

Current Clinical Research



Evaluation of a state-wide pre-hospital reperfusion program for STEMI patients in Queensland

Study Name:	Continuous data collection, data analysis and evaluation of a state-wide pre-hospital reperfusion program for patients with ST-segment elevation myocardial infarction (STEMI) in Queensland.
Status:	Ongoing
Background:	<p>Optimal pre-hospital management is critical for improving the outcomes of STEMI patients who are attended by paramedics. Beginning in February 2008, QAS Critical Care Paramedics commenced a pre-hospital reperfusion program for STEMI patients. The STEMI program has expanded over time, including the implementation of state-wide Clinical Practice Procedures, the introduction of enoxaparin (2011) and ticagrelor (2015), and the implementation of decision supported pre-hospital management by Advanced Care Paramedics (2015). An electronic database was developed to prospectively collect data on the pre-hospital clinical management of STEMI patients attended by QAS paramedics. Since January 2016, QAS joined the Queensland Cardiac Outcomes Registry (QCOR), which collects data on the in-hospital management and outcomes of STEMI patients admitted to public hospitals in Queensland. Continuous collection and analysis of the STEMI data provide important insights into patient outcomes and the quality of QAS pre-hospital services.</p>
Aim:	To continuously develop and maintain the STEMI database, and to analyse the data to evaluate service delivery and performance.
Outcome Measures:	<ul style="list-style-type: none"> - <i>Patient characteristics; spatiotemporal trends of STEMI cases; and the timeliness, safety and guideline-concordance of pre-hospital management for STEMI patients attended by QAS paramedics.</i> - <i>Clinical outcomes, survival and determinants of survival in STEMI patients attended by QAS paramedics.</i> - <i>Health economic evaluation of pre-hospital STEMI management.</i>
Study Design:	Continuous analysis of routinely collected data by QAS and linked hospital data for patients with STEMI who are attended by QAS paramedics.
Participation study sites:	Queensland Ambulance Service, Statewide Cardiac Clinical Informatics Unit (Queensland Health)
Statistical consideration:	Descriptive statistics are used initially. Logistic regression is used to assess potential determinants for patient outcomes.

Evaluation of a state-wide pre-hospital reperfusion program for STEMI patients in Queensland

Study (continued)

QAS involvement:

QAS leads all aspects of the project. The dataset comprises vital data contributed by paramedics through the STEMI data collection form, Reperfusion checklist, eARF, DCARF (where relevant) and ECG strip.

Further information:

Information Support, Research & Evaluation Unit (Tel: 07 3022 1934)



High Dose IM Naloxone study

Study Name:	Acute opioid withdrawal following high dose IM naloxone: a prospective pre-hospital series
Status:	Ongoing
Background:	<p>Naloxone is an effective and widely used antidote for opioid overdose, both in the pre-hospital setting and in emergency departments (ED). In the pre-hospital setting naloxone is given as either a large IM bolus or small titrated IV aliquots. Within EDs there is a preference for small titrated IV aliquots to minimise the risk of acute opioid withdrawal, which is thought to contribute to significant morbidity and potential mortality. However, a recent study found that a single large IM bolus of naloxone significantly reduced the need for subsequent naloxone infusions compared with titrated IV aliquots. It also found that the occurrence of serious withdrawal (measured by the need to subsequently administer droperidol for acute behavioural disturbance) is likely to be rare, with similar numbers between the single large bolus IM and titrated IV aliquot groups. Naloxone infusions are a resource intensive intervention requiring close observation within a critical care unit and reducing their requirement would be expected to reduce the resource burden in managing patients with opioid poisoning. Quantifying and characterising acute opioid withdrawal following high dose IM naloxone would be helpful to establish safety and efficacy which may promote its adoption into the emergency department setting.</p>
Aim:	To quantify and characterise acute opioid withdrawal following large bolus IM naloxone administration in patients with opioid toxicity managed by the Queensland Ambulance Service (QAS).
Hypothesis:	Acute opioid withdrawal following high dose IM naloxone administration is common, however it is usually mild and requires no intervention.
Study Design:	This will be a prospective observational study conducted by the Princess Alexandra Hospital (PAH) Clinical Toxicology Unit in conjunction with the QAS. The study will be based in Brisbane and encompass patients in the Metro North and Metro South catchments over a 24-month period.

High Dose IM Naloxone Study

Outcomes Measured:

Primary outcomes:

The rate of opioid withdrawal following naloxone administration evidenced by the presence of:

- Tachycardia
- Hypertension
- Vomiting
- Acute Behavioural Disturbance (SAT > 1)
- Seizure
- Myocardial ischaemia
- Arrhythmia
- Pulmonary oedema

Secondary Outcomes:

- Requirement for sedation following naloxone administration
- Requirement for further naloxone
- Duration of hospital observation following naloxone
- Failure to transport to hospital following naloxone administration

Study Design:

This will be a prospective observational study conducted by the Princess Alexandra Hospital (PAH) Clinical Toxicology Unit in conjunction with the QAS. The study will be based in Brisbane and encompass patients in the Metro North and Metro South catchments over a 24-month period.

Participation Sites:

Opioid overdose adult patients (>15 years) who receive 1.6mg IM naloxone in the pre-hospital setting in accordance with the QAS DTP for naloxone.

Statistical Consideration:

Primary and secondary outcomes will be reported using descriptive statistics

QAS Involvement:

This study will be a collaborative undertaking between the Princess Alexandra Hospital Clinical Toxicology Unit and the QAS.

Further information:

For further information contact the Queensland Ambulance Service Clinical Quality & Patient Safety Unit:
QAS.CQPSU@ambulance.qld.gov.au

CPR Induced Consciousness (CPRIC) Study Proposal

Study Name:	Return of consciousness during CPR in out-of-hospital cardiac arrest: insights into the epidemiology of a growing phenomenon
Status:	Ongoing
Background:	<p>When performed optimally, CPR can theoretically generate sufficient cerebral perfusion to induce consciousness in cardiac arrest patients. This phenomenon is referred to as CPR-induced consciousness (CPRIC). CPRIC is a growing phenomenon and has gained increasing attention in recent years.</p> <p>Manifestation of CPRIC provides challenges to resuscitators, potentially impeding successful resuscitative efforts. There is a need to investigate the incidence of this growing phenomenon. Knowledge on how often clinicians encounter CPRIC, their perception of the associated challenges, and how they manage these patients is critical to guide the development of guidelines on how to best manage this growing phenomenon.</p>
Aim:	<ol style="list-style-type: none">1. To investigate factors associated with the development of CPRIC among OHCA patients resuscitated by paramedics in Queensland.2. To investigate the incidence, characteristics and survival outcomes of all OHCA patients3. To investigate the perception and experience with CPRIC of paramedics in Queensland.
Outcomes Measured:	<ul style="list-style-type: none">• Incidence and characteristics of CPRIC• Factors determining the development of CPRIC• Comparison of survival between CPRIC and all other OHCA patients• Survival and factors influencing survival in CPRIC and in all other OHCA patients• Paramedics' perception of and experience with CPRIC
Study Design:	<ol style="list-style-type: none">1. Retrospective analysis of routinely collected data by QAS and linked hospital data for all OHCA patients who are attended by QAS paramedics.2. Online survey of QAS paramedics

CPR Induced Consciousness (CPRIC) Study Proposal

Participants:

All patients with OHCA and have QAS patient records
All paramedics employed by QAS

Participation Study Site:

Queensland Ambulance Service (QAS)

Statistical Consideration:

A variety of statistical analyses will be conducted to interpret the data collected.

QAS Involvement:

The QAS will lead and conduct all aspects of the project. Data collection comprises mandatory documentation contributed by paramedics through the eARF.

Further information:

For further information contact Dr Tan Doan at the Information Support, Research and Evaluation Unit:
Tan.Doan@ambulance.qld.gov.au

Queensland Ambulance Service Cardiac Arrest Outcomes Program

Study Name:	Queensland Ambulance Service Cardiac Arrest Outcomes Program
Status:	Ongoing Findings of the analysis using QAS cardiac arrest data from 2000 to 2016 are available at: https://www.ambulance.qld.gov.au/publications.html . Subsequent publications to follow.
Background:	The QAS Cardiac Arrest Outcomes Program encompassing the Cardiac Arrest Database (CADB) was established in 1999. Primary data sources include the electronic Ambulance Report Form (eARF), the Computer Aided Dispatch (CAD), the Death and Cardiac Arrest Report Form (DCARF), Electrocardiogram (ECG) rhythm strip and Corpuls Mission Protocol, and hospital discharge information. Key data elements such as ambulance response times, prevalence of bystander cardiopulmonary resuscitation, presumed aetiology and survival can be derived from the CADB. This project utilises the CADB to report the findings of out-of-hospital cardiac arrest (OHCA) attended by QAS paramedics to measure service delivery and performance.
Aim:	To investigate the clinical and demographic characteristics, and survival of OHCA patients who are attended by QAS paramedics.
Outcome Measures:	<ul style="list-style-type: none">• Spatiotemporal distribution of OHCA cases attended by QAS paramedics.• Demographic (age, gender, type of location of incidence, witnessed/unwitnessed arrest) and clinical (initial rhythm, aetiology) characteristics of OHCA cases attended by QAS paramedics.• Survival outcomes.
Study Design:	Continuous analysis of routinely collected data by QAS and linked hospital data for patients with OHCA who are initially treated by QAS paramedics.
Participation study sites:	Queensland Ambulance Service
Statistical consideration:	Descriptive statistics are used initially. Logistic regression is used to assess potential determinants for patient outcomes.
QAS involvement:	Queensland QAS leads all aspects of the project. The collection comprises vital data contributed by paramedics through the DCARF, eARF, ECG rhythm strip and Corpuls Mission Protocol.
Further information:	Information Support, Research & Evaluation Unit (Tel: 07 3022 1934)



Study Name:	PRE-HOSPITAL ANTI-FIBRINOLYTICS FOR TRAUMATIC COAGULOPATHY ASSOCIATED WITH HAEMORRHAGE (The P.A.T.C.H. Study)
Status:	Case enrolment: Enrolments for the PATCH study commenced early in 2015, with a recruitment target of 1412 cases over four years, across the four state ambulance services taking part. As of 12/12/2019 there were 972 enrolments in total, with the QAS having enrolled 115 cases. The projected finish date for enrolments is November 2020 and the results of the study are expected to be published in 2021.
Background:	Haemorrhage is directly responsible for most pre-hospital trauma deaths and about a third of in-hospital trauma deaths and early acute haemorrhage also contribute to late in-hospital mortality due to multi organ failure. Tranexamic acid (TXA) is a synthetic anti-fibrinolytic agent that stabilises clot formation. TXA was shown to reduce mortality in the CRASH-2 hospital RCT; these findings were established in countries within a limited trauma system. Whilst the findings from CRASH-2 are encouraging they require further validation within countries like Australia with more advanced trauma systems.
Aim:	To determine the effect of TXA on death and disability among severely injured patients who are likely to have acute traumatic coagulopathy (ATC).
Outcome Measures:	Primary outcome measure is the null hypothesis that pre-hospital administration of TXA, followed by in-hospital infusion does not improve outcomes at six months, measured by neurological outcomes, quality of life assessments, and mortality measures. Secondary outcome measures are coagulation profiles, confirmed vascular events (DVT, PE, Stroke) number of days in ICU and in hospital, blood and blood products use.
Study Design:	Prospective, multicentre, randomised, placebo-controlled and blinded trial of pre-hospital treatment with TXA for severity injured trauma patients and at risk of ATC as determined by a COAST score ≥ 3 . Trauma patients with COAST score ≥ 3 and who do not meet the exclusion criteria will be randomly allocated to one of the two treatment groups. Intervention group – receive TXA pre-hospital loading dose and infusion in hospital. Control group – receive placebo pre-hospital loading dose and infusion in hospital.

The P.A.T.C.H. Study (*continued*)

Participation study sites:

Queensland, Victorian, South Australian, Western Australian, Auckland/Hamilton Ambulance services. Alfred Hospital, The Royal Melbourne Hospital, Royal Adelaide Hospital, Flinders Medical Centre, Royal Perth Hospital, Sir Charles Gairdner Hospital, Gold Coast University Hospital, Princess Alexandra Hospital, Royal Brisbane and Women's Hospital, Auckland Hospital, and Waikato Hospital Hamilton NZ.

Statistical Considerations:

The trial recruitment target is 353 patients combined across all centres per year for four years.

QAS Involvement:

The High Acuity Response Unit clinicians will be selecting and enrolling trauma patients into the trial through applying the study exclusion criteria and the COAST score. The HARU clinicians will follow the research protocol, procuring a blood sample and then administering TXA or placebo (blinded).

Bottom Line:

The investigators expect pre-hospital administration of TXA to contribute to a significant reduction in death, major disability and coagulopathy in major trauma patients within mature trauma systems. TXA as an intervention that has the potential to be deployed into developed pre-hospital trauma systems without the addition of specialised equipment, and has the potential to lead to some of the biggest improvements in trauma outcomes from any pre-hospital intervention. Interventions that improve major trauma outcomes are very cost effective because the majority of patients are young adults and as such TXA has been forecasted to reduce ATC and therefore provide improvement in survival and return to independent living for trauma patients.

Reference:

PRE-HOSPITAL ANTI-FIBRINOLYTICS FOR TRAUMATIC COAGULOPATHY ASSOCIATED WITH HAEMORRHAGE (**The P.A.T.C.H. Study**) APP1032751

Further information:

Queensland Ambulance Service Clinical Quality and Safety Unit: **07 3635 3343**

Study Name:

**PREVALANCE OF PRE-HOSPITAL INJURY INDUCED COAGULOPATHY
(The PROPHIICY Study)**

Status:

Case enrolment: Recruitment of patients into the PROPHIICY study commenced in early 2017. The study has a total recruitment target of 550 patients over two years. As of 12/12/2019 there were 200 patients enrolled.

Background:

Approximately 7–15% of injured patients suffer from Acute Trauma Coagulopathy (ATC). ATC is associated with a fourfold increase in mortality. Although several studies have examined the prevalence of ATC on arrival in hospital, there have been no large studies examining the prevalence in the pre-hospital setting.

Aim:

To determine the pre-hospital prevalence of ATC in patients treated by the Queensland Ambulance Service (QAS) High Acuity Response Units (HARU). Secondary objectives are to determine the accuracy of a point of care INR (POC INR) device as well as the coagulopathy of severe trauma (COAST) and Trauma Induced Coagulopathy Clinical (TICCS) scores in predicting ATC.

Outcome Measures:
Primary Objective:

- To measure the prevalence and nature of on scene ATC in injured patients, using blood samples taken pre-hospital

Secondary Objectives:

- To examine the characteristics and outcomes of patients with prehospital ATC
- To examine if the nature of ATC changes during transport time
- To examine the accuracy of the COAST score and the TICCS in predicting pre-hospital ATC
- To examine the accuracy of POC INR device in detecting pre-hospital ATC

Study Design:

A prospective, observational case series study to examine the prevalence and characteristics of ATC in patients treated by clinicians of the QAS HARU.

The PROPHIICY Study (*continued*)

Participation study sites:

- Queensland Ambulance Service
- Gold Coast University Hospital Trauma Service
- Princess Alexandra Hospital Trauma Service
- Royal Brisbane & Women's Hospital Trauma Service

Statistical Considerations:

Recruitment target of 550 patients over 2 years

QAS Involvement:

"The QAS has received an external funding grant to conduct this research and are the lead investigators for this study. To measure the prevalence of ATC, HARU clinicians will take blood in the pre-hospital setting from eligible trauma patients and will have this analysed in a laboratory to see if coagulopathy is present. Two clinical screening tests (Coagulopathy of severe trauma – COAST and Trauma Induced Coagulopathy Clinical – TICCS scores) as well as a finger prick blood test, will also be evaluated to see if they can accurately predict the presence of ATC. The QAS will collaborate with the trauma centres to allow follow up of the involved patients. Data analysis will be conducted by the QAS Information support, Research and Evaluation department, with any resulting publications being affiliated primarily with the QAS"

Bottom Line:

If ATC can be identified in the pre-hospital setting, and the prevalence is known, this may improve the care of trauma patients by early notification to the trauma centre, and may open the door to clinical interventions to be commenced in the pre-hospital environment.

Reference:

Not applicable

Further information:

Queensland Ambulance Service Clinical Quality and Safety Unit: **07 3635 3343**

The **PROPHIICY** Study Information Brochure

The PREVALENCE OF PRE-HOSPITAL
INJURY INDUCED COAGULOPATHY
(PROPHIICY) Study

Would you like further information?

If you would like further information about or discuss
any aspect of this study, please feel free to contact us:

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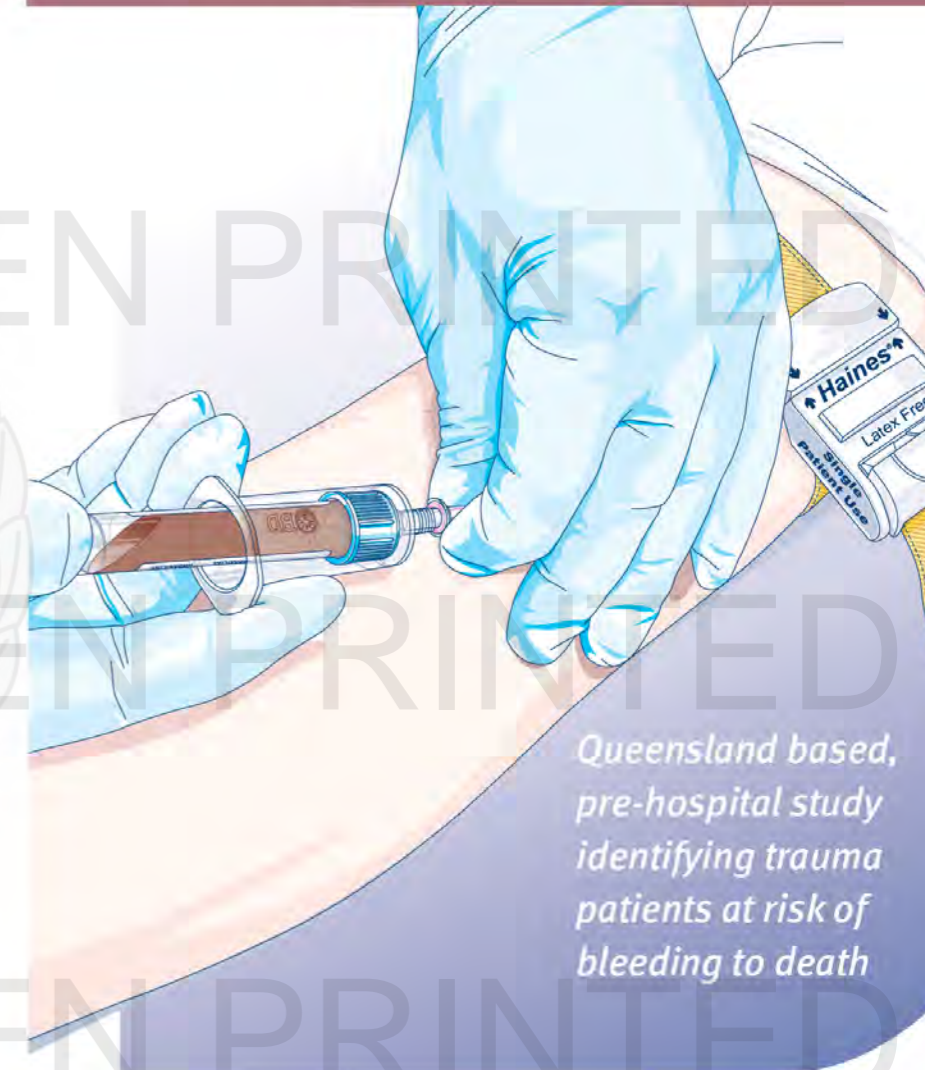
Should you wish to discuss the study in relation to
your rights as a participant, or should you wish to
make an independent complaint, please contact:

The Chairperson,
Human Research Ethics Committee,
Royal Brisbane & Women's Hospital
Herston, Qld, 4029
Telephone (07) 3646 5490,
Email: RBWH-Ethics@health.qld.gov.au



QUEENSLAND
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PROPHIICY PATIENT-FAMILY INFORMATION PAMPHLET
Version 1.3 Date 16/02/2016



Queensland based,
pre-hospital study
identifying trauma
patients at risk of
bleeding to death





PROPHIICY

QUEENSLAND AMBULANCE SERVICE

The PREVALENCE OF PRE-HOSPITAL INJURY INDUCED COAGULOPATHY (PROPHIICY) Study

“A Queensland based, pre-hospital study identifying trauma patients at risk of bleeding to death”

About the study

Injury is the leading cause of death and the second highest contributor to the burden of disease for Australians aged between 12 and 24 years. One of the contributing factors of trauma death is the inability for the trauma victim to clot properly. This condition is known as **Acute Traumatic Coagulopathy (ATC)**. Patients with ATC are up to four times more likely to die from their injuries than those with normal clotting.

This study aims to estimate how many injured patients have ATC at the time paramedics first treat them.

In this study, paramedics and doctors perform a quick finger prick blood test, during their initial treatment, to detect if there are any clotting abnormalities present. They will also take a small blood sample (10 ml) from patients before they arrive at hospital. The blood is then analysed in a laboratory to see if these results agree with the finger prick test.

Knowing which patients have ATC prior to arrival at hospital may pave the way for additional lifesaving treatment to be started on the way to hospital, and for more rapid intervention upon arrival at hospital.

What are the risks and benefits?

You (or your relative) would have had a blood sample taken prior to arriving in hospital. There may have been some discomfort when the blood was taken. Most participants would have had blood taken while the paramedics were inserting an intravenous cannula (a drip), so no additional pain occurred.

By participating in this study, you or your relative have helped us identify which trauma patients are at risk of abnormal clotting, so that we can develop better ways of treating ATC sooner.

Other than the blood samples being taken, you or your relative would have received normal clinical care.

Please contact the investigating team if you would like to discuss the risks and benefits further.



Ethics and Consent

The **PROPHIICY Study** has been approved by the Royal Brisbane and Women's Hospital Human Research Ethics Committee (EC00172), and the Queensland Civil and Administrative Tribunal (QCAT). It has been funded by the Queensland Emergency Medicine Research Fund. These bodies need to ensure that the correct processes will occur when the study is being conducted.

Patients entered in this study are likely to have received strong pain medication as part of their treatment, which affects an individual's ability to provide informed consent to participate in the study.

Because the PROPHIICY study has the potential to inform for faster diagnosis and management of ATC, QCAT has provided approval for informed participant consent to be waived.

To avoid any unnecessary anxiety to you or your relative, a study investigator or a member of the trauma service will discuss the study as soon as reasonably possible and clinically appropriate.

How is the study information stored?

The information will be stored as per the National Health and Medical Research Council guidelines. Participant information will be stored in a de-identified format that ensures patient privacy and anonymity. The data will be password protected and stored on a secure server. Only members of the research team will be able to access the data. The information will be stored for at least 5 years.



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STROKE PREHOSPITAL INFORMED DECISION-MAKING USING EEG RECORDINGS (The SPIDER Study)

Study Name:	STROKE PREHOSPITAL INFORMED DECISION-MAKING USING EEG RECORDINGS (The SPIDER Study)
Status:	Case enrolment: Recruitment of patients commenced on the 3rd September 2018, with a recruitment target of 165 across three specific groups (55 per group). The projected finish date is late 2019 with results expected to be published mid 2020 or early 2021.
Background:	The identification of acute ischaemic stroke (AIS) is difficult in the prehospital environment and clinicians can only rely on a clinical assessment to guide decision making on appropriate disposition for the AIS patient. Advances in endovascular care have now proved to result in significantly better outcomes for some AIS patients, namely those harbouring a large vessel occlusion within the middle cerebral arteries or internal carotid arteries. In-hospital studies have shown that the certain changes present on EEG are highly sensitive and specific for AIS versus controls. A quantitative measure can then be calculated (by computer algorithm) thus providing an interpretation akin to a blood pressure or blood glucose level (BGL). The next step is to determine the reliability of the Quantitative EEG reading within the prehospital environment and the ability to discern a large vessel occlusion stroke from a non-LVO stroke.
Aim:	To determine the ability of EEG measures to identify LVO stroke within the prehospital environment.
Outcome Measures:	The primary outcome measure is the null hypothesis that QEEG recordings cannot differentiate LVO versus non-LVO stroke. Secondary outcome measures are the ability of QEEG to differentiate stroke sub-types and stroke versus mimic.
Study Design:	Prospective, single site pilot project of all suspected acute stroke presentations.
Inclusion criteria:	<ul style="list-style-type: none"> • Screening positive on the Medical Priority Dispatch System™ (MPDS®) CPSS-based Stroke Diagnostic Tool administered via phone by the QAS Emergency Medical Dispatcher. • Evidence of a neurologic event in the opinion of an attending QAS paramedic. • Within the Royal Brisbane and Women's Hospital (RBWH) catchment area and to be transported and admitted to RBWH.

Study Name:	STROKE PREHOSPITAL INFORMED DECISION-MAKING USING EEG RECORDINGS (The SPIDER Study)
Exclusion criteria:	<ul style="list-style-type: none"> • Under 18 years of age • Pregnant • Previous Craniotomy
Participation study sites:	Queensland Ambulance Service – Metro North LASN Royal Brisbane and Women’s Hospital (RBWH)
Statistical consideration:	The recruitment target is 165 across 3 groups (Non-large vessel AIS, AIS with large vessel occlusion and all other neurological presentations).
QAS Involvement:	A dedicated study unit will respond within the RBWH catchment area. Attachment will occur via the Brisbane OpCen and with the use of the QAS iROAM system. The study paramedic will follow the research protocol and attach the EEG monitoring device and record the patient EEG until arrival at RBWH.
Bottom Line:	The investigators aim to gather pre-hospital EEG data on this group of patients to investigate the ability and reliability of EEG recordings to identify AIS with non-large vessel occlusion versus AIS with large vessel occlusion, as well as AIS versus stroke mimics. The EEG data will undergo post-hoc assessment to calculate the QEEG for comparison amongst groups. The long-term goal would be to develop a device that can assist pre-hospital clinicians in their diagnosis of stroke sub-types to better inform decision making.
Further information:	Study information presentation available at https://www.youtube.com/watch?v=LcnGnj-2Gg
References:	<ul style="list-style-type: none"> • Finnigan S, Van Putte M. EEG in ischaemic stroke: Quantitative EEG can uniquely inform (sub)acute prognoses and clinical management. Clinical Neurophysiology 2013, 124: 10-19. • Finnigan S., Wong, A. & Read S. Defining abnormal slow EEG activity in an acute ischaemic stroke: Delta/alpha ratio as an optimal QEEG index. Clinical Neurophysiology 2016, 127: 1452-1459. • Foreman B. & Claassen J. Quantitative EEG for the detection of brain ischemia. Critical care 2012, 16: 216. • Finnigan S, Rose SE, Walsh M, Griffin M, Janke AL, McMahon KL, Gillies R, Strudwick MW, Pettigrew CM, Semple J, Brown J, Brown P, Chalk JB. Correlation of Quantitative EEG in Acute Ischemic Stroke with 30-Day NIHSS score: Comparison with Diffusion and Perfusion MRI. Stroke 2004, 35: 899-903. • Finnigan S, Walsh M, Rose SE, Chalk JB. Quantitative EEG indices of sub-acute ischaemic stroke correlate with clinical outcomes. Clinical Neurophysiology 2007, 118: 2525-2532.