THE FEASIBILITY AND PRACTICALITIES OF PREHOSPITAL CLINICAL TRIALS

Katherine Hargreaves
University of Sheffield
The feasibility and practicalities of prehospital clinical trials

Kate Hargreaves
Supervised by Professor Steve Goodacre
In partnership with Yorkshire Ambulance Service
Outline

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Overview

- Practical and ethical barriers exist to conducting prehospital clinical trials, resulting in a poor evidence base to many treatments.

- Paramedics’ views are poorly understood and this questionnaire study aims to gather their perceptions of prehospital research.

- A good level of understanding and interest was reported, but significant issues were found and a need for better education and support identified.
Very few prehospital clinical trials are carried out, compared with other medical specialties (Callaham, 1997).

Research with designs falling lower in the hierarchy of evidence (e.g., observational trials, case reports) are relied upon.

The evidence base for the treatments and interventions delivered in the prehospital field is poor.
Background

Indentified barriers:

- Complex consent regulations, adhering to Declaration of Helsinki
- Practicalities of a changing environment
- Increased time requirements, on scene and completing paperwork
- Confusion over paramedics’ professional role
2 authors have collected paramedics’ perspective on prehospital clinical research:

- Schmidt et al in the US found paramedics reported that research is important, but significant practical barriers exist, and better education and integration would be beneficial (Schmidt et al, 2010).

- Burges Watson et al reported similar findings within US and UK paramedic populations, recommending increased paramedic involvement in trial design (Burges Watson et al, 2012).
Research aims

- To identify and clarify barriers to conducting prehospital clinical trials
- To gather and analyse paramedics’ perspectives towards prehospital research
Methods

Ethics approval sought, and approval given.

Questionnaire development:

- 5 semi-structured interviews with Yorkshire Ambulance Service paramedics
- Interview notes analysed informally for themes
  - Knowledge and use of clinical evidence
  - Paramedics’ training and professional role
  - Randomisation and consent
  - Additional training and education
Questionnaire design and administration:

- Questions based on themes identified through interview process, mostly using a Likert scale
- General principles of good questionnaire design adhered to
- Questionnaire administered to 300 paramedics in YAS at randomly selected stations via ‘research champions’ network
Methods

Analysis:

- Paramedics reported opinions were represented using percentages (and 95% confidence intervals)
- Hypotheses were tested using the Fishers exact test, independent samples t-test and regression analysis, dependent on the type of data
Results

- Response rate: 32%
- Excellent reported understanding of clinical trials and their value for an evidence base
- Low reported use of published evidence and poor confidence using this in practice
- Uncertainty that research is part of a paramedics’ role
- Significant concerns about additional time requirements and increased turn around times
Results

- Significant concerns that involvement in research is not supported by the service in terms of time and funding
- Ethical concerns about recruiting patients before consent
- Practical concerns about random allocation of participants
- Widespread enthusiasm for further education and training, if time and funding allowed
Results

Training route did not influence respondent reported understanding of:

- clinical trials (p=0.263)
- opinion about the importance of an evidence base (p=0.283)
- Feeling of professional responsibility (p=0.838)
Previous involvement in research did not influence respondent opinion on the importance of:

- an evidence base ($p=0.934$)
- gaining written informed consent ($p=0.326$)
Number of years practicing as a paramedic did not influence respondents opinions about:

- ‘personal experience is more important than evidence from clinical trials’ (p=0.582)
- ‘if I had to take part in addition training (eg GCP) I would find this interesting’ (p=0.111)
- ‘taking extra time to do additional paperwork during a shift could cause operational problems’ (p=0.936)
Discussion

- Significant ethical and practical barriers were identified.
- None of the variables hypothesised to impact paramedic opinion were found to do so, but this maybe as a result of non-responder bias.
- Similar conclusions drawn as previous researchers that more education and better integration of research is required.
Limitations:

- Low response rate – results not generalisable
- Questionnaire distribution problems
- Assumptions of analysis not met by data

Strengths:

- Topic
- Questionnaire design
Further work:

- Repeat study, aiming for higher response rate
- Collect experiences and attitudes of paramedics who have been involved in recruitment to a trial
- Assessment of actual understanding of clinical trials among paramedics (instead of reported understanding)
- Assessing the impact of strategies to encourage prehospital research:
  - 999 EMS Research forum
  - Ambulance service steering committees
Summary

- **Aim:** to examine the feasibility and practicalities of clinical trials, in the opinion of paramedics
- **Poor response to questionnaire means poor generalisability of these results**
- **High levels of reported interest and understanding of clinical trials, but significant ethical and practical barriers to conducting them**
- **Further education and support required if an increase in prehospital trials is to be achieved**
References


