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THE FEASIBILITY AND PRACTICALITIES OF PREHOSPITAL CLINICAL TRIALS

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The feasibility and practicalities of prehospital clinical trials

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In partnership with Yorkshire Ambulance Service

Outline

- Overview
- Background, related work and research aims
- Methods
- Results
- Discussion and future work
- Summary
- Questions

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 (eg observational trials, case reports) are relied upon
- The evidence base for the treatments and interventions delivered in the prehospital field is poor

Identified 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

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

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

- ❑ 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

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 additional 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

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Questions?

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