NHS Research and Development Forum

SHARED PRACTICE BULLETIN 2

Development and Sharing of Practice during COVID-19

August 2020

This is the second Forum bulletin designed to share initiatives and good work ongoing across the R&D management, support and leadership community in response to COVID-19 and re-setting research. The brief examples included are mixed but this bulletin has a particular focus on delivering vaccine studies. Each example has a lead contact identified for any queries or follow up.

Developing good practice together

The R&D community has shown immense flexibility, resilience and skill in managing the research response to COVID-19. The R&D Forum working group members have been hosting weekly hangouts to review developments, to share innovative practice and to support each other whilst quickly developing a national perspective of the practical issues affecting the development and delivery of research, including how these have changed as the UK-wide response has developed. The groups from across the R&D community have thus been uniquely placed to provide a meaningful contribution to the development of the national approach and to help with the national policy and guidance being produced. The R&D Forum will continue to support the Department of Health & Social Care and partners across the system to deliver the required COVID-19 research in a speedy and safe manner.

This bulletin is a means of sharing just **12 brief examples** more widely; there will be many more. As the landscape changes these examples may become outdated but we hope they are useful in general times too.

1. East Midlands Primary Care Restart Prioritisation Panel

NIHR LCRN East Midlands. NHS Nottingham and Nottinghamshire CCG

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The NIHR Clinical Research Network East Midlands in partnership with stakeholders has set up a virtual Primary Care Restart Prioritisation Panel.

The NIHR Restart Framework suggests that local sites establish an Assessment and Prioritisation Panel to assess whether preconditions have been met before restarting/starting studies. It was recognised that it would not be feasible for every research active GP practice to set up their own panel. An East Midlands wide panel enables the sharing of information and intelligence to inform decision making. A Study Local Restart Assessment Checklist has been created which Study Teams complete where the East Midlands is the lead CRN. This forms the basis of the panel's assessment. Liaison with other LCRNs will take place where they are the lead for a study.

The panel had its first virtual meeting on 18th June and is meeting for an hour each week while required. It includes representatives from the CRN Senior Management, Primary Care and Study Support Teams, CRN Primary Care Clinical Specialty Leads (GP) and CCG R&D leads. Views from other stakeholders will be obtained as required. All documentation and decisions taken at the meetings are being shared widely and published on the CRN East Midlands primary care website.

The final decision about whether a GP site will reopen or start a study will always be the responsibility of each GP practice but the aim of this approach is to make practice decision making easier.

What is good about this?

By working together collectively we are sharing intelligence and streamlining communications with GP practices thus enabling Study Teams and GP practices to restart or start studies when safe and feasible to do so.

2. Establishing and delivery of a COVID19 secure on-site monitoring facility and plans for a compliant remote monitoring capability

The Royal Marsden NHS Foundation Trust.

Contact: Mark Terry, mark.terry@rmh.nhs.uk

All monitoring was previously undertaken on-site in small monitoring rooms adjacent to clinical areas, which are no longer appropriate for use.

In response, we have:

- Worked with our Covid19 Silver Command and Trust Board to identify and equip a large new monitoring space (previously IT/EPR training rooms) which is in an external building on-site. We have implemented a new process which has been accepted by our external sponsors which enables on-site monitoring whilst ensuring social distancing, that includes staggered arrival times,

cleaning protocol, online booking system, equitable division of monitoring tables between teams, and rudimentary track-and-trace system

- Developed plans for a compliant remote monitoring capability to enable monitoring to take place off-site. Our plans which will enable our capability shortly involve a review of each study participant information sheet in line with HRA guidance, preparation of a letter of agreement for signature by monitors including our information governance policy/procedure and our IT acceptable use policy, system to enable time-limited and content-limited remote access via our IT department, and process for paper documents to be uploaded into our electronic document management system and/or MS Teams secure channels.

What is good about this?

Resuming on-site monitoring in a new Covid19 secure facility enables the resumption of set-up and recruitment to our research portfolio (in particular the commercial contract portfolio) which improves research finance position and facilitates patient access to research in a timely manner.

Developing remote monitoring capability offers a choice to both our research teams and external monitors, reduces footfall, positions us well for second-wave preparedness and provides a platform for a future-facing monitoring solution in the long-term

3. Pooling resources to ensure vaccine delivery

Cambridge University Hospitals NHS Foundation Trust

Contact: Dr Tracy Assari tracy.assari@addenbrookes.nhs.uk

At Cambridge we were one of the first UK teams to deliver Vaccine trials. The logistics were challenging and so we joined up with two other local Trusts from our academic partnership (Royal Papworth Hospital NHS Foundation Trust and Cambridge and Peterborough NHS Foundation Trust F) and pooled resources.

Staff from all three Trusts took part in the trial, with vaccination taking place at Cambridge University Hospitals. Follow ups were divided across all of the three Trusts and their Research delivery staff came together for the first time in order to deliver in all aspects of the study. There were regular teleconference meetings between the sites to co-ordinate and lots of effort between parties on the logistics.

What is good about this?

The model worked well to deliver the study in a short timeframe and CRN Eastern are proposing to use a similar hub/spoke model for future vaccine studies that come through the network. Relationships for the delivery of research were strengthened.

4. Out of hospital support for vaccine research

University of Southampton & Southampton University Hospitals NHS Foundation Trust

Contact: Robert Hull Robert.hull@nihr.ac.uk

The University of Southampton were happy to support the Oxford and Imperial COVID vaccine trial delivery in the sports hall to maintain a safe, socially distanced environment for research participants in the vaccine trials, away from an acute hospital setting. The hall will be available until it is required for socially distanced teaching in mid-September. Excellent project management and regional team working has been key to University Hospital Southampton (UHS) successfully delivering the studies.

These principles, with the support of the Integrated Care Systems of Hampshire and Dorset, will be deployed as further vaccine studies are planned in the region. For the phase I study we completed our early phase clinical risk assessment, which detailed the emergency contingency plan. A supporting slide set is available in the Forum resources exchange.

What is good about this?

Much needed extra capacity for vaccine delivery was created that ensured social distancing could also be maintained whilst reducing the burden on the acute hospital setting.

5. Excellent project management for successful delivery of UK vaccine studies

University College Hospital London

Contact: Pushpsen Joshi pushpsen.joshi1@nhs.net

At UCLH we have recruited really successfully to the Oxford Vaccine Trial and we are now delivering the Imperial Vaccine study. Our top tips for successful delivery are:

- **Project management and task force**. Besides the R&D office, the research team led by the PI must be proportional to the scale of the study. It is good to have an experienced project manager (not PI) leading the vaccine research team. Apart from clinical research staff involved in the trial, the team should have representations from communications, service support department, R&D, QA, delivery / research nurses. Everyone in the team needs to be aware of their roles, responsibilities & timelines. Especially with the participation of healthy volunteers, appropriate time should be given to informed consent and resolution of queries. Sometimes the trial is run from more than one physical site, which can be a logistical challenge.

- **Communication**: Communication is vital for any large scale trial to be set up in a short time. Regular daily meetings will keep information flowing, help track progress, adapt to any changes quickly and keep everyone on the same page. Use of Trust communication channels (including trust websites) will help recruit participants (staff or patients). It is a good idea to have the R&D or Trust communication representative present on the vaccine research team.

- **Sponsor's requirements for green light** – Being a CTIMP, local confirmation of capacity and capability may not be sufficient for the Sponsor to allow the sites to start with research activity. Sometimes the Sponsor may issue staged greenlight/s which is especially relevant when the timelines to start a trial may be tighter than usual. It is key to ensure localisation of documents, training and delegation logs, risk assessments, GMO approvals (something we do not come across in our day to day work), etc are all progressed along with the agreement to meet the proposed objectives.

- **Deadlines**: This is an important factor to consider where communications are required to raise awareness about the trial or to do an initial eligibility screening. Consequently, appropriate time should be allowed between the site confirmation and first visit to accommodate the release of the communications and/or analysis of the survey

- **Involvement of Pharmacy, Pathology and other support departments**. Vital for vaccine trial success. Even with an incomplete set of documents, it has proved very helpful to include support departments from an early stage to contribute to the logistics of the study. Vaccine trials may require healthy volunteers, so not being aligned with routine care appointments requires an extra level of cooperation between the staff on the ground and sample/IMP pathways.

- **Be prepared for amendments**. Depending on the phase of the trial, or the overlap between different phases, new information can come to light at any time. Every amendment may come with an updated version of an information sheet, protocol or consent. These may be issued within a day, so an appropriate system whereby superseded versions are discarded appropriately, and participants are reconsented if required needs to be designed so that the participants are receiving the latest information and consenting for the correct protocol.

- **Budget negotiations**. It is important to ensure there is enough funding to cover the costs of the study, but this can be a challenge for a big scale trial. The pace at which a site is expected to set up the trial makes budget negotiations even more tricky. Maintaining a handle on the funding without holding up the research is important to ensure the study runs effectively.

What is good about this?

Excellent project management has worked well for us with UCLH the 3rd top recruiting site nationally for the Oxford Vaccine Trial and leaving us well placed to successfully deliver the Imperial Vaccine Trial.

6. R&I Manager leads study into acceptability of research in care homes.

Royal Wolverhampton NHS Trust

Contact: Kelly Hard kellyhard@nhs.net

As manager of R&I, I've been awarded a sum of money through our local CRN to undertake research into the Acceptability of Research in Care Homes during the pandemic and post pandemic-with an emphasis on delivering vaccine studies in these high risk groups. This qualitative research aims to explore the very real barriers to undertaking vaccine studies in the care home environment and will feedback how to engage and deliver in these areas. Alongside delivering and engaging in a post-pandemic environment. The study is being run in conjunction with Dr. Annalise Weckesser from Birmingham City University and Sandra Prew

lead research nurse for the ENRICH project. We will be commencing the online survey and focus groups in september.

What is good about this?

It is rewarding for R&D management teams to practice what we preach by developing and contributing research to improve our own work. This study will support delivery of research in care homes with a focus on vaccine trials and the pandemic research endeavour

7. The SIREN Study: a system approach

Shopshire , Telford & Wrekin STP The Robert Jones and Agnes Hunt Orthopaedic Hospital NHS Foundation Trust & Shrewsbury and Telford Hospital NHS Trust

Contact: Teresa Jones teresa.jones6@nhs.net and Kelly Hard kellyhard@nhs.net

Following the letter from NHS England and NHS Improvement requesting all NHS Trusts and Foundation Trusts to participate in the SIREN study, the Shropshire, Telford & Wrekin STP decided that the study should be offered to all. The challenge was set and The Robert Jones and Agnes Hunt Orthopaedic Hospital NHS Foundation Trust (RJAH) and Shrewsbury and Telford Hospital NHS Trust (SaTH) were tasked with delivering the study to all NHS employees across Shropshire, Telford and Wrekin via a collaborative approach. RJAH and SaTH will co-ordinate and deliver with the other eligible NHS organisations, Shropshire Community Health NHS Trust and Midlands Partnership Foundation Trust, referring their staff to us via the PIC process.

The R&D managers of each of the organisations already have a good working relationship thus coming together to deliver a study jointly is a natural progression and one we see being repeated frequently in the future. Each organisation separately identified staff that could ensure a smooth delivery of the study and where there was an overlap, a discussion was had and the most appropriate staff member agreed upon. Recruitment is due to start in the next 2 weeks.

What is good about this?

This approach has allowed a single STP wide target; prevented arguments over capacity issues and who should have the largest recruitment; cross Trust working, enabling sharing of workload; the ability to provide a suitable location for staff to participate in the study; every member of the NHS Trusts within Shropshire, Telford and Wrekin the opportunity to take part in an important research study.

8. Lead nurse for COVID research secondment

Guys and St Thomas' NHS Foundation Trust

Contact: Rachel Fay Rachel.Fay@gstt.nhs.uk

The research and development department have supported the seconding of a new research team to solely cover COVID studies and trials within Guy's and St Thomas', this team has been established under the newly seconded COVID research Matron Karen Bisnauthsing. This newly seconded team is designed to facilitate the setting up, planning and implementation of COVID research with the focus on all NIHR, Urgent Public Health and CMO approved COVID trials and Non-commercial vaccine trials.

The trust prioritisation group assess all research that is conducted in the trust both new trials and the re-start of those put on hold for COVID. If deemed appropriate COVID specific studies are cascaded to the research Matron who then starts working on the feasibility, set-up, and opening of these trials. This post is key in the organisation of this research delivery team to optimise the trials opened and recruiting, to capture potential eligible groups in a timely fashion. The Matron works closely with a range of departments and multidisciplinary professionals to assist with the appropriate set-up of COVID specific trials and studies.

What is good about this?

This team is a specialist team that deals with COVID trials and all the caveats that are associated with them such as infection control implications, trials that are based in various settings of clinical and non- clinical areas around the hospital, with a variety of clinically unwell patients, staff and healthy participants.

The research Matron has oversight over the operations and strategic management of these trials to ensure a speedy set-up and an efficient, optimal recruitment. This post adds leadership and structure to how these trials are conducted at the trust and ensures they are conducted appropriately and safely within the changing trust policies for COVID to safeguard the patient/ participants recruited, staff working within the research team and work alongside patients entering the hospital for clinical care.

9. Summary of Restart for GPs to facilitate their understanding and the assessment of studies

Norfolk and Suffolk Primary and Community Care Research Office NHS Norfolk and Waveney CCG, Primary Care Research Cambridge and Peterborough, NIHR Clinical Research Network Eastern

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When the NIHR restart framework was first published we quickly realised that GP colleagues were at risk of disengaging from all the information that was also in the document but relevant to secondary care and large Trusts. We pulled together a local task group and translated the main messages from Restart into a primary care specific information sheet with assessment criteria for local capacity and capability in the surgery. This was accompanied by a more detailed risk assessment template that practices could use to inform decisions on individual studies. A link to the document is the Forum resources exchange

What is good about this?

It provides easily digestible information on Restart considerations specific to the Primary Care Setting, including setting out what was expected of the practice and what support the CRN and R&D teams would be providing.
This was a collaborative piece of work across the two Primary Care R&D teams and the CRN in the Eastern Region to ensure a consistent approach.

10. Priority Setting Partnership in Community Nursing

The project leads are from Kent, Leicestershire, Oxford and Northumbria

Contact: Lee Tomlinson lee.tomlinson@nhs.net Kent Community Health NHS Foundation Trust

A group of NIHR 70@70 nurses are leading on a James Lind Alliance, Priority Setting Partnership (PSP) in community nursing. The purpose of the Community Nursing PSP is to define the research priorities for the profession in partnership with people who access community nursing services and their carers. The focus is on community nurses who are providing care to adults in their own homes, in community clinics or in residential homes. Community nurses have knowledge and experience of supporting people with multi-morbidities, chronic and long-term conditions, such as heart failure, COPD, multiple sclerosis, Parkinson 's disease, cancer and diabetes. They provide support to patients and carers in the management of symptoms and exacerbations. This support increases the quality of life of people living with multiple morbidities, promoting their independence, as well as a service that is patient-centred, supportive and appropriate at all stages from diagnosis to end of life. The project leads cover a good geographical spread and they will also work with CHART and the R&D Forum to support maximum voice form patients and community nurses across England to contribute

What is good about this?

R&D colleagues have led on this Priority setting in action and shows how it can inform professional development strategies. This will be a fantastic opportunity to grow community-nursing research for an under-researched cohort of the population, much of which will respond to the Long Term Plan. The first steering group has just taken place, so keep a look out for opportunities to get involved with the first survey. Although this isn't about COVID19 colleagues in R&D have set it up during this time and it was just too good to keep out.

11. Psychological impact of COVID-19 pandemic and experience: An international survey from an R&D Dept.

Southern Health NHS Foundation Trust

Projects leads from Southern Health NHS Foundation Trust & University of Portsmouth

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The COVID-19 pandemic has threatened the health and lives of millions of people across the globe. It has impacted governments as a public health emergency with its rapid spread infecting a global population with over 19,718,030 confirmed cases and a total of 728,013 deaths resulting from COVID-19 infectious disease pandemic as of 10th August 2020 (WHO Coronavirus Disease (COVID-19) Dashboard. Since its onset the outbreak nearly brought the global community to a standstill, with lockdowns declared by governments across the globe. The pandemic not only severely impacted most vulnerable groups over 60s and those with underlying conditions including chronic respiratory disease, cardio-vascular disease, diabetes, hypertension, dementia (Lloyd-Sherlock et al., 2020; Guan et al., 2020) but also had disproportionate impact on Black, Asian Minority Ethnic (BAME) communities and healthcare professionals. The research community paused 'non-essential research activity to focus on urgent public health (UPH) studies aimed at finding an effective treatment to the virus. While the primary focus in public health and the research community during this unprecedented time has rightly been on preventing transmission of the virus and finding vaccines and a cure, mental health may be a secondary outcome of the virus and needs to be a primary focus as it effects will last long post-COVID-19.

What is good about this?

As an R&D department we have been able to conduct our own research to investigate and explore the psychological impact of COVID-19 across the UK and global population. Although the study could not compete for CRN resources designated for Urgent Public Health studies, it received overwhelming support from the research community who were able to support it at their sites.
The first wave of recruitment from May 2020 – 31st August 2020 has recruited a total of 29,134 participants in the UK. Wave 2 recruitment will open on 1st October - 31st Dec 2020.

Thanking all the NHS organisations and Primary Care sites who have supported recruitment during this difficult time and to the participants for their contribution in this investigation.

12. Engaging the BAME community in COVID19 Trials and more recently Vaccine Trials

Barts Health NHS Trust
Contact: Mays Jawad m.jawad@qmul.ac.uk and Neeta Patel neeta.patel6@nhs.net

BAME groups make up a large proportion of the population in East London and these proportions are predicted to increase in the future. We know generally out in the community, BAME communities are less likely to engage in healthcare research, and we need to understand why, if we are to be successful in our attempts to recruit BAME participants to our vaccine studies.

We have:

- Established a COVID-19 research PPIE advisory group, ensuring broad representation. This group has contributed to the development of the co-enrolment document set and both interventional and observational video scripts.

- Translated interventional/ observational videos into 9 languages (plus English) and shared them via NIHR's Be Part of Research and TrialsConnect (patient-led organisation) websites.

- Developed two videos to support Vaccine trials – an animated walkthrough of vaccine trials at Barts Health and a video to promote 'inclusion and diversity' in research. The second video will primarily be aimed at BAME communities and will seek to directly address concerns/ fears in a culturally sensitive manner. Co-chairs of the Trust's BAME Network plus two lay representatives of BAME backgrounds are actively involved in the development of the scripts.

- Held a consultation exercise to the Trust's BAME Network (approx. 90 attendees) to present a project proposal, seek views and engage members in a conversation about research. Follow-up activities include social media campaign and a webinar series (with local community members and other stakeholders) to explore views towards research (emphasis on participation but also involvement/ general engagement).

- Established links with the NIHR CRN East Mids lead who is engaging BAME communities for the NIHR within the Centre for BAME Health in Leicester. Primarily to share best practice and learning, pool resources and ensure broader reach than if we were to act as a stand-alone Trust.

- At the staff forum at Newham University Hospital and Whipps Cross University Hospital (part of Barts Health NHS Trust), two trial patients will speak about their experience of taking part in RECOVERY and how it's changed their view of research. Both are from BAME backgrounds.

- Supported with a widespread local communications campaign (both internal and external) to share best practice and learning.

What is good about this?

To meet the needs of BAME communities, it is important to embed their voice and their unique perspective into the heart of any decision-making. We have undertaken a multi-layered approach to enabling this.

- This shared practice bulletin is a means by which the Forum members can engage in discussion and support for each other.
- Additional resources can be can be accessed via the NHS R&D Forum Resources Exchange key word search COVID-19 or restart .
- Our monthly newsletter is a trusted source of all the lastest news, policy and regulatory requirements. Subscribe here:
- Coffee chats are 11am every Thursday morning. Join in by emailing info@rdforum.org.uk

Thank you for all you are doing towards COVID-19 and research