Evaluation of Paramedic Views of Their Role in Ambulance Based Clinical Trials: An Interview Study

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Abstract

Background: Prehospital ambulance-based research is a relatively new and growing field, with paramedics increasingly being asked to take on a new research role. We sought to understand paramedic perceptions of this role with particular emphasis on the ethical challenge of gaining consent and enrolling patients onto clinical trials in this setting.

Methods: We undertook semi-structured interviews with paramedics who were actively involved in recruiting and consenting patients to UK trials. Participants were questioned on their views about the ethical considerations in clinical trials including different consent processes and perceived barriers to research. Participants were chosen because they had enrolled at least one patient to a clinical trial within the 12 months prior to the interview taking place.

Results: Fifteen paramedics from East Midlands NHS Ambulance Trust UK (EMAS) were interviewed. Analysis highlighted seven themes: barriers and facilitators to participation; benefits of research; consent methods; future trials; managing patient participants; problems with consent; and reasons why paramedics participate (or not). Paramedics were generally comfortable with gaining consent for research and most did not see this as an additional burden. However, excessive paperwork and the prolonged handover times needed for paramedics to participate in research were seen to be problematic. All paramedics interviewed felt that research was important for advancing their practice and ensuring better outcomes for patients as a result of evidence-based practice.

Conclusions: Our findings highlight the need for future trials to consider how to minimize impact on the operational practice of paramedics through the use of existing processes that reduce additional paperwork and time pressures on paramedics.

Background

The role of the paramedic is changing as more prehospital treatments and alternative care pathways are introduced but, in spite of this, prehospital research is still a relatively new and growing field (1–4). Until recently prehospital care has relied on extrapolation from in-hospital trials but the increasing importance placed on evidence based practice has led to the development of research agendas within ambulance services (4, 5). The rapid development of ambulance based clinical trials has led to changes within the ambulance service in the UK, including a new role of research paramedic (5). Research paramedics have additional research responsibilities acting as facilitators for research and liaising between university-based research teams and operational paramedics. The research opportunities for operational paramedics are primarily through enrolling patients onto clinical trials and delivering study interventions (5). Our previous research found that ethical issues, in particular assessing capacity and gaining consent in the ambulance, have been highlighted as areas that need greater understanding (6, 7). Whilst the research paramedic will have greater involvement in the entirety of the trial, the operational paramedic's role will end once their interaction with the participant (patient) has been completed. This study sought to

determine the views of operational paramedics regarding these relatively new aspects of their roles, with the emphasis on exploring ethical challenges.

Previous interview studies with paramedics have tended to focus on the practical operational delivery of the intervention itself rather than ethical considerations (1, 3, 8, 9). Paramedics' traditional priorities of getting patients to hospital as soon as possible, whilst providing optimal care, may not easily align with research (1, 5, 10, 11). A questionnaire study with UK paramedics found that lack of time, support and opportunities for research also prevented participation (1). In contrast, stronger engagement by prehospital researchers with paramedics (10) can help to foster acceptance of emergency research.

This project sought the views of paramedics who had recently been involved in recruiting participants into clinical trials, specifically regarding the ethical considerations of undertaking research and the impact that enrolling patients to research in the ambulance may have on their practice.

Methods

This research was undertaken as part of a Wellcome Trust Seed Award grant, and as such there were limited time and funds available. Therefore, the study concentrated on a single Ambulance Trust. There are 10 Ambulance Trusts in England, East Midlands Ambulance Service NHS Trust (EMAS) serves 4.8 million people in a large geographical area encompassing five counties (Derbyshire, Leicestershire, Lincolnshire, Nottinghamshire and Northamptonshire) and has approximately 3,700 paramedics of which fewer than 0.5% are research active. EMAS is a strongly research active Trust and at the time of the study was actively involved in multiple trials.

Participant Recruitment

Participants were recruited using a purposive sampling technique. Prior to beginning recruitment, the trials being conducted within EMAS were assessed and two trials chosen as they represented different ethical challenges, in particular with regards to capacity and consent. The first was the AIRWAYS2 trial, which assessed two airway management methods for patients in cardiac arrest, who therefore lacked capacity to consent and were enrolled under a waiver of consent protocol (12). Additionally in this trial the paramedics, rather than patients, were randomized to the intervention arm (12). The second trial was RIGHT2, a double-blind drug trial determining the efficacy of glyceryl trinitrate (GTN) patches in suspected stroke (13). As strokes can affect mental function, capacity was assessed by the paramedics and then the appropriate method of consent used; these included informed consent from the patient, surrogate consent from a relative or if no relative was present the paramedic was able to give proxy consent (13). In order to be eligible to take part in the interviews for this study paramedics had to have successfully enrolled at least one patient to either trial. Early in the interview process it became apparent that most paramedics who undertook research were active on more than one trial so whilst the questions predominantly related to the methods used in the two trials above, several paramedics also mentioned

involvement in the Ambulance HYPO study, which was also recruiting patients at the time of the interviews. Table 1 lists the participants and the trials in which they were involved.

Table 1
Participant demographics.

Participant Number	Length of Service	Education	Active Trials
1	> 10 years	Higher Education	RIGHT2 & HYPO
2	1–5 years	Higher Education	RIGHT2 & AIRWAYS2
3	> 10 years	IHCD Paramedic Award	RIGHT2 only
4	> 10 years	IHCD Paramedic Award	RIGHT2 only
5	> 10 years	IHCD Paramedic Award	RIGHT2 & AIRWAYS2
6	5–10 years	IHCD Paramedic Award	RIGHT2 & AIRWAYS2
7	5–10 years	IHCD Paramedic Award	AIRWAYS2 only
8	5–10 years	Higher Education	RIGHT2, AIRWAYS2 & HYPO
9	1–5 years	Higher Education	RIGHT2, AIRWAYS2 & HYPO
10	1–5 years	Higher Education	AIRWAYS2 only
11	> 10 years	IHCD then Higher Education	RIGHT2 & AIRWAYS2
12	> 10 years	IHCD Paramedic Award	RIGHT2, AIRWAYS2 & HYPO
13	1–5 years	Higher Education	RIGHT2 & HYPO
14	> 10 years	IHCD Paramedic Award	RIGHT2 only
15	1–5 years	Higher Education	AIRWAYS2 only

Data Collection and Analysis

Fifteen interviews were undertaken by the lead researcher (SA) who was experienced in undertaking qualitative interviews but had not previously undertaken research within an ambulance service thereby limiting any potential for bias. No new codes were introduced after analysis of 13 interviews and therefore 15 interviews were deemed sufficient to achieve data saturation (14). Data were collected through semi structured interviews either via the telephone or in person at the paramedic's ambulance station. The type of interview was determined either through participant preference or through practical considerations. The interviews took place outside of the paramedics' normal working shift patterns; where possible the interviews took place immediately before or after a shift at the ambulance station.

Where shift patterns did not allow for this, paramedics were telephoned at a prearranged time that was convenient to them. All paramedics were paid up to 1-hour standard overtime rate for participating in the interview. The interviews lasted between 20 and 45 minutes and were recorded using a digital recording device. All recordings were transcribed verbatim as soon as possible after the interview and the digital recordings immediately deleted. Notes were taken during the interviews to ensure any areas of interest could be revisited through the questions; the notes were then referred to during the transcription process where necessary. Participants were asked about their experiences of prehospital clinical trials, the ethical considerations including consent processes, and barriers and facilitators in such trials.

The transcripts were analyzed through a reflexive thematic method (15) and coding was undertaken using NVivo 11. All transcripts were coded independently by two authors (SA and VP). The initial lists of codes were agreed through discussions between the coders. Codes were compared and consolidated before being grouped into higher order themes through discussions within the team.

Demographic Data

Previous research has suggested that length of service and education has an impact on paramedics' willingness to participate in research, with so-called 'old school' paramedics being less willing to be involved in recruiting patients onto research or taking part in research themselves as participants (7, 16). This did not appear to be the case in this study where there was an equal ratio of short to long serving paramedics (> 10 years, n = 7; <10 years, n = 8) (see Table 1). There was a wide range in the length of service with the least experienced paramedic having qualified less than one year prior to the interview and the most experienced having served 28 years within the ambulance service. Increasingly in the UK, paramedics are expected to undertake a Higher Education qualification in Paramedic Science rather than taking the vocational route to professional registration via Institute of Healthcare and Development (IHCD) certification. This is reflected in the demographic data for this study with those paramedics with 5 years or less experience having entered the profession through the Higher Education route. Again, this did not appear to have an impact on whether a paramedic decided to be interviewed for this study.

Findings

Through the analysis of the interview data seven themes were initially identified for further consideration, these were: barriers and facilitators; benefits of research; consent methods; future trials; managing patients; problems with consent; and reasons for participating (or not). Table 2 provides supplementary information for each theme along with relevant quotes. As with previous research in this field some of the participants responses related to operational aspects of the paramedic role and the impact of research on these rather than specific ethical considerations. The themes were further analyzed and regrouped into two broad areas that centered on ethical considerations.

Table 2
Description of main themes with relevant quotes.

Theme	Quote	Participant Number
Difference between consent to treat and consent for research	I mean I suppose it just depends how in-depth you know the trial is, to how complicated it would be to explain to the relatives and the family. You know, it's a bit of difficult one really that.	5
	And sometimes it does feel or that can be a little bit long winded, particularly if I am acutely aware that you know this patient is time critical and needs to go. It's not something that the family can sit around the table and discuss it over a cup of tea. You know 'well what would Dad want'.	9
	So, I do know a little bit, obviously it's bit more of a, you've got to actually sit down with the person and explain to them the process of that trial.	10
Consent as a tool to calm patients and family	Yeah, well it can be obviously it's a very distressing time on both and I think on the first one the relative was quite distressed um but it actually put their mind at ease a little bit with regards to what I was, when we explained about the trial they seemed quite keen on this occasion because it kind of put their mind at rest knowing that there was a possibility that something you know was going to be done to help them even more.	5
Involvement of family in the consent process	Um but obviously very aware of the fact that relatives feel quite powerless anyway when things happen to their loved ones. And actually, getting the relatives involved in consenting for the trial gives them a little bit of control back over the treatment that their loved ones are receiving. And that can be a positive thing eventually. I hope anyway.	4
	I think that in one of the cases I can think of it probably helped having the relative there because they kind of, kind of put it into context a little bit for the patient.	8
	…obviously if there's any sort of issue with them not understanding um or not being quite clear on what's you know the trial is all about or the process it involves but having the family there obviously that can help, from that point of view as well.	10
	So, it was quite difficult but we explained to the patient and to the patient's family what the trial was, and how it would work and what we would do this stage. And then what would happen at the hospital and then to be fair, his wife said yeah that was fine, but his grandson was there um as well. I think it was his grandson, it was either his grandson or his son, I think it… And he was really yeah whatever, whatever, yes let's get him enrolled, if it's gonna help let's do it.	13
Patients comprehension at the time of giving consent	…. the first was the daughter and I would of thought that she was struggling with the amount of information that was being passed over to her whilst her mum was critically ill. So, I'm not completely convinced that she would have taken all the information in and understood it.	1

Theme	Quote	Participant Number
Time pressure meaning that consent is not informed	It's not something that the family can sit around the table and discuss it over a cup of tea. I think the problem of that is um you know um whether there might be some um religious and/or other belief system that might contradict um that, you know where you have just gone in and bulldozed your way in.	9
	The only thing that was concerning me about it was the fact that this patient was literally a stone's throw from the hospital. And I know what's involved in enrolling this patient, so my concern then was when I get on scene if this patient is confirmed to be having a stroke, the patient can be in hospital before I've even got a consent because that's how close we are. So, what do I do?	5
Needing to persuade patients to consent to take part in research.	If you seem quite confident and believe in a trial I think yeah it would definitely help to recruit them.	3
	And just said look you know if it's not going to make things any worse and it might help then kind of 'what have you got to loose' sort of thing.	8
	You're trying to sell the fact that you know you get this treatment, there is evidence to suggest that you can make recovery, and also trying sell it that you know they get additional scans that normal patients [non-trial patients] won't get.	9
Paperwork interfering with patient care	The RIGHT2 pack you've got to give one to the patient notes, one for the doctor, one for your notes. Then the thing for the patient's relative, and you just think phew all this paperwork! (laughs) So I'm waiting for the crew to come - it's usually not very long. In that time, I've not done my own paperwork because I've been messing around doing this paperwork to gain consent to put the pack on. Oh and you just think whoo, um it just takes a bit of time.	6
	So, I found it quite daunting when I opened the pack and saw the paperwork. Although you know we'd gone through the actual process that you know you needed to get consent, and these are the questions that you needed to ask. However, when I opened the pack up for the first, and of course it was time critical as the patient was um had stroke like symptoms and obviously we were aware that it was time critical. So, it did sort of put you under a little bit of pressure.	13
	[It] was a bit of a shock because you don't even get any training on the paperwork. You know it's there and it's not until you unfold it and you think 'oh my lord!' Very complicated and it seemed back to front to me. So, I probably did make a hash of it but all the info was there if you know what I mean?	15

Challenges to gaining consent (consent methods and problems with consent)

Paramedics did not generally have concerns about being asked to take consent for research as they felt consent (for treatment) was an integral part of the role:

"…we have to obtain consent for everything that we do, even you know down to doing blood pressure… you are always explaining what you are doing and why." [Paramedic > 10 years-service]

Three participants mentioned the difference between consent to treat patients and consent for research. They particularly mentioned that in order to achieve informed consent they need to ensure that they could fully explain the intervention:

"I was terrified about recruiting my first patient into RIGHT2 because I was thinking this is going to be such a difficult thing to explain to somebody. Then I got my first stroke patient and did it…it seemed to flow really easily." [Paramedic 1–5 years-service]

All of the paramedics interviewed felt that it was best to gain consent directly from the patient and that in most cases, except where the patient was unconscious, this was possible. Some paramedics went further implying that the consent process had a positive impact on the patient and their relatives:

"…I've used it like a calming sort [of] tool…It's like not only are you there to help them but Oh my God, this paramedic is part of a national trial to do with strokes. It does come across as positive." [Paramedic > 10 years-service]

The next preferred option was to gain surrogate consent from a relative. Several pointed out that family members played an important role in the consent process regardless of the patient's capacity to consent for themselves. Often patients would seek the opinion of people with them:

"I tend to notice that if the patient is slightly older, even though you are talking to the patient, and they've got capacity…the first thing they do is look over at the family and go 'what do you think?'" [Paramedic 1–5 years-service]

The ability to waive consent for research enrolment was also discussed, particularly with reference to the cardiac arrest trial. The paramedics taking part in that trial felt comfortable with not gaining informed consent as the patients were unconscious and the protocol allowed the paramedics to act in their best interests. The remaining paramedics who were not involved in this trial agreed that waiver of consent would be appropriate as long as they (the paramedic) felt they were working in the patients' best interests. One paramedic pointed out that including the sickest patients was important for research to progress:

"And I think there does come a point with things where we have to involve people even if they haven't consented because we're never going to improve our clinical practice if we don't do that." [Paramedic > 10 years-service]

The final consent model of using paramedics as a professional representative or proxy, where paramedics would sign the consent form on behalf of a patient who lacked capacity provided they met the inclusion criteria of the trial, was perceived as more controversial and generated conflicting views among participants. The majority felt that as long as the patient clearly met the criteria and the potential benefits outweighed any potential harms, they would be able to sign on the patient's behalf. One felt however that is was never right for a paramedic to sign without at least gaining verbal consent, stating:

"To me it's dodgy for a paramedic to do it without knowing the full history because they may be suffering from an unknown illness." [Paramedic > 10 years-service]

Another pointed out that a paramedic cannot be aware of a patient's wishes regarding research:

"…it's obviously a bit nerve wracking because you're making a decision for somebody you've only known for a few minutes." [Paramedic > 10 years-service]

One issue that did raise ethical concerns was whether patients really understood what they were consenting to. One paramedic described a situation whereby the patient had capacity but seemed overwhelmed by the situation, stating:

"I was looking at him thinking 'I know you are saying yes and I know you are understanding it now, but I bet if I ask you in half an hour or an hour' ….there's just not enough time and brain space for them to take it in." [Paramedic > 10 years-service]

Related to this several paramedics felt that time pressure was an issue when it came to gaining consent and that any consent gained was not necessarily informed.

"And sometimes it does feel that it can be a little bit long winded, particularly if I am acutely aware that you know this patient is time critical and needs to go. It's not something that the family can sit around the table and discuss it over a cup of tea. You know 'well what would Dad want'." [Paramedic > 10 years-service]

The interview participants did express pressure to enroll patients onto trials and in some cases, this led to paramedics persuading patients to consent.

"But then trying to convince a patient to go onto it or give them the information to go on it. And then they ask you your personal opinion." [Paramedic > 10 years-service]

These interviews indicated a general consensus that consenting patients to research should not be seen as a barrier to ambulance-based research. The paramedics interviewed felt that as long as they themselves believed in the research and that there were clear implications for developing future practice, they would be confident in enrolling patients onto trials.

Other ethical challenges of undertaking research in the ambulance setting (barriers and facilitators; and managing patients)

Whilst consent itself was not seen as a barrier to research, participants did perceive a number of other obstacles. By far the most common cause for concern was the additional paperwork required as part of the trial. All interviewees mentioned paperwork however, for the stroke trial in particular, this was seen as problematic as the patient needed to have a copy of the consent form. Although completion of paperwork may not be directly seen as an ethical consideration the need to complete paperwork before arrival at hospital potentially interfering with patient care is an ethical concern as summarized by one paramedic:

“Because there’s all the paperwork… there’s my consent form - do that one first, then I’ve all these 3 to fill out and I’ve got my obs[ervations] before and after… right then there’s another sheet here… then I have to remind myself well what color belongs to what. Because there is all different sheets and they’re all different colors… so that’s my copy, that’s the patients copy, that’s the one for… and by the time you’ve done that you’re at the hospital and you’ve not looked at your patient once.” [Paramedic > 10 years-service]

Several participants pointed out that they had not received any training on completing the paperwork, which added to their anxiety when they were using the forms for the first time with a patient. Overall, they were satisfied with the trial specific training but felt that having access to the trial pack and paperwork before enrolling the first patient was important.

As previously, stated some paramedics reported that time pressures made it difficult to obtain truly informed consent because of this, others reported not attempting to recruit patients in some circumstances.

“Sometimes you can walk in and it’s not quite as cut and dry as you think. And then it becomes more complicated so you’re then thinking doing best for the patients as well as then thinking can I enroll them in this trial? So, then you’ve got to make that decision as to whether I enroll them in this trial or whether I just scrap it.” [Paramedic > 10 years-service]

This could be considered unethical since patients who were otherwise eligible were not given the opportunity to take part when they would potentially have wished to. Where the paramedics decision not to offer the opportunity is based on convenience (time pressures) rather than medical need this could be seen as problematic.

The overall feelings of the interviewees were summarized nicely by one participant who said in response to the question of why they might engage in research:

“I think it’s becoming more and more obvious now that the paramedic profession is changing and we need to become more involved in research and in steering the profession.” [Paramedic 5–10 years-service]

Discussion

It has been suggested that the prehospital setting will be the next great clinical 'laboratory' for advancing emergency treatments (7). Through this study we hoped to gain further insight into the role of paramedics in facilitating research and in particular any ethical considerations. The paramedics interviewed were operational paramedics whose involvement in research consisted primarily of enrolling participants and delivering interventions before arrival at hospital. Whilst delivery of the intervention did not present a challenge enrolling patients and gaining consent generated wider discussion.

In England and Wales, research is governed by two main regulations, the Mental Capacity Act (2005) and the Medicines of Human Use (Clinical Trials) Regulations (2004). These regulations set out how consent should be sought for research purposes and more importantly what steps can be taken to include individuals who lack capacity (whether temporarily or not) in research. Paramedics felt the idea of gaining consent was not problematic as gaining consent to treat was integral in their practice, however the reality of gaining consent for research was more complex. Gaining informed consent from the patient is uniformly the preferred method of enrolment onto research, however it has been suggested that it is never possible to truly gain informed consent for research in an ambulance setting (7). This is reflected by some paramedics in this study who felt that whilst patients might have capacity, the stress and urgency of the situation impacted on their ability to make an informed choice. Conversely, others felt that the process of explaining the research to the patient acted to calm them, they were then able to understand in more detail what was happening and therefore were able to consent.

Studies involving patients attended by paramedic practitioners found that patients viewed the paramedic as just below a doctor in terms of knowledge, and that they could trust them when making decisions about their care (17, 18). By extension it could be suggested that patients may feel inclined to agree to take part in research because a paramedic has recommended it. Recent literature has centered on the vulnerability of research participants to coercion (19, 20). In prehospital research it could be argued that anyone approached regarding research could be considered vulnerable due to the nature of the incident and the need for emergency care. Whilst there is no suggestion of deliberate coercion here, as our participants pointed out, the stressful nature of an ambulance attendance together with the clinical situation makes it difficult for patient participants to process, understand and retain information. The combination of the time sensitive and stressful nature of the incident could have led patients to agreeing to taking part in the research more readily than they might have done in different circumstances. The high levels of trust patients placed in paramedics could also be an influencing factor, although this is not necessarily problematic as there is often an element of trust involved in consent decisions and therefore consent based on trust is not less valid (21). It is, however, important that researchers bear these aspects in mind when designing research and consent protocols to ensure that autonomy is not lost.

Alternative methods of enrolling patients discussed in this study included waiver of consent or use of paramedic proxy consent. Waiver of consent has been suggested as the best option for all ambulance-based research (7) but this is not without concerns. The paramedics interviewed felt that waiver of consent was acceptable as long as the intervention was in the best interests of the patient and that it was up to the Research Ethics Committee to determine this was the case. In the UK community consultation is

not a legal requirement for research involving waiver of consent however, as a matter of best practice development of research protocols usually involves patient and public involvement (PPI) group consultation. A previous interview study discussed PPI consultation where it was suggested that up to 90% of consultees found waiver of consent acceptable but only when applied to a specific situation/research project and that it should not be used as a default (7).

Related to this are concerns about the use of paramedics as professional surrogates for consent. In the RIGHT2 trial paramedics were able sign the consent form on behalf of the patient and confirmatory consent was gained later from the patient or relative (13). Findings from a previous study suggested that paramedics are less well placed to fulfil the role of professional surrogate as they cannot be considered independent of the study (7) and that waiver of consent is a preferable option (22, 23). There is a question here regarding whether the paramedic is actually giving surrogate consent or simply confirming that the patient meets the inclusion criteria, and therefore this is simply another form of waiver of consent. Whilst this was not raised as a concern by the majority of our participants, some did express concerns over signing for a patient they had not previously met and for whom they did not have a complete medical history. Paramedics often have to make decisions regarding treatment for patients unable to consent and therefore may not recognize the potential conflict of interest when it comes to research.

Throughout the interviews capacity and consent were clearly the most prominent ethical consideration for paramedics. However, a number of other issues that could become ethical considerations were raised. In particular the complexity of paperwork was a cause for concern as this may reduce the paramedic's interaction with the patient during transit to hospital. This perceived impact on workload and compromise to care of the patient was highlighted as a reason why some paramedics chose not to participate in research or to not attempt to enroll patients, and is in line with similar previous research (1, 9–11). During the stroke trial in particular interviewees mentioned having to undertake routine observations and ensure that these were entered both on the electronic patient care record and on the trial paperwork (PM5; PM14). This duplication was felt to be unnecessary by the paramedics, who questioned whether it would be more effective for trial staff to have access to the electronic records rather than having to keep a separate paper copy for the trial. Innovative approaches are called for when collecting patient data as part of trials including adapting electronic records to reduce the paperwork burden on paramedics.

Finally, paramedics in the stroke study suggested that whilst the training on the intervention was adequate, it would also have been helpful to have access to a dummy trial pack as part of that training. Several stated that the first time they had access to the trial documentation was when they enrolled their first patient and that it was daunting to try to complete the paperwork whilst monitoring their patient's care. Some also stated that they had felt the need to undertake additional reading in order to understand why the intervention was being trialed and that it would be useful to receive this information as part of the initial approach when they were deciding whether to take part. It was also felt that this might encourage more paramedics to take part in the study.

Strengths and Limitations

This study offers a unique perspective on paramedics undertaking research in the prehospital ambulance setting, particularly in gaining a greater understanding of the ethical considerations of this type of research rather than simply the operational aspects, which differs from previous studies seeking paramedic views of their research role. A key limitation of this study was that it was undertaken in a single ambulance service. A second limitation was that only paramedics actively involved in research were interviewed as we wanted to gain the views of paramedics who were actively involved in enrolling patients into research. Both these limitations were due to the nature of project which was limited by time and funding. It would be interesting to seek the views of paramedics who chose not to be involved in research and particularly whether ethical considerations play a part in their decision not be participate.

Implications for further research

This study found that the paramedics interviewed were keen to be involved in research and could clearly see the benefits for both informing evidence-based practice and in furthering the development of the paramedic role. A recommendation of this study is that trial specific training should include access to all trial documentation (consent forms, participant information sheets) in advance so that paramedics can practice completing the paperwork beforehand to reduce the impact on patient care. Linked to this, innovative approaches to gathering trial data including from routine records could also reduce the burden on paramedics' time during the emergency event. Clarity regarding the purpose of the trial might also help increase the number of paramedics signing up as several mentioned that fear of de-skilling was a major factor in their own decision to sign up to a trial.

Conclusion

With this study we sought to understand paramedics' views on the ethical considerations when undertaking research in the ambulance, in particular the processes of enrolling and consenting patients into trials. We found that participants generally agreed that consenting patients to research was not seen as a burden, however paperwork and time pressures were seen as a challenge. All paramedics agreed that research was important to advance both the profession and wider patient care but not at the expense of the individual patient.

Declarations

Ethics approval and consent to participate

All paramedics gave written informed consent including consent to recording of the interview and the use of anonymized quotes for publication purposes. Ethical approval was gained from the UK Health Research Authority (UK HRA IRAS project ID: 203946).

Consent to Publish

All participants consented to the use of anonymized quotes and basic demographic data regarding length of service and training route for publication purposes, no other personal data was collected.

Availability of Data and Materials

Please contact author for data requests.

Competing Interests

The authors declare that they have no competing interests.

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Authors' Contributions

ANS and AL had the original idea for the study. SA completed the interviews. SA and VHP completed the analysis of the interviews and final themes were decided by ANS, VHP and SA. All authors contributed critical revisions and approved the final manuscript.

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References

1. Hargreaves K, Goodacre S, Mortimer P. Paramedic perceptions of the feasibility and practicalities of prehospital clinical trials: a questionnaire survey. Emergency Medicine Journal. 2014;31(6):499–504.
2. Siriwardena AN, Donohoe R, Stephenson J, Phillips P. Supporting research and development in ambulance services: research for better health care in prehospital settings. Emergency Medicine Journal. 2010;27(4):324–6.
3. Pocock H, Deakin CD, Quinn T, Perkins GD, Horton J, Gates S. Human factors in prehospital research: lessons from the PARAMEDIC trial. Emergency Medicine Journal. 2016;33(8):562–8.
4. O'Meara P, Maguire B, Jennings P, Simpson P. Building an Australasian paramedicine research agenda: a narrative review. Health Research Policy and Systems. 2015;13(1):79.
5. McClelland G. The research paramedic: a new role. Journal of Paramedic Practice. 2013;5(10):582–6.
6. Armstrong S, Langlois A, Laparidou D, Dixon M, Appleton JP, Bath PM, et al. 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. 2017;17(1):142.
7. Armstrong S, Langlois A, Siriwardena N, Quinn T. Ethical considerations in prehospital ambulance based research: qualitative interview study of expert informants. BMC Medical Ethics. 2019;20(1):88.
8. Ankolekar S, Parry R, Sprigg N, Siriwardena AN, Bath PMW. Views of Paramedics on Their Role in an Out-of-Hospital Ambulance-Based Trial in Ultra-Acute Stroke: Qualitative Data From the Rapid Intervention With Glyceryl Trinitrate in Hypertensive Stroke Trial (RIGHT). Annals of Emergency Medicine. 2014;64(6):640–8.
9. McClelland G, Pennington E, Byers S, Russell W, Lecky F. The challenges of conducting prehospital research: successes and lessons learnt from the Head Injury Transportation Straight to Neurosurgery (HITS-NS) trial. Emergency Medicine Journal. 2015:emermed-2014-203870.
10. Burges Watson DL, Sanoff R, Mackintosh JE, Saver JL, Ford GA, Price C, et al. Evidence From the Scene: Paramedic Perspectives on Involvement in Out-of-Hospital Research. Annals of Emergency Medicine. 2012;60(5):641–50.
11. Shaw L, Price C, McLure S, Howel D, McColl E, Younger P, et al. Paramedic Initiated Lisinopril For Acute Stroke Treatment (PIL-FAST): results from the pilot randomised controlled trial. Emergency Medicine Journal. 2014;31(12):994–9.
12. Benger JR, Kirby K, Black S, Brett SJ, Clout M, Lazaroo MJ, et al. Effect of a Strategy of a Supraglottic Airway Device vs Tracheal Intubation During Out-of-Hospital Cardiac Arrest on Functional Outcome: The AIRWAYS-2 Randomized Clinical Trial. JAMA. 2018;320(8):779–91.
13. Bath PM, Scutt P, Anderson CS, Appleton JP, Berge E, Cala L, et al. Prehospital transdermal glyceryl trinitrate in patients with ultra-acute presumed stroke (RIGHT-2): an ambulance-based, randomised, sham-controlled, blinded, phase 3 trial. The Lancet. 2019;393(10175):1009–20.
14. Hennink MM, Kaiser BN, Marconi VC. Code Saturation Versus Meaning Saturation:How Many Interviews Are Enough? Qualitative Health Research. 2017;27(4):591–608.

15. Braun V, Clarke V. Using thematic analysis in psychology. Qualitative Research in Psychology. 2006;3(2):77–101.
16. Evans B, Brown A, Bulger J, Fegan G, Ford S, Guy K, et al. P34 Paramedic trail blazers – why do paramedics take part in prehospital research? Journal of Epidemiology and Community Health. 2018;72(Suppl 1):A76-A.
17. Proctor A. Home visits from paramedic practitioners in general practice: patient perceptions. Journal of Paramedic Practice. 2019;11(3):115–21.
18. Brydges M, Denton M, Agarwal G. The CHAP-EMS health promotion program: a qualitative study on participants' views of the role of paramedics. BMC Health Services Research. 2016;16(1):435.
19. Largent EA, Grady C, Miller FG, Wertheimer A. Money, Coercion, and Undue Inducement: Attitudes about Payments to Research Participants. IRB: Ethics & Human Research. 2012;34(1):1–8.
20. Appelbaum PS, Lidz CW, Klitzman R. Voluntariness of Consent to Research: A Preliminary Empirical Investigation. IRB: Ethics & Human Research. 2009;31(6):10 – 4.
21. Kongsholm NCH, Kappel K. Is Consent Based on Trust Morally Inferior to Consent Based on Information? Bioethics. 2017;31(6):432–42.
22. Goldstein JN, Delaney KE, Pelletier AJ, Fisher J, Blanc PG, Halsey M, et al. A Brief Educational Intervention May Increase Public Acceptance of Emergency Research Without Consent. Journal of Emergency Medicine. 2008;39(4):419–35.
23. von Vopelius-Feldt J, Brandling J, Benger J. Variations in stakeholders' priorities and views on randomisation and funding decisions in out-of-hospital cardiac arrest: An exploratory study. Health Science Reports. 2018;1(9):e78.