UCLPartners

A Story of Surges, Super-Recruiters and Small Sites

Case Studies Uncovering the story behind successful RECOVERY trial recruitment at Barnet and Newham hospital sites in 2020-21

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Executive Summary

UCLPartners and the NIHR Clinical Research Network (CRN) North Thames undertook case studies at Barnet and Newham hospital sites to understand how COVID-19 research recruitment was achieved at unprecedented scale during the first two COVID-19 surges. Both were active sites for the RECOVERY trial (Randomised Evaluation of COVID-19 Therapy).

At Newham, recruitment to the RECOVERY trial was over 4 times higher than recruitment to all interventional studies conducted the previous year. At Barnet, RECOVERY recruitment represented a 5-fold increase.

To learn from this activity, a qualitative case study approach has been taken on both sites. Interviews of 21 staff members active in RECOVERY recruitment were undertaken to uncover the narrative behind this success and develop theories of change as to how improvements in trial recruitment can be sustained and built upon.

Nine themes arose from the interviews grouped under three headings:

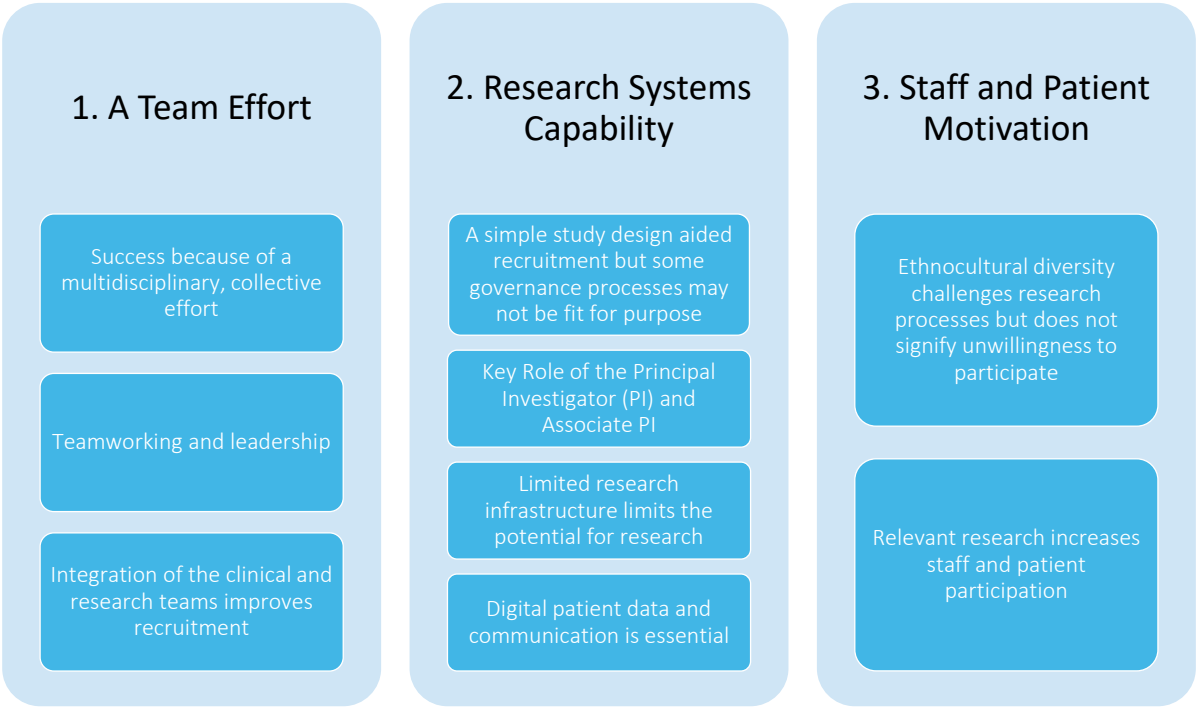

Figure 1: Factors contributing to success recruitment of trial participants

Successful trial recruitment at Newham and Barnet has shone a light on the appetite for research within communities underserved by research and has demonstrated the ability and achievement of small and newly formed research teams.

It falls now to the research community to consider these findings in the context of local objectives. There are implications for the those who fund research and those who undertake it, for those within

NHS providers and those in the wider clinical research ecosystem, for highly research active research organisations and those who aspire to be so.

Recommendations

Recommendations are specific to the different roles individuals play in research, from commissioning to front line teams.

Research funders and commissioners (including CRN)

- **Smaller hospital sites:** Establish permanent research capability on smaller hospital sites. This will require a change to the practice of awarding research funds retrospectively and consideration given to pump-priming research infrastructure on willing sites.
- **New resource models:** Invest in research programmes that further utilise innovative research resource models, such as associate PIs/co-investigators for increasing research capability and individual development opportunities (as well and to increase recruitment)
- **Network of resources:** Create a network of research resources to build an "Agile Workforce" in the case of a high impact research opportunities to deploy staff on a temporary basis.
- **Data management**: Further promote online trial databases to reduce need for paperwork and make data more accessible for performance and progress review

Research Teams

- **Research team composition**
    - **Associate PIs:** Develop research skills and confidence within clinical teams by offering opportunities for junior staff to take research roles by further testing the associate PI model, and allocate resources to facilitate this
    - **Diversity**: Ensure diversity in staff conducting research (both ethnocultural and staff role) to support increased participation from diverse populations and to improve research access
- **Consent:** Review consenting process for research participation – which is led by medical staff at present, but going forwards there could be instances where other clinical professionals could be equally appropriate to consent for research.
- **Clinical teams:** Integrate clinical teams into research processes and activity, with appropriate implications for workload management, allowing rapport to develop and work allocation to respond to local need.
- **Champion research:** Research personnel need to be physically present and visible to champion research and facilitate recruitment.
- **Data management:** Continue the roll out of electronic patient records and exploit them for purpose of increasing research participation and reducing the administrative burden, as well as improving performance and progress review

Our Approach

UCLPartners and The North Thames Clinical Research Network report here case studies from Barnet and Newham hospital sites to understand how research recruitment was achieved at unprecedented scale to the RECOVERY study during the first two waves of the COVID-19 pandemic.

Having spoken with those who were active in recruiting to RECOVERY, analysed interview transcripts and identified the themes and narratives behind successful recruitment – the results of these case studies are offered for the consideration of the research community within the UCLPartners geography.

The Context

The Sites

Recruitment to the RECOVERY study was rapid and at an unprecedented scale. Of all hospital sites in the UCLPartners' geography – Barnet and Newham most dramatically exceeded their previous recruitment to interventional trials

	2019/2020 recruitment to interventional NIHR portfolio studies	2020/2021 Recruitment to RECOVERY	Increase
Barnet Hospital	64	357	5.6 x
Newham General Hospital	51	215	4.2 x
North Middlesex Hospital	84	303	3.6 x
Whittington Health	59	184	3.1 x
Basildon University Hospital	159	481	3.0 x
Barking Havering and Redbridge	159	333	2.1 x

Figure 2: Table of the 5 UCLPartners sites with highest RECOVERY recruitment by comparison to previous research activity

Newham Hospital is one of the five sites that make up Barts Health NHS Trust. Barts Health is one of the most research active Trusts in the country, however most of the research takes place at either St Bartholomew's or The Royal London Hospital. RECOVERY opened at all Barts sites, as well as the newly formed Nightingale Hospital (hosted by Barts Health).

From the study opening at the Newham site on 4th April 2020 until the 31st March 2021, 214 patients were recruited. In the previous financial year, Newham recruited 50 patients to NIHR interventional trials.

Barnet Hospital is steadily growing its research portfolio. It is linked to the Royal Free Hospital Group which has a large research portfolio but mostly based from Royal Free London site. In the financial year 2019/20, Barnet recruited 96 participants into NIHR interventional trials. With RECOVERY it had recruited 357 by the end of FY 2021: more than a 5-fold increase.

The Surge

London NHS providers were severely impacted by the Covid-19 pandemic in the first two surges. The bed occupancy in London hospitals was over 5000 (1st surge) and just under 8000 (2nd surge). This had a massive knock on effect on elective services, non covid care, and health behaviours which will take time to fully evaluate. The covid pandemic has disproportionately affected Black, Asian and Minotiry Ethnic (BAME) populations, with increased vulnerability, comorbidities and workers in frontline and public facing roles. Newham is a borough with 37% of population living in poverty and 71% of population from BAME communities, and a busy hospital which is part of Barts Health NHS trust. Barnet hospital is part of the Royal Free NHS trust and serves a large population with one of the highest proportions of elderly of any London Borough and very large numbers of care homes.

Our Method

Interviews and Data Analysis

Working with Research and Development (R+D) leads, Principal Investigators (PIs) and clinical leadership from both sites, 15 or 16 individuals on each site were identified to participate in semi-structured interviews. 21 interviews were completed. Over 550 comments were reviewed, and analysed to identify themes and common narratives regarding trial recruitment.

Those invited to interview included:

- R+D leads
- PIs (including associate PIs)
- research nurses, midwives and clinical trial practitioners (some redeployed to RECOVERY)
- research pharmacists
- ward nurses
- trial managers
- doctors supporting recruitment and consenting patients (consultants and junior doctors)

Participants consented to being interviewed and were interviewed by the authors of this report. Interviews occurred by phone or videoconference using the semi-structured interview script (Appendix 1).

Potential themes were identified by the interviewer immediately after the interview and shared between the case study team based on memos made during interviews. The interview transcripts were aggregated, sorted by interview question and initial coding completed question by question – as task divided between 2 team members. The team met to discuss coding and generate themes with disputes resolved by discussion between all authors.

The Results

Interviewees

	Newham	Barnet
Invited to interview	15	16
Unavailable to interview	6	4
Unavailable to interview by team[1] Clinical/research/R+D	5/0/0	0/4/0
Total interviews completed	9	12
Number interviewed by team Clinical/research/R+D	6/3/0	2/7/3

Figure 3: Table of interviewee details by site

Interviews were not achieved with all invited and from neither site were ward nurses available for interview. None refused to interview but were unavailable or no response was received within the 5 week window.

Trial Recruitment Process

Unique to the RECOVERY trial was that it allowed staff to work on a Clinical Trial of a Medicinal Product (CTIMP) without the requirement of Good Clinical Practice (GCP) certification and informed consent could be taken by any site staff. Recruiting staff were required to complete the RECOVERY trial's online recruitment and consent training.

Barnet chose to have only doctors taking informed consent. Newham chose to have all research staff complete GCP and sign a delegation log.

[1] For the purposes of this report, the following categorisation has been used as a best descriptor of teams:
"Clinical Team" – principle investigators, associate principle investigators, consultants and junior doctors
"Research Team" – research nurses, midwives, clinical trial pharmacists and trial managers
"Research and Development Management" – R+D lead, R+D theme lead, R+D managers

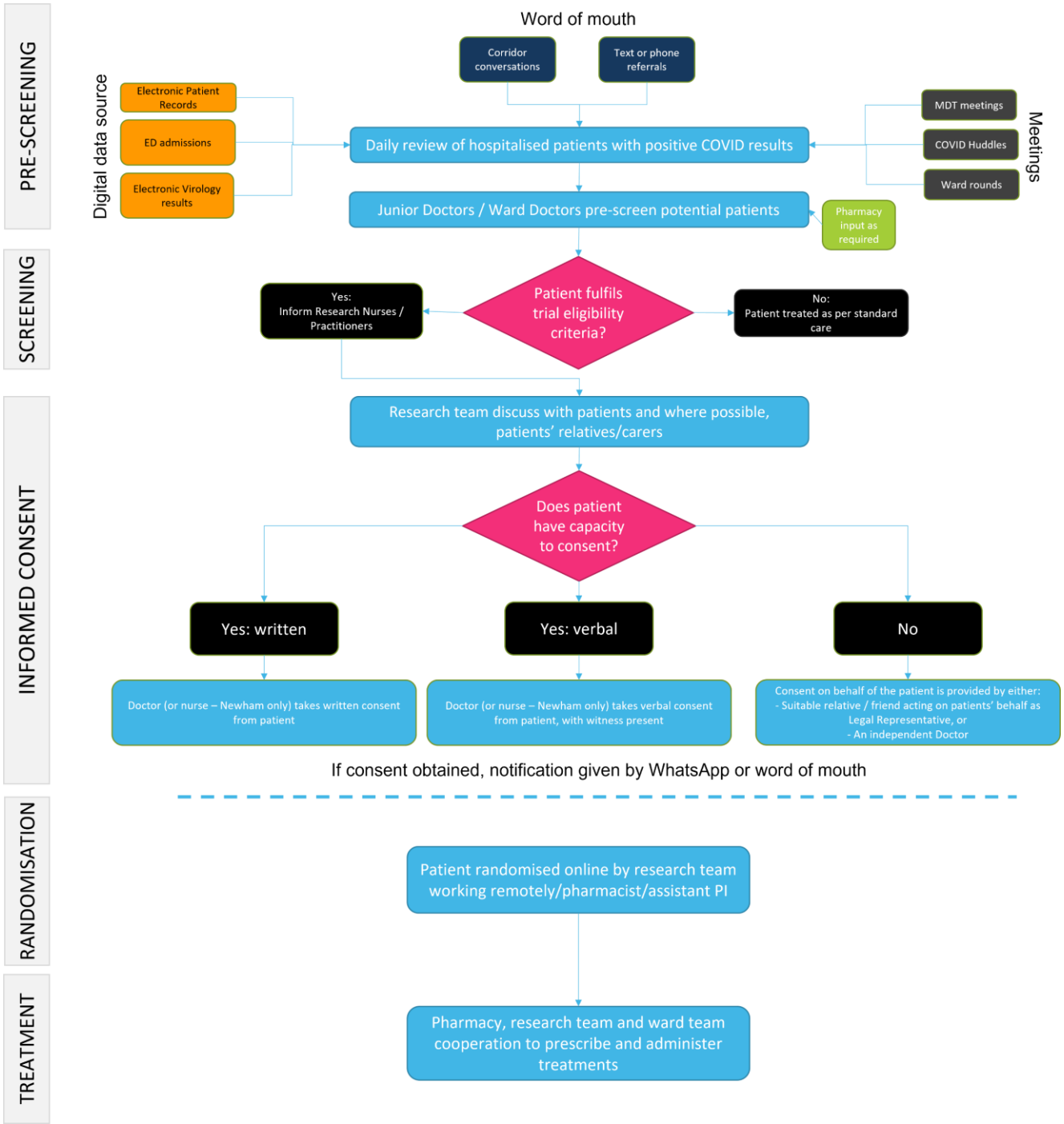

Figure 4: Schematic of recruitment to RECOVERY based on interview data for Newham and Barnet

First Wave

Barnet had a small group of research staff (N=5) working in a mixed model of onsite and remote support that they were able to draw upon. There was no native research team at Newham. On both sites, PIs recruited a large number of junior doctors who were active study advocates and co-workers alongside research staff.

Both sites received redeployed research staff: Barnet received nurses from Royal National Orthopaedic Hospital and the Royal Free site; the Newham team was wholly composed of staff from other Barts Health sites. Effective working relationships with the Newham clinical staff were built from scratch.

On both sites, identification of potential participants in the first wave was multimodal and multidisciplinary. The research team scoured electronic notes, lab results and admissions data. They attended ward rounds, MDT meetings and COVID huddles. Patients were also 'referred' by clinical teams via corridor conversations, by phone or text.

The Research Teams worked closely with the clinical team to ascertain eligibility and discuss the study either directly with the patient, or introduce the research team to family. Clinical trial pharmacists were available to support screening only at Barnet. Consultants or Junior Doctors took written informed consent – only at Newham would research nurses also consent patients.

Second Wave

For both sites, more patients required a large research team. Barnet obtained 3 additional research nurses (total=8). All research nurses were trained to administer Regeneron, 3 RN's were dedicated to administering it on the COVID wards and in ICU freeing up the other RN's to focus on patient recruitment. *Note: Occasionally when Regeneron was required to be administered to 2-3 individuals in a day the RN,s focused on patient recruitment would step in to help.*

At Barnet, a 7-day research service was established for the second wave. This was possible because of adjusted working patterns of research staff, reallocation of work between remote and onsite personnel and closer working with clinical teams – they describe working "as one".

At Newham, all COVID wards had staff identified and involved in the trial. The Doctors based on the respiratory and medical wards (in particular the RECOVERY Associate PIs) identified most patients during the day. Research staff were also deployed in, though these changed frequently which required re-establishing key working relationships with clinical staff.

Themes

Nine themes were identified from the transcripts of 20 interviews. These have been grouped into three main headings.

- A Team Effort
- Research Systems and Capability
- Staff and Patient Motivation

1. A Team Effort

Success because of a multidisciplinary, collective effort

Those interviewed at Barnet and Newham easily identified both teams and individuals who made recruitment possible. This included those with named research roles and those with clinical roles; junior doctors and consultants; redeployed research nurses and established team members; data managers and pharmacists; the hospital community, the RECOVERY team at Oxford and the MHRA.

> *"Newham has this community spirit, you cross paths with so many different people and you build relationships quite easily People are quite happy to help" – Research Team*[2]

Some identified individuals and teams who were difficult or even obstructive but successful recruitment was attributed to a collective effort and highly integrated team working. Interviewees identified a wide range of skills being made available by many: interpreting ICU notes, lobbying and advocacy, creative thinking, meticulous data entry and leadership. The "help" and "support" provided by team members were often referenced.

> *"Highly dedicated staff who were happy to move sites. Pharmacy who made it all happen. [The] amendments coordinator [had a] massive job keeping up" – Research and Development Management*

Teamworking and leadership are both necessary

Barnet

The research team worked dynamically and quickly to allocate and reallocate work amongst themselves. Interviewees describe "teamwork" as the means by which patients were recruited and a lesson to be learned from their experience.

> *"The team at Barnet were fantastic – so friendly, good to work with and for. It's so motivating to work with people who care about making a difference" - Research Team*

Senior leadership were present and active in leading the work. The associate PI role allowed for ongoing leadership and the coordination of screening, approaching and consenting patients.

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Newham

Similarly, there was an agile approach to the allocation and reallocation of work, considering the staff available and their strengths. The research team were physically present and personal relationship and networks are important enablers in recruiting both staff and patients.

> *"The team was the main factor for why we recruited so well in the second wave. Over my time there, I had built a lot of connections with infection control. People knew my name because I'd been shouting about RECOVERY since April." - Research Team*

Integration of clinical and research teams improves recruitment

Findings are mostly shared across sites but it is worth noting that Barnet recruitment was supported by an "army" of junior doctors working within the research team, whereas within Newham, roles were not delineated in the same way. Ongoing hearts and minds work is necessary on both sites, with some described as having "no interest in research".

Barnet

Recruitment from COVID wards was aided by the physical presence of research nurse, coordinating with the clinical team to identify patients and acquire consent. These relationships were built over time and enabled smoother recruitment in the second surge but hugely benefitted from a large team of foundation year doctors with a focus on trial recruitment.

> *"Rather than manually screening for potential participants, the team used the Doctors and staff on COVID wards to refer patients to the research nurses" – Research Team*

Administration of novel therapies was also a joint effort between clinical pharmacists and ward nurses working with their counterparts in the research team.

> *"The ward nurses too were supportive (usually the clinical and research nurses work quite independently) and were active in administering the trial interventions" – Research Team*

Newham

Interviewees reflect that ownership for trial recruitment should be shared between an integrated MDT which included research staff. It worked well for doctors to recruit patients within the ward round and have someone involved in the trial present on each ward.

> *"Key to success was having someone who was involved in the trial on each ward" – Clinical Team*

The administration of complex treatments was challenging and required more integrated working and goodwill.

> *"Ward nurses administered study treatment - oral pills. Over time, the team required more research nurse involvement to administer the trial treatment and follow-up" – Clinical Team*

2. Research Systems and Capability

A simple study design aided recruitment but some governance processes may not be fit for purpose

Interviewees from both sites compared the process of recruitment to RECOVERY with other trials and positively identified the design of RECOVERY as being faster, simpler, requiring less data capture, with more digital documentation and less paperwork. This meant it was possible to recruit many patients in a short period of time.

The online training modules were well received by recruiting teams and without the need for full GCP training, there was a larger team active in recruitment.

> *"Training [was] easy for consenting and randomisation [and] data entry [was] very easy" – Research Team*

RECOVERY protocols made provision for nurses to consent patients and where nursing led consented occurred, no concerns are raised about the quality of consenting. There were contrasting views on the merits of policies which limit consent to doctors. Some comments indicate that this distinction is a blunt instrument and did not achieve the desired outcome of safeguarding recruitment.

> *"More GCP training would have been helpful – [there was a} rather gung ho approach, encouraged numbers based approach rather than humanity in recruitment" – Research Team*

There were a small number of comments highlighting that the introduction of new treatment arms increased complexity and the changing protocols were difficult to keep up with. There were delays associated with R+D approval and this was considered a hinderance

> *"Approval of minor amendments and removal of treatment arms in the trial sometimes took a long time to be approved by R&D" – Research Team*

Key Role of the Principal Investigator (PI) and Associate PI

Half the interviewees across both sites highlighted the importance of the role of PI or associate PI. The PI role is positively viewed as motivating teams, driving recruitment and cohering the team.

The associate PIs were active in coordinating identification and consenting or participants. The role gave ownership and opportunity to junior doctors. Where the associate PIs were also leading ward rounds, recruitment was very successful.

> *"Associate PI scheme was good! Junior Doctors don't usually have the opportunity to get involved in clinical research - but there is a lot of interest" – Clinical Team*

Limited research infrastructure limits the potential for research

Neither site had large or mature research teams and they described being compromised in their ability to recruit until research teams were established. Research resources were redirected to RECOVERY as a singular trial of focus. For both sites, the staffing boost associated with this was core to the success of the work. Nonetheless, both sites felt that their RECOVERY research teams were underpowered and more patients could have been recruited with more staff.

"Patients [were] very open to research, staffing was the limit to recruitment, not patients themselves" – Research Team

It was highlighted that for so long as research funding follows successful recruitment, it is very difficult to establish mature trial teams and associated infrastructure in smaller hospitals.

Barnet

Alongside a PI and associate PI, a small number of research nurses and 10-15 junior doctors were utilised to swell the ranks of the research team (which included a clinical trial practitioner and research pharmacist). Trust communications raised the profile and the appeal of being research active.

Newham

Four associate PIs were appointed from within clinical teams and supported by redeployed research nurses but with limited research infrastructure, the interviewees detailed challenges such as not having an office, there being no research pharmacists on site and not having access to drug refrigeration.

"Had to develop whole new research team at Newham - nothing there before. Had to build relationships from scratch also. And infrastructure- no clinical trials pharmacy at Newham" – Research Team

Digital patient data and communication is essential

Several tech systems and communication channels were identified as essential agents in the successful recruitment and coordination of teams but this was not to the exclusion of analogue and in person communication, with whiteboards, physical office space and daily huddles also used and highlighted by interviewees as necessary features of work.

Almost all interviewees identified WhatsApp as the key communication channel for the research team – used for locating potential participants, dividing work and maintaining team morale. It was not used for patient identifiable data.

"Had a WhatsApp group to communicate in real time potential patients, who had been approached about the study, request for a Dr to consent, request for randomisation." – Research Team

Electronic patient records were a vital asset in finding and screening patients. Without this, it would not have been possible to make use of the support offered by remote working and conference calls. Mature and integrated EPR at Barnet enabled the strategic allocation of work to those in remote settings and onsite.

The trial website with online training resources and patient information were easy to access and share.

3. Staff and Patient Motivation

Ethnocultural diversity challenges research processes but does not signify unwillingness to participate

Newham

Despite the population at Newham having had very little previous exposure to research opportunities, many were willing to be involved. Many patients wanted their families involved in decision making but where translation services weren't available, it was harder to be sure of messages being conveyed correctly. Patient Information Sheets were provided in many languages but Tamil and Lithuanian were not provided (despite large local populations) and this limited recruitment.

> *"We never imagined that we would recruit 200 patients to Newham […] because there wasn't an embedded culture of research. We have learned that a lot patients are happy to have a trial explained to them." – Research Team*

Interviewees observed that sites within outer London present an opportunity to diversity study populations but this requires a research team. Better still, a diverse research team: recruitment was helped when the staff reflect the cultural diversity of the patient population.

> *"If [research is] only delivered by tertiary centres then [we] miss out a large sector of population and deprive them of access to emerging therapies." – Clinical Team*

Barnet

This was not identified as a theme.

Relevant research increases staff and patient participation

On both sites, staff were motivated because of the immediate threat posed by COVID and the shock of having no effective treatment.

> *"There were 16 deaths in 4 hours – this was the biggest motive" - Clinical Team*

Patients also understood the importance of the research, helped by the publicity of a BBC documentary. When dexamethasone was identified as effective, it was evident that trial outcomes were improving patient care. Care changed rapidly in response to the outcomes and this too was motivating.

A Call to Action

The narrative is compelling: underserved communities, organisations and staff, with limited previous exposure to research are both willing and able to engage in research. Small, focussed research teams are able to deliver at scale, to motivate one another, to integrate with clinical teams and to exploit digital systems and in doing so, open new chapters in the research activity of hospital sites.

There are opportunities to review decisions made regarding research infrastructure and research governance, particularly how and where research resource is distributed. Within UCLPartners geography, there is a mixed research portfolio, with both highly active research centres and areas of high disease burden but low research recruitment. For example, across the North Thames region (NIHR), only 4.3 of 1000 patients with a common mental health condition are recruited to a mental health research study (in South London – 57.1 per 1000). People from Black, Asian and minority ethnic backgrounds make up 13.8% of the UK population, but recruitment to COVID-19 studies from the same backgrounds was 9.26% and to vaccine studies was 5.72%.

Through continued partnership working across academia and healthcare providers, we have the capability and expertise to trial innovative solutions to diversifying research recruitment, improving research participation for staff and patients, and exploring how to further improve and refine our research ecosystem.

It is worth noting that the conditions of these case studies were unique to the context of the pandemic. With vaccines and treatments available for COVID-19 and as the system moves more explicitly into reset mode, attempts to replicate the workforce models and recruitment strategies outlined above need to be reviewed for feasibility and sustainable outside of the pandemic environment.

We call our clinical research community to gather and consider what could and should change in the way we resource and conduct research in order to increase access and participation for organisations, staff and the populations they serve.

Recommendations

Recommendations are specific to the different roles individuals play in research, from commissioning to front line teams.

Research funders and commissioners (including CRN)

- **Smaller hospital sites:** Establish permanent research capability on smaller hospital sites. This will require a change to the practice of awarding research funds retrospectively and consideration given to pump-priming research infrastructure on willing sites.
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Appendix

Appendix 1

No	Questions
1	What was your role in RECOVERY study?
2	How/why did you take that role
3	What was your experience of recruiting to the RECOVERY trial?
4	How would you compare your experience of recruiting to RECOVERY as compared to other research activity you've been involved in?
5	How did your team work? Division of labour?
5a	How did you identify patient's to approach about RECOVERY
5b	What technologies were most important in your recruitment work
5c	Were there systems or people who were particularly helpful?
5d	Were there systems or people who were a hinderance?
6	Having recruited so many to RECOVERY, what do you think should be learnt from this experience and carried to future research agendas?
6a	Lessons for your trust?
6b	Lessons for the CRN?
7	Do you have anything further you'd like to add?
8	Additional Information