Queen Victoria Hospital
NHS Foundation Trust

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Queen Victoria Hospital NHS Foundation Trust
Research & Development Annual Report

Report covering the period from
April 2019 to March 2020

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1. Executive Summary

- QVH has increased its research activity for the fifth successive year in a row.
- More and more of our patients have been offered the chance to take part in research. In 2019-20 we recruited 772 participants, of which **709** were to National Portfolio studies. This represents a **10%** increase in Portfolio recruits over the previous year.
- As a result of this excellent performance, our NIHR funding was increased by nearly **24%**.
- The Trust also had a major grant-funded study ongoing, to develop a new device to assist with the rehabilitation of facial palsy patients. This project was funded by the National Institute for Health Research (NIHR) Invention for Innovation (i4i), and Charles Nduka was the lead applicant. This was a collaborative effort with the University of Nottingham Trent and a commercial partner (Emteq).
- We are proud that four of our clinicians acted as Chief Investigators on National Portfolio studies (Charles Nduka, Raman Malhotra, Simon Booth, Emma Worrell). This is a significant achievement for a small Trust.
- We have also expanded work on commercial studies, and this year we undertook 5 such studies.
- QVH achieved the national target for time to first recruit on 100% of its non-commercial studies. We also achieved the national target time for study set up on 84% of our studies.

2. Introduction

It gives me great pleasure to introduce the annual Research and Development Report for 2019/2020. Research activity has continued to grow for the fifth consecutive year at the Trust. We recruited our largest number of patients ever into research studies. Our successes have been recognised by the National Institute of Health Research, which increased our core funding. This allowed us to expand the number of research staff employed at the Trust.

We have continued to forge successful alliances with a variety of partner organisations including Universities, NHS Hospitals and the private sector. Examples of these include the University of Oxford for the NINJA and Dupytren's studies, and our commercial work with Emteq and Smith & Nephew. This has allowed us to critically evaluate many of the innovative treatments we deliver to our patients.

QVH clinicians are both developing in-house research projects and ensuring the QVH is an active partner in appropriate multi-centres studies. I am particularly glad that this is not solely driven by doctors. Simon Booth, a Burns Nurse, and Emma Worrell, a Principal Prosthetist, are both Chief Investigators delivering nationally important research projects.

The Charitable Funds have been generous in their support of research at the Trust, and for the past two years have funded Jag Dhanda (Consultant Maxillofacial Surgeon) to work on maxillofacial research projects. This funding has now come to an end. We are very grateful to the Charitable Funds for the commitment they have shown.

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.

I hope that we will be able to build on the successes of 2019/20. However, the COVID pandemic will prove a challenge for research at the QVH. The NIHR initially asked that Trusts focus solely on COVID research. The QVH's primary focus has been to provide cancer and trauma services for the surrounding Trusts whilst endeavouring to remain COVID free. Thus far this has made it impossible for the Trust to participate in the large scale COVID studies. Things are now gradually returning to normal. We are trying to concentrate on studies that allow us to explore how to deliver care to patients at home rather than in the hospital environment. As the lockdown eases we are aiming to collaborate with Public Health England on a COVID prevalence study.

Historically wars and natural disasters have precipitated major innovations in technology and health care. I hope the same will happen as a result of the ongoing pandemic.

	Dr Julian Giles

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&D at QVH is performance-monitored by our local CRN. They track our research activity on a daily basis via an interactive online system (Edge), as well as via regular meetings and written reports. The key objective by which the CRN measures our performance is a 'Value For Money' (VFM) measure. QVH has consistently delivered one of the most cost-efficient R&D programmes in Kent/Surrey/Sussex, with a cost-per-weighted-recruit of around £62. The NIHR CRN also sets objectives for: total recruitment; time to first recruit; time to local approval; and recruitment to time and target. QVH has performed well on all these targets.

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 2019-20 that were recruited during that period to participate in research approved by the Health Research Authority was **772**, of which **709** were recruits to National Portfolio studies. This represents an **11%** increase in National Portfolio activity over the previous year.

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 **34** clinical research studies in 2019-20, as per the tables below.

Study ref in appendix	Study title	Start date	Principle Investigator	National Portfolio study	Recruitment in 2019-20

1	Clinical Characterisation protocol for Severe Emerging infection	03/02/20	N/A	Yes	0
2	Breastfeeding and anaesthesia	10/03/20	External	No	0
3	MET-REPAIR v1.0	06/01/20	Fiona Ramsden	Yes	5
4	MET-REPAIR-FRAILTY v1.0	06/01/20	Fiona Ramsden	Yes	5
5	SPaCE Pilot	23/08/19	Simon Booth	Yes	7
6	Organisational resilience questionnaire development and validation	06/06/19	External	Yes	
7	JaWPrinT	27/03/2019	Jag Dhanda	Yes	12
8	FFFAP Falls Audit Evaluation	18/10/2018	N/A	Yes	0
9	Allotex - IntraStromal - (PRO10)	08/02/2019	Samer Hamada	Yes	10
10	Single Use PICO NPWT Post-Market Safety and Efficacy Study	21/01/2019	Simon Booth	Yes	2
11	TEARS Grading scale: grading the clinical severity of epiphora	12/11/2018	Raman Malhotra	Yes	114
12	XEN45 in Angle Closure Glaucoma	22/10/2018	Gok Ratnarajan	Yes	1
13	Nail bed INJury Analysis (NINJA)	23/05/2018	Rob Pearl	Yes	17
14	DEFeND	11/12/2018	Jag Dhanda	Yes	5
15	Objective dynamic description of facial co-contractions and facial dominance in the general population	13/08/2018	Charles Nduka	Yes	0
16	Haemostatic markers in ECMO (HAE) study	25/01/2018	N/A	Yes	0

		17	Smartmatrix SMA0217	10/09/2018	Baljit Dheansa	Yes 6
		18	Patient experiences of adapting to life following orthognathic treatment for facial asymmetry	25/09/2018	Lindsay Winchester	Yes 4
		19	Ambulatory measurement of facial expressions in health and disease - FRAME	12/11/2018	Charles Nduka	Yes 110
		20	Improving perioperative care through the use of quality data: Patient Study of the Perioperative Quality Improvement Programme (PQIP)	03/05/2017	Julian Giles	Yes 194
		21	Ciclosporin 1mg/ml eye drop emulsion (Ikervis) for the treatment of severe keratitis in adult patients with dry eye disease, which has not improved despite treatment with tear substitutes	28/09/2017	Samer Hamada	Yes 0
		22	Validation of the MIRROR facial expression tracking application in healthy subjects and facial paralysis patients	11/03/20	Charles Nduka	Yes 0
		23	Lock & Key	08/06/2017	N/A	No 0
		24	Lugol's Iodine in Surgical Treatment of Epithelial Dysplasia in the Oral Cavity and Oropharynx - LISTER	07/12/17	Paul Norris	No 0
		25	A nationwide survey of prosthetic eye users: a collaborative study with all NHS ocular prosthetic service providers.	01/03/2017	Raman Malhotra / Emma Worrell	No 8
		26	Antibiotic Levels in Burn wound Infection (ABLE)	30/08/2016	Simon Booth	Yes 6
		27	EuPatch	01/07/2016	Samer Hamada	Yes 0
		28	Investigation of Potential Biomarkers in the Role of Scar Formation	16/03/2016	Baljit Dheansa	No 63
		29	SUBMIT	21/09/2016	Asit Khandwala	Yes 2
		30	A study to refine the CAR burns scales	03/11/2015	Simon Booth	Yes 101
		31	Molecular mechanisms and pathways of chronic inflammatory and degenerative diseases. (Dupuytrens patients)	30/11/2015	Loz Harry	Yes 100

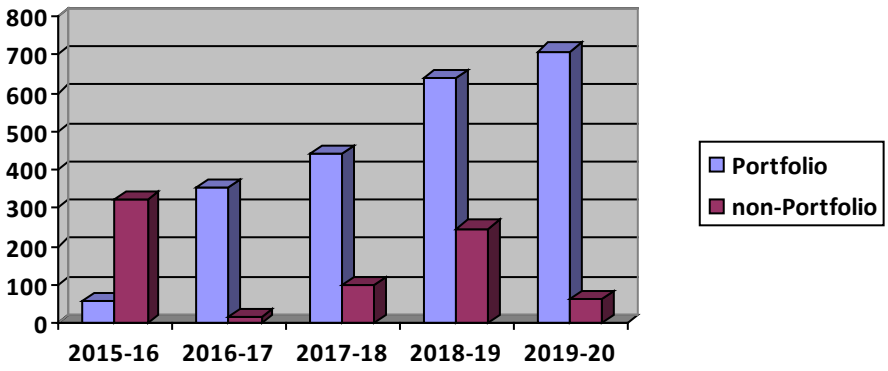
32	Molecular Genetics of Adverse Drug Reactions	31/01/2012	Baljit Dheansa	Yes	0
33	Leadership styles and their effectiveness in the NHS	04/06/19	External	No	0
34	The anatomy of flexor tendon repair	01/10/18	Rob Pearl	No	0

Involvement in NIHR Portfolio studies

Accruals for NIHR Portfolio studies are 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 four 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.

QVH recruited **709** Portfolio participants in 2019-20. This represents an **11%** increase over the previous year.

Research Participant Recruitment 2015-2020



Maxillofacial research funded by QVH Charitable Funds

Jag Dhanda was very generously funded by the QVH Charitable Funds for 3PA/week to focus on research. Two new studies were ongoing in 2019-20: DeFEND (Determining the Effectiveness of Fibrin Sealants in Reducing Complications in Patients Undergoing Lateral Neck Dissection - 4 patients recruited in 2019-20), and JaWPrinT (Jaw reconstruction with printed or flexed titanium and free tissue transfer – 12 patients recruited in 2019-20).

A third, SAVER (Sodium Valproate for Epigenetic Reprogramming in the Management of High Risk Oral Epithelial Dysplasia), is planned for 2020-21.

External Funding

Grant funding

The Trust held one grant in 2019-20, a prestigious NIHR i4i award, for which Charles Nduka was the lead applicant. This was a collaborative effort with the University of Nottingham Trent and a commercial partner (Emteq), to develop a new device to assist with the rehabilitation of facial palsy patients. The grant was worth a total of **£846,000** across all three partners.

Core funding

The CRN awarded the Trust **£172,308** core funding in 2019-20, plus £11,700 contingency funding and £3000 Specialty Lead Funding. 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	Staff	Name	Allocation
Lead Research Nurse	Gail	Pottinger	26,457
Research Nurse	Simon	Booth	25,697
Research Practitioner	Debbie	Weller	7,039
Research Nurse	Tracey	Shewan	41,900
Research Nurse	Cassie	Honeywell	27,286
Clinical Lead for R&D	Julian	Giles	5352
Clinical Trials Pharmacist	Judy	Busby	2094
Specialty Lead	Jagtar	Dhanda	3000
Head of Research	Sarah	Dawe	24,580
Research Governance Officer	Emma	Foulds	10,042
Training			0
Travel			1,564
Overheads			11,997

The Trust also received **£2,250** from the Brighton and Sussex Medical School to support the IRP students who undertake fourth-year research projects at the hospital.

Charitable Funding

The QVH Charitable Funds very generously supported a Maxillofacial Consultant to undertake research for 3PA/week. This is reported on under 'Research Activity' above.

The Scar Study has been kindly supported by the League of Friends and the QVH Charitable Funds, which between them funded 3 day/wk of a research technician. This study is investigating potential biomarkers in the role of scar formation. 63 participants were recruited in 2019-20.

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&D Governance Group two very involved patient representatives, who take an active role in advising on and monitoring the research activities of the Trust, and this year we also appointed a new Patient Research Ambassador. Patients are also often involved in the early stages of research projects via focus groups, who feed into protocol development. We have set up a Research Panel which has been established to suggest as well as review new research ideas for the QVH as they are being formulated.

In 2019/20 we continued to raise patient awareness of QVH as a research active organisation. A short video featuring both research patients talking about their own experiences and clinicians explaining about research benefits is now completed and running in outpatient waiting rooms on a timed loop. Leaflets and pull up banners are also in use throughout the organisation to advertise research opportunities.

Participant Research Experience Survey (PRES)
QVH takes part in the national anonymous PRES questionnaire. In 2019/20 we increased research participant engagement with PRES and extended invitations to patients in a broader range of clinical specialities to fully represent the diverse nature of the QVH clinical trials portfolio. 96 PRES responses were received in total.

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.

The findings show that there is a widespread recognition of research staff being friendly, professional and answering questions in an understandable manner, with 100% of respondents agreeing with this. 93% felt valued as a research participant, and 98% agreed that they had been given all the information they needed in relation to study. 90% reported having had a good experience of taking part in research.

Some 43% of participants were unaware that QVH was a research active Trust prior to joining their study. This is down from 67% the previous year, and shows that publicity we have put in place is starting to have a positive effect.

A new finding this year showed that 25% of patients were unsure of what to expect at follow up. Research Nurses are now providing more verbal instructions to supplement written leaflets; contact cards are also in process giving generic research e-mail and contact numbers for trial participants to use for any questions regarding their appointments. This intervention will be monitored over the coming year for effectiveness.

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&D 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

Clinical Lead for Research 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 four of our clinicians acted as Chief Investigators on National Portfolio research studies (Charles Nduka, Raman Malhotra, Simon Booth, Emma Worrell). This is a significant achievement for a small Trust.

In 2019-20, the Trust supported one Lead Research Nurse (0.6WTE), one Burns Research Nurse (1WTE), one Research Practitioner (1WTE), two Research Nurses (1.89WTE), and one Research Assistant (0.2WTE).

We have been fortunate to have the support of the QVH Charitable Funds, who have funded 3PA/year of a maxillofacial consultant's time for research (Jag Dhanda).

The Scar Study has been generously supported by the League of Friends and the QVH Charitable Funds, which funded 3 day/wk of a Research Technician.

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&D 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&D Department presently consists of one Clinical Lead for R&D, 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 the research management and governance. Other income to support the R&D infrastructure comes from commercial studies, which in addition to paying general Trust overheads, contribute a fee for R&D Department services in processing 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, and this year they have been managing royalties for a tracheostomy dressing device originally developed at QVH.

Training and Development

Local Training
Individual support tailored to the individual is provided by the R&D 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 providing an onsite trainer, enabling access to off-site courses at other Trusts, or by paying for staff to do an individual online course. One member of staff is a qualified GCP trainer, and also runs courses outside the Trust on behalf of the CRN. Commercial companies also regularly run refresher GCP courses for staff involved in the clinical trials they run at the Trust.

Our research staff also attended external courses on Project Management, Finance, Change Management, Influencing and Negotiating, Report Writing, Group Facilitation, as well as conferences on Head & Neck Cancer and at the British Burns Association.

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 Structure

R&D at the Trust is overseen by a Research & Development Governance Group. Its members include: Clinical Lead for R&D, Chief Pharmacist/Clinical Trials Pharmacist, Anaesthetics Lead, Burns Lead, Corneoplastics Lead, Hand Surgery Lead, Maxillofacial Lead, Deputy 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&D 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&D approvals and targets

QVH has effective, streamlined systems for managing R&D approvals in proportion to risk, and our turnaround times are swift. The R&D 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.

There are national targets for the processing of R&D applications and for time to first recruit. QVH approval times for clinical trials and for commercial studies are also reported quarterly to the NIHR, and published on the QVH website.

The proportion of new studies at QVH meeting the national HL04 target for site set up within

	40 days was **84%** in 2019-20. This compares to 71% nationally (2018-19 figures). For non-commercial studies, QVH achieved the HL05b target of 30 days to first recruit in **100%** of studies. This compares with 46% of non-commercial studies nationally (2018/19 figures). For commercial studies, QVH achieved the HL05a target first recruit within 30 days on **0%** studies (only one eligible study). This compares with 33% of commercial studies nationally (2018/19 figures). **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 four Chief Investigators at the Trust who have initiated QVH-Sponsored National Portfolio studies, as well as one Chief Investigator for a 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 plus phase IV CTIMPs. The Trust's capacity for R&D, and its commitment to research, is clearly stated in its official RDOCS (R&D Operating Capability Statement), which is a publically available document endorsed by the Board and published on the QVH website, according to national guidelines.

6.	Learning from Experience
	QVH has made excellent progress in growing its National Portfolio research activity over a sustained 5-year period, and this has been recognised by extra funding from our CRN. Prioritizing CRN targets ahead of other research objectives has resulted in R&D finances now being on a more secure footing. This has given research at QVH more stable foundation to build on in 2020-21.

7.	Recommendations
	Research activity at QVH has had five successive years of growth. In order to sustain this, consultant engagement needs to be developed.

8.	Future plans and targets

	Specific targets for 2020-21: • Support the national focus on COVID19 studies • Where required, redeploy staff to frontline care • Continue to recruit to non-COVID19 studies where possible Progress towards these targets will be monitored by the CRN and by the R&D Governance Group.

9.	**Conclusions and assurance**
	Research at QVH has benefitted from five successive years of growth, due to a sustained focus on meeting CRN targets. As a result of this activity, the CRN and NIHR have awarded us more core funding. This has put R&D finances on a stable footing. We expect a significant fall in activity in 2020-21 due to the COVID19 pandemic.

10.	Appendices

Registered research projects (with HRA Approval) ongoing in 2019-20

1 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

2 Breastfeeding and anaesthesia

Very few drugs make breastfeeding absolutely contraindicated (3). 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 (4,5).

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.

3 MET_REPAIR v1.0

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.

4 MET-REPAIR-FRAILTY v1.0

See above

5 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.

6 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.

7 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

8 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.

9 Allotex - IntraStromal - (PRO10)

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.

10 Single Use PICO NPWT Post-Market Safety and Efficacy Study

There is a significant amount of clinical evidence to show that NPWT may reduce oedema, increase healing and reduce chance of infection, through maintenance of pressure therapy, in closed incisions, but limited clinical evidence on skin grafts and flaps. In order to meet MDR regulation this study is being complete to assess performance efficacy and safety in skin grafts. In addition, a minor modification has been made to the pump to reduce noise level. Evidence on a small number of abdominal and knee incisions are also being collected to assess that the pump works in the same way as previously on these indications. Subjects with abdominal incisions, skin grafts and knee incisions following knee surgery will be recruited to the study and receive NPWT for 7 days. Functional performance of the system will be assessed through the use of pressure data loggers and acceptability of the device as assessed by patient and clinician. Safety will be assessed with a 30 day follow up to assess complications and device related events.

11 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.

12 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.

13 Nail bed INJury Analysis (NINJA)

Nail bed injuries are the most common hand injury in children in the UK. Treatment usually involves surgical repair of a laceration located underneath the fingernail. To do this the fingernail is removed, the laceration repaired, and the fingernail can be replaced or discarded. Historically the nail was replaced routinely but recent evidence indicates not replacing the nail may reduce the incidence of infection and post operative complications. The NINJA trial is a multicentre, parallel group, randomised controlled trial comparing replacing the nail to the alternative practice of discarding (not-replacing) the nail as part of the surgical nail bed repair for the treatment of nail bed injuries. This study will be undertaken at multiple UK sites, identified through the Reconstructive Surgery Trials Network (RSTN) over a 3 year period. Each patient will be followed up for 4 months.

14 DEFeND

A neck dissection is an operation to remove the glands in the neck either because they have cancer in them or they are at risk of cancer spreading to them. Complications after neck dissection are a significant problem for patients and may affect their quality of life. Research on understanding the feelings of patients who have had head and neck cancer, has shown that avoiding complications is very important to them.

We have found evidence that by giving patients a substance that copies the blood clotting process called Fibrin Sealant, we may be able to protect them from complications. This is because this substance can seal areas of bleeding and stick the raw surfaces of the wound together. Unfortunately, there is no high quality research that has been able to answer whether Fibrin Sealants can prevent complications after neck dissection. Therefore we have

designed a clinical trial to help us answer this important question. However, before this can be started we need to conduct a miniature version of the trial to make sure it has been designed in the best possible way.

15 Objective dynamic description of facial co-contractions and facial dominance in the general population

In the context of lack of research describing normal patterns of facial co-contractions, this project aims to elucidate this research question by measuring objective patterns in healthy subjects. This will allow a baseline to be defined for assessing patients with facial nerve pathology and subsequent treatments.

16 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

17 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.

18 Patient experiences of adapting to life following orthognathic treatment for facial asymmetry

The aims of this study are to understand patient experiences of undergoing orthognathic surgery for facial asymmetry and adapting to everyday life after treatment. Orthognathic treatment involves the use of orthodontic appliances (braces) and jaw surgery to correct major skeletal discrepancies in a person's jaw. Facial asymmetry is a notable discrepancy between the left and right sides of the face which affects a person's facial appearance. Symmetrical and asymmetrical faces have particular social meanings. There is a need to better understand patient experiences of facial asymmetry and adapting to facial change post-treatment.

The research will use interviews and photos to explore patient experiences before, during and after treatment. Patients of different ages and genders who have undergone orthognathic treatment for facial asymmetry will be recruited to the project. Participants will be encouraged to talk about their experiences of facial asymmetry, undergoing orthognathic treatment and their experiences of adapting to life since surgery. They will be encouraged to provide photos to illustrate their experiences and talk about these in their interviews. This project will allow us to develop recommendations for orthodontists and jaw surgeons on meeting the needs of their patients with facial asymmetry.

19 Ambulatory measurement of facial expressions in health and disease – FRAME

Spontaneous facial expressions are part of daily interactions, but can be affected by a number of health conditions. The aim of this project is to develop a sensor enabled glasses, that can detect facial expressions of the wearer to provide pervasive monitoring of treatment effects outside the clinic. Potential beneficiaries of this technology include service users with conditions that affect facial expressions such as those living with facial palsy, Parkinson's disease and depression. FRAME is being developed as a NIHR-funded project in partnership

between the host, Queen Victoria Hospital NHS Foundation Trust, and Emteq Ltd, a technology company co-founded by the study PI, Charles Nduka.

In order to assess facial expressions in specific conditions, we need to understand the patterns of data created by non-clinical volunteers as well as service users. The pilot study consists of 2 parts. First, we will investigate facial expression of service users living with these conditions and of healthy participants in response to standardised video clips designed to provoke emotional responses (Samson, Kreibig, Soderstrom, Wade, & Gross, 2016). Whilst participants are watching these videos, we will assess facial muscle activity using (i) electromyography (EMG), (ii) the non-invasive sensor technology, FRAME, embedded in a pair of glasses and (iii) video recording. This will enable us to establish a baseline and highlight markers which can help enable the technology to distinguish between emotional facial expression responses. We will also ask participants to complete a series of self-assessments. The second part of the study will investigate the recruitment usability, and retention rates of participants wearing FRAME over an extended period of time. This study will enable us to evaluate how well we can monitor facial expressions "in the wild" by having service users use the glasses at home. Participants will be asked to wear the FRAME glasses, during weekdays for up to 4 weeks at home. In addition to these measures, participants will be asked to complete short condition-specific questionnaire 3 times a day.

The eventual outcome of this pilot project will be a technology that will enable objective, remote measurement of facial expression responses.

20 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).

21 Ciclosporin 1mg/ml eye drop emulsion (Ikervis) for the treatment of severe keratitis in adult patients with dry eye disease, which has not improved despite treatment with tear substitutes

Dry eye disease (DED), also known as keratoconjunctivitis sicca, is a multifactorial, chronic and progressive ophthalmic disease causing inflammation and damage to the ocular surface, caused in part by increased osmolarity of the tear film.

Treatment depends on disease severity. Currently available medical options include artificial tear products, lubricants, topical steroids and ciclosporin A (CsA). Lubricants are classified as 'health products', proof of their efficacy is not required by Health Authorities [15], and many are

available over-the-counter. Mild to moderate DED can usually be treated symptomatically with tear substitutes, but few effective treatments exist for moderate to severe DED. Artificial tears provide short-term relief at best, and require frequent dosing.

The efficacy of Ikervis has been explored in trials however there is a lack of evidence from the real-world, observational setting. This non-interventional prospective study will evaluate the effectiveness, tolerability and safety of Ikervis in routine clinical practice. As such, the study will recruit a substantially more heterogeneous patient population than would be seen in a clinical trial.

22 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 (CVA)). 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 (sEMG) and using MIRROR.

23 Lock & Key

At any time, around 10% of people carry meningococcal bacteria in the nose and throat, which can cause meningitis, blood poisoning and other serious illnesses. Most people carry these bacteria and never become ill, yet a very small proportion go on to develop these illnesses which can result in life long disabilities or death. The mechanism by which this happens is poorly understood and has been studied in various ways, usually focussing on the bacteria or on the individual, but none has given a definitive answer. This study will be the first of its kind and will assess the interaction between the host and the bacteria at the genetic level, through genetic mapping, helping us to understand what makes some people susceptible to this infection.

The study will have minimal impact on individuals as we hope to use residual samples from those collected whilst they were in hospital or convalescing, though we will have the mechanism for collection of a new sample in the few cases where no residual is available. The study will include all cases recorded within a five year period regardless of age, and whether or not they survived. This is essential in gaining a breadth of information. The study will not affect the care pathway, which is explained in the information leaflet, but could contribute to the development of new treatments and vaccines, which it is anticipated would be of interest to anyone who has experienced this infection as those being invited to participate will either personally have done, or as the family of a case.

24 Lugol's Iodine in Surgical Treatment of Epithelial Dysplasia in the Oral Cavity

and Oropharynx

When patients are referred with abnormal lining tissue (mucosa) in the mouth or throat which has been present for more than two weeks a sample of this tissue (a biopsy) is taken to assess the surface cells under the microscope. In these abnormal areas, there can be changes to the cells: this is called dysplasia. The cells can be slightly abnormal or very severely abnormal. If they are very severely abnormal, a cancer is more likely to develop from them in the future. This is why these changes are also referred to as precancerous changes. We know that removing these cells can reduce the risk of cancer developing. However it is often difficult for surgeons to see clearly where the abnormal tissue ends and normal tissue starts.

Lugol's iodine stain, which has been used as an antiseptic for many years, is used in some other parts of the body to help identify these precancerous cells. We think that this stain might help us to be more sure of removing all of the precancerous/abnormal cells and leaving behind the normal areas. There is evidence which suggests that if we do this, fewer patients will develop cancer after surgery and so more will be successfully treated.

25 A nationwide survey of prosthetic eye users: a collaborative study with all NHS ocular prosthetic service providers.

Patients who wear an ocular prosthesis often suffer with dry eye symptoms. Up to 90% will also complain of socket discharge, many on a daily basis. No literature exists on their quality of life post eye loss or adapting to monocular vision. Psychometric questions from the National Eye Institute Visual Functioning Questionnaire, investigate the patient's quality of life and how the loss of an eye has impacted on patients' well-being.

Participants receive a questionnaire covering aetiology, length of prosthetic eye use, length of eye wear, age of prosthesis, cleaning regime, lubricant use, inflammation, comfort and discharge. Lower scores relate to a better-tolerated prosthesis. Is there an association between deposit build up, frequency of ocular polish, to socket discharge and dry eye symptoms? A series of quality of life questions probe the effects of monocular vision on day-to-day activities, hobbies, driving and how each patient regards their own general health after the loss of an eye.

26 Antibiotic Levels in Burn wound Infection (ABLE)

Burn wounds have a high risk of developing infections. Oral or intravenous antibiotics are routinely given to manage such infection; however, the appropriate use of antibiotic therapy as a means of treating infection has become a topic of international debate due to rise in antimicrobial resistance (AMR). Several issues within the management of burn wound infection have led to the question of therapeutic levels being found in the burn wound. The most common antibiotic used, Flucloxacillin, belongs to a family of antibiotic known as Beta-Lactam antibiotics. Unfortunately this group of antibiotics is known to bind to serum proteins in the blood, meaning a fraction of the original dose is available and active at treating infection. Secondly, the antibiotic needs to be transported to the area which needs treating. The body does this by transporting the drug through the blood; however, burn wounds have an impaired blood supply which would lead to the supposition that very low levels enter the wound. Furthermore, the wound environment may have an altered pH which may further prevent effective utilisation of the antibiotic as antimicrobials such as Flucloxacillin have a narrow band of acid/alkali that they can be effective in.

The main question that the study will answer will be whether we can find therapeutic levels of antibiotics in patients wounds, which are sufficient to treat the infection.
Participants will give consent to participate and then give a wound exudate swab and blood test to measure their levels of antibiotic. At each subsequent dressing change the wound swab and blood samples will be repeated until the participant finishes their course of antibiotics. This is likely to be up to a maximum of 4 blood samples and 4 additional wound swabs

The study population will be adults with burn injuries over and including 1% total body surface

area who are being treated with antibiotics for suspected or confirmed infection.

27 EuPatch

Amblyopia (also called lazy eye) is the most common disease affecting vision in childhood. It affects between 2 to 5% of the population and 90% of visits to children's' eye clinics are for the purpose of treating amblyopia. Currently 30% of children treated for amblyopia do not reach normal vision after a year or more of treatment. Amblyopia is usually treated with glasses wearing and by patching the better eye.

There is controversy whether a long period of glasses wearing before patching, called refractive adaptation, helps in treating children with amblyopia. Refractive adaptation has not been tested in a randomised controlled trial, and currently we do not know how long children wear glasses each day.

The purpose of this study is to perform the first randomised controlled trial to test whether refractive adaptation before patching improves the number of successfully treated children with amblyopia. We will use electronic monitors to measure how much children wear their glasses and patches each day and will determine how this relates to their improvement in vision. We will also investigate whether different types of amblyopia respond better to different treatments.

28 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.

29 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.

30 A study to refine the CAR burns scales

A burn injury can greatly impact upon a person's quality of life. In order to provide the most useful support it is vital for health workers such as doctors, nurses, psychologists and physiotherapists to know what are the most important issues to patients affected by burns. Therefore in collaboration with burn patients themselves, a survey has been developed which explores adult's experiences of living with a burn injury. The plan is for all adults that are seen in hospital for a burn injury to complete this survey, so health professionals can identify their support needs and their treatment progress.

We are asking adults living with a burn to complete this survey to test out the questions. The results of this study will help us shorten and refine the survey, so it can be used in burn units throughout the UK to provide the best possible care and support for patients and their families.

31 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.

32 Molecular genetics of adverse drug reactions

Adverse drug reactions (ADR's) are a common cause of drug-related morbidity and may account for about 6.5% of all hospital admissions. A meta-analysis of studies performed in the USA has shown that ADRs may be the fourth commonest cause of death. ADRs are also a significant impediment to drug development, and a significant cause of drug withdrawal. The purpose of this research is to (a) identify patients with different types of adverse drug reactions; (b) using DNA obtained from blood or Saliva samples from these patients, identify genetic factors which predispose to adverse reactions. The net effect of our research will be the development of genetic tests which can help in predicting individual susceptibility to adverse reactions prior to the medication's administration. Patients with a pre-disposition to reacting adversely can be prescribed alternative medication of monitored more closely during their treatment. This will reduce the harm for patients and save valuable resources for the NHS.

We aim to recruit 250 cases for each reaction for a period of eight years throughout multiple sites in the UK. Specific adverse drug reactions we are looking at include:

- Statin induced myotoxicity, characterised by high CK
- Severe hypersensitivity reactions including Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis
- Anaphylaxis induced by NMBA anaesthetics
- ACE inhibitor or ARB induced angioedema
- Taxane hypersensitivity
- Chemotherapy induced peripheral neuropathy
- Bleomycin induced lung toxicity
- Clozipine induced agranulocytosis or neutropenia
- Bisphosphonate-related osteonecrosis of the jaw
- Tenofovir associated renal injury
- Serious bleeds induced by warfarin or other anticoagulants

33 **Leadership styles and their effectiveness in the NHS**

There is an absence of empirical research comparing the leadership qualities and styles of NHS chief executives who have been recruited from the private sector and those recruited within the NHS.

The aim of this PhD research study is to explore and contrast the leadership attributes and styles of current NHS chief executives within the acute trust environment to bring new knowledge to this area of study.

34 The anatomy of flexor tendon repair

This study will be a joint project with the Department of Anatomy and Queen Victoria Hospital and look at different methods of tendon repair in cadaveric hands.

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.

New projects which are expected to start in 2020-21

- Facial muscle responses with reported pain scores
- SAVER
- NEON – flexor tendon repair
- Burn-code: multicentre review of burns patients
- IDose
- LOOC – lymphatic mapping of oropharyngeal cancer
- GENOMICC

11.	Report approval and governance
	This annual report has been reviewed by our R&D Governance Group, as well as by the Quality and Governance Committee.