HUMAN FACTORS IN PREHOSPITAL RESEARCH

Lessons from the PARAMEDIC trial

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ABSTRACT

Background

There is an urgent need to develop prehospital research capability in order to improve the care of patients presenting to emergency medical services (EMS). PARAMEDIC, a pragmatic cluster randomised trial evaluating the LUCAS-2 device represents the largest randomised controlled trial conducted by UK ambulance services to date. The aim of this study was to identify and analyse factors that may influence paramedic attitudes to, and participation in, clinical trials.

Methods

Personal and organisational experience from this trial was assessed by feedback from a workshop attended by collaborators from participating EMS, and a survey of EMS personnel participating in the trial. A work systems model was used to explain the impact of five interwoven themes – person, organisation, tasks, tools & technology and environment - on trial conduct including gathering of high quality data.

Results

The challenge of training a geographically diverse EMS workforce required development of multiple educational solutions. In order to operationalise the trial protocol internal organisational relationships were perceived as essential. Staff perceptions of the normalisation of participation and ownership of the trial influenced protocol compliance rates. Undertaking research was considered less burdensome when additional tasks were minimised and more difficult when equipment was unavailable. The prehospital environment presents practical challenges for undertaking clinical trials, but our experience suggests these are not insurmountable and should not preclude conducting high quality research in this setting.

Conclusions

Application of a human factors model to the implementation of a clinical trial protocol has improved understanding of the work system, which can inform the future conduct of clinical trials and foster a research culture within UK ambulance services.

What is already known on this subject

- Previous studies have either made quite general observations regarding the difficulty of undertaking research in the prehospital setting, or have reported on the experiences of a single EMS system.

- There are currently no clear strategies for implementation of a research protocol across multiple prehospital study sites.

What this study adds

- This study reports both local and global experiences of four EMS systems engaged in a large scale randomised controlled trial.

- Using a work system approach specific strategies for translating research protocols into the prehospital setting are identified.

INTRODUCTION

"I can't begin to tell you the things I discovered while I was looking for something else."
— Shelby Foote 1997

Research is considered core business in the UK National Health Service (NHS) but there has been little experience to date of conducting large scale clinical trials in the prehospital setting, an area of clinical practice where knowledge gaps are significant [1, 2].

Publications on the topic of prehospital medicine represented only 8% of published randomised controlled trials in emergency medicine between 2008 and 2011 [3]. Given the influence that prehospital interventions may have on patient outcome [4], emergency medical service (EMS) service participation in high quality research is needed in order to improve the evidence-base for prehospital interventions.

Ambulance services are key to developing prehospital research. In recent years NHS paramedics have contributed to prehospital trials in conditions such as myocardial infarction (STREAM [5], ATLANTIC [6]), stroke (PIL-FAST [7], RIGHT [8]), airway management (REVIVE [9]) and falls referral (SAFER-2 [10]) but challenges remain in developing and embedding a culture of research in this setting.

We have recently undertaken a pioneering multicentre prospective cluster-randomised trial involving cardiac arrest patients across four UK ambulance services: the Prehospital Randomised Assessment of a Mechanical compression Device In Cardiac arrest (PARAMEDIC) trial. This trial evaluated the LUCAS-2 mechanical chest compression device and was the largest (n=4471) published prehospital trial conducted in the UK to date [11,12]. Four of the 11 NHS ambulance services in England and Wales, serving a combined population of 13 million people, participated in trial recruitment. Ambulance crews were trained in use of the LUCAS-2 device and trial protocol. The unit of randomisation was the ambulance vehicle which determined whether manual or mechanical chest compressions were delivered during resuscitation. Normal resuscitation protocols were followed; including a protocol enabling the paramedic to recognise death and withhold resuscitation. Crews

recorded each care episode, including the designated intervention, in the usual way via paper or electronic device. Patients were automatically enrolled if a trial vehicle was first on scene and chest compressions were delivered. One service required notification via text message. All services monitored patient records for enrolment. Research paramedics (RPs) delivered training, collected primary data, tracked vehicles and devices and monitored protocol adherence.

We have used the lessons learnt from this trial to identify and analyse factors that may influence paramedic attitudes to, and participation in, research in order to inform design and conduct of future prehospital trials.

METHODS

We have employed a model to systematically analyse paramedic attitudes to research following their involvement with the PARAMEDIC trial in an attempt to understand the complex interactions that are involved in research participation. Human Factors recognises that people's behaviour is influenced by their interactions with their environment. This may include their interaction with other people, equipment, the organisational context and the environment within which tasks are performed [13]. The Systems Engineering Initiative for Patient Safety (SEIPS) model employs a work system approach to describe the multiple Human Factor interactions between people and their environment, tools, organisation and tasks (see appendix 1) [13, 14]. It has previously been used to understand barriers and facilitators to the addition of a new service to pharmacists' already busy workflow [15].

A facilitated workshop and subsequent survey were conducted during the final stages of recruitment to the PARAMEDIC trial, and a Human Factors framework was utilised to explore work system characteristics of a prehospital clinical trial involving UK ambulance personnel.

Study design

This was a two-part study seeking both an organisational and personal perspective.

Ethics: Health Research Authority Guidance indicates that REC review is not required for research involving NHS or social care staff recruited as research participants by virtue of their professional role [16].

Study I – Organisational perspective

Design & Setting

Study I was a facilitated workshop attended in May 2013, one month prior to the end of data collection, by collaborators and trial investigators hosted by the Warwick Clinical Trials Unit (CTU).

Population

33 people were invited to attend this meeting, including study investigators, clinical trials unit staff, ambulance service medical directors, ambulance service managers and research paramedics

Procedures

The key questions posed were 'what were the ambulance service experiences of the trial?' and 'what were the particular successes and difficulties?'. Each ambulance service presented their experiences (approximately 20 minutes each), followed by a general discussion. The workshop was facilitated by the Trial Co-ordinator (JH). Notes were taken by a member of Clinical Trials Unit (CTU) staff and the different services' presentations were collated and shared.

Data analysis

The main points of each presentation were summarised and coded. Codes were grouped for similarity and themes identified by one investigator (HP) in discussion with CD and TQ. Themes were grouped according to the SEIPS model as applied by Chui et al [15].

Study II – Personal perspective

Design & Setting

An online survey for ambulance personnel who had participated in the PARAMEDIC trial was developed by HP, informed by findings from the workshop. The questionnaire was constructed on Survey Monkey© (London, UK) and the link distributed via e-mail to trial

station staff in June 2013, two weeks after close of patient recruitment, followed by a reminder e-mail, sent 6 weeks later, to optimise response rate.

Population

The link was sent to all ambulance staff participating in the trial in one service. A total of five ambulance stations, serving a mixed urban and rural population, were involved in patient recruitment; 546 staff were trained in the trial procedures, representing 36% of this service's paramedic workforce.

Instrument

The survey consisted of 14 questions: four yes/no responses, four Likert scale responses (designed to force an opinion) and six multiple response options. The full questionnaire and an example screenshot are presented in appendices 2 and 3. There was also space to record free text. The multiple response options were based on anecdotal feedback received from staff during the patient recruitment period. Questions were checked by HP and CD for clarity and to avoid common pitfalls such as bias, double-barrelled or double negative and leading questions [17]. The survey was not piloted beyond the investigators prior to distribution.

Data analysis

Survey responses were collated by HP and common themes identified in discussion with CD. Face validity was not checked beyond the authors.

RESULTS

I Facilitated Workshop

Characteristics of attendees are presented in table 1:

Attendees' Job role
Research Paramedics x 10
Ambulance Medical Directors x 3
Ambulance Education Managers (clinical) x 3
Ambulance Research Managers x 3(1 clinical; 2 non-clinical)
Trial investigators x 5 (3 clinical; 2 non-clinical)
Clinical Trials Unit staff x 6 (1 clinical; 5 non-clinical)

Table 1: Characteristics of facilitated workshop attendees

Two members of the trial investigation team and one EMS medical director were absent, making this a representative sample of the invitees.

1. Person

It was universally reported by participants that they felt that staff attitudes towards the trial, and their skills and knowledge of the intervention (LUCAS-2) and study protocol were fundamental to success. Attitudes towards the trial seemed to be linked to attitudes towards the intervention, which workshop participants reported were overwhelmingly positive. Staff engagement was also supported by secondment of paramedics to co-ordinate the research locally. Staff were reported to more readily receive key messages about the trial from their peers compared to electronic circulation of written memos and directives.

Although skilled in resuscitation, ambulance staff required training in the device and trial protocol. Facilitated workshop participants reported a variety of approaches to educating

staff including 1-to-1 station based training, voluntary launch events and inclusion on mandatory updates, supplemented by the trial website (http://www2.warwick.ac.uk/go/paramedic). 'Launch events' were offered at multiple timeslots to allow for shift patterns and a certificate of attendance was provided. Events proved extremely popular at some stations, but were poorly attended at others. Staff were reported to be more likely to attend training if this caused minimal disruption to their day and their attendance was recognised. In one service, training became embedded in the organisation's continuous professional development (CPD) programme, which expedited training completion.

In order to reduce skill and knowledge decay, paramedics were provided with *aides memoire* of the trial protocol in the form of laminated cards, and were offered refresher training. This was reported to be easily facilitated in services where the trial became incorporated into CPD programme. One service produced a DVD summarising trial procedures which could be delivered locally.

2. Organisation

Although the relationships between participating ambulance services were important, those *within* each organisation were considered by workshop attendees to be key to success. Within each service many different departments had to be engaged in operationalising the research. This often involved navigating conflicting priorities such as the research priority that needed to base vehicles at their 'home' stations versus the priority to maintain a continuously operational fleet across a wide geographic area. This was particularly problematic in a service involving a small number of large stations as the surrounding stations were not involved.

Leadership or ownership of the research was reported to impact on compliance within each service (failure to use LUCAS-2 in the intervention arm or use of the LUCAS-2 in the control

arm). Each case of non-compliance was followed up. One research paramedic (RP) reported a noticeable improvement *"…when the Operational Directorate took ownership of compliance*".

This involved integrating the trial into normal practice and treating non-compliance as any other operational failure. Constructive strategies included supportive challenge of individual staff members and discussion in team meetings and appraisals.

Workshop attendees unanimously considered the culture of the organisation and the degree to which research was prioritised to be of crucial importance. The readiness with which this trial was accepted as core business of the service was felt to be influenced by the experience of involvement with previous research. Ambulance service communications departments regularly published articles in internal staff magazines to maintain trial profile and RPs published articles in industry and professional journals [18, 19]. Seasonal variation in ambulance service demand peaked over the winter months resulting in reduced availability for training and operational deployment of RPs. Additionally, all services were going through a period of organisational change during the trial, resulting in additional challenges.

3. Tasks

Varying approaches were taken to recruiting ambulance staff to take part in the trial. In most services ambulance staff took part in the trial by virtue of being based at participating stations. One service asked staff to volunteer, but their resulting overall compliance rates were lower than services mandating participation (overall 42% versus 57%, 68% and 75% at other ambulance services).

Research paramedics faced varying challenges accessing patient data. Locating the paper Patient Clinical Record (PCR) was reported to be straightforward in organisations where forms were scanned and held electronically, but more challenging when clinicians had been asked to file their paperwork for collection by the research paramedic. Much time was

reportedly spent collecting and tracking down misplaced forms, described by one RP as *"……a soul-destroying task after 3 years."*

In one service a request to paramedics to send a text message to research staff informing them of patient enrolment was often overlooked because of time pressures when they were dispatched to the next emergency call.

Seeking outcome data from hospitals revealed variability in hospital procedures for sharing information. Some hospitals required full application to their own Research and Development departments for approval and others accepted the generic national-level approvals.

4. Tools and technology

Ambulance staff in all services were reported by workshop attendees to have reacted positively to the trial intervention (LUCAS-2 device).

Information technology was reported to have provided superior data collection solutions in the form of scanned paper records or, preferably, electronic records.

Randomisation was determined by first vehicle on scene (intervention vehicles were equipped with LUCAS-2, control were not), automatically recorded by the computer aided despatch (CAD) system when a vehicle arrived within 200m of the address. Sometimes unreliable, since proximity to a location may not equate to a point of patient access, this necessitated the time-consuming task of contacting crews directly to investigate possible protocol errors. This was common to all services.

It was universally reported that RPs faced practical issues such as a lack of office space and hardware and a lack of availability of trial vehicles at trial stations. Often required as replacements for vehicles taken off the road for unanticipated repairs, this worsened with a seasonal increase in vehicle breakdowns.

5. Environment

The LUCAS-2 dimensions are 65cm x 33cm x 25cm when stowed. Stowage required careful consideration and vehicle layout, which had a major impact on device accessibility, was reported as a factor influencing willingness to use the LUCAS-2 device.

In one service some vehicles required minor alterations in order to safely stow the device. This work was reported to have received a low priority when vehicle workshops were experiencing high demand. Representatives from all services reported that crews perceived major benefits to using the LUCAS-2 in the ambulance during transportation, as they felt that it increased their safety and allowed them to focus on other patient care tasks.

In a time-pressed emergency environment EMS crews reportedly appreciated the simplicity of the study inclusion/exclusion criteria displayed on a laminated card inside the lid of the bag housing the trial device.

II Survey

Of the 540 questionnaires sent to participating staff in one ambulance service, 152 responses were returned (28%). 107 (72.8%) respondents indicated that they had used the LUCAS-2 device in practice during the trial. Responses are summarised in table 2:

1. Have you completed your training on the LUCAS-2 device? *No. of responses: 150*	Yes No	141 (94%) 9 (6%)
2. How easy was the device to learn to use? *No. of responses: 143*	Very easy Easy Difficult Very difficult	78 (54.5%) 64 (45.8%) 1 (0.7%) 0 (0%)
3. Prior to the trial had you heard of, or used, any type of mechanical chest compression device? *No. of responses: 128*	Heard of Used	112 (87.5%) 17 (13.3%)

4. What, in your opinion, are the advantages of using the device? *No. of responses: 146*	Quality of chest compressions Safety of crew in rear of vehicle Consistency of chest compressions Being able to give chest compressions when transferring patients down stairs Being able to give chest compression in the back of a moving vehicle Helps with patients moving and handling	137 (93.8%) 90 (61.6%) 135 (92.5%) 66 (45.2%) 122 (83.6%) 43 (29.5%)
5. What, in your opinion, are the disadvantages of using the device? *No. of responses:98*	Too heavy to take into patient's location Too noisy Too brutal looking Hospitals don't like it Unable to take patients down stairs with device attached Device is too efficient	46 (46.9%) 9 (9.2%) 29 (29.6%) 1 (1%) 47 (48%) 2 (2%)
6. Would you like to see this piece of equipment introduced into the service? *No. of responses: 145*	Yes No	136 (93.8%) 9 (6.2%)
7. Have you seen the LUCAS-2 device used in clinical practice? *No. of responses: 147*	Yes No	107 (72.8%) 40 (27.2%)
8. How many times have you either used or seen the device used in clinical practice? *No. of responses: 146*	Zero Once Twice Three times More than three times	19 (13%) 42 (28.8%) 40 (27.4%) 15 (10.3%) 30 (20.6%)
9. How important do you think it is for the service to be involved in clinical research? *No. of responses: 148*	Very important Important Not important I don't think the service should be involved in research	123 (83.1%) 24 (16.2%) 0 (0%) 1 (0.7%)
10. Have you been trained on the PARAMEDIC trial protocol? *No. of responses: 145*	Yes No	126 (86.9%) 19 (13.1%)
11. How easy was the protocol to understand? *No. of responses: 129*	Very easy Easy Difficult Very difficult	54 (41.9%) 72 (55.8%) 3 (2.3%) 0 (0%)
12. How easy was the protocol to remember in practice? *No. of responses: 128*	Very easy Easy Difficult Very difficult	36 (28.1%) 78 (60.9%) 13 (10.2%) 1 (0.8%)
13. What was good about being involved in the trial? *No. of responses: 134*	Using a new piece of kit Not having to complete a separate form for data collection Contributing to knowledge for the profession	84 (62.7%) 35 (26.1%) 94 (10.2%)

	It made cardiac arrest management easier	102 (76.1%)
	My patients' chances of survival were improved	97 (72.4%)
	It gave me a CPD opportunity	47 (35.1%)
	None of the above	5 (3.7%)
14. What was problematic about being involved in the trial? *No. of responses: 131*	Having to remember to text the RP after each cardiac arrest incident	62 (47.3%)
	Having an extra piece of equipment to carry around	49 (37.4%)
	Having an additional procedure to remember at a cardiac arrest incident	29 (22.1%)
	Trying to remember how to use the device	23 (17.6%)
	Trying to remember the trial protocol	33 (25.2%)
	None of the above	31 (23.7%)

Table 2: Survey results

1. Person

Almost all respondents (n=142, 98%) indicated that the study protocol was easy or very easy to learn to use. Almost all respondents (n=142, 98%) indicated that the study protocol was easy or very easy to understand and a high proportion of respondents indicated that the protocol was easy or very easy to remember in practice (n=126, 89%). However this may indicate a response bias since more than a quarter of all non-compliance was due to crew error [12].

2. Organisation

In response to the question "How important do you think it is for this Trust to be involved in research?" 147 respondents (99%) indicated that it was very important or important.

3. Tasks

Common problems identified by respondents included difficulty in remembering to send a mobile phone text message to alert the RP after each cardiac arrest (n=62, 47.33%) and having an extra piece of equipment to carry to a cardiac arrest (n=49, 37.40%).

4. Tools and technology

When asked what was good about being involved in the trial, a majority of respondents reported that they felt that it made cardiac arrest management easier (n=102, 76.12%).

5. Environment

Many respondents reported that they felt an improved ability to deliver chest compressions whilst moving (n=122, 83.6%) and increased safety in the vehicle saloon (n=90, 61.6%). Some respondents indicated that the device was too heavy to take to the patient's location (n=46, 46.9%).

Overall feedback is summarised in figure 1:

Person • *Perceived utility of a trial device likely to influence attitudes towards research* • *Various approaches towards training were necessary* • *Consider peer secondments to the role of research paramedics*
Organisation • *Internal service relationships and communications with staff are essential* • *Staff perceptions of 'ownership' of the research is likely to affect compliance*

• *Undertaking primary research fosters the development of a research culture*
Tasks • *Normalise participation in trials by including all staff* • *Develop data sharing agreements with local hospitals* • *Minimise requirements for additional tasks*
Tools and technology • *Lack of office space hinders day to day running of a trial* • *Electronic patient records likely to expedite data collection* • *Randomise by shift rather than by vehicle*
Environment • *Careful planning of stowage of kit may be required* • *Keep inclusion/exclusion criteria simple and visible* • *EMS providers don't see their environment as 'difficult'*

Table 3: Specific learning from conducting the PARAMEDIC trial

DISCUSSION

This paper presents the key lessons taken from operationalizing the PARAMEDIC trial protocol (table 3). The experience is viewed through a human factors framework in order to characterise some of the key relationships within the work system. Three main lessons, namely that staff *value* research activity, the activity is *normalised* and research tasks are *simple* to complete were considered important to the success of the trial.

We theorized that the positive attitudes displayed towards the research were linked to paramedics' perceived utility of the trial intervention, namely the LUCAS-2 device.

Survey respondents felt that it was important that the organisation valued research activity. This can be demonstrated through organisational alignment, whereby the cultural, structural and strategic aims of the organisation are congruent [20]. Vertical alignment (from top to bottom of the organisation) is achieved through strong leadership and horizontal alignment (across different departments) through effective inter-departmental relationships [21]. Protocol compliance in the trial improved as perceived ownership moved to the operational directorate of participating ambulance services. This served to integrate research into the existing ambulance leadership structure. By adopting the training in a mandatory CPD strategy, one ambulance service demonstrated that they prioritised and valued the research project. All services supported a research culture by seconding operational staff to research roles and conveying positive messages to staff via internal organisational publications.

A number of strategies served to normalise the research activities. As an activity becomes 'normal' so an individual is more likely to engage in that activity in order to gain and retain social approval [22]. Thus the activity becomes seen not only as 'what other would do' but also as 'what others would expect me to do'. Delivery methods of the standardised training materials varied within and between services, all reported perceived benefits associated with appointing practicing paramedics as RPs, in common with other trials [23]. Peer educators are better able to deliver information at an appropriate pace for socially similar learners and foster a trusting relationship whereby learners feel comfortable to ask questions [24]. Voluntary participation has been a feature of other recent EMS trials [7, 10] but proved the less successful strategy in our experience, resulting in lower compliance. Participation in the PARAMEDIC trial was on a mandatory basis in three of the four participating ambulance services.

The third important lesson was to keep tasks simple. Ambulance services have a culture of protocol adherence [4]. In the PARAMEDIC trial, there was minimal variation from normal protocols, in that only the method of delivery of chest compression varied. In the already high intensity environment that is the prehospital setting, it is important to minimise the need

for additional tasks. Previous studies have suggested calling a real-time notification line whereby clinicians phone a researcher to notify them of a patient enrolment immediately after patient handover at hospital [23]. Though unsuccessful in this trial, it has proved successful elsewhere [5].

Exposure of individual paramedics to out-of-hospital cardiac arrest is low: approximately once a year in our trial, in common with other studies [12, 25]. The ease with which staff reported they learnt and retained knowledge of the trial device and protocol was helped by the provision of aides memoire and refresher training. Visual reminders in proximity to equipment can help paramedics improve protocol compliance [23].

Data collection was challenging in this trial, in common with others' research in the 'chaotic' prehospital setting [23]. Use of electronic patient records may allow better record keeping and access to that information.

In services where vehicles moved stations during the trial, this reduced opportunities to develop familiarity and reduced expectation of carrying a device. Such familiarity would make its use simple to remember. One possible solution would be to randomise by shift rather than by vehicle. This proved successful in the one service in which it was tried. The prehospital setting is often considered to be a challenging environment in which to conduct research [7, 23].

CONCLUSION

The PARAMEDIC trial is the largest of its kind to date within UK ambulance services and has successfully engaged four UK ambulance services to recruit 4471 prehospital patients. Challenges in achieving this have been numerous but the experience, from an ambulance service perspective, has highlighted the important role that human factors play. Configuration of new systems, processes and teams was necessary to translate the

research protocol into practice. Throughout the trial, ambulance services evolved to find new ways of working to accommodate research and maximise engagement of staff.

A human factors analysis has allowed a better understanding of these challenges and potential barriers to future research in order to guide those planning further prehospital research.

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DECLARATION OF INTERESTS

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