> <li>- Would you personally engage in the process of health IT development? Why / why not? <ul style="list-style-type: none"> <li>o How would you want to be involved?</li> <li>o What would discourage you from engaging?</li> </ul> </li> <li>- Do you think clinicians, generally, want to be involved in the development of EMRs? Why / Why not?</li> <li>- Who do you think should be involved in EMR development?</li> </ul>	<ul style="list-style-type: none"> <li>- Do you consider yourself a user of medical records?</li> <li>- Do you think researchers should be considered when designing healthcare information systems and technologies?</li> <li>- Who do you think should be involved in the development process?</li> <li>- Would you personally engage in the process of health IT development? Why / why not? <ul style="list-style-type: none"> <li>o How would you want to be involved?</li> <li>o What would discourage you from engaging?</li> </ul> </li> </ul>

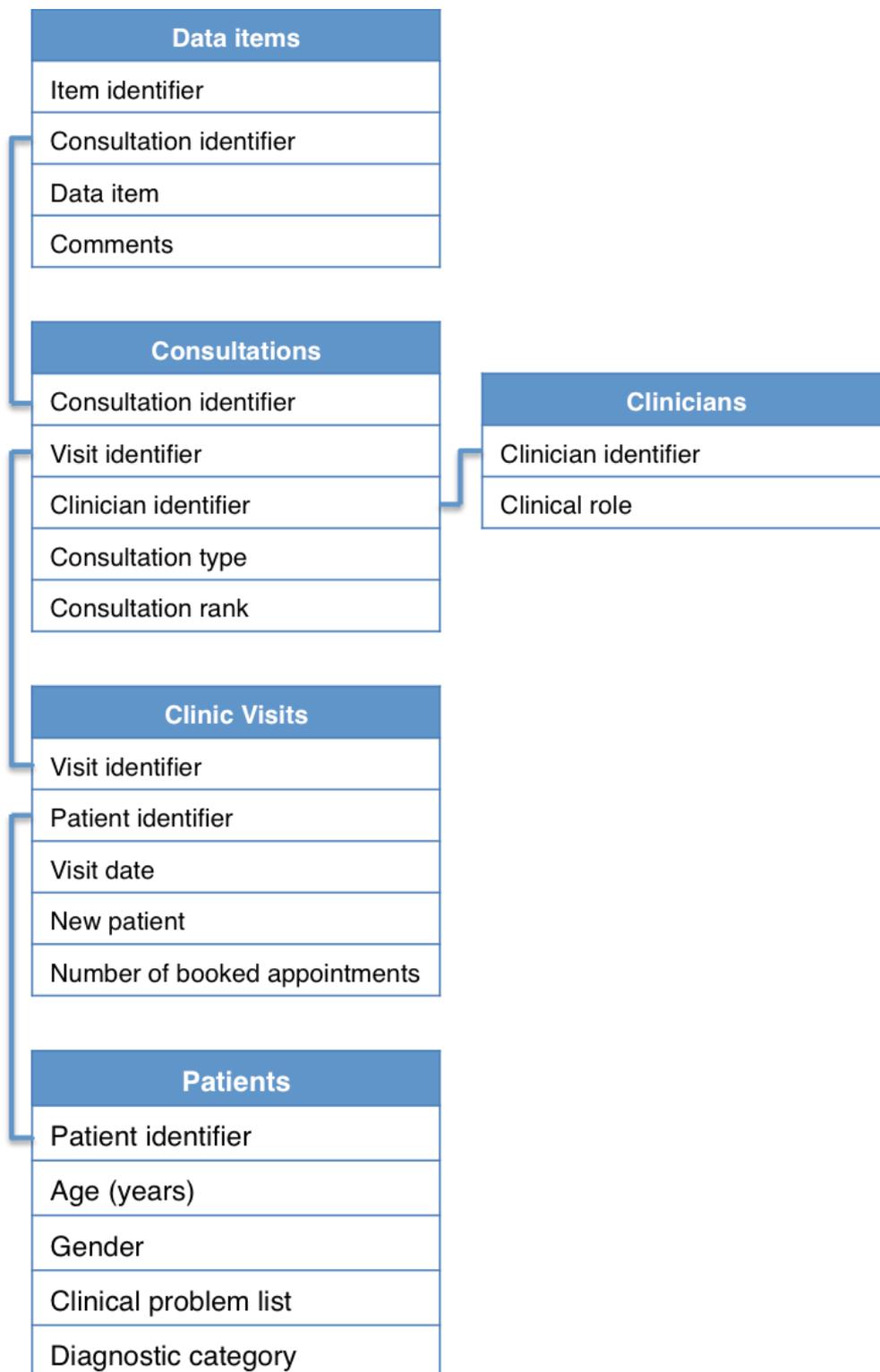
What about other stakeholders, such as researchers or policy makers?

Final comments and questions about my research

## Appendix E: Time-motion study database schema



## Appendix F: Medical record review database schema



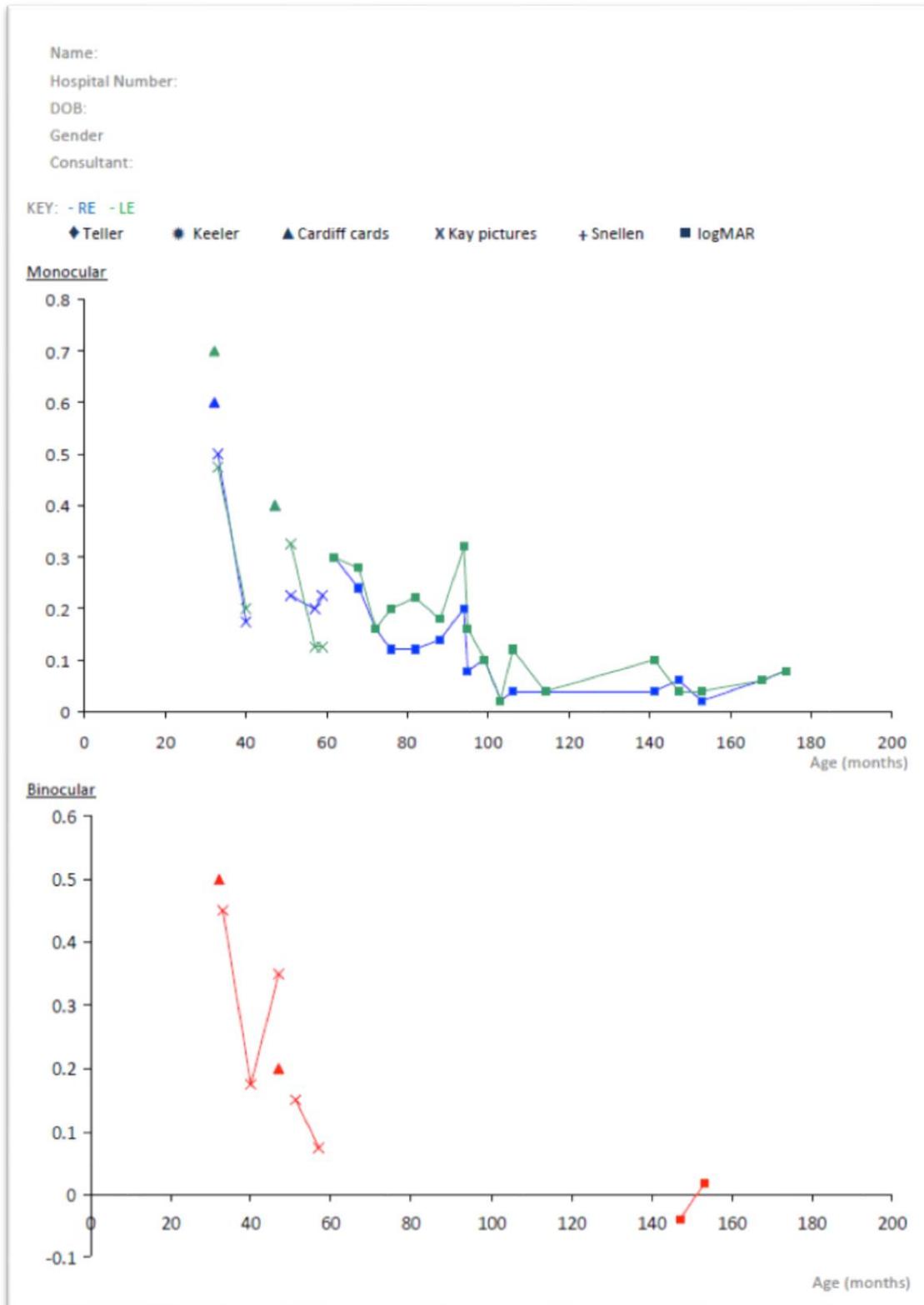
**Appendix G: The cluster membership characteristics for two outlier clusters produced by an agglomerative hierarchical sequence clustering of medical record data**

	Cluster A				
Clinic visit date	11-Nov	2-Nov	17-Nov	9-Nov	16-Nov
New patient	Y	N	Y	N	N
Clinic*	LO1	BO2	LO1	BO2	BO2
Gender	F	F	M	F	F
Age (years)	7	5	0	6	8
Diagnostic category	Retina	Glaucoma	Anterior segment	Strabismus	Neuro-ophthalmology
Consultation type	Orthoptics	Orthoptics	Orthoptics	Orthoptics	Orthoptics
Clinician*	K1M	K1M	K1M	P1M	P1M
Consultation rank	1	1	1	1	1
Item set length	60	50	53	42	47
Number of unique data items in set	41	37	38	29	33

	Cluster D			
Clinic visit date	14-Nov	17-Nov	14-Nov	10-Nov
New patient	N	N	N	N
Clinic*	LO1	LO1	LO1	BO2
Gender	F	M	F	F
Age (years)	1	2	0	6
Diagnostic category	Anterior segment	Glaucoma	Anterior segment	Strabismus
Consultation type	Optometry	Consultant	Consultant	Optometry
Clinician*	F1L	L2O	L2O	M3L
Consultation rank	2	2	1	1
Item set length	46	31	35	49
Number of unique data items in set	37	22	28	35

\* Pseudonyms were used to identify the clinic and the documenting clinician. They have been provided only to allow for comparisons between cluster constituents.

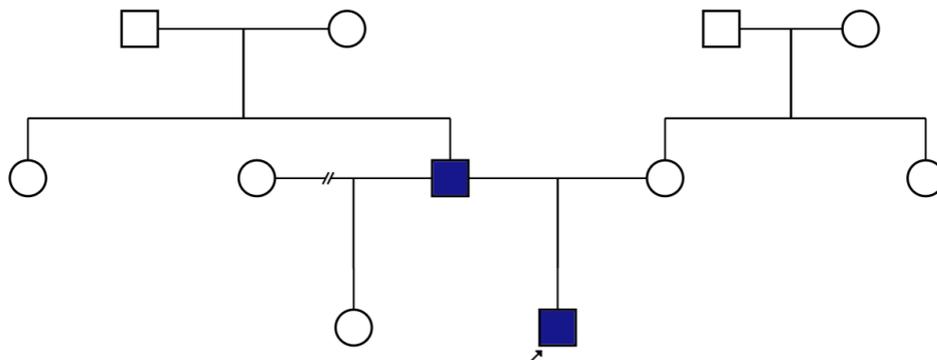
## Appendix H: Anonymised report of plotted visual acuities



## Appendix I: Pedigree drawing scenarios

### Scenario 1

A young boy, aged six months, has been referred to the GOSH ophthalmology clinic by a colleague in East Sussex as the mother would like a second opinion. From the age of three months, his mother noticed that his eyes made unusual movements. She has no eye problems; however, the father has congenital nystagmus – diagnosed during childhood – and has worn glasses since he was two years old. The patient's half sister (aged 8) has the same father, but no eye problems. There are no other siblings. Both mum and dad have a sister. All other family members are fit and well; there is no other relevant history of eye problems within the family.

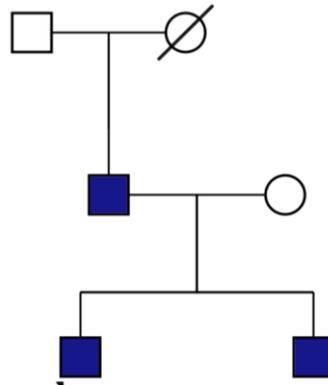


*System requirements:* A family with multiple partners and lines of descent, and to indicate a separation.

### Scenario 2

Two brothers have been referred to the clinic by the Genetics department at GOSH. The eldest son (14 years) was seen locally and diagnosed with retinitis pigmentosa. The father is under the care of Moorfields Eye Hospital. He was diagnosed with the same condition in his early twenties; it has been slowly progressing. The parents are now concerned their youngest son, aged 11 years, also has the condition and would like a clinical confirmation and to investigate possible genetic causes. There

is no other family history of eye problems; although, the paternal grandmother passed away aged 47.



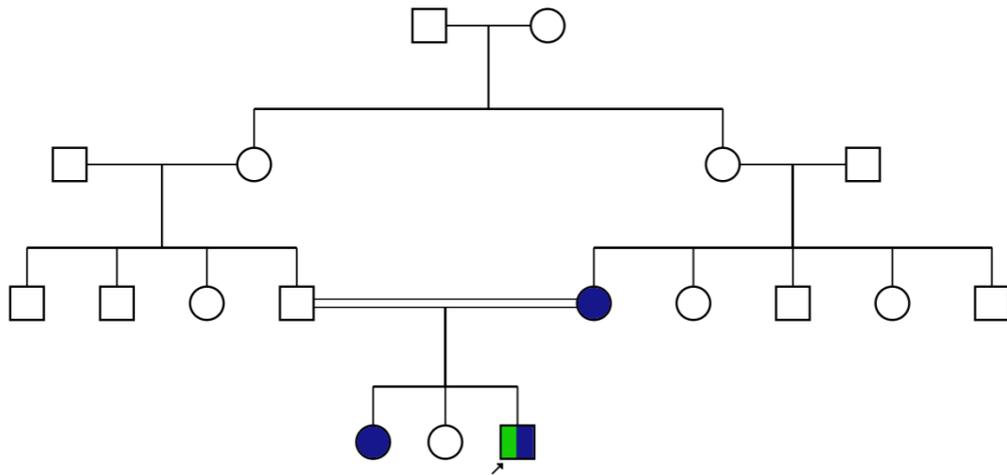
*System requirements:* to indicate a deceased family member and identify a dominant pattern of inheritance.

### Scenario 3

A mother, her sister and her youngest child – a 3 year old male – have come to the clinic. Both mother and son have sensorineural hearing loss; although, it is believed that mum's hearing problems are unrelated, and caused by a typhus infection when she was six months old. The aunt (mother's sister) interprets and reports the majority of the history.

The patient was born profoundly deaf; his mother believes he has no visual problems, however, his left eye has turned inwards since birth. They had been previously referred to GOSH ophthalmology for screening, but failed to attend a series of appointments and were discharged. He has now been re-referred following an appointment at the Royal London, where he was diagnosed with reduced vision and a left divergent squint. They noted an atrophic macular scar, believed to be secondary to a congenital infection. The patient is otherwise fit and well, having previously been screened and discharged by the cardiology department at GOSH.

He has two sisters: one aged eight years also affected by sensorineural hearing loss, and one aged seven years who is unaffected. Neither sister has an eye problem, nor is there any other relevant family history within the wider family. Mum has two brothers and two sisters, and Dad has one sister and two brothers. The parents are second cousins – mum and dad’s maternal grandmothers were sisters.



*System requirements:* to visualise two different phenotypes within a single pedigree, and to indicate a consanguineous family and draw a cycle graph.

## Appendix J: Standardised pedigree drawing features

Feature	Inclusion in case study pedigree drawing software
Male	
Female	
Gender not specified	
Affected individual	
Affected with $\geq 2$ conditions	
Multiple individuals, number specified	
Multiple individuals, number not specified	
Deceased	
Consultand	
Proband	<i>No differentiation was made between the proband and consultand.</i>
Stillbirth	 <i>The term intrauterine fetal demise was used by user preference.</i>
Pregnancy	
Pregnancy not carried to term	
A documented evaluation has been undertaken on individual	
Carrier	
Asymptomatic /	

presymptomatic carrier	<i>No differentiation was made between types of carrier.</i>
Uninformative study	<div style="text-align: center;">   Eu </div> <p data-bbox="715 405 1393 479"><i>Not a pre-defined symbol – required user to specify feature using annotated comments.</i></p>
Affected individual with positive evaluation	<div style="text-align: center;">   E+ </div> <p data-bbox="715 607 1393 678"><i>Not a pre-defined symbol – required user to specify feature using annotated comments.</i></p>

**Appendix K: SNOMED CT email questionnaire with cover letter  
and background information**

## SNOMED CT for Paediatric Ophthalmology

As we move toward the global adoption of electronic medical records, there is an increasing need to appropriately translate medical terminology into a structured, computer-readable coded format. The Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT) has recently been selected as the strategic coding terminology for NHS England to be used comprehensively across care provision by 2020, replacing the existing ICD10 and OPCS classifications.

With this in mind, we are undertaking a study that considers the suitability of SNOMED CT for paediatric ophthalmology as a means of identifying further areas of development required for the terminology.

This research is being conducted in the context of a national epidemiological study, the British Childhood Visual Impairment Study (BCVIS2), to consider the secondary uses of medical record data. BCVIS2 aims to determine the incidence, causes, mode/context of detection, associated factors, management and short-term health and social outcomes of all-cause childhood visual disability. Therefore, the data collected spans the breadth and depth of paediatric ophthalmic care.

We have devised a questionnaire using data items from the BCVIS2 data collection form. The study team has matched the data items to SNOMED CT codes, imagining the codes would be used to identify all of the appropriate data within a medical record.

There are two parts to the questionnaire. The first assesses the accuracy of SNOMED CT codes for paediatric ophthalmic concepts. The second aims to inform an expert-driven consensus on code selection.

In addition to the questionnaire, please find enclosed an overview of SNOMED CT and a copy of the BCVIS2 data collection form for your reference.

If you have any queries or comments, please do contact

Maria Cross: [maria.cross.11@ucl.ac.uk](mailto:maria.cross.11@ucl.ac.uk)

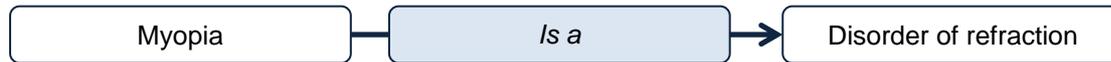
Jugnoo Rahi

Thank you for contributing to this work.

## ABOUT SNOMED CT

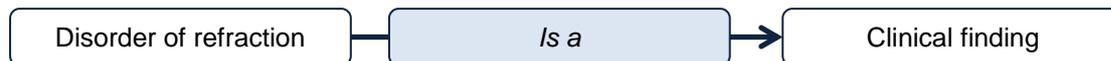
SNOMED CT is a standardised vocabulary of terms that describes the health and care of individuals. It is used to structure medical data into a computer readable format.

The vocabulary consists of concepts, each with a unique, computer readable numerical code associated to a human-readable textual description. Relationships or attributes link concepts with related meanings, for example:

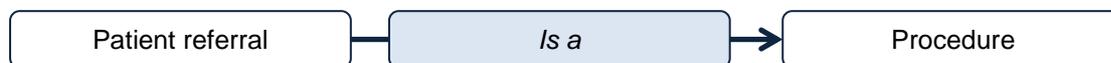


The use of “is a” relationships gives SNOMED CT a hierarchical structure. Below are descriptions of the main SNOMED CT hierarchies. You will appreciate that each hierarchy encompasses a wider range of concepts than you might expect.

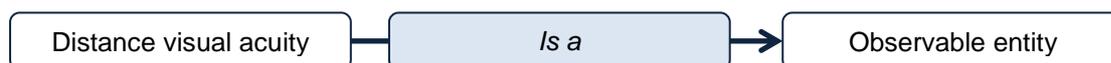
- Clinical finding: the result of an assessment, question or judgement, including reported symptoms, observations, diagnoses and disorders.



- Procedure: all activities performed within the provision of care, including referrals, telephone calls, invasive procedures, provision of medicines, and imaging.

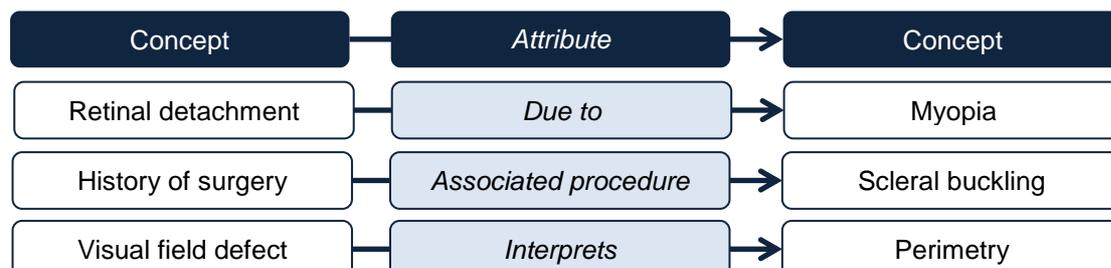


- Observable entity: a question or assessment that can produce an answer or result. Clinical findings are often the result of observable entities.



SNOMED CT codes can be combined using other attributes to form complex clinical expressions. *Laterality*, *finding site* and *due to* are examples of attributes.

The diagram below indicates how attributes can be used in this manner.



## **QUESTIONNAIRE PART 1**

Below are 12 clinical expressions taken from the BCVIS2 data collection form (the corresponding question number is also given).

Below each expression are SNOMED CT concepts that have been chosen by the study team to best represent the BCVIS2 expression; the SNOMED hierarchies that the chosen codes belong to are shown in brackets.

In some cases, more than one SNOMED concept was chosen to represent the BCVIS2 expression; these are listed with the linking attribute.

Please select how **accurate** you think the choices of SNOMED CT code are in representing the meaning of each BCVIS2 expression, from *1 – complete match*; *2 – partial match (too broad)*; *3 – partial match (too narrow)*; *4 – partial match (slightly different meaning)*; or *5 – no match*. Two examples are provided below.

### Example 1

#### BCVIS item 10.5: **Assessment by visual impairment team**

Seen by person (finding)

Here, the chosen SNOMED CT code is a partial match – too broad as it encodes the idea of an assessment, but does not specify whom with. There is no specific code for a visual impairment team.

### Example 2

#### BCVIS item 10.5: **Assessment by a geneticist**

Seen by clinical molecular geneticist (finding)

Here, the chosen SNOMED CT code is a partial match – too narrow as the meaning of the SNOMED CT code is more specific than the BCVIS2 expression – a clinical molecular geneticist is a subclass of geneticist.

#### 1) BCVIS2 item D: **NHS Number**

Patient National Health Service number (observable entity)

- |   |   |
|---|---|
| <input type="checkbox"/> 1 - complete match             | <input type="checkbox"/> 4 - partial match (slightly different meaning) |
| <input type="checkbox"/> 2 - partial match (too broad)  | <input type="checkbox"/> 5 - no match                                   |
| <input type="checkbox"/> 3 - partial match (too narrow) |   |

#### 2) BCVIS2 item D: **Bangladeshi**

Bangladeshi or British Bangladeshi – ethnic category 2001 census (finding)

- |   |   |
|---|---|
| <input type="checkbox"/> 1 - complete match             | <input type="checkbox"/> 4 - partial match (slightly different meaning) |
| <input type="checkbox"/> 2 - partial match (too broad)  | <input type="checkbox"/> 5 - no match                                   |
| <input type="checkbox"/> 3 - partial match (too narrow) |   |

3) BCVIS2 item D: **Ethnic group not stated or unknown**

Ethnic category not stated – 2001 census (finding)

- |   |   |
|---|---|
| <input type="checkbox"/> 1 - complete match             | <input type="checkbox"/> 4 - partial match (slightly different meaning) |
| <input type="checkbox"/> 2 - partial match (too broad)  | <input type="checkbox"/> 5 - no match                                   |
| <input type="checkbox"/> 3 - partial match (too narrow) |   |

4) BCVIS2 item 2.1: **Symptom of squint**

Eye symptom (finding)

- |   |   |
|---|---|
| <input type="checkbox"/> 1 - complete match             | <input type="checkbox"/> 4 - partial match (slightly different meaning) |
| <input type="checkbox"/> 2 - partial match (too broad)  | <input type="checkbox"/> 5 - no match                                   |
| <input type="checkbox"/> 3 - partial match (too narrow) |   |

5) BCVIS2 item 2.3: **First referred by ophthalmologist**

Referral by ophthalmologist (procedure)

- |   |   |
|---|---|
| <input type="checkbox"/> 1 - complete match             | <input type="checkbox"/> 4 - partial match (slightly different meaning) |
| <input type="checkbox"/> 2 - partial match (too broad)  | <input type="checkbox"/> 5 - no match                                   |
| <input type="checkbox"/> 3 - partial match (too narrow) |   |

6) BCVIS2 item 2.4a: **Referral date**

Date of procedure (observable entity)

Associated procedure (attribute)

Patient referral (procedure)

- |   |   |
|---|---|
| <input type="checkbox"/> 1 - complete match             | <input type="checkbox"/> 4 - partial match (slightly different meaning) |
| <input type="checkbox"/> 2 - partial match (too broad)  | <input type="checkbox"/> 5 - no match                                   |
| <input type="checkbox"/> 3 - partial match (too narrow) |   |

7) BCVIS2 item 3.4: **Multiple birth**

Multiple birth (finding)

- |   |   |
|---|---|
| <input type="checkbox"/> 1 - complete match             | <input type="checkbox"/> 4 - partial match (slightly different meaning) |
| <input type="checkbox"/> 2 - partial match (too broad)  | <input type="checkbox"/> 5 - no match                                   |
| <input type="checkbox"/> 3 - partial match (too narrow) |   |

8) BCVIS2 item 4.5: **Foster care**  
Child in foster care (finding)

- |   |   |
|---|---|
| <input type="checkbox"/> 1 - complete match             | <input type="checkbox"/> 4 - partial match (slightly different meaning) |
| <input type="checkbox"/> 2 - partial match (too broad)  | <input type="checkbox"/> 5 - no match                                   |
| <input type="checkbox"/> 3 - partial match (too narrow) |   |

9) BCVIS2 item 5.1: **Keeler visual acuity**  
Keeler acuity cards (procedure)

- |   |   |
|---|---|
| <input type="checkbox"/> 1 - complete match             | <input type="checkbox"/> 4 - partial match (slightly different meaning) |
| <input type="checkbox"/> 2 - partial match (too broad)  | <input type="checkbox"/> 5 - no match                                   |
| <input type="checkbox"/> 3 - partial match (too narrow) |   |

10) BCVIS2 item 7: **Refractive error resulting in VI / SVI / BL**  
Blindness AND/OR visual impairment level (finding)  
Due to (attribute)  
Disorder of refraction (finding)

- |   |   |
|---|---|
| <input type="checkbox"/> 1 - complete match             | <input type="checkbox"/> 4 - partial match (slightly different meaning) |
| <input type="checkbox"/> 2 - partial match (too broad)  | <input type="checkbox"/> 5 - no match                                   |
| <input type="checkbox"/> 3 - partial match (too narrow) |   |

11) BCVIS2 item 7: **Disorder of optic nerve resulting in VI / SVI / BL**  
Blindness AND/OR visual impairment level (finding)  
Due to (attribute)  
Disorder of optic nerve (finding)

- |   |   |
|---|---|
| <input type="checkbox"/> 1 - complete match             | <input type="checkbox"/> 4 - partial match (slightly different meaning) |
| <input type="checkbox"/> 2 - partial match (too broad)  | <input type="checkbox"/> 5 - no match                                   |
| <input type="checkbox"/> 3 - partial match (too narrow) |   |

12) BCVIS2 item 7: **Other disorder of whole globe or anterior segment resulting in VI / SVI / BL**  
Blindness AND/OR visual impairment level (finding)  
Due to (attribute)  
Disorder of vitreous body and globe (finding)

- |   |   |
|---|---|
| <input type="checkbox"/> 1 - complete match             | <input type="checkbox"/> 4 - partial match (slightly different meaning) |
| <input type="checkbox"/> 2 - partial match (too broad)  | <input type="checkbox"/> 5 - no match                                   |
| <input type="checkbox"/> 3 - partial match (too narrow) |   |

*END OF PART 1*

## **QUESTIONNAIRE PART 2**

Seven clinical expressions are presented, as in part one, with two SNOMED CT options that could be used to code the BCVIS2 expression or, in some cases, only one SNOMED concept is provided and the second option is *no appropriate SNOMED CT code*.

Please select the SNOMED option you think is most appropriate to represent each BCVIS2 expression, and use the space provided below the question to explain your choice.

1) BCVIS2 item 5.1: **logMAR visual acuity, both eyes open**

Option A: LogMAR visual acuity right eye (observable entity)

Option B: *No appropriate SNOMED CT code*

Option A

Option B

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2) BCVIS2 item 5.2: **Cannot see to recognise people**

Option A: Unable to recognise faces (finding)

Option B: Unable to recognise objects by sight (finding)

Option A only

Option B only

Both options A and B

Neither option A or B

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3) BCVIS2 item 6.4: **Normal MRI of brain / orbits**

Option A: *No appropriate SNOMED CT code*

Option B: Nuclear magnetic resonance normal (finding)

Interprets (attribute)

Magnetic resonance imaging of head (procedure)

Option A

Option B

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4) BCVIS2 item 10.3: **Hearing impairment**

Option A: Hearing problem (finding)

Option B: Hearing disorder (finding)

Option A only

Option B only

Both options A and B

Neither option A or B

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5) BCVIS2 item 10.3: **Learning impairment**

Option A: Impaired ability to learn new material (finding)

Option B: Learning difficulties (finding)

Option A only

Option B only

Both options A and B

Neither option A or B

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6) BCVIS2 item 10.3: **Speech/Language impairment**

Option A: Disturbance in speech (finding)

Option B: Speech and language disorder (finding)

Option A only

Option B only

Both options A and B

Neither option A or B

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7) BCVIS2 item 10.5: **Assessment by psychologist**

Option A: Psychological assessment (procedure)

Option B: Seen by psychologist (finding)

Option A only

Option B only

Both options A and B

Neither option A or B

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**END OF PART 2**

*Thank you for completing the questionnaire.*

Please return your responses to Maria Cross ([maria.cross.11@ucl.ac.uk](mailto:maria.cross.11@ucl.ac.uk)).