Research and Innovation Quarterly Update – Q2 19-20, October 3rd 2019

Performance

Recruitment:

SFH have recruited 894 patients in to National Institute for Health Research studies at Q2 (Data cut 23/09/2019) compared to 1242 this time last year.

Numbers of studies: 69 studies are currently open at SFH, 7 opened and 6 closed in Q2 19/20. 55 studies are actively recruiting with the KPI for RTT (Recruitment to Time and Target) of 80% met for both non-commercial and commercial studies, 80% and 100% respectively. Trials are spread across most specialities in the organisation with activity remaining high in Gastroenterology and Rheumatology.

DoH metrics: SFH reports quarterly to the Department of Health via the Clinical Trials Platform. The national KPI for NHS Trusts Q1 report was published in September 2019 with SFH remaining joint first place in league for delivery of commercial trials.

Commercial Research: 2 commercial trials opened in 19/20, 4 in set up.

Finance

The confirmed East Midlands CRN budget for 2019/20 is £713,387.00, a small decrease of 0.2% on 18/19. Q2 19/20 commercial income is £103,166.36, to be invested in growing research capacity and capability in line with NIHR Commercial Income Distribution Guidance, August 2015. The organisation has received Research Capability Funding (RCF) from DoH of £20,000 in 2019/20. This funding allows SFH to contribute towards sponsorship, governance costs; financial management and staff support for researchers working on NIHR adopted studies.

Patient Experience

SFH is using the NIHR Participant Research Experience survey and has been feeding in to this since January 2019. Results are publicly available via a web link dashboard. 305 patients surveyed to date with 272 (89%), saying they had a very good or good experience of taking part in research at SFH.

Progress against 2019 – 2020 Strategic Priorities

The focus this year remains the similar to last year as priorities around portfolio growth, quality improvement and engagement require a sustained focus over several years. However, supporting new researchers, clinical academic careers and driving the innovation agenda forward at SFH are also key objectives.

1. Targeted Performance - broadening the SFH research portfolio in order to support service delivery and innovative practices, with a particular focus on:

    - Increasing the number of patients who have access to research studies as part of their care pathway. There is also an aim to ensure maximum income return by achieving a balanced research portfolio. Clear focus remains on achieving time to target (RTT) in relation to recruitment, in order to maximise the annual performance premium awarded by the CRN.
      Measure - Recruitment target set at 1800 patients 2019/20
      80% of studies closing in year to have met RTT

Progress – on target

- Further develop research in areas previously not research active e.g ED/ENT and supporting capacity and capability to do this.
  Measure - Open and actively recruiting in to at least 2 studies in this area in 19/20

- Growth of commercial research activity through collaboration with EMCRN.
  Measure - increase in the number of site identification submissions, increased volume of SFH selected as a site, and open 6-8 commercial studies in 19/20

  Progress - On target

2. Quality and Engagement - Improving and contributing to the quality agenda through creating more research opportunities for patients and staff. Wider dissemination and promotion of local organisational behaviour that offers the best possible research choices and benefits to patients, and delivers research that is important to, and prioritised by patients. Support wider research and QI programmes across the Trust as appropriate
   Measure – Increased patient awareness that SFH is a research active Trust. Research promotional activities undertaken, ED Band 5 secondment to R&I for 12 months, NIHR high level objectives for PRES survey met and support provided for the Orthotic/NHSI patient experience project.
   Progress – on target

   Impact and Outcomes – evaluation impacts and outcomes from research SFH have participated in

   Progress - A list of 58 publications from the last 3 years was collated using the ORDA database where Sherwood Forest Hospitals and staff were named as affiliated authors. Studies verified as approved by R&I. There were a total of 32 studies. These trials were then investigated further to find evidence of changed practice as a result of these trials. NICE Evidence and the NIHR Portal (including the NIHR 100 impact case studies) were used as well as basic web searches. Seven studies were found to have changed practice (detailed in Appendix 1).

   Knowledge Management and Innovation – Collaboration with OD, QI and library services commenced.
   Progress - first meeting chaired by Adrian Piggott

3. Building Capacity and capability – Ensuring we have the right resources, staff and facilities to be able to offer and deliver high quality clinical trials in an equitable way to our patients now and in the future.
   Measure - Training opportunities for staff undertaken including clinical research training for secondee's and sessions on local university degree courses delivered by R&I team. Continue development of the Research Academy to develop clinical research nurse careers and aid recruitment.
   SFH to act as sponsor for a minimum of 2 studies.
   SFH to act as lead site for 1 grant application.

Progress – on track; sponsorship discussions for 2 studies, Orthopaedics and Health and Wellbeing. Supporting an application with EMCRN for an RfPB.
EM Research Design Service approaching SFH as a potential partner in national objective to increase funding applications from smaller less research active organisations

Risk

The R&I Director, Dr David Hodgson has given notice he will step down from this position by the end of Q3 after 5 years in this role. A new job role is currently being developed and is planned to be advertised for expressions of interest by end of September/early October. Interviews planned for early November to avoid the risk of a period without a director.

Summary

Our Research and Innovation department is now well established and includes a multidisciplinary infrastructure supporting a broad range of research activity across many clinical areas of the Trust. The service we provide continues to deliver better outcomes for our patients at SFH, allowing them access to new and different treatments. The reputation of the Research and Innovation department and SFH as a research active organisation continues to grow. We have strong associations with other NHS Trusts and Universities and are committed to expanding the research activity, breadth of our portfolio and facilities at SFH through development and delivery of our Research strategy.

At a local level research can have positive outcomes in terms of increased quality of care, patient satisfaction and financial benefits to the organisation. A Retrospective cross-sectional study looking at data For 129 English National Health Service hospital Trusts, from National Institute for Health Research study activity data, Summary Hospital-level Mortality Indicator (SHMI) scores and Care Quality Commission (CQC) ratings demonstrates a positive link between better CQC outcomes and the intensity of interventional research trials at NHS Trusts (Jonker and Fischer 2018). Previously the papers and evidence have only focused on mortality rates. It is important as a research active organisation that wherever possible we continue to make the changes and meet the requirements needed to advance our research activity and build research capacity for the future.

Appendix 1

Summaries of Research Impact at Sherwood Forest Hospitals

1. Use of evidence based practices to improve survival without severe morbidity for very preterm infants: results from the EPICE population based cohort.

What did this study do?

The EPICE cohort is a prospective study of all very preterm, stillborn and liveborn infants delivered in maternity hospitals in 19 regions in 11 European countries covering over 850 000 births annually. Data were collected on births occurring between April 2011 and September 2012. The EPICE protocol included 17 practices with varying levels of evidence, from which we identified four with a high level of evidence that are related to neonatal mortality and morbidity and that could be measured reliably using information from medical records.

What this study adds

Only 58.3% of very preterm infants admitted for neonatal care in 19 European regions received all of the four evidence based practices for which they were eligible

These very preterm infants had higher risk adjusted survival without severe morbidity, suggesting more comprehensive provision of evidence based practices could yield substantial gains

The study's findings support the growing focus on bundling effective practices to improve processes of care and to achieve best outcomes.

Further links:

ORDA Record: https://orda.derbyhospitals.nhs.uk/handle/123456789/1845

2. Saving Babies Lives Care Bundle (SPIRE)

What did this study do?

The Care Bundle focused on the following elements:

- reducing smoking in pregnancy
- closer monitoring of fetal growth restriction
- raising public awareness of monitoring reduced fetal movement
- effective fetal monitoring during labour.

The care bundle was tested and piloted by volunteer maternity care providers and NHS England will then consider how to support implementation nationwide, as part of the National Maternity Review.

Impact:

- Increase in the detection of small babies – there was a 59 per cent increase detection attributed to better monitoring and scanning in pregnancy
- Better awareness of a baby's movement in pregnancy – with a high number of women attending hospital due to reduced movement.
- Carbon monoxide testing for smoking in pregnancy was almost universal – Smoking is strongly associated with stillbirth. A 1 per cent increase in smoking rates increases the chances of stillbirth by 1.7 per cent. Alongside carbon monoxide monitoring there has been a decline in the number of women smoking, at time of booking
- Version two of the Saving Babies' Lives Care Bundle (SBLCBv2), has been produced to address the issues identified in the evaluation.

Prof Alexander Heazell, Professor of Obstetrics, University of Manchester, said: "This large scale evaluation of the NHS England Saving Babies Lives Care Bundle shows that the interventions to reduce cigarette smoking, detect small for gestational age babies, inform women about reduced fetal movements and improve monitoring of babies during labour, have been increasingly implemented in the early adopter maternity units. Over the same time period stillbirths have fallen by 20 per cent, meaning 161 fewer stillbirths in the participating units.

Further links:

Widdows K, Roberts SA, Camacho EM, Heazell AEP. Evaluation of the Implementation of the Saving Babies' Lives Care Bundle in early adopter NHS Trusts in England. Maternal and Fetal Health Research Centre, University of Manchester, Manchester, UK. 2018

Link to ORDA record: **https://orda.derbyhospitals.nhs.uk/handle/123456789/2073**

3. Dexamethasone versus standard treatment for postoperative nausea and vomiting in gastrointestinal surgery: randomised controlled trial (DREAMS Trial)

What did this study do?

DREAMS was a randomised controlled trial that compared a single 8mg intravenous dose of dexamethasone given at the start of anaesthesia with standard care. It included 1350 adults undergoing elective open or laparoscopic (keyhole) small or large bowel surgery at 45 hospitals in the UK. The majority were having bowel resection.

What are the implications?

This large trial gives confidence that a single 8mg dose of intravenous dexamethasone, given at induction of anaesthesia, is safe and effective for non-diabetic patients undergoing bowel surgery. It can reduce vomiting in the first 24 hours after surgery, without increasing short term adverse effects. Increased blood sugar levels, and the possibility of increased risk of cancer recurrence, remain a concern.

Quicker recovery for patients could reduce costs, though the length of hospital stay wasn't affected in this trial. Poor bowel motility (ileus) was not specifically reported as an outcome, but those in the dexamethasone group did return more quickly to eating, which is promising.

Further links:

DREAMS Trial Collaborators and West Midlands Research Collaborative. Dexamethasone versus standard treatment for postoperative nausea and vomiting in gastrointestinal surgery: BMJ. 2017;357:j1455.

NIHR SIGNAL: https://discover.dc.nihr.ac.uk/content/signal-000462/dexamethasone-before-bowel-surgery-reduces-postoperative-nausea-and-vomiting

Link to ORDA record: https://orda.derbyhospitals.nhs.uk/handle/123456789/1449

4. Ballooned Intercostal Drain Trial

What did this study do?

The use of a tube inserted between the ribs (intercostal drain) to remove air or fluid from around the lung is an essential tool in the management of respiratory patients. A common complication of drain insertion is accidental removal of the drain, usually as a result of inadequate securing techniques. This often results in the need for further medical or surgical procedures (including drain re-siting), with associated additional risk to the patient and an increase in health care costs. One suggested method to reduce premature drain removal is to use intercostal drains with ballooned tips. The balloon would then provide a relatively atraumatic physical obstruction to the drain insertion site.

We propose a trial of a dedicated ballooned intercostal drain to investigate whether a reduction in drain re-siting rates can be achieved. Pain scores will also be assessed during this trial to ensure that irritation of the lining of the lung and chest wall is not prohibitive.

This drain was designed by a medical student on placement at Sherwood Forest Hospitals.

Impact:

We conducted a pilot feasibility study at SFH of a dedicated 16F ballooned intercostal drain (Rocket Medical; Figure 1). Twenty patients requiring intercostal tube drainage as an in-patient for pleural effusion were recruited. Of the drains inserted, 1/20 (5%) was prematurely dislodged, comparing favourably with the literature. A larger randomised trial is due to complete in June 2019.

SFHT are participating in the larger trial due to complete Jun 2020 funded by Rocket Medical: http://www.isrctn.com/ISRCTN37304337

Further links:

Ross S, Ali H, Allsop L, et al P15 A pilot study of a dedicated ballooned intercostal drain. Thorax 2016;71:A91-A92.

ORDA Record: https://orda.derbyhospitals.nhs.uk/handle/123456789/1453

5. Azithromycin for Acute Exacerbations of Asthma : The AZALEA Randomized Clinical Trial.

What did this study do?

Guidelines do not recommend routinely prescribing antibiotics to people with an acute asthma attack. However, the antibiotic azithromycin is believed to have an additional effect of reducing inflammation and has been used to treat acute asthma attacks.

This study aimed to determine if azithromycin improved symptoms or speed of recovery when added to standard steroid treatment in people experiencing an asthma attack.

What did it find?

Among the 97 people who received azithromycin, the average symptom score fell from 4.14 (standard deviation [SD] 1.38) at baseline to 2.09 (SD 1.71) by 10 days later.

In the 102 people who received placebo, the average symptom score fell from 4.18 (SD 1.48) at baseline to 2.20 (SD 1.51) by 10 days.

At 10 days, the average symptom score was not significantly better in the azithromycin group than the placebo group (difference −0.166, 95% confidence interval −0.670 to 0.337).

Side effects were uncommon, although people in the azithromycin group experienced more gastrointestinal adverse events, such as diarrhoea (35 events compared with 24 events in the placebo group), and cardiac adverse events (4 events compared with 2 events).

What are the implications?

There are few implications for practice based on the findings of this study alone as it did not have enough participants to confirm if the drug has an effect or not.

Recruiting participants to this study was difficult because for each randomised patient, more than ten were excluded at screening because they were already receiving antibiotics to treat their asthma attack.

However, perhaps the most important finding was that current advice, which is not to prescribe antibiotics in patients with an asthma exacerbation, is not being followed in the UK.

Further links:

Johnston SL, Szigeti M, Cross M, et al. Azithromycin for acute exacerbations of asthma: the AZALEA randomized clinical trial. JAMA Intern Med.2016;176(11):1630-37.

Brusselle GG, Van Braeckel E. AZALEA trial highlights antibiotic overuse in acute asthma attacks. JAMA Intern Med. 2016; 176(11):1637-38.

ORDA Record: https://orda.derbyhospitals.nhs.uk/handle/123456789/1791

6. STAMPEDE – (Systemic Therapy in Advancing or Metastatic Prostate Cancer: Evaluation of Drug Efficacy)

What did this study do?

STAMPEDE aims to provide evidence as to what is the best way of treating men with newly diagnosed advanced prostate cancer.

STAMPEDE is a large clinical trial that aims to assess new treatment approaches for people affected by high-risk prostate cancer. The trial has been open since 2005 and has tested many different ways of treating prostate cancer and some results are now already known.

What have the results of the trial shown so far?

The addition of docetaxel was shown to benefit patients and this has led to a change in clinical practice.

In results presented in June 2017, the addition of abiraterone to androgen-deprivation therapy has also been shown to be beneficial.

In results presented in October 2018, the provision of radiotherapy to patients with metastatic prostate cancer, resulted in a substantial improvement in survival for some men.

Further links:

Case study: Improving treatment for advanced prostate cancer, NIHR June 2019

7. Faecal Immunochemical Testing (NICE FIT)

What did this study do?

The NICE FIT study is funded by NHS England to investigate whether the FIT (faecal immunochemical test) could be used to exclude bowel cancer in our population in England.

The NICE FIT study is the largest study in England investigating whether FIT can be used to rule out bowel cancer instead of a colonoscopy.

In February 2019 they achieved the recruitment target, with over 11 000 patients recruited to the NICE FIT study. The results of the study are expected later in 2019.

What are the implications?

Since bowel cancer screening began in the UK, it has made use of a certain type of faecal occult blood test - a guaiac-based test (gFOBT). Now, this test is being replaced by a Faecal Immunochemical Test (FIT) test.

NICE estimated that the sensitivity of the faecal immunochemical test to detect colorectal cancer ranged from 89% to 100%.

It could save the NHS millions, as each colonoscopy costs the NHS £372 compared to about £5 for the new tests.

The faecal immunochemical test is a powerful new technology which is likely to revolutionize the referral pathway for patients with suspected colorectal cancer.

A robust evidence base is needed so that the faecal immunochemical test can be embedded within National Institute of Health and Care Excellence guidelines to its full potential

Further links:

The faecal immunochemical test in low risk patients with suspected bowel cancer
Mr Nigel D'Souza and Mr Muti Abulafi
British Journal of Hospital Medicine 2019 80:1, 22-26

Faecal immunochemical testing in general practice
Nigel D'Souza, Anthony Brzezicki and Muti Abulafi

British Journal of General Practice 2019; 69 (679): 60-61.

Appendix 2

Our **Vision**

To make research part of our daily business

Our **Mission**

At SFH, research is about improving the care we give to our patients to make sure it is outstanding. Embed research excellence as part of our culture, and deliver this with a highly skilled knowledgeable workforce as part of everyday care.

Our **Aims:**

1. Strong research activity in more clinical specialities, define and secure our areas of strength and establish high class research facilities

    - Focus on priority areas where we have existing strengths
    - Embed research in as part of clinical service
    - Increase partnership working to make the most of our potential

2. Work with more industry organisations to deliver clinical trials that change people's lives for the better

    - Develop relationships with leading commercial sponsors and CRO's
    - Broaden our commercial research portfolio
    - Work in collaboration with EMCRN Industry team as a priority site for increasing commercial activity

3. Involve more of our patients and staff in high quality research

    - Make research more visible and provide more research opportunities for our patients
    - Enable patients to engage in PPI activities across our organisation and our region
    - Deliver research that is important to our patients
    - Improve the quality and standard of our care through participation in research

4. Develop and support a workforce with the skills to deliver world class research

    - Develop a sustainable research academy to build the skills of our staff
    - Develop career pathways for research staff and encourage collaborations with academic institutions
    - Engage and support our research investigators
    - Invest commercial research income in to building future capacity and capability