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## A qualitative synthesis regarding the factors surrounding UK critical care trial infrastructure

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1 A qualitative synthesis regarding the factors surrounding UK critical care trial infrastructure

2  
3 **Title :** A qualitative synthesis regarding the factors surrounding UK critical care trial  
4 infrastructure  
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22

23  
24  
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30

### 31 **Abstract:**

32  
33  
34 Conducting clinical trials in critical care is integral to improving patient care. Unique  
35 practical and ethical considerations exist in this patient population that make patient  
36 recruitment challenging, including narrow recruitment timeframes and obtaining patient  
37 consent often in time-critical situations. Units currently vary significantly in their ability to  
38 recruit according to infrastructure and level of research activity.  
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### 43 **Aim**

44  
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46 To identify potential barriers and facilitators to study delivery in order to inform strategies  
47 to enhance future critical care trial activity and identify how research staff could be  
48 supported. A secondary aim was to identify variability in the research infrastructure of UK  
49 intensive care units (ICUs) and their ability to recruit patients into clinical trials.  
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52

### 53 **Design**

54  
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56 We evaluated factors related to intensive care patient enrolment into clinical trials in the  
57 UK. This consisted of a qualitative synthesis carried out with two datasets of in-depth  
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3 interviews. Primary and secondary analysis of two datasets was undertaken in the thematic  
4 analysis.  
5

### 6 **Participants/Setting**

7  
8 Interviews were conducted with intensive care consultants, research nurses and trial  
9 coordinators (n=27) from across the UK (from each of the clinical research networks).

### 10 **Findings**

11 The synthesis yielded the following six themes: Organisational, Human, Study, Practical  
12 resources, Clinician, and Patient/family factors. The overarching core theme of Normalising  
13 Research was characterised by motivations for promoting research and fostering research-  
14 active cultures within resource constraints. There was a strong sense of integrating  
15 research in routine clinical practice, and recommendations are outlined.

### 16 **Conclusions**

17 The central and transferable tenet of Normalising Research advocates the importance of  
18 developing a culture where research is inclusive alongside clinical practice in routine patient  
19 care and is requisite for all healthcare individuals from organisational to direct patient  
20 contact level.  
21

22 **Keywords:** Qualitative synthesis; critical care trials; access to research; barriers; facilitators;  
23 normalising research  
24  
25

### 26 **Article Summary**

#### 27 **Strengths and limitations of this study:**

- 28 1. There are significant challenges to conducting trials in critical care in the UK due to  
29 time-limited opportunities for recruitment. Patients are almost always unable to  
30 provide informed consent, adding a layer of complexity.
- 31 2. Few in-depth studies have been conducted exploring this in the UK, and do not focus  
32 on less-research active units, so we do not know what the potential issues are for  
33 these units.  
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A qualitative synthesis regarding the factors surrounding UK critical care trial infrastructure

3. This study is the first to present new data on less-research active critical care units, and to present a synthesis of findings that focus on these issues for the UK
4. Drawing together two datasets presents a rich picture of barriers/facilitators to conducting critical care trials in the UK
5. Gaining perspectives across the multi-disciplinary team is important for understanding the complex issues associated with delivering trials, and provide context for the organisational settings.

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**Competing interests:** The authors have none to declare.

**Word count 4044**

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## 2 3 **Introduction**

4  
5  
6 Clinical trials in critical care are integral to improving patient care, presenting unique  
7 practical and ethical challenges including the time-sensitive treatment and enrolling patients  
8 who lack capacity.[1] Data exploring barriers to conducting clinical trials in this setting are  
9 scarce, but include managing changing clinical courses, communication breakdowns, and  
10 requests for more time for consent [2]. Our recent pilot study,[3] demonstrated enhanced  
11 patient recruitment in centres valuing research with equal importance to clinical care, with  
12 the most commonly cited barriers insufficient human and financial resource, inadequate  
13 personnel funding, and limited career opportunities impeding staff retention.[3] Several  
14 additional factors may also preclude recruitment, such as lack of clinician equipoise and  
15 competing clinical commitments.  
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18  
19 The UK National Institute for Health and Research (NIHR) is the government-funded  
20 research arm of the National Health Service (NHS), responsible for driving bench-to-bedside  
21 research with tangible patient benefit [4]. Unique infrastructure, including Clinical Research  
22 Networks (CRN) and specialty groups (SG) overseeing clinical areas such as critical care (CC),  
23 enhance the UK's national and international position to deliver high quality clinical trials.  
24  
25 Research teams invest significantly in recruitment to critical care trials with emphasis on  
26 mitigating modifiable factors. In particular, understanding barriers and facilitators in less  
27 research-active institutions, such as non-university-affiliated hospitals, is crucial to enhance  
28 trial infrastructure across the UK. Our aim was to identify potential barriers and facilitators,  
29 and understand variability, to critical care trial delivery in order to inform strategies to  
30 enhance future trial recruitment, and identify how research staff could be supported.  
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1 A qualitative synthesis regarding the factors surrounding UK critical care trial infrastructure  
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### 3 **Methods**

#### 4 Design

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8 A qualitative synthesis was conducted [5], involving two datasets comprising in-depth  
9 interviews with critical care consultants, research nurses, and trial coordinators (n=27)  
10 across England and Wales. Dataset 1 included 10 participants and is reported in detail  
11 elsewhere [3]. Dataset 2, a follow-on study, included a further 17 participants from  
12 different backgrounds/units specifically to explore issues in less research-active critical care  
13 units. Service evaluation and quality improvement methods underpinned the projects.[6]  
14 Therefore, this synthesis involved both primary and secondary data analysis. Qualitative  
15 synthesis is a well-established method that draws together findings to reach over-arching  
16 themes.[5], ensuring similar research can be reliably compared.[7,8] Patient/public were not  
17 involved in the design of this study since the focus is on research infrastructure.  
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#### 30 Data collection

31  
32 Individual telephone, digitally audio-recorded, interviews were conducted with participants,  
33 using a pre-determined interview schedule agreed by team consensus. Written and verbal  
34 project information was provided and confidentiality was assured. Transcripts were  
35 anonymised prior to analysis. Team review of the interview structure was refined as  
36 interviews progressed in both datasets and also informed refinement of the framework  
37 analysis [10]. This enhanced dependability and qualitative rigour through developing  
38 credibility and transferability.[11] NP was unknown to all but one participant.  
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#### 48 Ethical considerations

49  
50 The study was supported and facilitated by the NIHR Critical Care Specialty Group (NIHR  
51 CCSG). No ethical approval or written consent, as per the UK Health Research Authority,  
52 was required since only anonymised data with staff were used. No local institutional  
53 Research & Development (R&D) approval was deemed necessary, since this was a project to  
54 represent views on behalf of the NIHR CCSG and recruitment did not take place via  
55 institutions. Demographic data about each critical care unit's research activity were also  
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1 A qualitative synthesis regarding the factors surrounding UK critical care trial infrastructure  
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3 collected. Participation was voluntary; verbal consent was obtained both before and after  
4 the interview, to allow interviewees the opportunity to withdraw/withhold any data  
5 discussed.  
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### 11 Patient and public involvement

12 This study was focused on delivery and mechanistic issues behind research, therefore no  
13 patient/public involvement (PPI) was sought and patients/public were not involved in the  
14 design/conduct. However, priorities related to PPI in the NIHR Specialty Group, which  
15 several of the authors represent, informed this research, namely how can we support  
16 participation in research, a high-level NIHR objective.  
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### 24 Settings/sample

25 Two purposive samples were recruited, with the aim of representing different regions and  
26 professional grades (critical care nurses, trainees, trial co-ordinators and consultants) across  
27 the UK. The purposive sampling technique involved maximum variation sampling,[12] using  
28 UK trial accrual and activity data from the NIHR. The aim was to include clinicians  
29 representing critical care units across the 16 CRNs (15 in England, one in Wales).  
30 Specifically, the second dataset focused on units with limited trial recruitment, or engaged  
31 in few trials. Invites were circulated via the NIHR network using established mailing lists, and  
32 targeted recruitment to ensure unbiased representation. Using the principles of Grounded  
33 Theory,[13,14] a sample size of 20-30 interviews was deemed sufficient to build an  
34 emergent theory.  
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### 50 Analysis

51 Themes were explored at an overall and ICU-specific level. Potential barriers/facilitators  
52 within individual critical care units, hospitals, locally and nationally were identified. In both  
53 datasets, analysis was conducted using thematic analysis, a technique congruent with  
54 Grounded Theory [13] aided by principles of framework analysis,[10] where categories were  
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1 A qualitative synthesis regarding the factors surrounding UK critical care trial infrastructure  
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3 refined as analysis progressed. Data from verbatim transcripts were coded at a line level,  
4  
5 with sub-themes derived from those codes applied to a framework, with constant  
6  
7 comparison. Datasets were compared and contrasted, and a new framework was devised,  
8  
9 and all data were re-analysed according to this. An independent researcher verified the  
10  
11 analysis on anonymised data to enhance dependability. The framework provided a further  
12  
13 degree of dependability in regards to analysis,[11] and allowed for contextual differences to  
14  
15 emerge. The matrix provided detail of within case and cross-case analysis,[14] which was  
16  
17 developed into themes.

## 21 Findings

22  
23 In Dataset 1 (collected in 2015), 10 interviews were conducted across nine CRN regions  
24  
25 across England (n=8) and Wales (n=1). Dataset 2 (collected 2016/17) included 17 interviews  
26  
27 conducted across 12 English CRNs. Interviews ranged from 27-79 minutes. The framework  
28  
29 analysis for each studies yielded six main themes. Demographics are supplied in Table 1,  
30  
31 supplementary file 1.

## 36 Overarching findings from synthesis

37  
38 There was an overarching theme of *Normalising Research*, describing the notion that critical  
39  
40 care research should be entrenched in routine practice. Six sub-themes existed around this  
41  
42 central tenet: *Organisational, Human, Study, Practical resources, Clinician, and*  
43  
44 *Patient/family factors*. Resource issues permeated each theme and were evident  
45  
46 throughout the organisational, unit, study, or trial level, and at a human, individual level. In  
47  
48 centres, units, and teams where research activity was regarded with equal importance as  
49  
50 clinical activity, research was considered routine practice. Teams and individuals with a  
51  
52 strong sense of integrating research in routine practice acted as the motivating driving force  
53  
54 fostering a research culture, whether in primary, translational biomedical, or applied health  
55  
56 services streams. A broader cultural influence from organisations was also evident, where  
57  
58 research was seen as critical to organisational values, up to executive level, in turn  
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3 contributing to enhanced research activity. Barriers and enablers to trial activity and  
4  
5 conduct are outlined in each theme below.  
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### 8 **Organisational factors**

9  
10 This theme related to organisational systems in which units were situated. Research-active  
11 and less research-active institutions contrasted with regards prioritisation of research by  
12 senior management, with the latter placing lower profile on supporting and conducting  
13 research. This was particularly marked at challenging times e.g. during care failure reports,  
14 or financial or bed crises, even though these could be opportune periods for potential trial  
15 enrolment.  
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21 “Research and development is not high profile. At an organisational level it is service  
22 driven, research is seen as an aside and there is no support for it.” (Res nurse 2 Study  
23 2)  
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27  
28 Despite income-generating research activity, such as involvement in commercial studies,  
29 increased demand on resources posed limitations to engagement. Some critical care  
30 research leads had to seek executive and/or R&D approval prior to confirming participation,  
31 while others could decide unilaterally. Centre factors also determined how trials were  
32 embedded through initiatives that increased engagement such as simulated trial runs.  
33 Embedding research into routine, or what was perceived as ‘normal’, care required a  
34 conceptual shift.  
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41 “No, research is not a priority. New [intensive care unit] ICU consultants very keen,  
42 as are research [specialist registrars] SpRs. The resistance mainly comes from  
43 nurses. It is about perceived additional work or disagreement with the protocol. .  
44 .it’s not part of routine care” (Research nurse 4 study 1)  
45  
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48  
49 “Research should be part of everyone’s job. If prescribed it should be given,  
50 regardless of it is [part of] research or not.” (Research nurse 3, study 2)  
51  
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53

54 The nature of funding for research nurses, primarily funded via CRNs and dependent on trial  
55 activity levels, created significant challenges to research conduct, given the lack of  
56 continuity. Some units ensured varied funding sources beyond the NIHR, to include  
57 commercial and higher education, and internally managed their own research budgets. This  
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3 successfully allowed flexibility in deciding which trials to undertake, and managing staffing  
4 and out-of-hours support. Planning for future trials was evidently problematic on occasion.  
5  
6 During periods with fewer critical care trials, many research teams broadened activity to  
7  
8 cover Emergency Department (ED) and anaesthetic trials. Whilst this maintained research  
9  
10 activity overall, it also resulted in research teams having to cover many studies. Thus, it was  
11  
12 hard to focus on critical care trials when activity in this area resumed. For university-  
13  
14 affiliated hospitals, additional support for research overall could be obtained through links  
15  
16 with academia.  
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### 21 **Human and Unit resources**

22  
23 Staffing was a factor impacting on research delivery. Varied models existed for staffing  
24  
25 research teams, from rotational and secondments out of critical care, cross-hospital site and  
26  
27 cross-specialty working, to research staffing being managed via the CRN. Most research  
28  
29 staff had a clinical critical care background, which facilitated fluid working arrangements and  
30  
31 carryover of research skills to non-research staff. Many participants commented that while  
32  
33 critical care research staff could cover other specialties, reciprocal cover for critical care was  
34  
35 less successful given the unique patient population and time-limited nature of recruitment.  
36  
37 This was often poorly appreciated by hospital R&D and regional CRN level. Research staff  
38  
39 with a clinical background in critical care found communication easier and could support  
40  
41 clinical staff, thus developing a mutually beneficial working relationships and helping with  
42  
43 the normalisation of research. Grading of research nurse positions and lack of career  
44  
45 development was identified as problematic; line management sometime lay with the  
46  
47 regional CRN offices, rather than local critical care units. Some research-active centres  
48  
49 created attractive positions that afforded career progression and mitigated against job  
50  
51 insecurity, a common feature of research nurse roles that are primarily funded on a yearly  
52  
53 contract basis via the CRNs.

54 “The career ladder is limited for them and so they move to management or work in  
55  
56 R&D roles, and the use of temporary contracts is demoralising and a disincentive.”

57 (Consultant intensivist 1, study 1)  
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3 Few consultants received programmed activity (PA) sessions specifically for research,  
4 especially within non-university affiliated hospitals. Many clinicians relied upon financial  
5 support and time from their organisations to undertake research activity.  
6  
7

8  
9 “They do it effectively out of interest, there is nothing in their job plan apart from a  
10 reference to research, but no time to actually do it. . .it is voluntary and many don’t  
11 do it” (Research nurse 4, study 2)  
12  
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15 This lack of support overlaps with the organisational theme; allocated time and finances to  
16 support research activity was rare, occurring only in centres where research was viewed as  
17 core activity. Few medical trainees had opportunities for research involvement, and again  
18 primarily only in research-active centres with novel initiatives designed to engage those  
19 interested in research e.g. year-long fellowships with research contributing to their training  
20 programme. However, short clinical placements precluded meaningful trainee participation  
21 in primary research. Designated trial coordinators were rare in smaller non-university-  
22 affiliated hospitals with less opportunity to enrol patients. Unit, staffing and centre factors  
23 were closely associated in the two datasets. Unit factors pertained to strategies to enhance  
24 engagement, provision, recruitment and delivery of critical care research. These varied  
25 from simulated runs of screening, recruitment and intervention, to teaching programmes  
26 and incentive schemes. Having a physical presence on the unit was seen as a crucial  
27 element for ensuring clinical credibility. Driven individuals were critical to success in  
28 recruitment and study conduct, with both research nurses and consultants assuming  
29 principal investigator roles.  
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### 46 **Study/trial factors**

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48 Trial complexity appeared a considerable factor contributing to trial success, in terms of  
49 acceptance by local staff and potential ability to achieve recruitment targets. Feasibility and  
50 capacity assessment moderated concerns about delivering to time and target, a national  
51 metric captured by NIHR. Studies requiring significant pharmacy support (e.g. Clinical Trials  
52 of Investigational Medicinal Products [CTIMP]) had variable success with implementation  
53 and recruitment. Some units reported pressure from the regional CRN and local R&D  
54 departments to undertake high-recruiting studies, generating maximum income. In contrast,  
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3 complex studies perceived as interesting but with low recruitment targets would yield less  
4 or even insufficient income to cover costs. Demonstrating quick, tangible 'wins' for  
5 organisations and staff, through health service research, helped engagement. Complex  
6 studies were considered problematic for balancing effort against outcomes achieved, in  
7 particular the staff training requirements to implement detailed interventions, and strict  
8 eligibility criteria with narrow recruitment windows leading to few, if any, patients enrolled.  
9 Studies requiring significant preparation, including co-enrolment agreements, time-  
10 scheduling, competing population assessment, and importantly, ensuring unit staff were  
11 committed and had clinical equipoise, could be particularly challenging:  
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20 "they say they have equipoise, but when it comes down to it, they don't, you get  
21 surreptitious opposition and stark persuasion is used in those situations."  
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23

24 (Consultant intensivist 1, study 1)  
25

26 Time associated with daily screening was also a factor influencing success of complex trials;  
27 often this could not be performed remotely and required extensive clinical data review. In  
28 keeping with study set-up, funding was rarely allocated for this activity, or for follow-up. In  
29 units where research was considered part of routine practice, clinical staff also helped with  
30 identification of potential participants.  
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35  
36 "There needs to be appropriate costing of studies including NHS support costs, for  
37 drugs for example. . . long-term follow-up needs to be considered as well."  
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39

40 (Consultant intensivist 6, study 2)  
41  
42

43 Strategies to facilitate complex trials included engagement with local clinical staff to  
44 integrate the trial procedures with standard care, thereby enabling all staff to contribute to  
45 patient screening and enrolment, including out-of-hours. Units could achieve this through  
46 training and cross-team working.  
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## 52 **Clinician factors**

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54  
55 This theme focused on how unit clinicians, nurses, trainees and intensivists, were perceived  
56 as engaged in research; this did not appear linked to how research-active an organisation  
57 was. Where research staff originated from the unit this was a facilitator, often resulting in  
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3 good team working from both clinical and research team perspectives. Where research was  
4 viewed as additional activity, rather than integral to patient care, research staff reported  
5 cases of open hostility, particularly early on in their roles, until unit staff developed an  
6 appreciation for research.  
7  
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9

10  
11 “I’ve tried working on the unit and taking patients and doing shifts to build  
12 relationships” (Research nurse 7, study 2)  
13  
14

15 Research resources were factored by unit staff where there was good inter-boundary  
16 working. For instance, research staff attended senior nurse meetings to identify local issues  
17 that might adversely affect recruitment. Equally, unit staff could help identify barriers to  
18 recruitment to certain studies. Creating link roles supported nurse-level engagement and  
19 enhanced out-of-hours opportunities for recruitment when research nurses were not  
20 present. Very limited funding for out-of-hours cover enforced the need for research nurse  
21 flexibility.  
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29 Equipose featured again in this theme; clinicians could undermine research activity by  
30 appearing supportive in meetings, but not in practice. Permission to recruit patients had to  
31 be negotiated at an individual clinician level, which could compromise unit objectivity  
32 toward the study.  
33  
34  
35

36  
37 “The consultants are all GCP [Good Clinical Practice] trained but there is mixed  
38 interest and support, ranging from active obstruction. . . , to more neutral through to  
39 full support.” (Consultant intensivist 9, study 2).  
40  
41  
42

43 “People believe they have equipose but on the day people change what they do.”  
44 (Research nurse 5, study 2).  
45  
46

47 Investment for trainee engagement arose as an important issue, particularly in those less  
48 research-active organisations. Ensuring the next generation of critical care consultants  
49 prioritised research activity with clinical practice was recognised as imperative. Many  
50 trainees were taught to obtain patient consent. At the time of the study, regional trainee  
51 research networks were emerging across the UK. However, according to these participants,  
52 in larger portfolio NIHR trials trainee engagement was noted to be minimal, and unit  
53 pressures contributed to lack of engagement. Trainee fellowship roles successfully  
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3 addressed this in two units, with staff continuing research in their careers as consultants,  
4  
5 with an emphasis on personal motivation.  
6

7 "we actively encourage fellows not to go onto the [unit] rota so that their role is  
8  
9 protected for research." (Consultant intensivist 11, study 2)  
10

11  
12 Personal commitment was a key factor; research activity often required working beyond  
13  
14 allocated hours or sessions, or flexible working out-of-hours. This demonstrated how  
15  
16 research teams worked to emphasise how research should be considered the norm, with  
17  
18 efforts devoted to successful implementation comparable to efforts in clinical practice.  
19  
20 Skills of research nurses was a factor common to both datasets, with ability (and R&D  
21  
22 permission) to consent improving recruitment. Extended skills also meant that some  
23  
24 research nursing staff were supported to undertake further study, including at doctoral  
25  
26 level, fostering motivation, willingness to work flexibly and promoting emergence of  
27  
28 independent researchers. Portfolio studies requiring a nurse Principal Investigator  
29  
30 particularly motivated nurses. For consultants, feelings were mixed: studies with no  
31  
32 personal interest fostered less engagement, unless it was likely to be income-generating.  
33  
34

### 35 **Patient/family factors**

36  
37 Difficulties communicating information about trial procedures to patients and their families  
38  
39 was reported by participants. A positive but realistic attitude was deemed essential. The  
40  
41 volume of paperwork was identified as problematic. Ensuring that patients or families fully  
42  
43 understood complex research interventions, without overburdening them at a sensitive  
44  
45 time, was seen as central.  
46

47 "We've got savvier about taking consent and have learnt lessons; you don't gain it by  
48  
49 giving more paper." (Consultant intensivist 1, study 1)  
50

51  
52 Managing clinical uncertainty in the context of clinical trials was difficult. Whilst it did not  
53  
54 seem to hinder recruitment, managing the process was challenging for research staff. Many  
55  
56 families agreed to assent for patients for altruistic reasons, understanding there may be no  
57  
58 benefit to the patient. An important issue emerged in relation to addressing cultural  
59  
60 perspectives. Different attitudes were perceived towards research, centring on trust in

1 A qualitative synthesis regarding the factors surrounding UK critical care trial infrastructure  
2  
3 healthcare. Immediate dismissal by family members, on behalf of patients, was not  
4  
5 uncommon. Conversely, some reported a paternalistic medical attitude still prevailing.  
6  
7 Despite efforts to address this, provide more information and demonstrate equipoise,  
8  
9 families and patients were reluctant and preferred to defer to doctors' opinions regarding  
10  
11 enrolment.

12  
13 "I work in a deprived area with a lower level of education compared to the UK  
14  
15 average, because of that the cultural norms mean they tend to trust what the  
16  
17 doctors say: 'whatever you think doctor'" (Research nurse 11, study 2).  
18

19 Neither of these opposing views about consent were regarded by participants as hindering  
20  
21 recruitment. Units serving a disproportionately elderly or rural population reported  
22  
23 difficulties gaining access to relatives for assent, particularly where time-sensitive consent  
24  
25 was required. Research teams estimated a third of families were likely to decline  
26  
27 participation when calculating recruitment targets and reasons for non-participation  
28  
29 appeared to be complex and poorly understood. Where approaches to families were  
30  
31 prefaced by an explanation that research was part of normal clinical practice in that  
32  
33 particular unit, there was increased receptivity to recruitment. Reported preference for  
34  
35 treatment arms was rare, and usually managed through explanation. Facilitating  
36  
37 understanding was viewed as crucial when approaching families and patients for consent,  
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39 with issues related to ongoing assessment of mental capacity also highlighted as difficult.

40 A summary of all of these factors is outlined in Table 2 and represented in Figure 1.  
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54 Table 2. Summary and recommendations  
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58 Recommendations for normalising research in critical care 59 60
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## A qualitative synthesis regarding the factors surrounding UK critical care trial infrastructure

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4	<ul style="list-style-type: none"> <li>• 1. Training:</li> </ul>
5	<ul style="list-style-type: none"> <li>○ Offer Good Clinical Practice (GCP)/research training for all staff on induction; Research staff running GCP sessions for critical care staff</li> </ul>
6	<ul style="list-style-type: none"> <li>○ Offer research training by research staff for critical care nurses/AHPs to recruit/learn about research processes</li> </ul>
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11	<ul style="list-style-type: none"> <li>• 2. Staffing</li> </ul>
12	<ul style="list-style-type: none"> <li>○ Offer trainee fellowships to support medical trainees wanting a career in research</li> </ul>
13	<ul style="list-style-type: none"> <li>○ Create rotational nursing posts in critical care, overseen by senior research nurses</li> </ul>
14	<ul style="list-style-type: none"> <li>○ Facilitate reciprocal working between ICU staff and research teams; research staff working in ICU to enhance links and recruitment opportunities</li> </ul>
15	<ul style="list-style-type: none"> <li>○ Create more career structures for doctors, AHPs and nurses working in critical care research</li> </ul>
16	<ul style="list-style-type: none"> <li>○ Incentivise clinical staff with training opportunities</li> </ul>
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24	<ul style="list-style-type: none"> <li>• 3. Communication and interdisciplinary working</li> </ul>
25	<ul style="list-style-type: none"> <li>○ Attend senior nurse meetings in critical care</li> </ul>
26	<ul style="list-style-type: none"> <li>○ Create link nurse positions (to be extended to link trainee positions)</li> </ul>
27	<ul style="list-style-type: none"> <li>○ Engage with and attend unit staff meetings to identify study barriers</li> </ul>
28	<ul style="list-style-type: none"> <li>○ Create tools/training/peer review to aid conveying complex information to families and patients</li> </ul>
29	<ul style="list-style-type: none"> <li>○ Work on engagement and links with ED and other research departments in the same NIHR divisions to support teams</li> </ul>
30	<ul style="list-style-type: none"> <li>○ Ensure early scoping of capacity/equipose concerns by research team</li> </ul>
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35	<ul style="list-style-type: none"> <li>• 4. Funding/Trial Design</li> </ul>
36	<ul style="list-style-type: none"> <li>○ Negotiation of leveraged funding to ensuring staffing and trial continuity; maintain a broad study portfolio</li> </ul>
37	<ul style="list-style-type: none"> <li>○ Consider trial amendments in studies that are difficult to recruit to</li> </ul>
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## Discussion

This synthesis outlines six inter-related themes under a new over-arching theme of *Normalising Research*. Research activity was regarded as equally important as clinical work by these participants, albeit this was acknowledged as not a representative view across all organisations or units. Where research was embedded into routine care and considered as

1 A qualitative synthesis regarding the factors surrounding UK critical care trial infrastructure

2  
3 the norm, undertaking screening and recruitment were easier. Emphasising the need for  
4 normalcy of research, at unit and organisational level, means cohesive units evolve with the  
5 unified aim of leading improvements in patient care. However, there are prerequisites for  
6 normalcy, including communication towards a shared understanding [15] in this case, that  
7 research is an integral part of everyday patient care. Furthermore, this communication  
8 needs to take place at a systems level.[15] Specific issues in the synthesis related to  
9 variation in funded time and resources, clinician engagement, individual roles, and  
10 perceived gains from research, which proved noteworthy, acting as barriers or facilitators to  
11 clinical trial recruitment. Bruce et al,[1] outlined how navigating rapidly changing clinical  
12 courses and communication breakdown adversely affected recruitment.[1] That these  
13 factors did not emerge in this synthesis may reflect different healthcare systems, funding,  
14 and larger number of hospitals. Similarities emerged related to challenges of recruitment  
15 within narrow timeframes. Good communication between clinical and research teams was  
16 important for successful trial implementation.  
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32 Inclusion of data from less research-active organisations strengthens this study providing  
33 richer data, more transferable across the NHS and to healthcare systems in other  
34 jurisdictions. Our findings will resonate with other international settings where, despite  
35 variability in national infrastructure, similar challenges are faced by researchers. The tenet  
36 of normalising research transcends unit, institutional and country boundaries. Approaches  
37 to improve recruitment included simple incentive schemes to reward clinical staff,  
38 broadening the range of clinicians who could take consent. The latter is particularly  
39 pertinent to CTIMPs where time-limited recruitment was more relevant.[1,2] Previous work  
40 has suggested lack of equipoise as a barrier to enrolment;[16,17]. An area for further  
41 exploration relates to consent waivers, already explored in some recent research [1,16,19],  
42 albeit with less known of patient and family perspectives. 'Overburdening' has been  
43 described previously [20] as has concern regarding making initial approaches to families  
44 during particularly sensitive times [19-23] but again the patient/family voice in these studies  
45 is absent.[18- 20] This would be an important area for future practice and research.  
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58 In keeping with existing literature, competition between trials requiring similar patient  
59 cohorts and the number of eligible patients were further barriers to trial recruitment [1,23].  
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1 A qualitative synthesis regarding the factors surrounding UK critical care trial infrastructure

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3 Another factor related to lack of clear professional development opportunities and  
4 structured career paths. Recent strategy published by the NIHR offers novel career options  
5 for research staff [25,26] such as consultant research nurse models [24]. Emerging trainee  
6 networks across the UK have also helped create a case for formalised processes.[27, 28]  
7 NIHR initiatives to engender a culture of research in healthcare, with every patient being  
8 offered the opportunity to participate in research aimed at improving care [29] are also  
9 reflected in these individual participants' motivations to improve care through research.  
10 Systematic review and large-scale survey evidence highlight key areas to improve trial  
11 recruitment as training site staff, communication with patients, and incentives, albeit some  
12 suggestions are not applicable to an ICU setting, such as telephone calls to non-respondents  
13 and opt-out procedures.[30,31] There have been significant advances over the past five  
14 years in critical care research recruitment.[32] In a current climate of significant fiscal  
15 pressures in the UK healthcare system with £22 billion of NHS efficiency savings to be  
16 achieved by 2020,[33] there was still a universal desire to undertake critical care research.  
17 This was driven by key motivated individuals who viewed research as integral to best  
18 practice and normal care provision, as well as deriving evidence to drive and support best  
19 use of resources.  
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35 This qualitative synthesis draws together two sets of original research findings. A limitation  
36 is that data were not collected simultaneously, however, both studies complemented each  
37 other. The second study built on the first by focusing specifically on a target participant  
38 cohort not initially represented in order to generate novel data to further understand the  
39 question at hand. Furthermore, the timeframe between acquisition of each dataset was  
40 short (twelve months) with minimal, if any, change in practice likely occurring. Potential  
41 sampling bias from recruiting primarily research-active units in the first dataset, was  
42 mitigated by employing purposive recruitment in the second dataset from less research-  
43 active units, to build theory. Research-active and less research-active units were defined  
44 both on subjective reports from individuals, and standardised objective metrics. Qualitative  
45 research is often criticised for lack of generalisability, due to sample size limitations, but  
46 notions of transferability can be considered [8,11] and what Payne and Williams term  
47 'moderatum generalisations'. [34] Figure 1. outlines a summary of the main points and four  
48 key areas for learning. The core concept of Normalising Research can feasibly be applied  
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1 A qualitative synthesis regarding the factors surrounding UK critical care trial infrastructure  
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3 beyond critical care trials recruitment, across the full spectrum of clinical specialties  
4 represented within the NIHR, as well as internationally.  
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## 7 **Conclusion**

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10 This qualitative synthesis integrating two original datasets has yielded recommendations for  
11 improving trials recruitment in the unique clinical specialty of critical care. Several  
12 suggestions are made from the six themes that emerged: Organisational, Human, Study,  
13 Practical resources, Clinician, and Patient/family factors, under the overarching theme of  
14 Normalising Research, that relate to enhanced staffing, training, trial design and  
15 communication. Fostering a culture where research is considered part of routine patient  
16 care must be the ultimate goal, from organisational strategy to bedside care.  
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32  
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35

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37 collection and analysis of the two datasets, and the overall synthesis. GOG independently  
38 verified the first dataset and contributed to data analysis of the second dataset. NA  
39 contributed to the design, data collection and manuscript write-up. PD, PH and TW  
40 contributed to the design. SH and BC contributed to data collection, analysis and  
41 manuscript preparation. All authors have reviewed and contributed to the manuscript. NP  
42 is the custodian of the intellectual integrity and property arising from this project.  
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50 Patient consent: Not required.

51 Provenance and peer review Not commissioned; externally peer reviewed.

52 Data sharing statement: All data pertaining to this study are reported in this manuscript.  
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## 60 **References**

1 A qualitative synthesis regarding the factors surrounding UK critical care trial infrastructure

2  
3 1. Bruce CR, Liang C, Blumenthal-Barby JS, Zimmerman J, Downey A, Pham L, Thieret L,  
4  
5 Delgado E, White D. Barriers and Facilitators to Initiating and Completing Time-Limited Trials  
6  
7 in Critical Care. *Critical Care Medicine*. 2015. 43(12):2535-2543.  
8  
9

10 2. Kaur G, Smyth RL, Williamson P. Developing a survey of barriers and facilitators to  
11  
12 recruitment in randomized controlled trials. *Trials*. 2012;13:218.  
13  
14

15 3. Pattison N, Arulkumaran N, Humphreys S, Walsh T. (2017) Exploring obstacles to critical  
16  
17 care trials in the UK: A qualitative investigation. *Journal of the Intensive Care Society*. 18(1):  
18  
19 36-46  
20  
21

22 4. National Institute of Health Research (NIHR) (2016) NIHR: Our Purpose  
23  
24 Available at: <http://www.nihr.ac.uk/about-us> (accessed 21.1.17)  
25  
26  
27

28 5. Barnett-Page E, Thomas J. Methods for the synthesis of qualitative research: a critical  
29  
30 review. ESRC National Centre for Research Methods. 2009 NCRM Working Paper Series  
31  
32 Number (01/09)  
33  
34

35 6. Health Research Authority. Defining Research. Available at:  
36  
37 <http://www.hra.nhs.uk/documents/2016/06/defining-research.pdf> (accessed 24.5.17)  
38  
39

40 7. Heyvaert, M., Maes, B. & Onghena, P. Mixed methods research synthesis: definition,  
41  
42 framework, and potential *Qual Quant* 2013 47: 659. doi:10.1007/s11135-011-9538-6  
43  
44

45 8. Finfgeld-Connett D. Generalizability and transferability of meta-synthesis research  
46  
47 findings. *Journal of Advanced Nursing* 2010. 66 (2), 246-254  
48  
49

50 9. Eaves YD A synthesis technique for grounded theory data analysis. *Journal of Advanced*  
51  
52 *Nursing* 2001 35:654-63  
53  
54

55 10. Ritchie J, Spencer L. Qualitative data analysis for applied policy research. In: Bryman A,  
56  
57 Burgess R, editors. *Analysing qualitative data*. London: Routledge; 1994. pp. 173–194.  
58  
59  
60

1 A qualitative synthesis regarding the factors surrounding UK critical care trial infrastructure  
2

3 11. Lincoln YS, Guba EG. *Naturalistic Inquiry*. Newbury Park, CA: Sage Publications. 198 12.  
4

5 Suri H. Purposeful sampling in qualitative research synthesis. *Qual Res J*. 2011;11:63–75.  
6

7 13. Glaser BG, Strauss AL. *The Discovery of Grounded Theory. Strategies for Qualitative*  
8

9 *Research*. 1967. Chicago: Aldine Publishing  
10

11 14. Miles MB, Huberman AM. *An Expanded Sourcebook: Qualitative data Analysis*. 2nd  
12

13 Edn.1994. Sage Publications, Thousand Oaks, California, US.  
14

15 15. Habermas J. *The theory of communicative action: Vol 2. Lifeworld and system. A critique*  
16 *of functionalist reason*. 1987 Beacon Press Boston MA  
17

18 16. Morgenweck CJ. Innovation to research: some transitional obstacles in critical care units.  
19

20 *Crit Care Med*. 2003 Mar;31(3 Suppl):S172-7  
21

22 17. Donovan JL, de Salis I, Toerien M, Paramasivan S, Hamdy FC, Blazeby JM. The intellectual  
23 *challenges and emotional consequences of equipoise contributed to the fragility of*  
24

25 *recruitment in six randomized controlled trials*. *J Clin Epidemiol*. 2014 Aug;67(8):912-20  
26

27 18. Bigatello LM, George E, Hurford WE. Ethical considerations for research in critically ill  
28 *patients*. *Crit Care Med*. 2003 Mar;31(3 Suppl):S178-81.  
29

30 19. Lim DA, Chan MF, Childs C. Surrogate consent for critical care research: exploratory  
31 *study on public perception and influences on recruitment*. *Crit Care*. 2013 Jan 15;17(1):R5.  
32

33 20. Mehta S, Quittnat Pelletier F, Brown M, Ethier C, Wells D, Burry L, MacDonald R. Why  
34 *substitute decision makers provide or decline consent for ICU research studies: a*  
35 *questionnaire study*. *Intensive Care Med*. 2012 Jan;38(1):47-54.  
36

37 21. Dear RF, Barratt AL, Tattersall MH. Barriers to recruitment in cancer trials: no longer  
38 *medical oncologists' attitudes*. *Med J Aust*. 2012 Feb 6;196:112-3.  
39

40 22. Majesko A, Hong SY, Weissfeld L, White DB. Identifying family members who may  
41 *struggle in the role of surrogate decision maker*. *Crit Care Med* 2012. Aug;40(8):2281-6.  
42  
43  
44  
45  
46  
47  
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52  
53  
54  
55  
56  
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1 A qualitative synthesis regarding the factors surrounding UK critical care trial infrastructure

2  
3 23. Dickson S, Logan J, Hagen S, Stark D, Glazener C, McDonald AM, McPherson G. Reflecting  
4  
5 on the methodological challenges of recruiting to a United Kingdom-wide, multi-centre,  
6  
7 randomised controlled trial in gynaecology outpatient settings. *Trials*. 2013 Nov 15;14:389.  
8  
9

10 24. Currey J, Considine J, Khaw D. Clinical nurse research consultant: a clinical and academic  
11  
12 role to advance practice and the discipline of nursing. *J Adv Nurs*. 2011 Oct;67(10):2275-83.  
13  
14

15 25. National Institute for Health Research. NIHR Clinical Research Network: Developing our  
16  
17 Clinical Research Nursing Strategy 2017-2020. 2017. Available at:  
18  
19 [https://www.nihr.ac.uk/our-faculty/clinical-research-staff/clinical-research-](https://www.nihr.ac.uk/our-faculty/clinical-research-staff/clinical-research-nurses/Clinical%20Research%20Nurse%20Strategy%202017_2020FINAL.pdf)  
20  
21 [nurses/Clinical%20Research%20Nurse%20Strategy%202017\\_2020FINAL.pdf](https://www.nihr.ac.uk/our-faculty/clinical-research-staff/clinical-research-nurses/Clinical%20Research%20Nurse%20Strategy%202017_2020FINAL.pdf). Accessed  
22  
23 1.9.18.

24  
25 26. National Institute for Health Research. NIHR Clinical Research Network: NIHR CRN Allied  
26  
27 Health Professionals Strategy 2018-2020. 2018. [https://www.nihr.ac.uk/our-faculty/clinical-](https://www.nihr.ac.uk/our-faculty/clinical-research-staff/Allied%20Health%20Professionals/Allied%20Health%20Professionals%20Strategy%202018_20.pdf)  
28  
29 [research-](https://www.nihr.ac.uk/our-faculty/clinical-research-staff/Allied%20Health%20Professionals/Allied%20Health%20Professionals%20Strategy%202018_20.pdf)  
30  
31 [staff/Allied%20Health%20Professionals/Allied%20Health%20Professionals%20Strategy%20](https://www.nihr.ac.uk/our-faculty/clinical-research-staff/Allied%20Health%20Professionals/Allied%20Health%20Professionals%20Strategy%202018_20.pdf)  
32  
33 [018\\_20.pdf](https://www.nihr.ac.uk/our-faculty/clinical-research-staff/Allied%20Health%20Professionals/Allied%20Health%20Professionals%20Strategy%202018_20.pdf). Accessed 1.9.18.

34  
35 27. Shaw M, Harris B, Bonner S. The research needs of an ICM trainee: The RAFT national  
36  
37 survey results and initiatives to improve trainee research opportunities. *Journal of the*  
38  
39 *Intensive Care Society*. 2017;18(2):98-105.  
40

41 28. Moore JN, McDiarmid AJ, Johnston PW, Cleland JA. Identifying and exploring factors  
42  
43 influencing career choice, recruitment and retention of anaesthesia trainees in the UK.  
44  
45 *Postgrad Med J*. 2016 Jun 15. pii: postgradmedj-2015-133518. doi: 10.1136/postgradmedj-  
46  
47 2015-133518. [Epub ahead of print]  
48  
49

50  
51 29. Brown H, Hewison A, Gale N, Snelling I, Shneerson C. Every patient a research patient.  
52  
53 Evaluating the state of research in the NHS. A report commissioned by CRUK, 2015.  
54  
55 University of Birmingham.  
56  
57

58  
59 30. Bower P, Brueton V, Gamble C, Treweek S, Tudur Smith C, Young B Williamson P  
60

1 A qualitative synthesis regarding the factors surrounding UK critical care trial infrastructure

2  
3 Interventions to improve recruitment and retention in clinical trials: a survey and workshop  
4  
5 to assess current practice and future priorities *Trials*. 2014 15:399

6  
7  
8 31. Treweek S, Mitchell E, Pitkethly M, Cook J, Kjeldstrøm M, Johansen M, Taskila TK,

9  
10 Sullivan F, Wilson S, Jackson C, Jones R, Lockhart P: Strategies to improve recruitment to  
11  
12 randomized controlled trials. *Cochrane Database Syst Rev*. 2010, : -MR000013

13  
14  
15 32. Walsh T, Brett S. What are the priorities for future success in critical care research in the  
16  
17 UK? Report from a national stakeholder meeting. *Journal of the Intensive Care*

18  
19 Society. November 2015 vol. 16 no. 4 287-293

20  
21  
22 33. Dunn P, McKenna H, Murray R. Deficits in the NHS 2016. The Kings Fund. Available at:  
23  
24 <https://www.kingsfund.org.uk/publications/deficits-nhs-2016> (accessed Sep 1st 2018)

25  
26  
27 34. Payne G, Williams M. Generalization in Qualitative Research *Sociology* 2005. 39: 295-

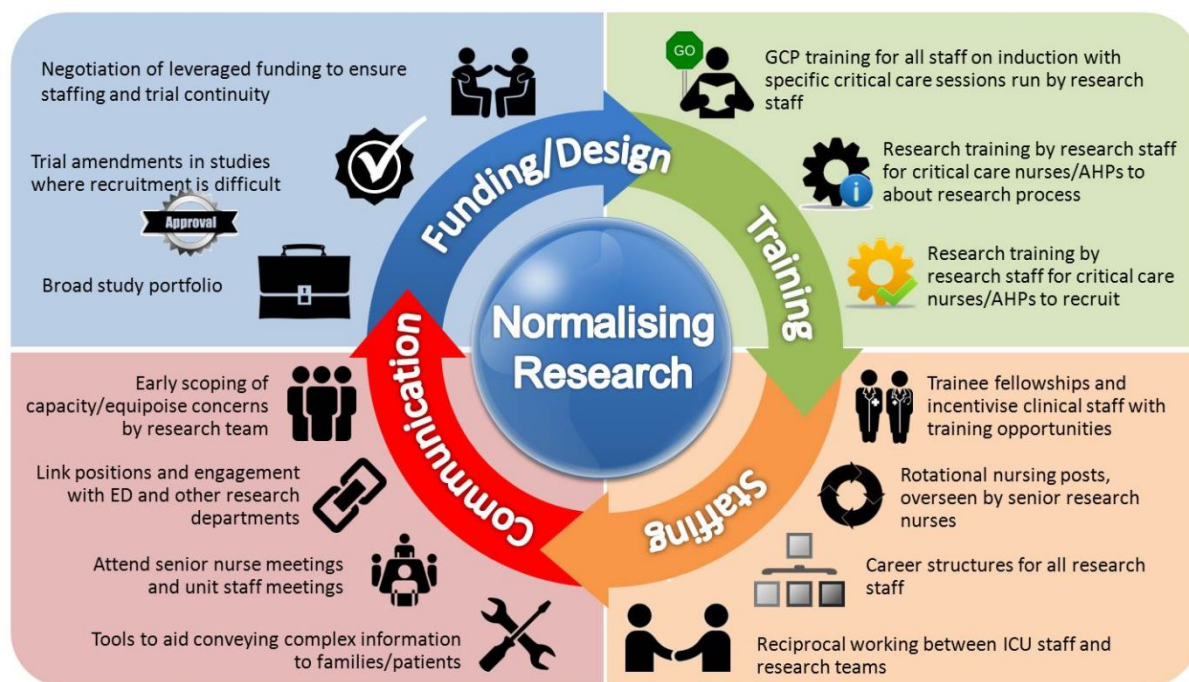
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33 Data access: All data pertaining to this project are reported here. Please contact the authors  
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35 regarding accessing aggregated data analysis. Raw data is not available to be shared since  
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37 this could lead to identification.  
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A qualitative synthesis regarding the factors surrounding UK critical care trial infrastructure

Figure 1. Normalising Research



A qualitative synthesis regarding the factors surrounding UK critical care trial infrastructure

Supplemental file

Table 1. Demographics and setting

Profession/Area	1. Level 3/2 beds	2. Annual admissions	3. General /Specialist unit	4. Research staff numbers	5. Research staff working*	6. Research team working patterns	7. Consultant numbers and working patterns	8. Details of consultant time for research	9. Number (total) of ongoing clinical trials (both NIHR and non- NIHR/in set-up)	10. Underway/active
Nurse CRN Eastern	14	1000	General	1 (work with Emergency Department [ED])	1 WTE	5 days/week 8-4pm (flexible)	7	1 PA†	6	5
Nurse CRN Yorkshire and Humber	24	1600	General	2	2 WTE	5 days (flexible – 9 hour cover)	13	0.5 PA (shared)	5	5
Nurse CRN West Midlands	25	1600	General	1 (was 4)	1 WTE	5 days/week; 8-4pm	<i>Data not provided/unknown</i>	1 PA	6	4
Consultant CRN Wessex	12	900	General	2 (across all Div 6, not just ICU)	1 WTE	5 days/week; 8-4pm	<i>Data not provided/unknown</i>	2 PAs	6	4
Trial co-ordinator CRN London South	63	3100	General/trauma	6 across ED/ICU	<i>Data not provided/unknown</i>	5 days/week (and on-call)	>50	0 PA	5	3
Consultant CRN North West London	44	2600	General/ Trauma/ Neuro	2 fellows + 5 RNs	2 fellows at 2 WTE; 5 RNs at 4.5 WTE. 1 WTE research assistant	7 days/week	21	1 PA	<i>Data not provided/unknown</i>	4
Nurse CRN Greater Manchester	40	2000	General	4 (across ED)	4 WTE	8-8pm 5 days/week + on	22	1 PA	8 + 2 in set-up + 1 ED	8

A qualitative synthesis regarding the factors surrounding UK critical care trial infrastructure

						call				
Nurse CRN TV and South Midlands	9	500	General	0.5	0.5 WTE	p/time (early/late shift pattern; weekdays)	10	0.5 PA	2	1
Consultant CRN Wessex	11	750	General	4 + 0.5 trainee	2.5 WTE + 0.5 WTE trainee	7 days/week (plus trainee shifts)	6	0 PA	4	2
Consultant CRN West Midlands	102	4000	Cardiac/ Trauma/ Burns/ Neuro/ General	7 (across ED/Trauma and ICU)	6 WTE (inc Trial Coordinator and administrators)	7 days/week	34	1 PA	7 + 2 in set-up	7
Consultant CRN North West Coast	33	1550	General	3	3 WTE + 0.5 trainee	5 days/week (flexible)	17	1 PA	3 + 1 in set-up	3
Consultant A. CRN West of England	15	5-600	General	0	0	N/A	18	0.5 PA	1 + 2 in set-up	1
Consultant B. CRN West of England	15	5-600	General	0**	0	n/a	18	0.5 PA	1 + 2 in set-up	1
Nurse CRN South West Peninsula	28	1700	General/trauma/ Neuro/ Cardiac	1 (across dermatology/neuro)	1 WTE	8-4pm; 5 days/week	14	Data not provided/unknown	0 (1 in set-up)	0
Nurse CRN West of England	20	1300	General	9	5 WTE + 4 rotational posts	7-7pm; 7 days a week	Data not provided/unknown	2 PAs (shared)	10	10
Nurse CRN East Midlands	69	4000	General/trauma/neuro	6 (covering ED) – split site	4.2 WTE	7-7pm; 7 days/week	Data not provided/unknown	0 PA	13	13
Nurse CRN Norfolk	19	850	General	2 (covering div 6)	1.45 WTE	8-4pm 5 days/week (+ on call)	Data not provided/unknown	0 PA	4 + 1 in set-up	4

## A qualitative synthesis regarding the factors surrounding UK critical care trial infrastructure

Nurse, Wales	33	1500	General/ neuro	5	4 WTE	8-4pm 5 days a week	14	1 PA	6	5
Nurse CRN North West Coast	35	1880	General	2	1 WTE band 7 shared 4 x band 6 (0.8)	7.30-3.30pm 5 days a week	13	0 PA	9	8
Nurse CRN South West Peninsula	26	1580	General/ Neuro	1	<i>Data not provided/unknown</i>	8-4pm 5 days a week	14	0 PA	7	5
Nurse CRN North East North Cumbria	18	1000	General	2	1 band 3 res asst; 1 band 6	9-5pm 5 days a week	9	0 PA	8	6
Nurse CRN East Midlands	19	1200	General	3	2.8 WTE	8-7pm	<i>Data not provided/unknown</i>	2 Pas	11	9
Nurse CRN Eastern	20	1890	General	4	<i>Data not provided/unknown</i>	8-8pm	<i>Data not provided/unknown</i>	1 PA	7	7
Nurse CRN Greater Manchester	19	1700	General	0.8	0.8 WTE	8-4pm	12	0 PA	4	4
Consultant CRN Wessex	24	1200	General	3	1.6 WTE + 2 WTE for 3 month rotations	7 days a week 8am-12pm	14	2 PAs	5	5
Consultant CRN London South	63	3500	General/ Neuro	9	2 band 7; 7 band 6*	8-8pm	<i>Data not provided/unknown</i>	1 PA	10	9
Nurse CRN West of England	21	2000	General	5	4 WTE (1 band 7; rest band 6)	7-7pm	12	<i>Data not provided/unknown</i>	8	8

†PAs=Professional Activities \*Working across all Division 6 studies, not limited to critical care; \*\*Able to access other Division 6 nurses when studies are active

A qualitative synthesis regarding the factors surrounding UK critical care trial infrastructure

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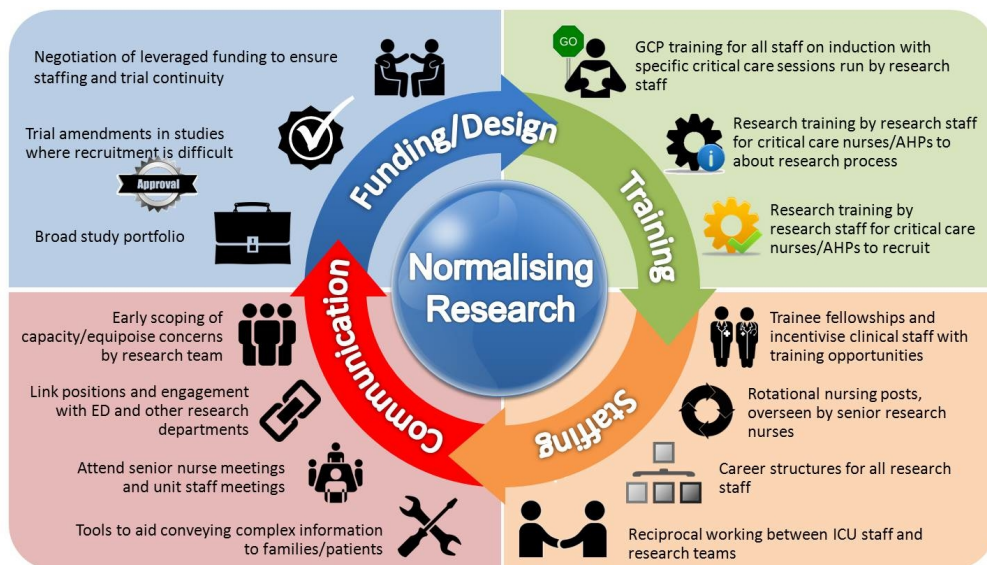


Figure 1. Normalising Research

242x137mm (150 x 150 DPI)

Supplemental file

Table 1. Demographics and setting

Profession/Area	1. Level 3/2 beds	2. Annual admissions	3. General /Specialist unit	4. Research staff numbers	5. Research staff working*	6. Research team working patterns	7. Consultant numbers and working patterns	8. Details of consultant time for research	9. Number (total) of ongoing clinical trials (both NIHR and non-NIHR/in set-up)	10. Underway /active
Nurse CRN Eastern	14	1000	General	1 (work with Emergency Department [ED])	1 WTE	5 days/week 8-4pm (flexible)	7	1 PA†	6	5
Nurse CRN Yorkshire and Humber	24	1600	General	2	2 WTE	5 days (flexible – 9 hour cover)	13	0.5 PA (shared)	5	5
Nurse CRN West Midlands	25	1600	General	1 (was 4)	1 WTE	5 days/week; 8-4pm	<i>Data not provided/unknown</i>	1 PA	6	4
Consultant CRN Wessex	12	900	General	2 (across all Div 6, not just ICU)	1 WTE	5 days/week; 8-4pm	<i>Data not provided/unknown</i>	2 PAs	6	4
Trial co-ordinator CRN London South	63	3100	General/Trauma	6 across ED/ICU	<i>Data not provided/unknown</i>	5 days/week (and on-call)	>50	0 PA	5	3
Consultant CRN North West London	44	2600	General/Trauma/Neuro	2 fellows + 5 RNs	2 fellows at 2 WTE; 5 RNs at 4.5 WTE. 1 WTE research assistant	7 days/week	21	1 PA	<i>Data not provided/unknown</i>	4
Nurse CRN Greater Manchester	40	2000	General	4 (across ED)	4 WTE	8-8pm 5 days/week + on call	22	1 PA	8 + 2 in set-up + 1 ED	8
Nurse CRN TV and South Midlands	9	500	General	0.5	0.5 WTE	p/time (early/late shift pattern; weekdays)	10	0.5 PA	2	1
Consultant CRN Wessex	11	750	General	4 + 0.5 trainee	2.5 WTE + 0.5 WTE trainee	7 days/week (plus trainee shifts)	6	0 PA	4	2
Consultant CRN West Midlands	102	4000	Cardiac/Trauma/Burns/Neuro/General	7 (across ED/Trauma and ICU)	6 WTE (inc Trial Coordinator and administrators)	7 days/week	34	1 PA	7 + 2 in set-up	7
Consultant CRN North West Coast	33	1550	General	3	3 WTE + 0.5 trainee	5 days/week (flexible)	17	1 PA	3 + 1 in set-up	3

Consultant A. CRN West of England	15	5-600	General	0	0	N/A	18	0.5 PA	1 + 2 in set-up	1
Consultant B. CRN West of England	15	5-600	General	0**	0	n/a	18	0.5 PA	1 + 2 in set-up	1
Nurse CRN South West Peninsula	28	1700	General/trauma/ Neuro/ Cardiac	1 (across dermatology/neuro)	1 WTE	8-4pm; 5 days/week	14	<i>Data not provided/ unknown</i>	0 (1 in set-up)	0
Nurse CRN West of England	20	1300	General	9	5 WTE + 4 rotational posts	7-7pm; 7 days a week	<i>Data not provided/ unknown</i>	2 PAs (shared)	10	10
Nurse CRN East Midlands	69	4000	General/trauma/neuro	6 (covering ED) – split site	4.2 WTE	7-7pm; 7 days/week	<i>Data not provided/ unknown</i>	0 PA	13	13
Nurse CRN Norfolk	19	850	General	2 (covering NIHR Division 6 studies)	1.45 WTE	8-4pm 5 days/week (+ on call)	<i>Data not provided/ unknown</i>	0 PA	4 + 1 in set-up	4
Nurse, Wales	33	1500	General/ neuro	5	4 WTE	8-4pm 5 days a week	14	1 PA	6	5
Nurse CRN North West Coast	35	1880	General	2	1 WTE band 7 shared 4 x band 6 (0.8)	7.30-3.30pm 5 days a week	13	0 PA	9	8
Nurse CRN South West Peninsula	26	1580	General/ Neuro	1	<i>Data not provided/ unknown</i>	8-4pm 5 days a week	14	0 PA	7	5
Nurse CRN North East North Cumbria	18	1000	General	2	1 band 3 res asst; 1 band 6	9-5pm 5 days a week	9	0 PA	8	6
Nurse CRN East Midlands	19	1200	General	3	2.8 WTE	8-7pm	<i>Data not provided/ unknown</i>	2 Pas	11	9
Nurse CRN Eastern	20	1890	General	4	<i>Data not provided/ unknown</i>	8-8pm	<i>Data not provided/ unknown</i>	1 PA	7	7
Nurse CRN Greater Manchester	19	1700	General	0.8	0.8 WTE	8-4pm	12	0 PA	4	4
Consultant CRN Wessex	24	1200	General	3	1.6 WTE + 2 WTE for 3 month rotations	7 days a week 8am-12pm	14	2 PAs	5	5
Consultant CRN London South	63	3500	General/ Neuro	9	2 band 7; 7 band 6*	8-8pm	<i>Data not provided/ unknown</i>	1 PA	10	9
Nurse CRN West of England	21	2000	General	5	4 WTE (1 band 7; remainder band 6)	7-7pm	12	<i>Data not provided/ unknown</i>	8	8

†PAs=Professional Activities \*Working across all Division 6 studies, not limited to critical care; \*\*Able to access other Division 6 nurses when studies are active



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# Reporting checklist for qualitative study.

Based on the SRQR guidelines.

## Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SRQR reporting guidelines, and cite them as:

O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. Standards for reporting qualitative research: a synthesis of recommendations. *Acad Med.* 2014;89(9):1245-1251.

	Reporting Item	Page Number
	#1 Concise description of the nature and topic of the study identifying the study as qualitative or indicating the approach (e.g. ethnography, grounded theory) or data collection methods (e.g. interview, focus group) is recommended	1
	#2 Summary of the key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results and conclusions	1
Problem formulation	#3 Description and significance of the problem / phenomenon studied: review of relevant theory and empirical work; problem statement	3
Purpose or research question	#4 Purpose of the study and specific objectives or questions	3
Qualitative approach and research paradigm	#5 Qualitative approach (e.g. ethnography, grounded theory, case study, phenomenology, narrative research)	4

and guiding theory if appropriate; identifying the research paradigm (e.g. postpositivist, constructivist / interpretivist) is also recommended; rationale. The rationale should briefly discuss the justification for choosing that theory, approach, method or technique rather than other options available; the assumptions and limitations implicit in those choices and how those choices influence study conclusions and transferability. As appropriate the rationale for several items might be discussed together.

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16	Researcher	#6	Researchers' characteristics that may influence the	4
17	characteristics and		research, including personal attributes, qualifications /	
18	reflexivity		experience, relationship with participants, assumptions	
19			and / or presuppositions; potential or actual interaction	
20			between researchers' characteristics and the research	
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27	Context	#7	Setting / site and salient contextual factors; rationale	4
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29	Sampling strategy	#8	How and why research participants, documents, or	4
30			events were selected; criteria for deciding when no	
31			further sampling was necessary (e.g. sampling	
32			saturation); rationale	
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36	Ethical issues pertaining	#9	Documentation of approval by an appropriate ethics	4
37	to human subjects		review board and participant consent, or explanation for	
38			lack thereof; other confidentiality and data security	
39			issues	
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43	Data collection methods	#10	Types of data collected; details of data collection	4
44			procedures including (as appropriate) start and stop	
45			dates of data collection and analysis, iterative process,	
46			triangulation of sources / methods, and modification of	
47			procedures in response to evolving study findings;	
48			rationale	
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53	Data collection	#11	Description of instruments (e.g. interview guides,	4
54	instruments and		questionnaires) and devices (e.g. audio recorders) used	
55	technologies		for data collection; if / how the instruments(s) changed	
56			over the course of the study	
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1	Units of study	#12	Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	5
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6	Data processing	#13	Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymisation / deidentification of excerpts	4
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14	Data analysis	#14	Process by which inferences, themes, etc. were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale	4
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21	Techniques to enhance trustworthiness	#15	Techniques to enhance trustworthiness and credibility of data analysis (e.g. member checking, audit trail, triangulation); rationale	4
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27	Syntheses and interpretation	#16	Main findings (e.g. interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	5
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32	Links to empirical data	#17	Evidence (e.g. quotes, field notes, text excerpts, photographs) to substantiate analytic findings	6
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36	Intergration with prior work, implications, transferability and contribution(s) to the field	#18	Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application / generalizability; identification of unique contributions(s) to scholarship in a discipline or field	10
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45	Limitations	#19	Trustworthiness and limitations of findings	11
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48	Conflicts of interest	#20	Potential sources of influence of perceived influence on study conduct and conclusions; how these were managed	2
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53	Funding	#21	Sources of funding and other support; role of funders in data collection, interpretation and reporting	2
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# BMJ Open

## A qualitative synthesis regarding the factors surrounding UK critical care trial infrastructure

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2019-030815.R1
Article Type:	Original research
Date Submitted by the Author:	07-Aug-2019
Complete List of Authors:	Pattison, Natalie; University of Hertfordshire and East & North Hertfordshire NHS Trust, School of Health and Social Work; University of Hertfordshire Arulkumaran, Nishkantha; UCL, Critical Care O'Gara, Geraldine; Royal Marsden Hospital NHS Trust Connolly, Bronwen; King's College London, Lane Fox Respiratory Unit Humphreys, Sally; West Suffolk Hospitals NHS Trust, Critical Care Walsh, Tim; University of Edinburgh Royal Infirmary Edinburgh, Critical Care Hopkins, Philip; Kings College Hospital, Critical Care Dark, Paul; University of Manchester, Intensive Care Unit
<b>Primary Subject Heading</b>:	Intensive care
Secondary Subject Heading:	Qualitative research
Keywords:	Qualitative synthesis, Critical care trials, Barriers, Facilitators, Normalising Research, Access to Research

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3 **Title:** A qualitative synthesis regarding the factors surrounding UK critical care trial  
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5 infrastructure  
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9 Professor of Nursing, University of Hertfordshire/East & North Herts NHS Trust  
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15 Royal Marsden Foundation NHS Trust, London, UK; Dr Bronwen Connolly\*, Guys and St  
16 Thomas’ NHS Foundation Trust/Intensive Care National Audit and Research Centre  
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18 (ICNARC), London, UK; Sally Humphreys, West Suffolk NHS Trust, Suffolk, UK; Professor Tim  
19 Walsh\*, University of Edinburgh, Edinburgh, UK; Dr Phillip Hopkins\*, Kings College Hospital,  
20  
21 London, UK; Professor Paul Dark\*, University of Manchester, Manchester, UK.  
22  
23

24  
25 \*Former/current members of the NIHR CRN Specialty Group for Critical Care  
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27

#### 28 **Abstract:**

29  
30 Conducting clinical trials in critical care is integral to improving patient care. Unique  
31 practical and ethical considerations exist in this patient population that make patient  
32 recruitment challenging, including narrow recruitment timeframes and obtaining patient  
33 consent often in time-critical situations. Units currently vary significantly in their ability to  
34 recruit according to infrastructure and level of research activity.  
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#### 39 **Aim**

40  
41 To identify variability in the research infrastructure of UK intensive care units (ICUs) and  
42 their ability to conduct research and recruit patients into clinical trials.  
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#### 46 **Design**

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48 We evaluated factors related to intensive care patient enrolment into clinical trials in the  
49 UK. This consisted of a qualitative synthesis carried out with two datasets of in-depth  
50 interviews (distinct participants across the two datasets) conducted with 27 intensive care  
51 consultants (n=9), research nurses (n=17) and trial coordinators (n=1) from 27 units across  
52 the UK. Primary and secondary analysis of two datasets was undertaken in the thematic  
53 analysis.  
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## Findings

The synthesis yielded an overarching core theme of Normalising Research, characterised by motivations for promoting research and fostering research-active cultures within resource constraints, with six themes under this to explain the factors influencing critical care research capacity: Organisational, Human, Study, Practical resources, Clinician, and Patient/family factors. There was a strong sense of integrating research in routine clinical practice, and recommendations are outlined.

## Conclusions

The central and transferable tenet of Normalising Research advocates the importance of developing a culture where research is inclusive alongside clinical practice in routine patient care and is requisite for all healthcare individuals from organisational to direct patient contact level.

**Keywords:** Qualitative synthesis; critical care trials; access to research; barriers; facilitators; normalising research

**Revised word count: 4688**



## Article Summary

### Strengths and limitations of this study:

1. There are significant challenges to conducting trials in critical care in the UK due to time-limited opportunities for recruitment. Patients are almost always unable to provide informed consent, adding a layer of complexity.
2. Few in-depth studies have been conducted exploring this in the UK, and do not focus on less-research active units, so we do not know what the potential issues are for these units.
3. This study is the first to present new data on less-research active critical care units, and to present a synthesis of findings that focus on these issues for the UK
4. Drawing together two datasets presents a rich picture of barriers/facilitators to conducting critical care trials in the UK
5. Gaining perspectives across the multi-disciplinary team is important for understanding the complex issues associated with delivering trials, however these need to be contextualised within the organisational settings.

**Funding:** This project was supported with infrastructure from the National Institute for Health Research Comprehensive Research Network in Critical Care (NIHR Theme Hub C King's College London).

**Competing interests:** The authors have none to declare.

## Background

Clinical trials in critical care are integral to improving patient care, albeit unique practical and ethical challenges exist including the time-sensitive nature of treatment and enrolling patients who lack capacity.[1] Data exploring barriers to conducting clinical trials in this setting are scarce, but include managing changing clinical courses, communication breakdowns, and requests for more time for consent [2]. Our previous study, focussing on research active centres,[3] described enhanced patient recruitment in centres valuing research with equal importance to clinical care, with the most commonly cited barriers insufficient human and financial resource, inadequate personnel funding, and limited career opportunities impeding staff retention.[3] Several additional factors may also preclude recruitment, such as lack of clinician equipoise and competing clinical commitments.

### Implications for the NIHR

The UK National Institute for Health and Research (NIHR) is the government-funded research arm of the National Health Service (NHS), responsible for driving bench-to-bedside research with tangible patient benefit [4]. Unique infrastructure, including the national coordinated Clinical Research Network (CRN) and specialty groups (SG) with oversight for specific clinical areas such as critical care (CC), enhance the UK's national and international position to deliver high quality clinical trials. Research teams invest significantly in recruitment to critical care trials with emphasis on mitigating modifiable factors. In particular understanding barriers and facilitators in institutions which are less research-active, such as non-university-affiliated hospitals, is crucial to enhance trial recruitment across the NIHR CRN.

Our objective was therefore to identify examples of these potential barriers and facilitators to patient enrolment in order to inform strategies to enhance future critical care trial recruitment, and identify how research staff could be supported in these organisations.

## Methods

### Design

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3 A qualitative synthesis was conducted [5], involving two datasets comprising in-depth  
4 interviews (n=27) with critical care consultants (n=9), research nurses (n=17), and trial  
5 coordinators (n=1) across England and Wales (26 hospitals; 27 units). Dataset 1 included 10  
6 participants and is reported in detail elsewhere [3]. For that dataset a sampling frame across  
7 the CRNs was used to represent a mix of smaller and larger ICUs, from teaching hospitals  
8 and district general type hospital ICUs, including one person within each CRN to ensure  
9 region-wide representation. Dataset 2, a follow-on study, included a further 17 participants  
10 from different backgrounds/units, with the aim of specifically exploring issues in less  
11 research-active critical care units. Service evaluation and quality improvement methods  
12 underpinned the projects.[6] Therefore, this synthesis involved both primary and secondary  
13 data analysis. Qualitative synthesis is a well-established method that draws together  
14 findings to reach over-arching themes.[5], ensuring similar research can be reliably  
15 compared.[7,8,9]

#### 28 Patient public involvement

29 Patient/public were not involved in the design of this study since the focus is on research  
30 infrastructure.

#### 36 Data collection

37 Individual telephone, digitally audio-recorded, interviews were conducted with participants,  
38 using a pre-determined semi-structured interview schedule agreed by team consensus. The  
39 aim of the second set of interviews was to understand how to engage and promote research  
40 activity and increase trial recruitment in critical care units that find it challenging to recruit  
41 to trials. Interview questions included: *What can you tell me about how the unit decides*  
42 *whether to participate in a research project? Tell me about the infrastructure in your critical*  
43 *care unit to support research. What is your experience of recruiting to time-limited critical*  
44 *care trials?* Written and verbal information about the project was provided and  
45 confidentiality was assured. Transcripts were anonymised prior to analysis. Team review of  
46 both the interview structure, which was refined as interviews progressed in both datasets  
47 (including more targeted questions to elicit nuances such as local capacity to conduct  
48 research) and also informed refinement of the framework analysis [10], enhanced  
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3 dependability in research findings and qualitative rigour through developing credibility and  
4 transferability.[11]  
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### 8 9 Ethical considerations

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11 The study was supported and facilitated by the NIHR Critical Care Specialty Group (NIHR  
12 CCSG). No ethical approval or written consent, as per the UK Health Research Authority,  
13 was required since only anonymised data with staff were used. No local institutional  
14 Research & Development approval was deemed necessary, since this was a project to  
15 represent views on behalf of the NIHR CCSG and recruitment did not take place via  
16 institutions. Demographic data about each critical care unit's research activity and staffing  
17 were also collected. Participation was voluntary and verbal consent was obtained both  
18 before and after the interview, to allow interviewees the opportunity to withdraw/withhold  
19 any data discussed.  
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### 31 Settings

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33 Two purposive samples were recruited, with the aim of representing different regions and  
34 professional grades (critical care nurses, trainees, trial co-ordinators and consultants) across  
35 the UK. The purposive sampling technique involved maximum variation sampling,[12] using  
36 UK trial accrual and activity data from the NIHR. The aim was to include clinicians  
37 representing critical care units across the 16 CRNs (15 in England, one in Wales).  
38 Specifically, the second dataset focused on units with limited trial recruitment, or engaged  
39 in few trials. We did not ascribe a set value to define 'less research active', but focused on  
40 unit-level activity in terms of participants recruited and active studies, according to NIHR  
41 yearly summary data. The NIHR centralises this information in a 'portfolio', and all sites are  
42 required to submit this information. Invites were circulated via the NIHR network using  
43 established mailing lists, and targeted recruitment to ensure unbiased representation.  
44 Using the principles of theoretical sampling (as used most commonly in Grounded  
45 Theory),[13,14] a sample size of 20-30 interviews was deemed sufficient to reach data  
46 saturation and build up a comprehensive picture of the UK landscape in relation to factors  
47 that influence critical care research provision.  
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## Analysis

Themes were explored at an overall and ICU-specific level. Potential barriers/facilitators within individual critical care units, hospitals, locally and nationally were identified. In both datasets, analysis was conducted using thematic analysis, a technique congruent with different types of qualitative research [15], aided by principles of framework analysis,[10] where categories were refined as analysis progressed. Data from verbatim transcripts were coded at a line level, with sub-themes derived from those codes applied to a framework, with constant comparison. Datasets were compared and contrasted, and a new framework was devised, and all data were re-analysed according to this. An independent researcher verified the analysis on anonymised data to enhance dependability. The framework provided a further degree of dependability in regards to analysis,[11] and allowed for contextual differences to emerge. The matrix provided detail of within case and cross-case analysis,[14] which was developed into themes.

## **Findings**

In Dataset 1 (collected in 2015), 10 interviews were conducted across nine CRN regions across England (n=8) and Wales (n=1). Dataset 2 (collected 2016/17) included 17 interviews conducted across 12 English CRNs. Two CRNs were not represented due to lack of response. Interviews ranged from 29-81 minutes (mean length was 45.2 mins). The framework analysis for each studies yielded six main themes. Demographics are supplied in Table 1, supplementary file 1.

## Overarching findings from synthesis

There was an overarching theme of *Normalising Research*, describing the notion that critical care research should be entrenched in routine practice. Six sub-themes existed around this central tenet: *Organisational, Human and Unit Resources, Study, Clinician, and Patient/family factors*. Resource issues permeated each theme to a different extent and were evident throughout the organisational, unit, study, or trial level, and at a human,

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3 individual level. Resources could be managed and influenced at an individual level, for  
4 instance. In centres, units, and teams where research activity was regarded with equal  
5 importance as clinical activity, research was considered routine practice. In turn, teams and  
6 individuals with a strong sense of integrating research in routine practice acted as the  
7 motivating driving force fostering a research culture, whether in primary, translational  
8 biomedical, or applied health services streams. A broader cultural influence from  
9 organisations was also evident, where research was seen as critical to organisational values,  
10 up to executive level, which in turn contributed to enhanced research activity. Barriers and  
11 enablers to trial recruitment and conduct are outlined in each theme below. A summary of  
12 these factors is outlined in Table 2 (supplementary file 2) and represented in Figure 1.  
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### 22 Organisational factors

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24 This theme related to the organisational system in which units were situated, and  
25 incorporated Trust or Board level factors; perceived priority of research; infrastructure; trial  
26 planning; funding and external links, such as academia. Research-active and less research-  
27 active institutions contrasted with regards prioritisation of research activity by senior  
28 management, with the latter placing lower profile on the support and conduct of research.  
29 This was particularly marked at challenging times e.g. during care failure reports, or financial  
30 or bed crises, even though these could be opportune periods for potential trial enrolment.  
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38 “Research and development is not high profile. At an organisational level it is service  
39 driven, research is seen as an aside and there is no support for it.” (Research nurse 2,  
40 study 2)  
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44 Despite income-generating research activity, such as involvement in commercial studies,  
45 increased demand on resources posed a limitation to engagement. Some critical care  
46 research leads had to seek executive and/or Research and Development Department (R&D)  
47 approval prior to confirming participation, while others could make these decisions  
48 unilaterally. Centre factors also determined how trials were embedded through initiatives  
49 that increased engagement such as simulated trial runs. Embedding research into routine,  
50 or what was perceived as ‘normal’, care required a conceptual shift.  
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58 “No, research is not a priority. New [intensive care unit] ICU consultants very keen,  
59 as are research [specialist registrars] SpRs. The resistance mainly comes from  
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3 nurses. It is about perceived additional work or disagreement with the protocol. .

4  
5 .it's not part of routine care" (Research nurse 4, study 1)

6  
7 "Research should be part of everyone's job. If prescribed it should be given,  
8  
9 regardless of it is [part of] research or not." (Research nurse 3, study 2)

10  
11 "The Trust don't adequately prioritise research; the management don't 'get it' and  
12  
13 [the] financial position takes precedence." (Consultant intensivist 13, study 2)

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15  
16 The nature of funding for research nurses, primarily funded via the CRNs and dependent on  
17  
18 trial activity levels, created significant challenges to research conduct, given the lack of  
19  
20 continuity. Some units ensured varied funding sources beyond the NIHR, to include  
21  
22 commercial and higher education, and internally managed their own research budgets. This  
23  
24 successfully allowed flexibility in deciding which trials to undertake, and managing staffing  
25  
26 and out-of-hours support. Planning for future trials was evidently problematic on occasion.  
27  
28 During periods with fewer critical care trials, many research teams broadened activity to  
29  
30 cover Emergency Department (ED) and anaesthetic trials. Whilst this maintained research  
31  
32 activity overall, it also resulted in research teams being stretched across many studies and it  
33  
34 was hard to focus on critical care trials when activity in this area resumed. For university or  
35  
36 university-affiliated hospitals, additional support for research overall could be obtained  
37  
38 through links with academia.

39  
40 "We have a historical arrangement with the University that they will fund a unit-based  
41  
42 research fellow for a year." (Consultant intensivist 11, study 2)

### 43 Human and Unit resources

44  
45 These sub-themes are reported together since they were closely aligned, incorporated  
46  
47 staffing; reciprocity within research and ICU teams; models of provision; management;  
48  
49 research opportunities and career structures (nurses/trainees). Staffing was a factor  
50  
51 affecting research delivery. Varied models existed for staffing research teams, from  
52  
53 rotational and secondments out of critical care, cross-hospital site and cross-specialty  
54  
55 working, to research staffing being managed via the CRN. Most research staff had a clinical  
56  
57 critical care background, which facilitated fluid working arrangements and carryover of  
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59 research skills to non-research staff.  
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3 “We instigated rotation of three months from ICU into the research team for 3  
4 months, introducing fresh people and it invigorated the team.” (Research nurse 15,  
5 study 2).  
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8

9 Many participants commented that while critical care research staff could cover other  
10 specialties, reciprocal cover for critical care was less successful given the unique patient  
11 population and the time-limited nature of recruitment, and this was often poorly  
12 appreciated by hospital R&D and regional CRN level. Research staff with a clinical  
13 background in critical care found communication easier and were able to support clinical  
14 staff, thus developing a mutually beneficial working relationships and helping with the  
15 normalisation of research. Grading of research nurse positions and lack of career  
16 development was identified as problematic; line management (direct management of the  
17 individual) was at times with the regional CRN offices, rather than the local critical care unit.  
18 Some research-active centres created attractive positions that afforded career progression  
19 and mitigated against job insecurity, a common feature of research nurse roles that are  
20 primarily funded on a yearly contract basis via the CRNs.  
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32 “The career ladder is limited for them and so they move to management or work in  
33 R&D roles, and the use of temporary contracts is demoralising and a disincentive.”  
34 (Consultant intensivist 1, study 1)  
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38 Few consultants received programmed activity (PA) sessions specifically for research,  
39 especially within non-university affiliated hospitals. Many clinicians relied upon financial  
40 support and time from their organisations to undertake research activity.  
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43

44 “They do it effectively out of interest, there is nothing in their job plan apart from a  
45 reference to research, but no time to actually do it. . .it is voluntary and many don’t  
46 do it” (Research nurse 4, study 2)  
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50 This lack of support overlaps with the organisational theme; allocated time and finances to  
51 support research activity was rare, occurring only in centres where research was viewed as  
52 core activity. Few medical trainees had the opportunity for research involvement, and again  
53 primarily only in research-active centres with novel initiatives designed to engage those  
54 interested in research e.g. year-long fellowships where research activity contributed to their  
55 training programme. Limited time was also a factor: “we have had less [trainees] over the  
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3 years, enthusiasm fades and other things take over” (Consultant intensivist 9, study 2).  
4  
5 However, short clinical placements precluded meaningful trainee participation in primary  
6  
7 research.

8  
9 “They mainly don’t get involved and when [they do], they don’t do their own research”  
10  
11 (Research nurse 15, study 2)

12  
13 Designated trial coordinators were rare in smaller non-university-affiliated hospitals with  
14  
15 less opportunity to enrol patients. Unit, staffing and centre factors were closely associated  
16  
17 in the two datasets. Unit factors pertained to strategies to enhance engagement, provision,  
18  
19 recruitment and delivery of critical care research. These varied from simulated runs of  
20  
21 screening, recruitment and intervention, to teaching programmes and incentive schemes.  
22  
23 Having a physical presence on the unit was seen as a crucial element for ensuring clinical  
24  
25 credibility.

26  
27 “ you need to be there, being present, going on ward rounds and to handovers...” (Research  
28  
29 nurse 14, study 2).

30  
31 Driven individuals were critical to success in recruitment and study conduct, with both  
32  
33 research nurses and consultants assuming principal investigator roles.

### 34 35 Study/trial factors

36  
37 This sub-theme was characterised by study practicalities and how studies could be  
38  
39 actualised within internal and external constraints. There were process and infrastructure  
40  
41 issues associated with studies that affected the team’s ability to conduct the trial.

42  
43 Trial complexity appeared a considerable factor contributing to trial success, in terms of  
44  
45 acceptance by local staff and potential ability to achieve recruitment targets. Feasibility and  
46  
47 capacity assessment moderated concerns about delivering to time and target, a national  
48  
49 metric captured by the NIHR CRN. Studies requiring significant pharmacy support, such as  
50  
51 Clinical Trials of Investigational Medicinal Products had variable success with  
52  
53 implementation and recruitment. Some units reported pressure from the regional CRN and  
54  
55 local R&D departments to undertake high-recruiting studies that yielded maximum income  
56  
57 generation, rather than complex studies perceived as interesting but with low recruitment  
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59 targets that might yield less or insufficient income to cover costs. Demonstrating quick,  
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3 tangible 'wins' for an organisation and staff, through health service research, helped  
4 engagement. Complex studies were considered problematic for balancing effort against  
5 outcomes achieved, in particular around training requirements for staff to implement  
6 detailed interventions, and strict eligibility criteria with narrow recruitment windows leading  
7 to few, if any, patients enrolled. Studies requiring significant preparation, including co-  
8 enrolment agreements, time-scheduling, competing population assessment, and  
9 importantly, ensuring unit staff were committed and had clinical equipoise, could be  
10 particularly challenging:  
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18 "they say they have equipoise, but when it comes down to it, they don't, you get  
19 surreptitious opposition and stark persuasion is used in those situations."  
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22 (Consultant intensivist 1, study 1)  
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25 Time associated with daily screening was also a factor influencing success of complex trials,  
26 as often this could not be performed remotely and required extensive clinical data review.  
27 In keeping with study set-up, funding was rarely allocated for this activity, or for follow-up.  
28 In units where research was considered part of routine practice, clinical staff also helped  
29 with identification of potential participants.  
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34 "There needs to be appropriate costing of studies including NHS support costs, for  
35 drugs for example. . . long-term follow-up needs to be considered as well."  
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38 (Consultant intensivist 6, study 2)  
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41 Strategies to facilitate complex trials included engagement with local clinical staff on the  
42 relevant unit to integrate the trial procedures with standard care, thereby enabling all staff  
43 to contribute to patient screening and enrolment, including out-of-hours. Units could  
44 achieve this through training and cross-team working.  
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### 51 Clinician factors 52

53 This theme focused on how unit clinicians, nurses, trainees and intensivists, were perceived  
54 as engaged in research; this did not appear linked to how research-active an organisation  
55 was. Where research staff originated from the unit this was a facilitator, often resulting in  
56 good team working from both clinical and research team perspectives. Where research was  
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3 viewed as additional activity, rather than integral to patient care, research staff reported  
4 cases of open hostility, particularly early on in their roles, until unit staff developed an  
5 appreciation for research.  
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9 “I’ve tried working on the unit and taking patients and doing shifts to build  
10 relationships” (Research nurse 7, study 2)  
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13 Research resources were factored by unit staff where there was good inter-boundary  
14 working. For instance, research staff attended senior nurse meetings to identify local issues  
15 that might adversely affect recruitment. Equally, unit staff could help identify barriers to  
16 recruitment to certain studies. Creating link roles supported nurse-level engagement and  
17 enhanced out-of-hours opportunities for recruitment when research nurses were not  
18 present. Very limited funding for out-of-hours cover enforced the need for research nurse  
19 flexibility.  
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26 Equipose featured again in this theme; clinicians could undermine research activity by  
27 appearing supportive in meetings, but not in practice. Permission to recruit patients had to  
28 be negotiated at an individual clinician level, which could compromise unit objectivity  
29 toward the study.  
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35 “The consultants are all GCP [Good Clinical Practice] trained but there is mixed  
36 interest and support, ranging from active obstruction. . . , to more neutral through to  
37 full support.” (Consultant intensivist 9, study 2).  
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41 “People believe they have equipose but on the day people change what they do.”  
42 (Research nurse 5, study 2).  
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46 Investment for trainee engagement arose as an important issue, particularly in those less  
47 research-active organisations. Ensuring the next generation of critical care consultants  
48 prioritised research activity with clinical practice was recognised as imperative. Many  
49 trainees were taught to obtain patient consent. At the time of the study, regional trainee  
50 research networks were emerging across the UK. However, according to these participants,  
51 in larger portfolio NIHR trials trainee engagement was noted to be minimal, and unit  
52 pressures contributed to lack of engagement. Trainee fellowship roles successfully  
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3 addressed this in two units, with staff continuing research in their careers as consultants,  
4  
5 with an emphasis on personal motivation.  
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7 "we actively encourage fellows not to go onto the [unit] rota so that their role is  
8  
9 protected for research." (Consultant intensivist 11, study 2)  
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12 Personal commitment was a key factor; research activity often required working beyond  
13 allocated hours or sessions, or flexible working out-of-hours. This demonstrated how  
14 research teams worked to emphasise the sense that research should be considered the  
15 norm, with efforts devoted to successful implementation comparable to efforts in clinical  
16 practice. Skills of research nurses was a factor common to both datasets, with the ability  
17 (and R&D permission) to consent improving recruitment. Extended skills also meant that a  
18 number of research nursing staff were supported to undertake further study, including at  
19 doctoral level, fostering motivation, willingness to work flexibly and promoting emergence  
20 of independent researchers. Portfolio studies requiring a nurse Principal Investigator  
21 particularly motivated nurses. For consultants, feelings were mixed: studies with no  
22 personal interest fostered less engagement, unless it was likely to be income-generating.  
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### 35 Patient/family factors

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37 This sub-theme encompassed issues such as participant burden, support available,  
38 communication, and anticipating declines to participate. Difficulties communicating  
39 information about trial procedures to patients and their families was reported by  
40 participants. A positive but realistic attitude was deemed essential. The volume of  
41 paperwork was identified as problematic. Ensuring that patients or families fully  
42 understood complex research interventions, without overburdening them at a sensitive  
43 time, was seen as a central issue.  
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51 "We've got savvier about taking consent and have learnt lessons; you don't gain it by  
52  
53 giving more paper." (Consultant intensivist 1, study 1)  
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55  
56 Managing clinical uncertainty in the context of clinical trials was difficult. Whilst it did not  
57 seem to hinder recruitment, managing the process was challenging for research staff. Many  
58 families agreed to assent for patients for altruistic reasons, understanding there may be no  
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3 benefit to the patient. An important issue emerged in relation to addressing cultural  
4 perspectives. Different attitudes were perceived towards research, centring on trust in  
5 healthcare. Immediate dismissal by family members, on behalf of patients, was not  
6 uncommon. However, sometimes families were keen, but patients weren't.

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11 "The patient, who was not intubated [breathing tube for mechanical ventilation],  
12 had capacity and her family were keen for her to take part, but she wasn't (Research  
13 Nurse 9, study 1).  
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17 Conversely, some reported a paternalistic medical attitude still prevailing. Despite efforts to  
18 address this, provide more information and demonstrate equipoise, families and patients  
19 were reluctant and preferred to defer to doctors' opinions regarding enrolment.  
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22  
23 "I work in a deprived area with a lower level of education compared to the UK  
24 average, because of that the cultural norms mean they tend to trust what the  
25 doctors say: 'whatever you think doctor'" (Research nurse 11, study 2).  
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30 Neither of these opposing views about consent were regarded by participants as hindering  
31 recruitment. Units serving a disproportionately elderly or rural population reported  
32 difficulties gaining access to relatives for assent, particularly where time-sensitive consent  
33 was required. Research teams estimated a third of families were likely to decline  
34 participation when calculating recruitment targets and reasons for non-participation  
35 appeared to be complex and poorly understood. Where approaches to families were  
36 prefaced by an explanation that research was part of normal clinical practice in that  
37 particular unit, there was increased receptivity to recruitment. Reported preference for  
38 treatment arms was rare, and usually managed through explanation. Facilitating  
39 understanding was viewed as crucial when approaching families and patients for consent,  
40 with issues related to ongoing assessment of mental capacity also highlighted as difficult.  
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## 51 52 53 **Discussion**

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55 This synthesis outlines six inter-related themes under a new over-arching theme of  
56 *Normalising Research*. Research activity was regarded as equally important as clinical work  
57 by these participants, albeit this was acknowledged as not a representative view across all  
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3 organisations or units. Where research was embedded into routine care and considered as  
4 the norm, undertaking screening and recruitment were easier. Emphasising the need for  
5 normalcy of research at a unit, as well as organisational level, means cohesive units evolve  
6 with the unified aim of improvements in patient care as the driving force. However, there  
7 are prerequisites for normalcy, including communication towards a shared understanding  
8 [16] in this case, that research is an integral part of everyday patient care. Furthermore, this  
9 communication needs to take place at a systems level.[16] Specific issues in the synthesis  
10 related to variation in funded time and resources, clinician engagement, individual roles,  
11 and perceived gains from research, which proved noteworthy, acting as barriers or  
12 facilitators to clinical trial recruitment. Bruce et al,[1] outlined how navigating rapidly  
13 changing clinical courses and communication breakdown adversely affected recruitment.[1]  
14 That these factors did not emerge in this synthesis may reflect different healthcare systems,  
15 funding, and the larger number of hospitals. Similarities emerged related to the challenges  
16 of recruitment within a narrow timeframe. Good communication between clinical and  
17 research teams was important for successful trial implementation.

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31 Inclusion of data from less research-active organisations strengthens this study providing  
32 richer data, more transferable across the NHS and to healthcare systems in other  
33 jurisdictions. Our findings will resonate with other international settings where, despite  
34 variability in national infrastructure, similar challenges are faced by researchers. The tenet  
35 of normalising research transcends unit, institutional and country boundaries. Approaches  
36 to improve recruitment included simple incentive schemes to reward clinical staff,  
37 broadening the range of clinicians who could take consent. The latter is particularly  
38 pertinent to CTIMPs where time-limited recruitment was more relevant.[1,2] Previous work  
39 has suggested lack of equipoise as a barrier to enrolment[17,18]. An area for further  
40 exploration relates to consent waivers, already explored in some recent research [1,17,19,  
41 20], albeit with less known of patient and family perspectives. 'Overburdening' has been  
42 described previously [21] as has concern regarding making initial approaches to families  
43 during particularly sensitive times [19-23] but again the patient/family voice in these studies  
44 is largely absent.[19-21] This would be an important area for future practice and research.

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3 In keeping with existing literature, competition between trials requiring similar patient  
4 cohorts and the number of eligible patients were further barriers to trial recruitment [1,24].  
5  
6 Another factor related to lack of clear professional development opportunities and  
7 structured career paths. Recent strategy published by the NIHR offers novel career options  
8 for research staff [25-27] such as consultant research nurse models [25]. The emergence of  
9 medical trainee networks across the UK have also helped create a case for formalised  
10 processes.[28, 29] NIHR initiatives to engender a culture of research in healthcare, with  
11 every patient being offered the opportunity to participate in research aimed at improving  
12 care [30] are also reflected in these individual participants' motivations to improve care  
13 through research. Systematic review and large-scale survey evidence highlight key areas to  
14 improve trial recruitment as training site staff, communication with patients, and incentives,  
15 albeit some suggestions are not applicable to an ICU setting, such as telephone calls to non-  
16 respondents and opt-out procedures.[31,32] There have been significant advances over the  
17 past five years in critical care research recruitment.[33] In a current climate of significant  
18 fiscal pressures in the UK healthcare system with £22 billion of NHS efficiency savings to be  
19 achieved by 2020,[34] there was still a universal desire to undertake critical care research.  
20 This was driven by key motivated individuals who viewed research as integral to best  
21 practice and normal care provision, as well as deriving evidence to drive and support best  
22 use of resources.  
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39 This qualitative synthesis draws together two sets of original research findings. Whilst data  
40 were not collected simultaneously, both studies complemented each other. The second  
41 study built on the first by focusing specifically on a target participant cohort not initially  
42 represented in order to generate novel data to further understand the question at hand.  
43 Furthermore, the timeframe between acquisition of each dataset was short (twelve months)  
44 with minimal, if any, change in practice likely occurring during the interim. Potential  
45 sampling bias from recruiting primarily research-active units in the first dataset, was  
46 mitigated by employing purposive recruitment in the second dataset from less research-  
47 active units. We also acknowledge the possible introduction of bias through refining the  
48 interview schedule as we proceeded through the interviews. Research-active and less  
49 research-active units were defined both on subjective reports from individuals, and  
50 standardised objective metrics. Qualitative research is often criticised for lack of  
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3 generalisability, due to sample size limitations, but notions of transferability can be  
4 considered [8,11] and what Payne and Williams term 'moderatum generalisations'. [35]  
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6 Figure 1. outlines a summary of the main points and four key areas for learning. The core  
7  
8 concept of Normalising Research can feasibly be applied beyond critical care trials  
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10 recruitment, across the full spectrum of clinical specialties represented within the NIHR, as  
11  
12 well as internationally.  
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## 17 **Conclusion**

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20 This qualitative synthesis integrating two original datasets has yielded recommendations for  
21  
22 improving trials recruitment in the unique clinical specialty of critical care. Several  
23  
24 suggestions are made from the six themes that emerged: Organisational, Human, Study,  
25  
26 Practical resources, Clinician, and Patient/family factors, under the overarching theme of  
27  
28 Normalising Research, that relate to enhanced staffing, training, trial design and  
29  
30 communication. Fostering a culture where research is considered part of routine patient  
31  
32 care must be the ultimate goal for those working at all levels, from organisational to  
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34 bedside.  
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44  
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48  
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51  
52 collection and analysis of the two datasets, and the overall synthesis. GOG independently  
53  
54 verified the first dataset and contributed to data analysis of the second dataset. NA  
55  
56 contributed to the design, data collection and manuscript write-up. PD, PH and TW  
57  
58 contributed to the design. SH and BC contributed to data collection, analysis and  
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3 manuscript preparation. All authors have reviewed and contributed to the manuscript. NP  
4 is the custodian of the intellectual integrity and property arising from this project.  
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7 Patient consent: Not required.  
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10 Provenance and peer review Not commissioned; externally peer reviewed.  
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13 Data sharing statement: All data pertaining to this study are reported in this manuscript.  
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## 18 **References**

- 19  
20 1. Bruce CR, Liang C, Blumenthal-Barby JS, Zimmerman J, Downey A, Pham L, Thieret L,  
21 Delgado E, White D. Barriers and Facilitators to Initiating and Completing Time-Limited Trials  
22 in Critical Care. *Critical Care Medicine*. 2015. 43(12):2535-2543.  
23  
24 2. Kaur G, Smyth RL, Williamson P. Developing a survey of barriers and facilitators to  
25 recruitment in randomized controlled trials. *Trials*. 2012;13:218.  
26  
27 3. Pattison N, Arulkumaran N, Humphreys S, Walsh T. (2017) Exploring obstacles to critical  
28 care trials in the UK: A qualitative investigation. *Journal of the Intensive Care Society*. 18(1):  
29 36-46  
30  
31 4. National Institute of Health Research (NIHR) (2016) NIHR: Our Purpose  
32 Available at: <http://www.nihr.ac.uk/about-us> (accessed 21.1.17)  
33  
34 5. Barnett-Page E, Thomas J. Methods for the synthesis of qualitative research: a critical  
35 review. ESRC National Centre for Research Methods. 2009 NCRM Working Paper Series  
36 Number (01/09)  
37  
38 6. Health Research Authority. Defining Research. Available at:  
39 <http://www.hra.nhs.uk/documents/2016/06/defining-research.pdf> (accessed 24.5.17)  
40  
41 7. Heyvaert, M., Maes, B. & Onghena, P. Mixed methods research synthesis: definition,  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
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55  
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2  
3 framework, and potential Qual Quant 2013 47: 659. doi:10.1007/s11135-011-9538-6  
4  
5  
6 8. Finfgeld-Connett D. Generalizability and transferability of meta-synthesis research  
7  
8 findings. Journal of Advanced Nursing 2010. 66 (2), 246-254  
9  
10  
11 9. Eaves YD. A synthesis technique for grounded theory data analysis. Journal of Advanced  
12  
13 Nursing 2001 35:654-63  
14  
15  
16 10. Ritchie J, Spencer L. Qualitative data analysis for applied policy research. In: Bryman A,  
17  
18 Burgess R, editors. Analysing qualitative data. London: Routledge; 1994. pp. 173–194.  
19  
20  
21 11. Lincoln YS, Guba EG. Naturalistic Inquiry. Newbury Park, CA: Sage Publications. 198 12.  
22  
23 Suri H. Purposeful sampling in qualitative research synthesis. Qual Res J. 2011;11:63–75.  
24  
25  
26 13. Glaser BG, Strauss AL. The Discovery of Grounded Theory. Strategies for Qualitative  
27  
28 Research. 1967. Chicago: Aldine Publishing  
29  
30  
31 14. Miles MB, Huberman AM. An Expanded Sourcebook: Qualitative data Analysis. 2nd  
32  
33 Edn.1994. Sage Publications, Thousand Oaks, California, US.  
34  
35  
36 15. Boyatzis, R. E. (1998). *Transforming qualitative information: Thematic analysis and code*  
37  
38 *development*. Thousand Oaks, CA: Sage.  
39  
40  
41 16. Habermas J. The theory of communicative action: Vol 2. Lifeworld and system. A critique  
42  
43 of functionalist reason. 1987 Beacon Press Boston MA  
44  
45  
46 17. Morgenweck CJ. Innovation to research: some transitional obstacles in critical care units.  
47  
48 Crit Care Med. 2003 Mar;31(3 Suppl):S172-7  
49  
50  
51 18. Donovan JL, de Salis I, Toerien M, Paramasivan S, Hamdy FC, Blazeby JM. The intellectual  
52  
53 challenges and emotional consequences of equipoise contributed to the fragility of  
54  
55 recruitment in six randomized controlled trials. J Clin Epidemiol. 2014 Aug;67(8):912-20  
56  
57  
58 19. Bigatello LM, George E, Hurford WE. Ethical considerations for research in critically ill  
59  
60 patients. Crit Care Med. 2003 Mar;31(3 Suppl):S178-81.

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2  
3 20. Lim DA, Chan MF, Childs C. Surrogate consent for critical care research: exploratory  
4  
5 study on public perception and influences on recruitment. *Crit Care*. 2013 Jan 15;17(1):R5.  
6  
7  
8 21. Mehta S, Quittnat Pelletier F, Brown M, Ethier C, Wells D, Burry L, MacDonald R. Why  
9  
10 substitute decision makers provide or decline consent for ICU research studies: a  
11  
12 questionnaire study. *Intensive Care Med*. 2012 Jan;38(1):47-54.  
13  
14  
15 22. Dear RF, Barratt AL, Tattersall MH. Barriers to recruitment in cancer trials: no longer  
16  
17 medical oncologists' attitudes. *Med J Aust*. 2012 Feb 6;196:112-3.  
18  
19  
20 23. Majesko A, Hong SY, Weissfeld L, White DB. Identifying family members who may  
21  
22 struggle in the role of surrogate decision maker. *Crit Care Med* 2012. Aug;40(8):2281-6.  
23  
24  
25 24. Dickson S, Logan J, Hagen S, Stark D, Glazener C, McDonald AM, McPherson G. Reflecting  
26  
27 on the methodological challenges of recruiting to a United Kingdom-wide, multi-centre,  
28  
29 randomised controlled trial in gynaecology outpatient settings. *Trials*. 2013 Nov 15;14:389.  
30  
31  
32 25. Currey J, Considine J, Khaw D. Clinical nurse research consultant: a clinical and academic  
33  
34 role to advance practice and the discipline of nursing. *J Adv Nurs*. 2011 Oct;67(10):2275-83.  
35  
36  
37 26. National Institute for Health Research. NIHR Clinical Research Network: Developing our  
38  
39 Clinical Research Nursing Strategy 2017-2020. 2017. Available at:  
40  
41 [https://www.nihr.ac.uk/our-faculty/clinical-research-](https://www.nihr.ac.uk/our-faculty/clinical-research-staff/clinical-research-nurses/Clinical%20Research%20Nurse%20Strategy%202017_2020FINAL.pdf)  
42  
43 [nurses/Clinical%20Research%20Nurse%20Strategy%202017\\_2020FINAL.pdf](https://www.nihr.ac.uk/our-faculty/clinical-research-staff/clinical-research-nurses/Clinical%20Research%20Nurse%20Strategy%202017_2020FINAL.pdf). Accessed  
44  
45 1.9.18.  
46  
47  
48 27. National Institute for Health Research. NIHR Clinical Research Network: NIHR CRN Allied  
49  
50 Health Professionals Strategy 2018-2020. 2018. [https://www.nihr.ac.uk/our-faculty/clinical-](https://www.nihr.ac.uk/our-faculty/clinical-research-staff/Allied%20Health%20Professionals/Allied%20Health%20Professionals%20Strategy%202018_2020.pdf)  
51  
52 [research-](https://www.nihr.ac.uk/our-faculty/clinical-research-staff/Allied%20Health%20Professionals/Allied%20Health%20Professionals%20Strategy%202018_2020.pdf)  
53  
54 [staff/Allied%20Health%20Professionals/Allied%20Health%20Professionals%20Strategy%20](https://www.nihr.ac.uk/our-faculty/clinical-research-staff/Allied%20Health%20Professionals/Allied%20Health%20Professionals%20Strategy%202018_2020.pdf)  
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56 [018\\_20.pdf](https://www.nihr.ac.uk/our-faculty/clinical-research-staff/Allied%20Health%20Professionals/Allied%20Health%20Professionals%20Strategy%202018_2020.pdf). Accessed 1.9.18.  
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3 28. Shaw M, Harris B, Bonner S. The research needs of an ICM trainee: The RAFT national  
4 survey results and initiatives to improve trainee research opportunities. *Journal of the*  
5 *Intensive Care Society*. 2017;18(2):98-105.  
6  
7  
8  
9 29. Moore JN, McDiarmid AJ, Johnston PW, Cleland JA. Identifying and exploring factors  
10 influencing career choice, recruitment and retention of anaesthesia trainees in the UK.  
11  
12  
13  
14 Postgrad Med J. 2016 Jun 15. pii: postgradmedj-2015-133518. doi: 10.1136/postgradmedj-  
15 2015-133518. [Epub ahead of print]  
16  
17  
18  
19 30. Brown H, Hewison A, Gale N, Snelling I, Shneerson C. Every patient a research patient.  
20  
21  
22 Evaluating the state of research in the NHS. A report commissioned by CRUK, 2015.  
23  
24  
25 University of Birmingham.  
26  
27 31. Bower P, Brueton V, Gamble C, Treweek S, Tudur Smith C, Young B Williamson P  
28  
29 Interventions to improve recruitment and retention in clinical trials: a survey and workshop  
30 to assess current practice and future priorities *Trials*. 2014 15:399  
31  
32  
33  
34 32. Treweek S, Mitchell E, Pitkethly M, Cook J, Kjeldstrøm M, Johansen M, Taskila TK,  
35  
36  
37 Sullivan F, Wilson S, Jackson C, Jones R, Lockhart P: Strategies to improve recruitment to  
38  
39 randomized controlled trials. *Cochrane Database Syst Rev*. 2010, : -MR000013  
40  
41  
42 33. Walsh T, Brett S. What are the priorities for future success in critical care research in the  
43  
44  
45 UK? Report from a national stakeholder meeting. *Journal of the Intensive Care*  
46  
47  
48 *Society*. November 2015 vol. 16 no. 4 287-293  
49  
50 34. Dunn P, McKenna H, Murray R. Deficits in the NHS 2016. The Kings Fund. Available at:  
51  
52 <https://www.kingsfund.org.uk/publications/deficits-nhs-2016> (accessed Sep 1st 2018)  
53  
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55 35. Payne G, Williams M. Generalization in Qualitative Research *Sociology* 2005. 39: 295-  
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3 Data access: All data pertaining to this project are reported here. Please contact the authors  
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Figure 1. Normalising Research

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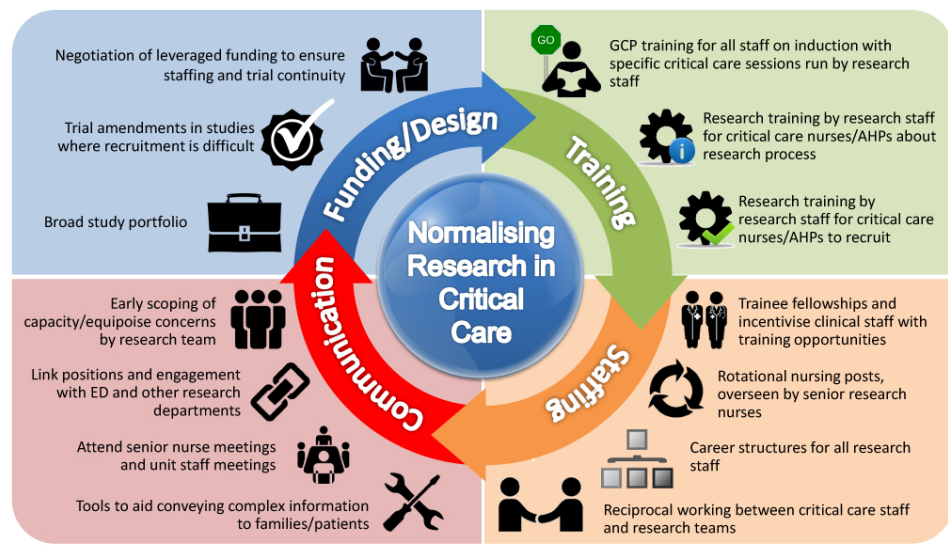


Figure 1. Normalising Research

Table 1 Participants/units (Supplemental File 1)

Profession and Area	Level 3/2 beds <sup>†</sup>	Annual admissions	General /Specialist unit	Research staff numbers including whole time equivalent (WTE)	Research team working patterns	Consultant numbers and funded consultant time (Professional Activity session [PA]) <sup>††</sup> for research	Number (total) of ongoing clinical trials (both NIHR and non-NIHR/in set-up)
Nurse/ CRN Eastern	14	1000	General	<b>1</b> (work with Emergency Department [ED]); (1 WTE)	5 days/week 8-4pm (flexible)	<b>7</b> 1 PA	<b>6</b>
Nurse/CRN Yorkshire and Humber	24	1600	General	<b>2</b> ; (2 WTE)	5 days (flexible – 9 hour cover)	<b>13</b> 0.5 PA (shared)	<b>5</b>
Nurse/ CRN West Midlands	25	1600	General	<b>1</b> (was 4); (1 WTE)	5 days/week; 8-4pm	<i>Data not provided/ unknown</i> 1 PA	<b>6</b>
Consultant/ CRN Wessex	12	900	General	<b>2</b> (across all Division 6*, not just ICU); 1 WTE)	5 days/week; 8-4pm	<i>Data not provided/ unknown</i> 2 PAs	<b>6</b>
Trial co-ordinator/ CRN London South	63	3100	General/trauma	<b>6</b> across ED/ICU; ( <i>Data not provided/ unknown</i> )	5 days/week (and on-call at weekends/nights as required)	<b>&gt;50</b> (exact number unknown) 0 PA	<b>5</b>
Consultant/ CRN North West London	44	2600	General/ Trauma/ Neuro	<b>2</b> fellows + <b>5</b> nurses; (2 fellows at 2 WTE; 5 nurses at 4.5 WTE. 1 WTE research assistant)	<b>7</b> days/week	<b>21</b> 1 PA	<b>4</b>
Nurse/ CRN Greater Manchester	40	2000	General	<b>4</b> (across ED); (4 WTE)	8-8pm 5 days/week (and on-call at weekends/nights as required)	<b>22</b> 1 PA	<b>8/ 2</b> in set-up
Nurse/ CRN TV and South Midlands	9	500	General	<b>0.5</b> ; (0.5 WTE)	part/time (early/late shift pattern; weekdays)	<b>10</b> 0.5 PA	<b>2</b>
Consultant/ CRN Wessex	11	750	General	<b>4 + 0.5</b> trainee; (2.5 WTE + 0.5 WTE trainee)	7 days/week (plus trainee shifts)	<b>6</b> 0 PA	<b>4</b>
Consultant/ CRN West Midlands	102	4000	General/ Cardiac/ Trauma/ Burns/ Neuro	<b>7</b> (across ED/Trauma and ICU); (6 WTE including Trial Coordinator and administrators)	7 days/week	<b>34</b> 1 PA	<b>7/ 2</b> in set-up
Consultant/ CRN North West Coast	33	1550	General	<b>3 + 0.5</b> trainee; (2.5 WTE + 0.5 WTE trainee)	5 days/week (flexible)	<b>17</b> 1 PA	<b>3/ 1</b> in set-up
Consultant/ CRN West of England	15	5-600	General	<b>0</b>	n/a	<b>18</b> 0.5 PA	<b>1/ 2</b> in set-up



Consultant/ CRN West of England	15	5-600	General	0**	n/a	18 0.5 PA	1/ 2 in set-up
Nurse/ CRN South West Peninsula	28	1700	General/trauma/ Neuro/ Cardiac	1 (across dermatology/ neuro); (1 WTE)	8-4pm; 5 days/week	14 <i>Data not provided /unknown</i>	0/ 1 in set-up
Nurse/ CRN West of England	20	1300	General	9; 5 WTE + 4 rotational posts	7-7pm; 7 days a week	<b>Data not provided /unknown</b> 2 PAs (shared)	10
Nurse/ CRN East Midlands	69	4000	General/trauma/ Neuro	6 (covering ED) – split site; (4.2 WTE)	7-7pm; 7 days/week	<b>Data not provided /unknown</b> 0 PA	13
Nurse/ CRN Norfolk	19	850	General	2 *; (1.45 WTE)	8-4pm 5 days/week (and on-call at weekends/nights as required)	<b>Data not provided /unknown</b> 0 PA	4/ 1 in set-up
Nurse/ Wales	33	1500	General/ Neuro	5; (4 WTE)	8-4pm 5 days/week	14 1 PA	6
Nurse/ CRN North West Coast	35	1880	General	2; (1 WTE nurse at band* 7 shared and 4 x nurse at band 6 at 0.8 WTE)	7.30-3.30pm 5 days/week	13 0 PA	9
Nurse/ CRN South West Peninsula	26	1580	General/ Neuro	1; ( <i>Data not provided /unknown</i> )	8-4pm 5 days/week	14 0 PA	7
Nurse/ CRN North East North Cumbria	18	1000	General	2; (1 nurse at band 3 research assistant; 1 nurse at band 6 WTE)	9-5pm 5 days/week	9 0 PA	8
Nurse/ CRN East Midlands	19	1200	General	3; (2.8 WTE)	8-7pm	<b>Data not provided /unknown</b> 2 PAs	11
Nurse/ CRN Eastern	20	1890	General	4; ( <i>Data not provided/unknown</i> )	8-8pm	<b>Data not provided /unknown</b> 1 PA	7
Nurse/ CRN Greater Manchester	19	1700	General	0.8; (0.8 WTE)	8-4pm	12 0 PA	4
Consultant/ CRN Wessex	24	1200	General	3; (1.6 WTE + 2 WTE for 3 month rotations)	8am-12pm 7 days a week	14 2 PAs	5
Consultant/ CRN London South	63	3500	General/ Neuro	9; (2 nurse at band 7; 7 nurse at band 6* WTE)	8-8pm	<b>Data not provided /unknown</b> 1 PA	10
Nurse/ CRN West of England	21	2000	General	5; (4 WTE (1 nurse at band 7; remainder nurse at band 6)	7-7pm	12 <i>Data not provided /unknown</i>	8

† Level 2 beds are where patients require more detailed observation or intervention including support for a single failing organ system or post-operative care and those 'stepping down' from higher levels of care Level 3 beds only. Level 3 care is defined as patients needing advanced respiratory support alone or support of at least two organ systems. Note basic respiratory and basic cardiovascular support occurring on one day count as one organ. This level includes beds for all complex patients requiring support for multi-organ failure. Flexible critical care beds where there is a mix of level 2 and level 3 beds (NHS data dictionary: [https://www.datadictionary.nhs.uk/data\\_dictionary/attributes/u/unit\\_bed\\_configuration\\_de.asp?shownav=1](https://www.datadictionary.nhs.uk/data_dictionary/attributes/u/unit_bed_configuration_de.asp?shownav=1)) ††PAs=Professional Activities Sessions are four hour weekly sessions for consultants only \*Working across all Division 6 studies, not limited to critical care; Division 6 is one of six NIHR overarching divisions that encompasses critical care, anaesthesia/peri-operative/pain, emergency care/injuries, surgery, respiratory,

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gastroenterology, infectious diseases/microbiology, hepatology, ophthalmology, ENT and \*\*Able to access other Division 6 nurses when studies are active. \* Band refers to the grade of nurse/research assistant as per Agenda for Change <https://www.nhsemployers.org/pay-pensions-and-reward/agenda-for-change/pay-scales/annual>. Band 7 is considered a senior nurse.

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Supplementary File 2. Table 2. Summary and recommendations

Recommendations for normalising research in critical care
<b>Organisational factors:</b>
<ul style="list-style-type: none"> <li>○ Training: Offer Good Clinical Practice (GCP)/research training for all staff on induction; Research staff running GCP sessions for critical care staff</li> <li>○ Offer research training by research staff for critical care nurses/AHPs to recruit/learn about research processes</li> <li>○ Negotiation of leveraged funding to ensuring staffing and trial continuity; maintain a broad study portfolio</li> <li>○ Work on engagement and links with ED and other research departments in the same NIHR divisions to support teams</li> </ul>
<b>Human and Unit resources</b>
<ul style="list-style-type: none"> <li>○ Offer trainee fellowships to support medical trainees wanting a career in research</li> <li>○ Create rotational nursing posts in critical care, overseen by senior research nurses</li> <li>○ Facilitate reciprocal working between ICU staff and research teams; research staff working in ICU to enhance links and recruitment opportunities</li> <li>○ Create more career structures for doctors, AHPs and nurses working in critical care research (through each of the bands, so there is an identified progression ladder up to the most senior grade)</li> <li>○ Incentivise clinical staff with training opportunities (e.g. create and offer free study opportunities in a clinical area associated with the relevant study)</li> </ul>
<b>Clinician factors</b>
<ul style="list-style-type: none"> <li>○ Communication and interdisciplinary working: Attend senior nurse/clinical meetings in critical care</li> <li>○ Create link nurse positions (to be extended to link trainee positions)</li> <li>○ Ensure early scoping of capacity/equipose concerns by research team</li> </ul>
<b>Study/trial factors</b>
<ul style="list-style-type: none"> <li>○ Consider/request trial amendments in studies that are difficult to recruit to</li> <li>○ Engage with and attend unit staff meetings early on in study planning to identify potential study barriers (such as out of hours pharmacy provision)</li> </ul>
<b>Patient/family factors</b>
<ul style="list-style-type: none"> <li>○ Create tools/training/peer review to aid conveying complex information to families and patients</li> </ul>

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- Have visible evidence of research activity in the unit (e.g posters) so it is apparent that research is part of routine care

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# Reporting checklist for qualitative study.

Based on the SRQR guidelines.

## Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SRQR reporting guidelines, and cite them as:

O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. Standards for reporting qualitative research: a synthesis of recommendations. *Acad Med.* 2014;89(9):1245-1251.

	Reporting Item	Page Number
	#1 Concise description of the nature and topic of the study identifying the study as qualitative or indicating the approach (e.g. ethnography, grounded theory) or data collection methods (e.g. interview, focus group) is recommended	1
	#2 Summary of the key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results and conclusions	1
Problem formulation	#3 Description and significance of the problem / phenomenon studied: review of relevant theory and empirical work; problem statement	3
Purpose or research question	#4 Purpose of the study and specific objectives or questions	3
Qualitative approach and research paradigm	#5 Qualitative approach (e.g. ethnography, grounded theory, case study, phenomenology, narrative research)	4

and guiding theory if appropriate; identifying the research paradigm (e.g. postpositivist, constructivist / interpretivist) is also recommended; rationale. The rationale should briefly discuss the justification for choosing that theory, approach, method or technique rather than other options available; the assumptions and limitations implicit in those choices and how those choices influence study conclusions and transferability. As appropriate the rationale for several items might be discussed together.

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16	Researcher	#6	Researchers' characteristics that may influence the	4
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19			and / or presuppositions; potential or actual interaction	
20			between researchers' characteristics and the research	
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27	Context	#7	Setting / site and salient contextual factors; rationale	4
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29	Sampling strategy	#8	How and why research participants, documents, or	4
30			events were selected; criteria for deciding when no	
31			further sampling was necessary (e.g. sampling	
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36	Ethical issues pertaining	#9	Documentation of approval by an appropriate ethics	4
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53	Data collection	#11	Description of instruments (e.g. interview guides,	4
54	instruments and		questionnaires) and devices (e.g. audio recorders) used	
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1	Units of study	#12	Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	5
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14	Data analysis	#14	Process by which inferences, themes, etc. were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale	4
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21	Techniques to enhance trustworthiness	#15	Techniques to enhance trustworthiness and credibility of data analysis (e.g. member checking, audit trail, triangulation); rationale	4
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27	Syntheses and interpretation	#16	Main findings (e.g. interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	5
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32	Links to empirical data	#17	Evidence (e.g. quotes, field notes, text excerpts, photographs) to substantiate analytic findings	6
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36	Intergration with prior work, implications, transferability and contribution(s) to the field	#18	Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application / generalizability; identification of unique contributions(s) to scholarship in a discipline or field	10
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45	Limitations	#19	Trustworthiness and limitations of findings	11
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48	Conflicts of interest	#20	Potential sources of influence of perceived influence on study conduct and conclusions; how these were managed	2
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1 <https://www.goodreports.org/>, a tool made by the [EQUATOR Network](#) in collaboration with  
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# BMJ Open

## A synthesis of qualitative research studies regarding the factors surrounding UK critical care trial infrastructure

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2019-030815.R2
Article Type:	Original research
Date Submitted by the Author:	17-Sep-2019
Complete List of Authors:	Pattison, Natalie; University of Hertfordshire and East & North Hertfordshire NHS Trust, School of Health and Social Work; University of Hertfordshire Arulkumaran, Nishkantha; UCL, Critical Care O'Gara, Geraldine; Royal Marsden Hospital NHS Trust Connolly, Bronwen; King's College London, Lane Fox Respiratory Unit Humphreys, Sally; West Suffolk Hospitals NHS Trust, Critical Care Walsh, Tim; University of Edinburgh Royal Infirmary Edinburgh, Critical Care Hopkins, Philip; Kings College Hospital, Critical Care Dark, Paul; University of Manchester, Intensive Care Unit
<b>Primary Subject Heading</b>:	Intensive care
Secondary Subject Heading:	Qualitative research
Keywords:	Qualitative synthesis, Critical care trials, Barriers, Facilitators, Normalising Research, Access to Research

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4 **Title:** A synthesis of qualitative research studies regarding the factors surrounding UK  
5 critical care trial infrastructure  
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#### 24 **Abstract:**

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Conducting clinical trials in critical care is integral to improving patient care. Unique practical and ethical considerations exist in this patient population that make patient recruitment challenging, including narrow recruitment timeframes and obtaining patient consent often in time-critical situations. Units currently vary significantly in their ability to recruit according to infrastructure and level of research activity.

#### 40 **Aim**

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To identify variability in the research infrastructure of UK intensive care units (ICUs) and their ability to conduct research and recruit patients into clinical trials.

#### 46 **Design**

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We evaluated factors related to intensive care patient enrolment into clinical trials in the UK. This consisted of a qualitative synthesis carried out with two datasets of in-depth interviews (distinct participants across the two datasets) conducted with 27 intensive care consultants (n=9), research nurses (n=17) and trial coordinators (n=1) from 27 units across the UK. Primary and secondary analysis of two datasets (one dataset had been analysed previously) was undertaken in the thematic analysis.

## Findings

The synthesis yielded an overarching core theme of Normalising Research, characterised by motivations for promoting research and fostering research-active cultures within resource constraints, with six themes under this to explain the factors influencing critical care research capacity: Organisational, Human, Study, Practical resources, Clinician, and Patient/family factors. There was a strong sense of integrating research in routine clinical practice, and recommendations are outlined.

## Conclusions

The central and transferable tenet of Normalising Research advocates the importance of developing a culture where research is inclusive alongside clinical practice in routine patient care and is requisite for all healthcare individuals from organisational to direct patient contact level.

**Keywords:** Qualitative synthesis; critical care trials; access to research; barriers; facilitators; normalising research

**Revised word count: 4688**

## Article Summary

### Strengths and limitations:

#### Strengths

- This qualitative synthesis uniquely draws together two datasets exploring the factors that enable or hinder critical care research and presents an overarching theme of normalising research, outlining factors necessary to achieve this.
- The dataset and purposive sample encompasses 14 out of 16 of the National Institute for Health's Clinical Research Networks across England and Wales, reflecting a broad range of research experiences in critical care units.
- The synthesis builds on previous research and highlights how integration and normalisation of research in clinical practice requires several interrelated factors including training, cultural receptivity, adequate funding, flexible study designs, good communication and interdisciplinary working at all levels, and a flexible staffing approach.

#### Limitations

- While we noted some similar challenges to study outside the UK, this study used two datasets solely from the UK, which has a robust critical care research infrastructure and may differ from other challenges across the world.
- This study focussed on samples from both research-active and non-research active units, however the qualitative purposive sampling, and small sample size (n=27) may have led to a sampling bias, meaning that the issues raised do not reflect all the issues encountered in practice.

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4 Health Research Comprehensive Research Network in Critical Care (NIHR Theme Hub C  
5 King's College London).  
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9 **Competing interests: The authors have none to declare.**  
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## 30 **Background**

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32 Clinical trials in critical care are integral to improving patient care, albeit unique practical  
33 and ethical challenges exist including the time-sensitive nature of treatment and enrolling  
34 patients who lack capacity.[1] Data exploring barriers to conducting clinical trials in this  
35 setting are scarce, but include managing changing clinical courses, communication  
36 breakdowns, and requests for more time for consent [2]. Our previous study, focussing on  
37 research active centres,[3] described enhanced patient recruitment in centres valuing  
38 research with equal importance to clinical care, with the most commonly cited barriers  
39 insufficient human and financial resource, inadequate personnel funding, and limited career  
40 opportunities impeding staff retention.[3] Several additional factors may also preclude  
41 recruitment, such as lack of clinician equipoise and competing clinical commitments.  
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## 50 Implications for the NIHR

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52 The UK National Institute for Health and Research (NIHR) is the government-funded  
53 research arm of the National Health Service (NHS), responsible for driving bench-to-bedside  
54 research with tangible patient benefit [4]. Unique infrastructure, including the national  
55 coordinated Clinical Research Network (CRN) and specialty groups (SG) with oversight for  
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3 specific clinical areas such as critical care (CC), enhance the UK's national and international  
4 position to deliver high quality clinical trials. Research teams invest significantly in  
5 recruitment to critical care trials with emphasis on mitigating modifiable factors. In  
6 particular understanding barriers and facilitators in institutions which are less research-  
7 active, such as non-university-affiliated hospitals, is crucial to enhance trial recruitment  
8 across the NIHR CRN.  
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15 Our objective was therefore to identify examples of these potential barriers and facilitators  
16 to patient enrolment in order to inform strategies to enhance future critical care trial  
17 recruitment, and identify how research staff could be supported in these organisations.  
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## 23 **Methods**

### 24 Design

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26 A qualitative synthesis was conducted [5], involving two datasets comprising in-depth  
27 interviews (n=27) with critical care consultants (n=9), research nurses (n=17), and trial  
28 coordinators (n=1) across England and Wales (26 hospitals; 27 units). Dataset 1 included 10  
29 participants and is reported in detail elsewhere [3]. For that dataset a sampling frame across  
30 the CRNs was used to represent a mix of smaller and larger ICUs, from teaching hospitals  
31 and district general type hospital ICUs, including one person within each CRN to ensure  
32 region-wide representation. Dataset 2, a follow-on study, included a further 17 participants  
33 from different backgrounds/units, with the aim of specifically exploring issues in less  
34 research-active critical care units. Service evaluation and quality improvement methods  
35 underpinned the projects.[6] Therefore, this synthesis involved both primary and secondary  
36 data analysis. Qualitative synthesis is a well-established method that draws together  
37 findings to reach over-arching themes.[5], ensuring similar research can be reliably  
38 compared.[7,8,9]  
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### 54 Patient public involvement

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56 Patient/public were not involved in the design of this study since the focus is on research  
57 infrastructure.  
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### Data collection

Individual telephone, digitally audio-recorded, interviews were conducted with participants, using a pre-determined semi-structured interview schedule agreed by team consensus. The aim of the second set of interviews was to understand how to engage and promote research activity and increase trial recruitment in critical care units that find it challenging to recruit to trials. Interview questions included: *What can you tell me about how the unit decides whether to participate in a research project? Tell me about the infrastructure in your critical care unit to support research.* See Supplementary file 1 for interview questions. Written and verbal information about the project was provided and confidentiality was assured. Transcripts were anonymised prior to analysis. Team review of both the interview structure, which was refined as interviews progressed in both datasets (including more targeted questions to elicit nuances such as local capacity to conduct research) and also informed refinement of the framework analysis, [10] enhanced dependability in research findings and qualitative rigour through developing credibility and transferability.[11]

### Ethical considerations

The study was supported and facilitated by the NIHR Critical Care Specialty Group (NIHR CCSG). No ethical approval or written consent, as per the UK Health Research Authority, was required since only anonymised data with staff were used. No local institutional Research & Development approval was deemed necessary, since this was a project to represent views on behalf of the NIHR CCSG and recruitment did not take place via institutions. Demographic data about each critical care unit's research activity and staffing were also collected. Participation was voluntary and verbal consent was obtained both before and after the interview, to allow interviewees the opportunity to withdraw/withhold any data discussed.

### Settings

Two purposive samples were recruited, with the aim of representing different regions and professional grades (critical care nurses, trainees, trial co-ordinators and consultants) across

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3 the UK. The purposive sampling technique involved maximum variation sampling,[12] using  
4 UK trial accrual and activity data from the NIHR. The aim was to include clinicians  
5 representing critical care units across the 16 CRNs (15 in England, one in Wales).  
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7 Specifically, the second dataset focused on units with limited trial recruitment, or engaged  
8 in few trials. We did not ascribe a set value to define 'less research active', but focused on  
9 unit-level activity in terms of participants recruited and active studies, according to NIHR  
10 yearly summary data. The NIHR centralises this information in a 'portfolio', and all sites are  
11 required to submit this information. Invites were circulated via the NIHR network using  
12 established mailing lists, and targeted recruitment to ensure unbiased representation.  
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14 Using the principles of theoretical sampling (as used most commonly in Grounded  
15 Theory),[13,14] a sample size of 20-30 interviews was deemed sufficient to reach data  
16 saturation and build up a comprehensive picture of the UK landscape in relation to factors  
17 that influence critical care research provision.  
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### 30 Analysis

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32 Themes were explored at an overall and ICU-specific level. Potential barriers/facilitators  
33 within individual critical care units, hospitals, locally and nationally were identified. In both  
34 datasets, analysis was conducted using thematic analysis, a technique congruent with  
35 different types of qualitative research, [15] aided by principles of framework analysis,[10]  
36 where categories were refined as analysis progressed. Data from verbatim transcripts were  
37 coded at a line level, with sub-themes derived from those codes applied to a framework,  
38 with constant comparison. Datasets were compared and contrasted, and a new framework  
39 was devised, and all data were re-analysed according to this. An independent researcher  
40 verified the analysis on anonymised data to enhance dependability and we coded to reach  
41 consensus in the case of coding differences. The framework provided a further degree of  
42 dependability in regards to analysis,[11] and allowed for contextual differences to emerge.  
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44 The matrix provided detail of within case and cross-case analysis,[14] which was developed  
45 into themes.  
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### **Findings**



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3 In Dataset 1 (collected in 2015), 10 interviews were conducted across nine CRN regions  
4 across England (n=8) and Wales (n=1). Dataset 2 (collected 2016/17) included 17 interviews  
5 conducted across 12 English CRNs. Two CRNs were not represented due to lack of response.  
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7 Interviews ranged from 29-81 minutes (mean length was 45.2 mins). The framework  
8 analysis for each studies yielded six main themes. Demographics are supplied in Table 1,  
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10 Supplementary file 2.  
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### 17 Overarching findings from synthesis

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20 There was an overarching theme of *Normalising Research*, describing the notion that critical  
21 care research should be entrenched in routine practice. Six sub-themes existed around this  
22 central tenet: *Organisational, Human and Unit Resources, Study, Clinician, and*  
23 *Patient/family factors*. Resource issues permeated each theme to a different extent and  
24 were evident throughout the organisational, unit, study, or trial level, and at a human,  
25 individual level. Resources could be managed and influenced at an individual level, for  
26 instance. In centres, units, and teams where research activity was regarded with equal  
27 importance as clinical activity, research was considered routine practice. In turn, teams and  
28 individuals with a strong sense of integrating research in routine practice acted as the  
29 motivating driving force fostering a research culture, whether in primary, translational  
30 biomedical, or applied health services streams. A broader cultural influence from  
31 organisations was also evident, where research was seen as critical to organisational values,  
32 up to executive level, which in turn contributed to enhanced research activity. Barriers and  
33 enablers to trial recruitment and conduct are outlined in each theme below. A summary of  
34 these factors is outlined in Supplementary file 3, Table 1 and represented in Figure 1.  
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### 48 Organisational factors

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50 This theme related to the organisational system in which units were situated, and  
51 incorporated Trust or Board level factors; perceived priority of research; infrastructure; trial  
52 planning; funding and external links, such as academia. Research-active and less research-  
53 active institutions contrasted with regards prioritisation of research activity by senior  
54 management, with the latter placing lower profile on the support and conduct of research.  
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3 This was particularly marked at challenging times e.g. during care failure reports, or financial  
4 or bed crises, even though these could be opportune periods for potential trial enrolment.  
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7 “Research and development is not high profile. At an organisational level it is service  
8 driven, research is seen as an aside and there is no support for it.” (Research nurse 2,  
9 study 2)  
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13 Despite income-generating research activity, such as involvement in commercial studies,  
14 increased demand on resources posed a limitation to engagement. Some critical care  
15 research leads had to seek executive and/or Research and Development Department (R&D)  
16 approval prior to confirming participation, while others could make these decisions  
17 unilaterally. Centre factors also determined how trials were embedded through initiatives  
18 that increased engagement such as simulated trial runs. Embedding research into routine,  
19 or what was perceived as ‘normal’, care required a conceptual shift.  
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27 “No, research is not a priority. New [intensive care unit] ICU consultants very keen,  
28 as are research [specialist registrars] SpRs. The resistance mainly comes from  
29 nurses. It is about perceived additional work or disagreement with the protocol. .  
30 .it’s not part of routine care” (Research nurse 4, study 1)  
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35 “Research should be part of everyone’s job. If prescribed it should be given,  
36 regardless of it is [part of] research or not.” (Research nurse 3, study 2)  
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39 “The Trust don’t adequately prioritise research; the management don’t ‘get it’ and  
40 [the] financial position takes precedence.” (Consultant intensivist 13, study 2)  
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44 The nature of funding for research nurses, primarily funded via the CRNs and dependent on  
45 trial activity levels, created significant challenges to research conduct, given the lack of  
46 continuity. Some units ensured varied funding sources beyond the NIHR, to include  
47 commercial and higher education, and internally managed their own research budgets. This  
48 successfully allowed flexibility in deciding which trials to undertake, and managing staffing  
49 and out-of-hours support. Planning for future trials was evidently problematic on occasion.  
50 During periods with fewer critical care trials, many research teams broadened activity to  
51 cover Emergency Department (ED) and anaesthetic trials. Whilst this maintained research  
52 activity overall, it also resulted in research teams being stretched across many studies and it  
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3 was hard to focus on critical care trials when activity in this area resumed. For university or  
4 university-affiliated hospitals, additional support for research overall could be obtained  
5 through links with academia.  
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9 “We have a historical arrangement with the University that they will fund a unit-based  
10 research fellow for a year.” (Consultant intensivist 11, study 2)  
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### 13 Human and Unit resources

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16 These sub-themes are reported together since they were closely aligned, and incorporated  
17 staffing; reciprocity within research and ICU teams; models of provision; management;  
18 research opportunities and career structures (nurses/trainees). Staffing was a factor  
19 affecting research delivery. Varied models existed for staffing research teams, from  
20 rotational and secondments out of critical care, cross-hospital site and cross-specialty  
21 working, to research staffing being managed via the CRN. Most research staff had a clinical  
22 critical care background, which facilitated fluid working arrangements and carryover of  
23 research skills to non-research staff.  
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31 “We instigated rotation of three months from ICU into the research team for 3  
32 months, introducing fresh people and it invigorated the team.” (Research nurse 15,  
33 study 2).  
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38 Many participants commented that while critical care research staff could cover other  
39 specialties, reciprocal cover for critical care was less successful given the unique patient  
40 population and the time-limited nature of recruitment, and this was often poorly  
41 appreciated by hospital R&D and regional CRN level. Research staff with a clinical  
42 background in critical care found communication easier and were able to support clinical  
43 staff, thus developing a mutually beneficial working relationships and helping with the  
44 normalisation of research. Grading of research nurse positions and lack of career  
45 development was identified as problematic; line management (direct management of the  
46 individual) was at times with the regional CRN offices, rather than the local critical care unit.  
47 Some research-active centres created attractive positions that afforded career progression  
48 and mitigated against job insecurity, a common feature of research nurse roles that are  
49 primarily funded on a yearly contract basis via the CRNs.  
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3 “The career ladder is limited for them and so they move to management or work in  
4 R&D roles, and the use of temporary contracts is demoralising and a disincentive.”

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7 (Consultant intensivist 1, study 1)  
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9 Few consultants received programmed activity (PA) sessions specifically for research,  
10 especially within non-university affiliated hospitals. Many clinicians relied upon financial  
11 support and time from their organisations to undertake research activity.  
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15 “They do it effectively out of interest, there is nothing in their job plan apart from a  
16 reference to research, but no time to actually do it. . .it is voluntary and many don’t  
17 do it” (Research nurse 4, study 2)  
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21 This lack of support overlaps with the organisational theme; allocated time and finances to  
22 support research activity was rare, occurring only in centres where research was viewed as  
23 core activity. Few medical trainees had the opportunity for research involvement, and again  
24 primarily only in research-active centres with novel initiatives designed to engage those  
25 interested in research e.g. year-long fellowships where research activity contributed to their  
26 training programme. Limited time was also a factor: “we have had less [trainees] over the  
27 years, enthusiasm fades and other things take over” (Consultant intensivist 9, study 2).  
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29 However, short clinical placements precluded meaningful trainee participation in primary  
30 research.  
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39 “They mainly don’t get involved and when [they do], they don’t do their own  
40 research” (Research nurse 15, study 2)  
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43 Designated trial coordinators were rare in smaller non-university-affiliated hospitals with  
44 less opportunity to enrol patients. Unit, staffing and centre factors were closely associated  
45 in the two datasets. Unit factors pertained to strategies to enhance engagement, provision,  
46 recruitment and delivery of critical care research. These varied from simulated runs of  
47 screening, recruitment and intervention, to teaching programmes and incentive schemes.  
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49 Having a physical presence on the unit was seen as a crucial element for ensuring clinical  
50 credibility.  
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57 “You need to be there, being present, going on ward rounds and to handovers...”  
58 (Research nurse 14, study 2).  
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3 Driven individuals were critical to success in recruitment and study conduct, with both  
4 research nurses and consultants assuming principal investigator roles.  
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### 10 Study/trial factors

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12 This sub-theme was characterised by study practicalities and how studies could be  
13 actualised within internal and external constraints. There were process and infrastructure  
14 issues associated with studies that affected the team's ability to conduct the trial.  
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18 Trial complexity appeared a considerable factor contributing to trial success, in terms of  
19 acceptance by local staff and potential ability to achieve recruitment targets.  
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23 "The complexity of the study and study information is a problem, for staff as well as  
24 families. . . It's easier to explain CTIMPS [Clinical Trials of Investigational Medicinal  
25 Products] versus devices and it's easier to gain consent in a complex study with a  
26 family who can understand." (Consultant intensivist 2, study 1).  
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31 Feasibility and capacity assessment moderated concerns about delivering to time and  
32 target, a national metric captured by the NIHR CRN. Studies requiring significant pharmacy  
33 support, such as Clinical Trials of Investigational Medicinal Products had variable success  
34 with implementation and recruitment. Some units reported pressure from the regional CRN  
35 and local R&D departments to undertake high-recruiting studies that yielded maximum  
36 income generation, rather than complex studies perceived as interesting but with low  
37 recruitment targets that might yield less or insufficient income to cover costs.  
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43 Demonstrating quick, tangible 'wins' for an organisation and staff, through health service  
44 research, helped engagement.  
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48 Complex studies were considered problematic for balancing effort against outcomes  
49 achieved, in particular around training requirements for staff to implement detailed  
50 interventions, and strict eligibility criteria with narrow recruitment windows leading to few,  
51 if any, patients enrolled. Studies requiring significant preparation, including co-enrolment  
52 agreements, time-scheduling, competing population assessment, and importantly, ensuring  
53 unit staff were committed and had clinical equipoise, could be particularly challenging:  
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3 "they say they have equipoise, but when it comes down to it, they don't, you get  
4 surreptitious opposition and stark persuasion is used in those situations."  
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7 (Consultant intensivist 1, study 1)  
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9 Time associated with daily screening was also a factor influencing success of complex trials,  
10 as often this could not be performed remotely and required extensive clinical data review.  
11 In keeping with study set-up, funding was rarely allocated for this activity, or for follow-up.  
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13 In units where research was considered part of routine practice, clinical staff also helped  
14  
15 with identification of potential participants.  
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19 "There needs to be appropriate costing of studies including NHS support costs, for  
20 drugs for example. . .long-term follow-up needs to be considered as well."  
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23 (Consultant intensivist 6, study 2)  
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25 Strategies to facilitate complex trials included engagement with local clinical staff on the  
26 relevant unit to integrate the trial procedures with standard care, thereby enabling all staff  
27 to contribute to patient screening and enrolment, including out-of-hours. Units could  
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29 achieve this through training and cross-team working.  
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### 38 Clinician factors 39

40 This theme focused on how unit clinicians, nurses, trainees and intensivists, were perceived  
41 as engaged in research; this did not appear linked to how research-active an organisation  
42 was. Where research staff originated from the unit this was a facilitator, often resulting in  
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44 good team working from both clinical and research team perspectives.  
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48  
49 "We try to pick out staff nurses with initiative and encourage them to apply [for  
50 research posts]. We've had some on the team who've worked in ICU, which helps,  
51 although where there is history it can create problems." (Research nurse 3, study 2)  
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55 "We are line managed by critical care staff, which is good, rather than by R&D and  
56 we both then have influence in critical care." (Research nurse 5, study 2)  
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3 Where research was viewed as additional activity, rather than integral to patient care,  
4 research staff reported cases of open hostility, particularly early on in their roles, until unit  
5 staff developed an appreciation for research.  
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9 “I’ve tried working on the unit and taking patients and doing shifts to build  
10 relationships” (Research nurse 7, study 2)  
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13 Research resources were factored by unit staff where there was good inter-boundary  
14 working. For instance, research staff attended senior nurse meetings to identify local issues  
15 that might adversely affect recruitment. Equally, unit staff could help identify barriers to  
16 recruitment to certain studies. Creating link roles supported nurse-level engagement and  
17 enhanced out-of-hours opportunities for recruitment when research nurses were not  
18 present. Very limited funding for out-of-hours cover enforced the need for research nurse  
19 flexibility.  
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22 Equipose featured again in this theme; clinicians could undermine research activity by  
23 appearing supportive in meetings, but not in practice. Permission to recruit patients had to  
24 be negotiated at an individual clinician level, which could compromise unit objectivity  
25 toward the study.  
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28 “The consultants are all GCP [Good Clinical Practice] trained but there is mixed  
29 interest and support, ranging from active obstruction. . . , to more neutral through to  
30 full support.” (Consultant intensivist 9, study 2).  
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33 “People believe they have equipose but on the day people change what they do.”  
34 (Research nurse 5, study 2).  
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37 Investment for trainee engagement arose as an important issue, particularly in those less  
38 research-active organisations. Ensuring the next generation of critical care consultants  
39 prioritised research activity with clinical practice was recognised as imperative. Many  
40 trainees were taught to obtain patient consent. At the time of the study, regional trainee  
41 research networks were emerging across the UK. However, according to these participants,  
42 in larger portfolio NIHR trials trainee engagement was noted to be minimal, and unit  
43 pressures contributed to lack of engagement. Trainee fellowship roles successfully  
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3 addressed this in two units, with staff continuing research in their careers as consultants,  
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5 with an emphasis on personal motivation.  
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7 "we actively encourage fellows not to go onto the [unit] rota so that their role is  
8  
9 protected for research." (Consultant intensivist 11, study 2)  
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12 Personal commitment was a key factor; research activity often required working beyond  
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14 allocated hours or sessions, or flexible working out-of-hours. This demonstrated how  
15  
16 research teams worked to emphasise the sense that research should be considered the  
17  
18 norm, with efforts devoted to successful implementation comparable to efforts in clinical  
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20 practice. Skills of research nurses was a factor common to both datasets, with the ability  
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22 (and R&D permission) to consent improving recruitment. Extended skills also meant that a  
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24 number of research nursing staff were supported to undertake further study, including at  
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26 doctoral level, fostering motivation, willingness to work flexibly and promoting emergence  
27  
28 of independent researchers. Portfolio studies requiring a nurse Principal Investigator  
29  
30 particularly motivated nurses. For consultants, feelings were mixed: studies with no  
31  
32 personal interest fostered less engagement, unless it was likely to be income-generating.  
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### 35 Patient/family factors

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37 This sub-theme encompassed issues such as participant burden, support available,  
38  
39 communication, and anticipating declines to participate. Difficulties communicating  
40  
41 information about trial procedures to patients and their families was reported by  
42  
43 participants. A positive but realistic attitude was deemed essential. The volume of  
44  
45 paperwork was identified as problematic. Ensuring that patients or families fully  
46  
47 understood complex research interventions, without overburdening them at a sensitive  
48  
49 time, was seen as a central issue.  
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51 "We've got savvier about taking consent and have learnt lessons; you don't gain it by  
52  
53 giving more paper." (Consultant intensivist 1, study 1)  
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56 Managing clinical uncertainty in the context of clinical trials was difficult. Whilst it did not  
57  
58 seem to hinder recruitment, managing the process was challenging for research staff. Many  
59  
60 families agreed to assent for patients for altruistic reasons, understanding there may be no



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3 benefit to the patient. An important issue emerged in relation to addressing cultural  
4 perspectives. Different attitudes were perceived towards research, centring on trust in  
5 healthcare. Immediate dismissal by family members, on behalf of patients, was not  
6 uncommon. However, sometimes families were keen, but patients weren't.

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11 "The patient, who was not intubated [breathing tube for mechanical ventilation],  
12 had capacity and her family were keen for her to take part, but she wasn't (Research  
13 Nurse 9, study 1).  
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17 Conversely, some reported a paternalistic medical attitude still prevailing. Despite efforts to  
18 address this, provide more information and demonstrate equipoise, families and patients  
19 were reluctant and preferred to defer to doctors' opinions regarding enrolment.  
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22  
23 "I work in a deprived area with a lower level of education compared to the UK  
24 average, because of that the cultural norms mean they tend to trust what the  
25 doctors say: 'whatever you think doctor'" (Research nurse 11, study 2).  
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30 Neither of these opposing views about consent were regarded by participants as hindering  
31 recruitment. Units serving a disproportionately elderly or rural population reported  
32 difficulties gaining access to relatives for assent, particularly where time-sensitive consent  
33 was required. Research teams estimated a third of families were likely to decline  
34 participation when calculating recruitment targets and reasons for non-participation  
35 appeared to be complex and poorly understood. Where approaches to families were  
36 prefaced by an explanation that research was part of normal clinical practice in that  
37 particular unit, there was increased receptivity to recruitment. Reported preference for  
38 treatment arms was rare, and usually managed through explanation. Facilitating  
39 understanding was viewed as crucial when approaching families and patients for consent,  
40 with issues related to ongoing assessment of mental capacity also highlighted as difficult.  
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## 50 **Discussion**

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53 This synthesis outlines six inter-related themes under a new over-arching theme of  
54 *Normalising Research*. Research activity was regarded as equally important as clinical work  
55 by these participants, albeit this was acknowledged as not a representative view across all  
56 organisations or units. Where research was embedded into routine care and considered as  
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3 the norm, undertaking screening and recruitment were easier. Emphasising the need for  
4 normalcy of research at a unit, as well as organisational level, means cohesive units evolve  
5 with the unified aim of improvements in patient care as the driving force. However, there  
6 are prerequisites for normalcy, including communication towards a shared understanding  
7 [16] in this case, that research is an integral part of everyday patient care. Furthermore, this  
8 communication needs to take place at a systems level.[16] Specific issues in the synthesis  
9 related to variation in funded time and resources, clinician engagement, individual roles,  
10 and perceived gains from research, which proved noteworthy, acting as barriers or  
11 facilitators to clinical trial recruitment. Bruce et al,[1] outlined how navigating rapidly  
12 changing clinical courses and communication breakdown adversely affected recruitment.[1]  
13 That these factors did not emerge in this synthesis may reflect different healthcare systems,  
14 funding, and the larger number of hospitals. Similarities emerged related to the challenges  
15 of recruitment within a narrow timeframe. Good communication between clinical and  
16 research teams was important for successful trial implementation.

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Inclusion of data from less research-active organisations strengthens this study providing  
richer data, more transferable across the NHS and to healthcare systems in other  
jurisdictions. Our findings will resonate with other international settings where, despite  
variability in national infrastructure, similar challenges are faced by researchers. The tenet  
of normalising research transcends unit, institutional and country boundaries. Approaches  
to improve recruitment included simple incentive schemes to reward clinical staff,  
broadening the range of clinicians who could take consent. The latter is particularly  
pertinent to CTIMPs where time-limited recruitment was more relevant.[1,2] Previous work  
has suggested lack of equipoise as a barrier to enrolment[17,18]. An area for further  
exploration relates to consent waivers, already explored in some recent research [1,17,19,  
20], albeit with less known of patient and family perspectives. 'Overburdening' has been  
described previously [21] as has concern regarding making initial approaches to families  
during particularly sensitive times [19-23] but again the patient/family voice in these studies  
is largely absent.[19-21] This would be an important area for future practice and research.

In keeping with existing literature, competition between trials requiring similar patient  
cohorts and the number of eligible patients were further barriers to trial recruitment [1,24].

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3 Another factor related to lack of clear professional development opportunities and  
4 structured career paths. Recent strategy published by the NIHR offers novel career options  
5 for research staff [25-27] such as consultant research nurse models [25]. The emergence of  
6 medical trainee networks across the UK have also helped create a case for formalised  
7 processes.[28, 29] NIHR initiatives to engender a culture of research in healthcare, with  
8 every patient being offered the opportunity to participate in research aimed at improving  
9 care [30] are also reflected in these individual participants' motivations to improve care  
10 through research. Systematic review and large-scale survey evidence highlight key areas to  
11 improve trial recruitment as training site staff, communication with patients, and incentives,  
12 albeit some suggestions are not applicable to an ICU setting, such as telephone calls to non-  
13 respondents and opt-out procedures.[31,32] There have been significant advances over the  
14 past five years in critical care research recruitment.[33] In a current climate of significant  
15 fiscal pressures in the UK healthcare system with £22 billion of NHS efficiency savings to be  
16 achieved by 2020,[34] there was still a universal desire to undertake critical care research.  
17 This was driven by key motivated individuals who viewed research as integral to best  
18 practice and normal care provision, as well as deriving evidence to drive and support best  
19 use of resources.

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35 This qualitative synthesis draws together two sets of original research findings. Whilst data  
36 were not collected simultaneously, both studies complemented each other. The second  
37 study built on the first by focusing specifically on a target participant cohort not initially  
38 represented in order to generate novel data to further understand the question at hand.  
39 Limitations include the timeframe between acquisition of each dataset, which although  
40 short (twelve months), might have resulted in practice changes occurring between the two  
41 data collection points. Potential sampling bias from recruiting primarily research-active units  
42 in the first dataset, was mitigated by employing purposive recruitment in the second dataset  
43 from less research-active units. Research-active and less research-active units were defined  
44 both on subjective reports from individuals, and standardised objective metrics, however  
45 this subjective/objective mix and lack of clarity could have introduced further sampling bias.  
46 We also only achieved interviews with 14 out of 16 CRNs, potentially missing important  
47 information from the other two CRNs. We also acknowledge the possible introduction of  
48 bias through refining the interview schedule as we proceeded through the interviews.  
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3 Qualitative research is often criticised for lack of generalisability, due to sample size  
4 limitations, but notions of transferability can be considered [8,11] and what Payne and  
5 Williams term 'moderatum generalisations'. [35] This is where core conceptual principles  
6 from the research, which would make sense across setting can be applied. Figure 1. outlines  
7 a summary of the main points and four key areas for learning. The core concept of  
8 Normalising Research can feasibly be applied beyond critical care trials recruitment, across  
9 the full spectrum of clinical specialties represented within the NIHR, as well as  
10 internationally.  
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## 21 **Conclusion**

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23 This qualitative synthesis integrating two original datasets has yielded recommendations for  
24 improving trials recruitment in the unique clinical specialty of critical care. Several  
25 suggestions are made from the six themes that emerged: Organisational, Human, Study,  
26 Practical resources, Clinician, and Patient/family factors, under the overarching theme of  
27 Normalising Research, that relate to enhanced staffing, training, trial design and  
28 communication. Fostering a culture where research is considered part of routine patient  
29 care must be the ultimate goal for those working at all levels, from organisational to  
30 bedside.  
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49 gave up their time to contribute.  
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54 **Author contributions:** NP conceived the project and was the lead, undertaking primary data  
55 collection and analysis of the two datasets, and the overall synthesis. GOG independently  
56 verified the first dataset and contributed to data analysis of the second dataset. NA  
57 contributed to the design, data collection and manuscript write-up. PD, PH and TW  
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3 contributed to the design. SH and BC contributed to data collection, analysis and  
4 manuscript preparation. All authors have reviewed and contributed to the manuscript. NP  
5 is the custodian of the intellectual integrity and property arising from this project.  
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9 Patient consent: Not required.  
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11 Provenance and peer review Not commissioned; externally peer reviewed.  
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14 Data sharing statement: All data pertaining to this study are reported in this manuscript.  
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## 17 18 19 20 **References**

- 21  
22 1. Bruce CR, Liang C, Blumenthal-Barby JS, Zimmerman J, Downey A, Pham L, Thieret L,  
23 Delgado E, White D. Barriers and Facilitators to Initiating and Completing Time-Limited Trials  
24 in Critical Care. *Critical Care Medicine*. 2015. 43(12):2535-2543.  
25  
26
- 27 2. Kaur G, Smyth RL, Williamson P. Developing a survey of barriers and facilitators to  
28 recruitment in randomized controlled trials. *Trials*. 2012;13:218.  
29  
30
- 31 3. Pattison N, Arulkumaran N, Humphreys S, Walsh T. (2017) Exploring obstacles to critical  
32 care trials in the UK: A qualitative investigation. *Journal of the Intensive Care Society*. 18(1):  
33 36-46  
34  
35
- 36 4. National Institute of Health Research (NIHR) (2016) NIHR: Our Purpose  
37 Available at: <http://www.nihr.ac.uk/about-us> (accessed 21.1.17)  
38  
39
- 40 5. Barnett-Page E, Thomas J. Methods for the synthesis of qualitative research: a critical  
41 review. ESRC National Centre for Research Methods. 2009 NCRM Working Paper Series  
42 Number (01/09)  
43  
44
- 45 6. Health Research Authority. Defining Research. Available at:  
46 <http://www.hra.nhs.uk/documents/2016/06/defining-research.pdf> (accessed 24.5.17)  
47  
48
- 49 7. Heyvaert, M., Maes, B. & Onghena, P. Mixed methods research synthesis: definition,  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

- 1  
2  
3 framework, and potential Qual Quant 2013 47: 659. doi:10.1007/s11135-011-9538-6  
4  
5  
6 8. Finfgeld-Connett D. Generalizability and transferability of meta-synthesis research  
7  
8 findings. Journal of Advanced Nursing 2010. 66 (2), 246-254  
9  
10  
11 9. Eaves YD. A synthesis technique for grounded theory data analysis. Journal of Advanced  
12  
13 Nursing 2001 35:654-63  
14  
15  
16 10. Ritchie J, Spencer L. Qualitative data analysis for applied policy research. In: Bryman A,  
17  
18 Burgess R, editors. Analysing qualitative data. London: Routledge; 1994. pp. 173–194.  
19  
20  
21 11. Lincoln YS, Guba EG. Naturalistic Inquiry. Newbury Park, CA: Sage Publications. 198 12.  
22  
23 Suri H. Purposeful sampling in qualitative research synthesis. Qual Res J. 2011;11:63–75.  
24  
25  
26 13. Glaser BG, Strauss AL. The Discovery of Grounded Theory. Strategies for Qualitative  
27  
28 Research. 1967. Chicago: Aldine Publishing  
29  
30  
31 14. Miles MB, Huberman AM. An Expanded Sourcebook: Qualitative data Analysis. 2nd  
32  
33 Edn.1994. Sage Publications, Thousand Oaks, California, US.  
34  
35  
36 15. Boyatzis, R. E. (1998). *Transforming qualitative information: Thematic analysis and code*  
37  
38 *development*. Thousand Oaks, CA: Sage.  
39  
40  
41 16. Habermas J. The theory of communicative action: Vol 2. Lifeworld and system. A critique  
42  
43 of functionalist reason. 1987 Beacon Press Boston MA  
44  
45  
46 17. Morgenweck CJ. Innovation to research: some transitional obstacles in critical care units.  
47  
48 Crit Care Med. 2003 Mar;31(3 Suppl):S172-7  
49  
50  
51 18. Donovan JL, de Salis I, Toerien M, Paramasivan S, Hamdy FC, Blazeby JM. The intellectual  
52  
53 challenges and emotional consequences of equipoise contributed to the fragility of  
54  
55 recruitment in six randomized controlled trials. J Clin Epidemiol. 2014 Aug;67(8):912-20  
56  
57  
58 19. Bigatello LM, George E, Hurford WE. Ethical considerations for research in critically ill  
59  
60 patients. Crit Care Med. 2003 Mar;31(3 Suppl):S178-81.

- 1  
2  
3 20. Lim DA, Chan MF, Childs C. Surrogate consent for critical care research: exploratory  
4 study on public perception and influences on recruitment. *Crit Care*. 2013 Jan 15;17(1):R5.  
5  
6  
7  
8 21. Mehta S, Quittnat Pelletier F, Brown M, Ethier C, Wells D, Burry L, MacDonald R. Why  
9 substitute decision makers provide or decline consent for ICU research studies: a  
10 questionnaire study. *Intensive Care Med*. 2012 Jan;38(1):47-54.  
11  
12  
13  
14  
15 22. Dear RF, Barratt AL, Tattersall MH. Barriers to recruitment in cancer trials: no longer  
16 medical oncologists' attitudes. *Med J Aust*. 2012 Feb 6;196:112-3.  
17  
18  
19  
20  
21 23. Majesko A, Hong SY, Weissfeld L, White DB. Identifying family members who may  
22 struggle in the role of surrogate decision maker. *Crit Care Med* 2012. Aug;40(8):2281-6.  
23  
24  
25  
26 24. Dickson S, Logan J, Hagen S, Stark D, Glazener C, McDonald AM, McPherson G. Reflecting  
27 on the methodological challenges of recruiting to a United Kingdom-wide, multi-centre,  
28 randomised controlled trial in gynaecology outpatient settings. *Trials*. 2013 Nov 15;14:389.  
29  
30  
31  
32  
33 25. Currey J, Considine J, Khaw D. Clinical nurse research consultant: a clinical and academic  
34 role to advance practice and the discipline of nursing. *J Adv Nurs*. 2011 Oct;67(10):2275-83.  
35  
36  
37  
38 26. National Institute for Health Research. NIHR Clinical Research Network: Developing our  
39 Clinical Research Nursing Strategy 2017-2020. 2017. Available at:  
40 [https://www.nihr.ac.uk/our-faculty/clinical-research-](https://www.nihr.ac.uk/our-faculty/clinical-research-staff/clinical-research-nurses/Clinical%20Research%20Nurse%20Strategy%202017_2020FINAL.pdf)  
41 [nurses/Clinical%20Research%20Nurse%20Strategy%202017\\_2020FINAL.pdf](https://www.nihr.ac.uk/our-faculty/clinical-research-staff/clinical-research-nurses/Clinical%20Research%20Nurse%20Strategy%202017_2020FINAL.pdf). Accessed  
42 1.9.18.  
43  
44  
45  
46  
47  
48 27. National Institute for Health Research. NIHR Clinical Research Network: NIHR CRN Allied  
49 Health Professionals Strategy 2018-2020. 2018. [https://www.nihr.ac.uk/our-faculty/clinical-](https://www.nihr.ac.uk/our-faculty/clinical-research-staff/Allied%20Health%20Professionals/Allied%20Health%20Professionals%20Strategy%202018_2020.pdf)  
50 [research-](https://www.nihr.ac.uk/our-faculty/clinical-research-staff/Allied%20Health%20Professionals/Allied%20Health%20Professionals%20Strategy%202018_2020.pdf)  
51 [staff/Allied%20Health%20Professionals/Allied%20Health%20Professionals%20Strategy%20](https://www.nihr.ac.uk/our-faculty/clinical-research-staff/Allied%20Health%20Professionals/Allied%20Health%20Professionals%20Strategy%202018_2020.pdf)  
52 [2018\\_2020.pdf](https://www.nihr.ac.uk/our-faculty/clinical-research-staff/Allied%20Health%20Professionals/Allied%20Health%20Professionals%20Strategy%202018_2020.pdf). Accessed 1.9.18.  
53  
54  
55  
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58  
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- 1  
2  
3 28. Shaw M, Harris B, Bonner S. The research needs of an ICM trainee: The RAFT national  
4 survey results and initiatives to improve trainee research opportunities. *Journal of the*  
5 *Intensive Care Society*. 2017;18(2):98-105.  
6  
7  
8  
9 29. Moore JN, McDiarmid AJ, Johnston PW, Cleland JA. Identifying and exploring factors  
10 influencing career choice, recruitment and retention of anaesthesia trainees in the UK.  
11  
12  
13  
14 Postgrad Med J. 2016 Jun 15. pii: postgradmedj-2015-133518. doi: 10.1136/postgradmedj-  
15 2015-133518. [Epub ahead of print]  
16  
17  
18  
19 30. Brown H, Hewison A, Gale N, Snelling I, Shneerson C. Every patient a research patient.  
20  
21  
22 Evaluating the state of research in the NHS. A report commissioned by CRUK, 2015.  
23  
24  
25 University of Birmingham.  
26  
27 31. Bower P, Brueton V, Gamble C, Treweek S, Tudur Smith C, Young B Williamson P  
28  
29 Interventions to improve recruitment and retention in clinical trials: a survey and workshop  
30 to assess current practice and future priorities *Trials*. 2014 15:399  
31  
32  
33  
34 32. Treweek S, Mitchell E, Pitkethly M, Cook J, Kjeldstrøm M, Johansen M, Taskila TK,  
35  
36  
37 Sullivan F, Wilson S, Jackson C, Jones R, Lockhart P: Strategies to improve recruitment to  
38  
39 randomized controlled trials. *Cochrane Database Syst Rev*. 2010, : -MR000013  
40  
41  
42 33. Walsh T, Brett S. What are the priorities for future success in critical care research in the  
43  
44  
45 UK? Report from a national stakeholder meeting. *Journal of the Intensive Care*  
46  
47  
48 *Society*. November 2015 vol. 16 no. 4 287-293  
49  
50  
51 34. Dunn P, McKenna H, Murray R. Deficits in the NHS 2016. The Kings Fund. Available at:  
52  
53  
54 <https://www.kingsfund.org.uk/publications/deficits-nhs-2016> (accessed Sep 1st 2018)  
55  
56  
57 35. Payne G, Williams M. Generalization in Qualitative Research *Sociology* 2005. 39: 295-  
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3 Data access: All data pertaining to this project are reported here. Please contact the authors  
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5 regarding accessing aggregated data analysis. Raw data is not available to be shared since  
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7 this could lead to identification.  
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Figure 1. Normalising Research

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Figure 1. Normalising Research

## Supplementary file 1. Interview Questions – exemplars/guide

(Questions drawn from across both studies - Dataset 1 and Dataset 2)

### Opening questions

- How is research organised in your critical care unit?
- Tell me about the infrastructure in your critical care unit to support research.
- What can you tell me about your research infrastructure in your organisation?
- How is this supported at different levels (*prompts*: local (unit)/division/board levels)?
- Can you explain what you see as the barriers, or facilitators to recruitment in NIHR trials?  
(*prompts*: Are there specific examples\* you can give me in your unit?)

### Culture -

- How do you embed a new (NIHR) study in your unit?
- How is research prioritised in your unit?
- What can you tell me about how the unit decides whether to participate in a research project?  
(*prompts*: any specific authorisation needed? e.g. clinical unit head/equipoise issues)

### Local/National -

- What do you see as barriers/facilitators at a network level? (*prompts*: Or outside of unit/organisational control?)
- What do you see as local recruitment barriers/facilitators (*prompts*: give examples - clinician buy-in/behaviour)?
- How do you embed research in your unit, and organisation?

### Process/Studies/People factors –

- Can you describe where study recruitment has gone well/not so well\*? (*prompts*: examples)
- What is your experience of how screening affects study recruitment? Tell me about how you screen patients for studies?
- Can you describe any patient/participant/family\* factors that facilitate/inhibit recruitment?  
(*prompts*: explore burdens/scheduling/demands of study)
- Tell me about how you recruit patients for studies? (*prompts*: families/process/infrastructure)
- What kinds of concerns have patients/relatives raised to you regarding study participation  
(*prompts*: related to placebo/randomization/uncertainty)?

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- Can you describe any study factors that facilitate/hinder recruitment? (*prompts: examples*)
  - Tell me about your experience in conveying complex information and gaining consent (*prompts: complexity of information/experience of team obtaining consent/language or cultural barrier*)?
  - For randomised trials, have you encountered patient/family preference for a particular therapy? If so, can you talk me through the issues encountered.
  - Can you describe any clinician factors (nurse or doctor) that inhibit/facilitate trial recruitment in your experience?
  - Tell me about the process for consent in patients without capacity? How does this affect recruitment to trials?
  - What can you tell me about recruitment to studies out-of-hours? (*prompts: who supports this?/Team working*)
  - What is your experience of recruiting to time-limited critical care trials?
  - What is the research staff infrastructure? How does this align with the clinical teams?
  - What is the experience of trainees in terms of research in the unit? (*prompts: structures, training opportunities*)?
  - How are trainees and nurses/AHPs supported to engage with research (*prompts: portfolio and non-portfolio; time/support to do 'own' research*)?

43 Are there any barriers we have not yet discussed?

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45 What suggestions do you have for enhancing study recruitment?

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47 Is there anything else you'd like to talk about in terms of facilitating research in critical care?

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49 How else can research be facilitated/supported in critical care?  
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Supplementary File 2. Table 1. Participants/units

Profession and Area	Level 3/2 beds <sup>†</sup>	Annual admissions	General /Specialist unit	Research staff numbers including whole time equivalent (WTE)	Research team working patterns	Consultant numbers and funded consultant time (Professional Activity session [PA]) <sup>††</sup> for research	Number (total) of ongoing clinical trials (both NIHR and non-NIHR/in set-up)
Nurse/ CRN Eastern	14	1000	General	<b>1</b> (work with Emergency Department [ED]); (1 WTE)	5 days/week 8-4pm (flexible)	<b>7</b> 1 PA	<b>6</b>
Nurse/CRN Yorkshire and Humber	24	1600	General	<b>2</b> ; (2 WTE)	5 days (flexible – 9 hour cover)	<b>13</b> 0.5 PA (shared)	<b>5</b>
Nurse/ CRN West Midlands	25	1600	General	<b>1</b> (was 4); (1 WTE)	5 days/week; 8-4pm	<i>Data not provided/ unknown</i> 1 PA	<b>6</b>
Consultant/ CRN Wessex	12	900	General	<b>2</b> (across all Division 6*, not just ICU); 1 WTE)	5 days/week; 8-4pm	<i>Data not provided/ unknown</i> 2 PAs	<b>6</b>
Trial co-ordinator/ CRN London South	63	3100	General/trauma	<b>6</b> across ED/ICU; ( <i>Data not provided/ unknown</i> )	5 days/week (and on-call at weekends/nights as required)	<b>&gt;50</b> (exact number unknown) 0 PA	<b>5</b>
Consultant/ CRN North West London	44	2600	General/ Trauma/ Neuro	<b>2</b> fellows + <b>5</b> nurses; (2 fellows at 2 WTE; 5 nurses at 4.5 WTE. 1 WTE research assistant)	<b>7</b> days/week	<b>21</b> 1 PA	<b>4</b>
Nurse/ CRN Greater Manchester	40	2000	General	<b>4</b> (across ED); (4 WTE)	8-8pm 5 days/week (and on-call at weekends/nights as required)	<b>22</b> 1 PA	<b>8/ 2</b> in set-up
Nurse/ CRN TV and South Midlands	9	500	General	<b>0.5</b> ; (0.5 WTE)	part/time (early/late shift pattern; weekdays)	<b>10</b> 0.5 PA	<b>2</b>
Consultant/ CRN Wessex	11	750	General	<b>4 + 0.5</b> trainee; (2.5 WTE + 0.5 WTE trainee)	7 days/week (plus trainee shifts)	<b>6</b> 0 PA	<b>4</b>
Consultant/ CRN West Midlands	102	4000	General/ Cardiac/ Trauma/ Burns/ Neuro	<b>7</b> (across ED/Trauma and ICU); (6 WTE including Trial Coordinator and administrators)	7 days/week	<b>34</b> 1 PA	<b>7/ 2</b> in set-up
Consultant/ CRN North West Coast	33	1550	General	<b>3 + 0.5</b> trainee; (2.5 WTE + 0.5 WTE trainee)	5 days/week (flexible)	<b>17</b> 1 PA	<b>3/ 1</b> in set-up
Consultant/ CRN West of England	15	5-600	General	<b>0</b>	n/a	<b>18</b> 0.5 PA	<b>1/ 2</b> in set-up

Consultant/ CRN West of England	15	5-600	General	0**	n/a	18 0.5 PA	1/ 2 in set-up
Nurse/ CRN South West Peninsula	28	1700	General/trauma/ Neuro/ Cardiac	1 (across dermatology/ neuro); (1 WTE)	8-4pm; 5 days/week	14 <i>Data not provided /unknown</i>	0/ 1 in set-up
Nurse/ CRN West of England	20	1300	General	9; 5 WTE + 4 rotational posts	7-7pm; 7 days a week	<b>Data not provided /unknown</b> 2 PAs (shared)	10
Nurse/ CRN East Midlands	69	4000	General/trauma/ Neuro	6 (covering ED) – split site; (4.2 WTE)	7-7pm; 7 days/week	<b>Data not provided /unknown</b> 0 PA	13
Nurse/ CRN Norfolk	19	850	General	2*; (1.45 WTE)	8-4pm 5 days/week (and on-call at weekends/nights as required)	<b>Data not provided /unknown</b> 0 PA	4/ 1 in set-up
Nurse/ Wales	33	1500	General/ Neuro	5; (4 WTE)	8-4pm 5 days/week	14 1 PA	6
Nurse/ CRN North West Coast	35	1880	General	2; (1 WTE nurse at band* 7 shared and 4 x nurse at band 6 at 0.8 WTE)	7.30-3.30pm 5 days/week	13 0 PA	9
Nurse/ CRN South West Peninsula	26	1580	General/ Neuro	1; ( <i>Data not provided /unknown</i> )	8-4pm 5 days/week	14 0 PA	7
Nurse/ CRN North East North Cumbria	18	1000	General	2; (1 nurse at band 3 research assistant; 1 nurse at band 6 WTE)	9-5pm 5 days/week	9 0 PA	8
Nurse/ CRN East Midlands	19	1200	General	3; (2.8 WTE)	8-7pm	<b>Data not provided /unknown</b> 2 PAs	11
Nurse/ CRN Eastern	20	1890	General	4; ( <i>Data not provided/unknown</i> )	8-8pm	<b>Data not provided /unknown</b> 1 PA	7
Nurse/ CRN Greater Manchester	19	1700	General	0.8; (0.8 WTE)	8-4pm	12 0 PA	4
Consultant/ CRN Wessex	24	1200	General	3; (1.6 WTE + 2 WTE for 3 month rotations)	8am-12pm 7 days a week	14 2 PAs	5
Consultant/ CRN London South	63	3500	General/ Neuro	9; (2 nurse at band 7; 7 nurse at band 6* WTE)	8-8pm	<b>Data not provided /unknown</b> 1 PA	10
Nurse/ CRN West of England	21	2000	General	5; (4 WTE (1 nurse at band 7; remainder nurse at band 6)	7-7pm	12 <i>Data not provided /unknown</i>	8

† Level 2 beds are where patients require more detailed observation or intervention including support for a single failing organ system or post-operative care and those 'stepping down' from higher levels of care Level 3 beds only. Level 3 care is defined as patients needing advanced respiratory support alone or support of at least two organ systems. Note basic respiratory and basic cardiovascular support occurring on one day count as one organ. This level includes beds for all complex patients requiring support for multi-organ failure. Flexible critical care beds where there is a mix of level 2 and level 3 beds (NHS data dictionary: [https://www.datadictionary.nhs.uk/data\\_dictionary/attributes/u/unit\\_bed\\_configuration\\_de.asp?shownav=1](https://www.datadictionary.nhs.uk/data_dictionary/attributes/u/unit_bed_configuration_de.asp?shownav=1)) ††PAs=Professional Activities Sessions are four hour weekly sessions for consultants only \*Working across all Division 6 studies, not limited to critical care; Division 6 is one of six NIHR overarching divisions that encompasses critical care, anaesthesia/peri-operative/pain, emergency care/injuries, surgery, respiratory,

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gastroenterology, infectious diseases/microbiology, hepatology, ophthalmology, ENT and \*\*Able to access other Division 6 nurses when studies are active. \* Band refers to the grade of nurse/research assistant as per Agenda for Change <https://www.nhsemployers.org/pay-pensions-and-reward/agenda-for-change/pay-scales/annual>. Band 7 is considered a senior nurse.

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Supplementary File 3. Table 1. Summary and Recommendations

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8	Recommendations for normalising research in critical care
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10	<b>Organisational factors:</b>
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12	○ Training: Offer Good Clinical Practice (GCP)/research training for all staff on
13	induction; Research staff running GCP sessions for critical care staff
14	○ Offer research training by research staff for critical care nurses/AHPs to
15	recruit/learn about research processes
16	○ Negotiation of leveraged funding to ensuring staffing and trial continuity;
17	maintain a broad study portfolio
18	○ Work on engagement and links with ED and other research departments in
19	the same NIHR divisions to support teams
20	
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23	<b>Human and Unit resources</b>
24	
25	○ Offer trainee fellowships to support medical trainees wanting a career in
26	research
27	○ Create rotational nursing posts in critical care, overseen by senior research
28	nurses
29	○ Facilitate reciprocal working between ICU staff and research teams;
30	research staff working in ICU to enhance links and recruitment opportunities
31	○ Create more career structures for doctors, AHPs and nurses working in
32	critical care research (through each of the bands, so there is an identified
33	progression ladder up to the most senior grade)
34	○ Incentivise clinical staff with training opportunities (e.g. create and offer free
35	study opportunities in a clinical area associated with the relevant study)
36	
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39	<b>Clinician factors</b>
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41	○ Communication and interdisciplinary working: Attend senior nurse/clinical
42	meetings in critical care
43	○ Create link nurse positions (to be extended to link trainee positions)
44	○ Ensure early scoping of capacity/equipose concerns by research team
45	
46	<b>Study/trial factors</b>
47	
48	○ Consider/request trial amendments in studies that are difficult to recruit to
49	○ Engage with and attend unit staff meetings early on in study planning to
50	identify potential study barriers (such as out of hours pharmacy provision)
51	
52	<b>Patient/family factors</b>
53	
54	○ Create tools/training/peer review to aid conveying complex information to
55	families and patients
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57	○ Have visible evidence of research activity in the unit (e.g posters) so it is
58	apparent that research is part of routine care
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# Reporting checklist for qualitative study.

Based on the SRQR guidelines.

## Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SRQR reporting guidelines, and cite them as:

O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. Standards for reporting qualitative research: a synthesis of recommendations. *Acad Med.* 2014;89(9):1245-1251.

	Reporting Item	Page Number
	#1 Concise description of the nature and topic of the study identifying the study as qualitative or indicating the approach (e.g. ethnography, grounded theory) or data collection methods (e.g. interview, focus group) is recommended	1
	#2 Summary of the key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results and conclusions	1
Problem formulation	#3 Description and significance of the problem / phenomenon studied: review of relevant theory and empirical work; problem statement	3
Purpose or research question	#4 Purpose of the study and specific objectives or questions	3
Qualitative approach and research paradigm	#5 Qualitative approach (e.g. ethnography, grounded theory, case study, phenomenology, narrative research)	4

and guiding theory if appropriate; identifying the research paradigm (e.g. postpositivist, constructivist / interpretivist) is also recommended; rationale. The rationale should briefly discuss the justification for choosing that theory, approach, method or technique rather than other options available; the assumptions and limitations implicit in those choices and how those choices influence study conclusions and transferability. As appropriate the rationale for several items might be discussed together.

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16	Researcher	#6	Researchers' characteristics that may influence the	4
17	characteristics and		research, including personal attributes, qualifications /	
18	reflexivity		experience, relationship with participants, assumptions	
19			and / or presuppositions; potential or actual interaction	
20			between researchers' characteristics and the research	
21			questions, approach, methods, results and / or	
22			transferability	
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27	Context	#7	Setting / site and salient contextual factors; rationale	4
28				
29	Sampling strategy	#8	How and why research participants, documents, or	4
30			events were selected; criteria for deciding when no	
31			further sampling was necessary (e.g. sampling	
32			saturation); rationale	
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36	Ethical issues pertaining	#9	Documentation of approval by an appropriate ethics	4
37	to human subjects		review board and participant consent, or explanation for	
38			lack thereof; other confidentiality and data security	
39			issues	
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43	Data collection methods	#10	Types of data collected; details of data collection	4
44			procedures including (as appropriate) start and stop	
45			dates of data collection and analysis, iterative process,	
46			triangulation of sources / methods, and modification of	
47			procedures in response to evolving study findings;	
48			rationale	
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53	Data collection	#11	Description of instruments (e.g. interview guides,	4
54	instruments and		questionnaires) and devices (e.g. audio recorders) used	
55	technologies		for data collection; if / how the instruments(s) changed	
56			over the course of the study	
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1	Units of study	#12	Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	5
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6	Data processing	#13	Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymisation / deidentification of excerpts	4
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14	Data analysis	#14	Process by which inferences, themes, etc. were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale	4
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21	Techniques to enhance trustworthiness	#15	Techniques to enhance trustworthiness and credibility of data analysis (e.g. member checking, audit trail, triangulation); rationale	4
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27	Syntheses and interpretation	#16	Main findings (e.g. interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	5
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32	Links to empirical data	#17	Evidence (e.g. quotes, field notes, text excerpts, photographs) to substantiate analytic findings	6
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36	Intergration with prior work, implications, transferability and contribution(s) to the field	#18	Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application / generalizability; identification of unique contributions(s) to scholarship in a discipline or field	10
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45	Limitations	#19	Trustworthiness and limitations of findings	11
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48	Conflicts of interest	#20	Potential sources of influence of perceived influence on study conduct and conclusions; how these were managed	2
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53	Funding	#21	Sources of funding and other support; role of funders in data collection, interpretation and reporting	2
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<https://www.goodreports.org/>, a tool made by the [EQUATOR Network](#) in collaboration with [Penelope.ai](#)

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