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Project Title

Healthcare Exemplar for Recovery from COVID-19 by Use of Linear Examination Systems

Short Project Title

Project HERCULES

Sponsor

Moorfields Eye Hospital NHS Foundation Trust

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National Institute for Health Research Biomedical Research Centre

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2. Study Summary

Full Study Title	Healthcare Exemplar for Recovery from COVID-19 by Use of Linear Examination Systems
Short Study Title	Project HERCULES
Sponsor Protocol Ref	JAYH1011
Study Design	Mixed Methods Evaluation Study
Study Participants	Adult patients attending follow up clinic appointments within the Glaucoma and Medical Retina Services at the new Moorfields Brent Cross Hub and at existing clinics across the Moorfields Eye Hospital Network
Planned Sample Size	3800 patients
Follow up Duration	No follow-up required
Planned Study Period	12 Months
Research Question/Aim(s)	1. What is the existing evidence about implementation, outcomes, and value of rapid diagnostic hubs? 2. What are patients' preferences for rapid diagnostic hubs for people with stable chronic eye conditions? 3. Which factors influence implementation and delivery of care in these rapid diagnostic hubs? 4. How do staff and patients experience these rapid diagnostic hubs? 5. What are the effects of different models/forms of rapid diagnosis hubs on delivery of care and patient outcomes? 6. Do rapid diagnostic hubs deliver cost effective and value-based health care?

4. Executive Summary

The COVID-19 pandemic has created the greatest health crisis in living memory. The suspension of non-urgent NHS work has led to millions of delayed appointments across the United Kingdom, and after years of health funding austerity, this backlog is potentially insurmountable. Bold, innovative solutions are required to help avoid many patients suffering avoidable harm because of delayed or missed appointments.

We will develop and deliver a new system of eye care as a template applicable for this and other high volume outpatient-based NHS specialities in the United Kingdom. With our research and commercial partners, we will design spacious, well-ventilated, high-efficiency clinics using an assembly line concept. We will use rapid, scalable, ultra-modern construction methods and the latest digital technology to create, equip and run these. Through an "open house" policy for patient representative organisations, media, NHS and government leaders, we aim to rapidly disseminate our experiences. We will provide detailed design specifications and operational protocols to ensure that this new system can be rolled out at scale and pace.

Prior to the COVID-19 pandemic, 3,384 ophthalmology patients suffered follow-up delays > 1 year, with 1% of these people suffering severe loss of vision.[1] The 2013 direct cost of NHS eye care was £ 3 billion, with a further £6 billion/year of indirect costs of sight loss. People fear blindness more than severe angina or kidney dialysis. Patients suffering chronic eye disease comprise a high-risk demographic for COVID-19 morbidity and mortality, most being elderly, many with multiple systemic comorbidities and disproportionately of Black, Asian & minority ethnic (BAME) heritage. Since the declaration of the pandemic, over one million NHS ophthalmology appointments have been delayed including, creating a huge backlog and the potential for thousands of cases of avoidable blindness, leading to a need to redesign how we can deliver care moving forward in the “era of pandemics”.[2]

5. Strategic Fit, Impact & Cost Saving

The recent 50% reduction in heart attack presentations highlight that fear and anxiety related to COVID-19 are major barriers to patients accessing NHS care. Reducing infection risk of both staff and patients is critical to reducing COVID-19 caseload and rebuilding trust in NHS outpatient services. We are therefore targeting the need to simultaneously introduce inter-personal distancing together with rapid, reactive capacity expansion in outpatient care to prevent vision loss in a system overwhelmed by effects of the COVID-19 pandemic. We believe these innovations will help to create a more sustainable, equitable and resilient system for outpatient care with relevance throughout the NHS, and which will safeguard the health and lives of both patients and staff in the "era of pandemics" and in the new way of life after.

Building on prior research and innovation, we will create an exemplar clinic demonstrating simultaneous implementation of inter-personal distancing together with rapid expansion of NHS outpatient capacity during COVID-19 post-peak recovery phases. We will set standards for a novel model of care, the principles of which will be applicable to many other high-volume NHS outpatient settings such as orthopaedics and cardiology, providing a toolkit for rapid scaling throughout the NHS.

With the suspension of routine NHS care during national lockdowns, and the later diversion of staff to provide super-surge capacity for acute COVID care and vaccine rollout, the COVID-19 pandemic has resulted in enormous backlogs of care for chronic blinding diseases. Nationwide, over one million ophthalmology appointments have been delayed, creating a huge workload backlog. Ophthalmology is the busiest NHS outpatient speciality (7.9 million episodes; 2018-19), and is perfectly suited to providing a testbed for rapid, research-driven innovation in care in the COVID-endemic era.

Our vision builds on a successful 10 year collaboration between Moorfields Eye Hospital and The UCL Department of Applied Healthcare Research, which provided proof of principle for an "assembly line" concept being a highly efficient method monitoring of stable chronic disease. This work showed a reduction of visit time from nearly 2 hours to 45 minutes. The need for monitoring of chronic eye disease is projected to grow year-on-year due to earlier diagnosis and greater life expectancy. The last two decades have seen remarkable

improvements in lifelong visual health through timely identification of sight threatening disease allowing targeted intervention from those at greatest risk. These gains are now at considerable risk over at least a decade.

The linear flow examination concept has proven efficient and well-accepted by patients. We aim to test and refine this system further to improve performance and to provide robust evidence that will inform healthcare policy and funding priorities in the post-pandemic decade.

The COVID pandemic has put NHS finances under unprecedented stress. The system of payment by results (PbR), introduced in 2003/04, has been suspended, and replaced by block contracting. This new funding system (lump sum for a specific – usually broadly defined – service independent of number of patients) will constrain operational budgets. In the context of vast increases in public debt, downward pressure on public service budgets will reduce access to healthcare, and lead to deteriorating health outcomes for the public and increased waiting lists. We will also evaluate the value for health.

We envisage 65-75% of all appointments for patients suffering macular degeneration, diabetic eye disease and glaucoma being delivered in such potentially highly-efficient “diagnostic hubs”. This will allow direct face-to-face hospital capacity to be directed to those immediately pre- or post-surgery, vulnerable patients or those living with disability. The design and operation of these hubs will provide a template for a new approach to delivering health care that will have global relevance.

6. Background & Justification

Prior to the COVID-19 pandemic, 3,384 ophthalmology patients suffered follow-up delays > 1 year, with 1% of these people suffering severe loss of vision.[1, 3] Since the declaration of the pandemic, over one million NHS ophthalmology appointments have been delayed, creating a huge workload backlog and the potential for thousands of cases of avoidable blindness. The 2013 direct cost of NHS eye care was £ 3 billion, with a further £ 6 billion/year of indirect costs of sight loss. People fear blindness more than severe angina or kidney dialysis. We are targeting the need for reactive capacity expansion in outpatient care to prevent vision loss in a system overwhelmed by effects of COVID-19. We believe these innovations will help to create a more sustainable, equitable and resilient system for outpatient care with relevance throughout the NHS, and which will safeguard the health and lives of both patients and staff in the “era of pandemics” and the new way of life after.

Health care systems worldwide were not designed to operate with widespread physical distancing measures in place. However, for the foreseeable future, all global healthcare providers need to operate with such distancing in place. This is occurring at a time when the demand on such systems, will be unprecedented as a backlog of outpatient appointments is released. Ophthalmology, the busiest NHS outpatient speciality (7.9 million episodes; 2018-19), is perfectly suited to providing a testbed for rapid, research-driven innovation in the COVID-endemic era. Bringing together remarkable multidisciplinary expertise in our team, we propose an exemplar clinic that provides proof of concept for rapid expansion of outpatient capacity across the NHS during recovery from COVID-19 peaks. Physically-distanced outpatient care will be provided in different configurations – lane, pods and pools. As we have proven in UK Biobank, and subsequently in NHS care, configuring clinic diagnostics and disease monitoring for maximum efficiency can reduce (and in many cases more than halve) patient journey time, increasing capacity.

With the need for reactive capacity expansion, we will rapidly train a healthcare naïve workforce to carryout sophisticated medical examinations. Design and modelling teams comprising healthcare architects and engineers will optimise the safe and efficient movement of patients and staff within the new clinic system. We will rapidly assess safety and efficiency of our new model of care. Ultimately, our goal is to develop a cost-effective, equitable and sustainable new model for providing NHS and global outpatient care.

7. Aims & Objectives

We aim to develop a cost-effective, patient-centred, equitable and sustainable new model for providing NHS and global ophthalmology outpatient care.

Summary

Building on prior research and innovation, we will create an exemplar clinic demonstrating rapid expansion of NHS outpatient capacity during COVID-19 post-peak recovery phases in a rapidly converted retail space, offering strong established transport links, ample parking, food, beverage toilet and retail facilities, at a time of collapsing commercial rent. We will set standards for a novel model of care, the principles of which will be applicable to many other high-volume NHS outpatient settings such as orthopaedics and cardiology, providing a toolkit for rapid scaling throughout the NHS.

In this proposal, we aim to deliver improvements in efficiency, and build additional clinic capacity, to help maintain services during the pandemic recovery phase, and aim to help restore activity levels pre-pandemic levels. We will focus specifically on the large number of patients who need monitoring for progression of chronic eye diseases such as age-related macular degeneration, diabetic retinopathy and glaucoma. We will fit out a retail unit in a major London shopping mall to serve as an Ophthalmic Diagnostic Hub. The diagnostic equipment utilised in this hub will be sourced from a variety of manufacturers to maintain heterogeneity, and will include Humphrey Automated Perimeters (HFA3) and Optical Coherence Tomography Devices (Cirrus OCT 6000) from Zeiss, Optical Coherence Tomography Devices (Spectralis) from Heidelberg Engineering and Ultra-Widefield Retinal Imaging Devices (California *rg*) from Optos. We will harness private sector expertise and energy to enhance efficiency digital technological tools to automate repetitive tasks such as entering names and ID numbers into each piece of test equipment, for each patient, at each visit. We will test different physical configurations of the clinic, which we call lanes, pods and pools. We have proven the performance gains from a diagnostic lane (analogous to an assembly line) in previous work (see below), but with the help of the UCL School of Management, we will seek further enhancements in efficiency. Architects and design engineers from UCL Bartlett Faculty of the Built Environment will create “Eye Pods” using rapid manufacturing techniques which allow a patient to rapidly rotate from one piece of test

equipment to the next, while being settled in a temperature, sound and light controlled environment, which also offers a physical barrier between staff and patient, thus reducing infection risk. Finally, we will test a system in which patients are directed to a sequence of "equipment pools", with multiple identical devices. The ability to match the number of devices to the demand for capacity will ensure an even, uninterrupted patient flow through the system. This approach is used in the world famous Aravind Eye Hospital, the biggest eye care system in the world.

We will collect detailed time and motion data on the movement of staff and patients, as well as detailed evaluation of the patient experience within the clinic to identify where improvements can be made, and further innovation can be targeted. We will test each of the three systems in an iterative manner at maximum capacity, again collecting time and motion data that will be used to compare efficiency and cost effectiveness of each, and also in the context of the current standard of care at Moorfields. These data will help determine the optimal approach(s), and provide robust, granular data around the true costs of delivery of eye care in the modern NHS. We believe this invaluable information will shape NHS ophthalmology for a generation.

7.1. Monitoring of Patient Flow within the Diagnostic Hub

We will capture real time measures of test times and the overall patient journey within the new Brent Cross Facility which is a CQC approved Moorfields site for delivering elective routine outpatient care, and at existing Moorfields Clinics at our Hoxton Diagnostic Hubs and at City Road. This will be performed by observers from the UCL Bartlett School of Architecture at the existing Moorfields sites. At the new Brent Cross site, this will be performed using a commercial partner (Ubisense - https://ubisense.com) who specialise in Ultra-Wideband Real-Time Location Systems that are able to track patient and staff movement across the clinical facility using wearable lanyards, during the three iterative configurations of the diagnostic hub. This will form one of the key outcome measures for the UCL Department of Applied Healthcare Research to evaluate overall system performance and economic viability. Patients will be asked to give informed consent to go through the time and motion monitoring, and for access to basic elements of their Moorfields medical records that are relevant to their

mobility through the diagnostic pathway and will also be invited to provide feedback through being a part of a “patient panel” which will inform subsequent iterations to be tested.

The following objectives are identified:

- Observe current journeys of glaucoma and medical retina patients through space with detailed timings of examinations on different stations;
- Comparison of patient journeys across existing clinics (Cayton St, Hoxton, City Road)
- Identify spatial factors versus technician versus patient factors in operations;
- Analyse the spatial network structure of the clinics;
- Suggest new flow models, optimizing spatial and temporal factors causing delays;

7.2. Optimising Patient Scheduling at Diagnostic Hubs

The collaboration with the UCL School of Management has two objectives than can be achieved using aggregated service level information from the glaucoma and medical retina services at Moorfields. This will not involve and individual level data or processing of any identifiable information. These comprise:

1. Derivation of Patient Schedules at the Brent Cross Hub Using a Simulation Model to Streamline Operations and Reduce Waiting Times.
2. Development of Prediction Models for the prediction of No-Show Patient Behaviour to Developing Accurate Patient Demand Models

7.3. Evaluation of the Efficiency, Performance and Patient Satisfaction of Reconfigurations of the Diagnostic Hub

This aspect of the project will be performed in collaboration with the UCL Department of Applied Health Research. This department has expertise in the evaluation of service innovations – those driven both by national policy, and local needs – using quantitative and qualitative approaches to assess innovations ranging from changes in management of services to new ways of delivering services to patients, and quality improvement initiatives.

The Rapid Service Evaluation team specialises in assessing if a new approach works well and rapidly understanding and sharing learning about that success with other parts of the health and care system.

7.3.1. Research Questions

With respect to this specific project, there are six research questions that will be addressed:

1. What is the existing evidence about implementation, outcomes, and value of rapid diagnostic hubs?
2. What are patients' preferences for rapid diagnostic hubs for people with stable chronic eye conditions?
3. Which factors influence implementation and delivery of care in these rapid diagnostic hubs?
4. How do staff and patients experience these rapid diagnostic hubs?
5. What are the effects of different models/forms of rapid diagnosis hubs on delivery of care and patient outcomes?
6. Do rapid diagnostic hubs deliver cost effective and value-based health care?

8. Study Design

8.1. Monitoring of Patient Flow within the Diagnostic Hub

Building on space syntax as a method and an understanding of spatial layouts as a network of connected elements, the following research questions are addressed:

1. Which underlying spatial network structures are currently in use at the Moorfields sites? Which implications do network structures have on flow processes?
2. How can the four stations required for glaucoma patients (three for medical retina) be arranged differently?
3. Which effects do different arrangements have on required room sizes, but also on inherent spatial flexibility in reconfiguring?
4. What happens when a modular diagnostic hub is multiplied and aggregated into larger clusters, i.e. which additional large-scale network super-structures are created and what are their implications for patient journeys?

While mostly addressing concrete examples and working with a clearly applied case, the research ultimately raises questions of wider relevance for architecture including what the definition of reconfigurable is; how flexibility is possible and at what level; and which implications flexibility has, both operationally for organizations, but also for healthcare architects in designing hospitals and determining e.g. grid systems. We will capture real time measures of test times and the overall patient journey at the new Brent Cross Facility, and within existing Moorfields Clinics at the Cayton Street and Hoxton Diagnostic Hubs, and City Road clinics. This will be performed by observers from the UCL Bartlett School of Architecture at the existing Moorfields sites. At the new Brent Cross site, this will be performed using a commercial partner (Ubisense - https://ubisense.com) who specialise in Ultra-Wideband Real-Time Location Systems that are able to track patient and staff movement across the clinical facility using wearable lanyards, during the three iterative configurations of the diagnostic hub.

8.2. Optimising Patient Scheduling at Diagnostic Hubs

8.2.1. Derivation of Patient Schedules at the Brent Cross Hub Using a Simulation Model to Streamline Operations and Reduce Waiting Times.

In order to achieve the first objective, data estimates will be used concerning:

i. Daily patient demand patterns.
ii. The composition of patients (Glaucoma vs. Medical Retina).
iii. The times that patients typically spend for each medical test.
iv. The overall capacity in the new clinic (number of machines and clinical staff), to design efficient schedules at the Brent Cross Hub.

Specifically, these schedules can inform stakeholders on the times that different follow-up or new patients will be asked to come into the clinic, as well as the times that they will be directed to perform different tests while at the clinic. For this aim, we will develop appropriate mathematical models using these inputs and rely on appropriate optimization frameworks for the derivation of the schedules. This simulation model can then be used, jointly with optimization frameworks, to investigate “what-if” type of questions. For example, how much time can we save if we add a machine of a certain type, or if we change the schedule in a certain way? The simulation model can also be used to aid in the design of the clinic in later

iterations e.g., to investigate the impact of having a linear or a modular design for tests at the clinic, or potentially a hybrid of these two designs.

8.2.2. Development of Prediction Models for the prediction of No-Show Patient Behaviour to Developing Accurate Patient Demand Models

For the second objective, we will rely on aggregated historical data about appointments and attendance records to develop new models for the prediction of no-show behaviour at Moorfields. Developing such a prediction model is important because it will allow stakeholders to identify better strategies to improve on the no-show rate. The scope of this last aim is broad and long term: It goes beyond the design of the new clinic at Brent Cross and relates to developing more reliable patient demand models, in general. One point of special interest is to study the impact of the pandemic on the non-attendance of booked patients, and to make predictions on the future repercussions of this behaviour

8.3. Evaluation of the Efficiency, Performance and Patient Experience of Reconfigurations of Diagnostic Hubs

Setting

- Innovation Hub (Moorfields at Brent Cross): This is a new diagnostic hub that will commence with a linear flow design, followed by two further rapid cycle revisions to incorporate innovations, e.g. ‘Eye-pod’ modular delivery system, pooled or zonal use of diagnostic equipment.

- Comparator Hubs (Moorfields at Hoxton (Medical Retina & Glaucoma), Moorfields at Cayton Street (Glaucoma) and Moorfields Medical Retina Diagnostic Clinic (City Road): The first diagnostic clinic at Cayton Street has been seeing glaucoma patients for over 5 years, although capacity has been significantly increased following the pandemic. Earlier this year a new diagnostic hub was set up at Hoxton using a linear design (https://www.moorfields.nhs.uk/news/moorfields-launches-new-diagnostic-hubs-safely-assess-more-patients-during-pandemic)

- Pre-Pandemic Standard Care (Face to Face Clinics at Moorfields City Road) Prior to the pandemic, over 80% of patients were seen in traditional face to face clinics at Moorfields. Across the United Kingdom, this was the usual standard of care with only a few units having established a diagnostic hub/clinic component.

The research questions will be addressed through a rapid, formative mixed methods evaluation,[4, 5] integrating:

8.3.1. Rapid Literature Review

This will aim to address RQ1 during months 1-3 of the project. We will identify the evidence base with respect to diagnostic hubs, including stakeholder views, the nature of evaluation, cost effectiveness, impact on quality of care and outcomes, impact on patient experience, and lessons for implementation.[6, 7] We will review all available systematic, scoping, or rapid reviews on this topic using key words identified in collaboration with clinical colleagues and a university librarian. The focus will be on the broad concept of diagnostic hubs, not just with reference to ophthalmology, and may include other relevant NHS specialities.

8.3.2. Analysis of Patient Preferences (with rapid formative feedback)

This will aim to address RQ2 and will take place from months 3-12 of the project. We aim to conduct a discrete choice experiment (DCE) with patients to analyse their preferences for different attributes of diagnostic services, in order to inform later innovation cycles at the Moorfields Diagnostic Hub at Brent Cross.

Attributes (and their levels) will be identified through a review of relevant literature, two focus groups with patients and clinician engagement. Attributes may include location and accessibility, speed, subsequent interactions with health professionals and the need for a return visit or further referral. The DCE will be designed using N gene software to ensure statistical efficiency. The final DCE will comprise an online survey which patients will be asked to complete, prior to their appointment and then after their appointment. Completed surveys will be analysed to understand the trade-offs between attributes and patient preferences for different diagnostic service scenarios. Heterogeneity in preferences pre- and post-appointment will be tested and will offer insight as to whether the diagnostic experience affects patient preferences. We anticipate that one of the scenarios will reflect ‘previous

experience' (e.g. pre-pandemic standard care delivered face-to-face at Moorfields City Road), and the survey tool will include questions about past experiences of care so that we can control for experience in the analysis. The cost of delivering different diagnostic scenarios can be estimated and compared with the cost of delivering care in the diagnostic hubs at Brent Cross and Hoxton, this will inform RQ6.

We will convene a patient focus group to help inform the attributes for the DCE and will approach patients from the "Research Opportunities at Moorfields" database who have already given prior consent to be approach about becoming involved with and shaping research, as well as patients attending the diagnostic hubs who we will ask for consent to approach for this purpose. We will also work closely with our partners from the Macular Society and Glaucoma UK in developing the focus groups, who are the two leading patient-based charities for macular disease and glaucoma in the United Kingdom.

Patients who have given prior consent will be approached by the clinical care team to obtain informed consent specific to participation in this aspect of the project. This will be submitted in detail as a substantial amendment once fully developed.

8.3.3. Qualitative Analysis of Care Delivery and Outcomes

This will address RQ3 and RQ4 and will take place throughout the project. We will analyse factors influencing the implementation and delivery of care in diagnostic hubs and explore how patients and professionals experience these hubs,[4, 8] in order to provide formative evidence that supports and informs development and implementation of the rapid cycle service innovations at the new Moorfield Diagnostic Hub at Brent Cross.

Data collection

Interviews will be conducted with a range of stakeholders (Table 1), including patients using new and established diagnostic services, staff (clinical, managerial, and administrative) working within the hubs, and stakeholders involved in the planning and oversight of the Moorfields Diagnostic Hub strategy. Interviews will focus on the development, delivery, and experience of the services, factors influencing implementation and quality of care delivery (including e.g. contextual factors), and areas where services might develop further.

Interviews will be conducted using semi-structured topic guides, focusing on such issues as background to services, implementation and governance, impact of services (on e.g. quality

of care, efficiency, outcomes, and patient experience), and potential for further adaptation and roll-out. Interviews will be digitally recorded (audio only) and stored on Moorfields secure servers prior to transcription by a professional transcription company. The interviews will be anonymised prior to transcription with no identifiable data discussed during the period that will be recorded.

Recruitment and Consent

Potential interviewees will be recruited as follows. The clinical care team will approach patients who have given consent to be contacted for further research about these services, and the evaluation team will approach members of staff based upon their role (as set out in Table 1) and who have indicated their willingness for team management to share their contact details. Potential interviewees will be contacted by e-mail or letter with a specific information sheet and consent form for this component. Potential interviewees will have at least 24 hours to decide whether or not they wish to take part. Whether an individual participated or not will be treated confidentially and will not be shared beyond the evaluation team. Interviews will be conducted only with informed consent from participants. If participants are happy to proceed, consent will be taken over the telephone and documented in a confirmation letter that will be sent to stakeholders and patients, and filed in the medical records where appropriate.

If participants raise any serious concerns about their care during the focus groups or any interviews, these will be dealt with via the NHS complaints process at Moorfields. Participants are provided with contact details about the Moorfields Eye Hospital Patient Advice and Liaison Process in the information sheet and will be provided with this information again should this scenario arise.

Table 1. Proposed stakeholder interviews disaggregated by site and innovation phase

Stakeholder group	Comparator Hub		Innovation Hub at Brent Cross				Total
	H	M	1	2	3	4	
Patients (macular degeneration, diabetic eye disease, glaucoma)	3	3	3	3	3	3	18
Service leaders and senior managers	1	1	1	1	1	1	6
Ophthalmology Clinical Team	2	2	2	2	2	2	12
Onsite hub staff - Moorfields technicians	1	1	1	1	1	1	6
Onsite hub staff - recruited from other industries	1	1	1	1	1	1	6
Partners (e.g. system designers)	2	2	2	2	2	2	12
Wider context (NHSE/I, commissioners, professional organisations)	-	-	-	-	-	-	6
Total	10	10	10	10	10	10	66

Note. 'H'=Hoxton; 'M'=Moorfields City Road; Interviews with service leads, ophthalmology team, and external partners are likely to be follow-up interviews with the same individuals over the course of the evaluation. We will interview wider context stakeholders twice – once at baseline, once near the end of the data collection phase. We are likely to interview different patients and onsite hub staff during each innovation phase.

Non-participant observations

These will be conducted on activities related to the diagnostic hub services (Table 2). These will include virtual observations of governance of the services (e.g. planning and oversight meetings, service reviews), implementation of hubs (e.g. design, training, and review activities), and within the constraints of pandemic safety requirements, the evaluation team will also observe delivery of the services (e.g. observing patients passing through the diagnostic hub process, how different staff support the delivery of the new services and how staff interact with patients to put them at ease). A particular focus would be the early stages of

implementation (as innovations "bed in") and later stages (to explore whether and in which ways innovations have been adopted by staff and how they are responded to by patients).

Observations will be recorded by researchers as field notes (by hand or electronically), guided by an observation template (developed based on initial findings from the literature review and exploratory discussions with service leaders).

Recruitment and consent

Observations will be conducted only with fully-informed consent from participants. Separate information sheets and consent forms have been developed for these components. For example, for meetings, information sheets will be shared with meeting members in advance, along with other meeting papers; researchers will only attend with permission from the Chair, and at the meeting the researcher will discuss the evaluation after obtaining informed consent from meeting attendees (this will be obtained either by telephone or in person depending upon how the meetings are arranged), and this will be recorded in meeting minutes. For service delivery observations, the evaluation team will engage with staff at meetings in advance of starting observations to obtain informed consent. Patients will be asked for consent to observe how staff interact with them in the overarching study consent form, and can opt out of this at any stage should they wish to. In all observations, individuals will be treated anonymously and no individuals will be identified in reports.

Table 2. Proposed non-participant observations disaggregated by site and innovation phase

Activity	Comparator Hub		Innovation Hub at Brent Cross				Total
	H	M	1	2	3	4	
Planning and oversight meetings	-	-	2	2	2	2	8
Training events	-	-	1	1	1	1	4
Delivery of service (working days)	1	1	1	1	1	1	6
Service reviews	-	-	1	1	1	1	4
Total	1	1	5	5	5	5	22

Note. 'H'=Hoxton; 'M'=Moorfields City Road;

Documentary analysis

This will be conducted on key documents (e.g. project plans, training materials, information supplied to patients) in order to gain further understanding of the processes of implementation and delivery of the new hubs. Documents will either be requested or provided by stakeholders (e.g. meeting chairs, programme leadership) or be obtained from the public domain.

8.3.4. Patient Outcomes, Cost, Cost-Effectiveness and Budget Impact

This will address RQ5 and RQ6 and will take place throughout the project. The quantitative analysis will consider three different sets of comparative analyses. Comparisons will be made (a) across sites, primarily comparing the diagnostic hubs in Brent Cross and Hoxton, but also where data allows these hubs to traditional face to face clinics (representing "pre-pandemic" standard care) at the Moorfields site in Central London; (b) across eye disease, macular degeneration, diabetic retinopathy and glaucoma; and (c) across hub configuration, linear, pod, pool, etc.

In addition to the routinely collected clinical and demographic data (Age, Ethnicity, Diagnosis, Visual Acuity, Visual Field Mean Deviation for Glaucoma Patients and Sight Registration Status), additional self-reported health outcomes and experience data will be collected from patients following informed consent. These will include: patient reported outcome measures (PROMs) EQ-5D-5L[9, 10] (with vision bolt-on) (pre and post diagnostic experience) and visual function (VF-14) questionnaire[11]; and patient reported experience measures (PREMs), modified from the Wales Value Based Healthcare programme.[12] Speed and number of different interactions through the hub, and the number of did not attends (DNAs) will also be collected. Secondary reading of the timeliness of the reporting of the clinical attendance and the outcome, will provide information on the clinical utility of the diagnosis or safety. This will be obtained in a pseudonymised manner by Moorfields Performance & Information. Financial information with respect to the cost of setting up and running the Hubs and the reimbursement of care via NHS England tariffs will be collected from Moorfields Finance

Department and by applying a microcosting approach (given activity, throughput and total cost).

The analysis will consider the outcomes (and experience) that each site delivers, whether there is variation across eye diseases and specifically within the various reconfigurations at Brent Cross with respect to whether the patient experience and health outcomes differ. The cost of delivering care (per patient) will also be compared and a comparative analysis will compare any difference in outcomes and cost per patient to understand if diagnostic hubs deliver value-based health care (or indeed efficiencies, i.e. cost savings). This will provide a within-year analysis of the most efficient model of diagnosis.

To consider the long-term sustainability of the rapid diagnostic hub model, a health economic model will consider the impact on the system beyond the diagnosis, including whether faster diagnosis delivers quicker treatment/management which is ultimately sight-saving for patients. The model will include the pathway from diagnosis to management and treatment, including the waiting time for each element of care. The model will be populated with data from case records, both time spent waiting and chance of referral.

To help inform any wider implementation beyond managing the COVID-19 backlog additional analyses will (a) consider what workforce composition may be required (more technicians and changing role for ophthalmologists), (b) explore the costings to inform a NHS tariff to incentivise such hub, (c) understand whether such hubs address or exacerbate health inequalities (analysis of sociodemographic characteristics of patients and where they travel from and how).

8.3.5. Integration of Evaluation Components and Results

The components of this evaluation are highly complementary. From the design stage onward, we will seek to integrate the lessons and foci of the workstreams in order to maximise this complementarity. For example, the literature review will help inform the interview topic guides, the DCE attributes and levels, and the outcome measures we analyse, whilst our topic guide will cover aspects of outcomes and cost-effectiveness.

Integrating our methods at the design stage will facilitate synthesis of results as the study progresses. A key example of this is that our qualitative data (in particular the focus on

implementation, fidelity, and outcome) will help identify factors that help explain the results observed in the DCE and the quantitative analyses.

8.3.5.1. Formation of a "Patient Panel"

We plan also to invite patients to join an ad-hoc advisory panel which will meet on a virtual basis between reconfigurations at the Brent Cross Hub. This panel will provide feedback on the patient experience and hub configuration which will contribute to and shape subsequent reconfigurations of the hub. We will seek consent from patients to approach them for this purpose.

9. Study Groups

9.1. Inclusion Criteria

i. Adult patients attending follow up clinic appointments within the Glaucoma and Medical Retina service at existing Moorfields sites (City Road, Cayton Street Diagnostic Hub, Hoxton Diagnostic Hub) and the new Moorfields Eye Hospital Diagnostic Hub at Brent Cross Shopping Centre.
ii. Age 18 years and over with no upper limit.
iii. Ability to comprehend spoken and written English (necessary for completion of questionnaires).
iv. Capacity to give informed consent and complete the study questionnaires.

9.2. Exclusion Criteria

If any of the following exclusion criteria are present, the patient will not be eligible for this study.

i. Unable to comprehend spoken and written English (necessary for completion of questionnaires).
ii. Lack of capacity to give informed consent.

10. Data Collection, Recruitment and Informed Consent

10.1. Monitoring of Patient Flow within the Diagnostic Hub

We will employ three different methods in the project:

1. Participant observations of examination times, undertaken by 3 trained research assistants (RAs) for a period of 3 days at the existing Moorfields Clinics. Data will be captured on tablets. At the new Brent Cross site, this will be performed using a commercial partner (Ubisense - https://ubisense.com) who specialise in Ultra-Wideband Real-Time Location Systems that are able to track patient and staff movement across the clinical facility using wearable lanyards, during the three iterative configurations of the diagnostic hub.
2. Space syntax analysis of existing layouts as well as suggested options for Brent Cross and the larger hospital aggregation. The analysis uses floor plans provided by Moorfields. Different modelling techniques will be used such as a visibility graphs (highlighting the patient experience); justified graphs based on stations / steps in the journey (highlighting flows); as well as space types (highlighting spatial bottlenecks and overlapping paths).
3. Mathematical models of operational processes and flow based on appointment schedules and the estimated variability of process durations that yield predictions of temporal bottlenecks, delays and inter-process queue sizes.

10.2. Optimising Patient Scheduling at the Diagnostic Hub

These objectives will be used through obtain service-level aggregated data from the Moorfields Performance Team and from the patient flow monitoring study regarding:

i. Daily patient demand patterns.
ii. The composition of patients (Glaucoma vs. Medical Retina).
iii. The times that patients typically spend for each medical test, and the duration between each test.
iv. The overall capacity in the new clinic (number of machines and clinical staff)
v. Historical data about appointment attendances, and failure to attend appointments. This will be analysed in time periods before, during and after the pandemic.

10.3. Evaluation of the Efficiency, Performance and Patient Satisfaction of Reconfigurations of the Diagnostic Hub

10.3.1. Recruitment

All patients scheduled to attend follow up appointments within the glaucoma and medical retina services at the above Moorfields sites that fulfil the inclusion criteria will be eligible to take part. We will also approach cohorts of patients attending the Moorfields Diagnostic Hubs at Hoxton, Cayton Street and City Road and Face to Face Clinics at Moorfields' Hospital sites for further comparisons.

Recruitment is planned to run over a nine-month period. The new diagnostic hub at Brent Cross will operate for three 8 week cycles seeing approximately 600 patients per week, with reconfiguration and evaluation in between. For each of the three iterations we will aim to recruit 20% of patients attending to the overarching study ie. 1000 patients per iteration with a balance of patients between the glaucoma and medical retina subspecialties.

For comparative data from the Moorfields Diagnostic Hubs (Hoxton: Medical Retina & Glaucoma) and traditional face to face clinics (Medical Retina & Glaucoma), we will aim to recruit a sample of 200 patients per clinic type during a 4-6 week sampling period. This will lead to an overall study population comprising 3800 patients.

10.3.1.1. Identification and Approach

This aspect of the study is designed to be pragmatic in nature, in order to provide minimal interruption to the delivery of routine clinical care. All patients will be sent a participant information sheet and consent form by post with their clinic appointment letter where possible. Patients will have adequate time to read through the participant information sheet and will have the opportunity to talk through the study with a Recruitment Coordinator on the day of their scheduled appointment, and have any questions answered before deciding whether or not to participate.

10.3.1.2. Consent

Once potential participants have had time to consider the study and ask any questions, should they wish to participate, they will be asked to sign a written informed consent form and

will be asked to complete the questionnaires that will be provided by the research team at the end of their diagnostic clinic appointment.

10.3.1.3. Data Collection

10.3.1.3.1. Clinical Parameters

The following information will be collected from the Moorfields electronic medical record following informed consent: Visual Acuity, Diagnosis, Visual Field Mean Deviation (for Glaucoma Patients), Stability of disease during the pandemic.

10.3.1.3.2. Questionnaires

Patients will be asked to complete the Vision Related Quality of Life Questionnaire (VF-14)[11] and Health Related Quality of Life (EQ-5D-5L)[10] with vision bolt-on[9, 13, 14] as a part of standard clinical care in advance of their attendance. At the end of their scheduled clinic attendance patients will be asked:

i. For permission to use their responses to the Vision Related Quality of Life Questionnaire (VF-14) as a part of this research project.
ii. For permission to use their responses to the Health-Related Quality of Life (EQ-5D-5L) with vision bolt-on questionnaire as a part of this research project.
iii. To complete a brief core service user questionnaire that evaluates patient experience within the facility (modified from NHS Wales). The modifications will include questions on access to the facility. An additional question will be included to compare their current experience to previous experience of attending a diagnostic clinic, or if this is their first experience in this pathway to understand how this compared to their previous experience.
iv. Later in the project, we plan to ask patients to complete a Discrete Choice Experiment prior to their attendance, and after their appointment. This will be in the form of a survey, and will additionally include questions about themselves (age, gender, ethnicity, postcode, mode of travel, if accompanied to appointment) and their past clinical experience (time since diagnosis and if they had an appointment deferred or delayed due to the pandemic). This will be submitted as an amendment to the ethics committee once fully developed.

We will be asking participants to complete paper-based questionnaires initially, but our trust is aiming to develop tablet based questionnaire entry using an approved product (https://www.smartsurvey.co.uk) which we hope to implement moving forward in line with trust information governance recommendations.

The Brent Cross diagnostic hub will run for a nine month period and therefore will allow comparisons of:

- Experiences of a cohort of patients who may experience two different configurations at Brent Cross
- Experience of patients between the Hoxton and Brent Cross Diagnostic Hubs
- Experience of patients between traditional Face to Face Clinics and Diagnostic Hubs

As part of later sub-study that will be submitted as an amendment, we will aim to explore patients' perspectives on how to manage a constrained budget within NHS eye services. This will explore how patients may trade-off delayed face to face clinic review, with sooner review in a Diagnostic Hub setting and also explore other financial and budgetary issues.

11. Data Handling and Record Keeping

We will adhere to Moorfields information governance policies that comply with the UK General Data Protection Regulation (GDPR) and Data Protection Act (2018) at all times so that personal identifiable information (PII) is protected. Confidential information will not be left unattended or within the view of any unauthorised person. Computers handling electronic data are password protected and will not be viewable by unauthorised staff. All co-investigators directly involved with patient contact in the study are employed by Moorfields under either a full employment contract or an honorary research contract.

Paper recruitment logs will be completed with the unique participant study identification number, name, hospital number and date of birth.

Clinical data will be stored on paper Case Report Forms with a unique study number, and entered on a Redcap database by the trial data officer. Data from the questionnaires

completed by participants will also be entered and stored on this database. The recruitment list linking study number to patient identifiable data will be held by the clinical care team in order to facilitate source data verification at data entry. The risk of re-identification by anyone other than the researchers of this project is minimal as medical and ophthalmological records are held by the NHS and are not publicly available, making it difficult for an intruder to identify a participant based solely upon the demographic or other collected data. Paper case report forms will be stored in locked cupboards within the Moorfields R&D offices until data has been electronically recorded and verified by the data management team. Our collaborators at UCL (UCL Department for Applied Health Research, UCL Bartlett School of Architecture and UCL School of Management) will be given data exports in Microsoft Excel for data analysis when the data management team at Moorfields have done the data quality checks and when data queries are resolved, which will contain pseudonymised study data only (see section 10.3.1.3 for details of study data collected). The transfer of the pseudonymised study dataset will be transferred out of Moorfields using secure online transfer or secure email. All study records will be retained for five years in secure storage within the Moorfields R&D offices following publication of the results.

We will be asking participants to complete paper-based questionnaires initially, but our trust is aiming to develop tablet based questionnaire entry using an approved product (https://www.smartsurvey.co.uk) which we hope to implement moving forward in line with trust information governance recommendations.

12. Statistical Considerations

12.1. Sample Size

This project comprises several objectives and strands relating to the optimal method to operate diagnostic hubs in the “post-pandemic era”. The more complex quantitative component comprising the Health Economic Analysis of Preferences, Cost-Effectiveness and Budget Impact, involves multiple comparisons between clinic settings, across eye disease and across hub configurations. One component of these analyses are the EQ-5D-5L Health Related Quality of Life Questionnaire.[10] A clinically meaningful difference in EQ-5D utility was considered to be 0.05 in study of interventions for glaucoma[15] and 0.074 in a general

healthcare setting.[16] These are smaller than the differences in EQ-5D reported between mild (0.84± 0.17) and moderate (0.68 ±0.26) glaucomatous visual field loss in UK patients.[17] This study design does not lend itself to conventional sample size calculations and therefore we have proposed a pragmatic approach to data collection that will enable meaningful comparisons to be made, based upon a realistic sampling approach to eligible patients during the study period. In this context it is proposed that erring on a larger achievable sample size is not unethical due to the non-intrusive observations being collected.

The new diagnostic hub at Brent Cross will operate for three 8 week cycles seeing approximately 600 patients per week, with reconfiguration and evaluation in between. For each of the three iterations we will aim to recruit 20% of patients attending to the overarching study ie. 1000 patients per iteration with a balance of patients between the glaucoma and medical retina subspecialties.

For comparative data from the Moorfields Diagnostic Hubs (Hoxton: Medical Retina & Glaucoma) and traditional face to face clinics (Medical Retina & Glaucoma), we will aim to recruit a sample of 200 patients per clinic type during a 4-6 week sampling period. This will lead to an overall study population comprising 3800 patients.

Smaller samples are required for the qualitative work as detailed earlier in this document. (Stakeholder Interviews- Table 1; Non-Participant Observations- Table 2).

Sample sizes for the DCE depend on the design of the experiment which is currently unknown (e.g. whether there are an interactions between attributes, for example distance from home and means of transport could be separate attributes, but are clearly correlated and would need to be modelled as such within the statistical design). A recent review[18] found most DCEs have an N<1000, therefore our proposed target sample of 3800 patients should be adequate even if only 25% complete the DCE.

12.2. Analysis

Qualitative analysis

This will be a rapid qualitative analysis, operating in multiple cycles (reflecting the intervention being studied).[4, 8] Our data will be drawn together using Rapid Assessment Procedures (RAP)

sheets, which permit data collection and analysis to be conducted in parallel. The initial RAP sheet will be developed based on interview and observation guides, then iterated in response to emerging data. Each member of the evaluation team involved in data collection will manage their own RAP sheet and one team member will act as a 'cross-checker' of the data to ensure consistency in data collection and analysis. The RAP sheets will be updated after each instance of data collection (e.g. interview, meeting observation), facilitate quick and ongoing analysis and feedback with stakeholders.

Quantitative analysis

The quantitative health economics data reflecting elicited preferences, patient outcomes and experience and the cost of care will be analysed in STATA using the most appropriate regression approach given the nature of the data, e.g. some form of logistic regression for the choice data (1,0) or a linear regression for quality of life metrics (continuous but bounded at 1 for perfect health). Regression models will control for confounders and interactions where necessary, initial descriptive statistics and correlations between variables will help inform the selection of these variables. The health economic model will be built and solved in Excel. Values for quality of life and cost will be sourced from published literature (including the tariff values to be applied to EQ-5D-5L responses) and national cost databases (NHS reference costs).

13. Study Administration

13.1. Withdrawal of Subjects

Participants are free to withdraw from the study at any time without giving specific reason. However, there is no involvement from participants other than the questionnaires completed on the day of their outpatient visit. If a participant withdraws, all data collected up to the point of withdrawal will be retained for the study. No further data will be collected from questionnaires or medical notes.

13.2. Compliance

13.2.1. Withdrawal of Subjects

Participants are free to withdraw from the study at any time without giving specific reason. However, there is no involvement from participants other than the questionnaires completed on the day of their outpatient visit. If a participant withdraws, all data collected up to the point of withdrawal will be retained for the study. No further data will be collected from questionnaires or medical notes.

13.2.2. Protocol Compliance

Non-compliance with the protocol will be documented by members of the research team and reported in writing to the sponsor. However, such incidents are not anticipated as all tools used within the study either comprise routine clinical observations or low risk validated questionnaires.

13.3. Ethical Considerations

This study is designed to be simple and pragmatic in nature. Minimal interruption to the delivery of routine clinical care by clinicians within busy clinics is necessary in order to make this study feasible, in order to achieve its important aims. Eligible patients will be provided with a participant information sheet in advance of attending their routine outpatient clinic consultation.

13.4. Management Arrangements

This project is sponsored by Moorfields Eye Hospital NHS Foundation Trust. Pseudonymised data will be transferred to our UCL research collaborators according to the requirements of our Information Governance Department and Data Protection Impact Assessment.

13.5. Patient & Public Involvement

This project is supported by three major patient centred charities who share the vision of this project. These charities are Glaucoma UK, The Macular Society and Diabetes UK. Glaucoma UK and the Macular Society have read and support this protocol with letters of support provided. They will also play a significant role in helping to develop the patient and public involvement as this iterative project progresses.

13.6. Finance and Insurance

This study is funded with support from the NIHR Moorfields Biomedical Research Centre at Moorfields Eye Hospital and the UCL Institute of Ophthalmology, Zeiss, Optos and Ubisense. Insurance for non-negligent and negligent harm will be covered by the Sponsor through the NHS indemnity scheme.

13.7. Data Transfer (Handling, Processing & Storage)

Pseudonymised study data (see Section 10.3.1.3) will be transferred to our collaborators at UCL (UCL Department for Applied Health Research, UCL Bartlett School of Architecture and UCL School of Management) in accordance with the Data Protection Impact Assessment and Information Governance evaluation at Moorfields Eye Hospital. This will be via secure email transfer or secure online transfer. This will be formalised under a study specific data sharing agreement between Moorfields and UCL as is standard practice.

13.8. Data Archiving

14. Reporting and Dissemination

The findings of this research project are of significant relevance to NHS eye care and ambulatory outpatient services, as we embark upon the recovery phase from the COVID-19 pandemic. These findings will be shared with regional Integrated Care Systems, NHS Improvement and the NHS Department for Outpatient Transformation to help inform planning for future diagnostic hub models across the United Kingdom.

The research outputs will be submitted for presentation at national and international conferences and for peer-reviewed publication in the domains of ophthalmology, patient experience, health economics and health care architecture.

The findings will be shared with the wider patient population in collaboration with our partners, the Macular Society and Glaucoma UK, who are the leading patient-focused eye care charities in the United Kingdom.

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