



Research and Development Report

2017 to 2019

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REPORT PERIOD: April 2017 to March 2019

1.0 Introduction

Research is considered core business for the NHS, bringing benefits to patients, clinicians and the NHS Organisation (Box 1). Principle 3 of the NHS Constitution is that, “The NHS aspires to the highest standards of excellence and professionalism,” and states, “The importance of innovation and medical research is underscored by this Principle as integral to driving improvements in healthcare services for patients (Handbook to the NHS Constitution, July 2015).

Box 1 – Why we do research

Benefits of research

For our patients:

- Patients in clinical trials do better regardless of which treatment they are on
- Most patients want to take part in clinical research
- Taking part in clinical trials results in improved clinical care.

For the NHS:

- Research findings result in better treatment for patients
- Improves use of scarce NHS resources
- Enables fair use of resources.

For healthcare clinicians:

- Involvement in research increases clinical skills
- Helps clinicians to understand evidence and use this in their clinical practice
- Improves job satisfaction
- Encourages team working.

For healthcare organisations:

- Involvement in research helps attract more forward-looking staff
- Increases the number of clinicians with expertise in research
- Drives the development of research relevant to the population served.

This report presents an overview of clinical research activity within the East of England Ambulance Service NHS Trust (EEAST), during the timeframe April 2017 to March 2019. This has been another busy period, in terms of numbers of research studies and numbers of participants recruited, similar to the previous reporting period.

Such continued participation in high quality clinical research activity has demonstrated the Trust's on-going commitment to improving the care it offers, in addition to making a contribution to wider health improvement.

Indeed, EEAST has been research active for a decade now, and research findings are being used to inform clinical and other service developments, where such evidence is available.

2.0 Research Policy, PID & RDOCS

A copy of the current approved Research and Development (R&D) Policy v4.0 can be obtained from the Trust website within the Clinical Quality / Research Support Services (RSS) folder. The aim of this policy is to advise the conduct of research within EEAST, which then complies with good research practice as detailed in the UK Policy Framework for Health and Social Care Research.

In line with legislation, Trust performance in initiating and delivering (PID) reports (about initiating Clinical Trials and delivering Commercial Contract Clinical Trials), are published on the Trust website within the Clinical Quality / RSS folder. It should be noted that such research activity forms a small proportion of the clinical research that EEAST undertakes.

Finally, EEAST R&D management arrangements, organisational study capabilities, and R&D interests are available via the R&D Operational Capability Statement (RDOCS) v5.0, on the Trust website within the Clinical Quality / RSS folder. This signposts the best person to contact within EEAST for any research enquiry, for example research passports, contracts, etc.

3.0 Research Networking Activity

Clinical Research Networks (CRNs) are responsible for allocating National Institute for Health Research (NIHR) monies to support delivery of NIHR Portfolio-adopted research activity. EEAST has maintained Partner Organisation status with CRN-Eastern throughout the reporting period, and regularly attends associated meetings.

The National Ambulance Research Steering Group (NARSG) has continued to meet bi-monthly during this reporting period, and EEAST maintained and further developed closer links with this increasingly important group for pre-hospital ambulance research development and delivery. NARSG

meetings alternate between a Research Development Meeting and an Operational & Governance Meeting, and London Ambulance Service currently Chair.

RSS team members also attended a variety of academic and research network groups, from which was sought guidance, support and linkages to researchers and other resources. Examples of such activity included, CRN Eastern Stroke Specialty group, Research Managers meeting, College of Paramedics events, Council of Allied Health Professionals Research group, Collaborations for Leadership in Applied Health Research and Care (CLAHRC) events, and University of East Anglia (UEA) Health and Social Care Partners.

4.0 Health Research Authority (HRA) Approval

The phased roll-out of the HRA Approval process, the new system for approving all research in the NHS led from England, was fully implemented by April 2016. HRA Approval provides a single governance approval for research, consisting of assessments by HRA staff alongside the independent Research Ethics Committee (REC) opinion where required. NHS Trusts now need only to assess their capacity and capability to deliver HRA Approved studies, before giving permission to start if feasible. EEAST has fully implemented the HRA Approval process. Up to date HRA guidance is available via <https://www.hra.nhs.uk/>

RSS team members have been trained to undertake the capacity and capability assessments, ensuring all arrangements are in place to successfully deliver a study via:

- Review of costings / research contracts / agreements (as necessary)
- Liaison with required support department(s)
- Advice regarding issuing of honorary research contracts or letters of access
- Provision of guidance on HRA requirements and applications
- Review of impact of amendments to existing studies

5.0 Research Project Activity 2017 to 2019

Nine studies which commenced in previous reporting periods remained active during 2017 to 2019. Of these, 7 were NIHR Portfolio projects, and 2 (OHCAO and RePHILL) remain on-going. This demonstrates the time commitment required, to deliver in particular the high quality Portfolio activity that EEAST undertakes.

RSS received a total of 14 new research study proposals, requiring capacity and capability assessments during 2017 to 2019. Two of these were NIHR Portfolio projects, 5 were high quality but non-Portfolio, and 2 were CLAHRC-sponsored studies. EEAST was requested to host 5 student-level research studies (MSc or PhD), whereby RSS offer mentorship within the Trust, as secondary support of University supervisors. Following assessments, all 14 studies were given approval to proceed. A summary of research projects with activity in the reporting period is presented in Table 1 below.

Table 1 demonstrates the breadth of research that the Trust is capable of supporting and delivering now. There are large randomised-controlled clinical studies like AIRWAYS-2 and RIGHT-2, big data studies such as OHCAO, EDARA and ExILEnS, and many smaller qualitative and quantitative projects. Further details about all research activity can be obtained from the Trust website within the Clinical Quality / RSS folder, or from RSS.

6.0 Recruitment of Research Subjects 2017/18 and 2018/19

The Trust recruited 191 participants (patients and Trust staff) into high quality NIHR Portfolio research studies during 2017/18, and a further 172 participants in 2018/19. The vast majority of this activity arose from Trust participation in the AIRWAYS-2, RIGHT-2 and RePHILL studies.

In addition, data on approximately 3,000 cardiac arrest patients per year was uploaded to the OHCAO registry study, and small-scale student-level projects offered wider opportunity for research involvement (these recruitment numbers are not currently captured routinely by RSS).

7.0 Financial Support

Financial support for research was obtained from contracted income related to delivery of some of the research studies during the reporting period. Over and above such income, during 2017/18 the Trust received

funding from CRN-Eastern of approximately £72k, and about £63k in 2018/19. CRN-Eastern funds were used to maintain the full-time Research Paramedic role within RSS, to support the Research Manager role, and ensure delivery of NIHR Portfolio research activities. CRN-Eastern support was utilised for Local Project Management System implementation, and capacity building activities within the Trust.

Table 1. Research projects which had activity undertaken in reporting period 2017 to 2019

Project title	Sponsor	Status & Notes
Out of Hospital Cardiac Arrest registry - OHCAO (NIHR Portfolio)	Warwick University	On-going from previous reporting period.
RePHILL air ambulance bloods study (NIHR Portfolio)	University of Birmingham	On-going from previous reporting period.
Variation in non-conveyance – VAN study (NIHR Portfolio)	Sheffield University	On-going from previous reporting period. Now completed.
Ambulance airway management study – AIRWAYS-2 (NIHR Portfolio)	South West Ambulance Service	On-going from previous reporting period. Now completed.
MIND Blue Light Resilience Programme research	University of Oxford	On-going from previous reporting period. Now completed.
Stroke GTN study – RIGHT-2 (NIHR Portfolio)	Nottingham University	On-going from previous reporting period. Now completed.
Ambulance staff suicide research	Association of Ambulance Chief Executives	On-going from previous reporting period. Now completed
Dementia fallers intervention – DIFRID study (NIHR Portfolio)	University of Newcastle	On-going from previous reporting

		period. Now completed.
Dementia multi-morbidities study – HOMEWARD (NIHR Portfolio)	University of West of England	On-going from previous reporting period. Now completed.
Evaluating diversion of alcohol related attendances – EDARA study	University of Sheffield	Started and completed within reporting period.
Electronic Records in Ambulance Services – ERA study (NIHR Portfolio)	Swansea University	Started and completed within reporting period.
Duty of Candour study	Imperial College	Started and completed within reporting period. Student.
Cultures of openness in the NHS	University of Leicester	Started and completed within reporting period.
Ambulance-led sepsis care	CLAHRC	Student Fellowship on-going
Design to care, exploring staff views of end of life study	CLAHRC	Permission to proceed Feb 2018.
What makes a good paramedic practice educator study?	Anglia Ruskin University	Permission to proceed March 2018. Student.
Incident reporting research	Plymouth University	Permission to proceed Sept 2018. Student research.
Exploring impact of alcohol licensing – ExILEns study	Bristol University	Feasibility checks on-going.
Evaluation of advanced clinical practitioners	Anglia Ruskin University	Permission to proceed Sept 2018.

Essex & Herts air ambulance service evaluation	Anglia Ruskin University	Permission to proceed Oct 2018. On-going.
Lifestyle factors and staff wellbeing	Liverpool John Moores University	Permission to proceed Feb 2019. Student. On-going.
Sleep and fatigue research	UEA	Permission to proceed Feb 2019. On-going.
Paramedic rescue personality research .	Anglia Ruskin University	Permission to proceed March 2019. Student. On-going

8.0 Research Capacity

The RSS function consisted of 2.8 Whole Time Equivalent (WTE) staff in 2017/18, but this reduced to 1.8 WTE in 2018/19 on completion of AIRWAYS-2.

Research awareness and knowledge-raising activity throughout the Trust utilised face-to-face discussions with staff, dissemination of research findings on the website, and at Clinical Development and Effectiveness Meetings, a stand at the Clinical Briefing Day, as well as regular articles in Trust publications.

Wider dissemination of the findings from research activities has been achieved through oral and poster presentations at external peer-reviewed meetings and conferences, as well as publications in peer-reviewed journals, copies of which can be obtained from RSS.

Trust staff undertaking graduate or post-graduate studies with a research element, whether financially supported by the Trust or not, continued to be encouraged to contact RSS for mentoring and support alongside their Higher Education Institution supervision.

Since the autumn of 2014, all student paramedics within the Trust have undertaken an introduction to research training module, which requires them to complete an Introduction to Good Clinical Practice (GCP) e-learning course. Similarly, all clinicians involved in research studies are expected to successfully obtain a GCP certificate.

9.0 NIHR Research Activity League Table

As part of the NIHR CRN objectives, every ambulance Trust was asked to recruit participants to two or more Portfolio research studies per year. Every one of the 10 Trusts in England, including EEAST, has met this target for two consecutive years.

A league table is published annually by the NIHR CRN, and aims to make engagement in Portfolio clinical research more transparent and accessible to patient, health and social care professionals, and decision-makers. The table data includes how much Portfolio clinical research is happening where, in which types of Trusts, and involving how many participants.

In the 2017/18 table, EEAST was 9th with regard the number of participants (n=191; range 100- 1,181) into research, and 4th in terms of number of Portfolio studies (n=4; range 2-8). Most recently, in the 2018/19 table, EEAST was 6th with regard number of participants (n=172; range 60-753), and joint 4th for number of Portfolio studies (n=3; range 3-8). The clinical research league table is available at www.nihr.ac.uk/nihrleaguetable.

10.0 Research Misconduct, Fraud and Complaints

Once again, no concerns or incidences have been raised in this reporting period.

11.0 Publications 2017-19

Prothero, L.S., de Carteret, E. and Nicholls, T. (2017) Missed opportunities in ambulance sepsis care? *Emergency Medical Journal*, 34(10), e9.3 - e10

Implementation and use of computerised clinical decision support (CCDS) in emergency prehospital care: A qualitative study of paramedic views and experience using Strong Structuration Theory. Porter, A. Dale, J. Foster, T. Logan, P. Wells, B. and Snooks, H. (2018) *Implementation Science*, 13:91.

Patient and clinician factors associated with prehospital pain treatment and outcomes: cross sectional study. Siriwardena, A. Asghar, Z. Lord, B. pocock, H. Phung, V. Foster, T. Williams, J. and Snooks, H. (2018) *American Journal of Emergency Medicine*, DoI: 10.1016/j.ajem.2018.05.041

Prehospital recognition and antibiotics for 999 patients with sepsis: protocol for a feasibility study. Moore, C. Bulger, J. Morgan, M. Driscoll, T. Porter, A. Islam, S. Smyth, M. Perkins, G. Sewell, B. Rainer, T. Nanayakkara, P. Okolie, C. Allen, S. Fegan, G. Davies, J. Foster, T. Francis, N. Smith, F. Ellis, G. Shanahan, T. Howe, R. and Snooks, H. (2018) Pilot and Feasibility Studies, 4: 64.

Hoare, S., Kelly, M.P., Prothero, L. and Barclay, S. (2018) Ambulance staff and end-of-life hospital admissions: A qualitative interview study, Palliative Medicine, 32(9), 1465 – 1473

Voss, S., Brandling, J., Taylor, H., Black, S., Buswell, M., Cheston, R., Cullum, S., Foster, T., Kirby, K., Prothero, L., Purdy, S., Solway, C. and Bengler, J. R. (2018) How do people with dementia use the ambulance service? A retrospective study in England: the HOMEWARD project. BMJ Open, 8(7), e022549

Prothero, L.S. and Wagner, A.P. (2019) Does ambulance care offer improved patient outcomes in diabetic ketoacidosis? Diabetic Medicine, 36 (S1), 79

The RIGHT-2 Investigators (2019) Prehospital transdermal glyceryl trinitrate in patients with ultraacute presumed stroke (RIGHT-2): an ambulance-based, randomised, sham-controlled, blinded, phase 3 trial. The Lancet, 393, 10175, 1009 - 1020; DOI:[https://doi.org/10.1016/S0140-6736\(19\)30194-1](https://doi.org/10.1016/S0140-6736(19)30194-1)

12.0 Research Presentations 2017-19

University of East Anglia 'Research in the Pre-Hospital Setting' (Annual lecture)

Collaborations for Leadership in Applied Health Research and Care Fellows Showcase (2017) 'Sepsis: not missing another case' (Oral and Poster)

Sepsis: Improving recognition and management (2017) 'Bridging the Gap: the handover between primary care, acute and the ICU setting' (Oral)

College of Paramedics: Clinical Conference (2018) 'Use of out-of-hospital NEWS in Sepsis' (Oral)

Sepsis Unplugged (2018) 'Use of out-of-hospital NEWS in Sepsis' (Oral)

Council for Allied Health Professions Research (2018) 'DKA: can paramedics make a difference?' (Oral)

Nursing, Midwifery and Allied Health Professional Research Conference (2018) 'Missed opportunities in sepsis care' (Oral)

Council for Allied Health Professions Research (2019) 'Ambulance clinician understanding of diabetic ketoacidosis: a survey-based evaluation' (Oral)

Nursing, Midwifery and Allied Health Professional Research Conference (2019) 'Does ambulance care offer improved patient outcomes in diabetic ketoacidosis?' (Oral)

13.0 Future Direction

Clinical research is considered core business within EEAST, and the Trust has built up a reputation for successful delivery of high quality research. Several studies hosted or sponsored by EEAST are due to receive funding decisions shortly, with success giving opportunity for the RSS function to increase in WTE capacity. In the meantime, the Trust will continue to drive the development of research grant applications in areas of importance to Trust patients and staff.

Resources allowing, the Trust will maintain and improve the links it enjoys with academic institutions within and external to the region, with the explicit aim of increasing the number of grant applications for research the Trust would subsequently host.

RSS will communicate opportunities for research skills development throughout the Trust, in order to increase research knowledge, particularly at the senior management level.

Resources allowing, RSS will support the Trust Clinical Strategy, as well as regional initiatives such as the CRN-Eastern strategy to maximise population access to NIHR Portfolio studies, and grow under-developed areas of research need.