

MAKE RESEARCH HAPPEN



Case Studies from the COVID-19 Research Community

#Red4Research 202

Forward

#Red4Research Case Studies

COVID-19 is affecting us all. On the front line and behind the scenes are incredible research teams collectively working to develop new diagnostics and treatments for COVID-19. COVID-19 has forced us to do things differently, to be more innovative and more responsive. Despite exceptionally challenging circumstances the research community has remained focused, embracing flexibility, levering technology and streamlining policies and procedures to deliver high quality research at an unprecedented pace and scale.

Research isn't however undertaken by individuals working in isolation, it is collegial, made possible by people around the world working together - research participants, patients, professionals, volunteers and regulatory bodies. This collection of case studies features some of the roles people have undertaken as part of COVID-19 research community, the impact of their role and their learning. The research case studies included are those who responded to a national call through the NHS R&D Forum and reflect the views of the individuals featured. The case studies are not representative of all the research roles but offer a snapshot into the COVID-19 research community.

#Red4Research aims to raise awareness and appreciation of all those working in COVID-19 research. It is all about positivity and inclusivity. The R&D community in collaboration with the health and care sectors and voluntary organisations has achieved a phenomenal amount during the COVID-19 pandemic. It continues to evolve ultimately delivering COVID-19 research studies at an unprecedented pace and scale.

Sally Humphreys #Red4Research Founder © Red4Research 2021

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Academic Staff



Academic Staff

Name: Dr Rosemary Godbold, Dr Lisa Whiting, Claire Adams, Yogini Naidu and Prof. Natalie Pattison

Job Title: Nurse Academics

Organisation: University of Hertfordshire

Role during COVID-19 pandemic: Teaching and research

Significant learning throughout the COVID-19 pandemic:

We carried out a qualitative study with final year student nurses who chose to work on the front line under the emergency Nursing and Midwifery Council (NMC) standards in the first wave of the pandemic. We learnt important lessons about the students' experience, their learning, the impact on them personally and emotionally and how they coped. It was a privilege to speak to this unique group of students, who overall had positive experiences, particularly because they felt they were particularly well prepared for qualification.

Impact and evidence of improvement or changes:

The learning we obtained from our students was used to inform the support for students going into placement since the first wave and into the second.

Unexpected changes:

We were surprised by how positive the students were about their experiences.

Three innovations or changes to keep:



Student support.

Blended learning approach.



Learning from student experiences.

Contact details for further information



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Name: Nicola Manning

Job Title: Research Matron

Organisation: University Hospitals Bristol and Weston NHS Foundation Trust

Role during COVID-19 pandemic:

As research matron it was my role to coordinate and support our research workforce in delivering the Urgent Public Health (UPH) treatment and vaccine trials. As our research teams are managed within the clinical divisions I negotiated with heads of nursing to ring-fence our research nurses to deliver the vital research.



I was also tasked with organising our vaccine trial clinics and pulled together research staff from across the whole trust to deliver a number of vaccine trials within extremely short timeframes. Due to the ongoing nature of the work, we then developed a specific vaccine and testing research team to manage these trials going forward. A large part of my role recently has been developing this team.

Significant learning throughout the COVID-19 pandemic:

I have learnt how important it is to lead by example. With regard to the vaccine clinics it was important that I was visible and, on the ground, to support the teams in a new area of research during a very stressful time. The team appreciated my presence and support which has been invaluable in strengthening my relationships with all research staff across the trust.

The flexibility and team work that all of our research teams demonstrated was outstanding and was vital in the successful delivery of the trials and in raising the profile of research across the trust and region.

Impact and evidence of improvement or changes:

The collaborative working across the teams was a really positive change that came out of COVID. The teams supported one another, built new relationships and developed new skills in areas they were previously unfamiliar with.

Unexpected changes:

The raised profile of research - seeing research change practice in real time and the public response to this has been incredible to witness. This is something I want to build on and use as a platform to encourage clinical staff to consider research as a career pathway.

Three innovations or changes to keep:



Collaborative working across all the research teams.



Development of vaccine research team expanding into non-COVID vaccine work.



Embedding Research into clinical practice.

Contact details for further information



Nicola.Manning@uhbw.nhs.uk

Name: Samantha Clarke

Job Title: Senior Research Nurse

Organisation: North Bristol NHS Trust

Role during COVID-19 pandemic:

Supporting the delivery and assisting in the coordination of COVID-19 Urgent Public Health research both on the wards in the hospital and then later as a regional hub for delivery of the vaccine trials.

Significant learning throughout the COVID-19 pandemic:

Although I've worked as a Band 7 for 5 years, my role was previously managing and coordinating a multicentre study and I had little experience in leading and managing teams.

Once the pandemic hit, our research structure very quickly evolved from multiple micro teams working within their own clinical speciality to us all coming together to form a large team working as one to deliver vital COVID-19 research. This required daily coordination from our research Matron and the Band 7s and was a role I thrived in. I thoroughly enjoyed the feeling of bringing everyone together with a shared purpose and problem solving within the team.

The most rewarding aspect of this new way of working was having the opportunity to work with the wider research team and getting to know so many of my colleagues.

Impact and evidence of improvement or changes:

We have worked hard to maintain the support offered across our micro teams. We pull together as a collective network and offer assistance in many ways, both with our day to day tasks but also pastorally.

We have also developed different ways of working with regards to technology. We utilise remote working and technological support to be able to offer much more flexibility both within our roles and in the way that we support our patients.

Unexpected changes:

Sponsors have worked hard to develop different ways of engaging with patients who may not be able to attend the research setting due to restrictions. One of the main changes is the implementation of electronic consent and ePROMS (patient reported outcome measures). Although I am yet to use it in practice, the theory of being able to reach a wider cohort of patients and support them in a much more flexible manner is very exciting.

Three innovations or changes to keep:



E-consent.

Shared learning and cohesive working.



A new balance of remote and on site working

Contact details for further information



Samantha.Clarke@nbt.nhs.uk



Name: Suriya Kirkpatrick

Job Title: Senior Research Nurse Cancer

Organisation: North Bristol NHS Trust

Role during COVID-19 pandemic:

I'm a senior research nurse with over 22yrs NHS experience. Due to preexisting health issues, I was advised to shield from March 2020. This was disappointing as I was unable to use my extensive clinical and research experience when the NHS needed me most.



I was swiftly set up to work from home finding creative ways to deliver on my role. I continued to manage my team; provided support for redeployed staff, supported staff to move on to new roles where their valuable skills were evident in supporting Urgent Public Health research, and interviewed, appointed and trained new staff. I provided guidance, indirect supervision and support for staff on how to meet trial requirements under COVID restrictions. I continued to respond to data queries and ensured safety data was logged in a timely manner.

I continued to support trials participants through remote follow up and arranged for trial medication to be delivered to their home address. By remaining their primary contact, I was able to provide opportunities to discuss anxieties about COVID 19 and advise them on managing their health, shielding, isolating, return to work. As a leader in my field and given that I was unable to work on the front line I supported my colleagues by providing peer support for cancer research nurses nationally. Where possible I supported UPH studies through data entry.

Significant learning throughout the COVID-19 pandemic:

Research nurses play a pivotal role in research set up and delivery. Having good communication skills and developing strong, trusting relationships with my patients from the outset enabled a smooth transition to remote monitoring.

Patients seemed to be more receptive to trials and they valued the support from the research nurse. We not only maintained patients on ongoing trials but were also able to open new studies and recruit new patients to observational studies as COVID restrictions began to ease off.

Impact and evidence of improvement or changes:

Improved processes for remote follow ups, collaboration across various clinical teams, optimising digital technology.

Unexpected changes:

I was surprised at how quickly we moved cancer patients on systemic anti-cancer treatment to remote follow up. This is something that we have been trying to do for years.

Three innovations or changes to keep:



Remote monitoring.

Use of digital technology.



Working from home more regularly and enabling team members do the same

Contact details for further information



Suriya.kirkpatrick@nbt.nhs.uk



Name: Fisayo Adeyemi

Job Title: Research Physiotherapist

Organisation: Guy's and St Thomas' NHS Foundation Trust

Role during COVID-19 pandemic:

Pre-pandemic I worked in the integrated respiratory team at Guy's and St Thomas' Trust (GSTT). I was redeployed to work in critical care as part of the acute respiratory Physiotherapy team pretty much straight away as the pandemic began.

I was deployed to a newly set up ICU created to cope with the demand of critically ill COVID patients. As a respiratory physio my role is to improve lung capacity, clear secretions, optimise



positioning and maintaining muscle length to reduce complications related to ICU acquired weakness.

I spent three months in ICU and cared for very poorly patients. After 3 months redeployment ended and I returned to my post. A 12 month secondment opportunity was offered through the physio department to join the COVID-19 Research team. I was fortunate enough to be awarded the opportunity. I was very excited to develop my non-clinical skills and get involved in clinical research.

I currently work on the PHOSP-COVID research study at GSTT which aims evaluate the long-term effects of COVID-19 on patients admitted to hospital. It has been very satisfying to see the recovery of participants who I cared for in the ICU during the first wave.

In addition, I have been studying for a Master's in Public Health (online) at the University of Edinburgh to further enhance my understanding of epidemiology, research methods and population health. With the hopes of leading my own research projects in the future.

Significant learning throughout the COVID-19 pandemic:

As the PHOSP-COVID study focuses on participant recovery, it has been evident that having someone with clinical skills relating to function and rehabilitation has been very important. I have picked up on clinically important events that others may have missed because of my particular training.

I am able to provide support for participants who need further support for Activities of Daily Living (ADLs), social care and their mental health as needed. This is really important for those recovering from COVID-19.

My role remains patient focussed and to advocate for patients ensuring the best overall outcomes.

I have a leadership role for the study as it needs excellent management for all the aspects in order to maintain good quality data for reliable results. I have trained all the staff appropriately for entering the large amount of data and I play a pivotal role for the research team.

I manage the coordination of booking participants, managing all referrals and liaising with multidisciplinary medical team. I am also improving my research and project management skills, liaising with research nurses, clinical trial practitioners, data managers and quality Assurance. Organising the site file, audits and data collection.

Impact and evidence of positive improvement or changes:

Urgent Public Health badging has meant resources allocated appropriately and the national coordination of a long term follow up study in PHOSP-COVID. COVID has forced the hand to the research and political world to work in a more coordinated and cohesive way. I believe that COVID has incited a fundamental shift in the way collaborative research will be conducted moving forward with more data sharing and swifter administrative process with an overall benefit for the research community and the lives of individuals we aim to improve.

Unexpected changes:

None.

Three innovations or changes to keep:



Potential for staying in research delivery and management.

To develop my research career and lead on my own studies.

Contact details for further information



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Name: Sam Harding

Job Title: Research Fellow

Organisation: North Bristol NHS Trust

Role during COVID-19 pandemic:

In March 2020 I was redeployed to the PPE COVID Bronze Command. This cell was established to co-ordinate and facilitate Face Fit Testing, and expanded into the sourcing PPE and ensuring the suitability (fit for purpose) of nationally and locally supplied PPE.

Significant learning throughout the COVID-19 pandemic:

As a trial manager, research fellow, and health psychologist, I was surprised by the amount of directly transferable person and research skills, and knowledge that I had.

Due to the rapidly evolving situation, it was not uncommon to be presented with multiple products against a single PPE requirement. Different manufacturers quoted different standards. These used a range of certification regimes. In most cases there was no simple direct comparison between them. This led to confusion when the national guidelines recommended masks that complied with a certain specification, but the ones available or supplied were certified to a different specification.

A key research skill that I have developed, and that I seek to develop in aspiring researchers, is the ability to examine data from different sources and understand how the measurement methodology can influence or change the final output.

Another key research attribute is always tracking back to the original data source. Several times a manufacturer would reference a test regime without explaining the context for that test. Only after examining the original test specifications would it be possible to fully evaluate a piece of PPE's compliance with the guidelines.

In other cases, knowing the exact test criteria and conditions for the national guidelines specifications would allow an evaluation of presented PPE. Even if they met a superficially higher standard on one metric, their construction or other design features would have failed the required specification and so they were deemed unsuitable.

While not primary research, it is a critical skill for conducting research using secondary sources.

Being able to rigorously evaluate and trace through the different specifications meant that when I was making recommendations on suitable or unsuitable masks for the Trust, I was able to back that up with written specifications and exceptions on individual mask designs.

In addition to data checking and validation, a research skill that was highly valuable during my redeployment experience was communication. Throughout the redeployment I worked with frontline staff who were tired, anxious and frightened and to be able to give clear, accurate and timely information provision was vital to help them confidently undertake their work. This is a very similar situation to working with patients to inform them of research opportunities during stressful healthcare situations.

Impact and evidence of improvement or changes:

I was very physically visible during the timeframe of my redeployment, and I ensured that I made time to talk and explain the situation. This gave me great exposure to a wide range of people, that expressed an interest in my *'normal role'* and pursuing their own research interests. Post redeployment this almost adhoc exposure, inspired the establishment of a monthly 'open to all' research chat (currently on teams and hopefully over coffee in the future).

Unexpected changes:

- Personal profile raised across the trust.
- Built relationships across divisions that have led to a greater number of Allied Health Professionals (AHP) being supported in application for clinical academic training packages.
- Raised awareness of Nursing, Midwifery and AHP lead research.

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Three innovations or changes to keep:

 Taking time to identify a critical friend within an area to try to challenge assumptions during project development. Be physically present. If I am not known to a team at the start of a conversation, take the time to build the relationship.



Increasing the contact within and between the research teams. Ensure idea exchange in working practices is facilitated.

Contact details for further information



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Clinical and Research Staff



Name: Mary Harrison

Job Title: Diabetes Nurse Educator and Research Associate

Organisation: University Hospitals of Leicester NHS Trust

Role during COVID-19 pandemic:

- Redeployed back to ICU (as an ex-ICU nurse).
- One shift a week on a vaccine trial through our NIHR Patient Recruitment Centre: Leicester.
- Chief Investigator of portfolio-adopted multimorbidity and COVID-19 study.
- Diabetes educator- trying to support Health Care Professionals look after people living with diabetes during the pandemic.

Significant learning throughout the COVID-19 pandemic:

I am even more certain that clinical academic career paths are the way to ensure clinically relevant questions and clinically ready research staff.

Impact and evidence of improvement or changes:

Increased use of IT systems- remote monitoring/screening.

True embedded knowledge of the clinical situation from redeployment helped shape the research studies I work on.

The enhanced focus on obesity as a dangerous, relapsing disease. The root cause for many life changing health issues.

Unexpected changes:

Redeployment back to ICU gave me a chance to look at research from the clinical staff standpoint. Insight I thought I still had was definitely enhanced.

Three innovations or changes to keep:



Keep advocating nurse researchers to have clinical duties.

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Keep using IT systems to undertake tasks like remote monitoring/screening.



Keep the increased focus on obesity being a driver for multiple long term condition.

Contact details for further information



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Communication and Engagement Staff



Communications

Name: Rachael Dowling

Job Title: Head of Research Communications

Organisation: University Hospitals of Leicester NHS Trust

Role during COVID-19 pandemic:

Working with our local and regional media, I regularly shared stories about the progress research was making to help overcome the pandemic and encourage people to take part in COVID research for new treatments and vaccines. This strategy was designed to boost morale among staff and the community, and show that research is the key



exit strategy to get us out this public health crisis. I am also the communications lead for two national urgent public health studies: UK-REACH, which is investigating the effects of COVID-19 on ethnic minority health and care workers, and PHOSP-COVID, which is studying the longer terms effects of COVID-19 on those who were hospitalised with the disease.

Significant learning throughout the COVID-19 pandemic:

Communications is vital to clinical research delivery because it is a key driver of recruitment. I feel privileged to be able to share the experiences of patients who have benefitted from research, and through them we are able to encourage and normalise participation in trials as part of clinical care. This encourages even more people to participate, helping us develop greater understanding of what works at a faster rate, which can ultimately save lives. It also brings hope at a time when the news agenda is very negative.

Impact and evidence of improvement or changes:

Research has become part of the narrative about what matters most to our trust more than ever before. Research news is part and parcel of all our corporate news channels, from e-newsletters and briefings to social media and public engagement.

Unexpected changes:

Our campaigns to engage with staff internally at our hospitals have had a phenomenal response. They have really supported COVID research, both as participants in studies and as volunteers to help with recruitment. I'm so proud that as a consequence we have over-recruited to many of the Urgent Public Health studies.

Three innovations or changes to keep:



Embedding research communications in Trust communications as 'business as usual'. Using digital platforms as the primary channels for engagement and participation.

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A tight focus on priorities: communications and engagement is a broad remit. Using a daily planner has helped us create real impact.

Contact details for further information



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Public Engagement Manager

Name: Claire O'Neill

Job Title: Public Engagement Manager

Organisation: Guys and St Thomas NHS Foundation Trust

Role during COVID-19 pandemic:

When the pandemic hit, we had to postpone or cancel all of our upcoming public engagement activities and events. I started to work even more closely with my colleagues in the R&D communications team to support them with things like internal communication with staff and social media.



I also began to work with my public engagement colleagues to relook at the ways in which we could safely work with our communities. Our summer school was already scheduled to take place in July 2020 but after working with our partners and local schools, we were able to pull together a reduced online programme to run in June via our YouTube channel. This allowed schools to support their students who were learning from home to take part in some interactive activities and to learn about careers in research and medicine.

We have taken the learnings from this to plan the 2021 summer school which will again be held virtually but will include live lessons and even more pre-recorded content and activities.

We have also recently launched a virtual library which members of the public and schools can use to access films of our staff talking about their roles and resources to support their learning.

Significant learning throughout the COVID-19 pandemic:

Being forced to work in new ways meant that I needed to learn a lot of new skills very quickly and forced me out of my comfort zone – filming, editing and then publishing videos of myself on YouTube is not something I ever thought I would do!

However, I found that I really enjoyed it and it was wonderful to know that we were able to provide some much needed support and structure both to the students and also to their teachers. It was (and still is) such a stressful time for all of us who were having to navigate this new world of home schooling so it was really rewarding to be a part of that.

It was also fantastic to see the response from our research colleagues who were so open to supporting us. Even with so many staff being redeployed to support our clinical colleagues working with COVID patients, our researchers have been so generous with their time. This has all made me feel immensely proud to work as a tiny part of the NHS.

Impact and evidence of improvement or changes:

Being forced to work so differently has allowed us to work much more flexibly with our communities and particularly with school children. In previous years, our summer school was limited to 20 places as we provided lunch and also chaperoned the students between sessions. Moving to an online programme allowed us to open up the summer school to twice as many students. Using YouTube meant that our staff could work much more flexibly as they could pre-record some content at a time that suited them and also meant that the students could watch them at their own convenience.

Adding live lessons to this year's school now means that our students will have the best of both worlds as we can work with the interactively whilst also providing them with some sessions which they can take part in around their schedule.

Unexpected changes:

We set up a Young People's Advisory Group a number of years ago and they have always been extremely helpful in advising and supporting us on a huge range of activities and projects. Moving to working and schooling from home has meant that we can meet with the group on a more regular basis online and they don't have to travel to us after school and then back home in the dark. The group have also been invaluable in helping us to plan the best way to engage with this year's summer school and the best way to get in touch with teachers and other school staff.

Three innovations or changes to keep:



Giving people the option of meeting online or offline.

Reaching out to our Young People's Advisory Group regularly.



Continuing to explore new and evolving technologies and platforms for engagement and communication.

Contact details for further information



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Clinical Trial Unit Staff



Administrators







Name: Keele Clinical Trials **Unit Project Administration** Team

Organisation: Keele University **Role during COVID-19** pandemic:

During the COVID-19 pandemic the team of dedicated project administrators at Keele Clinical Trials Unit (CTU) were vital to ensuring not only the existing portfolio of studies were maintained but also playing a key role in the data management of COVID-19 clinical trials with a local NHS Trust. This included, for some, switching from their office-based role to working in frontline research clinics within a hospital setting. Even whilst supporting this frontline research, the team managed to successfully maintain the data collection of existing trials at the CTU, this included the sudden shift to online data collection and the roll out of this to patients. Administrators were required to contact patients who were being followed-up in studies to ask for their email contact details to ensure that an online questionnaire could be sent to them.

Significant learning throughout the COVID-19 pandemic:

One of the most significant things that has been learnt is that processes can be adapted to fit the situation. The administration team has been flexible and has adapted to new working conditions, whether this being working at home or within a different setting to the normal office-based conditions. The value that this has brought to research at Keele CTU has been immense and has meant that research has been able to continue throughout the pandemic and has enabled the CTU to also support COVID-19 research locally which is really important in fighting the disease

Impact and evidence of positive improvement or changes:

Patients and study teams have had positive experiences of online data collection and protocol changes to keep this method of data collection for the remainder of the trial have been implemented. These methods have also been adopted for new trials moving forward, offering patients an alternative option to completing a pen-and-paper questionnaire. The online questionnaires allow for an instant receipt of data which has streamlined the administrative processes for studies allowing data to be accessible quicker.

Unexpected changes:

Some patients who were unable to provide online data were contacted at data collection time points by the administration team to collect their data over the telephone. In the height of the pandemic with the tightest restrictions on social contact these calls were appreciated by patients, not only for the purposes of providing their data, but also for the chance to have a conversation with someone. The rapport that this has built between some patients and the CTU is invaluable and has a positive effect on both current and future trials.

Three innovations or changes to keep:



Online data collection.

Improved engagement processes with patients.



Instant receipt of online data collection

Contact details for further information

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Database Manager

Name: Jo Smith

Job Title: Clinical Trial Unit Database Interface Manager

Organisation: Keele University

Role during COVID-19 pandemic:

During the COVID-19 pandemic I led the development of conversion of paper questions to an online data collection tool. (Keele Health Survey, which is underpinned by LimeSurvey). This tool was used to capture data

electronically and maintain participant follow-up during the COVID-19 lock down. Keele Health Survey training was initiated for a small number of CTU staff, to ensure capacity to build the online questionnaires. Between April and June 2020 16 questionnaire booklets (222 A4 pages) were converted from paper into an online format across four Trials. This was to enable continuation of critical follow-up data collection. The tool enabled a weblink to be generated which was provided to participants to enable participant completion of online questionnaires.

I was also part of a Task and Finish Group who were responsible for the management, review and standardisation of processes required to ensure questionnaires booklets were successfully converted into online data capture forms. The group were also responsible for considering other areas such as comparison of data completeness between paper and online, participant feedback on the use of online data collection and pros and cons of online data collection.

Significant learning throughout the COVID-19 pandemic:

One of the most significant things that has been learnt is that processes can be adapted to fit with the situation. The Keele Health Survey Task & Finish group and I had to familiarise ourselves with the new system and facilitate a new platform for online data capture.

There systems and processes were developed to ensure that recruited participants could still participate in research throughout the COVID-19 lockdown, which was valuable to research. Whilst data collection was continued the research study could continue to keep to its targets. Furthermore, this ensured that the results of studies could contribute to the development of treatments to ensure patients are continuing to receive the best healthcare.

Impact and evidence of positive improvement or changes:

A number of changes were made to the way that data was captured in studies. This brought with it improvements with over 50% of participants approached providing data online, and in one study this was over 70%.

Making the questionnaires available online saw a higher response rate than previously seen from postal questionnaires, however it was noted that missing data was slightly higher in the online platform. To combat this in future studies items on the online questionnaires can have more robust validation applied (e.g. mandatory questions) so that a response is required.

Costs were reduced for printing and postage requirements and also there was a reduced amount of CTU staff time spent doing data entry and data cleaning.

There was overwhelming positive feedback from participants who described the online questionnaires as user friendly.



Unexpected changes:

As there was no requirement for data cleaning this improved data integrity. There was still a requirement for administrators to collect data over the telephone if a participant was unable to complete the online questionnaire, and for future studies, it is envisaged that both an online and postal option would be preferred. This would ensure we 'reach the unreachable' and make sure that the research studies are not biased to only those able and willing to engage in an online capacity. The data also showed that questionnaires were being completed quicker online.

Three innovations or changes to keep:



Consider Online data collection at study design stage (including research studies of the older population).

- Give sufficient consideration to appropriate
 - consideration to appropriate validation settings in an online platform to ensure data completeness.



Collect patient email address routinely as part of 'contact details'.

Contact details for further information



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Health Research Authority



Health Research Authority

Name: Dr Janet Messer

Job Title: Director of the Approvals Service

Organisation: Health Research Authority

Role during COVID-19 pandemic:

I lead all the HRA's operational activities and their supporting functions. My team and I worked closely with our volunteer Research Ethics Committees and Confidentiality Advisory Group to expedite HRA Approval for urgent research into diagnostics, treatments and vaccines for COVID-19.

Significant learning throughout the COVID-19 pandemic:

I was struck by the ability of the whole research system to adapt and respond quickly and extremely effectively to the challenge the pandemic posed, while also ensuring high standards of ethics were maintained.

Collaboration is the foundation of our success and it's a real testament to what can be achieved when we are all working towards the same goal.

Impact and evidence of positive improvement or changes:

Learning from our experience of expedited approval for COVID-19 research, we designed a sustainable model of fast-track review for non-COVID clinical trials of medicines, showing we can provide a decision 50% faster than usual. We're now exploring options for a fast-track ethics review as part of the combined review with MHRA. We will also explore how a fast-track ethics review can be incorporated into wider rapid approval and study set-up processes.

Unexpected changes:

One of our biggest opportunities is to build on the awareness raised by COVID-19 of clinical research and reinforce the importance, value and safety of research in the UK. There is a huge of amount of learning and experience from work during the COVID-19 pandemic, which can help the HRA, other regulators, research sponsors, government and the NHS coordinate some great initiatives already started across the UK.

Three innovations or changes to keep:

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Joining up the research approval and set-up journey for COVID-19 was very valuable but needed lots of manual interventions. Our work on developing IRAS will really help to join things up better for the research community.

 Collaborating on guidance and processes to help the research community helped researchers find the information they needed to cope with novel situations. The Recovery, Resilience and Growth Programme provides a framework for collaborating to build further.

 So many people are taking part in COVID-19 research, many more are now aware of the value of health and care research. We will support and advise on the development of a suite of digital tools enabling the identification and recruitment of a wider range of research participants ways respecting confidentiality.

#Red4Research

Contact details for further information



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Name: Dr Anthony Lockett

Job Title: Expert member

Organisation: Health Research Authority - York Research Ethics Committee

Role during COVID-19 pandemic:

I am the alternate vice chair at York Research Ethics Committee (REC), and during the pandemic we also worked on ad-hoc activities such as the COVID-19 reviews. In the committee I take the position of being a medically qualified advocate, covering issues such as consent and vulnerability and mindful of the burden that clinical research can place on patients and their care givers

Significant learning throughout the COVID-19 pandemic:

I am a very strong advocate of the patients voices and needs. In the past patients were sometimes seen as a commodity in trials – thankfully not anymore. My personal view is that trial volunteers give us a great gift as medical researchers. This donation needs careful stewardship. It should not be abused by performing research of limited value, but at the same time recognising the jigsaw nature of research.

Impact and evidence of positive improvement or changes:

COVID-19 has been a turning point in so many ways.

The public health aspects (in the public interest) brings a different dimension to research; this was an unknown disease – could we stop it, could we treat it? In many ways it forced me to confront the needs of the many while protecting the sick.

Unexpected changes:

I have been impressed, humbled and moved by the work of the committees that reviewed the trials such as RECAP and the challenge trials. "Lay" members demonstrated a degree of ethical decision making that I did not anticipate, and to my academic mindset it was a real eye opener!

Three innovations or changes to keep:

Research should take into account the true cost of research to patients and carers (forgoing other treatments and the time they need to devote to the trial).

Name: Fast Track Team

Organisation: Health Research Authority

Role during COVID-19 pandemic:

During the pandemic the Fast Track Team comprising of diverse group of HRA staff, developed and implemented an expedited process to review COVID research.

The starting point for the process was triage; deciding which timelines the study was to be reviewed within; 24 hours, 36-72 or 1-2 weeks, depending on Urgent Public Health status and the area of research; diagnosis or treatment, transmission and immunity, and wider related research in to COVID. The criteria was adapted throughout the course of the pandemic.

Once submitted the study was expedited to a Research Ethics Committee (REC) and assessment review. To match the timescales of fast track, the Technical Assurance team facilitated a fast track review process for studies involving pharmacy or ionising radiation, ensuring technical reports were available for site set up. A matching service was enabled researcher to access public involvement support.

Over 700 COVID research studies were processed through Fast Track review process and received HRA & HCRW Approval, with some in as little as 2 days. Research summaries of studies were published within 3 days, rather than the standard 3 months to ensure transparency of the work underway and reduce duplication of studies.

Significant learning throughout the COVID-19 pandemic:

The review and assessment process itself did not have to change. It was just done more quickly, highlighting the process itself works well, without any superfluous steps along the way. It showed how adaptable people can be, how they come together with energy and a collective drive to deliver a vital service.

Impact and evidence of positive improvement or changes:

The principle change was the development of the Fast Track REC review for non-COVID studies. Other improvements were around the teams within HRA learning to adapt and support colleagues remotely. A monthly virtual pub quiz open to all HRA staff, their partners, families, and housemates brought people together for a light hearted 2 hours during the lockdowns.

Unexpected changes:

With the introduction of the virtual REC meetings, attendance at a REC by researchers improved. Minutes of the meetings were taken remotely, this has saved significant time on travel for staff. There has been a heightened interest and understanding of the importance of health research by the wider population.

Three innovations or changes to keep:



🖈 Fast track REC





Monthly virtual Pub Quiz

Contact details for further information



Fast.track@hra.nhs.uk

Health Research Authority



Name: Jen Harrison Job Title: Change Manager - Approvals Organisation: Health Research Authority Role during COVID-19 pandemic:

My role was to support the fast track COVID studies at the initial stages of the application process. Working closely with the Approvals Operations team, I manned the fast track inbox to answer queries on wide-ranging issues; reviewed and triaged applications for studies

expedited to fast track. And on occasion virtually held applicants' hands as they submitted the application in IRAS for the first time.

I attended NHS R&D Forum COVID coffee, and other meetings, providing updates, and most importantly listening to what was happening on the ground in R&D and fed this through to the HRA. This ensured the guidance was updated in response to issues.

Significant learning throughout the COVID-19 pandemic:

You can effectively connect with people using virtual technology. You can build good strong relationships and networks without always being face-to-face. I have connected with new colleagues during this time.

Being there to listen and support – even if it is just listening to a busy clinician work through the submission steps, having someone to speak is incredibly valuable in these times of stress. You can "see" a smile down the phone.

Impact and evidence of positive improvement or changes:

Fast implementation and widespread use of virtual meeting platforms and other IT systems. The wide acceptance of the meeting platforms has enabled me to provide updates at regional meetings that I used to attend in person. I, along with the other attendees have significantly reduced time lost due to traveling. Whilst I look forward to meeting people in the flesh again, having some meetings virtually enables more people to attend. A meeting is just the two hours it is set for, not an additional two or three hours in travel time as well.

Unexpected changes:

The positive energy of finding ways to do things, overcoming previous hurdles that had at times seemed too high to jump.

Three innovations or changes to keep:



Virtual meeting platforms to enable more people to attend meetings.

⁵⁵⁵	Vi m

Virtual periodic coffee meetings with colleagues.



Exploring jamboards. Something to consider going forward.

Contact details for further information



Jennifer.harrison@hra.nhs.uk



Name: Laura Bousfield

Job Title: Head of Feasibility and Start-up

Organisation: National Institute for Health Research Clinical Research Network Coordinating Centre (NIHR CRNCC)

Role during COVID-19 pandemic:

To maximise participant access to research, all NHS health and care organisations have the opportunity to express interest in participating in new research through a Site Identification service that the NIHR coordinates across the UK.



For the Vaccine Taskforce supported COVID-19 vaccine studies, this approach was adapted to ensure each of the regions (15 in England and each Devolved Administration) were collectively presented to the commercial Sponsor as the UK-wide recruitment strategy for fast paced everchanging COVID-19 caseloads across the UK.

Significant learning throughout the COVID-19 pandemic:

The power of partnership working with a common purpose. Delivering effective research at pace happens when all partners work together as a collective. Facilitating a service which enables the UK research infrastructure to present a collective strategy to Research Sponsors adds value that transcends organisational boundaries.

Impact and evidence of positive improvement or changes:

The pandemic has been a catalyst for innovative thinking and challenging long-established approaches. Proposing regional areas planning to deliver research through a hub and spoke approach during the early stage protocol development posed a number of challenges in place of the traditional 'named site selection' approach.

As with any new approach, significant effort was needed to address emerging concerns and more so during a time of complete societal change and uncertainty. Holding on to the shared values of working as a collective research system and widespread participant access provided the anchor for continuing to push this approach. Although variable in uptake at the time, the success of this approach where utilised has provided a proof of concept for future research delivery approaches, especially with the growth of integrated care models.

Unexpected changes:

Combined with COVID-19 admission and research activity data, made available as a collective report within the NIHR's Open Data Platform, the approach for UK-wide site identification service enabled the initiation of a discussion to consider opening in Wales where a study team had previously only considered English sites. Having data to support a proposed change in processes provided additional reassurance.

Three innovations or changes to keep:



Maximise patient access to new research across the UK through coordinating a site identification service that spans the collective research infrastructure.

- Utilise the powerful combination of healthcare data and research activity to champion the selection of a broader range of research locations across the UK.
- Align with the integrated
 care systems to propose innovative research delivery models that challenge traditional approaches to individual site selection.

Contact details for further information



supportmystudy@nihr.ac.uk

Name: Philip Good

Job Title: Study Start-up Manager

Organisation: National Institute for Health Research Clinical Research Network Coordinating Centre (NIHR CRNCC)

Role during COVID-19 pandemic:

NHS sites participating in COVID-19 vaccine studies were supported to set-up quickly through the utilisation of a national study resource review, undertaken by a National Coordinator based in the NHS who



worked directly with the Sponsor, alongside the Chief Investigator (CI) and their study team.

Significant learning throughout the COVID-19 pandemic:

The value of the NIHR CRN is the ability to connect people across the NHS research infrastructure. We have added value by linking people together during the pandemic, working towards a common purpose, and reducing duplication. This has enabled the NHS to work as a collective research system across organisational boundaries.

Impact and evidence of positive improvement or changes:

The collective purpose to undertake COVID-19 vaccine studies as quickly as possible was a catalyst to utilise a national approach for the existing study resource review which helped speed up sites opening to patient recruitment. The NHS costing community supporting the vaccine studies proactively shared experiences and learnings to apply to upcoming studies, improving the quality of each subsequent study resource review. This avoided delays due to resource negotiations prior to site opening.

Dace Dimzs-Jones at CRN Greater Manchester created an <u>infogram</u> as a way of sharing resource requirement learnings.

Unexpected changes:

The joined up approach empowered the collective NHS to justify study resource requirements and minimise cost variation between sites.

Three innovations or changes to keep:

Raise the profile of a connected, valued and trusted costing community embedded across the NHS to improve the accuracy of the initial study resource requirements and thus decrease site cost variations.

- Reinforce the benefits of a single costing methodology for commercial research across 219 separate NHS providers to speed up patient access.

Embed study resource reviews and subsequent costing as an integrated element of study set-up activities, not as a separate or parallel activity.

Contact details for further information



supportmystudy@nihr.ac.uk

Name: Laura Bousfield

Job Title: Head of Feasibility and Start-up

Organisation: National Institute for Health Research Clinical Research Network Coordinating Centre (NIHR CRNCC)

Role during COVID-19 pandemic:

NHS organisations have access to research activity data visualisation tool provided by the NIHR Open Data Platform (ODP). The COVID-19 pandemic enabled urgent public health research



activity to be displayed alongside COVID-19 admission data and ICU facilities. In a fast moving pandemic, daily updates to both caseload and research activity data were critical for real time, informed decision making.

Significant learning throughout the COVID-19 pandemic:

The value of the NIHR Clinical Research Network is the ability to connect people across the research infrastructure. This example brought health care and research information together in a single view which was used by the Chief Investigators, study teams and the lead Clinical Research Networks to make collective and informed decisions on the appropriate locations for upcoming research in real time. With the pandemic case load unpredictable and changing at pace - this visibility was an invaluable tool.

An example is the Phase II platform studies: ACCORD2, TACTIC-R, CATALYST and DEFINE which took place all across the UK.

"The four CIs of ACCORD2, TACTIC-R, CATALYST and DEFINE have really appreciated the insight and eagle-eye view intelligence around patient numbers and where they are."

Professor Ling-Pei Ho, Chair, NIHR Respiratory Translational Research Collaboration

Impact and evidence of positive improvement or changes:

NHS organisations were able to access caseload information and research activity within one tool. To support the NHS visualise these two key sets of information, the CRN worked with partners in NHS England and NHS Improvement to deliver this collective view.

This intelligence instantly and clearly identified sites which had developed effective ways of working resulting in a higher proportion of the COVID patients under their care being recruited into research. This view facilitated their experiences and good practice to be shared across the research infrastructure supporting increased recruitment across the Urgent Public Health study Portfolio.

This happened, for example, in the Recovery trial.

At University Hospitals Plymouth NHS Trust great clinical engagement, communication and team working meant a large proportion of COVID patients were offered the opportunity to take part in research.

Similarly North Tees and Hartlepool Hospitals NHS Foundation Trust was identified as a Trust where a particularly high percentage of patients with COVID were recruited into Recovery throughout the pandemic. Dr Prudon kindly shared the approach which enabled this in this <u>video</u>.

Unexpected changes:

Access to the functionality was available from early on and often presented as screenshots in presentations. Yet the real benefits were only seen when the data visualisation tool was utilised in it's live format to answer a specific question *'this week, where would be a good location to target for COVID-19 research recruitment'*. The engagement came from seeing the power of this in action.

Three innovations or changes to keep:



Demonstrate the power of nationally available data visualisation to inform local research decision making. Harness the power of data visualisation to support expressions of interest for new studies, not just COVID-19.



Utilise data visualisation to support placement of research across the UK and increase patient access.

Contact details for further information



supportmystudy@nihr.ac.uk

NHS R&D Forum



NHS R&D Forum

Name: NHS R&D Forum Working Groups

Organisation: NHS R&D Forum

Role during COVID-19 pandemic:

We convened weekly 'COVID Coffee' catch-ups to ensure our main Forum group members were supported and look out for each other but quickly realised that regular contact would be appreciated beyond group members. As the weeks went on, our community found emotional as well as professional support among colleagues whilst expertise, knowledge and information shared in real time that become invaluable to stakeholders leading the COVID research response. We collated experiences in shared practice guides, through surveys, via news items and in the Forum Resources Exchange, feeding directly into national research decision-making meetings.

Significant learning throughout the COVID-19 pandemic:

It is important to connect with people as people, not just as professionals or peers. Regular contact and informal conversation build relationships. A supportive community that is honest and regularly talking, benefits individuals, organisations and systems.

Allowing flexibility and providing opportunities for people to safely share and be themselves outside of rigid or formal meetings, and to bring humour and kindness encourages engagement and open sharing. If people can attend just for 10 minutes they can stay connected and feel supported. This is not "wasting time in unnecessary meetings" it is creating a network of support that can help when the time comes. It is possible to talk both safely and openly across diverse organisations if you are clear that the purpose is support for all.

Regular weekly 'drop-ins', in addition to formal meetings, opens conversation and opportunities to more members who might not otherwise engage and ensures stakeholders hear from across the spectrum of research experiences in real time.

Impact and evidence of positive improvement or changes:

Learning and practice changes have been picked up from the experience and expertise of group members. This has included the setting up of studies and vaccine hubs to onsite vs remote monitoring practice and methods of managing workload. Insights from COVID Coffee have influenced managed recovery and opened up conversations around finance, capacity and operational challenges. There is broader engagement across the research community, which in turn has created more interest in the Forum working group activities and outputs.

People continually and regularly turn up. We have developed roundtable conversations as a result of being able to quickly set up online conversations that would otherwise have been an organisational challenge and cost. Stakeholders from CRNCC and HRA have really valued the COVID coffee platform.

Three innovations or changes to keep:

Create more opportunities for conversations between groups, roles and organisations.

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	commu

p more and regular unications via differing routes to support all.



Foster Hive Mind. An email circulation list where people Foster Hive Mind. An email can contact other members for advice or support.

Contact details for further information



info@rdforum.org.uk
Research Operational Staff



Research Operational Staff

Name: Carolyn Maloney

Job Title: Head of Research Operations

Organisation: University Hospitals of Leicester NHS Trust

Role during COVID-19 pandemic:

First and foremost to ensure that the COVID-19 studies were approved very quickly to allow research teams to offer the opportunities to patients. I think we approved most early studies within 24 hours of getting the study on our desks. Then writing policy to accommodate the changes required, ensuring my team were OK working from home and able to do their jobs. I



was also involved in filtering requests for expedited reviews of priority COVID-19 work and making decisions about which were category 1 priority and which were not.

Significant learning throughout the COVID-19 pandemic:

Trust! Trust that the regulators will and are doing their bit. Trust in my colleagues and the clinical teams. We can move mountains and push things forward so quickly when everyone is facing in the right direction. Changes happened to process, attitudes and decision making so quickly we all had to work together. We can't do our jobs without each other. The back-office function was critical.

I was asked to explain how we were able to achieve what we did in our office by colleagues across the country. My answer was that we focused on what was important. I made a very quick decision about what was critical and what wasn't. I was described as 'gladiatorial' in that meeting – I'll take that!

Impact and evidence of positive improvement or changes:

A number of processes and ways we do things have changed and those changes are to stay. Speed of approvals is one key example. We focus on what we need to confirm that the research can go ahead, and what we need to collect after approval has been given.

Flexibility of approach and methods too. Previously it was thought impossible for my team to work out of the office and from home. It absolutely isn't. We'll be returning with a blended approach.

Unexpected changes:

Respect for the function of the office and the critical role was recognised. Relationships were strengthened as we worked closely together to move things forward.

I've identified some things that need work in the team, and many more things that need to be celebrated! My team are awesome!

Three innovations or changes to keep:



Blended approach to • working a combination of home & office. Stripping out unnecessary
checks pre-confirmation of capacity and capability, and developing post confirmation process. Diarising dedicated time for Team Well-being.

Contact details for further information



Carolyn.maloney@uhl-tr.nhs.uk

Infrastructure Manager

Name: Emma Beeston

Job Title: NIHR Infrastructure Operational Manager

Organisation: University Hospitals of Leicester NHS Trust

Role during COVID-19 pandemic:

Until October 2020 I was working as a Senior Research Nurse in the NIHR Leicester Biomedical Research Centre-Cardiovascular Theme, where I managed the Genetics and Biomarker Theme studies. When COVID-19 struck the studies that I managed all



paused and the delivery team were either redeployed to support their clinical colleagues or work on Urgent Public Health studies.

During this time, I also moved into a new role, still working for the Leicester BRC but as the NIHR Infrastructure Operational Manager. This meant moving to a new hospital base within University Hospitals of Leicester (UHL) and joining a new team. It is always a challenge moving into a new role, but this was magnified as all of the normal processes of meeting new people and settling into a new role where impacted by COVID-19, social distancing and working from home. Lots of teams meetings were scheduled and I was made to feel very welcome by everyone, both virtually and those that were working on site. During the first few months of my new role, the ENSEMBLE 2 vaccine trial commenced and as a registered nurse when asked if I would support the study by working as an unblinded nurse, I immediately said yes.

This proved to be a really good experience, allowing me to work alongside members of the team which I wouldn't ordinarily have in my new role. For example, the research delivery team in the Leicester Diabetes Centre, the clinical trials pharmacy team and other members of the study support and management teams. I felt welcomed into all of these teams and found that it was a really good way of getting to know people and putting faces to names during a very challenging time.

Significant learning throughout the COVID-19 pandemic:

The most significant thing that I have learned during the pandemic is how proud I am to be part of the fantastic, enthusiastic, resilient and adaptable team who deliver research within UHL. All too often it is easy to get bogged down in day to day work, targets and deadlines. Now and again it is important to reflect on the things that we achieve as a group.

I have always been passionate about research and in my role I work as part of a large multidisciplinary team to support the underpinning management of research delivery at our trust.

I feel that the COVID-19 pandemic has really shone a spotlight on research, highlighting not just within our trust but also the wider community what an important role research plays in advancing healthcare.

Impact and evidence of positive improvement or changes:

The whole of the research infrastructure in Leicester came together as a result of the pandemic. Regular Research and Innovation update meetings and communications were convened to share information across all groups. Nurses, associated support staff, administrators and members of management teams were redeployed where necessary to support both clinical colleagues and delivery of Urgent Public Health research.

Infrastructure Manager

Collaboration between research delivery and clinical teams improved with clinical teams across the trust supporting their research colleagues in the identification and recruitment of suitable patients into COVID-19 studies.

Unexpected changes:

An unexpected positive result was that I was able to work on a study which would not have been part of my new role. This gave me the opportunity to meet many people within my new extended team that I would otherwise not have had the chance to work with.

Three innovations or changes to keep:



Flexible working combining working from home and in the office. This has helped me to gain a better work life balance.



Some meetings online using teams or other videoconferencing platforms.

Contact details for further information



Emma.beeston@uh-tr.nhs.uk

Name: Marria Khan

Job Title: Senior Research Management and Governance Facilitator

Organisation: Barts Health NHS Trust

Role during COVID-19 pandemic:

A COVID-19 study review committee was set-up in response to a large volume of research related to COVID-19 which required urgent set-up. Over the past year my role has involved coordinating all the paperwork for the committee panel members to review and then setting up the studies via a fast track review process as well. In addition to that, I was responsible for the setup of these studies at Barts Health NHS Trust, including review of amendments for these studies.

Significant learning throughout the COVID-19 pandemic:

This was an opportunity which allowed us to challenge internal processes and standard operating procedures to find a way to fast track the review process whilst ensuring studies were compliant with applicable regulations which was necessary in order to ensure Urgent Public Health studies were being set up quickly.

The research teams were appreciative of this and respected the time, work and effort being put in to ensure their studies are in line with the governance framework and regulatory guidelines.

Good communication also played a critical role in allowing everyone involved to be kept informed on study set up progress to ensure expectations were met.

Impact and Evidence of improvement or changes:

Adapting the overall study set up review process to make the approval process faster and there was consistent communication.

Impact and Evidence of improvement or changes:

Knowing that setting up Urgent Public Health research studies in short timeframes/deadlines was helping at the frontline and was a key contribution in keeping important research going was definitely a motivation to carry on in times which felt difficult and stressful.

Three innovations or changes to keep:

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Adaptation of the study set up review process.

Enhanced communication and early engagement with supporting departments. Good communication with research teams to better meet expectations.

Contact details for further information

Marria.Khan@qmul.ac.uk

R&D Coordinator

Name: Mariusz Marcinkowski

Job Title: R&D Coordinator

Organisation: Guys and St Thomas' NHS Foundation Trust

Role during COVID-19 pandemic:

Reviewing amendments for sponsorship and ensuring we could implement at site.

Significant learning throughout the COVID-19 pandemic:

I have learned to stop and think in unprecedented busy times. We had surge of amendments and this led to development of new amendment processing tool. Together with amendments team we were also constantly updating and developing new template emails, informing researchers, about changes in processes to improve quality of incoming applications.

Research environments will never stop evolving and I believe our skill of adaptation, to changes, was greatly enhanced during the pandemic.

Impact and evidence of positive improvement or changes:

During exceptional surge of amendments with COVID-19 adaptations we developed automated tool which speeds up processing of amendments. The tool automatically checks 20 attributes, transfer study details, and contact details directly from EDGE and provides clear list of teams which have to be notified about the amendment. Additionally it populates automatically most used template emails with one click of a button.

I think the lockdown strangely improved efficiency of communication. Online meetings are easy to arrange and are removing the need of travel. I have also noticed that more people are engaged in team meetings. Although I would like to partly return to face to face meetings I will definitely continue to use MS Teams and Zoom, as additional tools, once we will be back in the office. I can't imagine to work without those programs.

Working from home was sometimes great sometimes not so i.e. juggling with home-schooling. I think overall we adapted exceptionally well to the new way of working and we can't forget the benefits of this. It affects positively work-life balance as we save a lot of time on commuting.

Unexpected changes:

Working from home and lockdown gave me more time to learn new things. I have learned Visual Basic, which I could put in practice straight away to improve efficiency in processing amendments.

Three innovations or changes to keep:



	Amendm
'	processi
	furthar a

Amendment	<u> </u>
processing tool with	2
further development.	_

Online meetings. Not as a replacement of face-to-face meetings but as an additional invaluable tool.



I am looking forward to come back to the office but think that a hybrid model of office and home working would be beneficial.

Contact details for further information



Mariusz.Marcinkowski@gstt.nhs.uk



Vaccine Staff

Covid-19

Vaccine 10 mL 100 units/mL Rx Only rDNA derivative

#Red4Research Case Studies

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Vaccine Volunteer

Name: Lisa Syne

Job Title: Volunteer

Organisation: Barts Health NHS Trust

Role during COVID-19 pandemic:

I have been volunteer steward at Excel vaccine centre since January 2021. It's a big building and people often get lost, so we are there to help them find their way, check in and get their vaccinations. We are there to give support with wheelchairs if people need them as well, as there can be lots of walking.

Significant learning throughout the COVID-19 pandemic:



I do lots of volunteering in *"normal"* times. Volunteering in vaccine centre has been very different people are generally very happy and excited to get their vaccines. They are more grateful for us as volunteers to help them. When I was volunteering, the Oxford Astra Zeneca vaccine was being given at Excel centre and knowing this was developed in UK was something to be proud of, seeing the freedom it was giving to people and saving lives.

Impact and evidence of improvement or changes:

The speed of vaccine development has meant many elderly people who have been shielding for a year, are now vaccinated and can start to get back to their normal activities. Many elderly said it was first time they had put proper shoes on in a year to come and get their vaccination. Many were excited and bit tearful as meant so much to them.

Unexpected changes:

Having been in lockdown since December 2020 I felt a bit cut off, I am used to being busy with my volunteering. It was such a relief for my own mental health to start volunteering at vaccine centre in January 2021, to mix with people and feel I was being helpful again.

Three innovations or changes to keep:



Keep volunteering and helping people.



Keep up to date with the latest research.



Continue to support the NHS.

Vaccine Trial Manager

Name: Gail Melvin

Job Title: Patient Recruitment Centre Research Business Manager

Organisation: NIHR PRC: Leicester, University Hospitals of Leicester NHS Trust

Role during COVID-19 pandemic:

I was responsible for setting up a COVID-19 vaccine trial whilst working from home and providing ongoing support to the delivery team. The study (ENSEMBLE2) was set up very quickly - 12 weeks from receiving the protocol to being open. I had to ensure we had the facilities, staffing, equipment and resources in place to run the study.

Significant learning throughout the COVID-19 pandemic:

When the study was recruiting I was responsible for ensuring our invoicing was correct to ensure we were recompensed for all the team's hard work. I have learnt a lot about how my role can greatly affect the income to the Trust from commercial sources. We need to have really strong measures in place to ensure we accurately record and request monies. The money is what keeps staff in post and our facilities open so it's a vital role.

Impact and evidence of improvement or changes:

We have had to find staff resource in large amounts and quickly. The connections we've made and processes we've learned about will prove helpful in the future.

It has also prompted us to look at more digital technologies.

Unexpected changes:

We have been able to have internal staff work with us who have never worked with us before and this has encouraged them to do further research with us.

Three innovations or changes to keep:

u_u IIII We are looking at investing in an

automated patient

booking system.

We are setting up our own patient registry on the back of the success of the vaccine registry We are encouraging commercial sponsors to make their research more remote.

Contact details for further information

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Gail.melvin@uhl-tr.nhs.uk





Name: Rachel Williams

Job Title: Regional Vaccine Trial Manager

Organisation: North Bristol NHS Trust

Role during COVID-19 pandemic:

My role has involved working collaboratively with the 5 NHS Trusts in the region as well as the Local Clinical Research Network to successfully deliver multiple COVID-19 vaccine trials in the West of England. I have worked with the research and R&D teams at each site to facilitate the setup and on the ground delivery of vaccination clinics for both commercial and non-commercial trials.

Significant learning throughout the COVID-19 pandemic:

Although teamwork has always been at the centre of our research ethos the pandemic has embedded the importance of continuous collaboration and resilience to achieve targets in a compressed time frame. Working with a united goal across all 5 hospital sites has developed and strengthened relationships and continues to do so. We have thrived whilst working together to deliver Urgent Public Health COVID Vaccine studies and provide research and vaccination opportunities to volunteers across the region. I have learnt that the nurses and wider research team that I have the pleasure to work with, will unite and tackle challenges head on. They are tenacious, selfless and dependable, and I continue to learn from them every day.

Impact and evidence of improvement or changes:

Significantly decreased turnaround time for clinical research studies to be reviewed, approved and implemented.

Increased awareness and interest in research both with our clinical colleagues and the public.

Unexpected changes:

Implementation of remote working and virtual meetings.

Three innovations or changes to keep:



Cross site working to broaden our workforce and learning opportunities.

Unity and cooperation across the research infrastructure at NBT.





Rachel.williams@nbt.nhs.uk



Ability to work from home enabling flexible working day.

Research Project Manager

Name: Kerry Hulley

Job Title: Research Project Manager

Organisation: Leicester Diabetes Centre

Role during COVID-19 pandemic:

I was tasked with coordinating the recruitment of participants to the ENSEMBLE2 COVID-19 vaccine trial. Working through many different channels such as the PRC self-referral hub to ensure recruitment targets were met and subsequently over achieved.

Implementing systems to support this process and within that, supporting staff to ensure effective teamwork within the dedicated



'ENSEMBLE 2' team who contacted, pre-screened participants and then started them on their study journey. My role evolved as the dynamics of the study changed and although challenging at times was extremely rewarding.

Significant learning throughout the COVID-19 pandemic:

Teamwork has been vitally important. The way that things would literally change from one day to the next and the fast pace of the study meant that colleagues worked collaboratively to complete tasks and overcome any challenges. Everyone supported each other working in very difficult times and on a very important piece of work.

Impact and evidence of improvement or changes:

Flexibility and the ability to change the way I work and what I work on within a quick timeline.

Three innovations or changes to keep:



Supporting and 'checking in' on colleagues.

\bigcirc	Defining
Ŵ	responsi

efining clear roles and

د جارج Flexible working

Contact details for further information

Kerry.Hulley@uhl-tr.nhs.uk

Receptionist

Name: Maryam Amatullah

Job Title: Receptionist

Organisation: Leicester Diabetes Centre

Role during COVID-19 pandemic:

During the first lockdown, reception closed to all visitors and there were fewer staff working in the department, as many were and still are working from home. Since it was no longer required for me to work on reception at this particular time, I was asked to provide support to other teams such as data input, filing medical records and preparing letters for the clinic.

Since last November, I have been working in an admin capacity for the ENSEMBLE2 COVID vaccine trial. This involved interacting with

patients, arranging appointments and follow ups. This was a complimentary role to my existing reception role.

Significant learning throughout the COVID-19 pandemic:

The ability to adapt to change – the 'new normal' – and be flexible in a challenging situation. I stepped up from working outside my normal job remit and adapted to the needs of the team that I was placed with.

Impact and evidence of improvement or changes:

My normal reception role temporarily ended at the start of the pandemic. When reception was back in operation it became my responsibility to ensure that only visitors with appointments are allowed to enter the department. I also helped with infection control by ensuring that visitors sanitised their hands, wore a face-covering and signed-in before having their temperature taken. We continue to follow these strict measures and social distancing to ensure the health and safety of all staff and visitors.

Unexpected changes:

I was given more hours to support the vaccine trial

Three innovations or changes to keep:

\leftarrow	I am more aware of
\rightarrow	how adaptable I
	actually am.

	I will always	welcome	а
5	challenge.		



I have realised my inner potential.

Contact details for further information



maryam.amatullah@uhl-tr.nhs.uk

