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 2018 to March 2019

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1.	Executive Summary

- QVH has had another exceptional year, with steep increases in activity.
- The CQC Inspection of February 2019 recognised research practice at the Trust as '**outstanding'**.
- We have worked hard to make sure that as many patients as possible get the opportunity to take part in research, and in 2018-19 we recruited 887 participants. This is a **64%** increase in total activity over the previous year, which in itself had seen a 47% increase in activity.
- Of these recruits, 640 participants were recruited into National Portfolio studies. This represents a **45%** increase over the previous year.
- Progress has been achieved despite being short-staffed during the year. Success has been due to a sustained focus on prioritizing CRN targets.
- This excellent performance has been recognised by the CRN, who have increased our core funding by **143%**.
- In 2018-19 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 three of our clinicians are acting as Chief Investigators on National Portfolio research studies (Julian Giles, Charles Nduka and Raman Malhotra), and two are members of NIHR faculty (Julian Giles and Charles Nduka). This is a significant achievement for a small Trust.
- We have built up a very productive relationship with the Brighton and Sussex Medical School to host a programme of undergraduate projects. This year we welcomed our ninth cohort of students, who spent nine months of their 4th year with us working on research/audit projects, supervised by QVH consultants.

2.	Introduction

It gives me great pleasure to introduce the QVH Annual Research report for 2018/19. This year has seen further significant increases in research activity at the Trust. When I wrote the introduction to the Annual Report last year I was concerned that it would be difficult to equal the amazing successes of 2017/18. I am delighted to report that we have not only matched our activity in 2017/18 but considerably surpassed it. In excess of 800 patients and staff were recruited to be involved in clinical trials. Our activity has increased by 64%. This is a record for us. Our team of research nurses and managers have worked tirelessly to achieve this success.

At the core of our vision for research is to ensure as many people at the QVH are given the opportunity to be involved in research. This allows us to develop and refine the excellent care we aim to provide to our patients. Publication of the results of formal research projects undertaken at the QVH allows us to shape and influence care provision both nationally and internationally. We have included some of the key publications coming from our hospital in this report.

Our unprecedented success has been recognised by the National Institute of Health Research Clinical Research Network (CRN). They have substantially increased the funding they allocate to the QVH. This has allowed us to recruit two additional research nurses to join the team. We are grateful to the CRN for their continued faith and support.

Jag Dhanda has continued to energise maxillofacial research. He has initiated several studies that we are jointly undertaking with the other leading head and neck cancer centres in the UK. DEFEND and JAWPRINT are now recruiting patients. Jag was appointed as the divisional lead for Kent Surrey and Sussex CRN. This has considerably lifted the profile of the QVH within our region.

Charles Nduka continues to be successful in driving forward his pioneering work to improve the care of patients suffering from facial paralysis. He is nearing the end of the clinical phase of the FRAME study. This study was supported by a prestigious NIHR i4i grant. Plans are afoot for how the prototype devices

	developed through the study can best be deployed to improve care of patients suffering from facial palsy. We have also aimed to bolster the number of commercial studies undertaken at the QVH. Examples of this include our forthcoming participation in a series of ophthalmic studies with Allotex, a company developing novel solutions to sight loss. Samer Hamada is the clinician primarily responsible for this. We are also proud to be collaborating in commercially-funded studies that explore new dressings to improve healing in patients with burns and other difficult to heal wounds. Baljit Dheansa and Simon Booth have been heavily involved in this. I hope that broadening our range of partners can widen our portfolio of research interests and opportunities. Increasing our commercial work will reduce our reliance on funding from the Trust and the CRN. In the coming year I hope that we can work harder to embed a research culture that encompasses all the health care professionals at the QVH. At the moment there are pockets of activity but I would like to see more clinicians, nurses and allied professionals involved in research that underpins the excellent care that we all strive to deliver. Dr Julian Giles

3.	Service aim, objectives and expected outcomes
	Research & Development aims to improve outcomes for patients both at QVH and in the wider NHS. This is achieved through a programme which focuses on quality, transparency and value for money. R&D at QVH is performance-monitored by our local CRN. They closely monitor 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 which we are set by the CRN is a Value For Money (VFM) measure. For the past three years, QVH has delivered one of the most efficient R&D programmes in Kent/Surrey/Sussex, with a low cost per patient recruited. The CRN also sets objectives for total recruitment; time to first recruit; time to local approval; and recruitment to time and target.

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 2018-19 that were recruited during that period to participate in research approved by a research Ethics Committee was **887**. This represents a **64%** increase in total 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 **40** clinical research studies in 2018-19, as per the tables below.

Study ref in appendix	Study title	Start date	Principle Investigator	National Portfolio study	Recruitment in 2017-18
1	JaWPrinT	27/03/2019	Jag Dhanda	Yes	0
2	FFFAP Falls Audit Evaluation	18/10/2018	N/A	Yes	0
3	Allotex – a prospective multicentre clinical study to evaluate the safety and effectiveness of the Transform corneal allograft for the treatment of hyperopia (PRO12)	08/02/2019	Samer Hamada	Yes	0
4	Allotex - IntraStromal - (PRO10)	08/02/2019	Samer Hamada	Yes	0
5	Single Use PICO NPWT Post-Market Safety and Efficacy Study	21/01/2019	Simon Booth	Yes	6
6	ADAPT - HCP Training in Assistive Technology	26/07/2018	N/A	Yes	0
7	TEARS Grading scale: grading the clinical severity of epiphora	12/11/2018	Raman Malhotra	Yes	72
8	XEN45 in Angle Closure Glaucoma	22/10/2018	Gok Ratnarajan	Yes	2
9	Nail bed INJury Analysis (NINJA)	23/05/2018	Rob Pearl	Yes	43
10	DEFeND	11/12/2018	Jag Dhanda	Yes	2
11	Validating a quality of extubation scoring system in a specialist airway centre	17/04/2018	Chet Patel	No	100
12	Objective dynamic description of facial co-contractions and facial dominance in the general population	13/08/2018	Charles Nduka	Yes	99

13	DALES - Drug Allergy Labels in the Elective Surgical Population	01/05/2018	Julian Giles	Yes	109
14	Haemostatic markers in ECMO (HAE) study	25/01/2018	N/A	Yes	0
15	Smartmatrix SMA0217	10/09/2018	Baljit Dheansa	Yes	4
16	Carbapenem-resistant Enterobacteriaceae Screening Survey v1	02/01/2018	N/A	No	0
17	Patient experiences of adapting to life following orthognathic treatment for facial asymmetry	25/09/2018	Lindsay Winchester	Yes	2
18	Ambulatory measurement of facial expressions in health and disease - FRAME	12/11/2018	Charles Nduka	Yes	32
19	Improving perioperative care through the use of quality data: Patient Study of the Perioperative Quality Improvement Programme (PQIP)	03/05/2017	Julian Giles	Yes	125
20	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	8
21	Head & Neck 5000 Follow Up Study	01/02/2018	Brian Bisase	Yes	3
22	Validation of the MIRROR facial expression tracking application in healthy subjects and facial paralysis patients	24/01/2018	Charles Nduka	Yes	0
23	Pharmacists' perceptions of patient medicines helplines.	08/02/2018	N/A	No	0
24	Lock & Key	08/06/2017	N/A	No	0
25	Lugol's Iodine in Surgical Treatment of Epithelial Dysplasia in the Oral Cavity and Oropharynx	21/11/2017	Paul Norris	No	9
26	MindSHINE 3	20/03/2017	N/A	Yes	0
27	A nationwide survey of prosthetic eye users: a	01/03/2017	Raman Malhotra /	No	92

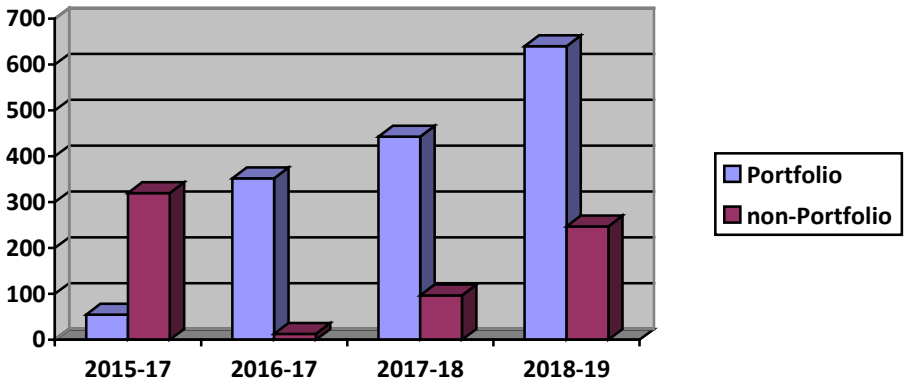
	collaborative study with all NHS ocular prosthetic service providers.		Emma Worrell		
28	Ex-vivo Infection Detection - EVIDEnT	20/10/2016	Simon Booth	Yes	6
29	Antibiotic Levels in Burn wound Infection (ABLE)	30/08/2016	Simon Booth	Yes	4
30	EuPatch	01/07/2016	Samer Hamada	Yes	0
31	Investigation of Potential Biomarkers in the Role of Scar Formation	16/03/2016	Baljit Dheansa	No	79
32	SUBMIT	21/09/2016	Asit Khandwala	Yes	2
33	A study to refine the CAR burns scales	03/11/2015	Simon Booth	Yes	3
34	Molecular mechanisms and pathways of chronic inflammatory and degenerative diseases. (Dupuytrens patients)	30/11/2015	Loz Harry	Yes	85
35	Molecular Genetics of Adverse Drug Reactions	31/01/2012	Baljit Dheansa	Yes	0
36	The co-administration of multiple drugs in intensive care units	04/02/2019	N/A	No	0
37	Experiences of using NHS patient medicines helplines	21/05/2018	N/A	No	0
38	The anatomy of flexor tendon repair		Rob Pearl	No	0
39	S100 and CD31 in tongue cancer	12/05/2014	Bill Barrett	No	0
40	Molecular prediction of metastasis in oral tongue squamous cell carcinoma	19/07/2012	Bill Barrett	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 three 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 **640** Portfolio participants in 2018-19. This represents a **45%** increase over the previous year.

Research Participant Recruitment 2015-2019



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 opened in 2018-19: DeFEND (Determining the Effectiveness of Fibrin Sealants in Reducing Complications in Patients Undergoing Lateral Neck Dissection) (2 patients recruited in 2018-19), and JaWPrinT (Jaw reconstruction with printed or flexed titanium and free tissue transfer).

A third, SAVER (Sodium Valproate for Epigenetic Reprogramming in the Management of High Risk Oral Epithelial Dysplasia), is planned for 2019-20.

Successful EME grant funding was obtained for a studying looking at lymphatic mapping of oropharyngeal cancer. The study is two phases (n=75 each) with no/no go decision between the two. Stage one is imaging protocol development and feasibility with radiotracer injection and imaging in theatre (freehand SPECT with Surgiceye) during EUA/biopsy. Pending on the success of imaging and the contralateral drainage rate in the first stage, stage two will be surgical intervention with SNB of contralateral nodes. Stage 1 begins in 2019-20.

Grant funding was also obtained from CRUK/Imperial for a PhD student to combine iknife and robot technology.

In February, Jag Dhanda was appointed KSS CRN Oral & Dental Specialty Lead.

Funding

Grant funding

The Trust had two grant-funded studies ongoing in 2018-19. We are the proud holder of a prestigious NIHR i4i grant, 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 is worth a total of **£846,000** across all three partners.

The Anaesthetics Department, led by Dr Julian Giles, was engaged in an NIHR RfPB grant-funded (**£79,688)** study looking at non-site-specific pain following breast surgery.

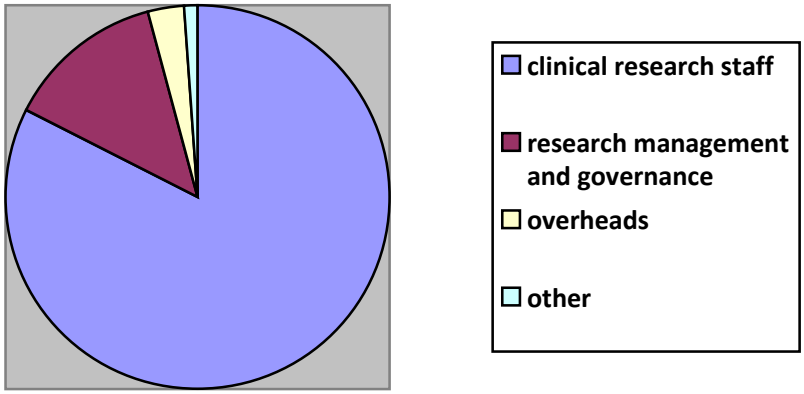
Core funding

The CRN awarded the Trust **£165,084** core funding in 2018-19, including £1500 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. The CRN undertook a financial audit of QVH in February 2019.

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

Resource	Staff	Name	Allocation
Lead Research Nurse	Gail	Pottinger	22,875
Research Nurse	Simon	Booth	54,131
Research Practitioner	Debbie	Weller	41,694
Research Nurse	Tracey	Shewan	12,246
Clinical Lead for R&D	Julian	Giles	5018
Clinical Trials Pharmacist	Judy	Busby	1728
Specialty Lead	Emma	Worrell	1500
R&D Manager	Sarah	Dawe	12,224
Research Governance Officer	Emma	Foulds	9710
Training			0
Travel			502
Overheads			5175



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, which funds 3 day/wk of a research technician. This study is investigating potential biomarkers in the role of scar formation.

Publications

We are proud to say that in 2018/19 QVH clinicians have continued to spread the results of their work extensively. There is little point in engaging in research if we do not effectively communicate the advances that we have made to the broader community. In the modern world there are a myriad of ways in which we aim to do this. Publishing articles in high impact, peer reviewed medical journals remains the traditional way to do this. QVH clinicians have contributed to over thirty such publications this year. Because of the breadth of collaborations coming up with an exhaustive list is difficult. We have listed a few of these below. We also encourage staff to 'spread the word' in other ways. Examples of this might include presentations at conferences, writing editorials, participating in teaching and engagement with patient groups. We have also been exploring the role of social media. I am delighted that publications are not confined to medical staff. We have been encouraging nurses and other members of the allied health care team to participate. Krissie Stiles and Simon Booth from the Burns team have been successful in publishing both research and educational articles. Listed below are a brief selection of research papers, editorials and educational pieces for 2018/19:

Quality of life and communication in orthognathic treatment. Susan L Catt, Sofia Ahmad, Jeremy Collyer, Lauren Hardwick, Nahush Shah & Lindsay Winchester; *Journal of Orthodontics*, 2018 45:2, 65-70. doi: 10.1080/14653125.2018.1458949

Effect of a punctal plug on ocular surface disease in patients using topical prostaglandin analogues: a randomized controlled trial. Sherwin JC, Ratnarajan G, Elahi B, Bilkiewicz-Pawelec A, Salmon JF. *Clin Exp Ophthalmol*. 2018 Apr 26. doi: 10.1111/ceo.13311.

Long-term outcome of flexible onabotulinum toxin: a treatment in facial dystonia. Bladen JC, Feldman I, Favor M, Dizon M, Litwin A, Malhotra R. *Eye (Lond)*. 2018 Sep 10. doi: 10.1038/s41433-018-0203-3.

The SILKIE (Skin GraftIng Low FriKtIon Environment) Study: A non-randomised proof-of-concept and feasibility study on the impact of low-friction nursing environment on skin grafting success rates in adult and paediatric burns. Hollén, Linda, Rosemary Greenwood, Rebecca Kandiyali, Jenny Ingram, Chris Foy, Susan George, Sandra Mulligan, Simon P Booth et al. *BMJ Open* 8, no. 6 (June 1, 2018): e021886. doi: org/10.1136/bmjopen-2018-021886.

Development of a high-throughput ex-vivo burn wound model using porcine skin, and its application to evaluate new approaches to control wound infection. Alves, Diana R., Simon P. Booth, Paola Scavone, Pascale Schellenberger, Jonathan Salvage, Cinzia Dedi, Naing-Tun Thet, A. Toby A. Jenkins, Ryan Waters, Keng W. Ng, Andrew D. J. Overall, Anthony D. Metcalfe, Jonathan Nzakizwanayo, and Brian V. Jones. 2018. *Frontiers in Cellular and Infection Microbiology* 8 (196). doi: 10.3389/fcimb.2018.00196

Objectively measuring pain using facial expression: is the technology finally ready? Dawes TR, Eden-Green B, Rosten C, Giles J, Governo R, Marcelline F, Nduka C. *Pain Management*. 2018 Mar;8(2):105-113.

Emergency management of burns: part 1. Stiles K. *Emergency Nurse*. 2018 May 10;26(1):36-42. doi: 10.7748/en.2018.e1815. Epub 2018 Apr 27.

Current trends in the medical management of osteoradionecrosis using triple therapy. Dhanda J, Rennie L, Shaw R. *Br J Oral Maxillofac Surg*. 2018 Jun;56(5):401-405. doi: 0.1016/j.bjoms.2018.03.009. Epub 2018 Apr 9.

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. Work has also been undertaken on raising patient awareness of research via a publicity campaign, with features on local radio and television, and in newsletters. We have also used leaflets, posters and videos within the hospital to inform patients and the public of the research we do.

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 R&D Manager and the Clinical Lead for Research regularly attend local finance and performance meetings, working closely with the CRN Link Manager and her team. Meeting CRN targets is a priority area for the Trust.

Staffing

Research Management and Governance

The R&D Department presently consists of one Clinical Lead for R&D, one R&D Manager (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 help support the R&D Manager's post. 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 handling their applications and setting up contracts.

Clinical Research Staff

In 2018-19, the Trust supported one Lead Research Nurse (0.5WTE), one Burns Research Nurse (1WTE), one Research Practitioner (1WTE), one Research Nurse (1WTE), 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 Anaesthetics Dept has one Research Registrar (0.2WTE), funded out of its clinical budget. The Scar Study has been generously supported by the League of Friends, which funds 3 day/wk of a Research Technician.

Some clinical departments also each have their own arrangements for Research Fellows, which are funded by the departments themselves and which are not managed by the R&D

Department. In addition, some clinical areas have successfully identified nurses who have been trained up to support research in their own department.

Intellectual property and Innovation

The Trust engages 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, as well as advising on a telemedicine referral image portal system (TRIPS).

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. We are fortunate to have the additional help of the University of Brighton, which has provided us with invaluable advice on study design, methodology and putting together grant applications.

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.

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.

Our Research Governance Officer attended the national R&D Forum Local Capacity and Capability training in February 2019.

Departmental meetings
Individual departments run their own Audit & Research meetings, providing a forum to discuss new ideas and present completed studies.

Research Design Service
The NIHR Research Design Service South East provides a very good service in supporting staff in RfPB grant applications on a one-to-one basis.

NIHR faculty membership
Julian Giles has been made a member of the faculty of the National Institute for Health Research (NIHR), by virtue of his successful grant application to the NIHR RfPB funding stream. Charles Nduka is also a member of faculty, following his NIHR i4i award.

Governance Structure

R&D at the Trust is managed via 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, R&D Manager, 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.

In February 2019, the Trust's R&D function was inspected by the CQC under its Well-Led section. The report is awaited.

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 median time for approval of new studies requiring formal Confirmation of Capacity and Capability in 2018-19 was **14 days** from date site selected, and the mean time was 28 days. This included 2 outliers of 95 days. The median time to first recruit from date site confirmed was **31 days** (this included one outlier of 149 days), and the mean time was 41 days. The proportion of new studies meeting the national HL04 target was **73%**. The proportion of new studies meeting the national HL05 target was **67%**.

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 three Chief Investigators at the Trust who have initiated QVH-Sponsored National Portfolio studies, as well as several Chief Investigators on 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 it's 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, and this has been recognised by significant extra funding from the CRN. Prioritizing CRN targets ahead of other research objectives has resulted in R&D funding now being on a more secure footing. This has given research a more stable foundation to build on in 2019-20.

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

8.	Future plans and targets
	Specific targets for 2019-20: • Meet CRN pledge for number of National Portfolio recruits • Meet national targets for commercial recruitment to time and target • Establish extra research nurse (funding already secured for this). • Develop PPIE (Patient and Public Involvement and Engagement) Progress towards these targets will be monitored by the R&D Governance Group.

9.	Conclusions and assurance
	Research at QVH has benefitted from three successive years of strong growth, despite a challenging understaffing situation. As a result of this activity, the CRN has awarded us considerably more core recurrent funding. This has enabled Research to make a positive contribution to the Trust's finances. Funding has been secured to address our staffing issues, but in order to sustain the current level of activity more consultant engagement needs to be developed.

10.	Appendices

Registered research projects (with HRA Approval) ongoing in 2018-19

1 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

2 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.

3 Allotex – a prospective multicentre clinical study to evaluate the safety and effectiveness of the Transform corneal allograft for the treatment of hyperopia (PRO12)

The purpose of this clinical research investigation is to evaluate the safety and effectiveness of implantation of the Allotex TransForm corneal allograft (TCA) for improving distance vision in hyperopic patients. The expected duration of the clinical investigation is 3 years, subject participation will last 2 years.

The Allotex TCA is a small piece of sterile human tissue designed to change the shape of the first layer of the eye known as the cornea (which is like the crystal on a watch), to adjust the point of focus of light at the back of your eye. The tissue source is specially treated human corneas from an eye bank in the United States.

Following topical anesthesia, the surgeon first creates a pancake-like flap of the cornea using

a laser. After the flap is created, your surgeon will place the TCA beneath the open flap and then complete the procedure by re positioning the corneal flap on the eye. When the flap is replaced, it lies on top of the TCA, causing the surface to change shape which will attempt to improve your distance vision and reduce your dependence on corrective lenses (spectacles and/or contact lenses). Up to 121 patients are being included in the clinical investigation.

4 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.

5 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.

6 ADAPT - HCP Training in Assistive Technology

This study asks Health Care Professionals in England and France to complete the online survey developed by the ADAPT team. The objective of the survey is to obtain feedback from those working with Assistive technologies, especially Health Care and Special Educational Needs Professionals on their:
• Knowledge and experience of training in assistive technologies
• Knowledge and experience working with assistive technologies
• Recommendations for training in the use of Assistive technologies and the support of those who use such technologies.

7 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.

8 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.

9 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 Reconstuctive Surgery Trials Network (RSTN) over a 3 year period. Each patient will be followed up for 4 months.

10 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.

11 Validating a quality of extubation scoring system in a specialist airway centre

A quality of extubation scoring system has previously been developed within a specialist airway centre (Queen Victoria Hospital). Extubation in this case refers specifically to the removal of an endotracheal tube ("breathing tube") in the immediate recovery period after surgery. This research aims to validate this scoring system by comparing objective scores assigned by two independent raters (anaesthetists of minimum ST5 registrar level experience or a recovery nurse trained to perform extubation independently) with a subjective assessment of the quality of the extubation process (as made by the extubating practitioner - i.e. usually an experienced recovery nurse, but may be another anaesthetist). The patients observed will not be subjected to any deviation from standard post-op care - the only variation is that their extubation will additionally be observed by the two professionals making their objective assessment of the process. No objective scoring system for the quality of extubation exists at present, despite it being well accepted that objective methods are superior to subjective assessment. Validation of this scoring system will therefore be useful for guiding future research comparing the effect of different anaesthetic techniques on quality of extubation, as well as for highlighting those factors that contribute most reliably to a safe, comfortable extubation (applicable for training).

12 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.

13 DALES - Drug Allergy Labels in the Elective Surgical Population

Self-reported drug allergies are common in the surgical population. Allergy labels are of particular concern for anaesthetists, whose patients are exposed to a wide range of drugs during the peri-operative period. Unfortunately, many of these labels are based on reactions not indicative of true allergy, but rather of side effects or other non-allergic phenomena. Allergy labels must be interpreted on the day of surgery, and may significantly influence peri-operative drug prescribing.

The avoidance of drugs due to an allergy label is potentially harmful, with important drugs unnecessarily avoided, and alternatives given which may be less effective and more toxic. A good example is the 'penicillin allergy' label. Around 10% of the population report penicillin allergy, but fewer than 5% of these will actually be allergic. Use of broad spectrum alternatives is detrimental to patients and healthcare services. Other examples relevant to anaesthesia include spurious allergy labels for opiates and non-steroidal pain killers; the impact of these has not been assessed previously.

We aim to define the prevalence of drug allergy labelling in the UK surgical population, and to determine the proportion of these labels which are likely to reflect true allergy. For a sub-set of allergy labels, we will study their impact on perioperative prescribing. We will also conduct an attitude and knowledge-based survey of anaesthetists, to explore understanding of drug allergies, the effect of allergy labels on prescribing habits, and ideas to help reduce the burden of inaccurate labelling in the future.

14 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

15 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.

16 Carbapenem-resistant Enterobacteriaceae Screening Survey v1

Enterobacteriaceae are bacteria commonly found in the human intestinal tract. Over the past decade these bacteria have become increasingly resistant to antibiotics known as carbapenems which are used to treat patients with severe infections. Such bacteria are called carbapenem-resistant Enterobacteriaceae or CRE. CRE pose a significant global threat to public health as they cause infections which are easily spread and are associated with high mortality rates. CRE infections are more common in countries where the use of antibiotics is not as regulated as it is in the UK.

The spread of CRE can be prevented by screening patients who have recently been in hospitals (in the UK or abroad) known to have problems with CRE. However, the European Centre for Disease Control also advises screening patients who have recently travelled to countries known for their high rates of CRE, even if they were not in contact with a healthcare institution.

This study aims to establish whether or not NHS Trusts are indeed screening all such high risk patients and if not why. The results will provide useful information for Infection Prevention and Control teams who are currently developing or reviewing their own CRE screening policies.

17 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.

18 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.

19 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).

20 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.

21 Head & Neck 5000 Follow Up Study

Head & Neck 5000 is a large observational study of people with head and neck cancer from across the United Kingdom. The overall aim of the Head & Neck 5000 Follow-up Study is to describe the social, lifestyle and clinical outcomes in people with head and neck cancer and relate these to information gained from the original Head & Neck 5000 study. In order to achieve this, participants who have taken part in Head & Neck 5000 for at least three years will be sent an invitation to complete the Follow-up Study questionnaire. Data will be collected from the medical notes and through linkage to national databases for all participants who consented to this.

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 Pharmacists' perceptions of patient medicines helplines.

The aim of the study is to explore pharmacy professionals' perceptions of the benefits of patient medicines helplines, their limitations, and ways that they can be improved. Through learning about pharmacy professionals' experiences and perceptions of medicines helpline services, we aim to make suggestions to improve how helplines are operated so that they better meet the needs of service users and providers. This accords with the NHS agenda of seeking service providers' views and experiences to improve service quality.

24 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.

25 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.

26 MindSHINE 3

Stress, anxiety and depression are significant causes of sickness absence among NHS employees, and contribute to the NHS having higher rates of sickness absence than any other public sector organisation in the UK. The effects of psychological distress not only impact healthcare workers as individuals, but can also have negative consequences for their patients via a compromised quality of care.

The term mindfulness refers to a specific way of paying attention, non-judgmentally, to present moment experiences. The development of mindfulness skills is considered to lead to a number of therapeutic benefits including increased compassion for oneself and others, and reductions in negative emotional states. A wealth of empirical research supports the effectiveness of mindfulness-based interventions (MBIs) among both clinical and non-clinical populations. More specifically, recent research reports significant benefits of traditionally delivered, face-to-face MBIs among NHS employees, and mindfulness-based self-help (MBSH) among medical students. Especially when considering the limited number of qualified practitioners available to deliver face-to-face MBIs, and the 24/7 nature of NHS working hours, MBSH may offer particular potential among NHS employees in terms of flexibility, accessibility

and cost-effectiveness.

The proposed Randomised Controlled Trial (RCT) is primarily intended to investigate the effectiveness of smartphone-delivered MBSH intervention 'Headspace' in reducing stress among NHS staff. A large sample of NHS staff will be randomly allocated to receive either Headspace or an active control condition (NHS website for work-stress). The RCT will also aim to answer questions relating to the effectiveness of Headspace in improving other markers of psychological well-being and psychological distress, sickness absence, and compassion. Objective and subjective measures of engagement will be taken, and mediation and moderation analysis will be conducted in order to establish the processes and factors influencing MBSH engagement and outcomes.

27 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.

28. Ex-vivo Infection Detection - EVIDEnT

Burn wound infections are difficult to diagnose. Diagnosis involves removing dressings, which may slow the healing process. A new dressing (SmartwoundT) may help to diagnose infection without needing to remove dressings, and capsules within the dressing will change colour if the number of bacteria in the burn wound indicate that it is infected. Before it is used with patients, we need to check whether the capsules can identify when bacteria are, or are not, present in wounds. This study will use samples from patients with and without infected wounds to check whether the capsules change colour in the presence of bacteria that are causing a wound infection. The samples will come from burn wound fluid (exudate) taken from used wound dressings, and from swabs and gauze used during normal care of patients with burns. Both adults and children with and without infected burn wounds, who attend one of four participating Burns Services will be asked to participate. Participants will be asked to consent to have their dressings kept by the study team once they have been removed during the course of their normal treatment, and for swab samples to be taken. From these a sample of exudate will be tested. Information will be recorded from participants' notes about their health, care, suspected presence of infection and need for antibiotics. Participants will be followed-up within 21 days, either as part of normal scheduled clinic visits or by phone, and will be asked about their wound healing and health status. The Smartwound dressing's ability to detect infection will be measured using visual assessment of colour change. Bacteria from the swab will be tested separately to confirm presence of infection. Findings from this study will indicate whether capsules are effective in detection of infection prior to studies into the development of their use in dressings.

29. 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.

30. 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.

31. 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.

32. 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.

33. 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.

34. 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.

35. 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

36 The co-administration of multiple drugs in intensive care units

Critically ill patients, especially those admitted to intensive care units (ICUs) tend to receive numerous drugs intravenously (IV) which can sometimes outnumber the available sites on the body for IV administration. Therefore, multiple drugs are administered through the same line using a Y-site connector, which is a small device that can be connected to the lumen of a central or peripheral venous catheter, allowing drugs to be mixed together in the tubing of the lumen before entering the patients' bloodstream. Co-administration of drugs in this way increases the risk of combining drugs which may not be compatible with each other. Mixing of incompatible drugs can result in chemical or physical reactions that may reduce the efficacy of one or more of the drugs. This could lead to patient harm or prolonged treatment. It is therefore important that IV drug compatibility is known and can be determined by healthcare professionals before co-administration. Data on compatibility is fairly limited with nurses sometimes using alternative ways to administer medicines safely to patients. This study aims to understand the practice surrounding coadministration of multiple medicines and collate drug combinations nurses would like to have compatibility information on.

37 Experiences of using NHS patient medicines helplines

Research suggests that recently discharged hospital patients often lack information about their prescribed medicines. Patient medicines helplines enable discharged patients to speak to a hospital pharmacist for medicines information. Patients can also call about medicines errors, and studies suggest that between 19-39% of calls avoid harm to patients. However, studies also suggest that patient medicines helplines are not as widely used as they could be. On average, acute Trusts receive 8 calls per week, and only 52% of Trusts in England currently provide the service.

Service evaluation survey studies have been conducted to examine what patients think of

medicines helplines. However, such studies have limitations. For example, surveys include questions and answer options which are important to the researcher, rather than allowing participants to provide information that is important to them. Also, service evaluations may be prone to bias, since they are typically conducted by the service operators. We would like to know more about the benefits of medicines helplines, and ways that they could be improved. Establishing this may help to increase their availability and use. To achieve this, qualitative research methods would be preferable.

This study involves carrying out interviews with patients and carers within one month of them using a medicines helpline service. The aim of the study will be to explore service users' experiences of the service, and how things have been for them since. Interviews will enable participants to use their own words to describe their experiences. Through learning about service users' experiences of patient medicines helplines, we aim to make suggestions to improve how helplines are operated so that they better meet the needs of patients and carers. This accords with the NHS agenda of seeking patients' and carers' views and experiences to improve service quality.

38 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.

39. S100 & CD31 in tongue cancer (Perineural and vascular invasion in tongue cancer: is detection improved using markers for nerves and blood vessels?)

Microscopic invasion of nerves and blood vessels in oral cancer is an unfavourable prognostic indicator, but depends on the histopathologist sampling the tumour adequately and then identifying these features in tissue sections using routine haematoxylin and eosin (H&E) stains. There is evidence that suggests that staining the section for a marker of nerves (S100 protein) and the cells lining blood vessels and capillaries (CD31) increases the microscopic detection of perineural and vascular invasion by 52% and 12% respectively. Thus nerve and vascular invasion could be significantly underreported.

We are currently auditing the incidence of perineural and vascular invasion by cancers arising in subsites swithin the oral cavity, and aim to assess the degree of underreporting, if any, in a sample of 60 cancers of the tongue. Thirty of these were originally reported as showing nerve invasion in the excision specimen, thirty were reported as negative. Only two were reported as showing vascular invasion.

40. Molecular prediction of metastasis in oral tongue squamous cell carcinoma (external study)

A cDNA microarray study carried out in Utrecht (Netherlands) discovered genetic differences between primary squamous cell carcinomas of the oral cavity and oropharynx that spread to the neck and those that do not. This work leaves the door open to genetic analysis of a tumour of the tongue that has yet to spread to the neck. It may be possible to check the genetic makeup of the tumour, using a combination of antibodies to help surgeons decide how likely a tumour is to spread to the neck and to decide whether or not a neck dissection operation or radiation to the neck is necessary. This could avoid unnecessary morbidity and mortality. Patients with squamous cell carcinoma of the oral tongue are to be identified with at least 5 year follow up i.e. diagnosed before October 2004. Two groups are to be identified: those with spread to the neck, and those who did not develop spread to the neck. Case notes are to be reviewed and all clinical data and treatment, overall and event free survival are to be recorded. The histopathology slides and blocks of tumour archival material are to be identified will be used to make a tissue microarray. This is a research technique which allows for genetic analysis of samples to be done more quickly than routine techniques. No new samples

	collection or patient interventions are to be undertaken. The data will then be analysed to see which markers show differential expression between the two groups, or have relationship to overall and event free survival. These markers, used in combination, may be used in future prospective studies and in treatment planning. **Planned projects – studies which had not been given Approval as of 01/04/19, but which are expected to start in 2019-20** • Facial muscle responses with reported pain scores • SAVER • Allotex 3 • SPACE • IDose

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.