

Research Annual Report 2018/19



Foreword

From the ability to precisely alter the genetic code of life to a better dressing for surgical wounds, research is changing the way disease and injuries are managed. Today, many conditions considered incurable 20 years ago are effectively treated thanks to researchers and the patients who asked what works and how? Our specialist Trust has a focus on the effects of disease and injury on our muscles, bones and joints. As we strive to deliver World class care, research is a core thread to the Trust's everyday functioning as this report shows. Highlighting our recent activity, this report also points to the future.



Mr Andrew Roberts, *Director of Research*

It is quite clear from The NHS England research plan of April 2017, the value placed on research in delivering future treatments to our patients: "NHS England has a legal duty to promote research and the use of research evidence in the NHS. We do this so that the NHS supports and harnesses the best research and innovations to improve patient outcomes, transform services and ensure value for money. Patients benefit from access to clinical trials including cutting edge treatments and the NHS benefits from new medicines, technologies and processes."

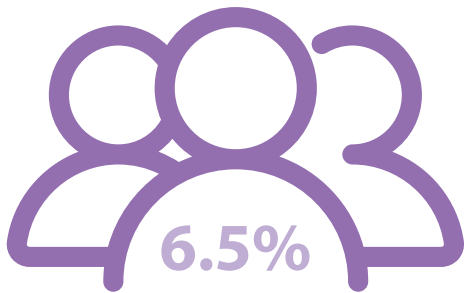
Our aim here at the Trust is to deliver against this plan by providing all of our patients with the opportunity to be involved in a research programme and by doing so having the chance to influence and change the treatments, services and care we offer. In this report we celebrate our successes and demonstrate how we are learning from the past, thus supporting the Trust's aim to be a world class provider of patient care and leader in MSK.

Teresa Jones, *Research Manager*

NIHR Research

For a second year running the number of participants contributing to National Institute for Health Research (NIHR) research in the West Midlands has exceeded the 70,000 mark with a record 73,920 people taking part in 2018-19 - the most ever in a single year. RJAH is 1 of the 25 NHS Trusts that contribute to these figures.

At RJAH during 2018-19 the number of people taking part in NIHR research grew by 6.5% (compared to 2017-18) to 871 participants in a total of 61 NIHR research studies, a growth of 17% on 2017-18. This growth is due to the support from our clinicians in both home grown sponsored studies and hosted studies.



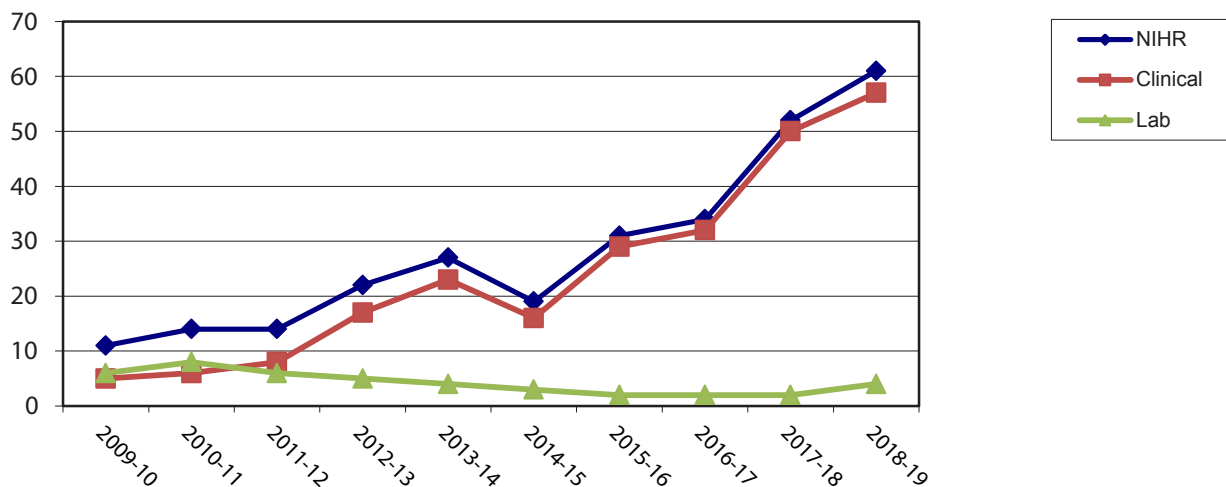
Growth in the number of people taking part in NIHR research

The NIHR's mission is to improve the health and wealth of the nation through research. This is delivered through 5 strategic work streams:

1. funding, supporting and delivering high quality research that benefits the NHS, public health and social care
2. engaging and involving patients and the public in order to improve the reach, quality and impact of research
3. attracting training and supporting the best researchers to tackle the complex health and care challenges of the future
4. investing in world-class infrastructure and a skilled delivery workforce to translate discoveries into improved treatments and services
5. partnering with other public funders, charities and industry to maximise the value of research to patients and the economy.

During 2018-19, RJAH opened 2 studies funded from the Health Technology Assessment Programme and 2 from the Research for Patient Benefit Programme.

The **Health Technology Assessment (HTA) Programme** supports research that is immediately useful to patients, clinical practice, and policy or decision makers to establish the clinical and cost-effectiveness for the NHS in comparison with the current best alternative(s).



HTA Study 1: DISC

(Dupuytren's interventions surgery vs collagenase)



This is a hosted study being led by Mr Cormac Kelly (Consultant Orthopaedic Surgeon)

Dupuytren's contracture is a common problem that affects the hand, caused by fibrous tissue forcing the finger to bend down into the palm meaning patients cannot straighten their finger. The common treatment is surgery to remove the tissue and straighten the bent finger; however a non-surgical treatment, an injection that softens the fibrous tissue followed by manipulation to straighten the finger is also available. Both treatments are offered on the NHS in England, but it is not known if one treatment is any better or worse than the other. The aim of this study is to find out whether collagenase injections are as good and as safe as surgery for treating this condition and to see which offers best value for money. The participants view is also being looked to see if they prefer one treatment more than the other.

This study is an example of how research can change the services offered at RJAH bringing benefit to the patient, the Trust and the NHS. During 2018-19 we recruited 4 patients into this study with a target of 72 before the end of the calendar year.

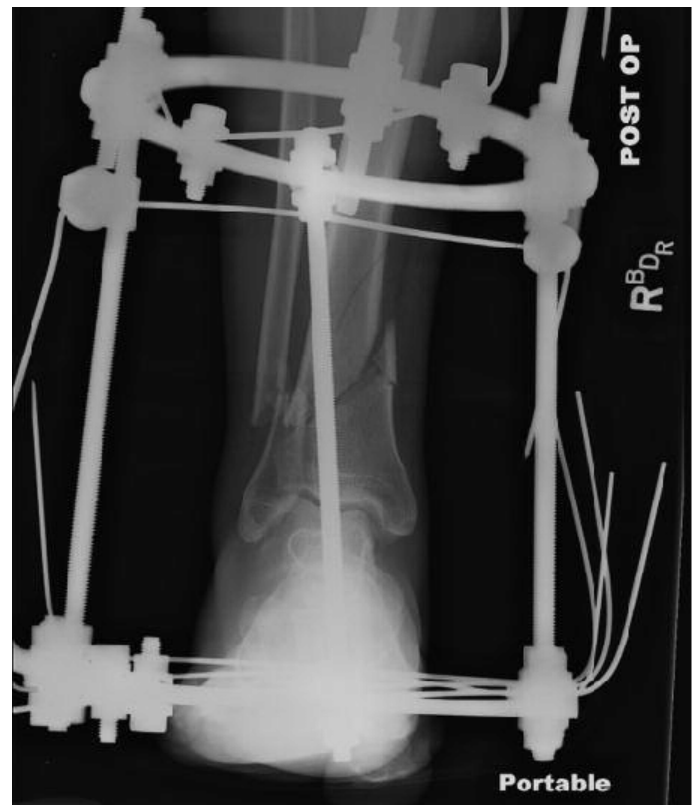


HTA Study 2: ACTIVE (External frame versus internal locking plate for articular pilon fracture fixation).



This is a hosted study being led by Mr Andrew Bing (Consultant Orthopaedic Surgeon)

A pilon fracture is a severe break of the shin bone where it forms the ankle joint, usually caused by a high-energy impact such as a fall from a height. These injuries are very difficult to treat, and can have a negative effect on a person's quality of life. Surgery is needed to fix the broken bone, by using a plate and screws (internal fixation) or using a ring frame or cage (external fixation). Although the internal plate is cheaper than the external ring, the internal plate may increase the chance of the patient getting a deep infection. There is genuine uncertainty amongst surgeons as to which option is best, hence the study.

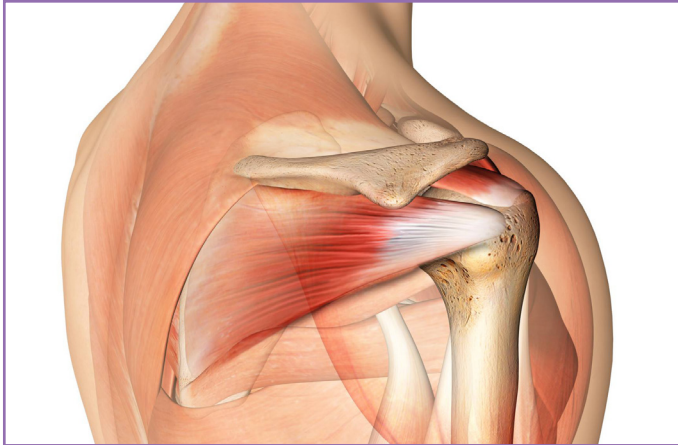


This study has a direct impact on the treatment choice we offer our patients with the added benefit to the NHS finances. This type of patient is rare to RJAH and as a result we are yet to recruit a patient.

The **Research for Patient Benefit (RfPB) Programme** funds NHS research covering a wide range of health service challenges. Inspired by patients and practice, led by the researcher, this scheme generates research evidence to improve, expand and strengthen the way that healthcare is delivered for patients, the public and the NHS.

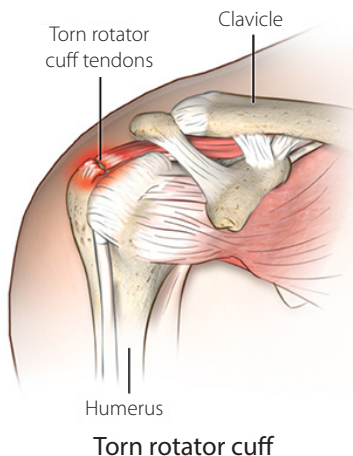
RFPB Study 1: The RaCeR study: rehabilitation following rotator cuff repair

This is a hosted study being led by Mr Cormac Kelly (Consultant Orthopaedic Surgeon)



Disorders of the muscles and tendons of the shoulder, the rotator cuff (RC), are the most common cause of shoulder pain. Injury to the RC, e.g. a tear, can result in significant pain and disability. The number of operations to repair the torn RC has increased significantly over recent years and surgical techniques have advanced but the rehabilitation after surgery has not. This is problematic because rehabilitation is key to good outcomes. However, it is not known when rehabilitation after surgery should begin. Currently most patients are advised to rest their arm in a sling for four to six weeks after the operation, but evidence suggests that starting rehabilitation early (as soon as possible after surgery) might help people return to their usual activities more quickly, which is important to patients. The aim of this small study is to assess the feasibility of conducting a larger trial which will test whether early rehabilitation is more clinically and cost-effective than the usual practice of delayed rehabilitation.

The study opened at RJAH at the end of January 2019, and 2 participants had been recruited by the end of the financial year (31st March 2019).



RFPB Study 2: Stratified Primary Care for Musculoskeletal Pain: The STarT MSK Trial

Musculoskeletal pain such as back, knee, shoulder, or multi-site pain is very common. It is the number one reason why people take time off work and accounts for 1/5th of all GP consultations. Most people soon recover, however approximately 1/3rd of patients still report disabling pain one year after consulting their GP. Early identification of this group of patients as well as finding more effective treatments for them is a high priority. Stratified care involves GPs using a short questionnaire to help identify patients who are at risk of having persistent disabling pain and providing recommended matched treatment options. The STarT MSK trial aims to establish if stratified GP care is more clinically and cost effective compared to usual GP care for these common musculoskeletal conditions.

RJAH is involved in this primary care study purely as a treatment site. Patients identified as high priority are treated by our highly experienced and specialised musculoskeletal physiotherapists thus avoiding the potential for prolonged treatment, pain and disability. This hosted study is an example of how RJAH can influence the greater NHS community by working with and establishing greater links with primary care to deliver the best for our patients. As a consequence, there is no direct recruitment attributed to RJAH.



Industry Funded Research

The importance of industry (commercial) funded research studies to the NHS is seen in several NHS documents. In the NHS England research plan, published in April 2017, NHS England commit “..to providing an environment where technologies can be developed and tested, and used to transform services to improve outcomes and reduce cost.” Industry funded studies bring savings to the NHS by providing new treatments and technologies, and by providing funds to conduct the study.

RJAH repeatedly works to fulfil this commitment and during 2018-19, was involved in the delivery of 18 commercially funded studies in rheumatology, paediatrics, knee replacement surgery to name but a few areas. *In fact during 2018-19 for all NIHR orthopaedic badged studies RJAH was the top recruiter with 246 participants over 14 studies. And since the beginning of 2017-18 to present day, RJAH are the top recruiting Trust NATIONALLY to commercial studies badged as orthopaedic.*

One commercial study opened during 2018-19 is the COMPACT study, which evaluates the real-world safety and effectiveness of a biosimilar used to treat rheumatoid arthritis conditions. Biosimilar treatments are generally less costly than the original drug, but their safety and effectiveness is questioned. This study is an example of how the 44 RJAH patients recruited during 2018-19 are directly impacting value for money through cost of drugs.

Industry funded studies bring savings to the NHS



Research Day

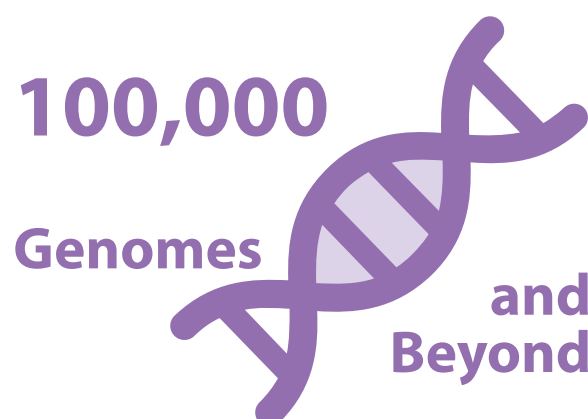
In April 2018, the Trust with the Orthopaedic Institute held its 19th Annual Research Day. This is an opportunity for clinicians and academic scientists to come together to present their research and to showcase their skills, knowledge and expertise with a view to fulfilling the NHS vision of delivering early stage, translational research through to bedside care



Prizes were given to the best posters and presentations for both the science and the clinical category.

- Jan Herman Kuiper won best science poster with **“Modelling and predicting the long-term outcome of Autologous Chondrocyte Implantation.”**
- Rohit Dhawan won best clinical poster with **“Weight bearing – how partial are we?”**
- Emma Howard won the Golden Test Tube, for the best science presentation with **“Development of a new single metric for the prediction of pathological fractures in patients with metastatic disease of the lower limb.”**
- Ashley Brown won the Programme Director’s Trophy with **“Twitching on the operating table: the acoustic signature of arthroplasty surgeons.”**
- Catriona Heaver won the Professor’s Medal with **“Greater Trochanteric Pain Syndrome – Focused Extracorporeal shockwave therapy versus corticosteroid injection: A randomised Trial.”** This study is in the process of being published and is a direct reply to the call by National Institute for Health Care Excellence (NICE) for further evidence to support the use of extracorporeal shockwave therapy for musculoskeletal conditions. This randomised controlled study followed patients for 12 months to assess the long term functional and quality of life outcomes. Depending on the results, this study could result in a new service being offered at RJAH to those patients who have failed the conservative management and left to live with the pain and disability of this condition.

The guest lecturer for the science section was **Dr Mark Cook**, Consultant Haematologist, Associate Director for Research (Cancer), Trust Lead Cancer Clinician, University Hospital of Birmingham, who delivered a fascinating talk on **“100,000 Genomes and Beyond - Informing Research and Clinical Practice.”** The 100,000 genome project, invited patients and their families with a rare disease, and patients with cancer to take part by donating a sample of their blood. Through sequencing the genome (DNA) collected, the team hope that a new genomic medicine service for the NHS can be created – transforming the way people are cared for. As a result, patients may be offered a diagnosis where there wasn’t one before as well as the potential of a new and more effective treatment. RJAH patients contributed to the project and many of our clinicians are eager to have access to the genomic data to further their own research. This is a fast moving and exciting area of research that RJAH are involved in.





Quality and Safety

Research in the NHS is conducted under the guidance of Good Clinical Practice, the international ethical, scientific and practical standard to which all clinical research is conducted. It provides public assurance that the rights, safety and wellbeing of research participants are protected. Patients should be fully informed and give their consent to taking part before participation in any research study. This in turn ensures quality reliable research data that evidences changes to improve care benefiting the patient and the wider NHS.

In April 2018, as a result of a concern raised through the whistleblowing policy, the research dept. was subject to an internal investigation followed by an external investigation by the Trust's auditors. The concern raised centred on 4 post market surveillance arthroplasty studies and the sharing of patient personal identifiable data with the commercial company seemingly without patient's consent. This was an information governance serious breach and was reported to the Information Commissioner's Office. The investigation concluded that this was a historic breach, dating back to between 2006 and 2013 and had occurred before the studies had transferred to the research dept. for management in 2014. However, this gave the dept. the opportunity to review their operating procedures and processes, and to develop a robust governance quality management system, so further safeguarding the Trust and our patients in the involvement in future research.



International Clinical Trials day

In May 2018, the dept. celebrated International Clinical Trials Day by manning a stand in the foyer of the Trust with a range of information posters and leaflets for staff and patients alike.

Clinical trials that are randomised controlled are considered to be of higher quality than those that are not; however, many patients do not understand the meaning of randomisation. Hence, we introduced the “**Randomisation Game**” where patients and staff were invited to choose any ball from the bag by chance. The ball chosen dictated whether a prize was won or not. This provided much fun and explained the meaning of randomisation in a simpler format.

NHS R&D Forum

The NHS R&D Forum is an annual event and in May 2018, 2 members of the research dept. attended the Conference, providing the opportunity to network and share ideas and concerns. It was clear that research in the NHS is important to ensure robust quality evidence to drive change to benefit our patients and provide value for money.

RJAH continues to be a research active Trust providing cutting edge treatments and services as a result to our patients, supporting the aim to be a provider of World Class patient care.

