

Research & Development

Six monthly Report

(April 2020- October 2020)

1 Introduction

- 1.1 The purpose of the report is to provide the NHS Hull CCG Board with a Research and Development (R&D) update, for the 6 monthly period of 1st April 2020 to 1st October 2020.
- 1.2 The update also focuses on the R & D response to the COVID 19 pandemic and assurance in respect of the proposed RESTART framework for non COVID studies.
- 1.3 The report recognises the role of R & D in the pandemic and provides evidence that NHS Hull Clinical Commissioning Group (ERY CCG) continues to maintain and develop its statutory duty to 'promote research, innovation and the use of research evidence' (Health and Social Care Act, 2012).
- 1.4 The report presents an update on the following:
 - The Research and Development response to COVID 19 and the Urgent Public Health (UPH) NIHR portfolio Study Activity
 - Status update(s) on CCG small grants funded projects
 - Status update on NHS Hull open Excess treatment costs
 - Update(s) on R&D strategic work into 2020/21

2. Background - Research & Development response to COVID 19.

- 2.1 In response to the pandemic the R & D shared service received a position statement from the Department of Health and Social Care; this being received on the 18th March 2020. The statement stated that until further notice the National Institute of Health Research (NIHR) which is supported by the Yorkshire and Humber Clinical Research Network was to 'pause' the site set up of any new or ongoing studies at NHS and social care sites, not nationally prioritised as COVID19 studies.
- 2.2 Any nationally prioritised COVID19 studies were to enable the clinical and epidemiological evidence was to be gathered, to inform national policy and enable new treatments, diagnostics and vaccine(s) to be developed and tested.
- 2.3 The pause excluded any studies being amended or implemented in response to COVID19 research programmes, thus supporting better diagnoses, test new treatments and help to prevent and manage the spread of the disease (HRA March 2020).
- 2.4 At the beginning of April 2020 details emerged of a 'ramping up' on the focus of fast tracked COVID 19 programmes. An example being the 2nd April 2020 directive from the Critical Emergency Management (CEM) and Chief Medical

Officers (CMO) offices for England, Northern Ireland, Scotland & Wales that every effort is placed on enrolling identified patients in the national priority clinical trials. 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) <https://www.recoverytrial.net>
- REMAP-CAP (critically ill patient trial) <https://www.remapcap.org>

2.5 Other priority studies (including some observational) can be found at:
<https://www.nihr.ac.uk/covid-19/urgent-public-health-studies-covid-19.htm>

2.6 The focus of trials was to achieve as easily as possible, so as not to place undue burden on the NHS; ensuring they are flexible in design to include additional treatments. The intention being that results will be shared as soon as possible to improve practice/care. The CMO also advised that where possible the recruitment of patients should be fast, and that any treatments are included in a trial where possible, as any treatments given outside of a trial are seen as wasted opportunities to inform research and provide benefit to others.

2.7 Prior to the CMO release the R & D shared service had also received the following commitments and mandates to ensure research continues to be a priority particularly with regard to new and emerging COVID19 studies. These included:

- HRA and NIHR –
<https://www.hra.nhs.uk/about-us/news-updates/research-nhs-during-covid-19-pandemic>
- NHS mandate -
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/875711/The_government_s_2020-2021_mandate_to_NHS_England_and_NHS_Improvement.pdf

2.8 The HRA continue to fast-track applications for COVID19 related studies, ensuring the prioritisation of these studies while making certain that clinical care and patient safety are priority. Other national research applications are being accepted for review but are likely to be delayed or moved to future Research Ethics Committee (REC) review.

2.9 With the recent pandemic the national priority has been on fast tracking urgent Public Health studies on COVID 19 and vaccine trial work.

2.10 The data from the NIHR outlined reflects the COVID 19 research activity in primary care across NHS Hull CCG.

3. Promotion of Research and use of Research Evidence.

3.1 National Institute for Health Research (NIHR) Portfolio Study Activity

3.1.1 The data from the NIHR portfolio study report presents the Urgent Public Health (UPH) COVID 19 study activity from the period 1st April 2020 to the end of September 2020. The report is shown in Appendix 1 and lists the number of practices recruiting and the UPH studies that have been recruited to.

3.1.2 The key UPH study that has recruited in primary care is the PRINCIPLE study being ran by Oxford University. A summary of the study is given below:

3.1.3 *The PRINCIPLE trial platform is a national priority trial to find treatments for COVID-19. It is now 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.

PRINCIPLE is currently evaluating usual care alone versus usual care plus azithromycin; or usual care plus doxycycline. Azithromycin is a commonly used antibiotic that is anti-inflammatory, treats community-acquired pneumonia and bacterial chest infections, and has antiviral properties. Doxycycline is another commonly used antibiotic.

The trial is being run by the University of Oxford and is funded by UK Research and Innovation and the Department for Health and Social Care through the National Institute for Health Research.

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.

3.2 Studies Funded by Hull CCG

3.2.1 Hull CCG has funded locally-grown research since 2013 as part of its commitment to promote research and the utilise evidence to inform its commissioning priorities.

3.3 Budget Year 2018-19

3.3.1 Speech & Language Therapy Review – Early Years Cohort.

Leads: Bernie Dawson/Mike Foers .Commissioning Manager(s). Linked with the University of Sheffield with Dr Judy Clegg.

Funding: £4,166 + VAT

Status: Progressing.

There have been some initial delays due to governance arrangements within Humber Teaching Hospital Foundation Trust (HTFT), access to the data. This is being resolved in collaboration with the HTFT Clinical Director.

3.3.2 Evaluation of Connect Well and Social Prescribing in Hull

Lead: Jo Bell

Funding: £49,990.76 (Hull CCG and Hull City Council Funding project)

Status: Progressing.

Further service user interviews and social care referrers have taken place. Further interviews with key stakeholders and wellbeing coordinators have been completed, to capture recent information regarding the working of the social prescribing service.

The Ethics approvals have been completed, for amendments to enable the introduction of online surveys and move interviews to remote methods (using online platforms and telephone).

Further progress is required for the following;

- Recruitment of service user participants.
- Survey to capture GP views; this has been circulated among GPs by the CCG.
- Access to data to enable quantitative analysis

The study will shape the development and delivery of social prescribing in Hull, through the identification of existing good practice, and recommendations for development. This may also identify areas of need identified by the pandemic, and have the potential to contribute to planning for the recovery phase of COVID-19.

3.3.3 Evaluating the impact of multi-professional teams on clinician and non-clinician wellbeing.

Lead: Lisa Billingham/ Prof Mike Holmes

Funding: £15,990.00

Status: Progressing.

The study team have introduced a wellbeing strategy. In addition to setting up a wellbeing oversight group and carrying out a staff survey to assess wellbeing before and after the introduction of the group, changing the culture of the organisation.

The study has benefitted the practice (across two cities) by raising the importance of wellbeing, signposting people to resources and gaining feedback. It has also generated a focus on compassionate leadership, using qualitative and quantitative mechanisms to measure the impact.

The research team continue to analyse the results but feel this has had a positive effect. The aim being to raise awareness and measuring the impact.

3.3.4 Initiative aim for R & D infrastructure and capacity building.

Lead: Dr Scot Richardson

Funding: £25, 764, 48

Status: Progressing.

Following the award of funding a research assistant was successfully recruited. The successful applicant has previous experience of working with primary care research teams (as part of the CRN) with a good understanding of research and fundamentally primary care research. Network of peer support established. The post commencement date was Monday 14th October 2019. This post is a permanent full time position.

The key priorities of the role are to support the existing research team and overall aims include:

- To increase research activity at the existing research active practices within the cluster.
- To increase the number of practices within the cluster being research active.
- To support James Alexander Family Practice to successfully take part in a second CTIMP trial and become a Research Ready Advanced Accredited Practice.
- To develop a network for patient engagement in relation to primary care research

3.4 Budget Year 2019-20

3.4.1 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.

3.4.2 A panel meeting was held and applicants were asked to present and take questions. The information below lists the projects have been awarded Hull CCG funding from R & D and the latest status report on current position with the projects.

3.4.3 Understanding facilitators and barriers to inform ongoing service development of the Integrated Care Service for older frail people at the Jean Bishop Centre.

Leads: Professor Fliss Murtagh/Mabel Okoeki (co-Leads), University of Hull, Allam Medical Building

Funding: £21,928

Status: Progressing with revisions, as requested by the funder Hull CCG.

This project Includes interviews with patients, families and professionals to understand facilitators and barriers to inform ongoing service development of the Integrated Care Service for older frail people at the Jean Bishop Centre. It was due to commence in Oct 2020 and is planned for 18 months.

Hull CCG have requested that as the Frailty Service adapts and extends its work to include some assessment of the wellbeing of patients who are discharged from hospitals to Care Homes who are assessed by the Frailty Service.

The following has been agreed:

- The current plans for PACE will be modification to move to telephone or virtual data collection due to the pandemic. There will also be fewer patient interviews and more family interviews (same number overall), given the challenges of telephone or virtual interview for older frail patients.
- The University of Hull team will add a short survey to gain feedback on the process for patients discharged from hospitals to Care Homes who are assessed by the Frailty Service.
- Online survey, with an option for postal survey if respondents do not have online access or skills. This would provide some 'headline' feedback about the process of assessment between hospital/care home/frailty team.
- A small number of 'in-depth' interviews and follow up to the surveys using telephone/virtual will be completed. These interviews will mainly be with families and care home staff, but could include patients if able.

The above actions can be achieved within the 18 month time frame of the PACE extension project (Oct 20 to Mar 22), and within the existing budget

(provided funding for April 2021. The CCG have given approval to this modification in study and timeline extension. Research Ethics approval is being sought and awaited before any data collection.

3.4.4 Teaming up for Health

Leads: Lizzie Borrill Hull KR Community Foundation. Hull Kingston Rovers Rugby League Club.

Funding: £84,000

Status: Progressing

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. Following the move the programme lead Benn Hardcastle is now leading the project until a new appointment.

The 'Healthy Mind Healthy You' project is expected to commence in January 2021. Three schools are identified for the first cluster (Archbishop Sentamu, Compass Academy and Aspire Academy) and all wanting to be part of the project. MIND has also been engaged and will be involved within the classroom and mentoring sessions.

The team are also looking at delivery of the programme via virtual means given impacts of COVID on school settings.

3.4.5 Moving in Dignity

Leads: Patience Young/ Linda Hoban

Funding: £10,000

Status: Progressing

The aim of the project is to change processes when assessing for and when providing support with moving and handling. Current provision states that a minimum of 2 people are almost always required when hoisting. There is however 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 led 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 to commission a Research Assistant to support the evaluation.

A research assistant has now commenced in post. A semi structured interview questions in conjunction with York St John University has been developed. The same interview questions are being used by the students from York St John University as part of work they are undertaking to support with the project.

The moving with dignity practitioner has begun to consent a small group of individuals for interview and has completed some additional webinars health and social care providers to support understanding of the project across the city. In addition to this also she has begun to consent a small group of individuals from the ceiling track only cohort and will be moving to the care package reduction cohort in due course.

It is however anticipated that the numbers are likely to be smaller than expected, due to the impact of Covid. We are nevertheless optimistic we will still have some rich qualitative data to support the moving with dignity project as a whole.

4. Non funded Hull CCG Studies

4.1 Primary care and community engagement to optimise time to presentation with Lung cancer symptoms in Hull

Lead: Julie Walabyeki, Research Fellow. The University of Hull

Funding: £712,501. Yorkshire Cancer Research

Status: The Study is progressing within timescales.

Practice recruitment:

Previous suspension of the practice recruitment with a process of revising the protocol and adaptation of the practice component of the PEOPLE-Hull study. The revised protocol has been finalised which is to be submitted as a substantial amendment to the Health Research Authority (HRA).

Community events:

It had been planned to extend the community events to end of this year, however, because of the coronavirus pandemic this component of our study was closed (September 2020). Yorkshire Cancer Research is in agreement with this decision. In the meantime during the lockdown period, we conducted three focus group discussions with the community support workers and one interview (former community support worker).

The members of public engaged with during the community events (July 2019- March 2020) is 1610. Furthermore, 1344 symptoms questionnaires were completed during the community events. Of these 364 blue cards were given to members of the public who reported having lung symptoms but had not consulted their doctor.

Lung Cancer Awareness Measure (CAM) survey:

To date, two rounds of data have been collected by the research company SMSR and is currently being analysed. The third round of data collection will start in November 2020.

Community focus group discussions:

The first two rounds of collected data are being analysed. The third round of focus group discussions has started (one focus group discussion completed and one has been scheduled). The team are conducting virtual discussions which has its disadvantages as some of the community groups members are not computer literate and others do not even own phones and some community group members cannot meet in one house to participate in the discussion virtually because of the social distancing regulations. The study has however made an impact on the local population:

During the second round of the focus group discussions it was discovered that many discussants, particularly those in deprived neighbourhoods had changed their behaviours which had not been anticipated during the study preparations. For example, one lady with difficulty in breathing who accessed her GP despite being reluctant to do so previously, the person was referred to specialist care. It is therefore found that the group are now more vigilant, stating that they try not to put off contacting their doctor for a symptom. Others changed GP practices, started using the walk-in centres and out of hours service, some reduced the number of cigarettes smoked daily.

One group in the deprived neighbourhood wanted the researchers to have regular health talks to educate them further on health issues. The impact of the website and social media is discussed fully.

4.2 Proactive Anticipatory Care Evaluation (PACE). (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).

Lead: Mabel Okoeki, Research Associate/Project Lead. The University of Hull

Funding: Not applicable – research posts funded through University of Hull but not project specific

Status: The study is currently ongoing.

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.

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 are complete, control group data collection continues, and analysis is yet to be undertaken.

The PACE study, in September 2020, received favourable opinions from both the University and NHS research ethics committees, to amend data collection with remote data collection (telephone/video) in light of COVID.

5. Excess Treatment Costs

5.1 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).

5.2 Status Updates

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

5.3.1 **BASIL III Balloon vs Stenting in Severe Ischaemia of the Leg-3**

Outcome: 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.

ETC funding: £5025.00

The study is progressing despite the pause in recruitment activity due to COVID-19. Since the study restarted in July, 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. Hull one of the top 3 recruiters for the whole study (41 centres in total).The study is benefiting local population with the potential for preventing extra surgical procedures (amputations), saving the local NHS time and money.

MHRA and FDA have stated their support for BASIL-3 is its' important in answering the question – what is best revascularisation strategies' for CLTI patients?

The database will close for analysis following completion of recruitment

5.3.2 HERO

Outcome: 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

ETC funding: £13068.40

The study has been open in 15 sites across Yorkshire and the South West. Nationally, recruitment is below target with some sites performing better than others.

The NIHR HTA has approved a trial extension in order to recruit to target nationally and the recruitment period extended to January 2021. Reaching recruitment target is expected prior to that date.

The clinical team in Hull have set a target of 4-5 recruits per month, leading to 2-3 intervention participants per month in line with maximum cumulative capacity of the treating therapists.

To date 22 study participants in Hull have been randomised to receive the trial intervention. This is implemented following successful discharged home from hospital or intermediate care after an acute injury/illness causing hospitalisation. Those randomised to receive the intervention receive further therapy in their own home from physiotherapy teams trained to deliver the HOPE programme intervention.

The original pilot trial suggests that those frail individuals in receipt of the intervention will improve/maintain their physical functioning when compared to those who do not receive the additional intervention post-discharge. The exercise programme aims to increase strength, balance and endurance toward increased functional capacity. The programme is 24 weeks in duration and aims to equip individuals with the ability to be self-maintaining at the end of the 24 week programme.

Number of participants recruited during this period per CCG area

Jan '20 – Sept '20 recruitment for Hull CCG: 0, of which 0 have been randomised to the intervention.

Our main challenge to recruitment nationally has been researcher capacity. This is also the situation in Hull. A researcher left the local site team in Sept 2019. Recruitment has been very low since. Various efforts have been made to resolve this issue, including the provision of additional funding from the CRN, but staff capacity issues pre-and since Covid have hampered availability of a researcher. As may be expected in this study population, dropout rates from the intervention are high. Reasons are due to many factors (illness, hospitalisation, death, change of social circumstances).

5.3.3 **CLASP – Cancer Life Affirming Survivorship in Primary Care**

The study aims to evaluate an online intervention offering lifestyle and wellbeing support for cancer survivors

ETC funding: £878.40

Recruitment completed March 2020. Now in follow up (notes review at 1 year) COVID has not had such a great impact on CLASP as recruitment was completed.

5.3.4 **ASPECT**

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

ETC funding: £6808.00

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 with the write up of the final report now well underway.

Like many studies, ASPECT faced several challenges in response to the COVID-19 pandemic. Although recruitment had been completed in January 2020, when government restrictions were introduced several participants were awaiting therapy, receiving therapy, or due to complete their 6-month follow-up assessments. This meant that many young people were due to receive their 6-month follow up assessment prior to receiving or completing therapy.

Although, aligning to government restrictions we were able to collect data for our 6 month follow ups remotely, we had to pause completion of our primary outcome measure (the behavioural approach task). Unfortunately, government restrictions were not eased sufficiently for us to return to completing this measure before the end of study data collection.

5.3.5 **MIDFUT – Multiple Interventions for Diabetic Foot Ulcer Treatment**

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.

Funding: £1873.20

The study was paused to recruitment due to COVID-19 and will be requesting a 6-month extension. 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 Research team are in contact with the CHCP podiatry clinic team, the Nurse Research team will be attending one of these clinics to review potential referrals with the intention 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.

5.3.6 **Cryostat**

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.

ETC funding: £16,000 pa

To date the following has been achieved

- Confirmation of well-structured multi-disciplinary team working.
- Introduction of wider processes to facilitate enhanced care for trauma patients.
- Continuation of recruiting every eligible patient
- Informed practice and progress as a Major Trauma Centre including the introduction of bespoke blood products kept in the department.

It is however acknowledged that the Research Nurse (Paul Williams) was redeployed until early November 2020, as a result of the current position and all ED studies are still paused.

6. **Strategic Work**

6.1 **NIHR RESTART framework for Non-Covid R & D Work**

6.1.1 As a result of the “second phase of response to COVID-19” a letter from the NHSE/NHSI CEO in late April 2020 advised the restart of non COVID-19 urgent services and some routine elective care. Data from local CRNS and NIHR Clinical Research Facilities indicated that NIHR staff previously deployed to clinical ‘front line’ could begin returning to research roles.

6.1.2 In response, the NIHR Coordinating Centre representatives and wider partners developed the **RESTART framework** which was published in May 2020. The goal was to RESTART a fully active portfolio of NIHR research while supporting important COVID 19 studies.

6.1.3 Aims and objectives of the RESTART Framework

The Framework set out three key aims which were:

- The restart of paused NIHR research that was underway in the health and care system prior to the COVID-19 'surge'.
- The commencement of 'new' NIHR research.
- The prioritisation of resources in the NIHR Clinical Research Network (CRN) and NIHR infrastructure more broadly.
- The Framework provided a set of guiding principles, preconditions, study prioritisation guidance and provides the focus of national roles in implementing RESTART. The Guiding principles focused on study viability, patient safety and capacity and site readiness to initiate the research/study.

6.1.4 **Appendix 2** sets out the NIHR checklist that is based on these guiding principles and provides a feasibility assessment.

6.1.5 All studies being restarted will be subject to Yorkshire & Humber CRN viability assessments which will look at study viability; how the study may have to adapt to changes in the way practices are now working; measures needing to be taken to ensure reductions in infection risk, PPE considerations and meeting new practices needs/policies; assessment of whether sites are 'open for business' – made by the sponsor, Chief Investigator(CI) and site; patient safety considerations and reassurance for study participants about safety; possible testing of participants for COVID-19; funder discussions to identify any necessary changes; plans for re-pause if needed in the future. (Restart Framework 2020).

6.1.6 The R&D service has been linking in with the Yorkshire & Humber Clinical Research Network to ensure local input and support to RESTART infrastructure locally and identify any blockages.

7. Research and Development shared Service Key Response to COVID 19 and potential RESTART work.

7.1.1 The team have been working collaboratively to achieved the following;

7.1.2 Working with the Yorkshire & Humber Clinical Research Network to set up and COVID19 Planning team, to establish what urgent studies are on the 'radar' on a fortnightly primary care/ Community and Mental Health tele call meeting.

7.1.3 Working with wider R & D partners, for example the Health Research Authority and local academic institutions across the region to look at

maximising urgent study set up and possible engagement of sites and principal investigators on COVID19 studies.

- 7.1.4 Strategically explore any R & D work streams that could make efficiencies possible across the interface of primary and secondary/community care trusts in the Yorkshire and Humber region focused on COVID19 R & D work.
- 7.1.5 Ensure that all relevant communications are shared in a timely and efficient manner, whilst continuing to work with CRN and primary care colleagues to focus interest and action towards implementing relevant COVID19 studies locally, where time, capability and priority allow.
- 7.1.6 As per the R & D service MOU, identify and provide an advisory service to research teams/sponsors and possible investigators locally in the Hull area that are linking in on the urgent COVID19 studies.
- 7.1.7 Support the CCG(s) with any requests to act as a collaborator on possible COVID19 'fast tracked' studies to the NIHR COVID19 centralised provision.

8 Research & Development Strategy/ Vision.

8.1 A revised R & D Partnership Vision was approved by the CCG Board in March 2019, collaborative working with Hull CCG, Hull City Council and Hull, York Medical School and The University of Hull.

8.2 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.

8.3 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.

8.4 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.

8.5 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.

8.6 During April 2020 to October 2020 the strategic work has been put on ‘hold’ and is being considered on a wider CCG(s) sub- system level.

9 Health Research, Innovation, Evaluation and Improvement Group.

9.1 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 by delivering on the Key aims set out in the CCG Vision.

9.2 During April 2020- October 2020, in view of the pandemic and wider organisational developments these meetings have been put on 'hold' whilst there are CCG(s) sub system discussions.

10 Development work

10.1 CCG Development work - Research Capability Funding

10.1.1 Hull CCG has been awarded Research Capability Funding for 2020-21 of **20,000**. This is ring fenced Department of Health funding that is to be utilised to support research capacity and research infrastructure in the Hull CCG area. The R & D shared service has made accessible the national guidance on how the funding can be spent, case study examples and dialogue has commenced on the next steps for the spend in 2020-21 via the wider R & D Executive committee.

10.2 Development work in 2020-21

10.2.1 The work that had been initiated for the R & D partnership vision is set out in the draft strategic action plan has been 'paused' in recognition not only of the pandemic but also the wider sub system CCG(s) organisational development work and its potential link(s) to the ICS model.

10.2.2 The Strategic work that was initiated as part of the R & D partnership Vision may need to be refocused and going forward may need to form part of the wider CCG discussions.

11. Summary

11.1 This status 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 report demonstrates how R & D has responded to COVID 19 in the period April 2020 to October 2020 and the priority that has been given to urgent public health studies.

Alongside this the status report shows how the locally grown 'green shoot' work funded by NHS Hull CCG has also responded to the current challenges and what modifications have been required, for example in regard to methodology and ethics.

11.2 The ambition of the study teams, local Investigators and wider stakeholders to continue to drive forward the research agenda needs recognition in the ever changing situation of the pandemic.

11.3 Although the wider CCG Strategic work has required a period of reflection there remains the impetus and enthusiasm to drive forward an R & D partnership Vision.

11.4 This prospective further work will aim to drive forward research, innovation, evaluation and improvement when addressing the healthcare priorities of the population in Hull and will help to ensure commissioning decisions are based on the best available evidence.

Report written by: Dr Marie Girdham R &D Lead Nurse Manager

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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
HRA	Health Research Authority

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Appendix 1



**NHS Hull CCG NIHR Research Activity from 1st April 2020 to 31st October 2020.
Data cut: 2nd November 2020**

NHS Hull CCG	
No Practices in CCG	39
No Practices Recruiting	4
% Practices Recruiting	10%
CCG Studies	3
CCG Recruitment	9

Note: the NIHR CRN Business Intelligence Unit (BIU) is currently updating the dataset on the number of practices in the CCG to reflect any changes.

Practice Name	Recruits	Study Short Name
DR GALEA & PARTNERS	1	PRINCIPLE
DR Gt HENDOWS PRACTICE	1	PRINCIPLE
EAST HULL FAMILY PRACTICE	1	PRINCIPLE
MODALITY PARTNERSHIP (HULL)	5	The Gentle Years Yoga Trial
MODALITY PARTNERSHIP (HULL)	1	FITNET NHS

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

The NIHR CRN Business Intelligence Unit (BIU) is currently updating the dataset on the number of practices in the CCG to reflect any changes.

Appendix 2 NIHR Study Local Restart Assessment Checklist

#	Factor	Requirement
1	Study viability	<ul style="list-style-type: none"> • Sponsor and funder have assessed and agreed to restart • Regulatory approvals in place • No impact on support for UPH COVID-19 studies • All necessary research funding is confirmed • Funding to meet any Excess Treatment Costs has been confirmed • Sponsor and funder are satisfied with the arrangements for patient and public involvement in the study
2	Safety	<ul style="list-style-type: none"> • Risk of exposure to COVID-19 for patients and staff has been mitigated • Physical access complies with government restrictions on social distancing • Assessment of COVID-19 testing and PPE requirements completed • Study arrangements comply with local organisation / site policies in respect of COVID-19 • Site compliance with regulatory requirements has been confirmed by the organisation's R&D Director or equivalent • Clear guidance on safety issues and precautions has been provided to participants and staff • Participants are asked and reassured about any concerns regarding COVID-19 - participants need to feel safe and confident
3	Capacity and site readiness	<ul style="list-style-type: none"> • Local clinical lead (Principal Investigator) confirmed and in place • Research staff in place • Health and care site / service 'open for business' to the full extent required for the study • Research management and support in place (site R&D office, CTU, LCRN) • All necessary supporting departments (e.g. pharmacy, pathology, radiology) have resource and capacity. Assess study dependencies. • All necessary supplies have been procured and are in place (including IMPs and PPE) • For paused studies, study data have been checked for data integrity to ensure that data remain robust and/or fit for purpose • Physical access arrangements for participants have been assessed and are satisfactory • Permission to restart from site legal entity
4	Prioritisation	<ul style="list-style-type: none"> • Not required if the study does not require NIHR-funded support • Where prioritisation is necessary, this should be on the basis of 'study urgency' (section 6)

