

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

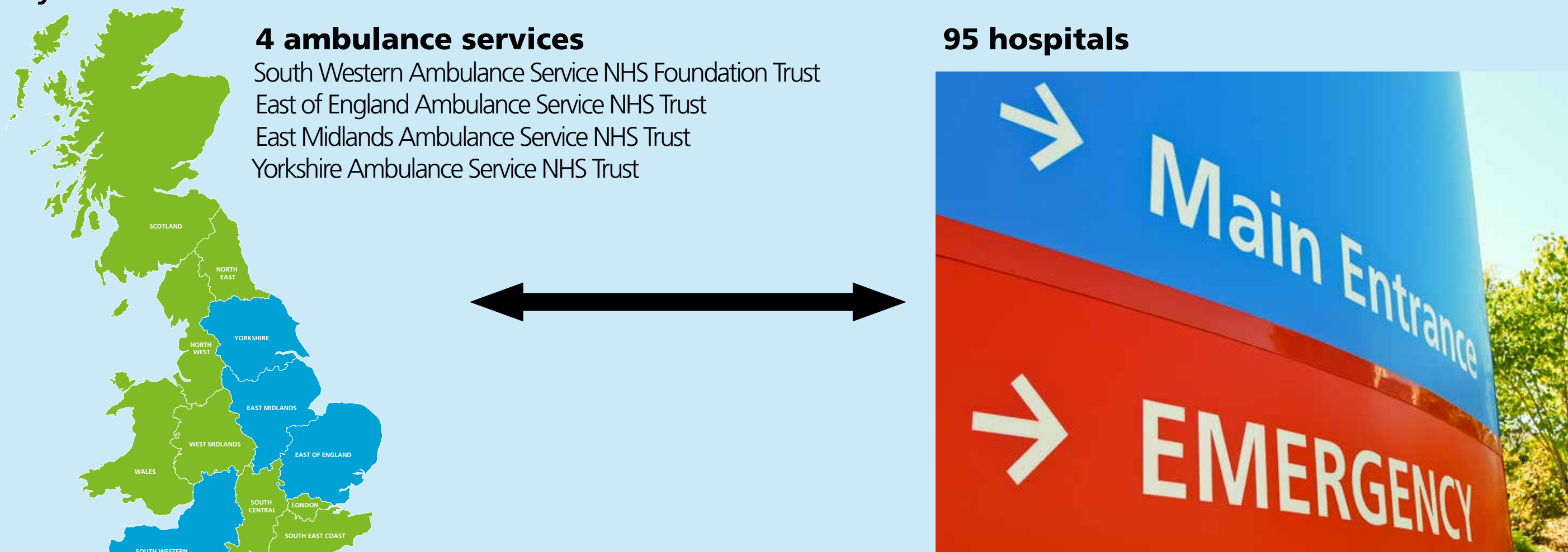
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BACKGROUND

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.



Obtaining approvals and site set-up can be complex, time consuming and expensive. We needed a strategy to minimize workload and reduce time-frames for obtaining approvals.

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.

AIRWAYS2 - Communication Pathways

Pre-hospital admission

Post hospital admission



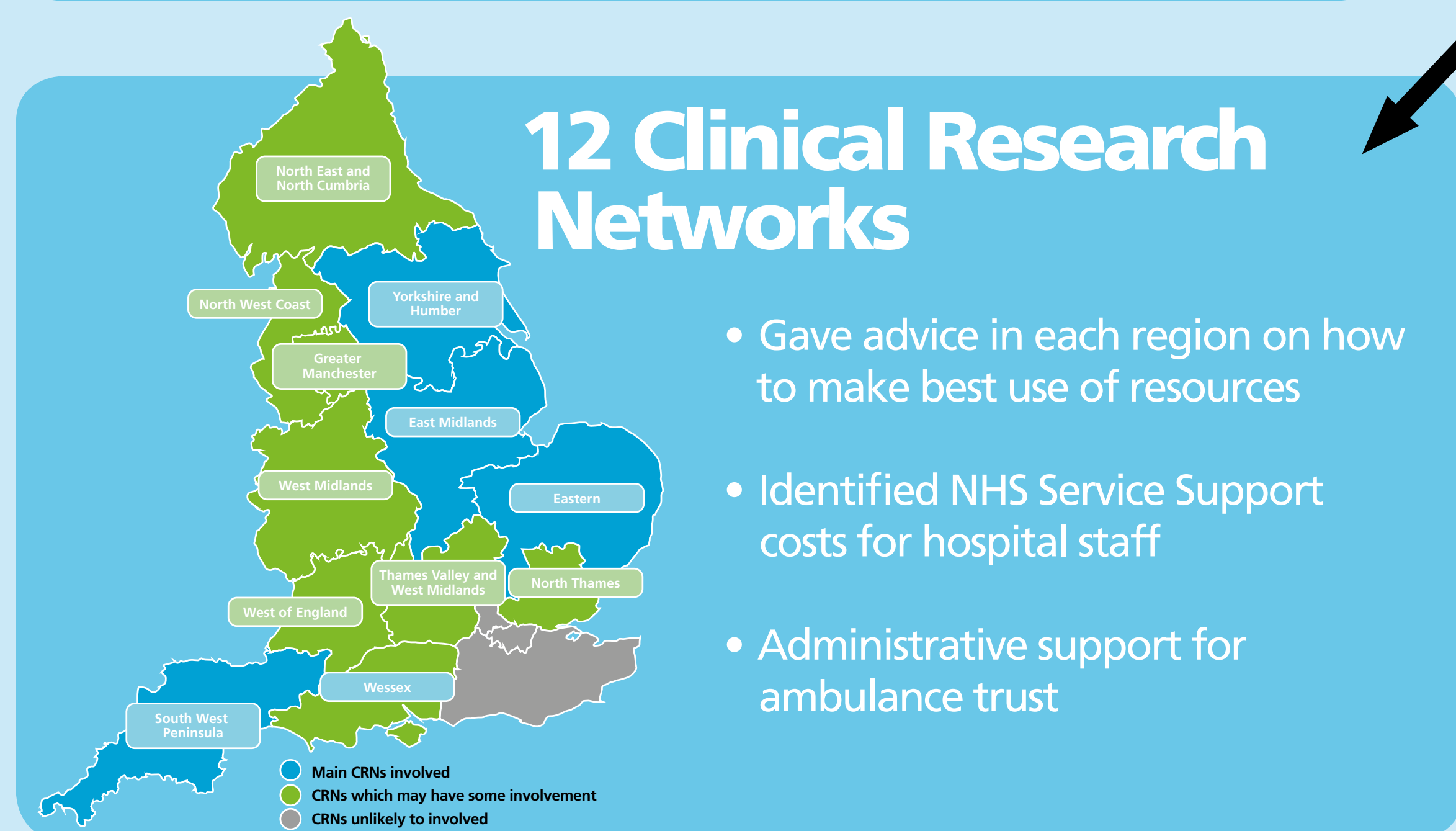
AIRWAYS2 - TMS
BRISTOL CTEU

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

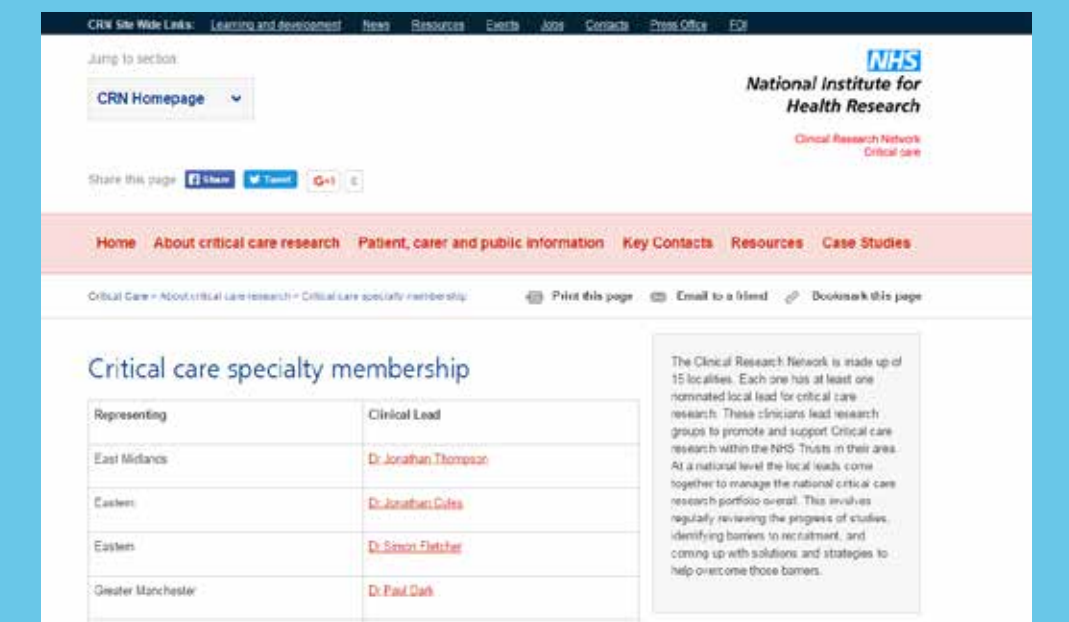


METHODS

- Consultation with ambulance services
- Establish Clinical Research Network contacts
- Involve critical care leads
- 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
SSI for each site	Generic SSI
Localised patient documents	No localisation of patient documents
Principal investigator	Local collaborator
Third party agreement	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
 - Frequently asked questions and answers from hospitals
- Local approvals (March 2015)
 - CSP generic SSI submitted
 - 1 page agreement

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 sites' participation and enables successful set-up of collaborative studies.