



Trust Board Meeting				31 July 2012	
Title	Research & Development Annual Report			Paper Ref	6.3
PURPOSE (X)		Information		Strategic Objective	Business Plan Objective
Approval	X	Decision			
Assurance	X	Discussion		3	
Purpose of the paper	This annual report provides a summary of research and development activity, and assurance that key governance criteria are fully met.				
Recommendation	<ul style="list-style-type: none"> ▪ It is recommended that the Board note the funding received from networks, and continue to support activity that assists YAS to improve patient care and clinical practice. ▪ It is recommended that the Board authorise the research Operational Capability Statement to be published on the trust website, summarising YAS research capability (Appendix 1). ▪ It is further recommended that the Board accept assurance regarding research governance. 				
Author	J Shewan P Mortimer		Accountable Director:	Dr A Walker	
RISK ASSESSMENT				Yes	No
Changes to the Corporate Risk Register and/or Board Assurance Framework					X
Resource Implications					X
Legal implications					X
ASSURANCE/COMPLIANCE					
CQC Registration Outcome(s)	Auditors' Local Evaluation		NHSLA Risk Management Standards for Ambulance Trusts		
NA	NA		NA		

1 PURPOSE

This paper provides a summary of research and development (R&D) activity, and assurance that key governance criteria are fully met.

It provides an opportunity for Board members to consider the draft research 'operational capability statement' which provides information and contact details for researchers and pharmaceutical companies seeking to conduct research in the NHS.

2 BACKGROUND

Research governance is delivered for the trust by staff mainly funded via West Yorkshire Comprehensive Local Research Network (WYCLRN). Research risks are managed by having in place robust processes to ensure YAS participates only in high quality research, monitors study conduct and performance, and assures YAS of regulatory compliance.

Research that is supported by the National Institute of Health Research is funded via WYCLRN. The National Institute for Health Research requires trusts to publish a research 'operational capability statement', as a condition of receipt of monies, and as part of a national work stream to facilitate research in the NHS. Statements from every NHS organisation in receipt of NIHR funding will be published on a national website, and also on NHS organisations' websites.

3 PROPOSAL

Receipt and ratification of this paper demonstrates YAS Board is assured of regulatory compliance and supports publication of the research operational capability statement. The report provides evidence to support assurance on our research governance for the Board.

4 RECOMMENDATIONS

- It is recommended that the Board note the funding received from networks, and continue to support activity that assists YAS to improve patient care and clinical practice.
- It is recommended that the Board authorise the research Operational Capability Statement to be published on the trust website, summarising YAS research capability.
- It is further recommended that the Board accept assurance regarding research governance.

5 ATTACHMENTS

- Research Annual Report 2011-2012
 - Appendix 1: Operational Capability Statement
 - Appendix 2: Certificate of Recognition

Research and Development Annual Report 2011-2012

Introduction

Research and Development (R&D) within YAS is overseen by the Associate Medical Director Dr Julian Mark, on behalf of the Medical Director Dr Alison Walker. During 2011-2012, the research team has continued to develop research alliances and has worked closely with the three Comprehensive Local Research Networks (CLRNs) to both enhance the research profile of YAS across Yorkshire & the Humber and to secure funding that continues to support the YAS research vision and strategy.

Quality and governance

The research management team has continued to systematically assess all research against legal, policy and ethical requirements to ensure that YAS participates in high quality studies only. Further details are provided below regarding YAS participation in a commercially sponsored drug trial. We have supported the national strategy to facilitate research by reducing bureaucratic barriers and speeding up the time taken by NHS organisations to approve participation in research.

YAS has achieved the fastest average approval time for a NHS organisation in West Yorkshire during 11-12 for high quality studies adopted by the National Institute for Health Research. Additionally, as part of implementing a national research work stream, trusts are asked to publish information about their research capability. The 'Operational Capability Statement' at appendix 1 describes the categories of research that YAS is prepared to participate in, and provides contact details to facilitate access to the organisation.

Evidence of compliance with key quality requirements from the Research Governance Framework for Health and Social Care is maintained.

The trust's Quality Account published in 2012 includes a section on our research and innovation, which reflects the information contained in this report.

The Clinical Effectiveness Group, a subgroup of the Clinical Governance Committee continued during 2011-2012 to monitor the research approval process and the necessary administrative and information systems to comply with local and national R&D requirements.

Research Activity

During 2011-12 YAS took part in eight research studies approved by an ethics committee:

- **Best Interests Decision Study** – 4 staff were interviewed to find out how the Mental Capacity Act (MCA) and related guidance are being used to protect and empower those who are judged to lack capacity.
- **High Quality Care for All/Quality and Safety in the NHS** – 349 staff completed a survey to evaluate the extent to which cultural and behavioural changes are occurring in the NHS, in response to recent drives to increase quality and safety in

healthcare. The project is particularly focused on generating sustainable lessons about how to improve quality and safety in the NHS.

- **The Ambulance Service Cardiovascular Quality Initiative (ASCQI)** – 407 staff completed a survey to explore the extent and variation in the use of quality improvement tools in ambulance services for the second phase of this study.
- **ATLANTIC** – 2 patients took part in a commercially sponsored multinational randomised controlled trial testing whether the use of an antiplatelet drug in ambulances compared to on arrival in angioplasty departments improves outcomes for patients having primary percutaneous angioplasty following a heart attack.
- **Developing Outcome Measures for Pre-hospital Care** – aiming to develop methods for measuring processes and outcomes of pre-hospital care, using literature review, consensus methods, create a dataset to routinely link pre-hospital, hospital and mortality data, develop methods to measure proposed indicators, and explore the practical use of the developed models.
- **Decision Making and Safety in Emergency Care Transitions** - a study designed to find out what is currently known about safety in pre-hospital emergency care and what are the key influences on safe decision making by emergency care staff directly involved in the care and transition of patients.
- **Exploring the feasibility and practicalities of research in the pre-hospital setting** - A staff survey to identify the barriers to undertaking pre-hospital research and to identify potential solutions.
- **CURE-RAPID** - Developing the Community Urgent Response Environment for Rapid Response Vehicles – a phased study looking at the possible future design of equipment carrying systems using focus groups and observation of staff using equipment with actor casualties.

The number of patients receiving NHS services provided or sub-contracted by YAS in 2011-2012 that were recruited during that period to participate in research approved by a research ethics committee was 2, plus 760 staff.

In 2011-2012 we also:

- supported 3 ambulance clinicians who were awarded bursaries to study research at masters level
- nurtured our 20 research champions to promote and encourage the principles and benefits of research. We wrote about the work of our champions to enter the Health Service Journal awards in the category of developing a research culture, and received a certificate recognising our efforts (attached as appendix 2). We will be evaluating the project before it finishes later in 2012. Phase 2 of the project (with a reduced number of champions with less development time but more focused on the delivery of research) is currently the subject of a bid for funding to the West Yorkshire CLRN.
- worked with three Comprehensive Local Research Networks (CLRNs) in Yorkshire & the Humber who have continued to fund YAS to encourage our development as a research active organization. Approximately £60,000 has been received this year to fund posts and projects within YAS. YAS works most closely with West Yorkshire CLRN who liaise with their south and north colleagues.
- had four peer-reviewed articles published related to research, audit and innovation activity:

Snaith B, Hardy M, Walker A. Emergency ultrasound in the prehospital setting: the impact of environment on examination outcomes. *Emergency Medicine Journal* March 2011, 10.1136

Taylor J. Putting Safety First, Newsletter, College of Paramedics, September 2011

Mark J, Walker A, Davey C. A mannequin study comparing suitability of the i-gel™ with a laryngeal mask airway device. Vol 3 No 8 • *Journal of Paramedic Practice*. Aug 2011

Darnell G, Mason S, Snooks H. Elderly falls: a national survey of UK ambulance services Online First doi 10.1136/emmermed-2011-200419

Participation in a drug trial

The ATLANTIC study mentioned above has been a significant research development for YAS, and required us to update our research governance policy and agree research income distribution principles. The governance policy embeds systems and processes to support compliance with the Clinical Trials Regulations 2006, which is the UK legislation relating to clinical trials of investigational medicinal products (drug trials). The ATLANTIC study is funded and managed by AstraZeneca, who take responsibility for the overall quality of the trial and provide no-fault indemnity for participants. The study is adopted onto the National Institute for Health Research portfolio of high quality trials, and gives YAS assurance from the 'research arm' of DH that the study is properly designed and supported.

The choice of a commercially-led study as our first drug trial provided confidence that the trial would be professionally managed and monitored, and that risks would be minimal. This confidence was supported by the company's willingness to work very closely with YAS at the feasibility stage when deciding whether the study could be opened in the UK, as it was initially set up for a European model of pre hospital care. All relevant departments and managers were included in feasibility discussions before YAS involvement in a drug trial was authorised by the executive group. Feasibility included everything from minimising potential impact on trust targets, to ensuring secure, temperature controlled storage could be made available on ambulance stations for the trial drug.

This is a 'phase four' trial, meaning that the drug is already licenced for the indication and the safety profile is very well known. The UK Chief Investigator is Dr R Storey in Sheffield Teaching Hospitals NHS Trust who has significant previous research experience with the drug. The local Principal Investigator is Dr Dave Macklin, who has completed the appropriate training to enable compliance with legal requirements. All paramedics recruiting patients to this trial have also received training in trial procedures and in consent.

We were the first UK NHS Trust to provide approval for the study, and have supported other ambulance services to set up the study by sharing experience and documents such as patient group directions (PGDs). AstraZeneca have provided training and support for

the study, and continuously monitor the quality of study conduct. To date, no adverse events relating to the YAS conduct of the study have occurred. Income from the study in 2011-2012 was £6,581 which recompensed YAS for management costs, paramedic training and the installation of a drug safe and security system.

Innovation

2011-2012 has seen exciting work by Cathryn James, Clinical Pathways Advisor, recognised with a national award. Cathryn won the NHS Clinical Leaders Network award for her project to improve telecare alarm services for patients using YAS services. Cathryn was also a finalist in the Medipex Software and Telehealth awards.

Appendix 1

NIHR Guideline B01 R&D Operational Capability Statement



Yorkshire Ambulance Service **NHS**
NHS Trust

Version History

Version number	Valid from	Valid to	Date approved	Approved by	Updated by
RDOCS/YAS 1.00	01/04/2012	31/03/2013	TBA	YAS Trust Board	Peter Mortimer, R&D Manager

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Mr David Whiting, Chief Executive Officer Date:	Dr Alison Walker, Medical Director Date:
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Organisation R&D Management Arrangements

Information on key contacts

Organisation Details	
Name of Organisation	Yorkshire Ambulance Service NHS Trust
R&D Lead / Director (with responsibility for reporting on R&D to the Organisation Board)	Dr Alison Walker, Medical Director YAS
Key Contact Details e.g. Research Governance Lead, NHS Permissions Signatory contact details	
Contact 1:	
Role:	Head of Research & Development
Name:	Jane Shewan
Contact Number:	07795-646475
Contact Email:	jane.shewan@yas.nhs.uk
Contact 2:	
Role:	Research & Development Manager
Name:	Peter Mortimer
Contact Number:	07730-426043
Contact Email:	peter.mortimer@yas.nhs.uk

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Information on staffing of the R&D Office

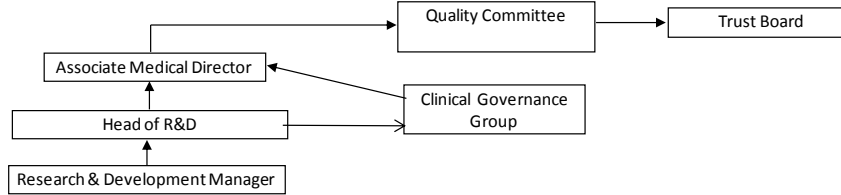
R&D Team		
R&D Office Roles (e.g. Governance, Contracts, etc)	Whole Time Equivalent	Comments indicate if part time/full time/shared/joint etc
Head of Research & Development	0.4	Part-time
Research & Development Manager	1	Full-time

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Information on reporting structure in organisation (include information on any relevant committees, for example, a Clinical Research Board / Research Committee / Steering Committee.)

Reporting Structures

The YAS Head of Research & Research & Development reports all activity relating to research to the YAS Clinical Governance Group and Associate Medical Director, who provides assurance to the Quality committee.



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Information on Research Networks supporting/working with the Organisation.

Information on how the Organisation works with the Comprehensive Local Research Network (CLRN), Primary Care Research Network (PCRN), Topic Specific Clinical Research Networks (TCRN)

Research Networks

Research Network (name/location)	Role/relationship of the Research Network eg host Organisation
West Yorkshire Comprehensive Local Research Network	Act as 'lead' CLRN on behalf of SYCLRN & NEYNL CLRN.
North East Yorkshire & North Lincolnshire Comprehensive Local Research Network	See above
South Yorkshire Comprehensive Local Research Network	As above
Northern & Yorkshire Primary Care Research Network	N&Y PCRN links to YAS via West Yorkshire Primary Care Advisory Group of WY CLRN
Yorkshire Cancer Research Network	Supports NCRN activity in Yorkshire
Yorkshire Stroke Research Network	Supports SRN activity in Yorkshire

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Information on collaborations and partnerships for research activity (e.g. BRC, BRU, Other NHS Organisations, Higher Education Institutes, Industry)

Current Collaborations / Partnerships

Organisation Name	Details of Collaboration / Partnership (eg University/Organisation Joint Office, external provider of pathology services to Organisation, etc, effective dates)	Contact Name	Email address	Contact Number
No formal partnerships				

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Organisation Study Capabilities

Information on the types of studies that can be supported by the Organisation to the relevant regulatory standards

Types of Studies Organisation has capabilities in (please tick applicable)

	CTIMPs (indicate Phases)	Clinical Trial of a Medical Device	Other Clinical Studies	Human Tissue: Tissue Samples Studies	Study Administering Questionnaires	Qualitative Study	OTHER
As Sponsoring Organisation	X	X	✓	X	✓	✓	
As Participating Organisation	✓ PHASE 3 OR 4	✓	✓	X	✓	✓	
As Participant Identification Centre	X	X	X	X	X	X	

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Which licences does the organisation hold which may be relevant to research?

Organisation Licences

Licence Name	Licence Details	Licence Start Date (if applicable)	Licence End Date (if applicable)
Example: Human Tissue Authority Licence			
None	Not applicable	Not applicable	Not applicable

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Organisation Services

Information on key clinical services contacts and facilities/equipment which may be used in studies for supporting R&D governance decisions across the organisation.

Clinical Service Departments

Service Department	Specialist facilities that may be provided (eg number/type of scanners)	Contact Name within Service Department	Contact email	Contact number	Details of any internal agreement templates
For information on resource availability (staff, vehicles or equipment) please use the R&D Manager as first point of contact					

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Information on key management contacts for supporting R&D governance decisions across the organisation.

Management Support e.g. Finance, Legal Services, Archiving

Department	Specialist services that may be provided	Contact Name within Service Department	Contact email	Contact number	Details of any internal agreement templates
Finance	Managing of the trust R&D budget	Helen Cullen	helen.cullen@yas.nhs.uk	01924-584206	
Human Resource	Validation of research passports and issue of letters of access and honorary contracts	Sally Peart	sally.peart@yas.nhs.uk	0845-1241241	

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Organisation R&D Interests

Information on the areas of research interest to the Organisation

Organisation R&D Areas of Interest

Area of Interest	Details	Contact Name	Contact Email	Contact Number
Alternative care pathways	These are research priorities for the trust. Please contact Head of R&D or R&D manager for details			
Pre-hospital ultrasound				
Boundaries of care				
Diabetes				
Patient safety				
Patient Experience				
Airway management				
Trauma and Cardiac care				

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Information on Local / National Specialty group membership within the Organisation which has been shared with the CLRN

Specialty Group Membership (Local and National)

National / Local	Specialty Group	Specialty Area (if only specific areas within group)	Contact Name	Contact Email	Contact Number
Local	Yorkshire Injuries & Emergencies Specialty Group	All areas of pre-hospital care	Jeanette Turner	j.turner@sheffield.ac.uk	

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Organisation R&D Planning and Investments

Planned Investment

Area of Investment (e.g. Facilities, Training, Recruitment, Equipment etc.)	Description of Planned Investment	Value of Investment	Indicative dates
There is no YAS planned research investment at this time			

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Organisation R&D Standard Operating Procedures Register

Standard Operating Procedures

SOP Ref Number	SOP Title	SOP Details	Valid from	Valid to
YAS is presently developing a suite of SOPs in line with recent Research Support Services (RSS) guidance - these will be published on the YAS Research intranet site				

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Information on the processes used for managing Research Passports

Indicate what processes are used for managing Research Passports

Research Passports are provided and managed by the R&D Department in partnership with the HR Department as required and in accordance with current national guidance

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Information on the agreed Escalation Process to be used when R&D governance issues cannot be resolved through normal processes

Escalation Process

The YAS Research Governance Policy clearly outlines the processes for the management of research study activity within the trust. Any issues relating to the conduct of a study will in the first instance be assessed by the R&D Manager for resolution and reported upon to the Head of Research. Failure to resolve will require escalation and reporting to the Associate Medical Director and beyond to the Medical Director who has overall trust responsibility for research activity. For NIHR research activity, further advice and support is available via the West Yorkshire CLRN.

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Planned and Actual Studies Register

The Organisation should maintain or have access to a current list of planned and actual studies which its staff lead or collaborate in.

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Other Information

For example, where can information be found about the publications and other outcomes of research which key staff led or collaborated in?

Other Information (relevant to the capability of the Organisation)

Research activity for the financial year is included within the YAS Annual Report which is published on the YAS Internet site. Additional supporting evidence is provided within the mandatory Quality Accounts which also is provided on the YAS web-site. YAS also has systems in place to comply with the requirements of the Research Governance Framework 2005 (RGF).

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CERTIFICATE OF RECOGNITION



**National Institute for
Health Research**

Clinical Research Network

The National Institute for Health Research
Clinical Research Network
wishes to acknowledge:

*Yorkshire Ambulance Service
NHS Trust*

for promoting a
Research Culture in their organisation

Dr Jonathan P Sheffield
OBE, MBChB, FRCPath
Chief Executive, NIHR Clinical Research Network

on 16 November 2011

