

# What are research nurses' experiences of obtaining consent from or for patients participating in emergency care research? A qualitative review

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DOI:

[10.1111/jocn.14984](https://doi.org/10.1111/jocn.14984)

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Document Version

Peer reviewed version

Citation for published version (Harvard):

Brown, P, Hewison, A & Newham, R 2019, 'What are research nurses' experiences of obtaining consent from or for patients participating in emergency care research? A qualitative review', *Journal of Clinical Nursing*, vol. 28, no. 23-24, pp. 4155-4165. <https://doi.org/10.1111/jocn.14984>

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Article type : Review

What are research nurses' experiences of obtaining consent from or for patients participating in emergency care research? A qualitative review.

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## Abstract

**Introduction:** If studies are to be valid, recruitment of representative samples is essential. In 2012 28% of UK emergency departments met the 80% standard for recruitment to trials set by the National Institute for Health Research. Research nurses play a vital role in the conduct of high-quality research and it has been argued that dedicated research nurses are needed if clinical trials are to recruit successfully to target.

This article has been accepted for publication and undergone full peer review but has not been through the copyediting, typesetting, pagination and proofreading process, which may lead to differences between this version and the Version of Record. Please cite this article as doi: 10.1111/jocn.14984

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**Review Question:** What are research nurses' experiences of obtaining consent from or for patients participating in emergency care research? A qualitative evidence review.

**Methods:** A qualitative integrative literature review with a narrative synthesis of the evidence. PRISMA guidelines for reporting systematic qualitative reviews (Supplementary File 1) were followed. A search of five electronic data bases was performed in December 2018 along with a hand search which yielded 125 citations: 10 papers and 1 PhD thesis met the review eligibility criteria. Methodological quality of the selected studies was evaluated and data were extracted and synthesised.

**Results:** Three themes were identified: Access, Organisation, and Timing. Research nurses encountered both general and specific barriers when seeking to obtain consent for participation in research. In particular it was found there was lack of experience among staff of working in emergency research and with securing deferred consent. The distinction between nurse researchers with a clinical role and those dedicated to solely to research only is often not clear and warrants further investigation.

**Conclusion:** Nurse Researchers with and without a clinical role can make a positive difference in recruitment to trials in emergency care. The involvement of dedicated research nurses in the consent process can increase recruitment to emergency care research. Experience of recruiting to clinical trials in non-emergency settings does not seem to help when recruiting for trials in emergency care.

### **What does this study contribute to the wider global community?**

There is a need for greater professional and public awareness of the need for research in emergency care.

There is a need for more training and education for research nurses involved in obtaining consent for research in the emergency setting, with a focus on understanding ethics.

Research ethics committees interpret guidelines concerning consent to participate in research in different ways. This can affect the approval process and limit recruitment to studies.

**Relevance to clinical practice:** There is a need for greater understanding of the experiences of dedicated research nurses in emergency care settings and in particular with regard to deferred consent.

### **1. Introduction**

Recruiting patients to research studies in emergency care research is important. There is a need to investigate the effectiveness of potentially lifesaving treatments in emergency situations and if studies are to be valid recruitment of representative samples is essential.

Recruiting patients for emergency care research is challenging for several reasons. There may be conflict between intervening in care, and observing and measuring care as part of the research role (Spilsbury et al, 2008). The speed of recruitment, for example where the trial intervention may need to occur within few hours and delays to enrolment might be life threatening (CRASH 2 Collaborators, 2010). Also there is a problem of participants' understanding of the complex nature of clinical trials (Lawton et al, 2017) particularly when in

most instances they will be experiencing stress and/or incapacitated and unable to provide valid informed consent (Armstrong et al, 2017; Levine et al, 2017; Harron et al, 2015).

Valid informed consent is regarded as the cornerstone of good practice in research involving human subjects however it is estimated that only 20% of patients who attend emergency departments and trauma centres have the mental capacity necessary to give consent (Johnson et al, 2016). Thus as well as the legal process of gaining prospective consent from patients in emergency departments there are processes for gaining consent when the patient is (temporarily or permanently) *incompetent* for research. Proxy consent by a legal representative is one well known process and staged or deferred consent is another. Staged or deferred consent is a relatively recent development in many countries (Medicines for Human Use [Clinical Trials] Regulations 2006). This involves staff making a decision to enrol an *incompetent* patient onto a research study without any form of consent being given at the time. However written informed consent from the trial participant or legal representative is legally required as soon as possible after this decision has been made (Kompanje et al, 2014). In the absence of such consent, research ethics committees can and do withdraw permission for the use of data which has been collected on this basis (Harron et al, 2015).

There is public support for recruitment of participants to clinical trials in emergency settings (Furyk et al, 2018; Rebers et al, 2016) and changes have been made to research regulations to make the process more straightforward (Medicines for Human Use [Clinical Trials] Regulations 2004- Amendments 2006 and 2008), including consent exception or waiver in the USA (FDA 1996). However researchers struggle to meet recruitment targets. For example in 2012 only 28% of UK emergency departments met the 80% standard for recruitment to trials set by the

National Institute for Health Research (Coates, 2013), resulting in studies being underpowered and under representative, limiting the quality and relevance of the findings (Donovan et al, 2014; Buckley et al, 2007; Burns et al, 2013).

Research nurses play a vital role in the conduct of high-quality research (Kaur, 2016; Cresswell and Gilmour, 2014; Spilsbury et al, 2008) and it has been argued that dedicated research nurses are needed if clinical trials are to recruit successfully to target (Kaur et al, 2016; Isaacman and Reynolds 1996). Understanding the experiences of research nurses involved in recruiting participants for research in emergency settings either as a result of a direct approach to patients, or their legal surrogate or non-prospectively (deferred), is thus important if recruitment rates are to improve.

## 1.2 Aim

The aim of the integrative literature was to address the following question: What are research nurses' experiences of obtaining consent from or for patients participating in emergency care research?

## 2 Methods

### 2.1 Search strategy

A systematised qualitative integrative literature review (Whittemore and Knafl, 2005) was undertaken. Ethical approval was not required. Thematic synthesis of the findings (Braun and Clarke 2006) is reported using the ENTREQ guidelines (Tong et al., 2012). The Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) guidelines (Moher et al,

2009) (See Supplementary file 1) were used, with a flowchart documenting the identification, screening, eligibility decisions taken, and summary of records included (Diagram 1 PRISMA search summary). A systematic search of the following data bases was undertaken: MEDLINE, CINAHL, EMBASE BNI and Nursing and Allied Health ProQuest. The following search terms and Boolean operators were used: Research nurses and Consent and Emergency care and Experiences, Views, Perceptions. As it was important to locate records relating to experiences of the consent process the terms 'experiences', 'views' and 'perceptions' were used. It was recognised that synonyms such as 'views' and 'perceptions' may have led to the identification of articles about the ethics of consent rather than actual experiences. These terms were included to expand the search given the limited number of records identified by a preliminary search (Table 1. Search tool and terms). Records reporting empirical data were included whilst those including opinions were excluded (Table 2. Inclusion and exclusion criteria). Although the inclusion criteria included reference to 'dedicated research nurses', distinguishing such nurses from clinical staff in the papers retrieved was very difficult.

Searches were limited to English language journals published in the period 1990 to 2018. The search was for articles from 1990 onwards because the USA introduced legislation for alternative methods of consent from this year, other countries subsequently introduced similar legislation. In the UK for example the Clinical Trial Regulations were amended in 2006 (2008 for children) to allow alternative forms of consent in emergency research (Medicines for Human Use [Clinical Trials] Amendment [No.2] Regulations 2006; Medicines for Human Use [Clinical Trials] and Blood Safety and Quality Amendment Regulations 2008) (Table 2.).

A hand search was performed of specific journals: *Trials*, *Nurse Researcher* and *Journal of Emergency Medicine* and by scanning reference lists for relevant articles to ensure no key sources were omitted from the review.

## 2.2 Search outcome

A total of 125 records was identified. This was reduced to 82 when duplicates were removed. The title and abstract of these records were screened against the inclusion criteria. A total of 14 papers and 1 PhD thesis met the inclusion criteria. (The PhD thesis was directly relevant to the review question and in view of the paucity of published literature available, was included). The full text articles were read and a further 3 were excluded at this stage as they did not meet the inclusion criteria. The final sample for review was 10 peer reviewed articles and 1 thesis (Diagram 1. PRISMA Search summary).

## 2.3 Quality appraisal

All of the studies were appraised using the Critical Appraisal Skills Practice tools (2017). All studies were of fair to good quality. Interviews and focus groups were the main methods of data collection, with 4 surveys that included free text or qualitative sections and 1 RCT which used free text from case notes in a category labelled 'other' as reasons for not recruiting. Thematic analysis was reported in 9 of the 11 studies, 1 of which used constant comparative method (Fram, 2013). The PhD study was an auto ethnography and constant comparative and framework method analysis were undertaken (Table 3. Data abstraction).



## 2.4 Data abstraction and synthesis

Braun and Clarke's (2006) framework was used for qualitative analysis. Line by line coding of the reported experiences was undertaken. Codes that were linked were organised into themes and then subthemes using an iterative process. Initial themes were identified by one of the authors, subsequently a second author repeated the process and finally all three authors audited the process and arrived at consensus on the themes of Access, Organisation, and Timing.

## 3. Results

All papers described the experiences of research nurses or midwives of the process of obtaining informed consent including recruiting without prior patient consent. Seven of the 10 records also reported the experiences of clinical staff and patients or/and parents.

While a high number of interviews were carried out in some studies not all were relevant to this review. For example, Lawton (2016, 2017) reported data from the same sample in two separate papers. They conducted 27 interviews with clinical staff although only 11 of these staff were research midwives, and only two had received consent from participants in an emergency medicine trial. The remaining interviewees were medical staff or midwives with no specific role in research. In some papers it was difficult to determine whether the experiences reported were those of clinical or research staff. For example Chhoa (2017) included 5 neonatal nurses and 4 midwives in her study, however it was not clear which were research staff. Cresswell (2014) described the background of 3 research nurses rather than individual experiences and did not report how recent their experiences of taking consent were.

In the 11 articles included in the review, the data from interviews with 42 research staff (nurses and midwives) about their views and experiences of the informed consent process in emergency research were included. Eighty one research nurses completed a questionnaire with both closed and open questions. A limitation of the studies was that they did not differentiate between the experiences of research staff and clinical staff. This was also found in work on recruitment to RCTs where it was not possible to identify whether researcher or clinician perceptions of recruiting participants to research were reported (Donovan et al, 2014; Newington & Metcalfe 2014). This was acknowledged in the papers which recommended further research be undertaken to investigate the recruitment practices of clinical staff involved in research as well as staff employed specifically to work on research projects.

### 3.1 Access

#### 3.1.1 Paternalism

Access to potential participants was hampered by a 'paternalistic' approach taken by some research nurses (Boxhall et al, 2016). Paternalism was defined in this paper as 'patients being prevented from making decisions for themselves' (p. 12) and it was reported implicitly in the other studies. For example, some research nurses chose not to approach patients who had suffered an acute stroke because they felt they were frail and unable to cope with the burden of participation. Similarly some consultants and research nurses thought recruitment (of children) in emergency situations was an additional burden for parents and this had an adverse effect on recruitment (Harron et al, 2015). However this was not evident in all studies (Woolfall et al, 2013).

Kaur et al (2016) found there were differences between the experience of medical staff and research nurses when recruiting children to trials, mainly with regard to willingness to approach parents for consent. Medical staff (Principal Investigators) did not find it difficult to approach parents to discuss consent, although they saw it as a hindrance for senior staff and research nurses felt it was better if senior nurses or doctors sought consent. Another example of 'paternalism' was in a trial investigating the removal of retained placenta (RP) (Lawton et al, 2016). Research staff (nurses and doctors) did not think it appropriate to obtain consent from all pregnant women in cases of RP because 'women are just so overwhelmed with all the information they get in pregnancy' (p. 10), even though the women reported they would have given consent if approached. The research nurses explained that this resulted from a conflict between maintaining the rights of the potential participant to be involved in the research and their duty of care as registered practitioners to not cause additional stress to the patients (Lawton et al, 2016).

### 3.1.2 Amount of experience

A lack of experience meant access to potential participants was reduced. Lack of experience on the part of researchers in approaching vulnerable patients and obtaining deferred consent, contributed to low recruitment in paediatric emergency care trials (Woolfall et al 2013). For example, in one paediatric study it was reported that when a child had died before obtaining deferred consent it was usually the 'senior person' (nurse or doctor unknown) who contacted the bereaved parents (Chhoa et al, 2017). Kaur et al (2016) found that some research nurses thought recruitment was managed more effectively if senior *clinical* doctors or nurses sought consent although the Principal Investigators of the study generally viewed this as a barrier to recruitment.

Boxall et al, (2016) found that less experienced nurses were reluctant to recruit patients to an adult acute stroke study because they did not want to bother patients with research or thought the participants could not cope with the extra burden of research (hence also falling into the 'paternalism' sub theme). The likelihood of this increased if the potential participant had severe symptoms.

Lawton et al (2017) found that previous experience or involvement in clinical trials did not give staff more confidence in obtaining consent in emergency care research because it entailed different challenges including the limited time for enrolment. Inexperienced staff were concerned that fully informed consent had not been given in some emergency situations (Chhoa et al, 2017). Lawton et al (2016 and 2017) found that less experienced staff insisted on written (fully informed) consent being obtained, rather than securing verbal agreement to be followed up with written consent at a later stage. However in one study research nurses did accept verbal consent before following up with written consent post intervention, irrespective of the amount of experience they had in this field (Chhoa et al, 2017). Lawton et al (2017) suggest the assumption of staff with less research experience was that written consent conferred a form of legal protection and thus explains their reluctance to obtain consent in other ways. Concerns about litigation, particularly in specialities such as obstetrics, were also identified as a reason less experienced staff avoided alternative approaches to obtaining consent (Lawton et al 2017; Chhoa et al 2017). For example Cresswell et al (2014) found some clinical nurse researchers in critical care asked a colleague to witness them taking consent. This reassured the nurse even though it is not a requirement.

### 3.2 Organisation

A study of recruitment to RCTs in acute stroke units found that research activity was seen as separate to routine care by clinical teams which did not always engage with the processes and communication systems that were necessary to recruit patients into trials (Stobbart 2012). Such engagement was necessary because the research nurses were not based in the emergency department or on the acute stroke unit and were not available 24 hours a day to obtain consent (Stobbart, 2012; Burns et al 2013; Cresswell and Gilmour, 2014). Lawton et al (2017) found that the practical demands of working on a busy obstetric unit meant staff preferred one person to obtain verbal and written consent at the same time. This was necessary because staff had large workloads and often had to move to work in other departments and it could not be guaranteed that if one person obtained verbal consent another would later secure it in written form. Rapid turnover of clinical and research staff in emergency care departments is also problematic for recruitment (Johnson et al, 2015). Another study found that staff felt the logistics and cost involved in asking every woman in antenatal care about a trial that would be likely to involve a relatively small number of women was a 'waste of resources' (Lawton et al, 2016). Kaur et al (2016) found that research nurses believed clinical staff lacked research experience and motivation which hindered recruitment and that the local research culture was unhelpful. However clinical staff also reported that having research nurses on site was essential to changing such culture for the better and increasing recruitment especially in emergency care (*ibid.*). Differences in hospital information systems can have an impact on recruitment of patients to research studies in emergency care (Johnson et al 2015). For example it was found that the time required to identify potential participants ranged from a few seconds to two hours, depending on the type of system in use. This occurred in part because some diagnoses e.g. head injuries may not be evident on 'the system' if a patient was admitted and classified as having multiple

trauma. The specific identification of a head injury required manual searching of patient records in some units.

Another organisational factor was the conduct of research ethics committees. The approval of research studies is often conditional on requirements stipulated by research ethics committees, which researchers must comply with, and in some circumstances may be constrained by.

Although national and international guidelines exist for the operation research ethics review, individual research ethics committees may interpret these guidelines differently. This can result in variability with regard to whether research applications are approved dependant on the understanding of consent processes.

### 3.3 Timing

The timing of informed consent in emergency care research is generally determined by the clinical trial protocol requirements and the need to initiate an intervention urgently. Chhoa et al (2017) questioned the validity of consent obtained from women in the late stages of labour. They contend the process is continuous and there is a need to balance the amount of information given to the patient in the time available with the woman's level of understanding. They recommend a two-stage consent process (oral and written) for low risk studies that do not involve complex designs. Woolfall et al (2013) also raised concerns about the timing of obtaining deferred consent from parents of children recruited into a clinical trial, although they found that significantly more parents approached for deferred consent provided consent than those approached prospectively. In addition, the deferred approach to consent "allowed research nurses to approach parents at a time when [they assumed] they were better able to process the information..." (*ibid.*, p. 6).

#### 4. Discussion

Accounts of experienced research nurses (and doctors) working in emergency care indicate they favour deferred consent to allow appropriate timing which has a positive impact on the nurse-patient/significant other relationship and that the participants/significant other appreciate it as well. However, this point is dependent as it is on the formation of relationships, may be specific to research nurses who are also clinicians involved in the nursing care of participants and may not be the same for research nurses without such clinical input. This may be the case for emergency care in settings other than the emergency department. For example acute stroke units, critical care units or obstetrics where the clinical nurse researcher has had time to form a relationship with the patient and family. It is also important to recognise that if recruitment to emergency care research is to increase, research nurses need experience of, and confidence in recruiting patients in emergency care settings.

The difference in experience was reflected in the reasons given by less experienced nurses for not offering participants/significant others the opportunity to participate in emergency care research. There seemed to be an assumption that it would be too much for them and/or that the professional duty of care was interpreted as to not burden them with additional stress. Interestingly most studies did not address the right of patients to be involved in research or the right to make such decisions for themselves (NIHR 2015). Some evidence suggests clinical teams have concerns about recruitment to clinical trials in emergency settings (Kaur et al, 2016). It is not entirely clear from the literature if this was the same with research nurses with a clinical role. However there is fairly strong evidence that patients/significant-others want to participate in research, or at least do not mind being asked to participate, and some studies show that rates of consent increase with the offer of deferred consent (Woolfell et al, 2013). Where this is less

clear is when a child or infant has died before deferred consent is obtained from the parent. One study found that some bereaved parents did not object to the deferred consent process when the intervention was a choice between one of three standard treatments. It is not clear if the response would be the same in studies with higher risk, novel interventions.

In the literature logistical barriers to access faced by parents and other people who would be able to give prospective 'proxy' consent or permission to emergency trials limits recruitment (Woolfall et al, 2013; Kaur et al, 2016; Boxall et al, 2016) and suggests a different approach is needed. For example in the USA the term 'proxy consent', when a relevant person (usually a relative) gives consent for the patient to participate in research, is now simply called 'giving permission'. There is also some bio-ethical and empirical literature questioning the reality of this concern about logistics (See for example Robertson et al, 2007).

Research ethics committees frequently do not give approval for projects which involve data collection if consent is not eventually obtained through the deferred consent process (Harron et al, 2015). Sometimes consent is not obtained because of a research ethics committee's requirement that no attempts should be made to make contact to obtain consent or permission from a patient who has been discharged or died, even though the intervention is used in standard practice and has already been given. Data collected from the intervention can then not be used for research purposes (Harron et al, 2015). The reasons given by research ethics committees for not approving projects are similar to those of less experienced research staff and reflect concerns about the additional stress or burden on participants' or their surrogates. This means that potential data is lost, yet evidence from experienced research nurses and from participants/significant others suggest they (participants /significant others) do not mind being approached. In addition some research ethics committees do not allow the clinical nurse to be



the first person to approach patients for consent because of fears of undue pressure (Cresswell and Gilmour, 2014). This may be a real or perceived fear but needs to be addressed, perhaps through education of staff about research ethics.

Different hospital organisational structures and policies affected recruitment to emergency care trials. The issues raised by research nurses are similar to those raised more generally about patient recruitment to research in healthcare organisations (Adams et al 2015). The recruitment and involvement of the public in research is a government priority in countries such as the UK and an aim of the NIHR clinical research network is to provide an effective research infrastructure (NIHR 2019). Yet significant organisational barriers remain including lack of proximity of research nurses to the clinical environment, league tables, and pay for performance (Adams et al 2015 p.4; Donovan et al 2016). This when combined with inexperienced researchers in emergency care and clinical staff prioritising 'care over research' seem to contribute to delays in recruitment (Adams et al, 2015; Tinkler et al 2018).

However this can be countered by employing research nurses as they improved research awareness and culture and were welcomed by clinical staff including research nurses with a clinical role (Kaur et al, 2016; Isaacman and Reynolds 1996). Generally, the experience of experienced research nurses in emergency care of proxy consent, assent or permission and deferred consent had a positive effect on recruitment. Stobbart (2012) found research nurses and clinical staff/clinical staff who were also involved in research viewed consent differently. For example clinical staff, both those with and without responsibilities for research, preferred enrolling patients on a study if it was for therapeutic rather than experimental reasons, perhaps highlighting a lack of knowledge about research. Such 'injurious misconceptions' (Snowden et al, cited in Stobbart, 2012, p. 187) are not it seems just held by patients and their proxies.

However, generally, the demarcation of research nurses who are also clinical nurses from those of research nurses involved purely with the research process is not clear in the literature though perhaps it is only the larger trials that are able to afford dedicated research staff.

#### 4.1 Further research

Key areas to be studied further include the experiences of obtaining consent in emergency care research, particularly in the emergency room or emergency department. There is also a need for greater understanding of the role of researchers generally and particularly in such a distinct area of research. There is a need for better understanding of the researcher's role and clarification of the clinician as researcher role with regard to the 'duty of care' and the 'duty' to enable the patients' right to participate in research. The use of the term researcher's role rather than nurse researcher or research nurse role is deliberate because of the increasing recognition of both generic role of advanced clinical practice and the distinctiveness of the research role.

#### 4.2 Limitations

Empirical data on the topic was limited, with only 10 published empirical studies and 1 PhD meeting the inclusion criteria none of which were from private for-profit trial centres where experiences may be very different. The themes identified in this review give an indication of the issues that need to be explored further to fully understand the topic. In addition, the roles of staff involved in the studies included in the review were not generally specified. It was often difficult to determine whether experiences of obtaining informed consent were from clinical staff working on research studies or full time research nurses. Another limitation was the small

number of emergency care settings covered in the papers. For example there was only 1 study of research nurses' experiences of obtaining consent for research in an emergency department, even though significant numbers of patients are recruited to research studies in these settings.

## **5. Conclusion**

There is a need to increase recruitment in emergency care research. Evidence suggests clinical research nurses can help facilitate this, particularly dedicated nurse researchers. The experiences of research nurses of gaining consent in emergency situations indicates there are general barriers to overcome that all or most staff recruiting patients to research studies encounter. These include perceived differences in clinical and research roles and duties, lack of knowledge among patients and clinical staff, and lack of experience among staff either in emergency care or research generally. In addition there are particular concerns for research nurses recruiting in emergency situations such as shortage of time for enrolment and lack of experience in obtaining deferred consent. The problems associated with recruitment based on research nurses' experiences need to be addressed because they are limiting the conduct of potentially lifesaving research.

## **6. Relevance to Clinical Practice**

This review suggests that there is a need for greater understanding of the experiences of research nurses in emergency care settings and in particular with regard to deferred consent.

Recruitment to clinical trials in emergency settings may be improved with more education and increased awareness of the role, particularly for more junior staff who recruit and obtain

consent, and also for clinical staff in these settings more generally in order to embed a culture of research in these settings.

This review also has relevance for research ethics committees as it indicates patients and/or relatives do not experience distress when approached for recruitment into clinical trials.

Research nurses need not take a 'paternalistic' approach to patients when recruiting to clinical trials and should enable patients and/or relatives to make informed decisions.

#### **Conflict of interest**

No conflict of interest declared by the authors.

#### **Funding**

This research received no specific grant from any funding agency in the public, commercial or not for profit sectors.

## References

- Adams, M. Caffrey, L. McKevitt, C. (2015) Barriers and opportunities for enhancing patient recruitment and retention in clinical research: findings from an interview study in an NHS academic health science centre. *Health Res Policy System* 13:8 1-9.
- Armstrong, S., Langlois, A., Laparidou, D., Dixon, M., Appleton, J P., Bath, P M., Snooks H., and Niroshan Siriwardena, A (2017) Assessment of consent models as an ethical consideration in the conduct of prehospital ambulance randomised controlled clinical trials: a systematic review. *BMC Medical Research Methodology*, 17(1), pp. 1-10. doi: 10.1186/s12874-017-0423-4.
- Bevans, M. Hastings, C. Wehrten, L. Cusak, G. Matlock, A. Miller-Davies, C. Tondreau, L. Walsh, D. Wallen, G. (2011) Defining clinical research nursing practice: results of a role delineation study. *Clinical and Translational Science*, 4:6 421-427.
- Boase, S. Kim, Y. Craven, A. Cohn, S. (2012) Involving practice nurses in primary care research; the experience of multiple and competing demands. *Journal of Advanced Nursing*, 68:3 590-599. Doi: 10.1111/j.1365-2648.2011.05764.x
- Boxall, L. Hemsley, A. White, N. (2016) Exploring recruitment issues in stroke research: a qualitative study of nurse researcher's experiences. *Nurse Researcher* 23: 5: 8-14.
- Buckley, B. Murphy, A. Byrne, M. Glynn, L. (2007) Selection bias resulting from the requirement for prior consent in observational research: a community cohort of people with ischaemic heart disease. *Heart*, 93: 1116-1120 doi: 10.1136/hrt.2006.111591.

Burns, K. Zubrinich, C. Tan, W. et al (2013) Research recruitment practices and critically ill patient's: a multicentre cross sectional, study. *American Journal of Respiratory and Critical Care Medicine*, 187: 1212-1218.

Chhoa, C. Sawyer, A. & Ayers, S. (2017) Clinicians' views and experiences of offering two alternative consent pathways for participation in a preterm intrapartum trial: a qualitative study. *Trials* 18:196 doi. 10.1186/s13063-017-1940-5.

Coates, T. (2013) Recruiting to 'time and target' in emergency care research. *Emerg Med J* 30: 609-10.

CRASH-2 Collaborators (2010) Effects of tranexamic acid on death, vascular occlusive events, and blood transfusion in trauma patients with significant haemorrhage (CRASH-2): a randomised, placebo-controlled trial. *Lancet* 376: 23–32.

Cresswell, P. Gilmour, J. (2014) The informed consent process in randomised controlled trials: a nurse-led process. *Nursing Praxis in New Zealand*, 30:1 17-28.

Dickert, N. Mah, V. Baren, J. Biro, M. Govindarajan, P. Pancioli, A. Silbergleit, R. Wright, D. and Pentz, R. (2013) Enrollment in research under exception from informed consent: the Patients' Experiences in Emergency Research (PEER) study. *Resuscitation*, 84(10), 1416-1421. doi: 10.1016/j.resuscitation.2013.04.006.

Donovan, J. Paramasivan, S. Salis I. Toerien, M. (2014) Clear obstacles and hidden challenges: understanding recruiter perspectives in six pragmatic randomised controlled trials. *Trials*, 15:5 1-12.

Donovan, J. Rooshenas, L. Jepson, M. et al (2016) Optimising recruitment and informed consent in randomised controlled trials: the development and implementation of the Quintet Recruitment Intervention (QRI) *Trials*, 17:283-294.

FDA (1996) 71 Fed. Reg 51143

Fram, S. M. (2013). The Constant Comparative Analysis Method Outside of Grounded Theory. *The Qualitative Report*, 18(1), 1-25.

Furyk, J. Franklin, R. Watt, K. Emeto, T. Dalziel, S. McBain-Rigg, K. Stepanov, N. Babl, F. (2018) Community attitudes to emergency research without prospective informed consent: A survey of the general population. *Emergency Medicine Australia*, 30:4 547-556.

Gamble, C. Woolfall, K. Willaimson, P. Appleton, R. Young, B. (2013) New European Union regulation of clinical trials is conflicting on deferred consent in emergency situations. *BMJ*, doi: 10.1136/bmj.f667 (Published 6 February 2013)

Gobat, N. Gal, M. Francis, N. Hood, K. Watkins, A. Turner, J. Moore, R. Webb, S. Butler, C. and Nichol, A. (2015) Key stakeholder perceptions about consent to participate in acute illness research: a rapid, systematic review to inform epi/pandemic research preparedness. *Trials*, 16:1 1-22. doi: 10.1186/s13063-015-1110-6.

Harron, K. Woolfall, K. Dwan, K. Gamble, C. Mok, Q. Ramnarayan, R. Gilbert, R. (2015) Deferred consent for randomized controlled trials in emergency care settings. *Paediatrics*, vol. 136, no. 5, pp. 1316-1322.

Issacman, D. Reynolds, E. (1996) Effect of a research nurse on patient enrolment in a clinical study. *Paediatric Emergency Care*, 12:5 340-342.

Johnson, R. Kuczawawski, M. Mason, S. (2016) Why is it so difficult to recruit patients to research in emergency care? Lessons from the AHEAD study. *Emerg Med J*, 33 52-56.

Kaur, G. Smyth, R. Powell, C. Williamson, P. (2016) A survey of facilitators and barriers to recruitment to the MAGNET trial. *Trials*, 17:607 doi 10.1186/s13063-016-1724-3

Kompanje, E. Maas, A. Menon, D. Kesecioglu, J. (2014) Medical research in emergency research in the European Union member states: tensions between theory and practice. *Intensive Care Medicine*, 40 496-503.

Lawton, J. Snowdon, C. & Morrow, S. Norman, J. Denison, F. Hallowell, N. (2016) Recruiting and consenting into a peripartum trial in an emergency setting: a qualitative study of the experiences and views of women and healthcare professionals. *Trials*, 17:195 doi. 10.1186/e13063-016-1323-3.

Lawton, J. Hallowell, N. Snowdon, C. Norman, J. Carruthers, K. Denison, F. (2017) Written versus verbal consent: a qualitative study of stakeholder views of consent procedures used at the time of recruitment into a peripartum trial conducted in an emergency setting. *BMC Medical Ethics*. 18:36 doi. 10.1186/s12910-017-0196-7.

Levine, A. Barry, M. Agrawal, P. Duber, H. Chang, M. Mackey, J. Hansoti, B. (2017) Global health and emergency care: overcoming clinical research barriers. *Society for Academic Emergency Medicine*, 24 484-493 doi:10.1111/acem.13142.

Medicines for Human Use (Clinical Trials) Amendment (No.2) Regulations 2006 2.

Medicines for Human Use (Clinical Trials) and Blood Safety and Quality Amendment Regulations 2008



Newington, L. and Metcalfe, A. (2014) Researchers' and clinicians' perceptions of recruiting participants to clinical research: a thematic meta-synthesis. *Journal of Clinical Medicine Research*, 6:3 162-172. doi: 10.14740/jocmr1619w.

National Institute for Health Research. (2015) Going the Extra Mile: Improving the nation's health and wellbeing through public involvement in research. The final report and recommendations to the Director General Research and Development/Chief Medical Officer Department of Health of the 'Breaking Boundaries' strategic review of public involvement in the National Institute for Health Research.

National Institute for Health Research (2019) NIHR Clinical Research Network <https://www.nihr.ac.uk/funding-and-support/documents/study-support-service/Recruitment%20Policy%20Document.pdf>

Poston, R. Buescher, C. (2010) The essential role of the clinical research nurse. *Urological Nurse*, 30:1 55-77.

Purdom, M. Peterson, S. Haas, B. (2017) Results of an oncology clinical trial nurse role delineation study. *Oncology Nursing Forum*, 44:5 589-595.

Rebers, S. Aaronson, N.K. van Leeuwen, F.E. and Schmidt, M.K. (2016) Exceptions to the rule of informed consent for research with an intervention. *BMC Medical Ethics*, 17(9), pp. 9. doi: 10.1186/s12910-016-0092-6.

Robertson, C. McCullough, L. Brody, B. (2007) Finding family for prospective consent in emergency research. *Clinical Trials* 4 pp. 631-637.

Rose, D.Z. and Kasner, S.E. (2011) 'Informed consent: the rate-limiting step in acute stroke trials', *Frontiers in neurology*, 2:65 doi: 10.3389/fneur.2011.00065.

Sahan, K. Channon, K. Choudhury, R. Kharbanda, R. Lee, R. Sheehan, M. (2016) Refining the enrolment process in emergency medicine. *Eur J Cardiovasc Med* 4:(1) p. 506-510.

Spilsbury, K. Petherick, E. Cullum, N. Nelson, A. Nixon, J. (2008) The role and potential contribution of clinical research nurses to clinical trials. *Journal of Clinical Nursing*, 17 549-557.

Stobbs L (2012) (Unpublished thesis) Conducting randomised controlled trials in an acute stroke unit: an ethnographic study <http://hdl.handle.net/10443/1944>

Tinkler, L. Smith, V. Yiannakou, Y. Robinson, L. (2018) Professional identity and the clinical research nurse: a qualitative study exploring issues having an impact on participant recruitment in research. *J. Adv. Nurs.* 74;318-328.

Votholt, V. Dickert, N. (2018) Uninformed refusals: objections to enrolment in clinical trials conducted under an Exception from Informed Consent for emergency research. *Journal of Medical Ethics*, 0: 1-4. Doi:10.1136/medethics-2017-104736.

Whittemore, R. Knafl, K. (2005) The integrative review: updated methodology. *J. Adv. Nurs.* 52(5):546-553.

Woolfall, K. Frith, L. Gamble, C. Gilbert, R. Mok, Q. Young, B. (2015) How parents and practitioners experience research without prior consent (deferred consent) for emergency research involving children with life threatening conditions: a mixed methods study. *BMJ Open*, 5:e008522.doi:10.1136/bmjopen-2015-008522

Woolfall, K. Frith, L. Dawson, A. Gamble, C. Lyttle, M. (2016) Fifteen minute consolation: an evidence based approach to research without prior consent (deferred consent) in neonatal and paediatric critical care trials. *Arch Dis Child Educ Pract Ed* 101:49-53.

Table 1: Search tool and terms

<b>(P) Research Nurses</b>	Research nurse Research practitioner Nurse researcher
<b>(E) Consent Emergency Care</b>	Consent Emergency Acute
<b>(O) Experiences</b>	Experience View Perception

Table 2: Inclusion and exclusion criteria

Inclusion criteria	Exclusion Criteria
Research in emergency settings	Non-emergency settings (studies that do not require an urgent decision on patient inclusion)
Research nurse (or equivalent) experiences of consent discussed	Research that reports opinions only or uses hypothetical scenarios
Research nurses (or equivalent) specifically employed to deliver research with no clinical role	Research only involving medical staff, public, patients, or clinical staff who are not specifically employed to deliver research
Consent used in the emergency setting discussed	Consent with patients in non-emergency settings
Records from 1990 onwards (this will include studies from the USA that implemented in law this process and post amendment of UK clinical trial regulations allowing for alternative consent options in emergency care)	Research conducted prior to 1990
Records in English language only	Non- English records

Table 3: Data abstraction

Author	Methodology	Clinical setting	Sample type, size and setting	Type of consent discussed	Analysis	Themes Identified / key outcomes
<b>Chhoa</b> C Y, Sawyer A & Ayers S (2017) Clinicians' views and experiences of offering two alternative consent pathways for participation in a preterm intrapartum trial: a qualitative study. <i>Trials</i> 18:196	Qualitative: Open ended interview questions	Obstetrics	17 clinicians from 7 hospitals: 8 medical staff, 5 nurses, 4 midwives. Quotes from 'research midwives' 'neonatal nurses' and 'research nurse'. Not clear how many research staff were interviewed.	Prospective, oral assent followed by written consent and prospective written consent only	Thematic analysis	<ul style="list-style-type: none"> <li>• The team approach to obtaining consent</li> <li>• The consent form as a record</li> <li>• Consent as a continual process</li> <li>• Different trials with different consent pathways</li> <li>• Balancing time, information, and understanding</li> <li>• Validity of consent</li> </ul>
<b>Woolfall</b> K. Frith, L. Gamble, C. Gilbert, R. Mok, Q. Young, B. (2015) How parents and practitioners experience research without prior consent (deferred consent) for emergency research involving children with life threatening conditions: a mixed methods study. <i>BMJ Open</i> <a href="http://dx.doi.org/10.1136/bmjopen-2015-008522">http://dx.doi.org/10.1136/bmjopen-2015-008522</a>	Semi structured questionnaire, interview and focus groups	Catheter trial emergency and elective	275 parents completed a questionnaire 20 families interviewed (23 parents) from 6 sites 17 practitioners 10 nurses and 3 consultant doctors from 5 sites and 4trial management/monitoring team focus groups 9 of the 10 nurses were involved in clinical care.	Deferred and prospective	Interpretive thematic With synthesis of quantitative data and ethical argument.	<ul style="list-style-type: none"> <li>• Practitioners (almost all no experience with deferred consent) views of deferred consent changed during the study</li> </ul>

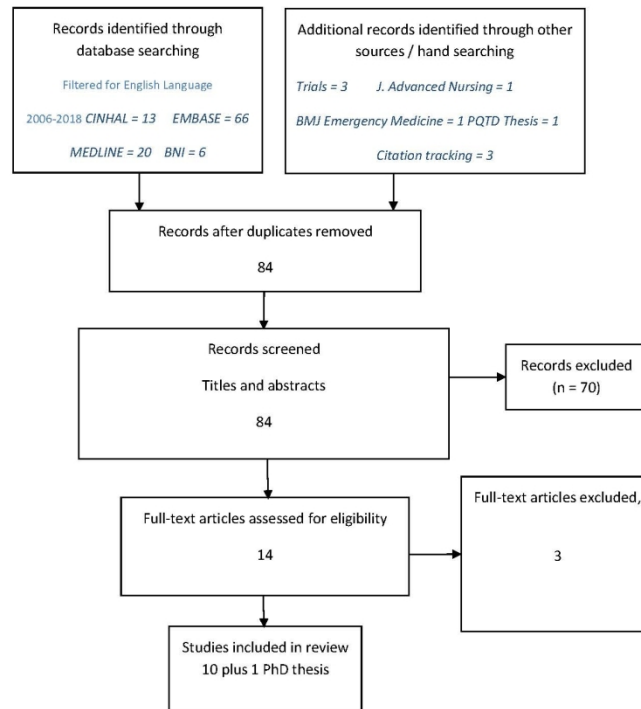
<p><b>Woolfall K.</b> Frith, L. Gamble, C. Gilbert, R. Q. Young, B (2013) How experience makes a difference: practitioners' views on the use of deferred consent in paediatric and neonatal emergency care trials. BMJ Medical Ethics 14:45 <a href="http://www.biomedcentral.com/1472-6939/14/45">http://www.biomedcentral.com/1472-6939/14/45</a></p>	20 item semi structured questionnaire	Paediatric emergency care and NICU	45 Emergency Care practitioners: 16 consultant doctors 29 research nurses	Deferred	Descriptive stats and thematic analysis	<ul style="list-style-type: none"> <li>Practitioners deviated from protocol and needed to gauge preferences of individual families and tailor their approach accordingly</li> <li>Timing: deferred consent allowed practitioners to approach parents at a better time for understanding</li> <li>Clarity of communication was important</li> <li>50% practitioners thought they could benefit from training</li> </ul>
<p><b>Lawton J,</b> Snowdon C &amp; Morrow S (2016) Recruiting and consenting into a peripartum trial in an emergency setting: a qualitative study of the experiences and views of women and healthcare professionals. Trials, 17:195</p>	Qualitative: Interviews of a pilot RCT	Obstetrics	22 participants. 27 staff; 10 doctors, 17 midwives, in 8 hospitals. 11 research midwives included in interviews. Not clear whether quotes were from midwives or research midwives.	Written, verbal	Thematic analysis	<ul style="list-style-type: none"> <li>Discordant views of whether fully informed consent was given</li> <li>Mixed views between patients and staff over the appropriate timing of information giving</li> </ul>
<p><b>Lawton J,</b> Hallowell N &amp; Snowdon C. (2017) Written versus verbal consent: a qualitative study of stakeholder views of consent procedures used at the time of recruitment into a peripartum trial conducted in an emergency setting. BMC Medical Ethics. 18:36</p>	Qualitative: In-depth interviews	Obstetrics	22 participants. 27 staff; 10 doctors, 17 midwives, in 8 hospitals. 11 research midwives included in interviews, only 2 were involved in the consent process in the project examined. Not clear whether quotes were from midwives or research midwives.	Written, verbal	Thematic analysis	<ul style="list-style-type: none"> <li>Written consent: protection for staff</li> <li>Previous clinical and trial experiences of staff</li> <li>Logistical challenges of alternative consent pathways</li> </ul>

<b>Cresswell, P &amp; Gilmour J (2014)</b> The informed consent process in randomised controlled trials: A nurse-led process. <i>Nursing Praxis in New Zealand</i> , 30(1), 17-28.	Qualitative: Semi-structured interviews	Mixed, including emergency. RCT's only	3 research nurses with experience in acute, community and university settings. Invited to participate through a research nurse study day, not clear if participants were from different settings	Proxy consent (reference to critical care only)	Thematic analysis (Braun & Clarke, 2006)	<ul style="list-style-type: none"> <li>• Protection &amp; access to patients</li> <li>• Participant advocacy, ensuring voluntariness and understanding</li> <li>• Promotion of the project and quality</li> </ul>
<b>Stobbert L (2012)</b> (Unpublished thesis) Conducting randomised controlled trials in an acute stroke unit: an ethnographic study  <a href="http://hdl.handle.net/10443/1944">http://hdl.handle.net/10443/1944</a>	Qualitative: Ethnographic study: Participant observation, semi-structured interviews & audio-recording of consent interactions	Stroke (Emergency research / hyper acute research)	2 acute stroke units 16 staff interviews that included 4 research nurses Participant observation over a period of 13months (279 hours) Observation of RCT's only	Written, prospective, proxy.	Constant comparative and framework methods	<ul style="list-style-type: none"> <li>• Organisational issues influencing interactions between patients and clinicians</li> <li>• Separating research and clinical practice</li> <li>• Clinical staff engagement with research</li> <li>• Dedicated research nurses closing the gap between research and clinical practice</li> <li>• Patients and the research participant role; a lack of familiarity with research</li> </ul>
<b>Harron, K. Woolfall, K. Dwan, K. Gamble, C. Mok, Q. Ramnarayan, P. Gilbert, R. (2015)</b> Deferred consent for randomised controlled trials in emergency care settings. <i>Paediatrics</i> , 136(5): 1316-1322	Retrospective case notes from an RCT	Paediatric intensive care	1358 admission notes 15 sites across 12 NHS Trusts	Deferred Prospective	Quantitative Categories with free text for reasons for non-consent as themes	<ul style="list-style-type: none"> <li>• Burden on child</li> <li>• Parent distressed or too much information</li> <li>• Not supportive of research generally</li> <li>• Social or language difficulties</li> <li>• Enrolment in another trial</li> <li>• Parents wanted standard treatment</li> </ul>

<b>Johnson, R.</b> Kuczawski, M. Mason, S. (2016) Why is it so difficult to recruit patients to research in emergency care? Lessons from AHEAD study. <i>Emerg Med J</i> 33: 52-56.	Survey 3 interviews	EDs	30 Ed sites Survey mailed to research nurses 3 interviews (consent for this actual study was waived)	Probably Prospective	Thematic	<ul style="list-style-type: none"> <li>• Difficult</li> <li>• Process in waiting rooms</li> <li>• Lack of dedicated research space</li> <li>• Patient perceptions of research</li> </ul>
<b>Kaur, G.</b> Smyth, R. Powell, C. Williamson, P. (2016) A survey of facilitators and barriers to recruitment to the MAGNET trial. <i>Trials</i> , 17(607) 1-10	Survey: quantitative with open questions	ED or Child assessment units	169 surveys 42 of whom were research nurses	Not stated	Thematic	<ul style="list-style-type: none"> <li>•</li> </ul>
<b>Boxall L,</b> Hemsley A, White N (2016) Exploring recruitment issues in stroke research: a qualitative study of nurse researcher's experiences. <i>Nurse Researcher</i> 23: 5: 8-14.	Qualitative: Semi-structured interviews & focus group	Stroke	12 research nurses from 9 hospitals	Delayed, surrogate, deferred	Thematic analysis	<ul style="list-style-type: none"> <li>• Impairments affecting mental capacity</li> <li>• Acute recruitment timeframe</li> <li>• Paternalism by research nurses</li> <li>• Low public awareness</li> </ul>



**Diagram 1: PRISMA Search Summary**



PRISMA Flowchart (Moher et al 2009)