East Lancashire Hospitals NHS Trust

Research and Development

Research bulletin, March 2020

Safe, effective care through research

ELHT consultant features in RDS NW video

Shalom Srirangam, Consultant Urologist at East Lancashire Hospitals NHS Trust (ELHT), features in a new video created by Research Design Service North West (RDS NW).

In the video, Shalom talks about the invaluable assistance provided by the RDS NW to support patient involvement, at an early stage of his research, and with the challenges of developing a funding application for his proposed study.

Shalom's research investigated the impact of kidney stone disease. Whilst much was known about the increasing incidence of the condition and the effect on the health service, there had been no UK research on the impact of kidney stone disease on individuals diagnosed with the condition. Shalom, with the support of RDS NW, set about addressing this question using patient diaries and validated quality of life questionnaires.

To view the video, visit the RDS NW website

National news features ELHT research

Research by ELHT Consultant Orthopaedic Surgeon, Professor Paton has been featured in a national news broadcast.

Professor Paton and colleagues conducted a 15-year study of Developmental Dysplasia of the Hip (DDH) in over 70,000 children in the north of England. Their research findings were published last month in the British Journal of General Practice and featured on ITV news.

The study highlighted the limitations of the current screening test, carried out at six to eight-weeks, which led to some cases of DDH being missed.

The authors recommend a second assessment at three to four months, performed by trained staff, in a primary care setting.

COVID-19 and Research

For an update on current guidance from the HRA, MHRA and the DHSC, please see page 5

Contact us

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Take part in research

How should health data be shared and used?

In February, the CLIMB project, a research study looking at how NHS data is shared and used, opened at ELHT.

The project is a collaboration of seven research teams from the University of Cambridge and Cambridge and Peterborough NHS Foundation Trust and is funded by the Medical Research Council.

The study is open to patients, staff and members of the public and collects information via an online questionnaire.

A total of 160 East Lancashire participants have completed the survey to date. Thank you to everyone who supported this important study.

Further information about the research and details of how to take part, can be found at the study website.

Research capacity and culture survey

Members of staff at ELHT who are involved in the diagnosis, treatment, care, or prevention of illness, injury and other physical and mental impairments of patients and service users (including those who provide supervision and training, and those in management roles) are being invited to complete the Trust's first Research Capacity and Culture (RCC) Survey.

Participation in the survey is really important in helping to improve approaches to support the development of research capacity at the Trust.

The survey is open to everyone whether research active/interested, or not and it will take about 10 minutes to complete. There will be a prize draw of £300 towards a Continuing Professional Development (CPD) related activity once the survey has been completed.

E-mail Researchideas@elht.nhs.uk (adding RCC survey in the subject heading) for more information.

The survey can be accessed using Google Chrome via the following link

Study news

Researching patient priorities in breast cancer research

Consultant Surgeons, Suzanne Gawne, Rebecca Wilson and Jane McNicholas are supporting the 4Ps (**P**ublic and **P**atient **P**erspectives and **P**riorities) study.

The research seeks to identify the research gaps in breast cancer care, and compare the gaps identified by the public and patients with those identified by breast cancer clinicians and non-clinical scientists.

The study is being conducted by The Northwest Breast Trainee Research Collaborative (NWBTRC). A series of listening events informed the development of the questionnaire, used in the current study.

To date, 41 East Lancashire participants have completed the study questionnaire. A huge thank you goes to the investigators, led by ELHT Principal Investigator Suzanne Gawne, for supporting the study.

Children's Acute Surgical Abdomen Programme

Congratulations to Principal Investigator and ELHT Consultant Anaesthetist, Dr Ian Clegg and the Women and Children's Health Research Team. They entered two patients into the Children's Acute Surgical Abdomen Programme (CASAP) within the first week of opening the study.

CASAP is a prospective, observational cohort study which aims to characterise the type and quality of care being delivered to children undergoing urgent/emergency abdominal surgery. The research is sponsored by University College London.

The women's and children's health team have also exceeded expectations for entering patients into a range of studies including Biojume, C-stich, NAPES, Big baby, CRAFT and UCON.

For more information about all of these studies, please visit the ELHT research webpages.

Reminders

R&D reference numbers

Please use the R&D reference number on your study correspondence and documents. It will help us to reconcile records stored in different locations and differentiate between projects that share the same acronym.

The reference number is a seven digit number e.g. 2020.001.

GCP training

Free, online, GCP training and refresher courses are available via NIHR Learn, the National Institute for Health Research accredited learning portal. We encourage all members of staff, whether current or aspiring researchers, to complete the training. Indeed over half of Specialty Trainees joining the Trust each year have their GCP certificate.

The frequency of GCP training is determined by a risk assessment, conducted by the sponsor of each research study. However, our policy at ELHT is to ask that Principal Investigators (PIs), Co-investigators, Associate PIs and members of the Research Delivery Team complete the training every two years.

Once completed, please download your certificate and forward this to the R&D Support Office. You can also provide an updated copy of your research CV, using the template on the HRA website.

New structure for ELHT research

Research is now part of a new Education, Research and Innovation Directorate. Education, Research and Innovation is central to what we do at ELHT from training the next generation of healthcare professionals to contributing new knowledge and improving patient care through research and innovation. We now have the wider support of a larger directorate and can utilise resources, which will allow us to take forward our aspirations for research and development for ELHT.

Professor Anton Krige is stepping down as Director of Research and Development at the end of March. We would like to thank Anton for all that he has done over the past seven years for Research and Development, as Director of R&D at ELHT. A recruitment process is currently taking place for a new Director of Research, Development and Innovation (RD&I). The new Director of RD&I will be announced shortly.

Network news

CRN GM customer satisfaction survey

An annual customer satisfaction survey has been launched by the Clinical Research Network Greater Manchester. Research funders, and the investigators and research teams conducting research, are encouraged to take part.

The survey comprises 15 questions to provide feedback on the CRN services received to support the delivery of research studies during the last 12 months. The survey should take no more than 10 minutes to complete and all responses are anonymous. The survey can be accessed here and closes on 1st April 2020.

Engaging with research

The NIHR Clinical Research Network, NHS Engagement Team have developed an online community, hosted on NIHR learn. The resource provides a self-assessment, toolkit of resources and learning to support research delivery staff to embed research into the NHS.

Nursing Times Awards

The Nursing Times Awards recognise the vital role of the clinical research nurse in delivering high quality clinical care and in helping to develop multi-disciplinary teams that deliver research. If you'd like to recognise the outstanding contribution of an individual nurse or team, please visit the Nursing times website. Nominations are open until 15th May 2020.

Research Fellowship scheme

The Applied Research Collaboration North West Coast (ARC NW Coast) have announced a research internship scheme designed to support staff interested in developing Fellowship applications to the National Institute for Health Research (NIHR). Fellowship applications could be at the Pre-doctoral, Doctoral or Advanced level. Salary backfill of £6,000 will be paid to the employing organisation in order to release their staff to complete the internship. The expected output will be a Fellowship application to the NIHR. Internship applications must be received by 5pm, Thursday April 9th 2020.To request an application form please contact arcnwc@uclan.ac.uk

Study publications

16 articles from the Global Leaders study

East Lancashire patients who took part in the international Global Leaders study have contributed data now published in a series of research papers in peer reviewed journals. In the last ten months, 16 papers, co-authored by Professor Scot Garg, ELHT Consultant Cardiologist and Global Leaders Principal Investigator, have been published. The study looked at anti-platelet strategies following percutaneous coronary intervention in patients with stable coronary artery disease or acute coronary syndromes. At two years, Ticagrelor in combination with aspirin for 1 month, followed by ticagrelor alone for 23 months wasn't superior to 12 months of standard dual antiplatelet therapy followed by 12 months of aspirin alone in the prevention of all-cause mortality or new Q-wave myocardial infarction. Over 250 East Lancashire patients entered the research study at the Trust between 2013 and 2015. Our thanks go to the patients and to Professor Garg and his clinical and research colleagues in cardiology. All of the papers can be viewed on PubMed.

ECLIPSE study

The administration of intravenous (IV) medication has traditionally been regarded as error-prone with high potential for harm. To investigate this further, the ECLIPSE study was carried out at 16 English NHS Trusts, looking at the prevalence, types and severity of errors and discrepancies in infusion administration. ELHT contributed to the study, led by Dr Justin Roberts, Consultant in Anaesthetics and Critical Care, and with support from Michelle Randall, Deputy Director of Pharmacy. The research found that discrepancies are common in everyday infusion administration, but most have low potential for patient harm. The authors recommended a review of policy around IV infusion administration and further work on understanding infusion administration as a complex adaptive system to deliver new insights into managing patient safety. The full publication can be found in the NIHR Health Services and Delivery Research journal.

Erratum: Sincere apologies, Mrs Nugent was the PI for the Phoenix study featured in our last edition.

The findings of the Phoenix trial have been published in the Lancet. Led by researchers at King's College London, the research compared early induction versus expectant management in women with pre-eclampsia at 34-37 weeks of pregnancy. The study found that planned delivery – starting delivery, either by induction of labour or by Caesarean section if needed, within 48 hours of the diagnosis of pre-term pre-eclampsia being made, reduced maternal complications including hypertension. The study was supported by the ELHT Reproductive and Children's Health Research Team under the leadership of Consultant Obstetrician and Principal Investigator, Mrs Nugent. It was funded by the NIHR's Health Technology Assessment (HTA) Programme and has also been published as an NIHR signal.

We would like to thank the East Lancashire patients who took part in these studies. The findings will help to inform and improve the care of future patients

Training

What is health research?

Date:	Courses start **16th March 2020** and **1st June 2020.** They run for 3 weeks and learners can join at any time
Cost:	Free, on-line course
Further information:	Visit the Future Learn website

For people new to research, those considering research as a career, or members of the public. Learn about different types of research, how people are kept safe during research, and what you can expect if you volunteer to take part and help find new and better ways of preventing, diagnosing and treating disease.

The Clinical Doctoral Research Fellowship

Aimed at:	Health and social care professionals who are not doctors or dentists
Award:	PhD and professional development, alongside continued clinical practice
Funding available:	PhD tuition fees, salary costs, the costs of a research project, tailored training programmes
Applications:	Closes 13:00 on 22 April 2020. Applicants are required to propose a clinical and academic host

COVID-19

Research organisations have issued guidance to sponsors, researchers and sites relating to the impact of COVID-19 on clinical research studies. A summary of current guidance is provided below. Please check for changes.

Sites are required to notify sponsors of any changes to trial recruitment or conduct, at their earliest convenience. These changes might require local reporting of protocol deviations or the submission of study-wide amendments. The Research Support Office is working on plans for research study prioritisation, which focuses on patient care and safety with research resources concentrated on pandemic research and research that impacts on clinical safety and/or outcomes. Over the coming days, Chief and Principal Investigators will be contacted by the Research Support Office to explore their study portfolio.

Key messages

Patient safety remains a priority

- ***Notify sponsors and the Research Support Office*** of any potential impact on recruitment, patient visits or staffing – these might trigger study amendments and contractual issues
- Ensure any ***protocol deviations*** are well documented and communicated with sponsors

The Research Support Office must be contacted about any issues relating to trial conduct arising out of COVID-19.

MHRA Published 12th March 2020

Sponsors of CTIMPs are advised:

- ***Protocol deviations*** resulting from Coronavirus (e.g. missed visits, difficulties obtaining wet ink signatures) may increase but will not constitute a reportable serious breach. All protocol deviations should be well documented, to enable appropriate evaluation for the trial. Changes to trial processes may be documented in SOPs
- ***Research staff*** may be called to assist in other areas of the NHS. A risk assessment, prioritising safety reporting activities, should document the impact. Remote monitoring (with participant consent) should be considered
- Prospective protocol waivers remain unacceptable. ***Participants must meet the eligibility criteria for CTIMPs***. Where they cannot complete key evaluations and their safety is compromised, consideration should be given to discontinuing their participation.
- ***Urgent Safety Measures***, halting recruitment or temporarily halting the trial may be employed. The latter should be submitted as a substantial amendment

Health Research Authority Advice to sponsors, sites & researchers, v2 17.3.20

The ***expedited review process*** will be used for:

- New studies relating to COVID-19
- New COVID-19 elements added to existing studies (e.g. including patients with COVID-19 to an existing trial of a treatment)

For ***study-wide changes*** in response to COVID-19:

- Adding ***testing for SARS-CoV-2*** as a safety measure – can be implemented as an urgent safety measure with subsequent notification
- ***Site monitoring*** or administrative procedures – should be submitted as a non-substantial (NS) amendment
- ***Patient visits*** (e.g. changing hospital visits to phone calls or reducing the frequency of visits) – the sponsor should risk asses the changes and submit low risk changes as a NS amendment but those that increase risk as a substantial amendment
- Courier delivery of ***treatment or investigational medicinal product*** or collection by a nominated individual (subject to participant consent) – the sponsor must risk assess the shipping and storage arrangements and submit a NS amendment for these temporary arrangements
- ***Temporary halt*** to some or all of the study or extending the duration of the study – sponsor to submit as a substantial amendment for CTIMPs or, for non-CTIMPs, either pause recruitment or report a formal halt as a NS amendment
- ***Study closure*** – the REC should be notified. For any studies involving treatment, a substantial amendment should be submitted where post study treatment cannot be provided in accordance with the PIS

Sites should notify sponsors of the following:

- ***Suspending recruitment*** – may result in a temporary halt or closure of a trial – see above
- ***Moving participant visits*** due to re-allocation of staff or to limit participant contact. The changes should be handled prospectively as an amendment or where time does not permit, implemented as urgent safety measures and reported retrospectively
- ***Withdrawal of participants*** Where post study care cannot be provided in accordance with the PIS, the sponsor should submit a substantial amendment for expedited review
- ***PI absence*** of >1 month – REC should be notified). PI absence of >3 months – alternative arrangements should be made

Department of Health: Impact of COVID-19 on NIHR research 16th March 2020

- Clinical professionals funded by the NIHR, working on topics other than COVID-19 should prioritise frontline care, where requested to by their employer
- Research pharmacists and laboratory technicians, should also prioritise support to frontline care
- Research studies funded or supported by NIHR may need to be paused
- Clinical trials funded or supported by NIHR should continue if discontinuing them will have significant detrimental effects on the ongoing care of individual participants involved in those studies.

A Q&A covering funding arrangements and decisions to pause research studies can be found on the NIHR website