Agenda item 6.3





Research & Development Annual Report (April 2020 - March 2021)

Contents	Page(s)
Introduction	3
Background	3
1. Promotion of Research and use of Research Evidence	3-22
1.1 NIHR Portfolio Study Activity 1.2 Studies Funded by Hull CCG	3-4 4-20
1.2.1 Budget year 2016-17 1.2.2 Budget year 2018-19 1.2.3 Budget year 2019-20 1.2.4 Non- funded CCG Studies	4-6 7-11 11-14 14-17
 1.3 Excess Treatment Costs 1.3.1 Status Updates 1.3.2 National Changes to the Excess Treatment Cost Process 	17-20 17-20 20
 1.4 Strategic Work 1.4.1 R & D Strategy/ Vision 1.4.2 Health Research, Innovation, Evaluation and improvement Group 1.4.3 Increasing the NIHR Portfolio Research Study Activity. 	20 20-21 21 22
2. Development Work	22
2.1.1 CCG Development work 2.2.2 Development work in 2020-21	22 22
Summary	23
Glossary	23
References	24
Appendices	25-28

Separate Papers

Paper 1 - An evaluation of Connect Well and Social Prescribing in Hull: Final evaluation report January 2019 – December 2020.

Paper 2 – PACE: Proactive Anticipatory Care Evaluation.

Introduction

The purpose of this Research and Development (R&D) Annual Report 2020-21 is to present information to the NHS Hull Clinical Commissioning Board on the NHS Hull CCG Annual Research and Development (R&D) activity for the period: **1st April 2020 to 31st March 2021**.

The report has previously been presented to the NHS Hull Clinical Commissioning Group Quality and Performance Committee, in June 2021.

The Annual report focuses on the R&D response to the COVID 19 situation and the locally grown non- COVID R & D studies and the possible development opportunities.

The report focuses on the following:

- R&D response to COVID 19 and the Urgent Public Health (UPH) NIHR portfolio Study Activity for 2020/21
- Status update reports on Hull CCG small grants funded projects
- Status update on Hull open Excess treatment costs
- Update(s) on R&D strategic development work into 2020/21

Background

In 2020-21 the role of Research & Development (R&D) in the pandemic has been recognised as pivotal in 'fighting' COVID 19. R&D has helped by gathering clinical and epidemiological evidence to inform national policy and generate new treatments, diagnostics and vaccine(s) to be developed and tested. Alongside this R&D has continued to support and provide the evidence that NHS Hull Clinical Commissioning Group (Hull CCG) has still maintained and developed its statutory duty to 'promote research, innovation and the use of research evidence' (Health and Social Care Act, 2012).

The nationally prioritised COVID19 studies have supported the creation of better diagnosis, tested potential new treatments and helped to drive forward the vaccine trial work.

At the beginning of April 2020 details emerged of a 'ramping up' on the focus of fast tracked COVID 19 research programmes. Examples of the trials in primary care, hospital settings and Intensive care Units (ICUs) included:

- PRINCIPLE (higher risk patients in primary care trial). www.principletrial.org
- RECOVERY (in hospital trial) <u>https://www.recoverytrial.net</u>
- REMAP-CAP (critically ill patient trial) <u>https://www.remapcap.org</u>

More information on the hospital and ICU trials is located on the links above and other COVID 19 priority studies (including some observational) are detailed at: <u>https://www.nihr.ac.uk/covid-19/urgent-public-health-studies-covid-19.htm</u>

1. Promotion of Research and use of Research Evidence.

1.1 NIHR Portfolio Study Activity.

The data from the NIHR portfolio study report presents the Urgent Public Health (UPH) COVID 19 study activity and the NON- COVID study activity between the period; **1st April 2020 to 31st March 2021.** The report is shown in **Appendix 1** and lists the number of practices recruiting and the studies that have been recruited to.

The data when compared to the previous year identifies a fall in actual participant recruitment yet the numbers of sites engaging in research in Hull has slightly increased from **9 GP sites to 12 GP sites**, engaging in research particularly the Urgent Public Health (UPH) COVID 19 study in primary care.

The Numbers of GP sites engaging in the UPH study in primary care has been **eleven**; the **PRINCIPLE** study has been the predominant UPH in primary care.

A summary of the study is given below:

The PRINCIPLE trial platform is a national priority trial to find treatments for COVID-19. It is a country-wide trial, and the only national priority platform trial in primary care. The trial is designed to test a range of treatments in the community, with treatment arms that can be stopped, replaced or added.

The aims are to find treatments for COVID-19 for people in the community who are at higher risk of complications and find medicines that can help people get better quickly and stop them needing to go to hospital

1.2 Studies Funded by Hull CCG

Hull CCG has funded locally-grown research since 2013 as part of its commitment to promote research and utilise evidence to inform its commissioning priorities. The reports below provide the progress updates on the status of studies allocated monies from the Hull CCG R&D budget since 2015.

The study progress reports for those studies still open are shown below. Closed studies will have been included in previous annual and status updates to the CCG.

1.2.1 Budget year 2016-17

Lesley Glover: Working with Older People to design sustainable healthy lifestyle interventionsDearEST lifestyle interventions refer to In everyday language these are good hydration (Drink),
healthy diet (Eat), exercise (movEment), rest (Sleep) and social interaction (Talk) (DEarEST).PurposeIn partnership with older people in Hull the research team will explore what it
means to maintain health and well-being in older age and the barriers and
facilitators to this.

Funding	£29964.00
Status	Closed. The recommendations from the end of study report were presented in Hull CCG R & D Annual report 2018-19.

1.2.2 Budget Year 2018-19

Applicant Name	Speech & Language Therapy Review – Early Years Cohort
and	
Research title	Bernie Dawson/Mike Foers Commissioning Manager(s) Linked in with the University of Sheffield with Dr Judy Clegg.
Funding Amount	£4,166 + VAT
Projected start	March 2019 – June 2021
and end date	(Timelines being addressed for completion of analysis/review)
Project	Project Brief/aims:
Aims/question(s) /outputs	1. Analyse anonymised data from a three-year period of referrals to Hull NHS Paediatric Speech and Language Therapy Service
	 To complete the analysis of the anonymised data to identify patterns and to explain the long waiting list times and make recommendation as to how the pathway from referral to appointment can be reduced.
	3. Write a report to the Hull Clinical Commissioning Groups making recommendations for service provision.
Applicant Name and Research title	Evaluation of Connect Well and Social Prescribing in Hull Jo Bell
Funding Amount	£49,990.76 (Hull CCG and Hull City Council Funding project)
Projected start and end date	January 2019 –December 2020
Project Aims/question(s) /outputs	The aims of this study were to explore and evaluate the extent to which identified outcomes were achieved in respect of social prescribing in Hull. Particularly for people with long-term conditions, complex conditions and frailty.
	The aims of the social prescribing service were identified as: 1. Improve the health and wellbeing of service users -including health, independence and ability to self-manage their care needs 2. Improve service user's self-reported wellbeing 3. Improve service user's ability to self-manage their condition 4. Provide timely access to social prescribing support and generalist welfare advice 5. Contribute to a reduction in primary care attendances for non-medical reasons, particularly for people with long-term conditions, complex conditions and frailty.

The study has been completed the final report has been submitted to the CCG and Hull City Council. This included recommendations for future delivery of social prescribing and the conduct of future evaluations. These have the potential to influence future developments of social prescribing locally. The final report has been received by the R&D service and will inform commissioning intentions/work going forward to help inform the needs of the local population.
Lisa Billingham/ Prof Mike Holmes - Evaluating the impact of multi-professional teams on clinician and non-clinician wellbeing.
£15,990.00
March 2019—December 2021
Aims: To evaluate the impact on wellbeing of staff by conducting a comparative study between practices with a multi-professional workforce and those with a more traditional workforce.
The findings will highlight benefits to multi-professional working, thereby providing evidence for the merits of investing in developing a multi-professional team.
Positive evidence will encourage more practices to adopt a multi- professional approach, which can increase access for patients in the current climate of workforce challenges.
By improving wellbeing and workload we will in turn be able to improve access to the team , which is the biggest issue facing many of our populations at this time.
The study has not been able to progress within planned timelines due to the Covid-19 pandemic and winter pressures.
Dr Scot Richardson (Lead) - For R & D infrastructure, capacity building and to 'grow' research in the locality and offer 'headspace' time.
£25,764,48
2019 – Present day
Initiative Aims:
 Develop and raise the awareness of primary care research agenda within Hull and specifically Hull North Research Cluster 1. Support and develop practices within Hull GP Collaborative to become more research aware and potentially facilitating them to become involved in primary care research activities. 2. Increase patient numbers within primary care research in Hull. 3. Design and carry out home grown research, sharing learning and experience within all groupings (networks) within Hull in order to foster a new culture of home-grown primary care

Having a Research Assistant within our practice has allowed for the expanding of research capacity. Allowing us the opportunity to be involved in Covid-19 trials has enabled us to help & educate our patients.
Details of the research studies engaged with are: DECIDE – TYPE 2 DIABETES Study Code D1690R00009 University of Liverpool
OPIOID ANALGESIC DEPENDENCE. University of Liverpool
PRINCIPLE – COVID-19. IRAS Ref: 281958 University of Oxford
COVID SEROLOGY SURVELLIENCE – COVID -19 The RCGP Research and Surveillance Centre (RSC) University of Oxford
COVID VIROLOGY SURVELLIENCE – COVID -19 The RCGP Research and Surveillance Centre (RSC) University of Oxford
REDUCE – DEPRESSION IRAS Ref: 266517 HYMS
MAGNIFY – COPD OPRIUK-1803 OPRI (Observational and Pragmatic Research International Ltd FRONTIER – MSK IRAS Ref: 261530 University of the West of England
CHILDRENS ECZEMA IRAS Ref: 270218 Rotherham Doncaster and South Humber NHS Trust Foundation
PEOPLE HULL – LUNG HEALTH IRAS Ref: 241021 HYMS
HULL ASTHMA PROJECT – ASTHMA AWARENESS HYMS
The team have found that recruitment was originally paused apart from Covid-19 trials but now experiencing studies opening up again. Also having our BEVAN Primary Care Network (PCN) research ready has helped in many areas.
Our research assistant has also helped another practice outside of our PCN become research ready and an invitation to join our cluster has

been accepted.
Covid-19 has impacted recruitment during the early stages.
The Research Assistant has encouraged 5 other practices within our PCN to become research ready and sign up to trials. The PCN has worked together with the PRINCIPLE Trial working alongside The Oxford University and have also worked together with an Opioid Analgesic Dependence study.
Being part of Covid-19 Studies is noted as having a huge impact on the current pandemic. The Research Assistant is also leading a Covid-19 Serology Surveillance Project (Blood sampling) which is amazing to be part of.
We are helping the local population in many areas with our variety of studies such as Covid-19, depression and dependence. Skin care MSK, Asthma etc.
Outcome: Definite increase with the practice capacity & portfolio of studies benefiting the local population

1.2.3 Budget Year 2019-20

In partnership with the Hull CCG Health Research, Innovation, Evaluation and Improvement group the R & D team held a Panel meeting in February 2020 to discuss three applications that had been received for possible R & D monies. A panel meeting was held and applicants were asked to present and take questions. The table below lists the projects have been awarded Hull CCG funding from R & D.

Applicant Name and Research title	Professor Fliss Murtagh/Mabel Okoeki (co-Leads) University of Hull, Allam Medical Building, Title: Understanding facilitators and barriers to inform ongoing service development of the Integrated Care Service for older frail people at the Jean Bishop Centre.
Funding Amount	£21,928
Projected	Sept 2020 – Sept 2021
Start and End	(Extended to March 2022 with impact of pandemic)
date	
Outline of study Aims/Research question	The study has commenced, and we have changed the title of the study to "Proactive Anticipatory Assessment of older frail people: how best to deliver follow up, improve care home transition, and develop future services". This is to reflect the additional area of focus requested by the funder, Hull CCG. The purpose of this study is to explore facilitators and barriers to inform ongoing service re-design of the Integrated Care Service for older frail people at the Jean Bishop Centre.

Г г	
	 The proposed study objectives are to: Identify facilitators and barriers to follow-through and possible impact from the patients' and family carers' perspectives. Understand perspectives and challenges faced by health professionals within the integrated care team, and within the primary and community services regarding this new model of care. Understand the feasibility of long-term monitoring of patients and their outcome once they are returned for primary care review.
	The initial plan was to explore through interviews with patients, families and professionals, facilitators and barriers to inform ongoing service development of the Integrated Care Service for older frail people at the Jean Bishop Centre. However, we have also included (as requested by the Hull CCG) a section to assess the wellbeing of patients who are discharged from hospitals to care homes and are assessed by the ICC Frailty Service.
	The team have scoped the literature to identify emerging evidence in this area of research, and ensure we build on existing and emerging evidence.
	A protocol for the study has been developed, reviewed and finalised by the research and Jean Bishop Integrated Care Centre (ICC) team. We decided within the protocol to divide the study into 2 sections/work package.
	The 1st work package includes interviews with patients and health professionals (HP) who have been assessed at the ICC and are affiliated with the ICC work respectively, with a focus on how effective follow-up after the ICC assessment is best achieved.
	The 2nd work package involves gathering patients' and family perspectives on the assessment by the ICC frailty team on their arrival at the care home. This will be a survey, followed (in a sub sample) by a short interview to explore further the answers provided in the survey.
	The team have developed and tested the survey questions, in discussion with the ICC team, including the online platform (the survey will be BOTH online and hard copy, to maximise responses)
	We have developed and refined the topic guide.
	All study documents including the survey, information sheets, consent form, study introduction leaflets, letter of invitations and topic guides have also been developed.
	The patient-facing study documents are currently being reviewed by the Patient and Public Involvement (PPI) group within the University.
	The team have identified all approvals (including NHS and university) needed for the study and are currently completing the necessary documentation. All organisation whose approvals are needed have

	been informed about the study.
	The planned submission for approvals was is March 2021 this will then see the commencement of recruitment and data collection once all approvals have been received.
Applicant Name	Benn Hardcastle Project Lead, Hull KR Community Foundation
and Research title	Hull Kingston Rovers Rugby League Club C/O NHS Hull CCG – Teaming up for Health Team (Contact Erica Daley)
Funding Amount	£84,000
Projected Start and End date	April 2021 (Start date delayed due to COVID-19), agreed by all parties. End date: July 2022
Outline of study Aims/Research question	The Hull KR Healthy Mind Healthy You Program is a five-step education program which uses the power of the Hull KR brand, and its elite players, to increase mental health awareness among children, young people and parents, reduce the stigma around mental illness, start positive conversations and encourage help-seeking behaviours.
	 Research questions: What impact does the programme have on young people's knowledge / awareness of mental health? Are young people more knowledgeable about mental health following completion of the programme? Do young people's attitudes toward mental health change? Are young people more likely to refer themselves or others to support following access to the programme? Are young people's families / carers more aware of referral routes and access to support after involvement in the programme? What are families / carers perceptions of the value of the Healthy Mind Healthy You Programme? To themselves? To their young person? What do teachers perceive as the impact of the programme on mental health and wellbeing in the school? To themselves? To the young person? To the school? Does the Healthy Mind Healthy You Programme impact on X (e.g. attendance levels, bullying reporting, student grades etc.)? Since delivery has taken place there has been a huge benefit to the local population. With the current pandemic, there has been a huge programme like 'Healthy Mind Healthy You' has given so many individuals the chance to think about their own mental health. It has also given them information about where they can seek help if they need it.

Applicant Name	Patience Young/ Linda Hoban
and	Moving in Dignity
Research title	
Funding Amount	£10,000
Projected	August 2020- March 2021
Start and End	
date	
Outline of study	The overall aim of the project is to change processes when
Aims/Research	assessing for, and providing support with moving and handling.
question	Current provision dictates that a minimum of 2 people are almost
	always required when hoisting. However, there has been research and
	evidence to suggest this is not always necessary or appropriate. The
	project will develop assessor's skills, competence and ability to change
	process. With the result being personalised care, rather than being
	determined by custom and practice.
	An evaluation of the project is to be undertaken, bringing in the
	application of a mixed methods approach. Connections have been
	made by the project lead(s) to York St John's University
	The study is progressing within planned timelines following the
	appointment of a research assistant in December 2020.
	The Research assistant has identified a cohort and commenced
	qualitative interviews; the preliminary interviews concluded by OT
	students from York St John University supported confirmation of the
	study design and are helping theme outcomes.
	All Primary objectives are on track in terms of review of the impact on
	care provision.

1.2.4 Non funded Hull CCG Studies

Applicant Name and Research title	PEOPLE-HULL: Primary care and community Engagement to Optimise time to Presentation with Lung cancer symptoms in HULL Julie Walabyeki Research Fellow The University of Hull
Funding Amount	£712,501 Yorkshire Cancer Research
Projected start and end date	June 2019, was expected to close May 2020 but delayed with pandemic delayed recruitment.
Progress Update from the Study Team	The overall purpose of this study is to develop and test a theoretically driven multi-faceted community-primary care linked intervention to improve presentation to GPs by patients with potential lung cancer symptoms , and onward referral by GPs of patients with potential lung cancer symptoms, ultimately reducing the number advanced stage lung cancers being diagnosed.
	The specific aims of this component are to:

1.Develop a theoretically driven community-based and general practice-delivered intervention to improve awareness and understanding of lung cancer symptoms in Hull:
 Raise the awareness of lung cancer symptoms via community awareness raising initiatives (building on our media campaign in Phase 1)
 Raise the awareness of lung cancer in practices via educational opportunities/events and quality improvement initiatives
c. Enable practices to respond to requests for appointments in a timely fashion.d. Invite patients for Lung Health Checks within practices
2. Evaluate the impact of the intervention in terms of uptake of the Lung Health Check, presentation with potential lung cancer symptoms, referral for chest X-ray (CXR) or urgent referral, proportion of emergency presentations, proportion of Stage III and IV cancers diagnosed.
The Research Questions are:
1.Does the intervention:
 a) Reduce the time from first symptom to help-seeking? b) Increase the number of smokers and ex-smokers consulting with respiratory symptoms? c) Reduce the number of consultations with relevant lung symptoms between first presentation and referral (or length of time from first relevant symptom to referral)? d) Increase the number of CXRs and urgent referrals to respiratory clinics, during and post-intervention? e) Reduce the rate of emergency presentations with lung cancer?
f) Down-stage the cancer diagnosis?
2. What is the uptake of the Lung Health Check?3.Is this intervention acceptable to patients and practitioners
Practice recruitment was due to commence in January 2021. However, this had to be suspended to March 2021 to allow for the COVID-19 vaccination programme to progress successfully within practices.
Practice component: The team have substantial amendment approval from the HRA and are on track to start recruitment in March 2021. A total of two practices have expressed their interest with further discussions taking place with other practices.
The third phase of the questionnaire distribution is underway, and 327 questionnaires have been completed so far, as of March 2021.
Practice media campaign development Campaign development is currently underway and community focus group discussions have taken place.

Applicant Name and Research title	The team have conducted five online focus group discussions with five community groups. The other groups have technological challenges such as no internet; no IT skills and some do not have telephones. They indicated their preference to face-to-face meetings which are not recommended currently due to COVID restrictions therefore this is postponed this to later in the year. The data analysis for the two previous rounds is currently underway. SENTINEL: Short Acting Beta Agonists (SABA) or commonly known as 'reliever Inhaler' Reduction Through Implementing Hull Asthma Guidelines.
	Senior Clinical Lecturer in Respiratory Medicine
Funding Amount	£406,092
Projected start	AstraZeneca through a Joint working agreement (JWA) with HUTH November 2020 -
and end date	December 2022
Progress Update	Project aims:
from the Study Team	To improve asthma outcomes through guideline implementation to reduce SABA over-reliance. Through reducing SABA prescribing and improving asthma outcomes, SENTINEL also aims to reduce the environmental impact of asthma treatment in the region. Data from our pilot PCN are very positive, demonstrating reduced SABA prescribing and a marked reduction in the proportion of inhaled therapies that are SABA. The full project evaluation will assess impact on exacerbations, but these data are not yet available. The project has also supported many patients to have asthma reviews that meet Quality and Outcomes Framework (QoF) standards.
Applicant Name	Proactive Anticipatory Care Evaluation (PACE)
and Research title	Mabel Okoeki Research Associate/Project Lead The University of Hull (A non-randomised, controlled study with an embedded qualitative component to assess the effectiveness of a proactive, anticipatory multidisciplinary care intervention for frail older people).
Funding Amount	Not applicable – research posts funded through University of Hull but
_	not project specific
Projected start and end date	01-10-2018 31/12/2021 (please note that end date was due to be 31/12/20 but COVID delays have prevented control group data collection between

	March 2020 and Jan 2021)						
Progress Update from the Study Team	This is a non-randomised control study evaluating the impact of a new integrated service (a frailty care pathway at the Jean Bishop Integrated Care Centre (ICC) and within care homes) on quality of life and wellbeing of frail older people living in Hull .						
	Aims : To look at the experiences of people that have used the ICC and how these experiences can be used to refine And improve the model of care provided.						
	The research question is as follows: What are the experiences of those people using the ICC and related services and how can these experiences be used to refine and improve the model of care provided?						
	[Please note that we are also looking at the impact of the ICC on self- reported quality of life and wellbeing of those people who receive ICC care; this will be reported separately)						
	This evaluation is being carried out by recruiting intervention (those accessing the new service) and control group (and those not accessing the service) participants to complete a validated health questionnaire.						
	Recruitment at the ICC and care homes was completed in April 2020, analyses of the intervention group have progressed well, but control group data collection was halted by COVID and was only able to re- start in Jan 2021.						
	 We have completed intervention group data collection (n=250) Control group data collection was paused by COVID but has now resumed (n = 28 to date) The comparative analysis cannot take place until the control group data is collected – so we have not achieved this objective We have however achieved the objective of undertaking a detailed analysis of the patient perspectives about the ICC We have presented these findings to the ICC team We are submitting a short report to a journal about the main findings of the experience of the ICC as an innovative model of care 						
	The final ICC Experience report was presented to the NHS Hull CCG Quality and Performance Committee in June 2021.						

1.3 Excess Treatment Costs

Excess Treatment Costs (ETCs) are the difference between the total treatment costs incurred as part of a research study and the cost of standard treatment. ETCs that occur in research in England funded by Government and Research Charity partner organisations should be met as part of the normal commissioning process (NHS England, 2015).

1.3.1 Status Updates

The table below provides progress updates from studies that have been allotted ETC funding from Hull CCG and are currently still open.

Study Title	BASIL III Balloon vs Stenting in Severe Ischaemia of the Leg-3
Study Details	To determine which of three methods (plain balloon, drug-coated balloon or drug releasing stent) keeps patients with severe limb ischaemia alive and with their leg intact, the longest.
Study End Date	2019
ETC Amount Approved	£5025.00
Progress Update from the Study Team	Despite the pause in recruitment activity due to COVID-19, since the study restarted in July 2020, Hull site have been able to recruit a further 3 patients.
	There are now less than 20 patients to recruit to the whole trial.
	The overall revised recruitment target has reduced to 389 participants. Hull site has now exceeded site target of 25 participants (agreed with PI and lead site).
	HUTH is one of the top recruiters in the UK for this trial. We have now recruited 28 participants.
	We are still one of the top 3 recruiters for the whole study (41 centres in total).
	The database will close for analysis following completion of recruitment.
Study Title	HERO
Study Details	To determine the clinical and cost effectiveness of a home-based exercise intervention for older people with frailty as extended rehabilitation following acute illness or injury, including internal pilot and embedded process evaluation
Study End Date	2021
ETC Amount Approved	£13068.40
Progress Update from the Study Team	Study lead confirmed there had been little change since the 2020 update due to the impacts of the pandemic. The trial has re-opened to recruitment nationally; however, some sites (including Hull) do not yet have capacity to re-open.

	A further extension is being sought in regard to the recruitment end po – which is currently extended to April 2021 due to time lost as result o COVID-19. The current recruitment figure stands at 619 with a target					
	742.					
Study Title	CLASP – Cancer Life Affirming Survivorship in Primary Care					
Study Details	The study aims to evaluate an online intervention offering lifestyle and wellbeing support for cancer survivors					
Study End Date	2019					
ETC Amount Approved	£878.40					
Progress Update from the Study Team	There has been a delay in follow up as recruitment finished later than anticipated, in March 2020. With follow up (notes review) at 1 year.					
Study Title	ASPECT					
Study Details	A randomised controlled trial comparing the clinical and cost-effectiveness of one session treatment with multi-session cognitive behavioural therapy in children with specific phobias					
Study End Date	2021					
ETC Amount Approved	£6808.00					
Progress Update from the Study Team	Recruitment to the study ended in January 2020 with 274 children and young people consenting to the trial. This exceeded our revised recruitment target of 246 that was set in July 2019 as part of our funded 7-month extension.					
	All study follow ups were completed in September 2020. We are shortly due to have the results reveal for the study in which we will find out whether OST demonstrates non-inferiority to CBT for treating specific phobias in children and young people.					
	The writing of our final report is well underway and on track.					
Study Title	MIDFUT – Multiple Interventions for Diabetic Foot Ulcer Treatment					
Study Details	Phase II – the study will investigate the short-term efficacy of 4 treatment strategies compared to treatment as usual (TAU); Phase III will investigate the clinical and cost effectiveness of a maximum of two treatment strategies continued from Phase II compared to TAU in the treatment of hard to heal Diabetic Foot Ulcers.					
Study End Date	2022					
ETC Amount Approved	£1873.20					
Progress Update from the Study	The study was paused to recruitment due to COVID-19 and will be requesting a 6-month extension.					

Team	 There has been difficulty recruiting overall across all sites in the trial. An amendment was submitted to rectify patient eligibility criteria to help improve recruitment. In Hull, we rely on referrals from the CHCP podiatry clinics. A site investigator meeting took place 23rd September 2020 to discuss restart. Substantial amendment 13 was approved. The team are in contact with the CHCP podiatry clinic team. The Nurse Research team will find time to attend one of these clinics to check if we are missing any potential referrals and if so, how we can help to improve the referrals. Exclusion criteria are prohibitive at the Hull site since the patients that are seen in the hospital setting are no longer eligible due to extent of deterioration of the wound. Patients that could be eligible are more likely to be seen at CHCP podiatry clinics
Study Title	Cryostat
Study Details	Cryostat-2: A multi-centre, randomised, controlled trial evaluating the effects of early high-dose cryoprecipitate in adult patients with major trauma haemorrhage requiring major haemorrhage protocol (MHP) activation.
Study End Date	01/07/2020
ETC Amount Approved	£16,000 pa
Progress Update from the Study	Due to the impacts of COVID-19 the trial was suspended in March last year with the redeployment of the research nurse to ED.
Team	Currently there has been no new recruitment to the trial and it remains in suspension.

1.3.2 National Changes to the Excess Treatment Cost Process

As of October 1st 2018, the way Excess treatment costs (ETCs) was paid changed. Under the revised system the local Clinical Research network (LCRN) now help manage the ETC process on behalf of the CCGs and in collaboration with NHS England. A defined threshold for providers has been calculated at 0.01% of operating income with a lower threshold of £10,000. The budget to reimburse ETC spend in excess of the (non –primary care) provider threshold is managed by the CRN with payments made by the LCRN on behalf of the CCGs in England.

1.4 Strategic Work

1.4.1 R&D Strategy/ Vision.

A revised R&D Partnership Vision was approved by the CCG Board in March 2019 with Hull CCG, Hull City Council and Hull, York Medical School, The University of Hull. The Vision was underpinned by National drivers, such as the Health and Social Care Act (2012) which placed a duty on commissioners to deliver the key statutory duties; to promote and support research, to use research evidence in commissioning and to ensure treatment costs in research are appropriately resourced. The vision aims to support the Hull Place Plan by:

- Ensuring those who commission and deliver health related services in Hull have the capacity and capability to make and direct evidence informed decision and conduct innovation, evaluation, and improvement work as a foundation for the Hull Place Plan objectives. This will enable a change in culture that supports the highest quality outcomes for the population of Hull.
- Increasing the involvement by patients, carers, and the people of Hull in the research cycle from conception of research through to dissemination of results- in order that their insight and experience can help to improve the quality, relevance and effectiveness of local studies.

The vision will look to embed a culture of integrated working and innovative approaches in all aspects of the CCG work with the aim of ensuring the people of Hull receive improved health and care outcomes.

It will aim to achieve excellence in supporting research, innovation, evaluation and Improvement and to routinely use the best available evidence in decision making that delivers the highest quality health and care outcomes for the people in Hull.

In 2019 - 2020, the following actions have been initiated but in response to COVID 19 progressing further strategic work has been postponed:

- A partnership Vision meeting has been held to initiate a performance delivery plan bringing in the necessary stakeholders.
- A DRAFT performance plan has been developed. Some initial work had been commenced but in response to the COVID 19 situation has been put on hold.
- A task and finish communications group was initiated with Partners to drive forward the key messages of the Partnership Vision.

During April 2020 to March 2021 the strategic work has been put on 'hold' and is being considered on a wider CCG(s) sub- system level.

1.4.2 Health Research, Innovation, Evaluation and Improvement Group.

In recognition of the national agenda and the establishment of a new partnership strategy to offer a firm commitment to the promotion of research, innovation, evaluation and improvement, a Hull Research, Innovation, Evaluation and improvement Group has been established and focuses on the following areas:

- Implementation of the overall delivery plan to meet the strategic aims of the Research, Innovation, Evaluation and Improvement Vision; which provides a framework for the CCG mandate to promote research and the use of research evidence.
- To achieve excellence in supporting Research, Innovation, Evaluation and Improvement by driving forward the strategic delivery plan which builds on the ambition to deliver the highest quality health and care outcomes for the people of Hull.
- Encompass the generation and application of Research, Innovative ideas, Evaluation and Improvement work, this will be underpinned be delivering on the Key aims set out in the CCG Vision.

How this strategic work is potentially restarted going forward in **2021-22** will be informed by the wider system level discussions.

With the pause in the strategic work, the R & D strategic action plan has not been revised for 2020-21.

1.4.3 Increasing the NIHR Portfolio Research Study Activity.

As per previous reporting, the shared R&D Service is continuing to engage with the Yorkshire and Humber Clinical Research Network (CRN). The aim of this partnership is to form a collaborative approach to improving the quality and quantity of local primary care engagement in research.

In 2019-20 the Yorkshire and Humber CRN underwent a strategic review of their role and functions, this has led to some of the engagement work with CRN being put 'on hold', dialogue has continued with the current CRN delivery team who in 2020-21 have been reconfigured into a newly established delivery team called the Agile Research Team (ART).

Work to proceed with linking in with the Yorkshire and Humber newly formed delivery team has restarted and partnership meetings are to be re- introduced in 2021-22.

2. Development work

2.1.1 CCG Development work.

 CROP – Campaign to Reduce Opiate Prescribing - A campaign to reduce Opiate Prescribing (CROP) has been instigated with research colleagues in West Yorkshire the Medicines Optimisation team are linked in with this piece of work, West Yorkshire have provided a summary of the key findings from the CROP Quality Improvement work that is included in **appendix 2** • **Research Capability Funding 2020-21** – Hull CCG was awarded Research Capability Funding for 2020-21 of 20,000. This is ring fenced Department of Health funding that can be utilised to support research capacity and research infrastructure in the Hull CCG area. National guidance stipulates how the funding can be spent. With the pandemic and the priority given to the urgent public health vaccine trials the scope for utilising this ring fenced funding had to be suspended with the focus being on the COVID 19 vaccine research.

2.1.2 Strategic Development work in 2020-21

The strategy would have been due for review in 2020-21 but with COVID 19 this work was paused.

In addition the wider sub system CCG(s) organisational development work and its potential link(s) to the ICS model have started to influence and shape the wider R & D discussions going forward at a place and system wide level.

Summary

This report presents evidence that Hull CCG continues to strive to be at the forefront in making the promotion of research and the use of research evidence a part of its core work.

The Annual Report demonstrates the following key highlights:

- The response of R&D to COVID 19 in the 2020-21 and its key role in gathering clinical and epidemiological evidence to inform national policy and generate new treatments, diagnostics and vaccine(s) to be developed.
- The priority that was given to urgent public health studies. In 2020-21 eleven GP practices in Hull participated in the Urgent Public Health study PRINICIPLE; this equates to just under half of GP practices in Hull. (Data cut from NIHR BI Unit 5-3-21)
- The enthusiasm and passion, that even with the challenges of COVID 19, meant non COVID work was still underway which is shown in the end of study reports attached and the Quality improvement work to improve asthma care for patients in Hull and the Campaign to reduce opiate prescribing work (CROP).
- The ambition of local study teams, local Investigators, and wider stakeholders to continue to drive forward the research agenda in the ever-changing situation of the pandemic and the adaptability to adjust study methodology and ethics.

Although the wider Hull CCG R & D Strategic work has required a period of reflection there remains the impetus and enthusiasm to drive forward an R & D strategy and push forward the mandate for Research and Development to help ensure commissioning decisions are based on the best available evidence.

Glossary of Terms

CRN	Clinical Research Network
DoH	Department of Health
DHSC	Department of Health and Social Care
Hull CCG	Hull Clinical Commissioning Group
NHS	National Health Service
R&D	Research and Development
NIHR	National Institute for Health Research
SABA	Short Acting Beta Agonists commonly referred to as 'reliever inhaler'.

References

Department of Health (2010) 'Equity and excellence: Liberating the NHS' [Online]. Available at:

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/213823/dh_11 7794.pdf

(Accessed 12 September 2018)

Department of Health (2011) 'Government response to the NHS Future Forum report' [Online]. Available at:

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/216361/dh_12 7719.pdf

(Accessed 12 September 2018)

Department of Health (2015) 'The NHS constitution' [Online]. Available at: <u>https://www.gov.uk/government/publications/the-nhs-constitution-for-england/the-nhs-constitution-for-england#</u> (Accessed 12 September 2018)

Health and Social Care Act (2012) 'Embedding research as a core function of the health service' [Online]. Available at: <u>https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/138273/C8.-</u> <u>Research-270412.pdf</u> (Accessed 12 September 2018)

NHS (2015) 'Delivering the Forward View: NHS planning guidance 2016/17-2020/21' [Online]. Available at:

https://www.england.nhs.uk/wp-content/uploads/2015/12/planning-guid-16-17-20-21.pdf (Accessed 12 September 2018)

NHS England (2015) 'Guidance on Excess Treatment Costs' [Online]. Available at: <u>https://www.england.nhs.uk/wp-content/uploads/2015/11/etc-guidance.pdf</u> (Accessed 12 September 2018)

NHS England (2017) 'Supporting Research in the NHS: A consultation covering changes to simplify arrangements for research in the NHS and associated changes to the terms of the NHS Standard Contract' [Online]. Available at:

https://www.engage.england.nhs.uk/consultation/simplifying-researcharrangements/user_uploads/supporting-research-consultation.pdf (Accessed 12 September 2018)

FINAL Version MG/TW June 2021

Appendix 1

NIHR National Institute for Health Research

NHS Hull CCG NIHR Research Activity from 1st April 2020 to the 31st March 2021

NHS Hull CCG	
No Practices in CCG	39
No Practices Recruiting	12
% Practices Recruiting	31%
CCG Studies	9
CCG Recruitment	145

NIHR ODP Data cut: 13th May 2021

NHS Hull CCG NIHR Research Activity from 1st April 2019 to the 31st March 2020

NHS Hull CCG				
No Practices in CCG	39			
No Practices Recruiting	9			
% Practices Recruiting	23%			
CCG Studies	8			
CCG Recruitment	305			
NULD ODD Data aut. 40th May 0004				

NIHR ODP Data cut: 13th May 2021

Practice Name	Recruits	Study Short Name
MODALITY PARTNERSHIP (HULL)	58	VIRUS WATCH V1
MODALITY PARTNESHIP (HULL)	9	REDUCE WORK STREAM 5
MODALITY PARTNESHIP (HULL)	8	PRINCIPLE
MODALITY PARTNESHIP (HULL)	5	THE GENTLE YEARS YOGA
MODALITY PARTNESHIP (HULL)	1	FITNET
MODALITY PARTNESHIP (HULL)	1	A STUDY EXPLORING RECRUITMENT BARRIERS TO HYVET 2
JAMES ALEXANDER FAMILY PRACTICE	14	RECAP
JAMES ALEXANDER FAMILY PRACTICE	8	CLINICAL PHARMACIST ECZEMA IN CHILDREN STUDY
JAMES ALEXANDER FAMILY PRACTICE	2	FRONTIER

JAMES ALEXANDER FAMILY PRACTICE	2	REDUCE WORKSTREAM 5
EAST HULL FAMILY PRACTICE	3	PRINCIPLE
KINGSTON MEDICAL GROUP	1	PRINCIPLE
THE SUTTON MANOR SURGERY	1	PRINCIPLE
DR IA GALEA AND PARTNERS	2	PRINCIPLE
SYDENHAM GROUP PRACTICE	3	PRINCIPLE
CITY HEALTH PRATICE LTD	1	PRINCIPLE
DR GT HENDROW'S PRACTICE	1	PRINCIPLE
DRS RAUT AND THOUFEEQ	22	RECAP
DRS RAUT AND THOUGEEQ	1	PRINCIPLE
EAST PARK PRACTICE	1	PRINCIPLE
HAXBY GROUP LTD	1	PRINCIPLE

NHIR ODP Data cut: 13th May 2021

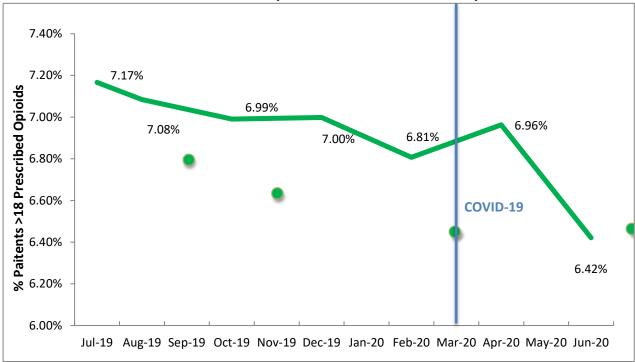
NB: Data is owned by and extracted from the NIHR CRN Business Intelligence Unit (BIU).

Acknowledgements and thanks to the Local Clinical research nurse team in supporting this practice level data cut.

Appendix 2

CROP

The Campaign to Reduce Opioid Prescribing (CROP) was carried out across 4 CCGs in the Humber and Coastal Vale Region. General Practices received tailored audit and feedback reports over a 12 month period. It was designed to focus on the prescribing of opioids for non-cancer pain in general practice.





The graph above demonstrates that the overall percentage of patients above the age of 18> prescribed opioids has reduced prior to the COVID-19 pandemic (up to report five) and continued to do so at report seven. However we know that the restrictions imposed by the national lockdown meant that for varying reasons prescribing of opioids was impacted, for example, virtual or telephone general practice consultations and patients and the public not presenting at general practices. Differences may also have arisen due to prescribing consultations being carried out over the phone or via a video conference without the ability of the prescriber and patient to meet face to face.

The reduction in the % of patients translates into 1672 patients no longer receiving a repeat opioid prescription.

	Report 5			Report 7				
						5%	project	
	prescribing	5% efficiency	project cost	Total	prescribing	efficiency	cost	Total
All CCGs	£29,466.88	£29,626.90	£18,000.00	£41,093.78	£107,804.34	£41,477.66	£18,000.00	£131,282.00
Hull CCG	£22,095.64	£10,882.64	£6,600.00	£26,378.28	£57,181.29	£15,235.70	£6,600.00	£65,816.98

In Hull CCG it is believed that the CCG through less prescribing activity also achieved a saving amounting to £57000 in cash saving and an efficiency gain of £15000 meaning a possible overall saving of approximately £65000.

Summary attained via West Yorkshire R & D Team.