

Why you should read this article:

- To learn about the experience of early phase cancer research nurses during the COVID-19 pandemic
- To appreciate the challenges and positive developments brought about by the COVID-19 pandemic in relation to nurses working on early phase cancer clinical trials
- To recognise the positive implications for future cancer research nursing practice

Effect of COVID-19 on cancer research nursing services

Ben Hood, Ruth Boyd, Tracey Crowe et al

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Correspondence

ben.hood@nhs.net
Twitter @Ben_CRUKnurse

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Abstract

This service evaluation examined the experiences of adult and children's cancer research nurses working on early phase cancer clinical trials during the coronavirus disease 2019 (COVID-19) pandemic. A questionnaire was provided to early phase cancer research nurses at experimental cancer medicine centres, and alongside this there was an online discussion with eight of the nurses. The themes developed from the findings and online discussion provided an insight into the challenges faced by early phase cancer nurses during this unprecedented time and into some of the innovations, such as virtual appointments, adopted to overcome them. COVID-19 had a significant negative effect on the cancer research nurse workforce. However, peer support, networking opportunities, reflection and embracing innovation provided support for nurses and enhanced person-centred care.

Author details

Ben Hood, Cancer Research UK nurse consultant, Sir Bobby Robson Cancer Trials Research Centre, Northern Centre for Cancer Care, Freeman Hospital, Newcastle upon Tyne, England; Ruth Boyd, Cancer Research UK senior research nurse, Northern Ireland Cancer Centre, Belfast City Hospital, Belfast, Northern Ireland; Tracey Crowe, lead paediatric research sister, The Royal Marsden Hospital, The Royal Marsden NHS Foundation Trust, Sutton, England; Karen Turner, Cancer Research UK senior research nurse, Institute of Cancer and Genomic Sciences, University of Birmingham, Birmingham, England; Sandie Wellman, Cancer Research UK senior nurse, Oxford University Hospitals NHS Foundation Trust, Oxford, England; Hannah Brown, Experimental Cancer Medicine Centre project manager (workforce), Cancer Research UK, London, England; Alice Johnson, paediatric oncology research sister, University Hospital Southampton NHS Foundation Trust, Southampton, England

Keywords

cancer, cancer research, clinical trials, coronavirus, COVID-19, research, randomised controlled trials

Background

Early phase clinical trials in cancer care are the cornerstone of future developments in treatment and are critical to enhancing the therapies available for patients. Phase 1 and 2 clinical trials provide evidence of safety and efficacy that is critical to drug licensing. Treatments in phase 1 and 2 clinical trials have not yet been approved for use in humans and represent the first phase of testing to ascertain if a new treatment is effective, safe, if there are side effects and optimal dose. Only when these criteria have been established can such treatments progress to phase 3 clinical trials and

thereafter gain approval through the National Institute for Health and Care Excellence (NICE) to be used in the NHS. However, in situations where no further treatment options are available to a patient with cancer, treatments being tested in phase 1 and 2 clinical trials can be made available and offer these patients a chance to continue treatment against the disease (Cancer research UK 2021).

Across the UK, a network of 18 adult and 11 children's experimental cancer medicine centres (ECMCs) support phase 1 and 2 clinical trials research. Cancer research nurses have a vital role in the care of patients in early

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phase clinical trials and the coordination of research studies. However, these nurses have had to adapt to the changing landscape of experimental cancer therapies, which has seen clinical trials becoming more complex and more challenging to deliver within the NHS due to increasingly stringent requirements (Ali and Riches 2021, Cancer Research UK 2021).

When the coronavirus disease 2019 (COVID-19) pandemic was first recognised in the UK in March 2020, the Medicines and Healthcare products Regulatory Agency (MHRA) introduced a temporary halt to non-COVID-19-related clinical trials (MHRA 2020). During this unprecedented period of health service upheaval, although cancer research nurses could maintain clinical research in some adult and children's early phase clinical trial centres, the halt to recruitment generally meant that many patients could not access potentially life-preserving or life-extending treatments.

In May 2020, the National Institute for Health and Care Research (NIHR) launched a research 'restart framework' (NIHR 2020a) which focused on early phase trials and enabled recruitment to cancer-related clinical trials alongside COVID-19 research. However, the ongoing disruption caused by COVID-19 across cancer care and research and support services continued to present major challenges. For example, anecdotal discussions between the authors and other members of the ECMC Research Nurses Network Group detailed stress among cancer research nurses and disruption to services. Consequently, the group undertook a service evaluation to demonstrate the effects of the COVID-19 pandemic on early phase cancer research nursing. This service evaluation aimed to record cancer research nurses' reflective accounts of their experiences throughout the pandemic to provide a foundation for shared learning among the UK's network of ECMCs.

Literature review

Before commencing the service evaluation, the authors undertook a literature search of health service library databases using key words related to cancer research nurses' experience of the COVID-19 pandemic, for example 'cancer research', 'impact of COVID-19' and 'clinical research'. The search was limited to literature relevant to the UK.

The findings demonstrated that during the COVID-19 pandemic, clinical cancer research was affected by the measures brought in to combat it across all UK healthcare services (NICE 2021a, 2021b). During the pandemic, cancer treatments were prioritised

over cancer research. To minimise patient and staff exposure to the virus, government recommendations included use of personal protective equipment (PPE), a ban on family members visiting patients in hospital, reduced waiting room time, social distancing measures, remote consultations and home delivery or drive-through medicine services.

Evidence showed that patients with haematological malignancies experienced a more severe COVID-19 trajectory and that patients with leukaemia were more likely to die compared with patients with solid organ tumours (Lee et al 2020). However, in the UK the risk to children with a cancer diagnosis who also had COVID-19 did not increase compared with the general paediatric population, with no associated deaths related to COVID-19 reported (Millen et al 2021, 2022).

The effects of COVID-19 on early phase cancer trials reflected wider pandemic-related changes to clinical research practice in the UK (MHRA 2020). Patients were asked to stay away from hospitals and some trial medicines were posted to patients. The MHRA acknowledged there would be an increase in clinical trial protocol deviations during COVID-19 and emphasised that patient safety was the priority, recommending that risk assessments at study and patient level should be conducted (MHRA 2020). The MHRA also noted that resource assessment may be necessary as hospital-based research staff may be 'required to assist in other areas' (MHRA 2020). Many clinical research nurses were redeployed to work on dedicated COVID-19 wards or wards that were under pressure due to staff sickness, or to work on COVID-19 vaccines studies.

Despite having paused the setting up of new studies that were not prioritised as national COVID-19 studies at the start of the pandemic in March 2020, the NIHR clinical research network recommended that during a second wave the restart framework, instigated in May 2020, should continue and that redeployment of clinical research nurses should only occur in 'exceptional circumstances' (NIHR 2020a, 2020b, 2020c).

Cancer research in children's oncology experienced major interruptions to early phase trial centres throughout Europe due to COVID-19. Across 31 hospitals in 12 countries it was reported that the closure to recruitment of phase 1 and phase 2 studies was 49% and 61% respectively (Rubio-San-Simón et al 2020). In addition, the researchers noted that the significant burden of staff shortages had resulted in a 61% decrease in

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recruitment to phase 1 and phase 2 studies compared with 2019 averages. The UK was one of the countries to experience the greatest decrease in study recruitment among the 12 countries surveyed.

Aim

The aim of the service evaluation was to identify the effects of the COVID-19 pandemic on early phase clinical research nurses. The project focused on challenges they experienced, positive developments and lessons learned that could inform practice across ECMCs. The evaluation also aimed to inform the members of the ECMC Research Nurses Network Group of emerging and future workforce needs.

Method

The service evaluation was undertaken between May and July 2021. The experience of early phase cancer research nurses during the pandemic was not reflected in the literature, therefore an ECMC research nurse project working group (the authors of this article) agreed a set of questions informed by their experiences at their workplaces. The questionnaire included a mixture of structured and open questions and space for free-text comments, and covered staff redeployment, working environment, main challenges, positive developments, job satisfaction, effect on cancer trials and support required in the future to aid cancer research nurses.

The authors invited ECMC early phase adult and children's cancer research nurses, via email through the ECMC network, to complete the anonymous questionnaire. In addition, respondents were invited to take part in an online discussion about the effects of COVID-19. Four adult and four children's cancer research nurses who completed the questionnaire also agreed to participate in the online discussion which was facilitated by the ECMC research nurse project working group. The nurses who took part in the online discussion were asked:

- » What were the main challenges?
- » What service developments took place in your area during COVID-19?
- » What lessons were learned from the pandemic to aid future nursing practice?

Responses to these questions were documented during the discussion by the facilitators.

A content analysis approach (Hsieh and Shannon 2005) was used to examine the data from the questionnaires and from the online discussion retrospectively. The themes were developed using a qualitative data analysis computer software package (NVivo).

Thereafter themes were agreed through a process of review and debate among the ECMC research nurse project working group for validity and reliability.

Ethical approval

Formal ethical approval was not required because this was not a research project; however, ethical research principles concerning the collection, storage and use of data were adhered to. Respondents were emailed information about completing the questionnaire or taking part in the online discussion via the professional ECMC network (ecmcnetwork.org.uk). This invitation email explained that participation was voluntary and no identifying personal information would be collected. All of the nurses and institutions that volunteered to be involved gave permission for data collected to be used for service evaluation and publication. The process of data collection and the evaluation itself were approved by the ECMC network.

Findings

Questionnaire data were received from 44 cancer research nurses – 31 from adult ECMCs (70%) and 13 from children's ECMCs (30%). Data analysis of the questionnaires produced the following themes:

- » Effects of COVID-19 pandemic on early phase research nurse redeployment.
- » Challenges for nurses.
- » Positive developments identified during the COVID-19 pandemic.
- » Potential implications for developing practice.

Data analysis of the online discussion produced the following themes:

- » Challenges in early phase research nursing during the COVID-19 pandemic.
- » Main positive developments in early phase cancer trials during the COVID-19 pandemic.
- » Lessons learned for future practice.

Themes from the questionnaire data

Effects of COVID-19 pandemic on early phase research nurse redeployment

During the pandemic, 19 (43%) of the respondents were redeployed from early phase clinical trials. Redeployment of nurses took place in 54% of children's ECMCs compared with 39% of adult ECMCs. Figure 1 shows the length of redeployment during the COVID-19 pandemic. Respondents in adult ECMCs were more likely to be redeployed for over three months compared with those in children's ECMCs.

Key points

- Ongoing disruption caused by COVID-19 across cancer care and research has presented major challenges for early phase cancer research nurses
- Providing effective care and managing the safety of patients and staff were among the challenges for early phase cancer research nurses during the early part of the pandemic
- Changes necessitated by the pandemic, such as remote appointments and electronic consent, are potential future innovations for this practice area
- Peer support and networking opportunities can support cancer nurses during periods of practice change, anxiety and service development

Figure 2 shows respondents' main place of work during 2020-21 and emphasises that most respondents continued working in hospitals (19/31 (61%) in adult and 9/13 (69%) in children's hospitals).

Table 1 shows the effect of the COVID-19 pandemic on cancer research nurses' job satisfaction. Most respondents reported that their job satisfaction at the time of the evaluation was the same or higher than it had been before the pandemic.

Challenges for nurses

Table 2 emphasises the main challenges the respondents experienced in undertaking early phase research nursing during the COVID-19 pandemic. Managing their emotions and the emotions of others was a particular issue for respondents in children's ECMCs, while changes in care and communication was also cited frequently as a challenge by respondents in children's centres.

There was also anxiety associated with new pandemic-related adaptations, with one respondent stating:

'At the start of the pandemic there was a lot of anxiety – from the staff regarding PPE and how to get it, and from the patients trying to decide whether to attend or not when they had had received a letter to isolate.' (Nurse working in an adult ECMC)

Anxiety for other respondents was reflected in safety concerns. One respondent stated:

'... much more communication is via telephone contact, and this has meant an adaptation to communication skills; it has been difficult [for us] to lose the direct support and involvement of family and carers, particularly for providing information on complex trials and safety.' (Nurse working in a children's ECMC)

In the free-text comments, the most prevalent themes about the challenges

experienced in undertaking early phase research during COVID-19 were clinical trials being stopped and supporting patients and carers in adult and children's centres. Another theme was 'continuing challenges' due to the COVID-19 pandemic and comments indicated that some challenges, such as social distancing and working environment, staffing levels and staff sickness, redeployment and anxiety, had persisted from the start of the pandemic until the end of the evaluation period. Figure 3 demonstrates the continuing challenges due to the COVID-19 pandemic identified in the free-text comments.

Other emerging challenges that became apparent towards the end of the evaluation period were restarting trials and staff fatigue and morale. One respondent described the ongoing challenge of working in services that were recovering from COVID-19:

'... trying to pick up workload to return to "normal" levels; continued uncertainty; will certain ways of working continue or change again; how do we move forward positively?' (Nurse working in an adult ECMC)

Positive developments identified during the COVID-19 pandemic

Respondents reported several positive developments due to the COVID-19 pandemic. Remote study monitoring, which included remote patient assessment, was most frequently cited. Changes that enhanced convenience for patients participating in trials were also viewed positively by respondents:

'Considering some of our patients travel considerable distances to get to us, having the opportunity to reduce visits, use local services and the shipping of drugs has been fantastic for them.' (Nurse working in a children's ECMC)

An increase in team motivation to address new challenges was the most commonly cited

Figure 1. Length of respondents' (n=19) redeployment during the coronavirus disease 2019 (COVID-19) pandemic

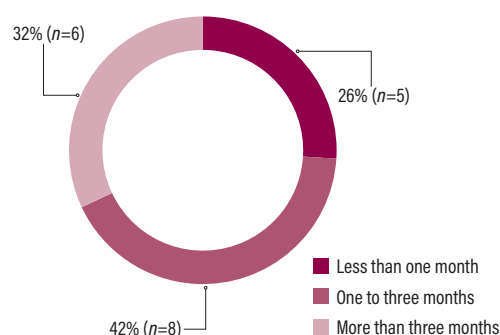
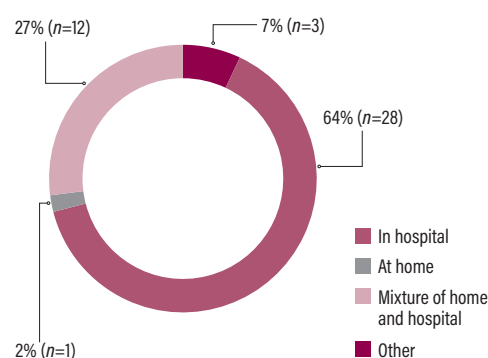


Figure 2. Respondents' (n=44) main place of work during 2020-21



positive development in adult ECMCs. One respondent commented:

'It [the pandemic] has encouraged innovative thinking and practices.' (Nurse working in an adult ECMC)

Themes from respondents' comments about positive developments included flexible working and innovations in remote care. One respondent reported:

'The remote consent was something very new to us, for one of our tissue-testing studies it worked really well.' (Nurse working in an adult ECMC)

Potential implications for developing practice

When respondents were asked about the status of the early phase trials portfolio at the time of the evaluation, responses were spread across the categories of 'rebuilding' ($n=19$; 43%), 'similar to pre-pandemic' ($n=14$; 32%) and 'larger than pre-pandemic' ($n=11$; 25%).

In terms of future practice, positive developments identified during the COVID-19 pandemic included online patient appointments, online patient consent to take part in trials and reduced patient travel time. Most respondents provided recommendations for the development of service provision (Figure 4), with remote consent and remote patient visits being important themes. Specific suggestions included:

'More use and standardisation of e-consent across ECMCs.' (Nurse working in an adult ECMC)

'Further development of our virtual communication tools. We have much better contact virtually with patients, especially extra-regional. Collaborating with other hospitals and agencies seems easier. Early phase research nursing networks are stronger than they have ever been.' (Nurse working in a children's ECMC)

Themes generated from online discussion Challenges in early phase research nursing during the COVID-19 pandemic

The online discussion revealed challenges associated with the COVID-19 pandemic that were also identified in the questionnaire responses, including redeployment, limitations in patient and family support, clinical trials being stopped and anxiety and stress. However, new issues also emerged, such as 'lockdown fatigue', cancer research nurse retention and concerns about delayed presentation and diagnosis of cancer. Figure 5 shows the main challenges identified during COVID-19 in the online discussion.

Main positive developments in early phase cancer trials during the COVID-19 pandemic

The main developments identified in the online discussion were similar to those identified in the questionnaire responses, for example the use of virtual appointments and creative service delivery, such as online consent and peer support. The online discussion emphasised the clinical versatility of cancer research nurses and that the pandemic was a time of reflection and upskilling. Figure 6 shows main positive developments in early phase cancer trials during COVID-19 identified in the online discussion.

Lessons learned for future practice

The online discussion about lessons learned and positive implications for cancer nurses' future practice endorsed creative methods of working, collaboration in clinical trial delivery, the use of virtual appointments and remote services. The participants also recognised increased flexibility and working from home during the pandemic as opportunities for future practice. Other lessons were the importance of avoiding cessation of clinical trials where possible and avoiding

Table 1. Effect of the coronavirus disease 2019 (COVID-19) pandemic on cancer research nurses' job satisfaction

How would you describe your job satisfaction working in early cancer trials now compared to pre-COVID-19 pandemic?

Satisfaction	Adult nurses ($n=31$)	Children's nurses ($n=13$)	All ($n=44$)
Higher	10 (32%)	2 (15%)	12 (27%)
The same	16 (52%)	10 (77%)	26 (59%)
Lower	5 (16%)	1 (8%)	6 (14%)

Table 2. Main challenges experienced by cancer research nurses during the coronavirus disease 2019 (COVID-19) pandemic

Challenge	Adult nurses ($n=31$)	Children's nurses ($n=13$)	All ($n=44$)
Coping with changes in patient care and communication due to personal protective equipment and social distancing measures	18 (58%)	10 (77%)	28 (64%)
Managing an increased workload or increased complexity of work due to relocation or disruption in early cancer trials workforce	20 (65%)	8 (62%)	27 (61%)
Managing changes in the feasibility of protocol procedures and/or assessments for patients	14 (45%)	5 (38%)	20 (45%)
Managing increased emotions (self or others), for example anxiety due to COVID-19	20 (65%)	11 (85%)	31 (70%)

redeployment; two of the eight participants in the online discussion felt undervalued by redeployment and were leaving the specialty. Figure 7 details the lessons learned during the COVID-19 pandemic that could aid future nursing practice identified in the online discussion.

Figure 3. Continuing challenges due to the coronavirus disease 2019 (COVID-19) pandemic identified in the free-text comments

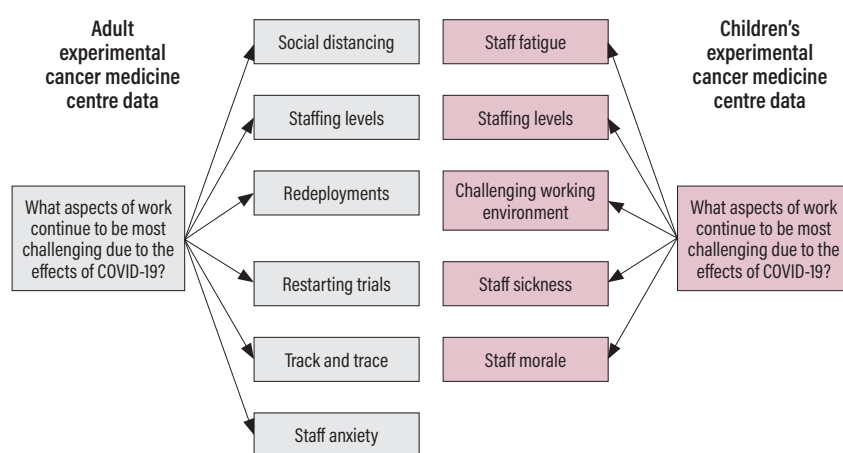


Figure 4. Respondents' recommendations for development of service provision

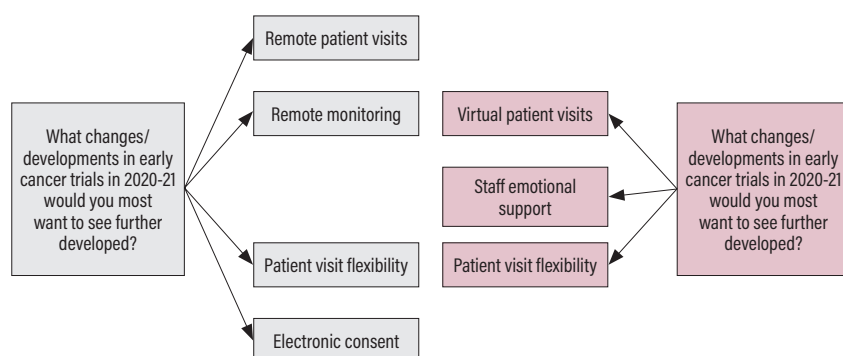
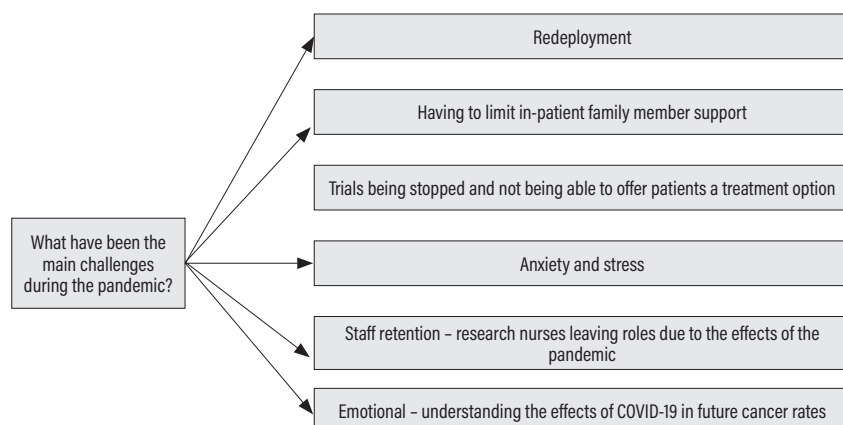


Figure 5. Main challenges identified during the coronavirus disease 2019 (COVID-19) pandemic in the online discussion



Discussion

One of the primary objectives of this service evaluation was to identify the experiences of cancer research nurses and lessons learned from the changes brought about by the COVID-19 pandemic. In this way, the authors hoped to shape future practice.

Emotional effects

This service evaluation emphasised the emotional toll the COVID-19 pandemic had exerted on cancer research nurses. There were two dimensions to this – anxiety for self and others, and stresses associated with work and workforce changes, such as staff absences, hurdles to research delivery and feeling undervalued by others. Clinical trials being stopped and staff redeployment also conflicted with the nurses' dedication to maintaining the delivery of vital research opportunities for patients with cancer.

Respondents from children's ECMCs reported challenges with patient care and communication more frequently than those from adult ECMCs. It was also notable that 'staff emotional support' was requested by both groups, but less frequently by adult respondents than those from children's ECMCs.

There is no research comparing the psychological effects of the pandemic among staff in adult and children's settings. However, it is evident that cancer research nurses were not alone in experiencing stress during the pandemic or that they required support. Davies et al (2020) described the use of tailored psychological support to meet the needs of oncology staff during the pandemic and remarked on their conflict between providing optimal patient care and minimising the risk of contracting COVID-19. This was in addition to the challenges of staff shortages and redeployment, which 'could make staff vulnerable to moral injury' (Davies et al 2020). Petrella et al (2021) identified high levels of psychological distress in healthcare workers at a London hospital during the pandemic, indicating the need for staff to continue engaging in support services to mitigate the symptoms of burnout.

Clinical trial and work disruption

Clinical trials being stopped was a concern to respondents and the findings emphasised a variable picture regarding the recovery of trial activity following the COVID-19 pandemic, reflecting the fragile eco-system of healthcare research. Health authorities in the four UK nations have acknowledged that

lessons have been learned from the pandemic and future attempts to 'build back better' include 'embedding clinical research at the heart of patient care across the NHS, making participation as easy as possible and ensuring all health and care staff feel empowered to support research' (Department of Health and Social Care 2021).

A significant proportion of respondents experienced disruption to their work during the pandemic. While the findings suggested that most respondents to the questionnaire rated job satisfaction as similar to, or higher than, pre-pandemic levels, the online discussion explored the negative consequences, such as low self-esteem and staff retention issues, which may have longer-term workforce consequences.

It is unclear if positive changes implemented during the pandemic, such as flexible working, upskilling and wider role recognition, will be sustained. Resources to rebuild clinical cancer research capabilities are required urgently to protect and expand the expert research nurse workforce.

Person-centred trials and electronic consent

This evaluation was a useful exploration of cancer research nurses' perspectives on the retention of many of the innovations that arose during the COVID-19 pandemic. For example, respondents advocated for remote appointments, electronic consent, clinical trial medicine delivery and close-to-home assessments and tests, where deemed safe. The benefits of these innovations included increased patient convenience and reduced travel, as well as reduced risk of contracting COVID-19.

The potential to build on these pandemic-driven innovations and develop more person-centred trials is reflected in the literature. Lorusso et al (2020) suggested that the effects of the pandemic on clinical research presented an opportunity to alleviate bureaucracy, reduce research costs and promote access to clinical trials. While acknowledging the need for patient visits and specialist requirements of first-in-human cancer research, some authors have proposed a risk-based 'adaptive approach' (Tiu et al 2020) and 'hybrid models' with some remote components (Tan et al 2020).

Götzinger et al (2020) suggested that 'adopting a patient-centric view of clinical research and modernising clinical trial protocols may enhance patient safety and experience while improving research efficiency and outcomes.' To mitigate pandemic-related risks while future-proofing clinical

research, recommendations included the use of electronic consent, screening schedules that are convenient for patients, training patients in how to undertake home assessments, such as recording vital signs or the use of wearable technology, and provision of venepuncture closer to home (Götzinger et al 2020).

In this evaluation, one of the notable beneficial innovations referenced throughout the questionnaire responses and the online discussion was electronic consent. Electronic consent was introduced at the Sir Bobby Robson Cancer Trial Research Centre in Newcastle upon Tyne, England, during the early part of the COVID-19 pandemic. Patients said it was an easy way to consent as it dramatically reduced their travel time to appointments. It also enabled patients to invite family members from anywhere in the world to take part in discussions about consent and to support them to make the decision to participate in a trial (Cancer Research UK 2021).

Figure 6. Main positive developments in early phase cancer trials during the coronavirus disease 2019 (COVID-19) pandemic identified in the online discussion

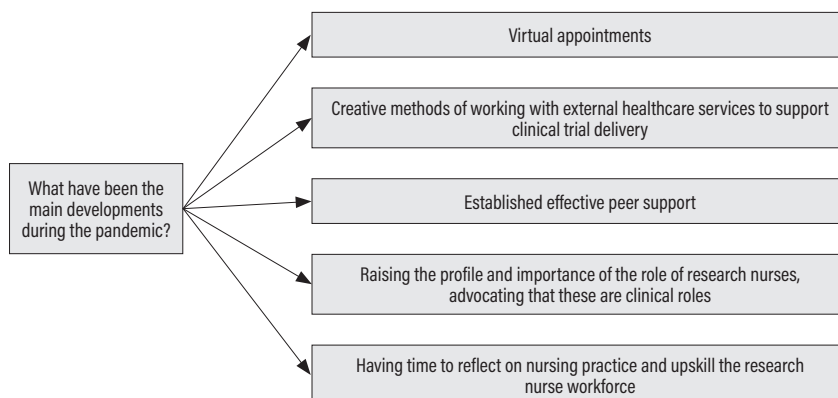
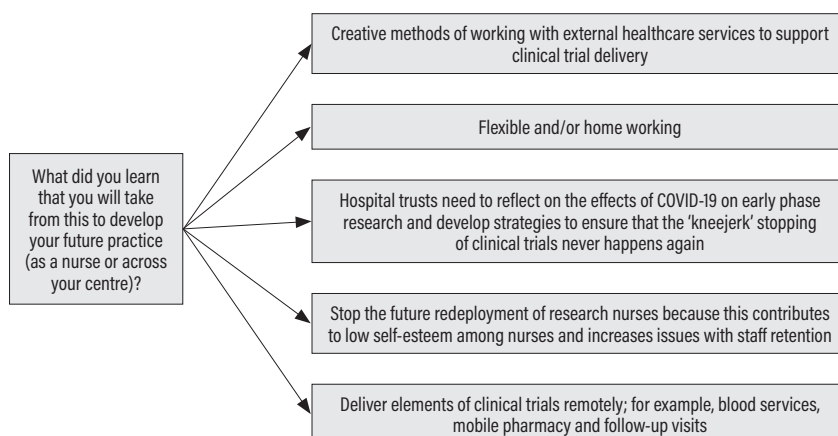


Figure 7. Lessons learned during the coronavirus disease 2019 (COVID-19) pandemic that could aid future nursing practice identified in the online discussion



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Supporting early phase cancer research nursing

Despite the challenges of the COVID-19 pandemic, the nurses who participated in the evaluation maintained their patient focus and commitment to early phase cancer research nursing. However, the emotional toll of the pandemic, the pressures felt by the early phase research nurse workforce and changes in the clinical research landscape meant there was a need for support.

Respondents said the increased use of remote technology was an effective method of facilitating effective networking, while 'effective peer support' was one of the main developments reported by participants in the online discussion. A stronger support network is, therefore, an important legacy of the pandemic. Respondents cited peer nursing support from the ECMC Research Nurses Network Group as an activity they would value, therefore this function of the group could be developed further, alongside networking and sharing good practice.

Limitations

Although most UK ECMCs were represented in the data, the number of respondents from each centre was low. This meant the sample size was small and not, therefore, a true representation of the views of all ECMC nurses. At the time of writing, the COVID-19 pandemic was ongoing, so the findings represent only a snapshot of the respondents' lived experience of part of the pandemic.

Recommendations for practice

The authors' recommendations for cancer research nurses' practice based on the evaluation findings are as follows:

- » Flexibility such as remote appointments and electronic consent in early phase trials can enhance patient convenience and support access to research.
- » Research nurse leaders have a vital role in influencing the development of person-centred cancer clinical trial design.
- » Increased awareness of the value of clinical trials and the role of cancer research nurses are vital to address staff retention and morale within the workforce.
- » Peer support and networking opportunities for early phase cancer research nurses provide valuable connections with colleagues during periods of practice change, anxiety and service development.

Conclusion

This evaluation detailed the experiences of cancer research nurses in conducting early phase cancer clinical research during the COVID-19 pandemic. The findings indicated that early phase cancer research nurses faced many challenges, including providing effective care and managing anxieties related to the pandemic and the safety of patients and staff. However, many of the changes necessitated by the pandemic, such as remote appointments, electronic consent and trial medicine delivery, were identified as potential future innovations.

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