PhRASe

Prehospital Recognition and Antibiotics for 999 patients with Sepsis: a feasibility study

Chris Moore[1], Jenna Bulger[2], Sam Ricketts[1], Matt Morgan[3], Timothy Driscoll[2], Alison Porter[2], Saiful Islam[2], Mike Smyth[4], Gavin Perkins[4], Bernadette Sewell[2], Timothy Rainer[3], Prabath Nanayakkara[5], Chukwudi Okolie[2], Susan Allen[3], Greg Fegan[2], Jan Davies[6], Theresa Foster[7], Nick Francis[3], Fang Gao Smith[8], Gemma Ellis[3], Tracy Shanahan[3], Robin Howe[9], Helen Snooks[2]

1 Welsh Ambulance Services NHS Trust, Wales, UK
2 Swansea University, Wales, UK
3 Cardiff and Vale University Health Board, Wales, UK
4 University of Warwick, England, UK
5 VU University Medical Centre, Netherlands
6 Patient Representative, UK
7 East of England Ambulance Service NHS Trust, England, UK
8 University of Birmingham, England, UK
9 Public Health Wales, Wales, UK

Contact: j.k.bulger@swansea.ac.uk

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Background:

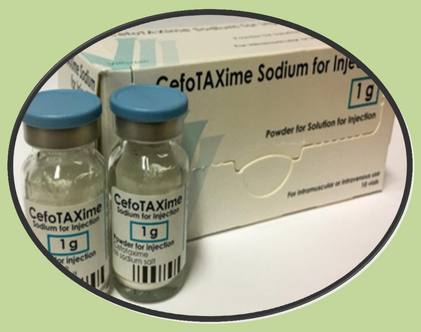
Sepsis is a common condition which kills between 36,000 and 64,000 people in the UK every year. Early recognition and management of sepsis has been shown to reduce mortality and improve the health and well-being of people with sepsis. Paramedics frequently come into contact with patients with sepsis, and are well placed to provide early diagnosis and treatment. This feasibility study aims to find out whether paramedics can identify, collect blood cultures from, and administer intravenous (IV) antibiotics to patients with 'Red Flag' sepsis. We aim to test the feasibility, safety and acceptability of our trial design and data collection methods, to determine whether to proceed to a fully-powered trial.

Methods:

Paramedics received training to assist them to recognise 'Red Flag' sepsis using a screening tool, obtain blood cultures, and administer IV antibiotics. If 'Red Flag' sepsis was suspected, paramedics randomly allocated patients to intervention or usual care using individually issued scratch cards. Patients were followed up at 90 days using linked anonymised data to capture length of hospital admission and mortality. We also collected self-reported health-related quality of life at 90 days. We interviewed patients and held a focus group with paramedics, to explore their views of the study and intervention.

Quantitative Results:

- Seventy-four of 104 (71.2%) eligible paramedics who work in the Cardiff and Vale locality expressed an interest to take part in PhRASe. Fifty-four paramedics completed their training (51.9%).
- Patients were recruited from 1.12.17 to 31.5.18.
- In total, 118 patients were randomly allocated to trial arms; four patients dissented to be included in the trial, leaving 114 patients to follow-up. Two patients requested no further correspondence so we could collect data from their medical records only (one from each arm of the trial).
- Twenty-six patients were recognised as eligible for the study but were not randomised. Reasons given include unavailable scratchcards (n=9); no PhRASe kit in the vehicle (n=2); and lack of time (n=2).
- The total number of patients identified as eligible was 144, and paramedics successfully randomised 118 of these (81.9%).
- Sixty-two patients (54%) were allocated to the intervention arm. The mean age of the control arm was 71.2 years (range 28-97); 33 (65%) control participants were female. In the intervention arm the mean age was 75.6 years (range 30-99) and 38 patients (61%) were female.
- Nine patients in the control group (18%) and 17 in the intervention group (28%) were already taking antibiotics at the time of their 999 call.
- Thirteen patients were not recognised as having 'Red Flag' sepsis by study paramedics whilst 118 (90%) were.
- Eighteen protocol deviations were recorded, as in the table to the right.
- Based on diagnoses recorded in the ED notes, 51 of the 114 patients were diagnosed with sepsis (44.7%). Thirty-nine patients were recorded as having a non-viral infection (34.2%), most commonly pneumonia or urinary tract infection.
- Based upon results recorded from hospital notes, in total 28 of the 114 patients died (24.6%): eight in the control group (15.4%) and 20 in the intervention group (32.3%). Three patients in the intervention group (4.8%) were admitted to the intensive care unit (ICU). No patients (0%) in the control group were admitted to ICU.



Deviation	n
Allergy to antibiotics (none given)	4
Lost or damaged scratchcards	4
Blood culture forms not completed	1
Patient not recorded in randomisation log	3
Incomplete dose of Cefotaxime administered	1
Scratchcards used out of order	1
Control patient given intervention	1
Missing kit or component.	2
Patient taken to non-receiving hospital	1
TOTAL	18

Qualitative :

At the end of the patient recruitment period, we conducted a focus group with five study paramedics (three female, two male). The focus group was conducted by one member of the research team (AP) who had not previously had contact with members of the group. All members of the focus group had identified patients eligible for the study (ranging from 2-6 patients per paramedic). All but one had delivered the intervention to patients (ranging from 2-3 per paramedic).

- Paramedics reported that they had found the screening and randomisation straightforward, but the taking of blood cultures was challenging on the ambulance. Though they were satisfied with the training, they suggested that confidence and competence with taking blood samples improved greatly only once they had started delivering the intervention, and required time and practice to develop.

"I think it feels like you need an extra hand…'Cause you've got to keep it aseptic and non-touch but when you've got a cannula and when you've got the blood pots also and you've got the what's it, a Vacutainer, it's just a bit fiddly. Yeah, especially when they're on the side of the stretcher and you're kneeling down beside them" MS2

- Paramedics were positive about the intervention as a way to improve patient care:

"The patients that I saw, their NEWS score, they improved so much just having the antibiotics pre-hospitally, didn't they?" FS2

- However, two raised concerns that the intervention would delay the patient's conveyance to hospital, suggesting that this would be more of a concern where the patient lived close to hospital, rather than in rural areas.
- Paramedics suggested the trial could be improved by including Emergency Medical Technicians (EMTs) in the training, even if they were not responsible for delivering the intervention:

"Just so that they were aware, so that maybe they could, you know, wipe the bottle and stuff and pass it to us, so it was more [flow] to the actual procedure...That's probably my only improvement to it, and then that way the technicians who were involved in the trial as well, 'cause I know they felt that they were a bit separated, the fact that it was just aimed at paramedics" FS3

Discussion:

We are awaiting access to anonymised follow-up data from SAIL, so we are not yet able to assess all of our progression criteria. When we have the data, we will be in a position to determine whether we will seek funding to proceed with a fully-powered trial. We have, however, insights from this feasibility study that would be utilised in a fully-powered trial – for example, that EMTs should be included in study training sessions so they have an awareness of study procedures and can provide assistance to study paramedics. We do not yet know the cause for the difference in death and ICU admissions between groups, but will verify this when SAIL data is available, and investigate this further as appropriate.

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