Queen Victoria Hospital
NHS Foundation Trust

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Queen Victoria Hospital NHS Foundation Trust
Research & Innovation Annual Report

Report covering the period from
April 2020 to March 2021

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1.	Executive Summary
	• R&I has faced unprecedented challenges in 2020-21 due to the Covid pandemic, but commitment and effort has enabled Research to perform better than expected. • All activity was suspended in Q1 following national guidance. In Q2 a restart programme was begun, with the reintroduction of participant recruitment where clinical services permitted. Patient pathways were adapted to ensure that participation in research remained safe and met national protocols. By Q4 all our research projects were successfully reopened and recruiting. • QVH worked with Public Health England on the high profile SIREN study. This study was prioritised ahead of all other research work. Early results from this study informed the government's roadmap for exiting lockdown, and the research was cited by the Chief Medical Officer Chris Whitty in his national televised Downing Street briefing. • We also took part in the Clinical Characterisation Protocol for Severe Emerging Infection Covid study. • One of our research nurses was seconded to run the Staff Testing Lab for most of 2020-21, to help with the Trust's covid effort. This, along with staff sickness, had an impact on our capacity to undertake research. We have now recruited a replacement, who will start work in April 2021. • In 2020-21 we recruited **353** participants, of which **328** were to National Portfolio studies. This represents a drop of 54% in recruits over the previous year, reflecting the impact of the pandemic. • We are proud that three of our clinicians acted as Chief Investigators on National Portfolio studies (Charles Nduka, Raman Malhotra, Baljit Dheansa). • Once the national picture allowed, we continued our work on commercial studies, and this year we undertook two such studies. • R&I has been working towards a cost-neutral position for the several years, and this year we are pleased to report that we made a £11,668 favourable contribution to the Trust's bottom line for the first time. We also ended the year ahead of Budget by £56K. We expect to be able to maintain a cost-neutral position throughout 2021-22.

3.	Service aim, objectives and expected outcomes
	Research & Development improves outcomes for patients both at QVH and in the wider NHS. This is achieved through research which gives meaningful, transparent and valuable information. As the new Director of Research & Innovation, it gives me great pleasure to introduce the annual Research and Innovation Report for 2020/2021. It has been a challenging year for clinical and ultimately research activity performance monitored by our local CRN. Research activity is tracked on a daily basis via an interactive performance system (Edge), to help provide guidance and initiatives. Our research team has continued to recruit patients into existing and new projects. Our efforts have been recognised over the past year by the National Institute of Health Research, which supported us with a 'Value For Money' (VFM) measure. This year, our VFM was impacted by the pandemic, with a cost-per-weighted-recruit of around £172. The drive to grow and support research continues to be a priority for the Trust. This year will see the introduction of our new Research Innovation strategy defining our vision for 2021 to 2023. The focus is to strengthen our position across the sector by seeking collaboration with organisations, both commercial and academic, in the region. I am also tremendously grateful for all the hard work put in by the research nurses, and by Sarah Dawe and Emma Foulds who oversee the managerial and governance arrangements. Mr Zaid Sadiq

4.	Activity analysis/ achievement

Research Activity

The number of patients receiving NHS services provided or sub-contracted by the Queen Victoria Hospital NHS Foundation Trust in 2020-21 that were recruited during that period to participate in research approved by the Health Research Authority was **353** of which **328** were recruits to National Portfolio studies. This represents a 54% decrease in National Portfolio activity over the previous year, reflecting the significant impact of the pandemic.

Participation in clinical research demonstrates QVH's commitment to improving the quality of care we offer and to making our contribution to wider health improvement. Our clinical staff stay abreast of the latest possible treatment possibilities and active participation in research leads to successful patient outcomes.

QVH was involved in conducting 30 clinical research studies in 2020-21, as per the tables below. We are particularly proud of our contribution to the national SIREN study, for which we recruited 201 participants. This study was key in forming the government's roadmap out of lockdown.

Since QVH was a 'covid-free' Trust, we were not able to participate in many national covid studies. Patient numbers were also reduced as the Trust curtailed normal elective work in order to focus on emergency treatment and cancer work. This meant that we were unable to recruit to many of our usual studies.

Study ref in appendix	Project Short title	Start date	Principle Investigator	National Portfolio study	Recruit-ment in 2020-21
1	DA VINCI activity 1a (citizen science)	20/10/2020	N/A	Yes	0

		2	SARS-COV2 immunity and reinfection evaluation (SIREN)	17/08/2020	Julian Giles	Yes	201
		3	The drivers for, and barriers to, radiographers reporting chest X-ray images in acute NHS Hospitals in England	28/05/2020	N/A	No	1
		4	NHS Work Communication & Impact of Covid19	22/05/2020	N/A	No	0
		5	The COVID-19 Resilience Project	22/05/2020	N/A	No	24
		6	COVIDA	06/05/2020	N/A	No	0
		7	GenOMICC	05/05/2020	Julian Giles	Yes	0
		8	National breastfeeding and anaesthesia survey	10/03/2020	N/A	No	0
		9	NEON - digital NErve, suture Or Not	18/11/2020	Rob Pearl	Yes	1
		10	MET-REPAIR	06/01/2020	Fiona Ramsden	Yes	30
		11	MET-REPAIR-FRAILTY	06/01/2020	Fiona Ramsden	Yes	30
		12	Leadership Styles and their effectiveness in the NHS. A study of Chief Executives in Acute Trusts	04/06/2019	N/A	No	0
		13	SPaCE Pilot	23/08/2019	Simon Booth	Yes	0

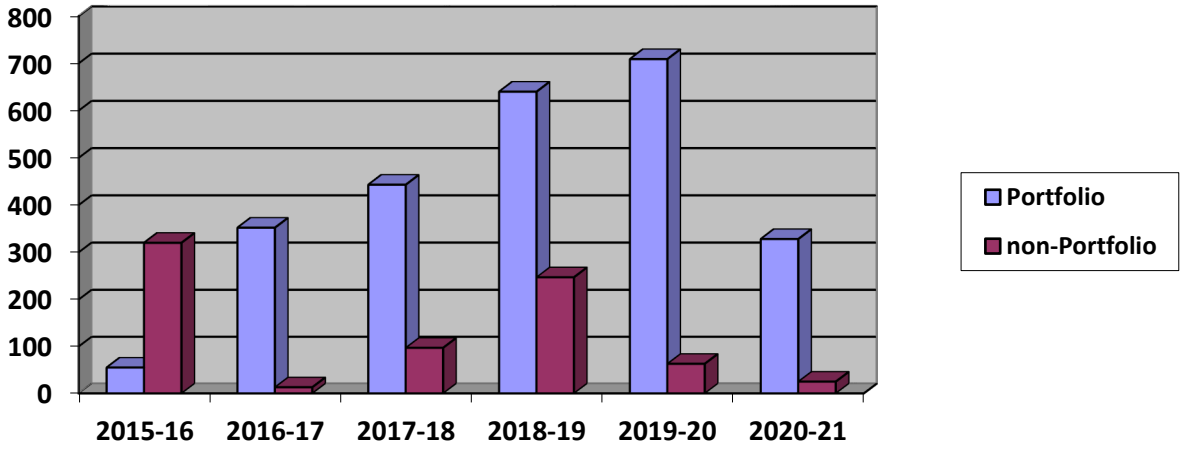
14	Are subjective pain scores related to facial muscle activity? - EMG pain scores	15/09/2020	Charles Nduka	Yes	3	
15	JaWPrinT	27/03/2019	Jag Dhanda	Yes	1	
16	FFFAP Falls Audit Evaluation	18/10/2018	N/A	Yes	0	
17	Allotex IntraStromal	08/02/2019	Samer Hamada	Yes	0	
18	The anatomy of flexor tendon repair-IRP student study	01/10/2018	Rob Pearl	No	0	
19	TEARS	12/11/2018	Raman Malhotra	Yes	25	
20	XEN45 in Angle Closure Glaucoma	22/11/2018	Gok Ratnarajan	Yes	0	
21	Haemostatic markers in ECMO (HAE) study	25/01/2018	N/A	Yes	0	
22	Smartmatrix SMA0217	10/09/2018	Baljit Dheansa	Yes	1	
23	Perioperative Quality Improvement Programme: Patient Study	03/05/2017	Julian Giles	Yes	6	
24	Validation of MIRROR application for facial paralysis	11/03/2020	Charles Nduka	Yes	0	
25	Investigation of Potential Biomarkers in the Role of Scar Formation	16/03/2016	Baljit Dheansa	Yes	0	
26	SUBMIT	21/09/2016	Asit Khandwala	Yes	0	

27	Molecular basis of chronic inflammatory and degenerative diseases	30/11/2015	Asit Khandwala	Yes	29
28	Clinical Characterisation Protocol for Severe Emerging Infection	03/02/2020	N/A	Yes	1
29	Is MGI or upper marginal entropion a contributing factor in the development of SLK	25/02/21	Raman Malhotra	No	0
30	Human factors knowledge in orthodontics		Sofia Ahmad	No	0

Our work on NIHR Portfolio studies

Recruitment to NIHR National Portfolio studies is recorded and monitored via a national database, and the level of CRN funding received by the Trust is partly determined by these accrual figures. In the past five years, the number of Portfolio participants recruited has greatly exceeded the number of non-Portfolio recruits, reflecting a strategic push to increase the proportion of Portfolio studies we undertake. This year activity was severely curtailed due to the COVID19 pandemic and QVH recruited **328** Portfolio participants – a **54%** decrease over the previous year.

Research Participant Recruitment 2015-2020



External Funding

Core funding

The CRN awarded the Trust **£187,643** core funding in 2020-21, plus £5000 contingency funding, £3750 Specialty Lead Funding, and £5000 funding for the SIREN study. The CRN determines its level of funding using an algorithm based on the number of patients recruited to Portfolio studies over the previous two years. This activity-based funding formula is a key driver for how research work is prioritized at QVH.

Funding was allocated according to CRN guidelines in the following way:

Resource	Allocation
Lead Research Nurse	31,824
Research Nurse B7	20,058
Research Nurse B6	41,900
Research Nurse B6	38,195
Bank Nurses	3416
Research Assistant	5048
SIREN study lab costs	2916
Director of Research & Innovation	1445
CRN Specialty Lead	3750
Head of Research	43,080
Research Governance Officer	7501
Training	0
Office/IT/Travel/consumables	2589
Overheads	10,558

The Trust also received **£2,822** from the Brighton and Sussex Medical School to support the IRP students who undertake fourth-year research projects at the hospital.

	R&I has been working towards a cost neutral position for the past few years, by reducing costs and increasing income. This year we for the first time we made a favourable contribution at year end, of £11,668. We also ended the year £56K ahead of budget. We expect to be able to maintain a cost-neutral position throughout 2021-22.

5.	Involvement & Engagement

Patient and Public Involvement and Engagement

QVH continues to work to find meaningful ways to involve patients and members of the public in its research activity. We are fortunate to have on our R&I Governance Group two very involved patient representatives, who take an active role in advising on and monitoring the research activities of the Trust. Patients are also sometimes involved in the early stages of research projects via focus groups, which feed into protocol development.

As in person clinic attendance was replaced with more telephone or video consultations, the opportunities for public involvement decreased, but we were still able to take part in the national anonymous PRES questionnaire, and received 42 completed questionnaires.

Data from PRES is reviewed regularly throughout the year and helps us better understand the experience of research participants and how we might improve their experience. The results are shared both internally and with our CRN. Action plans are in place to address the main PRES findings.

Comprehensive Research Network (CRN)

The Trust is a member of the Kent, Surrey, and Sussex Comprehensive Research Network (CRN). We work with the CRN to maximize opportunities for Portfolio studies, identify new studies the Trust may participate in, and implement new national systems and structures. The CRN distributes R&I resources amongst its members according to an activity-based algorithm. The CEO sits on the CRN Partnership Board, and the Head of Research and the Director of Research & Innovation regularly attend CRN finance and performance meetings, working closely with the CRN Link Manager and her team. Meeting CRN targets is a priority area for the Trust.

Our people

Clinical Research Staff

We are proud that two of our clinicians acted as Chief Investigators on National Portfolio research studies in 2020-21 (Charles Nduka, Raman Malhotra).

In 2020-21, the Trust supported one Lead Research Nurse (0.6WTE), one Burns Research Nurse (1WTE), two Research Nurses (1.89WTE), and one Research Assistant (0.2WTE). Our

Burns Research Nurse was seconded to the Staff Testing Lab throughout most of 2020-21 in order to support the COVID effort.

Some clinical departments also each have their own arrangements for Research Fellows. These are funded by the departments themselves and are not managed by the R&I Department. In addition, we have identified nurses within different clinical areas who have been trained up to support research in their own department.

Research Management and Governance

The R&I Department presently consists of one Director of Research & Innovation, one Head of Research (0.66WTE) one Research Governance Officer (13.8h/wk), and one Research Assistant (0.2WTE).

Funding was received from the Comprehensive Research Network (CRN) to support research management and governance. Other income to support the R&I infrastructure comes from commercial studies, which in addition to paying general Trust overheads, contribute a fee for R&I Department services in assessing applications, setting up contracts, and implementing and monitoring studies.

Intellectual property and Innovation

The Trust has engaged the services of NHS Innovations South East to assist with commercializing and developing its intellectual property.

Training and Development

Local Training
Individual support tailored to the individual is provided by the R&I Department to all new researchers who require guidance developing their protocols, navigating the approvals process and setting up their studies.

It is a legal requirement that all staff involved in clinical trials complete Good Clinical Practice (GCP) training, and the Trust has facilitated this for staff – either by enabling access to off-site courses at other Trusts, or by paying for staff to do an individual online course. Commercial companies also regularly run refresher GCP courses for staff involved in the clinical trials they run at the Trust.

This year our research staff also attended courses on phlebotomy, vaccinations, covid testing, psychological safety in teams, Nudge theory, and research capacity & capability.

CRN training
The Trust also has access to training provided by the CRN for any studies which are accepted onto the National Portfolio. A wide range of courses are offered, including GCP training.

Research Design Service
The NIHR Research Design Service South East provides a very good service in supporting staff making grant applications. They provide us with invaluable advice on study design and methodology.

Governance

R&I at the Trust is overseen by a Research & Development Governance Group. Its members include: Director of Research & Innovation, Chief Pharmacist/Clinical Trials Pharmacist, Anaesthetics Lead, Burns Lead, Corneoplastics Lead, Hand Surgery Lead, Maxillofacial Lead, Director of Nursing, Oncoplastics Lead, Healthcare Science Lead, Orthodontics Lead, Head of Research, Finance Department Representative, Designated Individual with Responsibility for Human Tissue Authority License, and External Academic Advisors from the University of Brighton. The Group also has two very active patient representatives who play a valuable role in advising on new projects.

The R&I Governance Group reports to the Quality and Risk Committee.

The Director of Nursing acts as the Trust's Nominated Consultee for research participants unable to consent.

***Trust policies which cover R&D*:** Adverse Event Reporting Policy, Research Fraud Policy, Code of Practice for Researchers, Pharmacy policy for Clinical Trials, Intellectual Property Policy.

R&I approvals and targets

QVH has effective, streamlined systems for managing R&I approvals in proportion to risk, and our turnaround times are generally swift, although this year approval times nationally were slower due to the service being reorientated towards the covid effort. The R&I Dept provides guidance with using the national IRAS applications system, and works with the Health Research Authority (HRA) to approve studies and ensure they meet national guidelines. We use the Edge online system to manage and monitor research here at the Trust.

Sponsorship status

Some research carried out at QVH is investigator-led ie designed and conducted by our own staff, and these require the Trust to provide structures to support pre-protocol work and peer-review, as well as the subsequent management of active projects. We currently have two Chief Investigators at the Trust who have initiated QVH-Sponsored National Portfolio studies, as well as one Chief Investigator for a non-Portfolio study.

No research study may begin in the NHS without a Sponsor being identified. The Trust continues to offer its researchers the benefits of providing Sponsor status for the studies they initiate. QVH believes that it is right to support its researchers in developing new projects, and to encourage the spirit of intellectual enquiry, and so continues to provide Sponsorship status for all single-site non-CTIMPs.

6. Learning from Experience

Research staff were very flexible in reconfiguring the service to meet the challenges of Covid, and supported each other in a rapidly evolving and challenging environment. R&I has maintained its financial stability, and indeed has made an £11K favourable contribution to the Trust's bottom line for the first time. This year we prioritized Covid research ahead of other research objectives, but this now needs to change in order to continue to guarantee future funding and make research opportunities more available to a wider group of patients again.

7.	Recommendations
	Research activity was hit by the pandemic this year, and we now need to focus on rebuilding our National Portfolio work in order to create a solid core of studies, so that we can return to our pre-pandemic levels of activity. This will entail a sustained focus on supporting and developing Portfolio studies.

8.	Future plans and targets
	Specific targets for 2020-21: • Continue to support the national focus on COVID19 studies • Build up recruitment to non-COVID19 Portfolio studies with the aim of getting back to our pre-pandemic level of activity Progress towards these targets will be monitored by the CRN and by the R&I Governance Group.

9.	Conclusions and assurance
	Research experienced a fall in activity in 2020-21 due to the COVID19 pandemic. The Trust was designated a cancer hub in the initial phase of the pandemic, and ceased elective work in order to focus on this and emergency work. This meant that we were unable to recruit to the majority of our studies for the first half of the year. Subsequent to this, staff sickness and staff redeployment also took its toll on research activity. Therefore our recruitment figures can only be taken to represent around 6 months full activity. Research staff responded well to the unprecedented challenges, and by Q4 all our research studies were open once again, the service having been reconfigured. We were also able to recruit a new research nurse to replace a member of staff who had been seconded. We will focus on rebuilding our non-Covid Portfolio research in 2021-22 as a priority. R&I maintained robust finances despite the challenging environment. We have been working towards a cost neutral position for several years, and this year we were able to make a £11,668 favourable contribution to the Trust's bottom line for the first time. We also ended the year £56K ahead of budget. We expect to maintain at least a cost neutral position in 2021-22. The CRN has confirmed that we will receive a 3% uplift in funding for 2021-22. We expect to return to our pre-pandemic levels of recruitment by the end of 2021-22.

10.	Appendices

Registered research projects (with HRA Approval) ongoing in 2020-21

1 DA VINCI activity 1a (citizen science)

People affected by dementia and some other forms of cognitive impairment in hospital settings face a range of risks that present important challenges in providing them with high-quality care. One possible intervention to support care is a visual identification system. A visual identification system includes an object placed on or near a patient (e.g. a different colour wristband or a sticker with a special symbol) that is paired with an appropriate care response. Such visual identifiers, as part of wider approaches to providing person-centred care for this group, help staff in recognising people with cognitive impairment quickly and easily, and adapt their care accordingly. Several such systems have been developed, but none has been subject to systematic development informed by design principles, nor has any system been rigorously evaluated. Some concerns have been raised about such systems, but these have not been systematically addressed. We propose to carry out a study on the use of visual identification systems for people with dementia and some other forms of cognitive impairment in hospital settings.

As an important first part of this wider study, we propose to undertake an exercise using a citizen science platform (Thiscovery, an online tool that allows people across the UK to contribute their views, experience and preferences) to ask staff using visual identification systems in acute hospitals across the UK to provide brief information on the systems they are using. The survey will be open for two months.

The results will feed into later stages of the programme, including a participatory process of identifying an existing system that might be developed further (or alternatively co-designing a new system based on the needs and preferences of patients, carers and staff), and to ensuring acceptability and workability in practice.

2 SARS-COV2 immunity and reinfection evaluation (SIREN)

This study aims to find out whether healthcare workers who have evidence of prior COVID-19, detected by antibody assays (positive antibody tests), compared to those who do not have evidence of infection (negative antibody tests) are protected from future episodes of infection. In this study, we will recruit healthcare workers to be followed for at least a year and study their immune response to the virus causing COVID-19, called SARS CoV2. We will do this by collecting data on their history of COVID-19 infection and any new symptoms. All NHS staff who deliver care to patients are being asked to have a nose and throat swab every other week in order to detect mild cases or cases who do not have symptoms. This is the main test that is currently used to detect and diagnose infection. It looks directly for the virus in the nose and throat. Once the infection is cleared, we cannot detect virus in samples. Therefore, we will also ask these individuals to have blood samples taken every other week to determine whether they have antibodies to the infection. These blood samples allow the previous infection to be detected as the response to infection in the body is to produce small particles in the blood called “antibodies”. It takes up to 4 weeks to make enough antibodies to fight the infection. But once someone recovers, antibodies stay in the blood at low levels– this is may help prevent us from getting infected with the same infection again. However, for SARS CoV2 infection we do not know yet if the detection of antibodies protects people from future infections. Through this study, we will provide this very important information which will help to understand the future impact of COVID-19 on the population.

3 The drivers for, and barriers to, radiographers reporting chest X-ray images in acute NHS Hospitals in England

This survey will seek to generate an overview of the current state of reporting radiographers (RR) reporting chest x-rays and future employment levels via training numbers. An electronic qualitative-style survey will be distributed to Radiology departments in 149 acute NHS trusts in England enquiring about their employment and training of chest xray reporting radiographers (CXR-RR). Thematic analysis with be undertaken using NVIVO 12 Plus.

4 NHS Work Communication & Impact of Covid19

The primary aim of this questionnaire study is to investigate the impact of work-related communication before and during COVID-19 pandemic on the work-life balance of healthcare workers.

A secondary aim is to explore what improvements can be made to communications to support work-life balance and to look at direct professional and patient related communication usage.

The study objectives are to ascertain: The volume of communication prior to the COVID-19 pandemic; The volume of communication during the COVID-19 pandemic; Changes in direct communication between patient and care professional due to COVID-19; Communication platforms used by healthcare workers and the frequency of their use during COVID-19 pandemic; Understanding the use of Teams recently made available to staff across the NHS ; Estimating work and off duty time spent on managing communications such as emails prior to and during the COVID-19 pandemic; Respondents' views of the impact of work-related communication on their work-life balance and the ability to switch off communications when needed.

5 The COVID-19 Resilience Project

It is vital that we explore the immediate and longer-term psychological impact of COVID-19 on NHS staff in order to better understand how to effectively support staff psychological wellbeing and mental health during this time.

This self-report questionnaire project will aim to: Evaluate the impact of COVID-related stressors on a range of mental health outcomes of interest, including anxiety, depression, post-traumatic stress, general well-being and compassion fatigue/burn-out; To investigate the effect of relevant psychological markers of risk and resilience that might aggravate or buffer the impact of COVID-related stressors on mental health and well-being outcomes; Evaluate impact of COVID-19 on post-traumatic growth and compassion satisfaction; Follow-up the impact over time, by inviting participants to re-complete the questionnaires after 4, 8, and 12 months; Gather follow-up qualitative data to further explore the above topics

6 COVIDA

An online questionnaire study to understand the psychological impact of the Covid-19 outbreak on the lives of health care professionals.

7 GenOMICC

The GenOMICC (Genetics of Susceptibility and Mortality in Critical Care) study will identify the specific genes that cause some people to be susceptible to specific infections and consequences of severe injury. Our hope is that identifying these genes will help us to use existing treatments better, and to design new treatments to help people survive critical illness. To do this, we will compare DNA and cells from carefully selected patients with samples from healthy people.

8 National breastfeeding and anaesthesia survey

Very few drugs make breastfeeding absolutely contraindicated. An evolving knowledge of pharmacology and breast milk physiology has led experts to suggest that mothers can resume breastfeeding following anaesthesia as soon as they feel able.

There is currently no national guidance on breastfeeding and anaesthesia. Supporting breastfeeding peri-operatively is essential to provide infant nutrition, maintain lactation and prevent breast engorgement & mastitis. Anaesthetist give a range of advice to breastfeeding mothers, which may cause distress to mother and infant and result in the premature end to their breastfeeding journey, depriving mother and baby of the health benefits. It is difficult to justify anaesthesia being a reason for women ceasing to breastfeed.

This project seeks determine current practice nationally through the use of a short online survey of currently practicing anaesthetists. The survey has been piloted in North Bristol NHS Trust, yielding 51 responses with grade of anaesthetist proportionally representing the department.

9 NEON - digital NErve, suture Or Not

Digital nerves are small nerves that pass along the side of each finger and provide sensation to the fingertips. These nerves can be accidentally cut when handling sharp objects like a knife or broken glass. The NEON study aims to find out whether sewing the ends of the cut nerve surgically is beneficial or even needed. Thoroughly cleaning the cut wound before closing the skin is a much simpler procedure, and may be satisfactory for patients.

There is some evidence that both treatments give good results. There is also some evidence that patients may not fully recover the feeling in their injured finger, even after the nerve has been sutured. Research so far has been conflicting and is of varying quality. For example, some studies do not directly compare treatments, or do not ask patients about their views of recovery.

NEON will compare surgical procedures for digital nerve repair, with or without stitches (also known as sutures). 478 patients with a single digital nerve injury will have one of these two treatment options by random allocation. Patients will complete questionnaires measuring fingertip sensation, quality of life and health resource use up to 12 months after the operation. They will also attend clinic visits at 3 and 12 months. Longer term follow up (12-24 months after randomisation) to determine re-operation rates will be collected using routine hospital data.

10 MET-REPAIR

This study seeks to investigate the prognostic value of estimation of a patient's exercise capacity prior to major noncardiac surgery. Current guidance from the European Society of Anaesthesia and European Society of Cardiology, American College of Cardiology and American Heart Association recommends that patients' exercise capacity should be estimated in terms of metabolic equivalents (METs). The number of METs reflects the increase in oxygen consumption during an activity compared to when at rest. For example, if 1 MET equates to a patient at rest and 4 METs is walking up two flights of stairs, the latter activity requires four times as much oxygen consumption. The primary objective is to determine whether the number of METs a patient can achieve, as estimated using a questionnaire, is associated with major adverse cardiovascular events or cardiovascular mortality around the time of surgery, and if so, what is the value for METs that can best predict whether a patient will suffer these complications?

In a substudy, the patient's NTproBNP (N-Terminal prohormone of Brain Natriuretic Peptide) level will be measured to determine whether NTproBNP improves prediction of perioperative cardiovascular events and cardiovascular mortality when added to clinical data and estimated

METs. If such associations exist, they will add to the methods available for establishing patients' risk of morbidity or mortality when they undergo major surgery.

11 MET-REPAIR-FRAILTY

See above

12 Leadership Styles and their effectiveness in the NHS. A study of Chief Executives in Acute Trusts

This research will focus on 5 main areas, these being the organisational structure of the NHS with emphasis on the executive tier within acute trusts, the historic development of the NHS chief executive as a substantive role, NHS leadership recruitment, development and education, leadership and followership theories and their application within the NHS and a critical examination of effectiveness when applied to leadership.

As this study does not have a pre-defined hypothesis it will utilise a grounded theory approach (Corbin and Strauss, 2015), allowing the researcher to explore the inner experiences of participants, explore how meanings are formed and transformed while exploring areas not yet thoroughly researched. This open-ended research will focus primarily on qualitative methods, however given the complexity of the subject and the need to compare a number of responses from NHS leaders, quantitative methods may also be utilised. The qualitative approach allows for greater study of the participants in this research, which in turn will allow for a more open and constructive dialogue.

To conduct this research a number of visits to NHS facilities shall take place. It is also important to visit the NHS leadership academy in Leeds or London. During these visits it is intended to interview current NHS chief executives to gather first hand descriptions of management styles within each setting. A semi-structured approach to the interviews will allow for a more fluid and descriptive dialogue.

13 SPaCE Pilot

The objective of this pilot study is to evaluate the technology that is intended to be incorporated into a SPaCE-swab sensor kit. The kit is intended to be a low cost, fast, near-to-patient method of assessing the infection state of a wound. It would rapidly indicate wound colonisation (onset of infection) by the four principal microbial wound pathogens: Staphylococcus aureus, Pseudomonas aeruginosa, Candida species, and Enterococcus faecalis.

14 Are subjective pain scores related to facial muscle activity? EMG pain scores

This study aims to discover if we can compare the pain felt by patients with a measurement of how their faces move. Facial movements will be assessed using muscle activity sensors worn like a pair of glasses/ goggles that measure underlying muscle activity. Past studies show facial expression is sensitive to the intensity of pain. Laboratory studies looking at pain in volunteers suggest facial electromyography (EMG) to measure muscle activity could be a useful tool to determine the pain an individual is suffering. This may have particular relevance to patients where communicationis limited eg dementia.

This is a small-scale study to validate an experimental model in the clinical environment. We propose studying at patients receiving a local anaesthetic injection before planned hand operation. Whilst they are receiving the injection we will record the facial muscle response non-invasively using specialized goggles containing muscle sensors. Simultaneously we will record the patients experience of pain using a self-reported visual analogue score (VAS). Importantly pain expectation will also be considered, and we will also be assessing participant anxiety traits and status prior to intervention.

50 adult patients requiring hand surgery under a local anaesthetic block at the Queen Victoria Hospital will be studied. The study will be the observation and recording of data from patients undergoing routine clinical care only. It will not involve any additional procedures. The study will run for 6 months and we will publish all the findings within 1 year

15 JaWPrinT

JaW PrinT is a 'real-world' prospective observational pilot study, evaluating the clinical effectiveness, usability and economics of two approaches to mandibular reconstruction surgery (figure 1). Patient participants will be recruited prospectively over a minimum period of 18 months (with observation of at least 10 participants in each treatment pathway). The figures are based upon the historical clinical practice of the research site, with both techniques in equal use; choice depending on resources, surgical training requirements and surgeon's clinical preference.

As a purely observational study, treatment choice will be made in the normal clinical manner and will in no way be influenced by the study itself. Participants will be followed up at their routine outpatient clinics (6 weeks, 6 months and 1 year postoperatively) with prospective outcomes data collection

16 FFFAP Falls Audit Evaluation

Audit and feedback is widely used within quality improvement initiatives as a strategy to improve professional practice. However, the use in practice of these tools needs to be carefully designed and adapted to the specific local context to be effective. Falls are the most frequent patient safety issue experienced by old patients during an acute hospital episode, resulting in over 2,000 hip fractures annually as well as considerably other injury, distress, and anxiety, plus increased healthcare expense.

This research will explore current use and opportunities of improvement of the National Audit of Inpatient Falls (NAIF), one of the work-streams of the Falls and Fragility Fracture Audit Programme (FFFAP), which is a national programme of quality improvement managed by the Royal College of Physicians (RCP) in the Clinical Effectiveness and Evaluation Unit (CEEU).

The purpose of this project is to provide a scientific evaluation to better understand the barriers and enablers to the use of the NAIF data by clinical services in their quality improvement work to reduce the incidence of inpatients falls. In particular in this research we aim to investigate technical, social and contextual factors, related to the audit and feedback process of the NAIF programme in order to explore how the audit data and reports from 2017 are perceived, received, and acted upon. The results of this research will be used to make recommendations as to how to improve the audit and wider programme 2018-2021 and more in general to inform future National Clinical Audits.

17 Allotex - IntraStromal

The objective of this clinical study is to evaluate the safety and effectiveness of intrastromal implantation of the Allotex TransForm corneal allograft (TCA) for improving near vision in presbyopic subjects.

The Allotex TCA is a piece of acellular cornea, sterilized with electron beam radiation and shaped to a particular shape using a laser. The availability of precise laser shaping systems and sterile corneas are the key factors that make the use of allogenic implants possible. One size of the TCA is available which has a +2.50 D power with a diameter of 2-3.5 mm and a

central thickness of 15-25 microns. The TCA is applied to the surface of the cornea at the layer known as Bowman's membrane, which is just underneath the epithelium.
The goal is to enhance the visual performance of the patient with a material that is 100% biocompatible and precisely shaped for the individual's needs.

18 The anatomy of flexor tendon repair

This study is a joint project with the Department of Anatomy and Queen Victoria Hospital and look at different methods of tendon repair in cadaveric hands. The study will be conducted by a student from BSMS.

Specifically, the volume of the knot and suture material as a proportion of the cross sectional area of the tendon, the circumference of the tendon repair site and the degree of shortening will be measured in cadaveric hands for different types of tendon repair.

19 TEARS Grading scale: grading the clinical severity of epiphora

Epiphora (watery eye) is a common presentation to the ophthalmology clinic, with most patients being amenable to surgical (61-69%) or non-surgical treatment. Surgically-amenable epiphora affects an estimated 16/100 000 persons rising to 100/100 000 in 75-84 year olds. While in some, the epiphora represents no more than a tolerable nuisance, in others it significantly affects their quality of life. At the more severe end of the spectrum, some cases require repeat medical attendances and hospital admissions for systemic infection. With ever-increasing financial constraints on healthcare providers, there is a need for clinicians and healthcare commissioners to better prioritise patients for surgical intervention.

The 'TEARS scale' was developed through extensive literature review, patient focus groups and consultation with an expert panel of consultant ophthalmologists. Disease severity is graded based on 4 subscales: symptom frequency, the effects on patients and healthcare providers, patients' functional status, and the compounding effect of ocular surface disease. This prospective study aims to validate the TEARS scale by recruiting adult patients presenting to oculoplastic clinics with epiphora. Two clinicians will complete the TEARS grading scale at the study entry point. Patients will complete two questionnaires: The Watery Eye Quality of Life score (WEQOL) and The Lacrimal Symptom Questionnaire (Lac-Q).
In a subset of patients who have previously agreed with their clinician to undergo either surgical or non-surgical intervention, the TEARS scale will again be completed at their clinical review by two clinicians between 3 and 6 months after their initial visit. Patients will again complete the WEQOL and Lac-Q, as well as the Glasgow Benefit Inventory (a measure of change in quality of life).

The scale's reliability will be evaluated through statistical testing of inter-rater agreement. Construct validity will be assessed by the scale's correlation with patient-reported outcome measures and by evaluating its responsiveness to surgical intervention.

20 XEN45 in Angle Closure Glaucoma

Glaucoma is an eye condition where the optic nerve is damaged by the high pressure of the fluid in the eye (aqueous humour). Aqueous humour is produced by a ring of eye tissue called the ciliary body, located behind the iris (coloured part of the eye). It flows through the pupil and drains out through a spongy network of holes called the trabecular meshwork (which sits in the angle formed where the iris meets the cornea). In Angle Closure Glaucoma (ACG), the outer edge of the iris and cornea come in contact, closing the drainage angle. This prevents the aqueous humour from draining and causes the pressure in the eye to build up.
Currently available treatment for ACG consists of procedures to reduce eye pressure, including laser treatment, lens extraction, eye pressure-lowering medications, and incisional surgeries. There are no minimally invasive glaucoma surgery options available for ACG.
XEN45 Glaucoma Treatment System (referred to as XEN) potentially alleviates this

unmet need. XEN comprises of the Gel Implant and the Injector. The Gel implant is a soft gelatinous implant, approximately 6 mm long and as wide as a human hair. After implantation in the eye, it acts as a conduit for the drainage of aqueous humour in the eye.

The current study, sponsored by Allergan, is a prospective, multicentre, single arm, open-label (the participants and study team will know which treatment the participant is assigned to) clinical trial in patients with ACG. Approximately 65 patients will be implanted with XEN in one eye and followed for 12 months to evaluate its safety and effectiveness. Participants will be enrolled at approximately 15 research sites in the Asia-Pacific and European regions

21 Haemostatic markers in ECMO (HAE) study

Multicentre, prospective cohort study of haemostatic activation markers and correlation with bleeding and thrombotic complications in patients receiving extracorporeal membrane

22 Smartmatrix SMA0217

This is a multi-centre, non-comparative, prospective study to demonstrate that the Smart Matrix dermal replacement scaffold has an acceptable safety profile and enables healing in full-thickness surgical wounds. Approximately 40 patients scheduled for elective surgical excision of suspected or histologically proven BCC or SCC lesions who meet the inclusion and exclusion criteria and provide written informed consent will be enrolled in the study.
The study will be conducted in 2 stages, with the first 12 patients (the safety cohort) reviewed by the Data Monitoring Committee (DMC) to assess the safety and performance of Smart Matrix.

When the safety cohort reaches the Week 6 post-operative time point, safety and the requirement for rescue therapy, in the opinion of the Investigator, will be assessed to decide if the study should continue to full enrolment.

23 Improving perioperative care through the use of quality data: Patient Study of the Perioperative Quality Improvement Programme (PQIP)

Over ten million operations take place in the UK NHS every year. The number of patients which are at high risk of adverse postoperative outcomes has grown substantially in recent years: this is attributable to a combination of an ageing population, the increased numbers of surgical options available for previously untreatable conditions, and the increasing numbers of patient presenting for surgery with multiple comorbidities. Estimates of inpatient mortality after non-cardiac surgery range between 1.5 and 3.6% depending on the type of surgery and patient related risks. Major or prolonged postoperative morbidity (for example, significant infections, respiratory or renal impairment) occur in up to 15% of patients, and is associated with reduced long-term survival and worse health-related quality of life; this signal has been consistently demonstrated across different types of surgery, patient and healthcare system.

Data from the US demonstrate wide variation in risk-adjusted mortality & morbidity rates between healthcare providers, suggesting that at least some complications after surgery could be avoidable if standards of care were improved. It is likely that the same is true in the UK; however, there is currently no unified national system for measuring complications or patient reported outcomes across different types of major surgery in the NHS. In order to address this gap, the National Institute for Academic Anaesthesia's Health Services Research Centre (NIAA-HSRC) has launched the Perioperative Quality Improvement Programme (PQIP) for the UK. PQIP will measure risk-adjusted morbidity and mortality, as well as process and patient-reported outcome data in adult patients undergoing major surgery (eg lower GI resection, upper GI resection, liver resection, cystectomy, major head and neck reconstructive surgery, thoracic resection).

24 Validation of the MIRROR facial expression tracking application in healthy subjects and facial paralysis patients

Facial paralysis (FP) presents from either a peripheral nervous abnormality (most commonly Bell's Palsy) or a central nervous lesion (usually a cerebro-vascular accident). Bell's Palsy accounts for 60% of cases of facial palsy, causing up to 24,800 new UK cases annually, leaving upwards of 100,000 people living with permanent disability. Of the 152,000 CVAs per year in the UK, many patients suffer resultant chronic facial movement problems. Current methods for tracking facial expression recovery include subjective measures, e.g. doctor-delivered grading systems, and objective measures, e.g. 2D / 3D imaging (photography and/or stereophotogrammetry) or videos of dynamic facial function. However, a consensus method for objectively measuring initial paralysis and monitoring progress towards normal facial expressions remains elusive. Gold standard treatment for FP includes daily rehabilitative exercises, but patients often fail to perform these regularly due to lack of feedback on exercise efficacy leading to demotivation and non-compliance with the prescribed physiotherapy. This in turn reduces patients' likelihood of recovery of normal facial function.

A new iPad-based non-invasive physiotherapeutic software application (MIRROR) has been developed, allowing FP patients to objectively track their paralysis / facial expressions in real-time via MIRROR's immediate feedback on exercise performance. To validate MIRROR, a study has been designed to analyse the facial movements of healthy and FP patients pre- and post-administration of Botulinum toxin (BT). Each subject's response to BT over the period of action of the injected BT will be assessed. Subjects will have their facial expressions quantitatively analysed via subjective grading scales validated for use in FP analysis, 2D / 3D imaging, via surface-electromyography and using MIRROR

25 Investigation of Potential Biomarkers in the Role of Scar Formation

The reason for the development of a scar is not clearly understood and the causes are multi-factorial. In simple terms, scarring may be a direct consequence of evolutionary changes that have lead to a rapid healing of the wound site in order to prevent infection. As a consequence of this speed of wound epidermal closure, the cells in the dermis of the skin are prone to produce inappropriate amounts of extracellular matrix molecules. It is this over production that leads to the formation of a scar.

The only example of scar-free healing is in utero. Surgery performed on a foetus in the third trimester (and these often save lives of unborn children) do not leave any traces of surgical intervention. A child is born without a scar. This amazing ability is lost shortly after birth and for the rest of adulthood, any post-traumatic event to the skin results in the production of a scar. The Queen Victoria Hospital (QVH) is a regional centre for burns and plastic surgery. The hospital treats patients with acute wounds and those undergoing surgical reconstruction or scar revision. As part of this treatment scar tissue will often be removed and disposed of as clinical waste. This redundant scar tissue offers the possibility of developing a clearer understanding of the mechanisms of scar formation.

26 SUBMIT

Metacarpal fractures are common, accounting for 40% of all hand injuries and many can be treated non-operatively. However, surgery is reserved for cases in which an adequate reduction of both angular and rotational deformity cannot be maintained or where an adjacent ray is damaged.

A variety of surgical strategies exist, including percutaneous kirschner wiring, intramedullary fixation, and fixation with plate and screw construction. A plate secured along the dorsal midline of the metacarpal has been shown to be the best biomechanical method of fixation, and allows early aggressive hand therapy post-operatively.

Traditionally, bicortical fixation is the standard practice, where both dorsal and palmar cortices of the metacarpal are drilled though. However, such practice is not without risk. In this method, the flexor tendons and neurovascular bundles at risk from over-zealous drilling through the palmar cortice. Correct screw size selection is also critical as overly long screws can irritate and cause rupture of flexor tendon. More recently, with the advent of a new generation of locking plates, unicortical fixation, where only the near cortex is drilled, has been used to treat fractures. Unicortical fixation is a surgically less complex operation, can theoretically cause less damage to surrounding soft tissues and avoids the complications associated with incorrectly sized screws.

This trial aims to compares the functional outcomes and complications of patients having unicortical versus bicortical fixation for diaphyseal metacarpal fractures.

27 Molecular mechanisms and pathways of chronic inflammatory and degenerative diseases

Using synovial tissue in explant cultures obtained from rheumatoid arthritic patients undergoing joint replacement surgery, the Kennedy Institute was the first research laboratory in the world to identify the pathogenic role of the inflammatory cytokine tumour necrosis factor alpha (TNF) in Rheumatoid Arthritis (RA). Biological therapies that block the function of TNF are now clinically proven and over one million people worldwide have been treated successfully with this drug. However, this is not a cure for RA, so current research activities at the Kennedy are aimed at understanding those events that trigger RA, and developing better therapies for this disease.

Patients scheduled to undergo a surgical procedure as a result of arthritis or other inflammatory diseases, will be given the option to take part in our study. In addition, waste tissue will be obtained from an amputation as a result of a traumatic injury and adipose as a result of an abdominoplasty. A qualified clinician / GCP trained team member will take written, informed consent prior to surgery. Waste tissue from surgery is collected in a sample pot and couriered to the Kennedy Institute. This waste tissue includes joints (cartilage and bone), periarticular tissue, connective tissue (muscle and fascia) and other soft tissue such as skin.

The tissue will be processed ex vivo to liberate single cell suspensions, which will then be cultured for up to 5 days or long term lines will be derived. Cell supernatants will be analysed for cytokine, MMP and other inflammatory mediators by ELISA and cell phenotype determined by Flow cytometry. In addition, mRNA will be harvested and gene expression determined by TaqMan PCR. The histopathology of the tissue will also be looked at.

28 Clinical Characterisation Protocol for Severe Emerging Infection

This is a standardized protocol for the rapid, coordinated clinical investigation of severe or potentially severe acute infections by pathogens of public health interest. Patients with a spectrum of emerging and unknown pathogens will be enrolled. This protocol has been designed to maximize the likelihood that data and biological samples are prospectively and systematically collected and shared rapidly in a format that can be easily aggregated, tabulated and analysed across many different settings globally. The protocol is designed to have some level of flexibility in order to ensure the broadest acceptance and has been initiated in response to the recent cases of novel coronavirus (nCoV) in 2012-2013, Influenza H7N9 in 2013 and viral haemorrhagic fever (Ebolavirus) in 2014. Information will be circulated by the Investigators and disseminated by the NIHR Clinical Research Network to clarify the eligibility criteria in the event of the emergence of a pathogen of public health interest. The study is now recognised by the NIHR as being an Urgent Public Health Research study

29 Is MGI or upper marginal entropion a contributing factor in the development of SLK

The Corneoplastic Unit at the Queen Victoria Hospital often manages patients with superior limbic keratoconjunctivitis (SLK). We hypothesise that meibomian gland inversion (MGI)

and/or upper marginal entropion is a major contributing factor in the development of SLK, and is currently under-recognised. This prospective observational cohort study aims to answer the research question: "Is MGI or upper marginal entropion a contributing factor in the development of SLK?". This study will take place over six months, within the Ophthalmology department of an NHS site, and include all patients identified as possessing features of SLK.

30 Human factors knowledge in Orthodontics Team

Student project

New projects which are expected to start in 2021-22

- SAVER - maxfacs
- Burn-code: multicentre review of burns patients
- GRRAND-F – physiotherapy for H&N patients
- LOOC – lymphatic mapping of oropharyngeal cancer

11.	Report approval and governance

	This annual report has been reviewed by our R&I Governance Group, as well as by the Quality and Governance Committee.