At the start of 2020, our research department at Chesterfield Royal Hospital was working hard to incorporate several new primary care studies to our existing portfolio of commercial and non-commercial research. At this already busy time, we were selected to participate in several Covid-19 urgent public health studies to further our understanding of the virus, improve patient care and inform public health policy. An urgent public health study is a protocol designated high priority by the National Institute for Health Research (NIHR). We knew Covid-19 was becoming more serious by the hour, but we did not expect it to touch our hospital of 20 wards and around 550 beds. In the weeks before the World Health Organization (WHO) declared that SARS-CoV-2 (Covid-19) had reached pandemic status, we began making urgent preparations to get the new studies set up, sort equipment and documents, and communicate with trial teams and sponsors of the other trials in which we were already involved. We were concerned about the potential impact on our existing non-Covid-19 portfolio of studies, and the possibility of staff redeployment as and when the need arose. As we put in place preparations to conduct the first urgent public health studies, we realised our already quite small team of 10 clinical research nurses was going to be reduced to only four who could carry out face-to-face work with suspected or confirmed cases of Covid-19, because of the increased risk of serious illness for some staff.

For this reason, we had to divide our team into two:
- Those at higher risk, who would not see patients but would, instead, do vital data collection and follow-up;
- Those at lower risk, who could meet with patients who tested positive for Covid-19.

Within a matter of days, our team had rapidly changed in both form and function. We shared anxieties about the many unknowns of this novel virus, including its potency and deadliness. In this rapidly evolving situation, we had concerns about whether we would have sufficient amounts of the correct personal protective equipment in place when we needed it. At this
point we could not help but feel overwhelmed and fearful about the future.

As the incidence of new cases of Covid-19 increased, we focused our attention on the RECOVERY Trial (www.recoverytrial.net), a new national NIHR-adopted study evaluating potentially life-saving treatments. This study was – and still is – paramount to the discovery of treatments, and its successful recruitment has been encouraged by the UK’s four chief medical officers. We now had a purpose and were keen to help our clinical teams find an answer to the big Covid-19 question: which treatments are effective?

**Eligibility checklist**

One way to achieve successful clinical research is to establish good working relationships between research and clinical teams (Newington and Metcalfe, 2014). Due to the unprecedented demand on services, we knew we had to act swiftly to minimise any burden on our hospital’s clinical teams. Our aims were not only to ensure adherence to study protocols, but also to reduce additional demands on clinicians who were working in extremely challenging circumstances amid the uncertainties of this new disease.

We were working to an innovative protocol – a type of study platform that is increasingly being used in clinical research practice. It not only means treatments can be removed and added as new significant data arises, but also that trained research nurses – rather than only doctors, as has been the case traditionally – can obtain valid informed consent from patients. After careful evaluation, we knew this would be a game-changer for us.

As we opened our site to recruitment, we trialled a doctor-delivered consent process. However, we soon experienced an increase in patients requiring urgent treatment, which reduced the availability of our respiratory consultants to complete valid informed consent. To help, we devised an eligibility checklist to evaluate whether each potential participant met the inclusion criteria for the study, while also considering potential exclusion factors. The checklist was created by the coordinated efforts of research nurses and a senior clinical pharmacist, who examined the main contraindications for potential life-saving treatments included in the study against the most common drugs and offered guidance on potential interactions.

Once approved by the principal investigator for use on our wards, we started using this tool to identify eligible patients. We

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**Fig 1. Recruitment process flowchart**

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[Flowchart showing the recruitment process flowchart with decision points and processes described in the text.]

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completed our assessment of each potential patient, which was then signed by a doctor trained as per the protocol. Once eligibility had been confirmed, the research nurses felt more comfortable approaching each patient to discuss the study in depth and receive informed consent directly if the patient was willing to take part. This approach sped up the screening process and left more time for consent.

The recruitment process used is outlined in Fig 1. A separate process was used for patients lacking capacity which involved using a legal representative.

Adapting the team
We believe this is an important example of how research nurses can foster relationships between healthcare workers and adapt generic trial procedures to the specifics of the healthcare setting in which they work. The design of an urgent public health study and the priority granted by the NIHR does allow a greater degree of adaptability, enabling rapid development and review to deliver valid outcomes quickly in a changing clinical situation.

The research nurse binds every team member involved in both the clinical performance and management of a trial, ensuring adherence to protocol and Good Clinical Practice (GCP) guidelines (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), 2016). Despite the best-laid plans, this chain can become stretched to breaking point, especially in district general hospitals or smaller settings, where aspiring to conduct gold-standard clinical research may not be met with enthusiasm from all clinicians due to the demands of their own workloads.

In our experience, one of the positive consequences of the pandemic has been to strengthen the links between clinical practice and clinical research, due to the willingness of everyone to work collaboratively towards a common cause. The new environment in which we found ourselves was welcoming and easy to engage with; we were able to move across different multidisciplinary teams and recruitment to our studies was very well received.

With the support of our colleagues we were able to keep the experience as patient centred as possible. This allowed us considerable time with potential participants to ensure they understood the risks and benefits. Working like this ensured our role as patient advocates came before the needs of the study, despite the pandemic.

“We had a purpose and were keen to help our clinical teams find an answer to the big Covid-19 question: which treatments are effective?”

Receiving consent
The procedure of informed consent is a communication process through which nurses already help patients understand information and select an action congruent with their health beliefs and desires (Meade, 1999). Our experience, during the pandemic, led us to consider whether there is a need to further develop nurse-delivered consent processes in intervention studies. In research, what is the rationale behind the difference in those processes free of pressure and based on logical reasoning – assuming that patients receive adequate information about the nature, alternatives, risks and benefits of the proposed intervention (Leino-Kilpi et al, 2000). Communication and collaboration between the research team and the participant underpin this process, which can be defined as a form of shared-decision making (King and Moulton, 2006) – shared because of the fundamental value that a dialogue occurs in which there is appropriate passage of information to protect the patient and the clinician (Susilo et al, 2012).

According to the Health Research Authority’s consent and participation guidance (Bit.ly/HRAConsentPrinciples), when seeking consent from potential participants, it is critical to appropriately support them in making their decision. The researcher must:

- Have in-depth knowledge of the protocol and potential implications for participants;
- Understand the alternatives that may be available to potential participants, including treatment alternatives;
- Be able to communicate effectively with potential participants, including explaining complex scientific and medical concepts;
- Appreciate how to optimise the voluntary nature of decision making, thereby avoiding undue influence.

Research nurses already apply these principles in their daily work to comply with GCP guidelines (ICH, 2016) and the Nursing and Midwifery Council’s (2018) code of conduct. GCP guidelines say that the process of passing information and ensuring sufficient time has been provided to the subject or subject’s legal representative can be delegated by the investigator to someone with appropriate skills and knowledge. Nowhere in the guidelines does it specify which profession is more suited to receive consent.

At the start of the Covid-19 pandemic, our team of research nurses considered the obstacles we might face in the consent process for urgent public health studies that had been set up and opened in a very short space of time – namely:

- The limited time at physicians’ disposal, given the exceptional clinical pressures;
- The potential influence medics may have on a patient’s decision to take part, given the therapeutic uncertainty with which they were working.

The intensive nature of caring for patients with Covid-19 reduced the availability and time a physician had to carry out the consent process. Informed consent is a sensitive process that must be individualised (Turnham et al, 2020) but, due to the fast-paced clinical environment, this became more challenging. We were concerned this might drastically limit the number of patients we could approach to participate in the trial and reduce access to potentially life-saving treatments. There was also concern that some patients might...
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feel rushed into making a decision to please their doctors or lack the confidence to decline to consent. In the pressured clinical environment, we were concerned that the careful, time-consuming communication needed to prevent such outcomes might be lost and patient-centred care reduced.

As research nurses and health professionals, one of our main duties is to act as patient advocates. With this in mind, we took precious time to take a step back and analyse our situation from a patient’s perspective. With support and supervision, taking charge of the informed consent process was the single most efficient action our team could have made. We took control of the process and ensured all ethical and legal implications of each case were followed at every step. In doing so, we prioritised patient autonomy and dignity, sought to understand each patient’s values, and engaged with each potential participant without pressure or coercion.

This approach is already used in non-Covid-19 trials conducted by the University of Oxford and both authors have been involved in a specific phase III clinical trial that allowed trained research nurses to receive consent. The specific pathway established by the team was endorsed by the research and development lead, the medical lead for research, and included in the design of the RECOVERY protocol; as such, it was permitted by the study team and its sponsors. We believe this approach helped our small research team to randomise >23% of patients admitted with confirmed/suspected Covid-19 to the RECOVERY trial, having approached >70% with detailed information about it (Fig 2). The overall national recruitment rate to RECOVERY is estimated to be around 13%.

Conclusion

Our aspiration may be to foster a collaborative culture, in which the aims and reality of research and clinical practice are aligned, but this is often unachievable. Due to the current state of the healthcare system in which we work, which means many routine demands are not met, the needs of research can often fall to a lower level of priority. This is, perhaps, especially true in smaller hospitals when compared with larger university teaching trusts. This is where the role of the research nurse has real potential. Nurses are uniquely placed to convene multidisciplinary health teams, and to drive and engage teams of all sizes, with the aim of improving patient safety, outcomes and wellbeing (Jackson et al, 2020).

Evidence suggests patients who are consented by nurses have a better understanding of the alternative treatments they may receive (Waloszkova et al, 2021). Research nurses act as patient advocates and, in collaboration with other health professionals, can ensure a correct consent process is adhered to. This strongly reflects the guidance outlined in the International Council of Nurses’s (2012) ethical code.

Research nurses are skilled in ensuring the disclosure of information, checking comprehension and maintaining patient independence in the informed-consent process (Cantini and Ellis, 2007). If correctly trained, senior research nurses with extensive experience of receiving valid informed consent should be actively encouraged to carry out this process, at the very least for phase III trials, if permitted by study sponsors. Indeed, empowering nurses to work to their full potential, based on their specialist education and training, is one of the WHO’s (2020) care recommendations in terms to nurses’ development.

Nursing care is the greatest investment made in healthcare and, accordingly, has the greatest potential impact on patient outcomes (Nayna Schwerdtle et al, 2020). Allowing research nurses to develop their skills with creativity and confidence is vital to empowering them. This, in turn, creates a better research experience for patients by encouraging autonomy, ownership and accountability. In short, if you enhance nursing, you enhance all health care (The Lancet, 2019).

The role of clinical research has never been more visible and relevant than right now and the impact research has on patient care has been hugely acknowledged (Barrett, 2020). Following on from a year that celebrated nurses and midwives, perhaps we should cast some light on research nurses who have provided incredible knowledge and skills alongside frontline staff. NT

Fig 2. Study participants and total admitted and treated for Covid-19 infection, 1 March–20 September 2020

<table>
<thead>
<tr>
<th>Total of patients admitted and treated for SARS-CoV-2 infection</th>
<th>Total of patients approached with Patient Information</th>
<th>Total of patients randomised to the Study</th>
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<td>March to September 2020</td>
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References