Perspectives: Reflections on the COVID-19 response: putting clinical research nursing on the map

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Authors’ Note

This perspective is presented in two parts. In the first, three clinical research nurses from the Glasgow Clinical Research Facility (GCRF) reflect on the impact of the COVID-19 pandemic on their clinical and research practice. In the second part, a student nurse deployed to the GCRF reflects on her experience offering a complementary perspective.

Prior to COVID-19, Glasgow Clinical Research Facility (GCRF) was a busy clinical research unit with in excess of 100 multi-disciplinary team members undertaking approximately 400 studies in various stages of development – from set-up, open/recruiting, follow-up, closing down studies and archiving.

When we heard that the difficult decision had been made by the research leadership level to put the majority of these studies on hold in order to maintain participant safety and support the start-up process for the fast approaching COVID-19 clinical research portfolio, we were worried. The initial questions we asked all centred around the safety of our current participants; how would they get their bloods reviewed? Would they still receive their trial drugs? What if they reported an adverse event (AE), serious adverse event (SAE) or suspected unexpected serious adverse reactions (SUSARS)? A contingency plan was put in place to allow for scheduled follow-ups for patients involved in clinical trials of investigational medicinal products (CTIMPs) and other studies involving devices. Where possible these were conducted remotely using a direct-to-patient service for delivery of equipment, devices and medicines following medical or nursing review.

In a timeline that felt like overnight, we were reduced from running over 400 studies, to just a handful. It was no longer safe to bring participants into a hospital setting for routine research visits. As nurses, we were readying ourselves to join our colleagues in clinical areas to help with the massive influx of patients with COVID-19. Within days, however, new COVID-19 research protocols had been given approval to recruit and we were with our colleagues on the front line, but

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with a different remit: to collect as much information about the emerging disease as possible. As an often overlooked specialty in nursing, this was a proud moment for our clinical research nurses as it felt like we were able to do our part to help fight COVID-19, using our honed set of research skills to deliver essential information.

Urgent Public Health Research (UPH) focused on the coronavirus itself and its mode of action to help us understand the disease process and host response, development of safe and effective treatments and potential prophylaxis in the urgent quest for a vaccine. Our COVID-19 portfolio included studies of varying intensity from data collection, sample collection to intervention studies looking at possible drug treatments. Expedited approvals and a cohesive team approach enabled these studies to be actively recruiting within a short period of time, and all had high recruitment opportunity because of the sharp rise in hospital admissions with COVID-19. Expedited approvals and ever-changing amendments were, at times, difficult to keep up with which led to anxiety amongst the staff as this was a big change to our normal procedures. Excellent team working and regular meetings ensured we were able to implement these and maintain the safety of our participants.

Although we were used to working in a fast paced, pragmatic unit, we had to adopt a new working environment which led to a change, not only in the way we utilised the GCRF but also to our overall working conditions. The small group of patients who had to attend their regular safety visits were given a dedicated space and where possible, equipment within the GCRF, in order to minimise the risk of infection. Allocated clinic rooms were introduced for COVID-19 study visits and also for specific follow-ups where patients who had either been symptomatic and/or previously tested positive for COVID-19 could attend. Due to the acute clinical emergency presented by COVID-19 infection, we established a seven-day service and introduced extended working hours, which was not without challenges. Skill mix was at the forefront of the development of the new rotas in order to ensure that a steady mix of CRNs were available for ward reviews, including ICU/HGU, and non-COVID-19 reviews, whilst ensuring availability for early starts, later finishes and weekend working – all the while ensuring that the GCRF environment adhered to the government mandated social distancing guidance.

We split ourselves into three main teams (data entry, non-COVID-19 facing and COVID-19 facing), each team had their own tasks and challenges but each team had additional stresses – the COVID-19 facing team had the worry of knowing that despite the use of PPE, they were putting their health, and possibly families’ health, at risk to ensure good data was obtained; the non-COVID-19 and data team were worried for their co-workers and some of us felt guilty that our own health was impacting on us being able to share the COVID-19 facing team’s workload.

A large majority of patients admitted to hospital with COVID-19 were given the opportunity to participate in research, but there was also a sense of guilt as we entered wards, HDU and ICU, and saw staff under immense pressure supporting patients with COVID-19. How could we offer a potential new treatment, collect our samples and then (it felt like) walk away? But of course if research was not able to continue through the pandemic, we would not have been able to offer patients and the public the hope of finding a treatment. So when the first evidence-based treatment of dexamethasone that came out of the RECOVERY study we had all been working on was announced, it felt like an incredible honour to have been part of this. We were under no illusion that we could not have achieved this without patients and their relatives agreeing to risk taking trial treatments, but as the nation clapped on a Thursday to support the NHS, a huge sense of pride was felt, and a few tears shed, knowing we had contributed to the national effort with our specialised research skills.
The logistics of further splitting the GCRF’s new teams became a challenge when the UPH COVID-19 vaccine portfolio was given ethical approval for initiation at site. The three main teams had to be split into further teams of blinded and un-blinded nurses. At this stage, the non-COVID-19 facing team felt like we had more to offer our colleagues as we could be more hands-on with overall aspects of the vaccine studies.

CRNs are used to having time for site initiation visits (SIVs) and investigator meetings where training is extensive and thorough. Due to the UK wide lockdown, these SIVs moved from face-to-face teaching to being carried out remotely via video link and in some cases, were completed in condensed intense sessions, which left some of the nurses feeling like we did not have enough preparation time to confidently start these trials. Our education team had been enveloped into the wider research team, but was still able to help immensely to close any information gaps by ensuring that small information sessions were held regularly and that we were all trained to deliver vaccines. Bi-daily team updates, known as huddles, were carried out to keep us updated on the ever-changing COVID-19 picture.

Vaccine clinics brought research into the news once again and the overwhelming support from volunteers willing to roll up their sleeve and risk a new vaccine was outstanding. Another intense effort from the whole research team enabled us to appoint, consent and vaccinate in a superhuman time frame to ensure that the data could be accurately analysed to advise the national vaccine programme. The stomach lurching moments were still part of the role; a waiting room full of volunteers waiting for safety data to be reviewed to allow for vaccination to continue; safe un-blinding to be completed for hundreds of participants to allow them to get the now-approved Pfizer vaccine. Long hours were put in to ensure the safety of the participants and to ensure reliable data.

The constantly evolving COVID-19 portfolio resulted in a steep learning curve with a high turnover of documents and processes, again requiring a lot of flexibility from all teams as patients would require last minute changes to clinic appointments and documentation, new equipment being organised and set up. Adaptability is not only important for growth and development within the research nursing post but is also essential to allow you to rapidly learn new processes, techniques, behaviours and skills, especially in response to the continual changing requests and conditions that accompany research during a global pandemic.

Juggling COVID-19 work and restarting the postponed or halted research studies were now our priority. Believe it or not, life goes on and we needed to approach the ‘new normal’ with the enthusiasm and drive of pre-pandemic research. An influx of new staff is helping to support this but all need to be trained in research skills before they can work independently.

Supporting staff to work in such a dynamic and at times emotionally difficult environment was of paramount importance to our team. Managing the logistics and skill mix of the team to implement and safely carry out new complex trials during such a fast moving time tests all aspects of leadership, especially when the situation is compounded by a reduced nursing capacity due to an increased level of staff sickness prior to the testing programme being implemented for staff symptomatic of COVID-19.

Every member of staff within the GCRF has contributed to the COVID-19 pandemic showing admirable efforts in not only adapting their working schedule but also adjusting their role to accommodate the ever-changing practices. Like the rest of the NHS, there are staff members who went above and beyond, such as cancelling planned leave, postponing retirement, as well as increasing working hours in order to provide effective, essential research practice. Without research teams working tirelessly to provide data on COVID-19 disease progression, treatments and prevention, we would not be where we are today. It could be said that every cloud has a silver lining; those clinical colleagues who once did not even know that there was a research facility in Glasgow, now come to us to ask advice about delivering medicines; we are asked questions about research as we enter wards and
potential participants are suggested to us, having spiked the interest of our nursing colleagues. That lesser known speciality of research nursing is now on the map. Let us keep it there!

When it was announced that the Nursing and Midwifery Council had introduced emergency standards (Nursing & Midwifery Council, 2021) at the request of the UK government to allow student nurses to support the NHS without being supernumerary during the first wave of the pandemic, I was scared. I was concerned that foregoing my supernumerary status would be a detriment to my education. The decision to be made, whether to ‘opt in or opt out’, was a difficult one. Opting in meant a potential negative impact to my learning and risking my family’s health with this unknown trajectory of this new disease. But opting out meant that my final year as a student nurse would be extremely pressured to make up the 380 hours alongside theory and the year 3 hours that already had to be completed. I was conflicted in my decision making, but I decided that ‘opting-in’ was the right decision for me.

Due to the emergency, our placement was brought forward by 3 weeks which involved my university, Glasgow Caledonian University, having their staff work around the clock to meet the demands of the NHS, along with the constant demands from students who were anxious about what the emergency standards meant to them. It was not an easy task; however, they did an amazing job showing impressive teamworking. I was allocated Glasgow Clinical Research Facility (GCRF) as my placement.

Whilst student nurses understand that research in nursing is a professional obligation of the Nursing and Midwifery Council (2018), it is well documented that evidence-based practice theory modules are challenging for student nurses as they find it irrelevant to practice (Ferguson et al., 2017). Therefore, I was apprehensive as to what learning opportunities this placement would provide and, importantly, if I would be able to meet the essential skills cluster requirements to be signed off as a year 2 student.

Upon my arrival, it was clear that the team members were enthusiastic about my placement. My allocated mentor spent time with me to build a mutually respectful relationship and discuss what knowledge and skills I had and what I wanted to achieve from this placement. This person-centred approach allowed me to flourish and gain confidence as a year 2 student. Throughout the whole time at the GCRF, I was provided with continuous constructive feedback and constant revisiting of the goals we set for my learning which is an essential component in any clinical learning environment (Jefford et al., 2021).

Clinical Research Nurses (CRNs) are extremely adaptable and have an advanced knowledge base. They act as advocates to preserve patient safety whilst ensuring the integrity of the research they carry out. It was also evident that CRNs use a holistic approach to critically assess the research needs rather than have a task-orientated approach.

During my time at the GCRF, I was able to learn about the trajectory of the COVID-19 disease through analysing the data, observe participant recruitment for the drug trials that may help treat symptoms or reduce the impact of the virus and help trial the efficacy of the Oxford AstraZeneca vaccine.

These trials helped me understand the importance of good documentation, the challenges that come with consenting for participants who are unable to consent due to their illness and the ethical decisions that doctors and CRNs face. I was also involved in collecting biological samples and clinical and demographic data. I also received additional training on Good Clinical Practice, basic life support, anaphylaxis and intra-muscular injections. Additionally, I saw first-hand the infection prevention and control (IPC) innovations the CRN’s were able to implement in order to continue research protocols taking place which Iles-Smith (2020) attests are essential skills for the flexibility and contingency planning in times of public health emergencies.

This placement enabled me to be more curious, think critically, be adaptive and innovative which are all essential attributes of being a nurse. Being part of such a positive culture which nurtures
students helped me to bridge the gap between theory and practice in terms of evidence-based practice. I did not apply to do a nursing degree with the intention to be involved in research; I applied as I wanted to make a positive impact on patients’ lives. However, it was unmistakable from this placement that CRNs play a huge part in this too. This placement mitigated my initial concerns about being a detriment to my learning, and in fact, it has enhanced it. Offering student nurses more research placements in order that pre-registration students’ perceptions of research are changed (Council of Deans of Health, 2019) will produce research confident students nurses who understand the significance of research and feel empowered to use it to improve patient outcomes.

Editors’ note

Together, these two perspectives illuminate the impact that COVID-19 had on research activity and a strong insight into the contribution CRNs made to the international endeavour to understand the disease, identify effective treatments and support the development of the vaccine. This was undoubtedly a challenging period that demanded strong leadership, adaptability and the development of an environment and culture that facilitated innovative solutions. Whilst the authors describe the experience in one research facility in Scotland, we feel sure their perspectives will resonate more widely, and hopefully reflect the emphasis placed on greater innovation and flexibility within clinical research and higher education.

References

Council of Deans of Health (2019). Becoming research confident. Research in pre-registration curricula for nursing, midwifery and allied health programmes in the UK. London: Council of Deans of Health. Available at: https://councilofdeans.org.uk/wp-content/uploads/2019/05/CODH.RIPR_.report_v3-002.pdf

Ferguson C, Digiacomo M, Gholizadeh L, et al. (2017) The integration and evaluation of a social-media facilitated journal club to enhance the student learning experience of evidence-based practice: A case study. Nurse Education Today 48: 123–128. DOI: 10.1016/j.nedt.2016.10.002

Iles-Smith H (2020) How research nurses and midwives are supporting Covid-19 clinical trials. Nursing Times 116(11): 20–22. https://www.nursingtimes.net/rolesclinical-research-nurses/howresearch-nurses-and-midwives-are-supporting-covid-19-clinical-trials-06-10-2020/

Jefford E, Nolan S, Munn J, et al. (2021) What matters, what is valued and what is important in mentorship through the appreciative inquiry process of co-created knowledge. Nurse Education Today 99: 104791. DOI: 10.1016/j.nedt.2021.104791

Nursing & Midwifery Council (2018) The Code [online]. London: Nursing & Midwifery Council. Available at: https://www.nmc.org.uk/standards/code/ (accessed 21 January 2021).

Nursing & Midwifery Council (2021) Current emergency and recovery programme standards [online]. London: Nursing & Midwifery Council. Available at: https://www.nmc.org.uk/globalassets/sitedocuments/education-standards/current-emergency-and-recovery-programme-standards.pdf (accessed 25 February 2021).

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