Rapid Recognition and Treatment of Stroke

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Outline

- Newcastle Rapid Ambulance Protocol
- Development of FAST
- Pre-hospital care
- Qualitative work with paramedics
- Development of PIL-FAST study
Management of Acute Stroke

**Recognise**
Symptom recognition, Call 999

**React**
Transfer to hospital with Acute Stroke Unit

**Respond**
Brain scan and medical assessment

**Reveal**
Confirm diagnosis, assess for clot-busting drugs

**Rx/Reperfusion**
Clot-busting drugs, aspirin, close monitoring

**Rehabilitation**
Team assessment and treatment

**Reintegration**
Patient support groups, family, community
“The typical patient loses 1.9 million neurons each minute in which stroke is untreated”

Saver, Stroke 2006
Newcastle Stroke Admissions 1993

Suspected Stroke

Newcastle General Hospital (A&E)
250 patients

Royal Victoria Infirmary (A&E)
250 patients

Freeman Hospital (Acute Stroke Unit)
250 patients
Rapid Ambulance Protocol

Acute Stroke Symptoms 999

Ambulance Control

Paramedical team

Paramedical Assessment

Suspected Stroke

Freeman Stroke Unit

Non-stroke

Freeman Emergency Admission Suite

All 999 patients with suspected stroke not in coma to be taken to Freeman Emergency Admission Suite

notify unit

radio control
Rapid Ambulance Protocol

May 1997 – July 1998:
• 123 patients referred directly to the Acute Stroke Unit by paramedics
• 102 acute stroke, 21 were non-strokes

Time from first symptom to admission to the Stroke Unit:
• Referral from GP 6.0 hours (average)
• Via Rapid Ambulance Protocol 1.2 hours (average)
  – Symptom onset to contact emergency service 33 mins
  – Contact to arrival of paramedic team 8 mins
  – Time from arrival of paramedics to arrival at stroke unit 22 mins

25-30 patients / month triaged to Newcastle ASU
  – 80%+ confirmed stroke/TIA maintained over 10 yrs

Harbison et al, Lancet
Development of Face Arm Speech Test (FAST)

• Development group met for one day
  – Gary Ford, Damian Jenkinson (Stroke Physicians)
  – Ed Glucksman (Emergency Medicine Consultant)
  – Tom Quinn (Cardiac Thrombolysis Project)
  – David Hodge, Peter Cuthbertson, Lee Varnett (Northumbria Ambulance)
  – John Glasspool, Catherine Owen (Janssen-Cilag, UK)
  – Mark O’Connor, Bernie Rochford (Caldwell Gardiner Communications)
  – Reviewed North American Experience (Cincinnati and Los Angeles instruments)

• Emphasis on producing a simple assessment, to be incorporated in existing ambulance record form

• Training items
  – Video
  – Lecture notes
  – Slides/overheads
Los Angeles Pre-hospital Stroke Screen (LAPSS)

**Tests:**
- Blood glucose
- Arm strength
- Facial smile
- Grip

**Excludes:**
- Those under 45 years old
- Patients with seizures (fits)
- Symptoms of more than 24 hours
- Patients who are wheelchair bound or bedridden

- From 1298 calls LAPPS correctly identified 91% of the 36 patients who had a stroke
Paramedic Assessment Stroke Severity

- Los Angeles Motor Scale (LAMS)
  Facial weakness (0-1), arm strength (0-2), grip (0-2)

- Correlates with baseline NIHSS and 3 month mRS

- Acute anterior circulation stroke patients < 12 hrs onset LAMS ≥ 4 predicted persisting large vessel occlusion
  sensitivity 0.81
  specificity 0.89

Cincinnati Stroke Assessment

- Evaluated 74 patients treated in NINDS trial and 22 non-stroke patients evaluated in the ER.
- Facial weakness, arm weakness and dysarthria identified all of the stroke patients.
- An out-of-hospital scale using
  - Facial palsy
  - Arm weakness
  - Language disturbance (when saying “The sky is blue in Cincinnati”)
- Picked up all 95% of strokes seen by paramedics
Face Arm Speech Test

- Modified Cincinnati instrument – speech and conscious level
  - Facial Palsy
  - Arm Weakness
  - Speech Impairment
  - Test All Three

- Exclude patients with Glasgow Coma Scale \( \leq 6 \)
Paramedic Stroke Recognition Skills

- Agreement in picking up signs used in the FAST test between paramedics and stroke physicians:

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<thead>
<tr>
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<th>Paramedic</th>
<th>Stroke Physician</th>
<th>Kappa</th>
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<tbody>
<tr>
<td>Facial weakness</td>
<td>68%</td>
<td>70%</td>
<td>0.49 (fair)</td>
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<tr>
<td>Arm weakness</td>
<td>96%</td>
<td>95%</td>
<td>0.77 (good)</td>
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<tr>
<td>Speech disturbance</td>
<td>79%</td>
<td>77%</td>
<td>0.69 (good)</td>
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Mohd-Nor, Stroke, 2004
Symptoms in 630 Newcastle Stroke Admissions

One Sign:
- Arm weakness 77 %
- Leg weakness 68 %
- Face weakness 65 %
- Speech disturbance 31 %
- Visual disturbance 9 %

Two Signs:
- Arm or Speech 90% 
- Arm or Face 81% 
- Arm or Leg 79% 

Three Signs:
- Arm or Speech or Face 91%
Increasing Public Awareness

Recognise stroke F.A.S.T.

Only a hospital test can confirm a stroke for sure, but it is important to know the signs and the Face Arm Speech Time test (F.A.S.T.) can help you recognise them for stroke or TIA.

F.A.S.T. was developed by leading stroke physicians and is used by emergency services to help them detect the signs.

Has their face fallen on one side? Can they smile?
Can they raise both arms and keep them there?
Is their speech slurred?
Time to call 999 if you see any single one of these signs

If the person has failed any of these tests, dial 999 for an ambulance immediately so they can be taken to hospital for urgent treatment. Paramedics and ambulance staff are trained to assess patients with suspected stroke and get them to hospital quickly.
Eight designated HASUs
London 2010

- Second biggest killer and commonest cause of disability
- 11,500 strokes a year in London – 2,000 deaths
London Stroke Care
Audit of the first 6 months

- Feb- Jul 2010: proportion of patients admitted directly to a HASU increased from 33% to 69%
- Average journey time from home to a HASU 14 min.
- Kings HASU with the longest average transfer time 17 min.
- The average time from LASD taking the call to arrival at a HASU is 55 minutes
- 587 patients thrombolysed          Feb – Jun 2010
  174                                Feb – Jun 2009
- 14% thrombolysis rate for patients brought by LAS to hospital in 2010
- 12% thrombolysis rate assuming incidence data of 11,000 strokes per year in London.
Paramedic Interventions
Stroke / TIA

- Triage – Stroke Centre
- Pre-notification – plan imaging, stroke team ready to assess patient on arrival
- Begin communication with patient and family about the stroke care pathway
- Oxygen
- BP lowering
- Statins – early prevention/ neuroprotection
- Anti-platelets – early prevention
- Neuroprotection
Developing and Assessing Services for Hyperacute Stroke

NIHR Applied Research Programme Grant

Four research strands:
• Public and professional awareness of stroke
• Stroke thrombolysis awareness and training
• Service design for stroke thrombolysis
• Paramedic led stroke research

DASH 4
• Interviews with paramedics about stroke research
• Create a new pre-hospital stroke study
• Paramedic research training
• Feasibility of paramedic-led blood pressure lowering
Hyperacute Stroke Services

Collaborative

Local
Redirection
Telemedicine
Service descriptions

Local service design (no collaboration)
- Eligible for thrombolysis only (n=6)
- All acute stroke (including thrombolysis) (n=8)

EMS redirection of patients (n=14)
- No redirection (n=5)
- "Drip and ship" (n=6)

Telemedicine (n=11)

Pooled estimate for 5 collaborative services with comprehensive stroke register

Nazliel et al, Stroke 2008

Pooled treatment rate (95% CI) per 100 ischemic strokes

3.1 (2.1 – 4.1) [n=31,411]

5.7 (4.6 – 6.9) [n=7,815]

Price et al, Exp Rev Neurotherapeutics, 2009
FAST MAG

- *Field initiation of Magnesium neuroprotective therapy in acute stroke (FAST-MAG)*

- Phase 3 randomised controlled trial: patients with acute stroke receive an infusion or magnesium or placebo before admission to hospital

- 500 patients in 2 yrs

- Physician Investigator initiation of phone elicitation of consent in the field

FAST-MAG Pilot Study

- Open-label clinical trial paramedic initiation iv magnesium (4g loading, 16g/24hr in hospital) in patients with likely stroke (LAPPS +ve), 45-95yrs, < 12hr onset
- N=20, age 74 (44 – 92 yrs)
- Final diagnosis was cute cerebrovascular disease in all (ischemic 80%, hemorrhagic 20%).
- Study infusion median of 100 (24-703) min after symptom onset, 70% <2 hours
- Paramedics rated patient status on hospital arrival: improved 20%, worsened 5%, and unchanged 75%.
- Median NIHSS on hospital arrival 11 in all patients 16 in patients unchanged since field treatment start
- 3 month functional outcome (mRS 0-2) 60%
- No serious adverse events
- Field initiation of Mg in acute stroke patients is feasible and safe. Pre-hospital trial conduct substantially reduces on-scene to needle time and permits hyperacute delivery of neuroprotective therapy.

Saver et al, Stroke 2004
FAST-MAG: Consent in the field

- FAST-MAG pilot
- Written informed consent forms, dedicated trial cellular phones connecting to on call physician-investigators.
- Physician-investigator discussed trial with patient or on scene legally authorized representative (LAR)
- 32 patients met consent elicitation criteria
- 20 (63%) were enrolled.
- Non-enrollment:
  - patient not competent and no on-scene LAR (n=5)
  - patient/LAR declined participation (n=4)
- 15 (75%) participants were competent
- 5 (25%) were not competent and were enrolled by LAR family members
- Site of consent: home (n=15), work (n=2), other (n=3)
- Consent via cell phone (n=11), landline (n=9)
FAST-MAG: Consent in the field

• Comparison with patients enrolled in prior studies employing standard in-hospital consent

• Pre-hospital consent procedures reduced time from paramedic arrival on-scene to start of study agent
  26 (15-64) vs 139 (66-300) min, p < 0.0001

• No prolongation in on-scene to ED arrival time
  37 vs 34 min, p = 0.50

• No patient/family withdrew consent during 3-month follow-up period.
Qualitative Study of FAST MAG Paramedic Views

- Semi-structured interviews with 30 firefighter/paramedics participating in the FAST-MAG trial halfway through recruitment.
- Purposive sampling:
  - 4 high recruiting paramedic teams (> 8 enrolments)
  - 3 low recruiting paramedic teams (1-3 enrolments)
  - 1 teams attempted to but recruited no patients
- Analysis was conducted using a framework approach.
- Three key themes:
  - Workforce practice
  - Concerns about patient benefit
  - Time constraints
- Involving paramedics in protocol-led research was feasible.
- Perceived advantages of involvement in research included access to a treatment that would benefit patients and enhanced professional identity.
Qualitative Study of FAST MAG Paramedic Views

• Paramedic confidence in research limited by lack of research experience, concerns about personal responsibility and accountability, resistance to change, the environmental context in which they work, and limitations on autonomous practice.

“We were in the shadow of the hospital, literally, the shadow of the hospital was on top of the building that we were inside of. So we had to be quick, you know.”

• Involvement in research was viewed as inhibiting autonomous practice

• Paramedics appeared frustrated that the research was protocol led.

• Time spent on scene obtaining consent involved the diminution of autonomy as clinicians led the process

• Trial was seen to be ‘taking time’ in ways that were not consistent with their time-based culture within the service.
Qualitative Study of FAST MAG Paramedic Views

“... it’s so stringently regulated and if you make mistakes you could blow the study and then you know it, so now it’s not only do you have okay I have a treatment of a patient that could be critically medically ill but now I have to follow these strict guidelines that if I screw up or, or step outside of the parameters of these guidelines I can be in extreme trouble.”

• Paramedic confidence in research was limited by lack of research experience, concerns about personal responsibility and accountability, resistance to change, the environmental context in which they work, and limitations on autonomous practice.

“...it has to be the perfect patient, the perfect time with the perfect doctor”.
“You can’t become a fire fighter unless you are a paramedic nowadays, I wanted to be a fire fighter”
Barriers to Pre-hospital Research
UK perspectives

• NE ambulance service paramedics views and perspectives on the barriers and facilitators to implementing pre-hospital stroke assessment, treatment and consent to treatment and research involving stroke patients

• 7 focus group discussions – 58 paramedics NE Ambulance Service

• Themes identified using Framework approach
Barriers to Pre-hospital Research
Physical Context

• **Isolation**
  “It’s quite difficult from a paramedic point of view because you are totally autonomous, you are out there on your own and you are making decisions. Sometimes you may have the opportunity if you wanted to, to ring the hospital but it’s not like where you work in hospital, where there is loads of people around that you can turn to and go ‘Well what do you reckon about doing it like this or how about we do it like that?’”

• **Time**
  “I’m concerned with this if you tell a patient this is evidence based they’ll accept it but if you say it’s a clinical trial you might get into a discussion of “where’s this come from?” and by the time you’ve turned round, the patient is dead. Do you know what I mean? You’ve wasted all that time.”

• “But to be perfectly honest, working in town, by the time we get a patient onto a vehicle, we tend to do obs en route to hospital. You know, your second base line obs on route to hospital, then by the time we fill in the paperwork that we fill in, we, you know you might have a few minutes for a bit nicety with the relative and the patient, but you haven’t got a great deal of time to start explaining a trial or receiving erm permission to do something.”
Barriers to Pre-hospital Research
Physical Context

• Working on the streets
“It’s not like the hospital setting, it’s the great outdoors and it can be quite violent out there sometimes. Even though it doesn’t seem hostile, you can say the wrong thing or do the wrong thing, all of a sudden they are up a height, you know? There are some parts of this parish that you don’t linger in, just get the patient out and sorted out in the ambulance, away from the relatives”

• Trust and Kindship
“No I think most people, you know, you get a pulse oximeter and if you say put your finger in there I’m going to give you an electric shock, 9 times out of 10 they’ll still put their finger in won’t they?”
Barriers to Pre-hospital Research
Paramedic Role and Identity

• Disappointment and frustration
  “At the end of the day we just stick 100% oxygen mask on them and transport them to the hospital you know. Bill and Bob from the local taxi firm could do that.”

• Undervaluing of skills
  “I think some GP’s actually get aggravated when you question what they have done, because I mean you turn up,... the doctor is there with a lady who has had a stroke and you go ‘yep, no problem, you do your own first sets of observations, you go ‘have you done a BM’? ‘Oh no’ and you are questioned because you are questioning the doctor and it, I am sure it boils down to the fact that a lot of them are just plain old ignorant of how we work these days.”
Barriers to Pre-hospital Research Management Issues

• Lack of support
  “personally I would give it [research intervention], on the one proviso that I have the full backing of the service of whoever it was that was conducting the study – that’s the one problem where it all falls down. We very rarely, and I don’t mean this is any negative way, but we very rarely get the backing that we readily deserve. Sometimes...you’re in a bit of a quandary you know, I’m damned if I do and I’m damned if I don’t.”

• Remuneration
  “I think your problem with the thrombolysis as well, there was an awful lot to do with the agenda for change, to do with being paid for the job that you were doing, taking on the responsibility that wasn’t being paid for, that’s where most of the grievances came from with thrombolysis.”

• Bureaucracy
  “Because any research has got to be supported by evidence. So there has got to be paperwork involved, it’s just how much more are you going to land on me.”
Barriers to Pre-hospital Research Consent

• Consent in usual practice
  “I mean on a day-to-day basis, apart from thrombolysis, consent is just so not something we think about. It’s just implied consent. You know because...the fact that they have phoned an ambulance, they want something to happen and if we are saying this is what we are going to do, we don’t have an issue with consent because they don’t say what do, I mean they might say ‘what’s that tablet for?’ you know what I mean.”

• Consent for research
  “Well how do you go about determining capacity to give, you know to give it a treatment?”
  M: “Well firstly I think erm to start with, you ask them first of all if they can retain and hold the knowledge that you have just given them, and therefore they will be able to tell you the fact that they understand it. Erm, one of the issues we have with capacity, under the stroke situation mind, I have major reservations about it at all to be honest.”
Barriers to Pre-hospital Research Randomisation

- Randomised treatments

  “I think the paramedics would want to give a definitive treatment, rather than be randomised and say that as [FG4PM2] said we give them drug x or drug y, not knowing what it is. Currently we all stick by protocols, protocols are that we give drug a for that, drug b for that and rather than randomise what you are giving the patient, we currently give them definitive treatments and I think the majority of paramedics would rather stay on that.”

- Research not in patient interest

  “Well, I look at it that you’re withholding something from one patient which you’re giving to another patient, yeah”

  “If they asked me for my opinion I would say “I wouldn’t have it”. Because it’s for research”
Pre-hospital Research Issues

- Desire to ‘do something’ for stroke patients
- Environment influenced willingness to undertake research
- Mixed views about changing role
- Need for clear protocol
- Randomisation seen as unfair and dishonest by some paramedics – definitive treatment wanted
- Unfamiliar with capacity assessment
Paramedic Initiated Lisinopril For Acute Stroke Treatment (PIL-FAST)

- Lisinopril (5-10mg) once daily for 7 days or until discharge if sooner
- Single sublingual dose in the field, further doses in hospital
- Pilot feasibility study 40 patients
- New arm weakness, conscious (eyes open spontaneously), Systolic BP > 160 mm Hg (second of two seated/lying readings)
- Pre-randomisation
- One treatment pack carried on ambulance
- Study packs allocated to stations and used sequentially
Hypertension in acute stroke is common and associated with worse stroke outcome.

Previous RCTs have shown that blood pressure can be lowered in acute stroke but this has not resulted in improved stroke outcome.

There may be several reasons for this but due to the rapid progression of brain injury after stroke, timing of treatment may be important.

Previous RCTs commenced BP lowering after arrival of patients at hospital – this might have been too late for a beneficial effect.

The earliest time BP lowering could start is during contact with the emergency medical services (i.e. paramedics).
CHHIPS – Systolic BP Changes

SBP (mmHg)

randomisation  4h  8h  24h  2 wks

- placebo
- labetalol
- lisinopril

Potter et al, Lancet Neurology 2009
# CHIPS - Change in Neurological Status

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<thead>
<tr>
<th></th>
<th>Labetalol (n=56)</th>
<th>Lisinopril (n=57)</th>
<th>Placebo (n=59)</th>
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</thead>
<tbody>
<tr>
<td>Increase in NIHSS &gt; 4 at 72 hrs, n (%)</td>
<td>1 (2%)</td>
<td>6 (10%)</td>
<td>3 (5%)</td>
</tr>
<tr>
<td>Dead at 72 hrs, n (%)</td>
<td>0 (0%)</td>
<td>1 (2%)</td>
<td>3 (5%)</td>
</tr>
<tr>
<td>SAEs</td>
<td>26 (46%)</td>
<td>34 (59%)</td>
<td>35 (59%)</td>
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Potter et al, Lancet Neurology 2009
PIL-FAST aim and objectives

• **Study aim**
  – To assess the feasibility of a randomised controlled trial of paramedic initiated treatment for patients with symptoms of recent stroke.

• **Primary objective**
  – To demonstrate whether it is possible to enrol at least four patients per month into the trial (from an ambulance service covering a population of 500,000).
PIL-FAST aim and objectives

Secondary objectives

• To report the proportion of suspected acute stroke patients admitted to research sites during the trial duration who fulfilled the study eligibility criteria.
• To report the proportion of study eligible patients enrolled into the study by a research trained paramedic.
• To determine the additional time spent on scene by research trained paramedics to enrol a participant into the study.
• To collect and report clinical data to inform the design of a definitive multicentre randomised controlled trial:
  - change in blood pressure
  - change in neurological score (National Institute of Health Stroke Scale)
  - dependency score (Barthel ADL Index, Modified Rankin Scale)
  - change in renal function
  - mortality
• To report adverse events in control and intervention groups during the study.
PIL-FAST: Recruitment

1. Recognition of new acute stroke
2. Screen as suitable for study
3. Screen of capacity
4. Take “field” consent
5. Use of trial pack and documentation
6. Monitoring of patient’s condition for study
7. Handover patient and pack to research site A&E
8. Stroke team / research review and research consent
9. Feedback to NEAS
10. Consider assent if next of kin
11. Telephone support
Overview of PIL-FAST

- Adults with suspected hyperacute stroke and hypertension identified by research trained paramedics

- Consent or assent attained by research trained paramedic

- Randomisation to lisinopril or placebo (administration from pre-randomised study pack)

  - Intervention: Lisinopril 5-10mg daily for 7 days
  - Control: Matched placebo daily for 7 days

- Blood pressure monitoring

  - Day 3: Blood pressure measurement, National Institute of Health Stroke Scale

  - Day 7: Blood pressure measurement, National Institute of Health Stroke Scale, Barthel ADL index, Modified Rankin Scale, Renal function, Mortality
Inclusion criteria

- Adults ≥ 40 years old
- New unilateral arm weakness thought to be due to acute stroke within 3 hours of symptom onset
- Hypertension as defined by systolic BP >160mm Hg on two consecutive seated or lying readings taken 5 – 10 minutes apart
- Conscious (eyes open spontaneously ie “A” on Alert, Voice, Pain, Unresponsive (AVPU) scale)
- Patient being transported to a PIL-FAST trial site (i.e. Royal Victoria Infirmary, North Tyneside General Hospital and Wansbeck General Hospital)
- Verbal consent obtained from participant or next of kin
Exclusion criteria

- Age < 40 years
- Females who are pregnant, lactating or at risk of pregnancy (i.e. who are not surgically sterile or at least 1 year post last menstrual period)
- Any presentation of suspected stroke without unilateral arm weakness
- Cannot establish that stroke onset time (i.e. when patient was last seen well without symptoms) was within the last 3 hours
- Systolic BP < 160mm Hg
- Reduced level of consciousness (below “A” on AVPU scale)
- Patient not being transported to PIL-FAST trial site
- Absence of participant or next of kin consent
- Known to be taking ACE-inhibitor or Angiotensin II Receptor Blocker medication already
- Known sensitivity to lisinopril or other ACE-inhibitor medication
Exclusion criteria cont.

- Pulse > 120 beats per minute
- Seizure activity in this illness episode (witnessed or history)
- Hypoglycaemia (blood glucose < 3.5 mmols/l)
- Cannot walk independently prior to stroke (walking stick / frame is allowed)
- Obvious understanding or memory problems when next of kin is absent
- Significant head trauma or brain surgery in the last 3 months
- Known renal failure
- Known liver failure (or currently jaundiced)
- Uncontrolled heart failure (breathlessness at rest)
- Receiving palliative care for known malignancy
- Currently enrolled in a clinical trial assessing a study drug
The paramedic routine clinical assessment of a suspected stroke patient should enable eligibility for the trial to be determined.
Consent in PIL-FAST

- Verbal consent obtained by attending research trained paramedic. Short and simple process to enable patients to receive treatment as soon as possible and prevent delay in transfer to hospital.

- Formal written consent obtained by hospital research team following more detailed discussion and a patient information sheet.
• Your symptoms suggest you have had a stroke.
• Your blood pressure is high.
• We are working with doctors at Newcastle University to find out if it is possible to use a blood pressure lowering treatment before patients reach hospital.
• In some people this might improve recovery after stroke, but it is not proven.
• Would you be willing to take part in a study to help?
• This means receiving a small dose of a blood pressure lowering tablet or an identical “dummy” tablet before reaching hospital. The type of tablet people receive is decided by chance.
• You will be offered one or two of these extra tablets for the next seven days.
• If you agree to take part then you will be told more about the study at hospital and given the option to pull out if you change your mind.
• Your treatment and care will not be affected if you decide not to take part.
Paramedic consent script

- Can I check you understood what I said about the study?
  - What do we think is wrong with you at the moment?
    [answer: stroke]
  - What did I say about your blood pressure?
    [answer: high]
  - What will you receive if you do help with the study?
    [answer: tablet]

- If the patient cannot answer these questions correctly, they may not give consent to enter the study. They can only be considered for the study if a next of kin/close relative is willing to provide assent.
Randomisation: the “trial pack”

- The trial pack will contain:
  - Paramedic paperwork
  - Study medication
  - X1 vial of water
  - X1 5ml syringe
  - X1 syringe crusher
  - Some will have a temperature monitoring device
Approval of study medication administration by paramedics: PGD

NORTH EAST AMBULANCE SERVICE (NEAS) – NHS TRUST
CLINICAL CARE AND PATIENT SAFETY DIRECTORATE

Patient Group Direction (PGD) for the Administration of:

Lisinopril 5mg tablets or matching placebo by research trained paramedics according to the Paramedic Initiated Lisinopril For Acute Stroke Treatment (PIL-FAST) trial protocol.

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<thead>
<tr>
<th>PGD comes into effect</th>
<th>Date:</th>
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<tr>
<td>[Review]</td>
<td>Date:</td>
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<tr>
<td>[Expiry]</td>
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Name of Medicine: Lisinopril 5mg tablets or matching placebo

Professionals to which PGD applies: Registered Paramedics practising as Paramedics in the North East Ambulance Service who have attended PIL-FAST trial training sessions and been assessed as competent for trial procedures

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<th>Chief Executive (NEAS)</th>
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<td>Director of Clinical Care and Patient Safety (NEAS)</td>
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<td>Pharmacist on behalf of North East Ambulance Service – NHS Trust</td>
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<td>Medical Director/Adviser on behalf of North East Ambulance Service – NHS Trust</td>
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PIL-FAST: Handover

- Exact process
- Clinical details first
- Pass on monitoring form
- Pass on study pack
- Sign off research paperwork (identifiably)
- Remind triage to notify research or clinical stroke team contact
- Notify NE Ambulance Service of patient recruited
- Renew ambulance pack
Following arrival at hospital...

- Consent will be confirmed (in writing) following a more detailed study discussion
- Appropriateness to continue study medication will be reviewed following availability of clinical data not available pre-hospital (e.g. renal function)
- A dose review will be performed to determine the need for 5 or 10 mg lisinopril/matched placebo
- Treatment will continue for 7 days
- Outcome assessments at 3 and 7 days by SRN CTOs (BP, NIHSS, Barthel, MRS, renal function)
- “Reverse” screening log will be completed by SRN CTOs
- Data will be entered onto a secure website
Pre-Hospital Stroke Care

- Stroke care pathway starts in the pre-hospital pathway
- Ambulance services need to be part of hyperacute stroke services
- More work needed to improve and evaluate ambulance dispatch to 999 calls
- Key role in triage and pre-notification
- Research culture needs to be developed
- Specific issues of paramedic culture need to be addressed to introduce studies
  - time, autonomy, isolation
- Pre-hospital services work to time metrics