East Lancashire Hospitals NHS Trust

Research and Development

Bulletin, February 2018

Safe effective care through research

Helping pregnant women to stop smoking

Researchers at East Lancashire Hospitals NHS Trust (ELHT) are supporting two research studies looking at different ways to help pregnant women to stop smoking. MiQuit 3 is looking at a text message smoking cessation programme and the PREP study is comparing the use of e-cigarettes versus nicotine patches.

ELHT patient the first to take part in MiQuit 3 study

The ELHT women's health research team have recruited the first participant to the MiQuit 3 study and were the first UK site to open to recruitment. The study comprises a randomised controlled trial and meta-analysis, testing the effectiveness and cost-effectiveness of MiQuit, a text-message, smoking cessation programme for pregnant smokers. Rates of smoking in pregnancy are on the increase but pregnancy is the life event which most motivates attempts to stop smoking. MiQuit advice is relevant to pregnancy as it is highly-tailored to gestation. MiQuit 3 is funded by Cancer Research UK and led by Professor Tim Coleman at the University of Nottingham.

PREP study: A multi-centre RCT of electronic cigarettes and nicotine patches

Pictured L-R: Nicola Moss, Research Support Officer, and Dr Martin Maher, ELHT Principal Investigator for the PREP study

When pregnant women stop smoking during pregnancy the birth outcomes for their babies are improved. However, the majority of women in this situation will continue to smoke throughout their pregnancy. Researchers at ELHT are supporting the PREP study which aims to improve smoking cessation rates in pregnant women. The PREP study led by researchers at Queen Mary's University Hospital, London, compares the use of e-cigarettes with nicotine patches on smoking cessation rates in women who are 12 to 24^{+6} weeks-gestation and identified as daily tobacco smokers. The ELHT research team led by Mr Martin Maher, will be monitoring smoking cessation rates in the women who take part in the study, through follow-up questionnaires during pregnancy. For further information or to refer interested women, please contact womenandchildrensresearch@elht.nhs.uk,Tel: 13464 or 13081.

In this edition

Contact us

For support and information on research at East Lancashire Hospitals NHS Trust, please contact:
Research and Development (R&D) Department
Level 3, Royal Blackburn Hospital
Tel: 01254 733008
Fax: 01254 733683
Email: research@elht.nhs.uk

Celebrating research at ELHT

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

Neonatal team celebrate 2 years of Planet-2 data

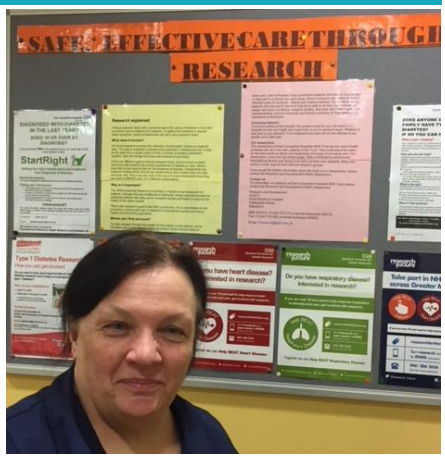
Pictured L-R: Dr Andrew Cox, Neonatal Consultant and PLANET-2 PI, Emily Andrews, Research Nurse, Ruth Dawson, Senior Sister NICU, Kaylee Scothern, Neonatal Nurse NICU, Usma Iqbal, Neonatal Nurse NICU

The prize-winning clinical and research team on the neonatal intensive care unit celebrated a milestone for their work on the Planet-2 study. The team received their prize as recognition for collecting 2 years of data for the study. Planet-2 is looking at when best to give platelet transfusions to premature babies who have low platelet levels and no signs of bleeding. The study is sponsored by NHS Blood and Transplant and led locally by Principal Investigator Dr Andrew Cox. It's the second time the team have been recognised for their work on the study, having recruited the 550th participant just over a year ago.

Raising awareness of research

Diabetes research at ELHT

Another opportunity to raise awareness of research has been seized with a new notice board in the outpatients area where patients with diabetes wait to have bloods taken. Research Nurse, Yvonne Grimes, pulled together a fantastic range of resources to inform patients about the opportunities for research in the Trust and elsewhere. "I hope it all helps to make patients aware of the opportunities for research" said Yvonne. "It's great how supportive the staff in the outpatient department have been." A huge thank you goes to Outpatient Sister, Rochelle Newton, for identifying a free notice board and putting up all the materials.



Pictured right: Research Nurse Yvonne Grimes

I AM RESEARCH

70 YEARS OF THE NHS 1948 - 2018

Festival of Learning #lovetolearn

This year at ELHT we'll be celebrating International Clinical Trials Day on 20th May, the Festival of Learning between 4th and 22nd June and the 70th birthday of the NHS on 5th July. Exact details of events, dates, activities and locations are still being agreed but the Research and Development department will seize the opportunity to raise awareness of research and the research activity within the Trust. If you'd like to contribute ideas and get involved, please contact Hazel Aston.

Network news

Research for the future: Help to recruit to your research studies

Research for the Future is an NIHR CRN Greater Manchester initiative, designed to facilitate recruitment to NIHR portfolio studies in Greater Manchester. Three 'Help BEAT' campaigns (diabetes, respiratory and heart disease) encourage people to register on the Research for the Future database. In doing so, people give their consent to be approached by researchers about studies that may be of interest. Research for the Future currently has 5500+ volunteers living in and around Greater Manchester, registered on the database.

Researchers can utilise the service to identify potential participants for their portfolio and non-portfolio research studies, patient panels or focus groups. Ethical permission to identify participants from a database must be in place. To find out more about Research for the Future and the Help BEAT campaigns visit www.researchforthefuture.org or telephone 0161 206 6891.

Research to form part of CQC monitoring and inspection programme

Research is to be recognised for its role in improving care. The National Institute of Health Research (NIHR), the Health Research Authority (HRA) and the Medicines and Healthcare Products Regulatory Agency (MHRA) are working with the Care Quality Commission (CQC) to develop new research indicators for use as part of the CQC's monitoring and inspection programme. The new indicators, which should be available this spring, aim to give NHS organisations the opportunity to showcase research as part of their assessment by the CQC, demonstrating their commitment to high quality patient care. Find out more.

NIHR Clinical Research Network to support broader range of research studies

The NIHR Clinical Research Network (CRN) is extending support into health and social care research taking place in non-NHS settings. This includes studies running in care homes or in hospices. The CRN will also be able to better support research into public health, for example in schools and other community settings. The changes, which commenced at the start of the year, will help to answer important questions for these patient populations. Find out more.

NIHR CRN contracts extended

The Department of Health (DoH) has agreed to extend the contract for the National Institute for Health Research (NIHR) Local Clinical Research Network (CRN) through to 31st March 2022. "This extension is recognition of the excellent collective development and delivery of the NIHR Clinical Research Network over the past four years" commented Dr Jonathan Sheffield, Chief Executive Officer for NIHR Clinical Research Network. "East Lancashire Hospitals NHS Trust is a valuable asset to this partnership" said Debbie Vinsun, Chief Operating Officer for NIHRCRN Greater Manchester, "and we look forward to continue working with you in the new year and beyond into 2022."

Training opportunities

NHS R&D forum masterclasses

Regulatory Inspection Ready
22nd March, East Midlands

Data Management for Research in a Healthcare Setting
17th April 2018, Manchester

For further info contact R&D forum

Improving Health by Improving Trials: Clinical Trials Training for Investigators
University of Liverpool
24th – 28th September 2018
£475, CPD accredited – 30 points awarded for full week attendance

The programme will include trial design and conduct, recruitment of trial participants, public and patient involvement, data analysis and reporting and health economics

To register for this course, please click here

Regulatory update

Data protection regulations

Existing law sets out clear rules for the processing of personal data. Those rules will change on 25th May 2018, when the new EU General Data Protection Regulation (GDPR) comes into force. How the GDPR will be applied in the UK will be set out in a new Data Protection Act, which Parliament has yet to agree.

What will this mean for research?

Previously, the HRA held a consultation about an opt-out clause to meet the requirements in the GDPR that relate to consent. This could have had significant impact for research. However, the legal basis for data processing within research has now been clarified as a 'task in the public interest' and not 'for consent'. Therefore, in most cases, the impact on individual research projects is expected to be limited.

Sponsors may revise patient information sheets and consent forms to comply with the GDPR requirement for transparency about data processing. The HRA confirms that for most existing studies, changes to PIS and consent forms can be made as non-notifiable, non-substantial amendments.

The Common Law Duty of Confidentiality is not changing, so consent is still needed to access and use confidential patient information for research.

The HRA continues to offer information and operational guidance. **The HRA asks that no amendments are made until the UK legislation has passed through parliament.** The HRA guidance is a living document and may be subject to further changes.

Delay to the implementation of the EU Clinical Trials Regulation

The EU Clinical Trial Regulation was due to be implemented in October 2018 but this has been postponed until 2019. This is to allow more time for the development of the EU wide clinical trial portal and database. At present, it's not clear whether the new regulations will come into application before or after the UK leaves the EU in March 2019. For further details

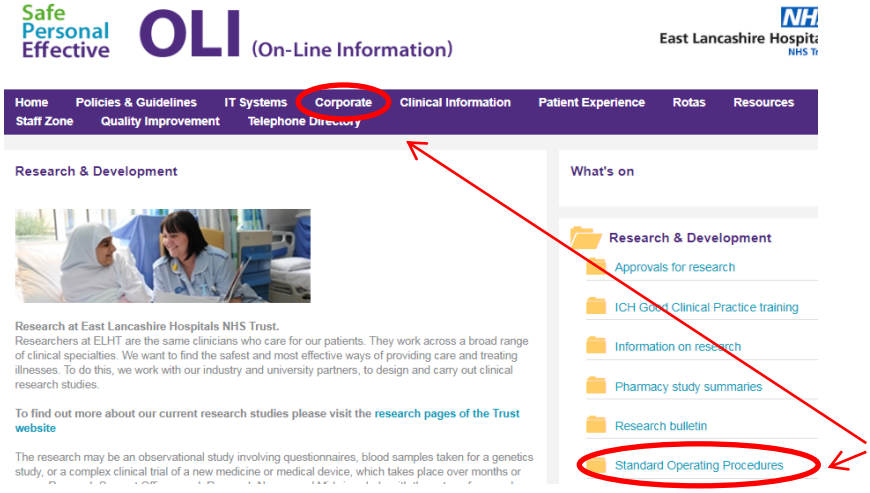
New licensing system for administration of radioactive substances

The Ionising Radiation (Medical Exposure) Regulations 2018 (IR(ME)R) came into force in England, Scotland and Wales this month. The regulation requires that both employers and practitioners hold a licence to administer radioactive substances for diagnosis, treatment or research. The Administration of Radioactive Substances Advisory Committee (ARSAC) will update its approvals process in response to the changes. For further information.

EU regulations on medical devices and in vitro diagnostic medical devices

New EU regulations for medical devices (MDR) and in vitro diagnostic medical devices (IVDRs) were entered into force on 25th May 2017, signalling the start of a transition period before they apply across the EU. The new regulations are applicable to a wider range of products, classify and assess devices according to risk and impose stricter requirements for post marketing surveillance. The MDR and IVDR will apply in EU member states from 26th May 2020 and 2022, respectively, which is after the UK leaves the EU in March 2019. For more information and future updates visit the MHRA website.

New Standard Operating Procedures introduced



Two new R&D standard operating procedures (SOPs), for certified copies and data entry, have been introduced and all other R&D SOPs and work instructions (WI) have just been updated. The documents are located on OLI which is best viewed in Google Chrome. Instructions for accessing the SOPs are shown below. For further information, please contact the R&D office.

Access the R&D SOPs here