Overcoming the challenges of setting-up a large and complex pre-hospital trial

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BACKGROUND
Different types of airway management are routinely used within the English ambulance service. Currently the type of airway management a patient receives depends on the guidelines issued by the local ambulance service and the preference of the attending ambulance staff. Currently, health outcomes in out of hospital cardiac arrest patients are poor with less than 1 in 10 patients surviving to discharge from hospital. There is real uncertainty amongst paramedics and airways experts about the best method to use to ensure a clear airway during an out of hospital cardiac arrest. The AIRWAYS-2 study will look at two of these routine methods of managing an airway: the use of a tracheal tube (intubation) or the use of an i-gel (airway device which sits up top of the voice box). The study will try to determine which airway management gives the best survival and recovery in out of hospital cardiac arrest patients.

THE CHALLENGE
In order for this study to be set-up successfully, it was essential to obtain support and approvals from the four ambulance services taking part in the study and every hospital served by those four ambulance services.

STRATEGY
Engage with all stakeholders
Ensure all stakeholders were well informed during planning and set-up phase
Clear message about why the study is important

AMBULANCE SERVICE
Very early engagement
Two investigator meetings prior to patient recruitment

12 Clinical Research Networks
• Gave advice in each region on how to make best use of resources
• Identified NHS Service Support costs for hospital staff
• Administrative support for ambulance trust

RESULTS
Local R & D approval was obtained from all 95 hospitals served by the four participating ambulance services. All set-up milestones were achieved and the first patient was enrolled on time (June 2015).

CONCLUSIONS
Ambulance services are increasingly research active. Incidents attended can be life-threatening emergencies but good quality pre-hospital studies are possible. Early and comprehensive engagement assists with site participation and enables successful set-up of collaborative studies.

STUDY DESIGN
Parallel two-group multi-centre cluster randomised controlled trial.
Randomisation is at the level of the paramedic.
The study will enrol more than 9,000 patients and 1,500 paramedics.
Patients receive the trial intervention pre-hospital, and the primary outcome and other data are collected in-hospital.

METHODS
Consultation with ambulance services
Establish Clinical Research Network contacts
Involves critical care lead
Coordination of study in CSP, streamlining the approval process
Identify local collaborators in each hospital
Obtain local R & D approvals

Critical care leads
• Promoted study
• Opened lines of communications in hospitals
• Helped to identify suitable local collaborators

Stream-line approvals
Normal Process AIRWAYS2
1 page introduction to trial
2 page R&D contact (December 2014)
3 page introduction to trial
4 page study design summary
5 page responsibilities
6 page Frequently asked questions and answers from hospitals
7 page Local approvals (March 2015)
8 page CIP peer, S1I submitted
9 page 1 page agreement

Communications with hospitals
• R&D contact (December 2014)
• 1 page introduction to trial
• Identify local collaborator (January - March 2015)
• Study design summary
• Responsibilities
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