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 2021 to March 2022

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1. Executive Summary

- Our focus during 2021-22 has very much been on recovering from the pandemic and rebuilding our programme of research studies, which had to be curtailed during the height of COVID19. This led to a considerable expansion in activity, with our key performance metric of recruitment increasing by **63%**.

- Last year R&I were able to make a favourable contribution to the Trust's bottom line for the first time, and we were pleased to have been able to repeat this in 2021-22, with **a £10,705** contribution. We also ended the year **£75,169** ahead of budget.

- In 2021-22 we recruited **575** participants, of which **535** were to National Portfolio studies. This represents an increase of **63**% in recruits over the previous year, reflecting the bounce back from the pandemic. We expect this increase in activity to continue throughout 2022-23.

- We continued to support the important national SIREN study, which informed government policy regarding the pandemic.

- In common with much of the NHS, we had challenges with staff sickness, which did impact on our capacity to undertake research, but we now have a highly experienced, full research nurse team to support studies going forwards.

- We are proud that three of our clinicians acted as Chief Investigators on National Portfolio studies (Charles Nduka, Raman Malhotra, Baljit Dheansa). These are studies that we have initiated and designed ourselves, and which have been adopted onto the prestigious National Portfolio – the UK gold standard for high quality clinical research.

- We took part in the national anonymous Participant in Research Experience Survey, which showed that **98%** of our respondents felt that their participation was valued; **99%** agreed that research staff always treated them with courtesy and respect; and **88%** said that they would consider taking part in research again. Respondents commented on the friendliness and professionalism of research staff, and of the benefits of taking part - both for themselves and for future generations

2. Introduction

As the Director of Research & Innovation, it gives me great pleasure to introduce the annual Research and Innovation Report for 2021/2022.

The Research & Innovation team has worked hard to implement the post COVID-19 recovery plan. We have continued to support a diverse range of existing studies, as well as initiating new research projects. The department continues to grow a robust research portfolio with an active presence as part of the regional CRN and at a national level. We have seen an increase in patient recruitment, which has contributed to a positive financial position.

I would like to thank the researchers, research nurses and the administrative team. I also would like to pay tribute to all the members of the Research Governance Group, who continue to support the research we run at the Queen Victoria Hospital .

Mr Zaid Sadiq

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 a research programme which focuses on quality, transparency and value for money. R&I at QVH is performance-monitored by our local CRN. Research activity is tracked on a daily basis via an interactive online system (Edge), as well as via regular meetings and written reports. One key objective by which the CRN measures our performance is a 'Value For Money' (VFM) measure. This year, our VFM greatly improved as we began to recover activity following the pandemic, with a cost-per-weighted-recruit of around £140 – a 19% improvement over the previous year.

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 2021-22 that were recruited during that period to participate in research approved by the Health Research Authority was **575** of which **535** were recruits to National Portfolio studies. This represents a 63% increase in National Portfolio activity over the previous year, reflecting the significant increase in activity following 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 23 clinical research studies in 2021-22, as per the tables below.

Study ref in appendix	Project Short title	Start date	Principle Investigator	National Portfolio study	Recruit-ment in 2021-22
1	SNAP3	21/03/2022	Fiona Ramsden	Yes	48
2	MIDI (MR Imaging abnormality Deep learning Identification)	04/10/2021	Ian Francis	Yes	115

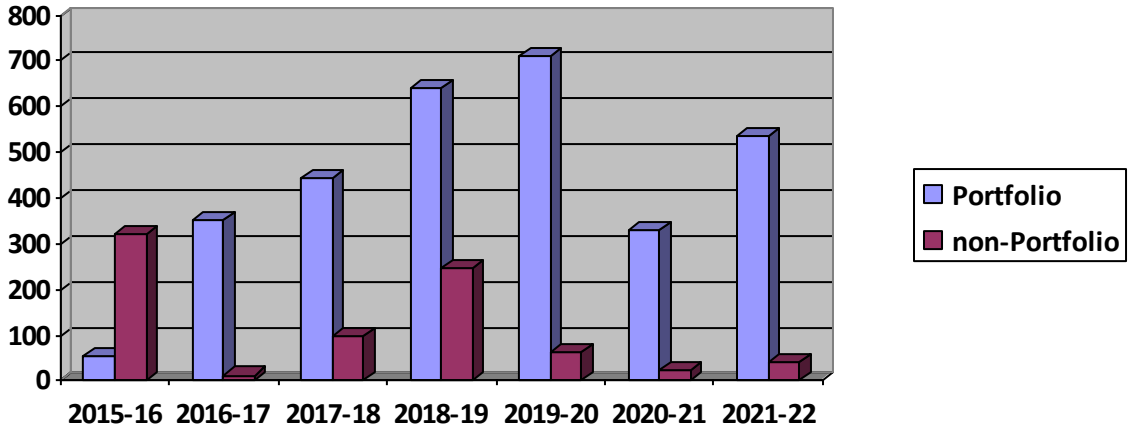
3	Organisational resilience questionnaire development and validation	24/01/2022	external	Yes	0	
4	Dystonia grading scales study	01/07/2021	Raman Malhotra	No	38	
5	QoL and functional outcomes after Mandibulectomy Reconstruction	30/04/21	Jag Dhanda	No	0	
6	SAVER	29/10/2021	Zaid Sadiq	Yes	1	
7	SARS-COV2 immunity and reinfection evaluation (SIREN)	17/08/2021	Julian Giles	Yes	In follow up	
8	The COVID-19 Resilience Project	22/05/2021	N/A	No	0	
9	GenOMICC	05/05/2021	Julian Giles	Yes	0	
10	NEON - digital NErve, suture Or Not	18/11/2021	Rob Pearl	Yes	5	
11	Are subjective pain scores related to facial muscle activity? - EMG pain scores	15/09/2021	Charles Nduka	Yes	53	
12	The anatomy of flexor tendon repair-IRP student study	01/10/2018	Rob Pearl	No	0	
13	TEARS	12/11/2018	Raman Malhotra	Yes	39	

14	XEN45 in Angle Closure Glaucoma	22/11/2018	Gok Ratnarajan	Yes	Closed to recruitment
15	Haemostatic markers in ECMO (HAE) study	25/01/2018	N/A	Yes	0
16	Smartmatrix SMA0217	10/09/2018	Baljit Dheansa	Yes	In follow up
17	Perioperative Quality Improvement Programme: Patient Study	03/05/2017	Julian Giles	Yes	191
18	Validation of MIRROR application for facial paralysis	11/03/2021	Charles Nduka	Yes	paused
19	Investigation of Potential Biomarkers in the Role of Scar Formation	16/03/2016	Baljit Dheansa	Yes	16
20	SUBMIT	21/09/2016	Asit Khandwala	Yes	Closed to recruitment
21	Molecular basis of chronic inflammatory and degenerative diseases	30/11/2015	Asit Khandwala	Yes	67
22	Clinical Characterisation Protocol for Severe Emerging Infection	03/02/2021	N/A	Yes	1
23	Is MGI or upper marginal entropion a contributing factor in the development of SLK	25/02/21	Raman Malhotra	No	2

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 six 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 bounced back from the COVID19 pandemic with a **63%** increase in participant recruitment over the previous year, at **535** recruits.

Research Participant Recruitment 2015-2022



External Funding

Core funding

The CRN awarded the Trust **£193,273** core funding in 2021-22, plus £5835 contingency funding, and £6000 Specialty Lead Funding. The CRN determines its level of funding partly 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 B7	30,078
Research Nurse B6	43,468
Research Nurse B6	41,918
Research Nurse B6	26,301
CRN Specialty Leads	6000

Head of Research	44,256
Office/IT/consumables/training	2169
Overheads	10,913

The Trust also received **£750** 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, and last year we were in a position for the first time to make a favourable contribution at year end. We have managed to improve this contribution in 2021-22, with a contribution of £10,705 to the Trust's bottom line. We also ended the year £75,169 ahead of budget.

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 we gradually took on more research activity, the opportunities for public involvement increased, and we were able to take part in the national anonymous PRES (Participant in Research Experience Survey) questionnaire, and received 68 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. Overall, the PRES survey paints a positive picture of people's experiences of taking part in research. Respondents comment on the friendliness and professionalism of research staff, and of the benefits of taking part, both for themselves and for future generations. **98%** of people felt that their participation was valued; **99%** felt that research staff always treated them with courtesy and respect; **88%** said that they would consider taking part in research again.

Clinical Research Network (CRN)

The Trust is a member of the Kent, Surrey, and Sussex Clinical 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 CR N 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 three of our clinicians acted as Chief Investigators on National Portfolio research studies in 2021-22 (Charles Nduka, Raman Malhotra, and Baljit Dheansa).

In 2021-22, the Trust supported one Lead Research Nurse (0.6WTE), one B7 Research Nurse (0.7WTE), three B6 Research Nurses (2.61WTE), and one Research Assistant (0.2WTE). Our B7 Research Nurse was seconded to the Staff Testing Lab throughout most of 2021-22 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 Clinical 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 ACCORD cost attribution, Evolve,

special needs for learning disability and autism awareness, Covid 19 vaccination, risk assessments, paediatric consent, Lab training, as well as attending the British Burns Association Conference, an Ophthalmic Study Day, and a Plastics Study Day

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 offers 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 & Innovation 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. 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 (Raman Malhotra and Charles Nduka), as well as two Chief Investigators for non-Portfolio studies.

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
	This year we have focussed our efforts on rebuilding our research programme following the pandemic. There remains work to be done, but we have made good progress. Despite the challenges of the past year, R&I has maintained its financial stability, and has made a £10,700 favourable contribution to the Trust's bottom line.

7.	Recommendations
	Research has made a significant step in getting back to our pre-pandemic levels of activity, with a 63% increase in recruitment over the previous year. We need to continue this good work in the coming year and sustain our focus on supporting and developing Portfolio studies in order to achieve our pre-pandemic levels of activity.

8.	Future plans and targets
	Specific targets for 2022-23: • Continue to rebuild our research programme with the aim of getting back to our pre-pandemic level of activity • Maintain at least a cost-neutral position Progress towards these targets will be monitored by the CRN and by the R&I Governance Group.

9.	Conclusions and assurance
	Research recovered well from the challenges of the Covid19 pandemic, with a 63% increase in activity. We expect to get back to our full pre-pandemic levels of activity by the end of 2022-23. On the front line and behind the scenes our research team continued to work collectively on rebuilding our research programme. COVID-19 has forced us to do things differently and to be flexible, but the team has responded well to this. R&I maintained robust finances despite the challenging environment. This year we were able to make a £10,700 favourable contribution to the Trust's bottom line, and ended the year £75K ahead of budget.

10.	Appendices

Registered research projects (with HRA Approval) ongoing in 2021-22

1 SNAP3

More older people are undergoing surgery as the population ages and surgical care improves. Frailty is an agerelated syndrome that increases an individual's vulnerability to adverse outcomes in response to illness, injury and surgery. Delirium is a period of temporarily altered, fluctuating consciousness, triggered by illness, surgery or environment. There is evidence that surgical outcomes are worse in patients with these conditions. The purpose of SNAP3 is to investigate which patients are frail and which are at risk of delirium. It will investigate current perioperative care and its outcomes.

The research includes three parallel studies which will run in NHS hospitals within the UK. S2 and S3 are service evaluation surveys for clinicians and are included for completeness:

2 MIDI (MR Imaging abnormality Deep learning Identification)

There is a wide variation in how incidental findings (IFs) discovered in 'healthy volunteers' are managed. Routine reporting of 'healthy volunteer' scans by a radiologist is a challenging logistic and financial burden. It would be valuable to devise automated strategies to ensure that IFs can be reliably and accurately identified potentially removing 90% of scans requiring routine radiological review, thereby increasing the feasibility of implementing a routine reporting strategy.

An automated strategy could also address the unmet clinical need in identifying abnormalities quicker, potentially allowing for early intervention to improve short and long-term clinical outcomes. Radiologist shortages and increased demand for MRI scans mean delays in reporting, particularly in the outpatient setting.

Deep learning is a new technique in computer science that automatically learns hierarchies of relevant features directly from the raw inputs (such as MRI or CT) using multi-layered neural networks. A deep learning algorithm will be trained on a large database of head MRI scans to recognise scans with abnormalities. This algorithm will be trained to classify a subset of these scans as normal or abnormal. The technique will then be tested on an independent subset to determine its validity.

If the tested neural network has a high diagnostic accuracy, future research participants may benefit as currently not all institutions review their research scans for incidental findings. Similarly, in those cases where scans may not be reported for weeks, patients may benefit. In both research and clinical scenarios, an algorithm would quickly identify abnormal pathology and prioritise scans for reporting.

In summary, the aim is to develop a deep learning abnormality detection algorithm for use in both the research and clinical setting.

3 Organisational resilience questionnaire development and validation

This research involves exploratory testing of a widely used, but poorly tested concept of organisational resilience in a healthcare context. Resilience refers to the ability of an organisation to 'bounce back' or recover from an unexpected event. Unexpected events, such as infection outbreaks have a significant adverse impact on many hospitals.

Understanding what constructs constitute resilient approaches at organisational level will help improve hospitals' preparedness and response to unexpected events.

A questionnaire designed to ascertain the constructs comprising organisational resilience will be developed from the literature and a case study and then validated across a sample of hospital staff from England. The results from the questionnaire will be collated and statistically analysed. The analysis will attempt to validate the questionnaire as a tool to test organisational resilience in a hospital context. The research aims to provide an improved understanding of organisational resilience in healthcare with the aim of developing practical strategies that can be adopted by hospitals to become more resilient and maintain or improve their healthcare outcomes.

4 Dystonia grading scales study

Essential blepharospasm (EB), hemifacial spasm (HFS) and aberrant regeneration of the facial nerve (AFR) are all movement disorders treated with botulinum toxin. Botulinum toxin (BoNT) was first approved for medical use on extraocular muscles to treat non-accommodative strabismus and, subsequently, efficacy was demonstrated in EB, HFS and AFR. A number of different measurement tools and scales have been used to evaluate the effects of BoNT on various aspects of blepharospasm, including force of eyelid closure, severity of muscle spasms and patient functional status.

Today the rating instruments have coalesced into several main clinical scales including the Jankovic Rating Scale and the Blepharospasm Disability Index (BSDI).
Instruments that assess activities of daily living or patient functional status are rated by the patients themselves. These scales recognise the importance of improvement in activities of daily living as an outcome of therapy. Whilst the validity of the BSDI is well documented to date the FDS has not been fully validated by any other centre apart from the original describer.

The principle aim of this study is to repeat validation of the FDS against the BSDI which has been validated by several groups since its original description. In particular we aim to compare the rating scales with respect to their metric properties in patients with EB, HFS and AFR. The metric properties of the scales, with special regard to their usefulness for assessment of treatment efficacy, include evaluating the internal consistency (as an aspect of reliability), convergent validity and equivalence in comparison to the other scales and sensitivity to change with treatment as another aspect of validity.

5 Quality of Life and functional outcomes after Mandibulectomy Reconstruction

Traditionally, fibula free flap is used for reconstruction of segmental mandibulectomy defects. However, donor site morbidity is a recognized problem with Momoh et al., (2011) reporting donor site complications as high as 30%. This has significant implications on patients (pain and mobility) and the NHS due to increased hospital visits and costs associated with treating these complications.

Bowe et al. (2020) published a cohort of 30 patients who have undergone reconstruction of posterolateral segmental mandibulectomy defects (Brown Class I Defects) with a mandibular reconstruction plate (MRP) and anterolateral thigh (ALT) axis free flap with a low incidence of complications, demonstrating its feasibility of use as an appropriate reconstructive option in this specific cohort of patients.

This retrospective questionnaire-based study aims to compare donor site morbidity and patient experience in terms of functional outcomes and quality of life for those patients who underwent ALT or FFF for the reconstruction of segmental mandibulectomy defects. We will be using three standardized questionnaires that have been validated for use in head and neck cancer patients.

In a separate arm of the study, we will also be looking at the role of vacuum-assisted closure (VAC) compared to simple pressure dressings + split-thickness skin grafts (STSG) in influencing these outcome measures. We recently presented a retrospective audit investigating the role of VAC dressings which demonstrated a reduction in healing time and re-admission rates to hospital in relation to the donor site. We are keen to build upon this preliminary work in this study.

The eventual aim of this project would be a work-up to a prospective randomized controlled trial to investigate donor site morbidity and functional outcomes of ALT versus FFF in reconstruction of segmental mandibulectomy defects.

6 SAVER

Individuals can develop patches (oral dysplasia) on the lining of the mouth which are at risk of developing into cancer. Standard treatments include surgery or close surveillance, although these treatments are not completely effective, as up to 25% of patients progress to oral cancer even after surgery. Oral cancer treatments can be curative, especially when caught early, but the side effects include damage to speech, swallowing, appearance and reduction in quality of life, which are permanent. Additionally treatment for oral cancer carries a high economic burden and the World Health Organisation has recommended a shift in policy towards early diagnosis and prevention. Survival rates for oral cancer have remained largely unchanged for decades, at around 50-55% overall survival by 5 years. There is, therefore, a need to develop and evaluate new prevention treatments for this condition. It is thought that more effective treatment for oral dysplasia would reduce the incidence of oral cancer.

SAVER is a phase II clinical trial with embedded mechanistic and feasibility studies. It is randomized, double blind and placebo controlled with a planned recruitment of 110 patients. The randomisation is in the ratio 2 SV (73 patients) :1 placebo (37 patients). The study population includes patients with premalignant oral lesions that have a histological diagnosis of oral epithelial dysplasia (OED) and are at high risk (considered to be at least 20% over 5 years of malignant transformation).

The aim of this phase II trial is to investigate the effects of sodium valproate as epigenetic chemopreventive therapy on high risk oral dysplasia. In particular, we will establish: clinical activity, mechanism of action and, feasibility of conducting such research in the NHS, in order to inform a decision on a larger phase III trial.

7 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.

8 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

9 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.

10 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.

11 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

12 anatomy of flexor tendon repair-IRP student study

13 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.

14 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

15 **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

16 Smartmatrix dermal replacement

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.

17 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).

18 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

19 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.

20 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.

21 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.

22 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

23 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.

New projects which are expected to start in 2022-23

- LOOC – lymphatic mapping of oropharyngeal cancer
- FIRST – splints for flexor tendon repairs
- Mucograft in maxfacs patients
- MelMart II
- MAGIC = paediatric melatonin prior to anaesthesia
- PATHOS
- FRONTIER corneo microstent
- RAPTOR – treatment of mandibular osteoradionecrosis following H&N cancer
- Laser imaging of flaps in breast reconstruction

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.