Queen Victoria Hospital
NHS Foundation Trust

Research & Development Annual Report 2016-2017

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Foreword

This has been a busy and successful year for research at the Queen Victoria Hospital. Research underpins the excellent care we strive to deliver, and the reputation of the hospital is founded upon a long tradition of ground-breaking innovative research that stretches back sixty years.

I am happy to say that there has been a significant upswing in both the quantity of studies undertaken and the number of patients recruited into high-quality projects during the last year. We have recruited 333 patients into studies on the NIHR national portfolio in 2016/17. This represents a six-fold increase in recruitment into studies that are deemed to be of national importance. Several of these prestigious projects are 'home grown'. Charles Nduka is a recipient of an NIHR i4i award. I have just completed a study funded by the Research for Patient Benefit scheme run by the NIHR. We are also forging increasingly strong alliances with several academic partners, who have acknowledged our ability to deliver studies to time and target. Particular examples of this are our collaboration with the University of Oxford in their research into Dupytrens contracture. This is a common debilitating disease for which many patients are treated at the QVH. We have also worked with the University of Nottingham to develop new techniques to treat facial palsy.

Our increased research activity has made us increasingly reliant on our very hard-working research team. Gail Pottinger, Simon Booth and Debbie Weller have worked hard to ensure that as many patients as possible are offered the opportunity to be involved in research. Sarah Dawe and Emma Foulds have been instrumental in making sure that we comply with the serpentine regulatory framework that governs research within the NHS. I congratulate the team on all their hard work, and it is certainly now bearing fruit. We will have difficulty sustaining this pace of growth in our activity though, unless our local CRN are able to provide additional funding support. We hope this doesn't prevent us from taking part in all the projects that are open to us in the forthcoming 2017/18 year.

Our seventh annual Trust Research Day was particularly successful. We were pleased to welcome our first international keynote speaker, Professor Koshima from the University of Tokyo Hospital, who came to describe the latest advances in microsurgery. He paid tribute to the contribution of QVH surgeons in the development of plastic surgical techniques.

We bid farewell to Dr Brian Jones who had been on secondment from the University of Brighton as the director of research development. We learnt the value of having academic partners, and we wish Brian well in his new role.

The Blond McIndoe Research Foundation (BMRF) closed its laboratories at the end of 2016. This was a sad day for research at the QVH. The laboratories have been on the QVH site for many years, and there have been many successful projects between the BMRF scientists and our clinicians during this time. However the BMRF have now changed the way that they support research. They are moving towards becoming an independent grant-awarding body, rather than undertaking research within their own laboratories. I am glad to say that the QVH has been one of the first recipients of funding from the reborn BMRF. They have kindly made a substantial grant to support the work we have been doing to collect discarded scar tissue in an attempt to understand why patients develop scars. We hope this will be the start of a new and successful collaborative relationship.

Julian Giles
Clinical Lead for R&D
Consultant Anaesthetist

Highlights

- QVH has had an extremely successful year for activity in National Portfolio research studies. We have significantly increased the number of participants recruited into these studies, as well as increasing the overall number of studies we are involved in. Recruitment increased from 55 in 2015-16 to 352 in 2016-17, with the number of Portfolio studies increasing from 6 to 26. This reflects a major strategic push to develop our Portfolio activity. We also have several major studies in the pipeline for 2017-18, so expect this boost in recruitment to continue.
- The Trust had six fully grant-funded studies ongoing in 2016-17. We are a collaborator on an MRC (Medical Research Council) grant with the University of Brighton for an award to develop novel infection detection dressings. The grant was worth £1.2 million across all partners.
- We are also the 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 fund a study 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 (National Institute for Health Research) RfPB grant-funded study (£79,688) looking at non-site-specific pain following breast surgery, whilst the Burns Department was working on a collaborative study with the BMRF (Blond McIndoe Research Foundation) funded by a grant from Sparks (£211,402**)** to look at the use of sprayed cells on paediatric burns. The grant supported the full-time salary of a PhD researcher.
- Our Burns Research Nurse Simon Booth has been working on an NIHR grant-funded MRes at the University of Brighton (£37,504), and further nurse (Liz Blackburn) is also undertaking an NIHR-funded MRes.
- The Trust currently has four Chief Investigators on National Portfolio research studies (Julian Giles, Baljit Dheansa, Simon Booth and Charles Nduka), and two members of NIHR faculty (Julian Giles and Charles Nduka). It is unusual for a Trust of our size to have either Chief Investigators or NIHR faculty on their staff.
- We have begun recruitment for a major new study looking at potential biomarkers in the role of scar formation. Funding has been secured for the purchase of lab equipment and materials necessary for the study, and for 4 days/week of a lab-based researcher to carry out the study.
- We have established a very successful programme of regular undergraduate projects with Brighton and Sussex Medical School. This year we hosted our seventh cohort of students, who spent nine months of their 4th year with us working on research/audit projects, supervised by QVH consultants. Their studies were all presented at our Research Day on Monday 27 June. Students have been greatly impressed with the support they have received at QVH, and the departments they have worked in have also benefitted from the energy students have brought to studies. These projects have also helped to foster closer links with our colleagues at BSMS.
- We were very fortunate to have two high-profile speakers at our seventh annual Research Day in June. Prof Isao Koshima (University of Tokyo Hospital) spoke to a packed audience about advances in microsurgery, and Prof Matt Costa (University of Oxford) presented the DRAFFT trial and changing clinical practice in UK trauma. Our Research Days are helping to build a multidisciplinary approach, and foster a culture where participation in R&D is a regular part of clinical life.
- The Trust is grateful for the continuing support of the CRN, who have awarded core funding to support a variety of research posts at the hospital. We are actively working with the CRN to grow research in Portfolio studies and to continue to improve set-up times.

Research Activity

The number of patients receiving NHS services provided or sub-contracted by the Queen Victoria Hospital NHS Foundation Trust in 2016-17 that were recruited during that period to participate in research approved by a research Ethics Committee was 365.

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 32 clinical research studies in 2016-17, as per the tables below.

Study ref in appendix	Study	Start date	CI/PI	Status	National Portfolio study	Recruit-ment in 2016-17
1	Epidemiology of Critical Care provision after Surgery (EpiCCS) - SNAP 2	21/03/17	Julian Giles	Closed	Yes	104
2	Implementation, impact & costs of policies for safe staffing		External	Registered	Yes	0
3	MindSHINE 3	20/03/17	External	Open	Yes	10
4	A nationwide survey of prosthetic eye users: a collaborative study with all NHS ocular prosthetic service providers.	21/02/17	Raman Malhotra / Emma Worrell	Open	No	0
5	Developing and validating a new self-report measure of compassion	27/01/17	Jenny Gu (External)	Open	Yes	17
6	Knowledge, attitudes and perceptions of 1. General practitioners 2. Junior doctors 3. Antimicrobial pharmacists 4. Dentists & nurses towards antimicrobial prescribing in England		External	Registered	Yes	0
7	Intraoperative Hypotension in Elder Patients (IHypE)	30/11/16	Julian Giles	Open	Yes	14
8	Ex-vivo Infection Detection - EVIDEnT	15/11/16	Simon Booth	Open	Yes	16
9	Evaluating the ten year impact of the Productive Ward		External	Registered	Yes	0

10	Antibiotic Levels in Burn wound Infection (ABLE)	01/09/16	Simon Booth	Open	Yes	8
11	EuPatch	01/07/16	Samer Hamada	Open	Yes	1
12	Informing the Development of Online CBT Materials for an Integrated Approach to Delivering CBT		External	Open	Yes	0
13	Mycobacterium szulgai infections - a case series from England and Wales		External	Open	Yes	1
14	WEB-RADR - Comparison of ADR reports received via Yellow Card app with casenotes		External	Open	Yes	0
15	Repurposing anti-TNF for treating Dupuytren's disease (RIDD)	03/10/16	External	Suspended	Yes	0
16	Investigation of Potential Biomarkers in the Role of Scar Formation	16/03/16	Baljit Dheansa	Open	No	5
17	Use and usefulness of patient experience data: national survey of patient experience leads in NHS acute trusts		External	Registered	Yes	0
18	A Study to Address Some Human Resource Planning/ Development Issues in the seven day NHS to Bridge Skill Gaps in Hospitals		External	Registered	Yes	0
19	A survey to provide baseline activity in relation to ward sister/charge nurse supervisory roles		External	Registered	Yes	0
20	SUBMIT	13/09/16	Asit Khandwala	Open	Yes	6
21	NexoBrid for children with thermal burns	24/05/16	Baljit Dheansa	Open	Yes	0
22	A study to refine the CAR burns scales	03/11/15	Simon Booth	Closed	Yes	16
23	Molecular mechanisms and pathways of chronic inflammatory and degenerative diseases. (Dupuytren's patients)	30/11/15	Loz Harry	Open	Yes	126
24	SILKIE	30/09/15	Simon Booth	Closed	Yes	33

25	Incidence of obstructive sleep apnoea risk in surgical patients	16/06/14	Tim Vorster	Suspended	No	0
26	Post-treatment Care Pathway in Long-term Head & Neck cancer	16/07/14	Brian Bisase	Closed	No	8
27	Molecular Genetics of Adverse Drug Reactions	31/01/12	Baljit Dheansa	Open	Yes	0

Study ref in appendix	Studies not involving patient recruitment in 2016-17	Start date	Principal Investigator
28	Extrinsic lingual muscle involvement by oral cancer	28/09/15	Bill Barrett
29	S100 and CD31 in tongue cancer	01/06/14	Bill Barrett
30	Molecular prediction of metastasis in oral tongue squamous cell carcinoma	19/07/12	Bill Barrett
31	Clinical evaluation of the effect that sprayed culture keratinocytes have on early wound healing in children (grant funded)	20/09/11	Baljit Dheansa

Study ref in appendix	Studies fully recruited and in follow up during 2016-17	Start-date	Chief Investigator
32	The effectiveness of Lugols Iodine to assist excision of marginal dysplasia at resection of oral and oralpharyngeal squamous carcinoma	10/07/12	Paul Norris

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 accrual figures. In a very pleasing development, the number of Portfolio participants recruited greatly exceeded the number of non-Portfolio, reflecting a strategic push to increase the proportion of Portfolio studies we undertake.

QVH recruited **352** Portfolio participants in 2016-17 – up from 55 the previous year.

Funding

Grant funding

The Trust had six fully grant-funded studies ongoing in 2016-17. 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 fund a study 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.

We are also a collaborator on a MRC (Medical Research Council) grant application with the University of Brighton for an award to develop novel infection detection dressings. The grant was worth **£1.2 million** across all partners, with **£19,403** for QVH.

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, whilst the Burns Department was working on a collaborative study with the BMRF funded by a grant from Sparks (**£211,402)** to look at the use of sprayed cells on paediatric burns. This grant supported the salary of a PhD researcher.

Our Burns Research Nurse Simon Booth was working on an MRes at the University of Brighton, funded by an NIHR grant for **£37,504**, and a further nurse (Liz Blackburn) was also engaged on an NIHR-funded MRes (also with full salary cover).

Core funding

The CRN awarded the Trust **£65,541** core funding in 2016-17, **£7500** flowthrough funding, and **£3014** contingency funding. The CRN determined the 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**
Research Practitioner	Debbie	Weller	34,766
Research Nurse	Simon	Booth	15,177
Research Nurse	Gail	Pottinger	2367
Consultant	Julian	Giles	4657
Consultant	Loz	Harry	3014
Clinical Trials Pharmacist	Judy	Busby	1668
R&D Manager	Sarah	Dawe	10,678
Training			214
Office expenses			187
Travel			341
Overheads			2986

The Trust also received **£4,500** from the Brighton and Sussex Medical School to support the IRP students who undertake fourth-year research projects at the hospital.

Commercial and other external study funding

Further income was received for undertaking external trials in 2016-17 as follows:

External study	**Income (£)**

Thea	2821
Nexobrid	3314
Silkie	8755
RIDD	5300

Charitable Funding

The Blond McIndoe Research Foundation generously provided funding for a 0.8WTE Research Technician to work on a study investigating potential biomarkers in the role of scar formation.

Publications

Within the R&D Community we have often struggled to understand how we define the role of 'development'. Development is clearly important, but what is it and how we define its success is more difficult. One way of considering what development might be is to consider how things we do at the QVH affect people elsewhere. The QVH has long influenced the way that care is delivered within the broader health care community. Our influence extends far beyond the confines of East Grinstead.

At the suggestion of James Gardiner, one of the much valued lay members of the R&D Governance Group, we have included a synopsis of the publications that the clinicians at the QVH have contributed to in the last year. We consider that this provides some measure of how we help to develop excellent care. The 'gold standard' for research is usually considered to be a controlled clinical trial. We are pleased to say that the QVH is heavily involved in clinical trials. We develop 'home grown' studies and we also act as a centre for 'multi-centre' clinical trials. However, research trials are only the tip of the iceberg. Evidence-based healthcare also relies on people producing high quality publications that describe things such as case series, editorials, and the drawing up of guidelines by acknowledged experts. I am happy to say that all these types of publication are represented in the list below. As you will see many of these publications are not purely 'research' but often showcase how the ideas developed at the QVH can affect the way care is delivered far more broadly.

Cooper L, Lui M, Nduka C. Botulinum toxin treatment for facial palsy: A systematic review. J Plast Reconstr Aesthet Surg. 2017 Jun;70(6):833-841. doi: 10.1016/j.bjps.2017.01.009. Epub 2017 Feb 16. Review. PubMed PMID: 28389084.

Hussain A, Nduka C, Moth P, Malhotra R. Bell's facial nerve palsy in pregnancy: a clinical review. J Obstet Gynaecol. 2017 May;37(4):409-415. doi: 10.1080/01443615.2016.1256973. Epub 2017 Jan 31. PubMed PMID: 28141956.

Cooper L, Mosahebi A, Henley M, Pandya A, Cadier M, Mercer N, Nduka C. Developing procedure-specific consent forms in plastic surgery: Lessons learnt. J Plast Reconstr Aesthet Surg. 2017 Mar;70(3):428-430. doi: 10.1016/j.bjps.2016.11.015. Epub 2016 Nov 26. PubMed PMID: 27964830.

Ziahosseini K, Venables V, Neville C, Nduka C, Patel B, Malhotra R. Occurrence and severity of upper eyelid skin contracture in facial nerve palsy. Eye (Lond). 2016 May;30(5):713-7. doi: 10.1038/eye.2016.21. Epub 2016 Mar 4. PubMed PMID: 26939561; PubMed Central PMCID: PMC4869134.

Malhotra R, Ziahosseini K, Litwin A, Nduka C, El-Shammah N. CADS grading scale: towards better grading of ophthalmic involvement in facial nerve paralysis. Br J Ophthalmol. 2016 Jun;100(6):866-70. doi: 10.1136/bjophthalmol-2015-307167. Epub 2015 Oct 15. PubMed PMID: 26472405.

Neville C, Aslett M, Venables V, Nduka C, Kannan R. An objective assessment of Botulinum toxin type A injection in the treatment of post facial palsy synkinesis and hyperkinesis using the Synkinesis Assessment Questionnaire (SAQ). Journal of Plastic Reconstructive & Aesthetic Surgery · June 2017. DOI: 10.1016/j.bjps.2017.05.048

Mavridou, I., McGhee, J. T., Hamedi, M., Fatoorechi, M., Cleal, A., Ballaguer-Balester, E., Cox G, Nduka, C. FACETEQ interface for emotion expression in VR. In Virtual Reality (VR), 2017 IEEE (pp. 441-442). IEEE.

Br J Oral Maxillofac Surg DOI: http://dx.doi.org/10.1016/j.bjoms.2017.04.014 Care of long-term survivors of head and neck cancer after treatment with oral or facial prostheses, or both. E. Worrell, L. Worrell, B. Bisase

J Laryngol Otol. 2016 May;130(S2):S83-S89 Oral cavity and lip cancer: United Kingdom National Multidisciplinary Guidelines. Kerawala C, Roques T, Jeannon JP, Bisase B

Int J Surg Pathol 2016 Sep 12. Epub 2016 Sep 12. Dentigerous Cyst and Ameloblastoma of the Jaws: Correlating the Histopathological and Clinicoradiological Features Avoids a Diagnostic Pitfall. Andrew W Barrett, Kenneth J Sneddon, John V Tighe, Aakshay Gulati, Laurence Newman, Jeremy Collyer, Paul M Norris, Darryl M Coombes, Michael J Shelley, Brian S Bisase, Rachael D Liebmann

Br J Oral Maxillofac Surg 2015 Sep 29. Epub 2016 Sep 29. Current surgical management of metastases in the neck from mucosal squamous cell carcinoma of the head and neck. Ben Green, Brian Bisase, Daryl Godden, David A Mitchell, Peter A Brennan

Head and neck sarcomas: A single institute series. Vassiliou LV, et al. Oral Oncol. 2017. Vassiliou LV, Lalabekyan B, Jay A, Liew C, Whelan J, Newman L, Kalavrezos N.

Transoral laser microsurgery versus radiation therapy in the management of T1 and T2 laryngeal glottic carcinoma: which modality is cost-effective within the UK? Prettyjohns M, et al. Clin Otolaryngol. 2017.

Prettyjohns M, Winter S, Kerawala C, Paleri V; the NICE cancer of the upper aerodigestive tract guideline committee. Robinson M, Bhide S, Capel M, Cox L, Fenlon M, Newman L, Orr S, Roques T, Smith A, Spraggett S, Talwar B, Thavaraj S, Thornton J, Wong WL.

Mucosal melanoma of the upper airways tract mucosal melanoma: A systematic review with meta-analyses of treatment. Jarrom D, et al. Head Neck. 2017. Jarrom D, Paleri V, Kerawala C, Roques T, Bhide S, Newman L, Winter SC.

Dentigerous Cyst and Ameloblastoma of the Jaws. Barrett AW, et al. Int J Surg Pathol. 2017. Barrett AW, Sneddon KJ, Tighe JV, Gulati A, Newman L, Collyer J, Norris PM, Coombes DM, Shelley MJ, Bisase BS, Liebmann RD.

Inflammatory pseudotumour of the maxilla. Kichenaradjou A, et al. Oral Maxillofac Surg. 2016. Kichenaradjou A, Barrett AW, Norris P, Rowell N, Newman L.

Current Concepts in Osteoradionecrosis after Head and Neck Radiotherapy. Dhanda J, et al. Clin Oncol (R Coll Radiol). 2016. Dhanda J, Pasquier D, Newman L, Shaw R.

Efficacy, outcomes, and complication rates of different surgical and nonsurgical treatment modalities for recurrent/residual oropharyngeal carcinoma: A systematic review and meta-analysis. Jayaram SC, Muzaffar SJ, Ahmed I, Dhanda J, Paleri V, Mehanna H. Head Neck. 2016 Jul

Current Concepts in Osteoradionecrosis after Head and Neck Radiotherapy. Dhanda J, Pasquier D, Newman L, Shaw R. Clinical Oncology (R Coll Radiol). 2016 Jul 28(7):459-66.

The Molecular Biology of Head and Neck Cancer. Dhanda J, Shaw RJ In: Maxillofacial Surgery. Brennan et al (Ed). 2017 3rd Edition. UK Churchill Livingstone

Facial Feminization Surgery. Altman K In: The Transgender Handbook: A guide for transgender people, their families and professionals. . Eds: Bouman WP, Arcelus, J. 2017. Nova Science Publishers. New York.

The Role of the Orthognathic Surgeon in Facial Feminization Surgery. Altman K. In: Orthognathic Surgery: Principles, Planning & Practice. Eds: Naini FB, Gill DS. 2017. Wiley Blackwell

Roxburgh, J., A. D. Metcalfe, and Y. H. Martin. The effect of medium selection on adipose-derived stem cell expansion and differentiation: implications for application in regenerative medicine. Cytotechnology 68.4 (2016): 957-967.

Masud, D., Moustaki, M., Staruch, R. and Dheansa, B., 2016. Basal cell carcinomata: Risk factors for incomplete excision and results of re-excision. Journal of Plastic, Reconstructive & Aesthetic Surgery, 69(5), pp.652-656.

Staruch, R.M.T., Jackson, P.C., Hodson, J., Yim, G., Foster, M.A., Cubison, T. and Jeffery, S.L.A., 2016. Comparing the surgical timelines of military and civilians traumatic lower limb amputations. Annals of Medicine and Surgery, 6, pp.81-86.

Sayma, M., Booth, S., Weller, D. and Dheansa, B., 2017. A retrospective study: Can we differentiate between repeat self-inflicted burn patients and those who commit a self-inflicted burn as an individual occurrence?. Journal of Plastic, Reconstructive & Aesthetic Surgery.

Gilleard, O., Walsh, K., King, I., Tsang, C., Rahman, S. and Dheansa, B., 2016. Evaluation of a new suture otoplasty technique. JPRAS Open, 7, pp.16-18.

Weir, A.G., Page, P.R. and Dheansa, B.S., 2016. Comparison of Short-Term Surgical Outcomes Between NHS and Private Sector Abdominoplasty Surgery. In Aesthetic Plastic Surgery of the Abdomen (pp. 523-526). Springer International Publishing.

Effect of Manuka Honey on Eyelid Wound Healing: a Randomised Controlled Trial
R Malhotra, K Ziahosseini, C Poitelea, A Litwin, S Sagili Ophthal Plast Reconstr Surg. 2016 Jul 13. [Epub ahead of print]

Can we improve the tolerance of an ocular prosthesis by enhancing its surface finish? AS Litwin, E Worrell, JCP Roos, B Edwards, R Malhotra Ophthal Plast Reconstr Surg. 2017 Mar 7. doi:10.1097/IOP.0000000000000891

Periorbital Autologous Fat Grafting in Facial Nerve Palsy. WF Siah, AS Litwin, C Nduka, R Malhotra. Ophthal Plast Reconstr Surg. 2017;33(3):202-208.

Emergency Eye Care of Post-surgical Facial Palsy - Technical Tip: External Weights to treat lagophthalmos. K Ziahosseini, V Venables, C Neville, C Nduka, R Malhotra. (Accepted J Neurol Surg B Skull Base – July 2016)

A hazard of hyaluronidase use for orbital blocks. P Tan, SM Ali, R Malhotra Anaesthesia. 2016 Aug;71(8):988-9. doi: 10.1111/anae.13597.

Orbital exenteration: review of indications, technique and complications. S Sagili, R Malhotra (Accepted Expert Review of Ophthalmology-May 2016)

Infrastructure

The R&D Department presently consists of one Clinical Lead for R&D, one R&D Manager (0.66WTE) and one Research Governance Officer (13.8 h/wk).

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, pay a fee for R&D Department services in handling their applications and setting up contracts.

Clinical Research Staff

In 2016-17, the Trust supported one Burns Research Nurse (0.5WTE), one Lead Research Nurse (0.5WTE) and one 1WTE Research Practitioner.

The Anaesthetics Dept has one Research Registrar (0.2WTE). These have traditionally been funded out of clinical budgets, but increasing support for them is being obtained from grant awards.

The Trust supported two MRes students in 2015-16, funded by grant awards. The students were registered at the University of Brighton.

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.

Comprehensive Research Network (CRN)

The Trust is a member of the Surrey, Sussex and Kent 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 Clinical Lead for R&D sits on the CRN Partnership Board, and the R&D Manager regularly attends local meetings, working closely with their Chief Operating Officer and the Lead Research Management & Governance Manager. Meeting CRN targets is a priority area for the Trust.

CRN targets

National targets have been introduced to stretch and improve performance, with a variety of metrics being measured. Study set-up time and time to first recruit and were tracked according to national metrics, with regular data returns made to both the CRN and the NIHR. These reports are made publically available on the QVH website.

QVH has performed extremely well on these high level objectives, with a mean time from Date Site Selected to Date Site Confirmed (local QVH approval) of **13 days** in 2016-17.

Intellectual property

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 advising us on royalties for a tracheostomy dressing device originally developed at QVH.

Consumer involvement

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. 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 & television, in newsletters (QVH News, Research & You). We have also used leaflets, posters and videos within the hospital to inform patients and the public of the research we do.

Training and Development

The Trust supported (via grant awards) two nurses to undertake MRes courses at the University of Brighton, and one (grant funded) PhD student, also registered at the University of Brighton.

Local Training

Individual training 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 Claire Rosten from the University of Brighton, who 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.

The R&D Manager regularly attends induction to speak to all new clinical recruits. They are all issued with an R&D pack which includes all up to date R&D policies. This is a useful forum to quickly identify trainees who are interested in R&D, and provide them with guidance and assistance.

CRN training

The Trust also has access to training provided by the CRN for any studies which are accepted onto the National Portfolio. These mainly focus on GCP training, but training is also provided for research nurse skills.

Annual Trust R&D Day

We were delighted with the success of our seventh Trust R&D Day on 27 June 2016, which featured two very high profile speakers - Prof Isao Koshima (University of Tokyo Hospital) and Prof Matt Costa (University of Oxford), as well as showcasing current and planned studies from QVH staff, and studies undertaken by Brighton and Sussex Medical School IRP students. These meetings have proved to be very popular with clinicians from all departments. The full programme was as follows:

- BSMS IRP student presentations (Benjamin Moxley-Wyles; Syed Naqib; Dhiraj Sharma; Parviz Sorooshian) and Prize Giving
- University of Brighton translational research (Bhavik Patel, Colin Smith, Greg Scutt)
- Prof Isao Koshima (University of Tokyo Hospital)

- Prof Matt Costa (University of Oxford) – The DRAFFT trial and changing clinical practice in UK trauma
- University of Brighton and QVH joint projects (Simon Booth, Diana Alves)
- QVH research groups updates (Sue Catt, MJ Hallam, Jag Dhanda, Charles Nduka)

Departmental research meetings

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

Research Design Service

Our Research Design Service (RDS) at the University of Brighton provides a good service in training staff in RfPB grant applications, and supporting individual researchers 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, Director of Nursing, Oncoplastics Lead, Healthcare Science Lead, Orthodontics Lead, R&D Manager, Finance Dept representative (R&D budget accountant), Designated Individual with responsibility for Human Tissue Authority license, External academic advisor from the BMRF, External academic advisor from BSMS, and two 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, and the R&D Manager provides a presentation to them once annually.

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, Overheads Policy. In addition, we have a comprehensive range of Standard Operating Procedures, in line with national guidance, to ensure consistency in our approach to R&D approvals: P02-Manage Study Participating Planning Tool v1; PO3 Confirm Study Approvals v1; PO4 Setup and Control External Agreements v1; PO5 Setup and Control Internal Agreements v1; PO6 Setup and Control Study Processes v1; PO7- Give NHS Permission v1; PO8-Oversee Study v1; S04-Ensure Study Funding and Approvals are Managed v1; S05-Manage Study Sponsor Planning Tool v1; S06-Give Decision on Sponsoring v1; S07-Provide and Manage External Agreements v1; S08-Ensure NHS Permission is Received by the CI v1; S09-Ensure Study Oversight v1; S10-Ensure Study Closedown is Managed v1.

R&D approvals

The Trust uses national systems to manage studies in proportion to risk, and has adopted the Research Support Services framework recommended Standard Operating Procedures (SOPs). The R&D Dept provides extensive guidance with using the national IRAS applications system. Researchers are given bespoke one-to-one support with their applications.

There are national CRN targets for the processing of R&D applications (40 days from the receipt of valid research application; 30 days from local approval to first recruit. QVH approval times for clinical trials and for commercial studies are reported quarterly to the NIHR, and published on the QVH website.

QVH has highly effective and efficient research approvals systems. Our mean time from receipt of valid application to local approval (Confirmation of Capacity and Capability) for all studies was **13 days** in 2016-17. Mean time to recruit of first participant for all studies that recruited in 2016-17 was **37 days** – this included one outlier study (148 days) which has been extremely difficult to recruit to nationally. The median time to first recruit from local approval was **26 days** for all studies that recruited in 2016-17.

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 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.

Registered Research & Development projects (with HRA Approval) ongoing in 2016-17

1. **Epidemiology of Critical Care provision after Surgery (EpiCCS) - SNAP 2**
   Principal Investigator: J Giles
   Status: Closed
   EpiCCS will describe the epidemiology of perioperative risk and outcome, and critical care referral and admission after inpatient surgery in the UK. A secondary aim is to estimate the clinical effectiveness of planned postoperative critical care admission as an intervention to reduce postoperative morbidity.
   EpiCCS will be a prospective observational cohort study.
   Data will be collected by perioperative anaesthetists on all patients undergoing inpatient surgery in participating UK hospitals for one week. Postoperative morbidity will be recorded for patients who remain in hospital on Day 7 after surgery. In a sub-group of patients, quality of recovery will also be recorded on Day 3, both for inpatients and for those already discharged from hospital (through telephone interview). Mortality data will be collected through linkage facilitated by the HSCIC. The dataset will also include patient risk factors, and questions about clinical decision-making and resource availability related to critical care referral and admission.
   The epidemiology of perioperative risk stratification, postoperative care and patient outcome will be described. Multivariable regression, instrumental variable and propensity score

matched analyses will be conducted to ascertain the clinical effectiveness of postoperative critical care admission in reducing adverse outcomes after inpatient surgery.

2. **Implementation, impact & costs of policies for safe staffing**
   Principal Investigator: External
   Status: ongoing
   The Francis Inquiry highlighted the lack of evidence-based decisions on nurse staffing as a factor contributing to poor care and higher death rates at Mid-Staffordshire. He recommended that the research evidence be used by NICE (the National Institute For Health and Care Excellence) to develop guidance on safe nurse staffing levels. Guidance for acute adult wards was published in 2014. NICE also endorsed the Safer Nursing Care Tool (SNCT), which estimates nursing staff requirements for acute hospital wards by assigning patients to one of five categories, based on how ill they are and the typical time taken to care for similar patients (known as 'dependency').

   Our study will examine implementation of safe staffing policies in the NHS. We will undertake a national survey to identify how implementation of safe staffing approaches have varied. At four case study sites we will examine implementation in more depth, using economic and qualitative methods. We will look at how patients' need for nursing care, as measured by the SNCT, varies from day to day and compare it to actual staffing, and explore the costs and consequences of different approaches

3. **MindSHINE 3**
   Principal Investigator: External
   Status: Open to recruitment
   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.

4. **A nationwide survey of prosthetic eye users: a collaborative study with all NHS ocular prosthetic service providers.**
   Principal Investigator: R Malhotra

Status: open
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.

5. **Developing and validating a new self-report measure of compassion**
Principal Investigator: External
Status: ongoing
Compassion is defined as consisting of the following five elements: (1) recognising suffering, (2) understanding the universality of suffering in human experience, (3) feeling moved by the person suffering and connecting with their distress, (4) tolerating uncomfortable feelings aroused (e.g. distress, anger, fear) so that we remain open to and accepting of them in their suffering, and (5) acting or being motivated to act to alleviate suffering. This definition of compassion was put forward following a review of theoretical conceptualisations of compassion. As part of the same review paper, the authors also systematically reviewed questionnaire measures of compassion and concluded that none of the existing measures comprehensively captured the construct and many had poor or inadequately tested psychometric properties. The current project aims to address the omission in the literature and develop a new, psychometrically-robust questionnaire measure of compassion, both towards the self and towards other people. Participants will be 1,300 NHS employees working in an NHS Trust in the Kent, Surrey, and Sussex region.

6. **Knowledge, attitudes and perceptions of 1. General practitioners 2. Junior doctors 3. Antimicrobial pharmacists 4. Dentists & nurses towards antimicrobial prescribing in England**
Principal Investigator: External
Status: ongoing

7. **Intraoperative Hypotension in Elder Patients (IHypE)**
Principal Investigator: J Giles
Status: Closed
Blood pressure falling during an operation is very common, particularly in those aged over 65. Despite this, there is no widely agreed definition on what blood pressure values constitute a 'low' reading and there remains some uncertainty over when to treat it despite the existence of national guidelines. The purpose of this study is to describe the lower limit of blood pressure encountered during surgery in those aged greater than 65 in the UK. It may be possible that managing blood pressure differently in the future might reduce strain on different body systems, including the kidneys, heart and brain.
This study involves the analysis of data routinely collected during normal clinical care. No additional treatments, observations or tests are being made. Routine information about health will be noted including: medicines, method of anaesthesia, operation, blood pressure as well as evidence of strain to the kidneys or heart from the results of routine postoperative blood tests.

8. **Ex-vivo Infection Detection - EVIDEnT**
Principal Investigator: S Booth
Status: recruiting

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.

9. Evaluating the ten year impact of the Productive Ward

Principal Investigator: External

Status: open

Our overall research question is whether the 'Productive Ward: Releasing Time to Care' programme (PW) has had a sustained impact at the clinical microsystem level in English NHS acute trusts since its introduction in 2007.

Clinical microsystems can be a team, practice, ward or clinical unit; this proposal focuses on a quality improvement intervention specifically designed to improve the efficiency of hospital wards. The PW programme aims to: (1) increase the proportion of time nurses spend in direct patient care, (2) improve experience for staff and patients, and (3) make structural changes to the use of ward spaces to improve efficiency in terms of time, effort and money. Consequently the PW has the potential to meet health needs (by improving the efficiency of care) and is directly concerned with the organisation and delivery of health care. The NHS Institute for Innovation & Improvement (NHSI) developed PW in 2005 and 2006 and first implemented it in England in 2007. It is a self-directed quality improvement (QI) toolkit consisting of three foundational or 'core' modules and eight process modules. In subsequent years, the PW has been adopted and implemented internationally.

Our study will identify and evaluate any sustained impacts and wider legacies of the PW in Trusts in England which have adopted the programme. We will explore how varying times of adoption ('early', 'late') and differing local approaches to implementation (e.g. whole hospital roll out, pilot wards) have shaped such impacts and/or wider legacies over the previous decade.

10. Antibiotic Levels in Burn wound Infection (ABLE)

Principal Investigator: S Booth

Status: Recruiting

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.

11. EuPatch

Principal Investigator: S Hamada
Status: recruiting
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.

12. Informing the Development of Online CBT Materials for an Integrated Approach to Delivering CBT

Principal Investigator: External
Status: open

13. Mycobacterium szulgai infections - a case series from England and Wales

Principal Investigator: External
Status: open

14. WEB-RADR - Comparison of ADR reports received via Yellow Card app with casenotes

Principal Investigator: External
Status: Open
At the moment reporting of adverse drug reactions by hospital personnel is mainly done by paper or through the web-based form. The aim of creating a new reporting tool, the app, is to increase reporting and to make reporting easy with the hope of gathering new information

about ADRs which will help to evaluate the benefit-harm of drugs. However, it is important to make sure that the reports received through the app capture the clinical data accurately. The following study will be aimed at investigating the accuracy and trustworthiness of reports received through the app. The live App data covers the whole of the UK. All adverse drug reactions reported through the Yellow Card app from patients and health care professionals (HCPs) nationally. HCPs will include pharmacists, doctors and nurse specialists. Depending on workload, the study team will investigate all reports, where the reporter agrees to supply extra information from patient case notes.

15. Repurposing anti-TNF for treating Dupuytren's disease (RIDD)

Principal Investigator: L Harry

Status: Suspended

Dupuytren's disease is a very common condition that causes the fingers to curl into the palm and can be extremely debilitating. In early disease hard nodules develop in the palm. There is no approved treatment for early disease. Once patients have established deformities, the diseased tissue can be removed surgically or cut using less invasive techniques such as a needle or an injection of an enzyme. However, recovery following surgery usually takes several months and the recurrence rates with the nonsurgical techniques are high.

We have unravelled the molecular mechanisms that start and maintain the disease process. Based on these findings we plan to test a drug currently approved for use in patients with rheumatoid arthritis. The drug will be injected directly into the diseased tissues in the palm to maximise it's effect. We will first conduct a small trial in 40 patients with established disease to determine the best dose inhibiting the activity of the cells responsible for the disorder (Part 1).

Next we will assess whether the drug at this dose prevents progression in 138 patients with early disease (Part 2). If effective, this will represent the first targeted therapy involving a simple injection for patient's with early Dupuytren's disease that will preserve hand function and avoid the need for surgery.

16. Investigation of Potential Biomarkers in the Role of Scar Formation

Principal Investigator: B Dheansa

Status: recruiting

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.

17. Use and usefulness of patient experience data: national survey of patient experience leads in NHS acute trusts

Principal Investigator: External

Status: Open

18. **A study to address some human resource planning/development issues in the seven day NHS to bridget sill gaps in hospitals**
Principal Investigator: External
Status: Open
An extensive analysis of the literature above led us to conclude that job re-design in a seven-day NHS will empower HCAs to perform skillfully, following a carefully designed/monitored skill-training package. This is exploratory research to generate data through structured interviews with health care assistants and their supervisors, as well as FGDs, observations and interactions with concerned professionals and recipients of services (patients and the public). The research questions are:

    a. How do HCAs experience nursing care as part of the skill-mix and modernisation strategies? What aspects of nursing care are needed in terms of a job re-design for HCAs and how far the modernisation strategy is replicable in an enriched job re-design for a seven-day NHS?

    b. How does the absence of clearly defined job descriptions for HCAs and registered nurses affect job satisfaction for HCAs and how this can be improved in a job re-design in seven day NHS?

    c. What new skills are needed by the HCAs to perform during weekends and evenings in an enriched job role?

19. **A survey to provide baseline activity in relation to ward sister/charge nurse supervisory roles**
Principal Investigator: External
Status: Open

20. **SUBMIT**
Principal Investigator: A Khandwala
Status: recruiting
Metacarpal fractures are common, accounting for 40% of all hand injuries and many can be treated non-operatively. However, surgery is reserved for cases in which an adequate reduction of both angular and rotational deformity cannot be maintained or where an adjacent ray is damaged.
A variety of surgical strategies exist, including percutaneous kirschner wiring, intramedullary fixation, and fixation with plate and screw construction. A plate secured along the dorsal midline of the metacarpal has been shown to be the best biomechanical method of fixation, and allows early aggressive hand therapy post-operatively.
Traditionally, bicortical fixation is the standard practice, where both dorsal and palmar cortices of the metacarpal are drilled though. However, such practice is not without risk. In this method, the flexor tendons and neurovascular bundles at risk from over-zealous drilling through the palmar cortice. Correct screw size selection is also critical as overly long screws can irritate and cause rupture of flexor tendon. More recently, with the advent of a new generation of locking plates, unicortical fixation, where only the near cortex is drilled, has been used to treat fractures. Unicortical fixation is a surgically less complex operation, can theoretically cause less damage to surrounding soft tissues and avoids the complications associated with incorrectly sized screws.
This trial aims to compares the functional outcomes and complications of patients having unicortical versus bicortical fixation for diaphyseal metacarpal fractures.

21. **NexoBrid for children with thermal burns**
Principal Investigator: B Dheansa
Status: recruiting
Nexobrid is a gel containing enzymes derived from the pineapple plant. These enzymes can remove or breakdown unhealthy tissue, thereby avoiding the need for surgery. Whilst

Nexobrid is approved for use in adults, it is currently not licensed for use in paediatric cases. The present study aims to assess the use of Nexobrid in children with deep burns between 1 and 30% total body surface area, versus standard of care.

22. A study to refine the CAR burns scales

Principal Investigator: S Booth
Status: PIC study
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.

23. Molecular mechanisms and pathways of chronic inflammatory and degenerative diseases

Principal Investigator: L Harry
Status: recruiting
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.

24. SILKIE - Can skin grafting success rates in burn patients be improved by using a low friction environment – a feasibility study?

Principal Investigator: B Dheansa
Status: closed
This study aims to find out if it is feasible to use low friction (slippery) sheets for burn patients requiring skin grafts.
Skin grafts are required to ensure healing after burns that are deeper or take longer than 21 days to heal. Each year approximately 1000 skin grafts are undertaken in England and Wales; 75% in adults and 25% in children (1). Around 20% will fail completely or partially, with some wounds needing re-grafting. Further surgery, taking skin from another part of the body, longer hospital stays and increased scarring are all consequences which can be distressing for patients and expensive for the NHS.
Graft loss can be caused by rubbing or stretching skin and moving new graft cells causing failure of attachment to the wound. Friction between dressings and bed sheets can cause

this rubbing or stretching causing shearing. If dressings and patients were able to slide over the sheet when the patient moves in bed, then the graft may have more chance of 'taking'. Reduced friction bed sheets are in use in the UK with premature babies and other patients to prevent pressure sores, but not yet in burns services.
Adult and paediatric patients with burns and scalds who are selected to undergo skin grafting to achieve healing after burn injury as part of normal clinical care and are nursed on sheets for at least one overnight hospital stay.

25. Quantifying the incidence of obstructive sleep apnoea (OSA) in a surgical cohort attending pre-assessment

Principal Investigator: T Vorster
Status: recruiting
OSA (obstructive sleep apnoea) is a condition that causes interrupted breathing during sleep as a result of a blockage or partial blockage to the airway. The resultant lack of oxygen causes the individual to come out of deep sleep in an attempt to restore normal breathing. This happens cyclically overnight and results in unrefreshed sleep. Symptoms can include loud snoring and regularly feeling tired during the day despite getting adequate sleep. We plan to screen all surgical patients for OSA using two validated screening tools called the STOP-Bang questionnaire and the Epworth Sleepiness Scale. Studies have shown that a STOP-Bang score of 4 or more OR an Epworth score of 12 or more is suggestive of OSA.

26. Post-treatment care pathway in long-term survivors of head and neck cancer with oral and/or facial prosthesis

Principal Investigator: N Ghazali
Status: recruiting
The study aims to understand the experience of the post-treatment pathway of care in a group of long-term HNC survivors; explore the impact of ablative HNC surgery; explore the perceived need of supportive care (i.e. allied health services, psychosocial care, peer support, and complementary care) both at long-term follow-up and, retrospectively, during treatment and at 2 years post-treatment; explore the usage of supportive care (i.e. allied health services, psychosocial care, peer support, and complementary care) at long term follow up, and retrospectively, during treatment and at 2 years post-treatment; and explore the outcomes of supportive care service usage valued by patients.

27. Molecular genetics of adverse drug reactions

Principle Investigator: B Dheansa
Status: open
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 ToxicEpidermal 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

28. Extrinsic lingual muscle involvement by oral cancer
Principal Investigator: Bill Barrett
Status: ongoing

29. S100 & CD31 in tongue cancer (Perineural and vascular invasion in tongue cancer: is detection improved using markers for nerves and blood vessels?)
Principal Investigator: Bill Barrett
Status: ongoing
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
within 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.

30. **Molecular prediction of metastasis in oral tongue squamous cell carcinoma (external study)**
Principle Investigator: B Barrett
Status: ongoing
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.

31. **Clinical evaluation of the effect that sprayed culture keratinocytes have on early wound healing in children**
Chief Investigator: B Dheansa
Status: completed; grant funded study; PhD project
Data from patients between the age of 1 and 15 years who have suffered a burn injury and received treatment in the QVH Burns Unit will be used to establish a database of scarring severity following treatment for burn of scald injuries. The data to be stored will be photographs, records of skin colour and the speed of healing. The severity of scarring will be evaluated using the Internationally recognised Manchester scar scale which measures skin colour, scar contraction and skin smoothness and is a recognised measure of scarring. Additional information such as cause of burn, area and depth of burn, time to heal, area healed at each dressing change or prior to treatment and any complications will be assessed or measured and recorded. Other information including referral source, first aid administration, previous health problems, medication and employment status will also be collated for research purposes. Existing data in the form of photographs and Manchester scar scale score will also be used provided the patient has consented to the use of photographic images for research purposes using the consent form currently in use.

32. **A multi-centre, randomised controlled trial assessing the effectiveness of Lugol's Iodine to assist excision of moderate dysplasia, severe dysplasia and carcinoma insitu at mucosal resection margin of oral and oropharyngeal squamous cell carcinoma**
Principle Investigator: P Norris
Status: in follow-up
Research evidence suggests that persistence of precancer tissue at the edges of tissue resected to treat oral cavity and oropharynx cancer leads to greater risk of recurrence of cancer at the primary site.
Currently, tumour tissue can be distinguished clinically by the surgeon operating to remove cancer.
Unfortunately, detected precancer change in the tissue next to the cancer itself is much more difficult. This leads to precancer tissue persisting at the edges of the removed tissue in around a third of patients treated. We aim to test whether use of a staining method will enhance accuracy of removal of precancer tissue. Precancer cells are abnormal in many ways. One effect of the changes is that they cannot store glycogen. This means that they do no stain darkly with iodine, as normal tissue does. This difference may allow us to better identify these precancer cells at the time of cancer excision and so remove all precancer cells at the same time. This may reduce the risk of second primary cancers developing in the same area of the mouth and throat. This study will be a randomised, controlled, blinded trial. Patients will be randomised to have cancer resection with or without the staining method. We will then compare the proportion of cancers removed which have precancer cells at the edges in each of the groups. This will allow us to assess whether this method is effective in helping us to remove all of the precancer tissue.
The pathologist will assess resected cancer specimens in exactly the same way as it is carried out currently. They will not know which patients are in the staining group and so assessment of the effect of using the stain is blinded.

Planned projects: studies which had not been given approval as of 01/04/17, but which are expected to start in 2017

- Validation of the MIRROR facial expression tracking application in healthy subjects and facial paralysis patients
- FRAME – a study to validate a device to assist with facial palsy rehabilitation exercises
- RE-ENERGIZE – a study to look at the effect of glutamine on burns healing

- ICON – a study to investigate the use of Ciclosporin 1mg/ml eye drop emulsion for the treatment of severe keratitis in adult patients with dry eye disease
- A follow-up study to refine the CAR burns scales
- A study to investigate paediatric nail bed injuries
- Perioperative Quality Improvement Programme