

# Research and Development

Bulletin, November 2018

## Safe effective care through research

### 20,000 thank yous

East Lancashire Hospitals NHS Trust (ELHT) reached an important milestone by entering the 20,000<sup>th</sup> patient into a clinical research study.

The research team celebrated and **wished patients 20,000 thank yous** for their contribution to research at ELHT.

Speaking at the event, Anton Krige, Consultant Anaesthetist and Associate Director for R&D, congratulated the team and highlighted the value of research.

**"It's a fantastic achievement.** We have research in almost every specialty in the Trust. The findings of the research we've contributed to has real value in our departments, and we know of the evidence that research active Trusts have better outcomes."



Michelle Stephens, R&D Manager for Delivery, thanked past and current members of the research team for their hard work and dedication in bringing research opportunities and new discoveries to patients in the Trust.

Writing in his weekly blog, Kevin McGee, ELHT Chief Executive congratulated the research team:

"ELHT has a culture of high quality research and innovation and I want to congratulate our research staff on achieving the milestone of recruiting the 20,000<sup>th</sup> ELHT research patient. We know that research leads to new treatments for patients, brings potential benefits for individuals who take part in research studies and helps to improve the health of the nation. Of course, the success of clinical research relies on the willingness of patients to get involved and it's thanks to the great research staff we have that so many East Lancashire patients say yes to research. **Well done everyone and keep up the excellent work.**"

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### Contact us

For support and information on research at East Lancashire Hospitals NHS Trust, please contact the Research and Development (R&D) Department  
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### Celebrating research at ELHT

If you'd like to include a story about your research, please contact: [hazel.aston@elht.nhs.uk](mailto:hazel.aston@elht.nhs.uk)

## ELHT researchers celebrate excellence in clinical research



Matt Milner pictured receiving the CRN Greater Manchester Research Administrator/Co-ordinator of the Year award

ELHT members of staff were among those celebrating excellence in clinical research at the sixth annual Greater Manchester Clinical Research Network awards. Shortlisted for awards were Mr Srirangam (Investigator of the Year), Bev Hammond (Research Midwife of the Year) and Matt Milner (Research Administrator/Coordinator of the year).

The awards were announced at a ceremony in Manchester, hosted by Debbie Vinsun, CRN GM Chief Operating Officer and Martin Gibson, CRN GM Clinical Director. It was a record year for entries, with an unprecedented 230 nominations to the awards.

Michelle Stephens R&D Manager for Delivery commented: "This was a huge achievement and something we should all be proud of. I am sure you will all join me in sending Matt huge congratulations in winning this award."

## Study news

### ACE team recruit first patient

A patient at East Lancashire Hospitals NHS Trust (ELHT) is the first to take part in the ACE research study.

The research collects cognitive assessment data in patients with metastatic prostate cancer who've started abiraterone acetate and prednisolone (AAP) or enzalutamide (ENZ) as a line of therapy

Both AAP and ENZ have been shown to extend survival and improve health-related quality of life for this group of patients, but information about their early impact on aspects of cognitive impairment, fatigue and depression is limited.

Alongside their usual hospital follow-up, participants in the ACE study will complete a series of cognitive assessments and questionnaires over a 12 month period. Led locally by Principal Investigator, Dr Omi Parikh, and supported by the Trust's Cancer Research Team, the study opened at ELHT on 9<sup>th</sup> November and will continue for two years.

Dr Parikh thanked patients for taking part in the research. "I'm really pleased to be offering trials which evaluate quality of life to our patients and I'm very grateful to the patients for taking part. I'd also like to thank the research team for facilitating this quite complex trial and overcoming multiple barriers to have been able to recruit our first patients in a matter of weeks of opening the trial.

The research is led by Chief Investigator, Professor Amit Bahl and sponsored by University Hospitals Bristol NHS Foundation Trust. The study is funded by a grant from Janssen-Cilag Limited.



Pictured L-R: Maricica Zabrautanu, Team Lead, Sarah Keith, Research Nurse, Janet Ryan-Smith, Research Support Officer, Jeanette Smalley, Senior Research Support Officer

## ELHT first Northern site to recruit to EVAREST

In patients suspected of having ischemic heart disease, stress echocardiography is used to detect possible underlying coronary artery atherosclerosis and to determine its severity.

The EVAREST study is testing whether novel imaging or blood biomarkers, such as extracellular vesicles, measured before and after the stress echo can be used to improve the diagnostic accuracy of the test.

EVAREST is led by Chief Investigator, Professor Paul Leeson, from the University of Oxford. A total of 5000 adults with suspected coronary artery disease, referred for stress echocardiogram as part of their standard clinical care, will take part in the study and so far 1600 have been recruited.

Consultant Cardiologist, Dr Sanjay Banypersad, is the Principal Investigator for EVAREST at ELHT. The first East Lancashire patient joined the study at the start of November, making ELHT the first Northern site to recruit a participant. Already 20 East Lancashire patients have joined the study.

## 250 patients contribute to PQIP

The Perioperative Quality Improvement Programme (PQIP) aims to improve the perioperative care of patients undergoing major non-cardiac surgery.

The study measures complication rates and patient reported outcomes, feeding back results in real-time, in order to support the implementation of best practice.

Thanks to the hard work of Principal Investigator Mike Pollard, Research Nurse Jill Fitchett, and the wider PQIP team, over 250 participants have been recruited into the study.

In the 2017-18 PQIP annual report ELHT was named an exemplar site for the enrolment of Lower GI & Urology patients on enhanced recovery (ER) pathways and the team invited to share details of the ER pathway with other UK sites.

## Trust's research culture celebrated at National Collaborator Meeting



Pictured L-R: Mrs Kalsang Bhatia, ELHT Principal Investigator for UCON, Elaine Nicholls, Patient representative, Bev Hammond, ELHT Research Midwife, Professor Hilary Critchley, Chief Investigator for UCON, Professor Jane Daniels, Nottingham Clinical Trials Unit, Lee Priest, Senior Trial Manager, BCTU

The “wonderful support and research expertise” at East Lancashire Hospitals NHS Trust (ELHT) has been praised by staff at the Birmingham Clinical Trials Unit (BCTU), at the University of Birmingham.

ELHT Consultant Gynaecologist, Mrs Bhatia is the local Principal Investigator for the UCON study which aims to improve treatment for women with heavy menstrual bleeding. Heavy periods have a major impact on women's health with over 1 million women in the UK seeking help every year.

The research is looking at whether treatment with Ulipristal Acetate is more effective than conventional management of the condition. A total of 302 women across the UK will take part in the research and be



followed-up for 12 months after receiving treatment.

To date, 16 East Lancashire women have joined the study. Lee Priest, Senior Trial Manager, wrote “Mrs Bhatia and the team have been research champions and a great example to other sites in recruiting patients and in turning a challenge into a positive thing.”

Professor Hilary Critchley, Chief Investigator for the UCON trial, invited Mrs Bhatia and ELHT Research Midwife, Bev Hammond to speak at the UCON Collaborator’s meeting. The meeting took place on 24<sup>th</sup> October 2018 at Birmingham Clinical Trials Unit, University of Birmingham and was attended (in-person and by teleconference) by site research teams across the UK.

Following an insightful and well received presentation, the research team was congratulated for having an efficient research culture and for the coordination and awareness of the study between gynaecology, pathology, pharmacy and research departments.

“The support for UCON provided by Dr Kalsang Bhatia, Bev Hammond and their team at ELHT has been terrific and it is great to have such an enthusiastic team working with us on this important study for women: thank you ELHT.”

Highlighting the value of research, Lee continued, “Without research of course, treatment options may become stuck in the past, and we are all patients at some point.”

UCON is sponsored by the University of Edinburgh/NHS Lothian. You can find out more about the study website at the [BCTU website](#).

## Publications

### STAMPEDE study

The latest findings from the STAMPEDE trial have been reported in the [Lancet](#) and in the [national media](#). Since opening in 2005 the trial has recruited over 10,000 participants. The latest report looked at the addition of radiotherapy to standard care for men with newly diagnosed advanced prostate cancer. The findings show that radiotherapy helped patients whose cancers had spread locally into the nearby lymph nodes or bones, with an 11% increase in survival at three years compared to men who received hormone therapy alone. Radiotherapy did not help those whose cancers had spread more widely.

### Planet-2 study

The findings of the PlaNet-2 study have been published in the [New England Journal of Medicine](#) and in the [national media](#). The study, carried out over a 6-year period, involving 660 premature babies with low platelet counts (severe thrombocytopenia), discovered that giving fewer platelet transfusions, and only in the babies with the lowest platelet levels to begin with, could prevent death or serious bleeding in seven out of every 100 with the condition.

Speaking in the newspaper article, Doctor Andrew Cox, Consultant Neonatologist and Principal Investigator for PlaNet-2 at ELHT, said: “We really appreciate the selflessness of parents who agree to enrol their unwell babies into clinical trials. We often see premature babies in our unit with low platelets, and the result of the PlaNet-2 trial will guide us in managing these babies more safely and effectively. Babies and their families beyond those who so generously took part in the trial will benefit, and it is likely that more premature babies will survive because of them. This is a wonderful legacy, for which all those who care for sick babies should be thankful.”



This work uses data provided by patients and collected by the NHS as part of their care and support.

#dataisvaluable

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.

## News in brief

### **CASSAVA surveys research questions in preterm labour**

The CASSAVA study, sponsored by the University of Edinburgh and NHS Lothian, is seeking the views of health professionals and patients with an [online survey](#). It aims to identify current practice and the research questions about the best way to give birth, for women in premature labour. For more information visit the [CASSAVA website](#).

### **GLAD study seeks 40,000 volunteers who've experienced clinical anxiety or depression**

The NIHR and King's College London are seeking 40,000 people diagnosed with depression or anxiety to contribute to the [Genetic Links to Anxiety and Depression \(GLAD\) study](#). Developed in collaboration with mental health charity MQ and with patients and service users, GLAD will establish the largest ever database of volunteers who can be invited to take part in research exploring the genetic factors behind the two most common mental health conditions – anxiety and depression.

### **NIHR launch 70@70 Research Leadership Programme for senior nurses and midwives**

70 successful applicants will form [a new community of senior clinical nurses and midwives](#). Through protected time, they will be able to dedicate two days a week (over a period of three years) to fostering a culture of innovation, with the ultimate goal of delivering high quality, evidenced based nursing, midwifery and healthcare practice. The closing date for applications to cohort 1 is 30<sup>th</sup> November.

### **NIHR directory for Clinical Research Practitioners**

The NIHR Clinical Research Network, in collaboration with the Academy for Healthcare Science, has launched the [Clinical Research Practitioner Directory](#), paving the way for accredited registration, similar to that found in nursing, pharmacy and other allied health professions.

### **NIHR Clinical Research Network Greater Manchester (NIHR CRN GM) surpasses annual recruitment target**

The NIHR CRNGM 2018-19 recruitment target, has been exceeded, with 4 months of the year still to go. The annual target, set by the CRN Coordinating Centre, was 46,000 with a local target of 47,085 participants. By 19<sup>th</sup> November, 47,103 participants had taken part in research across 784 portfolio studies. Debbie Vinsun, CRNGM Chief Operating Officer, said: "I would like to say a huge thank you to everyone across our network for making this fantastic achievement possible".

### **Third film in the NHSWonderWomen series launched**

NHSWonderWomen is a series of films showcasing the talent of North West women working in health and social care research. The films produced by NHS R&D North West, aim to inspire future generations of researchers. [The third film from the series](#) has been launched, featuring the work of Professor Sally Spencer, Director of Clinical Research at Edge Hill University.

### **NIHR Research Design Service North West (RDS NW)**

The latest edition of the NIHR RDS NW bulletin has been published. The bulletin includes information on social care research funding applications, intellectual property, funding opportunities and events.

### **Research measures included in CQC well-led inspection framework**

Research measures have been published as part of the revised Care Quality Commission (CQC) Trust-wide, well-led inspection framework. The framework asks how patients and carers are given the opportunity to participate in clinical research. It will also look at staff awareness of research activity and the support it requires and the Trust's internal reporting systems for its research range, volume, activity, safety and performance. Further details can be found on the [CQC website](#).

### **National Directive on Commercial Contract Research Studies**

A new national [directive on commercial contract research studies](#) came into force on 1<sup>st</sup> October 2018. It sets out new requirements to harmonise and streamline the costing and contracting for commercial contract research, through the use of an unmodified model site agreement and the NIHR industry costing template.