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JRCALC
JOINT ROYAL COLLEGES AMBULANCE LIAISON COMMITTEE

ASA

In this Issue:

Principles for Best Practice in Clinical Audit

In March the National Institute for Clinical Excellence (NICE) published their long awaited guidance document covering '***Principles for Best Practice in Clinical Audit'***. The book, jointly endorsed by the Commission for Health Improvement (CHI), aims to support staff leading clinical audit and clinical governance projects in the NHS.

The book aims to support NHS staff by detailing the methods, tools, techniques and activities related to each stage of clinical audit. It contains sections on preparing for audit, selecting audit criteria, measuring levels of performance, and making and sustaining improvements in care.

Copies of the book were mailed out to NHS organisations in mid-March. NHS organisations should have received four free copies of the book, which were mailed to Chief Executive Officers, clinical governance leads and libraries as appropriate.

Principles for Best Practice in Clinical Audit draws on a systematic review of literature relating to audit, which is outlined in Appendix XI and included in full on an accompanying CD-ROM.

Appendix II of the book includes links to a wide range of online resources to support staff implementing clinical audit projects.

The book will help clinical staff learn lessons from everyday practice to help them improve the care they give to patients. It is being published in response to demand from healthcare professionals throughout the NHS who are keen to develop effective tools to review their practice.

The publication of *Principles for Best Practice in Clinical Audit* follows the Government's strong support for clinical audit in its response to the Bristol Royal Infirmary Inquiry (Kennedy Report). As part of its response the Government agreed with Kennedy's recommendation that "*clinical audit should be compulsory for all healthcare professionals providing clinical care.*"

Clinical audit is a key component of clinical governance, enabling healthcare professionals to systematically review the care they are providing for patients, and implement changes where necessary in order to ensure best practice. *Principles for Best Practice in Clinical Audit* describes the methods, tools, techniques and activities related to each stage of clinical audit – preparing for audit, selecting audit criteria, measuring level of performance, making improvements and sustaining improvements.

The message of the book is that a dual approach is needed to ensure local success in clinical audit, with a supportive local environment encouraging appropriate investment in audit accompanied by effective clinical audit methodology.

Professor Sir Michael Rawlins, NICE Chairman, said: " There is a real need for the NHS at a local level to make a commitment to clinical audit as part of a process of continuous quality improvement throughout the NHS. The Report of the Bristol Royal Infirmary Inquiry focused hearts and minds on the issue of quality in the NHS. We must support healthcare professionals throughout the NHS to ensure they have sufficient time and resources to review the care they are providing for patients, and can implement changes where necessary to bring that care closer to best practice."

CHI's Chair, Dame Deirdre Hine, said: "I am very pleased that we are jointly publishing this report with NICE. This report is a valuable tool for clinical staff. Learning the lessons from practice is vital so that we can deliver improvements to patients' care in the future. I commend this report to those working in NHS organisations as a useful guide o how to implement clinical audit effectively."

Principles for Best Practice in Clinical Audit has been written by experts from the Quality Improvement Programme at the Royal College of Nursing and from the Clinical Governance Research and Development Unit at the University of Leicester. The book was funded by NICE.

As part of the development of the book it was reviewed by the Ambulance Service Association National Clinical Effectiveness Programme to ensure its relevance to NHS ambulance staff.

To download a copy of the book visit www.nice.org.uk

Links to the book can be accessed from the ASA site www.asancep.org.uk

For more information on CHI visit www.chi.nhs.uk

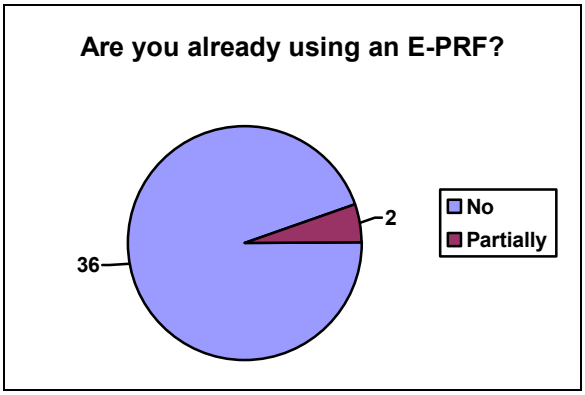
Principles for Best Practice in Clinical Audit is published by Radcliffe Medical Press Ltd (ISBN 1-85775-976-1). Copies of the book cost £19.95 for NHS staff and organisations, and £29.95 for those who do not work for the NHS. For more information please contact Radcliffe Medical Press Ltd, telephone 01235 528 820, email contact.us@radcliffemed.com or alternatively visit the website at www.radcliffe-oxford.com

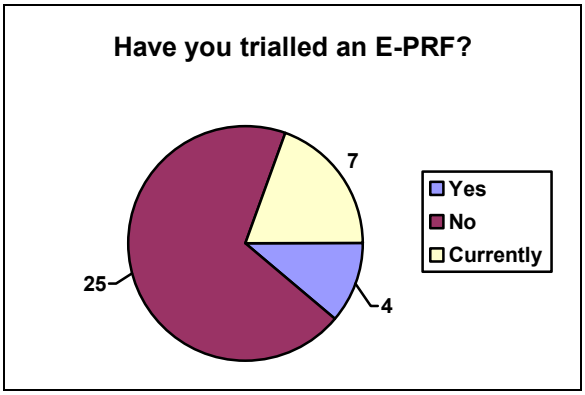
Electronic Patient Report Forms (E-PRF's)

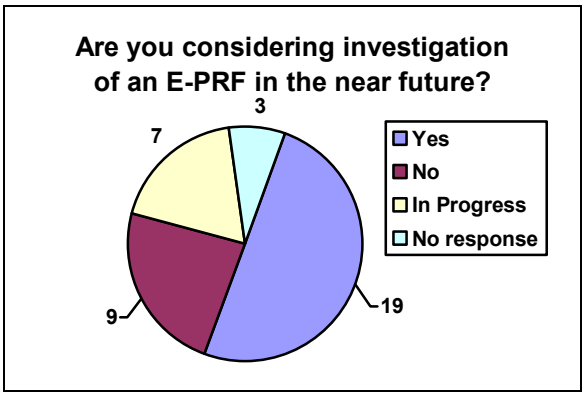
In December 2001 the Royal Berkshire Ambulance Service NHS Trust circulated a survey to all ambulance services to provide a snapshot of the status of electronic patient report forms in the UK.

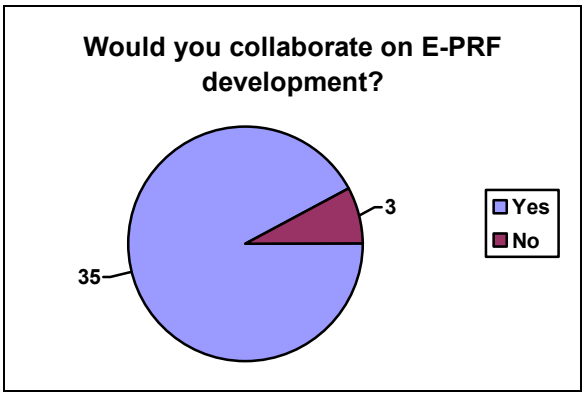
Some of the findings are listed here, whilst the ASA/JRCALC Clinical Effectiveness Committee are currently looking at a way to take this forward on a national basis for UK ambulance services.

All 38 services in and around the UK responded to the survey.









Summary of comments and conclusions:

- Ambulance services are struggling with this issue with confused or no guidance

- The lack of national co-ordination may result in difficulties linking different products
- Services do not have resources in time, finance or available expertise for this initiative
- Services are moving at different paces or not at all
- Lack of purchasing power inhibits god software development and interfacing

The ASA/JRCALC Clinical Effectiveness Committee will take these issues on-board as part of its programme for the coming year and will focus the development of specifications for E-PRF's for all ambulance services.

The CHI Experience

The Commission for Health Improvement is currently undertaking clinical governance reviews in three ambulance services: - Hereford & Worcester; East Anglia and Greater Manchester. A similar review is being undertaken in Scotland.

The ASA are to hold a one-day seminar for ambulance trusts to learn more about the issues involved in a CHI clinical governance review. The draft programme is as follows (subject to changes and confirmation):

The CHI Clinical Governance Review:
Ambulance Service Experience and Implications

10:00	Coffee & Registration
10:30	Introduction and aims – Peter Innes (ASA)
10:40	The CHI Review Process and Outcomes – TBC (CHI)
11:40	Ambulance Service Assessor's View
12:00	Experiences from local services under review
13:00	Lunch
13:45	*What next?*
14:30	Panel discussion
15:30	Close

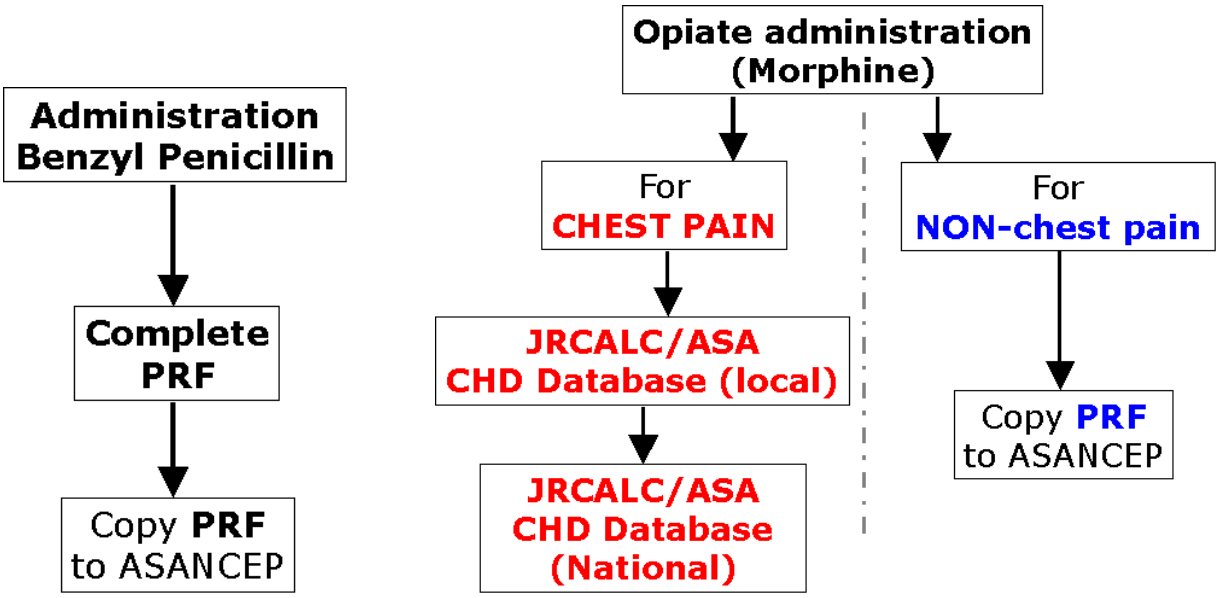
These details are subject to change prior to the date of the seminar as speakers are confirmed. For up-to-date details on the programme visit the website www.asancep.org.uk
For booking details please call Cheryl Williams in the ASA office on 020 7928 9620 or check the website www.asa.uk.net

National Clinical Audit Update

Seminars
During January and February 2002 the project team of Stuart Nicholls, ASA Clinical Effectiveness Programme Manager, Lesley Cave, Clinical Audit & Research Manager, London Ambulance Service, and Lucy Evans, Clinical Audit Manager, Twoshires Ambulance Service held a series of seminars to promote the CHD project and gain feedback from the users following installation of the database.

Introduction
A representative from JRCALC introduced each of the four seminars - Dr M Colquhoun (Chippenham), Dr T Clarke (Bolton), Mr T Quinn (Leicester) and Professor D Chamberlain (London) – covering the reasons for both the seminar and the national clinical audits, which include the National Service Framework for Coronary Heart Disease, the National Plan and the requirements of the Medicines Commission.

Audits of Benzyl Penicillin and Morphine
The mandatory clinical audits of Benzyl Penicillin for meningoccocal septicaemia and morphine sulphate for pain relief were described by Stuart Nicholls. Anonymised copies of the patient report forms (or a data file containing the relevant information) must be sent to the ASA National Clinical Effectiveness Programme (ASANCEP) for entry to the national databases. The diagrams below depict the process in detail:



SEACAG Introduction & Development
Lesley Cave introduced the work of the South East Ambulance Clinical Audit Group and provided examples of previous collaborative and comparative clinical audits conducted by the group including studies of hypoglycaemia and cardiac arrest. Lesley highlighted the lessons

learned and how these were incorporate into the development of the national clinical audit of CHD. The main emphasis was on the development of the CHD data set to ensure a common approach to data collection using set definitions and formats. This consensus work was undertaken by 11 ambulance services.

Lucy Evans then described how this work in formulating the data set was transformed into the database model using Microsoft Access, again highlighting the lessons learned from previous collaborative audits within SEACAG. Validation checks, mandatory and optional fields have been included to ensure data collection is easy for the user and as error free as possible. The database has been designed to ensure good data is put in to ensure good data is produced in the analyses.

Both Lesley and Lucy then presented examples of how the national CHD audit worked within their local services – London and Twoshires respectively.

Installation and Implementation
Stuart Nicholls went on to describe the implementation process and inclusion criteria for the audit.

Stage 1: Ambulance Trusts are asked to provide the ASANCEP with information on ***ALL*** patients who have been treated with thrombolysis, opiates, or penicillin (for meningoccocal septicaemia)

Stage 2: Further pilot testing of the database by SEACAG and regional focus groups.

Stage 3: (Continuous ACS data collection & audit to be implemented from March 2002) Trusts asked to provide ASANCEP continuous data on all (100%) patients with presumed cardiac pain and a potentially qualifying ECG for whom prehospital thrombolysis *could* be considered, whether or not it was administered, together with the reason if it was not given (e.g. not policy)
(No further development - except on pilot basis - until all Trusts established at Stage 3)

Stage 4: Trusts will be asked to provide information on all cases of cardiac arrest for whom resuscitation was attempted. This will be implemented at a later date (in consultation with Trusts during Stage 3)

Stage 5: Trusts will be asked to provide data on all patients with chest pain thought to be cardiac in origin. We recognise that this stage may present appreciable logistical difficulties because of the numbers involved. To be implemented at a date to be decided and in consultation with Trusts, but not before the end of 2002.

A demonstration of the database was given showing all the data input screens, reporting features, and options available to tailor the database to local requirements. An overview of the archiving process and how to export data to the ASANCEP was also presented.

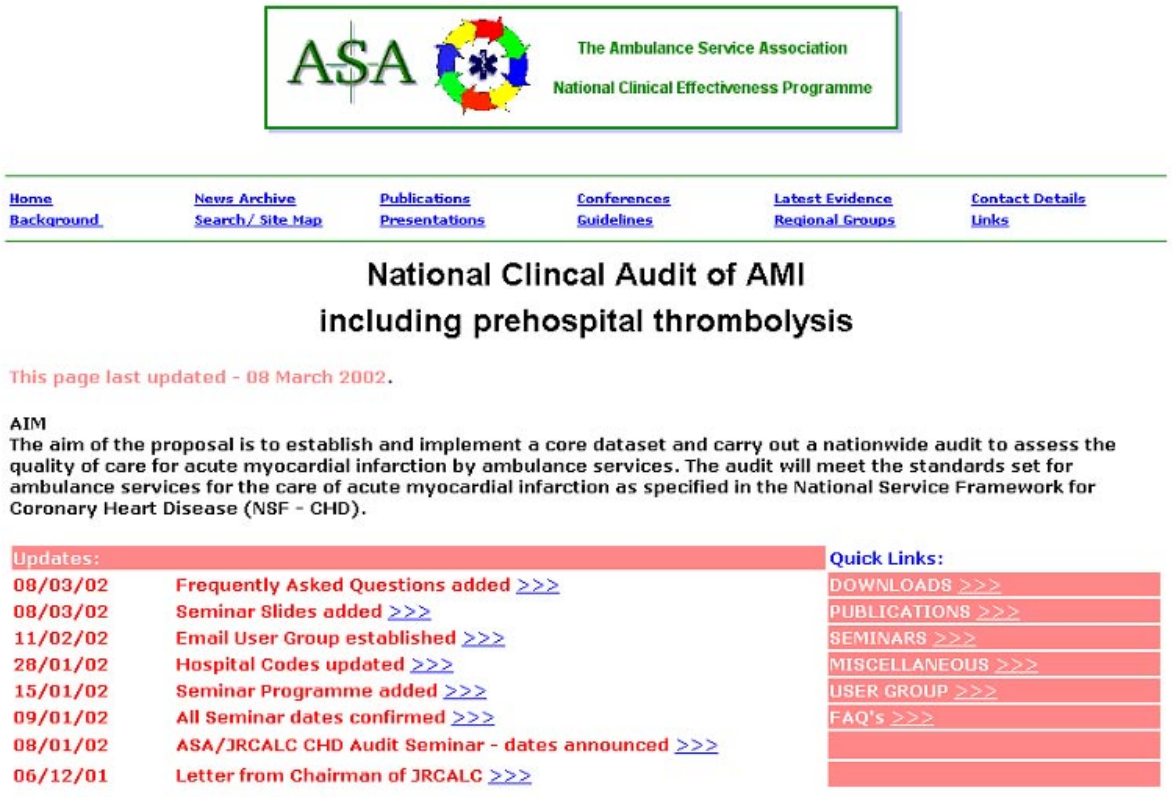
Reports and Future Development
A few examples of the analyses that will be produced from the national comparative audit were given highlighting the need to benchmark and the gains to be had from sharing best practice.

Feedback from the SEACAG pilot, the seminars and the user group (see below) will be incorporated into subsequent versions of the database. The ASA and JRCALC will continue to engage with the Royal College of Physicians and the Myocardial Infarction National Audit Project (MINAP) to look to integrate the two systems in the future. Work is also on-going with the NHS Information Authority to produce a wider data set for CHD.

Website
You can view all the relevant documentation, monitor the progress of the project and get up-to-date news via the project website:

www.asancep.org.uk/ami.htm

For those using the database there is also an email group to support all users where you can swap ideas, pick up handy hints and share your experiences in collecting the national audit data.



Each seminar concluded with a panel session for delegates to question the project team and JRCALC representative on any aspect of the audit. All of the feedback obtained will be fed into the future development of the database and the project.

Just a reminder that previous editions of *CANDOUR* can be viewed via the ASANCEP website at www.asancep.org.uk/candour.htm which provides an index and contents from Issue 2 (February 1999) to the current Issue.

East Midlands Ambulance Service NHS Trust

A Comparison Review of Pre-Hospital Thrombolysis Pilot Times In A Rural / Urban Area Of The East Midlands

By Andy Silver – Clinical Governance Manager
Clare Fellows – Clinical Audit Co-ordinator

1. Introduction

In November 2000, East Midlands Ambulance Service NHS Trust (EMAS) became the first Ambulance Trust in the UK to implement a paramedic Pre-Hospital Thrombolysis (PHT) pilot. The pilot was reviewed in February 2002 [1] and subsequent to the review it was decided to examine the predicted time benefits of PHT. To this end, the 33 patients within the PHT pilot were divided into two groups for comparison: group 1 comprising of the 16 patients who received paramedic thrombolysis in the community and group 2 being the 17 patients with signs and symptoms of acute myocardial infarction (AMI) and treated within the same time frame but excluded from receiving PHT either by the thrombolysis assessment criteria, the ECG criteria, or by being in close proximity to a receiving hospital. For the purpose of this review it was decided not to look at actual in-hospital thrombolysis times, but to use a predicted average door-to-needle time of 15 minutes.

2. Background

Paramedic PHT within the UK is a relatively new concept. In view of this, EMAS was faced with the question of how to introduce paramedic PHT in a safe, controlled manner that supported both patients and staff. There are a number of international studies evaluating the effectiveness of PHT using different models. Based on the limited evidence available, it was decided to use a very cautious approach and begin with a small pilot scheme, to be rolled out gradually as experience and confidence grew. In selecting which thrombolytic drug to use, ease of administration was felt to be one of the most important factors. Therefore, after examining the current evidence, it was decided to use a double bolus drug called Reteplase. All patients who received PHT were administered the second bolus in hospital within the required 30 minute time frame.

Reteplase (r-PA) is a genetically engineered deletion mutant of wild-type t-PA. The structural differences lead to different functional properties, such as a prolonged half-life (approximately 13 minutes). It is not weight adjusted and is administered as a double bolus 30 minutes apart. Clinical trials to support this drug are: INJECT (1995) [2], RAPID 2 (1996) [3] and GUSTO-3 (1997) [4].

2.1 The Pilot

A set of operating procedures for the Paramedic, Control and Hospital were produced. The attending Paramedic would assess the patient and, on suspicion of a myocardial infarction, perform a 12 lead ECG. If this demonstrated an infarction and the travelling time to hospital was more than 30 minutes from the *'call for help'*, the patient would then be assessed against the PHT assessment sheet. If all the criteria were fulfilled, then the ECG would be transmitted to the receiving unit. The paramedic would carry out this procedure on route to hospital, cutting down the on-scene time. Ambulance control would then be informed as to the destination unit that the ECG had been sent to. Ambulance control would contact the unit to ensure that they were aware that an ECG had been transmitted to them. The Hospital would confirm that the 12 lead ECG complied with the ECG diagnostic criteria and this would be relayed back to the attending paramedic prior to the administration of the thrombolysis. If the journey time was greater than 30 minutes, or on arrival at CCU no doctor was available to authorise the nursing staff to administer the second dose, it would then be administered by the paramedic. This is because Reteplase has a 30-minute time dependency between doses.

To help provide a seamless pathway of care, the paramedic transmits the ECG from a 'Medtronic Physio Control Lifepak 12' ECG machine to the Receiving Unit where a nominated senior cardiac nurse or medical practitioner confirms the ECG criteria to thrombolyse. The legal decision to thrombolyse is made by the paramedic under a patient group direction (PGD). This model provides additional support for the paramedic in their decision making process.

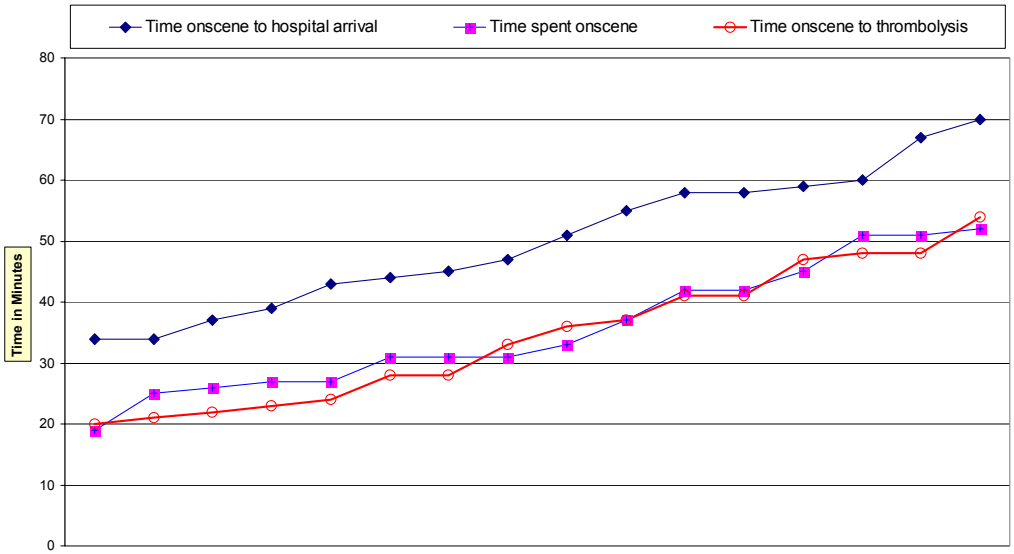
Initially all communications were established to pass through the ambulance control centre. This caused some concerns and confusion leading to an increase in time delays to thrombolysis with the first three patients. To rectify this, mobile telephones were introduced onto all ambulances carrying out PHT, in order to facilitate direct contact with the CCU. Dedicated receiving telephones within the CCU are utilised for this purpose. This improved many aspects of the system such as staff support, transfer of relevant patient information, thrombolysis times, team working with the crew and CCU staff and the assistance of medical authorisation for any patient that falls outside the pilot criteria. Medical authorisation for such patients has occurred on two occasions, each patient presenting as being previously fit but falling outside the age criteria.

The Joint Royal College Ambulance Liaison Committee (JRCALC) thrombolysis question criteria for the use of Streptokinase was adapted for use with Reteplase. The following amendments were made: a diastolic blood pressure of <95 mmHg was added to the question covering blood pressures; the time frame was increased from 3 hours to 6 hours from onset of symptoms to thrombolysis; the minimum heart rate was lowered from 50 to 40 beats per minute; the QRS width was changed to 0.12mm or less from 0.14mm in order to exclude Bundle Branch Block (BBB) (Appendix 1).

In total 41 paramedics underwent training over a 9-month period. All staff had been previously fully trained in performing and diagnosing 12 Lead ECGs for a minimum of 12 months. A one-day training programme, to reinforce existing knowledge and introduce thrombolysis, was produced with support from Roche (the manufacturers of Reteplase) who also provided training videos, drug packs and training slides covering thrombolysis. Staff were given a 12-lead ECG pass/fail examination prior to commencing the training programme.

3. Review

From the data obtained from the 16 patients in the PHT group, the following time frames were reviewed: total time spent on scene, time from arrival on scene to administration of thrombolysis and time from arrival on scene to arrival at hospital (graph 1). The PHT group was compared against the group of 17 patients who were excluded from receiving PHT by the assessment criteria (appendix 1). The reasons for the exclusion of these patients are shown in Table 1. This second group had the following times reviewed: total time spent on scene, time from arrival on scene to arrival at hospital and time from arrival on scene to predicted time of administration of in-hospital thrombolysis (graph 2). The time of in-hospital thrombolysis was estimated by using a 15 minute door to needle time, which should be achievable with appropriate pre-arrival information in most prepared A&E / CCU departments within the UK.



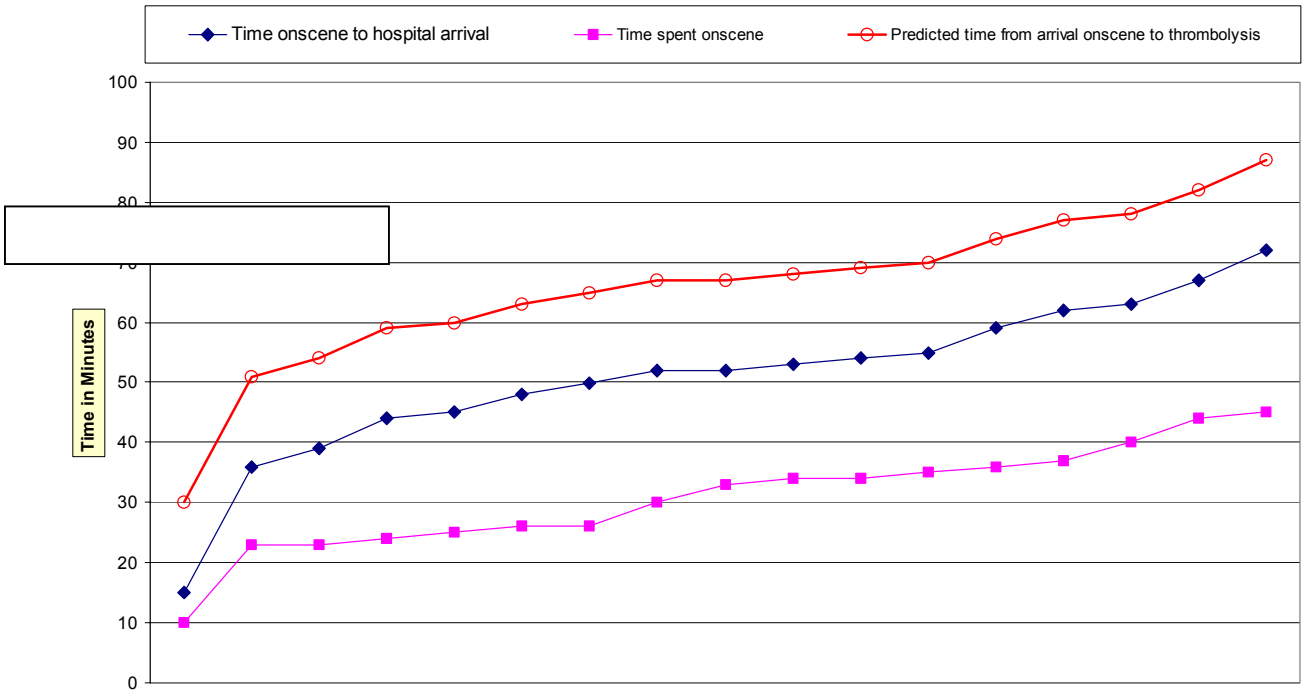


Table 1: Reason for Exclusion from PHT

No of Patients	Reason for Exclusion		No of Patients	Reason for Exclusion
1	Close proximity to hospital		1	Liver Failure
3	Bundle Branch Block		1	Peptic Ulcer
3	Onset of symptoms >6 hours		2	High / Low Blood Pressure
2	Less than 2 mm ST Elevation		1	Taking Warfarin
1	Unable to send ECG		1	Recent Operation
1	Confusion over recent Thrombolysis			

4. Results

The data was collated and mean and median times were calculated (table 2).
From this data, it would appear that **by spending an extra 4.5 minutes on scene, patients can receive thrombolysis with Reteplase an average of 34 minutes earlier than if taken directly to hospital.**

This data although limited in patient numbers is shown to be of relevance when compared with the data from the preliminary results of the ER TIMI 19 trial (209 patients) which showed a median time from arrival on scene to administration of thrombolysis (Reteplase) as 31 minutes in the pre-hospital group compared against a control group of 504 patients treated in-hospital at 64 minutes. This demonstrated a 33 minute median time saving to thrombolysis [5].

Table 2: Comparison Times

Total time spent on scene (minutes)				
	Mean	*Median*	*Lower Range*	*Upper Range*
PHT Group	35.5	32	19	52
Excluded Group	31	33	10	45
Arrival on scene to hospital arrival (minutes)				
PHT Group	50	49.5	34	70
Excluded Group	51	52	15	72
Arrival on scene to administration of thrombolysis (minutes) *(estimated 15 minutes door to needle time is used in the excluded group)*				
PHT Group	32	34.5	20	54
Excluded Group	66	67	30	87

Appendix 1

Primary Assessment

1. Is the patient conscious, coherent, and able to understand that clot-dissolving drugs will be used?
2. Has the patient had symptoms characteristic of a coronary heart attack and did the worst pain build up over several minutes, rather than starting totally abruptly over several seconds, with a typical distribution of pain for 30 minutes duration or more?
3. Is the patient aged between 14 and 75 years of age
4. Did the continuous symptoms start less than 6 hours ago?
5. Can you confirm that breathing does not influence the severity of the pain?
6. Can you confirm that the heart rate is between 40 –140 BPM?

7. Can you confirm that the systolic blood pressure is more than 80mmHg and less than 160 mmHg and that the diastolic pressure is below 95mmHg?
8. Does the electrocardiogram show abnormal ST segment elevation of 2 mm or more (0.08 seconds after the J point) in at least standard leads or at least 2 adjacent precordial leads, not including V1 ? (ST elevation can sometimes be normal in V1 and V2).
9. Is the QRS width 0.12 mm or less, and is bundle branch block absent from the tracing?
10. Can you confirm that there is NO atrioventricular block greater than 1st degree? (If necessary after treatment with IV atropine).

Secondary Assessment (Contraindications)

11. Can you confirm that the patient is not likely to be pregnant, nor has delivered within the last two weeks?
12. Can you confirm that the patient has not had a peptic ulcer within the last 6 months?
13. Can you confirm that the patient has not had a stroke of any sort within the last 12 months and no permanent disability from a previous stroke?
14. Can you confirm that the patient has not been treated for any other serious brain condition? (This is intended to exclude patients with cerebral tumours)
15. Can you confirm the patient has no diagnosed bleeding tendency, has had no blood loss within the last 8 weeks (except for normal menstruation), and is not on ANY anticoagulant therapy i.e. (Heparin, Warfarin) except Aspirin?
16. Can you confirm the patient has not had any surgical operation, tooth extractions, significant trauma, or head injury within the last 3 months?
17. Can you confirm that the patient has not had chest compression for resuscitation for a period of longer than 5 minutes within the last 10 days?
18. Can you confirm that the patient is not being treated for liver failure, renal failure, or any other severe systemic illness?

References:

1. East Midlands Ambulance Service NHS Trust PHT Audit Report (Feb 2002)
2. International Joint Efficacy Comparison of Thrombolytics (INJECT). Randomised, double-blind comparison of reteplase double bolus administration with streptokinase in acute myocardial infarction. *Lancet*.1995;346;8971:329-336
3. Bode C, Smalling RW, Berg G et al. Randomised comparison of coronary thrombolysis achieved with double bolus reteplase (recombinant plasminogen activator) and front-loaded, accelerated alteplase (recombinant tissue plasminogen activator) in patients with acute myocardial infarction (RAPID II). *Circulation*.1996;94:891-898
4. A comparison of reteplase with alteplase for acute myocardial infarction. The Global Use of Strategies to Open Occluded Coronary Arteries (GUSTO-III). *N Engl J Med*.1997;337:1118-1123
5. Morrow DA, Antman EM, Sayeh A et al. Pre-hospital administration of reteplase for ST-segment elevation MI: preliminary results of the ER-TIMI 19 trial. *ESC 2001*