SESLHD PROCEDURE COVER SHEET



NAME OF DOCUMENT	Alteplase (Recombinant Tissue Plasminogen Activator) in Adult Acute Ischaemic Stroke – Management of
TYPE OF DOCUMENT	Procedure
DOCUMENT NUMBER	SESLHDPR/236
DATE OF PUBLICATION	May 2025
RISK RATING	High
LEVEL OF EVIDENCE	National Safety and Quality Health Service Standards: Standard 1 - Clinical Governance Standard 4 - Medication Safety Standard 8 - Recognising and Responding to Acute Deterioration
REVIEW DATE	May 2027
FORMER REFERENCE(S)	PD 229
EXECUTIVE SPONSOR or EXECUTIVE CLINICAL SPONSOR	Clinical Stream Director, Medicine
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FUNCTIONAL GROUP(S)	Critical Care and Emergency Medicine, Medicine
KEY TERMS	Stroke, Ischaemia, Alteplase, Recombinant Tissue Plasminogen Activator, Thrombolysis
SUMMARY	The document outlines the expected process and clinical indicators required for the administration of Alteplase (Recombinant Tissue Plasminogen Activator) in the management of Adult Acute Ischaemic Stroke.

COMPLIANCE WITH THIS DOCUMENT IS MANDATORY

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1. POLICY STATEMENT

Patients with acute ischaemic stroke and eligible for thrombolytic therapy in South Eastern Sydney Local Health District (SESLHD) will:

- Be administered Alteplase in a safe manner in accordance with Australian National Stroke Foundation Guidelines.
- Receive adequate and appropriate monitoring during and after the administration of Alteplase to ensure timely recognition of any potential adverse effect(s) of the medication.
- Have a management plan to minimise the risk of potential complications as a result of the administration of Alteplase.

2. BACKGROUND

Acute ischaemic strokes are commonly caused by blood clot(s) in a cerebral artery or arteries. Reperfusion therapy with intravenous thrombolysis and/or endovascular thrombectomy are extremely time critical after stroke onset to restore the circulation to the affected area. In 2011, the Therapeutic Goods Administration (TGA) recommended the use of Alteplase for the treatment of acute ischaemic stroke initiated within 4.5 hours of stroke onset after the exclusion of intracranial haemorrhage by appropriate imaging techniques¹. Due to the limited time window, it is imperative that the identification of stroke symptoms, triage, assessment, investigation and radiological imaging occurs in a coordinated and timely manner (refer to Appendix 1 and Appendix 2).

The introduction of reperfusion service to a Stroke Unit must be implemented in a safe manner due to the variation in infrastructure at different facilities within the Local Health District (LHD). Refer to Appendices 3 and 4 for the National Stroke Foundation recommended elements of a stroke service. Hospitals classified as 'Comprehensive Stroke Centre' and 'Primary Stroke Centre' should offer thrombolysis. ⁶

This document outlines the inclusion and exclusion criteria and clinical indications for the administration of Alteplase (Recombinant Tissue Plasminogen Activator) in the adult patients with acute ischaemic stroke. It aims to expedite access to clot-lysis intervention and restore circulation to the ischaemic brain areas, thus limiting the extent of brain injury and improving outcome after stroke.

Since the administration of Alteplase carries risk of bleeding, close neurological and haemodynamic monitoring of the patient before, during and after the administration of Alteplase is crucial to detect early signs of deterioration for escalation and initiation of urgent interventions to halt the progression of the adverse effects.

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3. TARGET AUDIENCE

The procedure targets all nursing, medical and allied healthcare members involved in the care of the patients with acute ischaemic stroke receiving thrombolytic therapy with Alteplase.

4. RESPONSIBILITIES

4.1. Bed Managers and Patient Flow Managers will:

- Facilitate patient flow to provide timely access to Alteplase
- Coordinate patient admission or transfer to the emergency department, acute stroke unit or intensive care/ high dependency unit to ensure access to the appropriate monitoring modality for the administration of Alteplase
- Escalate issues encountered in providing patient timely access to Alteplase.

4.2. Nurse Unit Managers will:

- Facilitate admission or transfer of patient to allow timely access to Alteplase
- Ensure adequate resources are available to safely manage patient requiring the administration of Alteplase, including staff allocation and skill-mix
- Ensure the practice surrounding the administration of Alteplase is compliant with the SESLHD Procedure
- Collaborate with key stakeholders to implement process to support the timely management of patient with acute ischaemic stroke in line with the <u>Acute Stroke</u> <u>Clinical Care Standard (2019)</u>².

4.3. Emergency, Radiology, Pathology and Critical Care staff will:

- Respond to the 'Acute Stroke Call' notification as per local process
- Facilitate timely triage, health assessment, investigations and radiological imaging of the patient to establish eligibility for Alteplase
- For patients eligible for Alteplase, prepare and administer the Alteplase as per SESLHD procedure in consultation with the treating Neurologist/ Stroke physician
- Provide close monitoring and assessment of the patient before, during and after the administration of Alteplase
- Escalate accordingly for any adverse event(s) as per local process
- Complete all documentation required in the patient's health record.

4.4. Stroke Physicians/ Neurologists will:

- Lead the Alteplase service
- Respond to the 'Acute Stroke Call' notification as per local process
- Establish patient's eligibility and make decision to administer Alteplase, including dosage required
- Oversee the direction of patient's overall clinical management
- Escalate accordingly for any adverse event(s) as per local process.

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• Complete relevant documentation required in the patient's health record.

4.5. Basic Physician Training (BPT) and/or Other Neurology Medical officers will:

- Respond to the 'Acute Stroke Call' notification as per local process
- Establish patient's eligibility and undertake direction from Stroke Physician/ Stroke Neurologist to administer Alteplase, including dosage required
- Prescribe the required dose of Alteplase clearly
- Escalate accordingly for any adverse event(s) as per local process
- Complete all documentation required in the patient's health record.

4.6. Stroke Clinical Nurse Consultants/ Nurse Practitioners will:

- Lead the Alteplase service
- Facilitate timely triage, health assessment, investigations and radiological imaging of the patient to assess suitability for Alteplase
- For patients eligible for Alteplase, prepare and administer the Alteplase using standard medication management process as per <u>NSW Health Policy Directive</u> <u>PD2022 032 - Medication Handling in NSW Public Health Facilities</u>³
- Collaborate with key stakeholders to implement process to support the timely management of patient with acute ischaemic stroke in line with the <u>Acute Stroke</u> Clinical Care Standard (2019)²
- Complete all documentation required in the patient's health record
- Continuously evaluate the process in the management of patient requiring the administration of Alteplase
- Ensure the practice surrounding the administration of Alteplase is compliant with the SESLHD Procedure.

4.7. Registered Nurses will:

- Facilitate timely triage, health assessment, investigations and radiological imaging of the patient to assess suitability for Alteplase
- For patients eligible for Alteplase, prepare and administer the Alteplase using standard medication management process as per <u>NSW Health Policy Directive</u> <u>PD2022 032 - Medication Handling in NSW Public Health Facilities³</u>
- Provide close monitoring and assessment of the patient before, during and after the administration of Alteplase.
- Escalate accordingly for any adverse event(s) as per local process.
- Complete all documentation required in the patient's health record.
- Maintain currency of knowledge in the management of patient requiring administration of Alteplase.

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5. **DEFINITIONS**

Acute Ischaemic Stroke: a sudden onset of neurological dysfunction caused by acute focal injury to the central nervous system as a result of interruption or cessation of blood supply with evidence of tissue ischemia/infarct in the brain imaging. The underlying pathology is presumed to be an inadequate blood supply to a part of the brain as a result of low blood flow, thrombosis or embolism associated with diseases of blood vessels, heart or blood.

Acute Stroke Team (In-hours): Registrar (Neurology), Stroke Basic Physician Trainee (BPT), Stroke Clinical Nurse Consultant/ Nurse Practitioner (CNC/NP), Stroke Fellow (ideally) and/or Stroke Physician.

Alteplase: Thrombolytic drug which converts plasminogen to plasmin to catalyse the breakdown of fibrin https://www.tga.gov.au/resources/artg/6424

NIHSS: National Institutes of Health Stroke Scale, a systematic tool which provides quantitative measure of stroke-related neurologic deficit.

Neuro-COU: Neurosciences Closed Observation Unit which provides an intermediate level of care between a general ward and an intensive care unit.

rt-PA: recombinant tissue plasminogen activator, a class of drugs which catalyses plasminogen to plasmin leading clot breakdown eg alteplase, tenecteplase.

Stroke Physician criteria:

- Participating in an 'Acute Stroke Call' roster.
- Experienced in the assessment, treatment and management of acute stroke.
- Experienced in the interpretation of cerebral CT scans.
- Participant of the Area Stroke Group and/or Stroke Services NSW.
- Regular participant in local Stroke Morbidity and Mortality meeting.
- FRACP or equivalent.

The 'Stroke Unit Multidisciplinary Team' consists of staff from the following disciplines:

- Medical (neurology, geriatrics, rehabilitation or general physician specialities experienced in the assessment, treatment and management of acute stroke);
- Nursing (specialist nurses: CNS/ CNC/ NP/ Stroke Coordinator);
- Allied healthcare staff, including speech pathologist; physiotherapist, occupational therapist; social worker; dietician, psychologists and pharmacist.

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6. CLINICAL PROCEDURE

6.1. General Requirements for the Administration of Alteplase

- a) Intravenous alteplase in acute ischaemic stroke must only be undertaken in patients satisfying specific inclusion and exclusion criteria ⁴. Refer to <u>Appendix 2</u>.
- b) Intravenous alteplase in acute ischaemic stroke should be given under the authority of a stroke physician and Stroke Unit Multidisciplinary Team with expert knowledge of stroke management, experienced in the use of intravenous thrombolytic therapy and with pathways and protocols available to guide medical, nursing and allied health during the acute phase of clinical management, including guidance in acute blood pressure management ⁵.
- c) Administration of intravenous alteplase should only be undertaken in a hospital setting with appropriate infrastructure, facilities and networks. Refer to Appendices 3 and 4 for National Stroke Foundation recommended elements of a stroke service. Hospitals classified as 'Comprehensive Stroke Centre' and 'Primary Stroke Centre' should offer thrombolysis⁶.

Intravenous alteplase should be delivered in a well-resourced and skilled Emergency Departments (ED), Acute Stroke Units and/or Intensive Care Unit with adequate expertise and infrastructure for monitoring, rapid assessment and investigation of patients with acute stroke. Collaboration between clinicians in pre-hospital emergency services, emergency medicine, neurology and radiology is essential to ensure prompt identification of potentially eligible patients. Stroke Units offering a thrombolysis service must undertake regular and ongoing quality improvement initiatives and internal audit.⁶

Alteplase for ischaemic stroke is <u>only</u> to be administered in facilities that have developed a well-planned and clearly defined thrombolysis service.

As a minimum this service should have all the elements of a stroke service as well as:

- A lead clinician who is responsible for overseeing and monitoring the Thrombolysis service;
- Coordinated Emergency Department system with established protocols in the use of validated screening tools, triage categories, rapid imaging, rapid referral and involvement of stroke team, administration of intravenous Alteplase and ECR intervention/ transfer.
- Rapid access to CT brain (24/7), ideally to include CT perfusion and aortic arch to cerebral vertex angiography.
- Staff (nursing & medical) are skilled in the administration process and management of patient before, during and after the administration of Alteplase.

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- A clearly defined protocol outlining the clinical area, with reference to adequate staffing levels, for the patient to be safely monitored and managed post Alteplase administration.
- d) All hospitals should be routinely collecting and monitoring a minimum data set for all acute stroke admissions and participate in periodic national organisational survey and use these data to inform quality improvement activity. ⁶

6.2. Prior to the Commencement of Alteplase

Note key time-of-onset metrics: Patients are potentially eligible for alteplase within 4.5 hours after the onset of stroke symptoms, or (in the presence of appropriate cerebral perfusion parameters as determined by the Stroke physician) up to 9 hours after the time the patient was last known to be well, or from the midpoint of sleep for patients who wake with stroke symptoms⁷.

- 1. Identification of stroke symptoms, allocation of Triage Category 2, or for an inpatient stroke, escalate as per local process.
- 2. Initiate assessment process including: prompt medical review, inclusion/exclusion criteria for Alteplase administration, urgent blood tests and non-contrast CT brain (NCCT), which may progress to CT Angiogram (CTA) and CT Perfusion (CTP), if required (Appendix 1).
- 3. Immediate notification of the Acute Stroke Team (during business hours) or on-call consultant/or Stroke/Neurology Registrar or Fellow on-call for Stroke (during afterhours).
- Completion of the NIHSS by the Acute Stroke Team (in-hours) or after-hour medical officers/ ED MO (after-hours).
- 5. Insertion of two (2) large bore (preferably, 18G) peripheral intravenous cannulas.
- 6. Investigations (marked as 'Urgent'), include Coagulation Studies, EUC, FBC, LFT, blood glucose, group and hold (G&H) and pregnancy test (if applicable).
- 7. All NCCT/CTA/CTP images immediately reviewed by a Radiologist, Neuroradiologist, Neurologist or Stroke Physician.
- 8. Confirm completion of inclusion/exclusion criteria checklist by the Stroke team (inhours) or after-hour medical officers/ ED MO (after-hours) to verify patient's eligibility to receive alteplase. See Appendix 2.
- 9. The treating Neurologist must authorise the administration of alteplase after the clinical assessment of the patient or after the discussion with the delegate who has examined the patient and reviewed the NCCT/CTA/CTP images.
- Ensure the prescription of alteplase is completed by the Stroke team as soon as patient is eligible.
- 11. Consent for the administration of alteplase obtained by the treating Stroke physician/ Stroke team **considering the circumstances that may pertain: time**

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constraint, possible aphasia, neglect or agnosia in accordance with NSW Health-Consent to Medical and Healthcare Treatment Manual (2020)⁸. Most acute stroke patients will not be able to provide informed consent. Therapy should not be delayed or withheld in cases where legally authorised representatives are not present with the patients.

- 12. Neurological and haemodynamic observations.
- 13. Continuous cardiac rhythm monitoring.
- 14. Blood pressure (BP) management to achieve systolic BP less than 185mmHg and diastolic BP less than 110mmHg, if applicable. A radial arterial line may be inserted in the Adult ICU/HDU environment for close BP monitoring and frequent blood sampling, if deemed to be clinically indicated.
- 15. An indwelling urinary catheter (IDC) is only indicated in a patient with urinary retention, and a nasogastric tube (NGT) is only indicated when a patient is likely not able to pass the 'Acute Screening of Swallowing in Stroke/ TIA' (ASSIST), or cleared by the Speech Pathologist. If indicated, consider the insertion of the devices prior to the administration of Alteplase. Emergent placement of NGT prior to thrombolysis is almost never required.
- 16. Confirmation of bed availability in the ASU, AICU/HDU, Neuro-COU as per site-based policy.
- 17. Patient weight.

6.3. Prescribing alteplase

Alteplase must be prescribed on the National Inpatient Medication Chart (NIMC) or electronic Medication Administration Record (MAR) in accordance with NSW Health Policy Directive PD2022 032 - Medication Handling in NSW Public Health Facilities³. The powerplan of "Alteplase for Acute Stroke" must be selected when prescribing on MAR.

6.4. Administration of Alteplase⁹

- Within 4.5 hours after the onset of stroke symptoms, or up to 9 hours after the time of last known to be well, or from the midpoint of sleep for patients who wake up with stroke symptoms, and when deemed clinically appropriate by Stroke physician. ⁷
- The administration should be performed by skilled Registered Nurse or Medical Officer. Endorsed Enrolled Nurse may assist in the care for the patient under direct supervision of a Registered Nurse.

Reconstitute alteplase (Actilyse®)

Reconstitute immediately before administration as per manufacturer's instruction to the concentration equals to 1mg/mL. Link to the Actilyse® product information.

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Dosage (refer to dosage schedule for the 'Administration of alteplase for the treatment of Acute Ischemic Stroke' form – Appendix 2)

- Total dose of 0.9mg/kg (to a maximum 90mg) administered as:
 - 10% of total dose as a bolus injection over 1 minute, then
 - o Remaining 90% of the dose as an infusion over 60 minutes.

Reconstitution and Dilution

- Reconstitute each vial of Alteplase using the sterile water supplied with the vial i.e. 50mg with 50mL and 10mg with 10mL.
- Slight foaming upon reconstitution is not unusual. If this occurs, leave to stand for a few minutes.
- Mix using gentle swirling or slow inversion. Vigorous shaking must be avoided.
- DO NOT use vial if vacuum is not present.
- Reconstituted preparation results in a colourless to pale yellow transparent solution.
- If further dilution for the infusion dose is required, use 0.9% Sodium chloride only.

Procedure:

- Observe hand hygiene as per <u>SESLHDPR/343 Bare Below the Elbows</u>¹⁰.
- Adhere to standard medication management process as per <u>NSW Health</u> <u>Policy Directive PD2022_032 - Medication Handling in NSW Public Health</u> Facilities³.
- A medical officer (Registrar level or above) must be available onsite during the administration of the Alteplase.
- Ensure emergency equipment (including defibrillator) is available, functional and close to the patient.
- Prepare the prescribed dose of Alteplase as per Dosage Schedule using aseptic technique (Appendix 2).
 - Bolus dose (10% of total dose) should be prepared in a 10 mL syringe.
 - The remaining dose (90% of total dose) can be prepared in a 50mL syringe using a syringe driver (pump), or a burette using an infusion pump. Prime the line using a dedicated infusion line.
- Clean cannula port with alcohol.
- Flush the cannula to ensure patency and inspect cannula site for extravasation, swelling or inflammation.
- Administer the required bolus dose (over 1 minute).
- Infuse the remaining dose over 60 minutes.
- Monitor and record observations as per **Section 6.4** during the infusion.
- On completion of the infusion, flush line with 30mL 0.9% Sodium chloride.

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Complete all relevant documentation in the patient's health record.

6.5. Care Post- alteplase Administration (first 24 hours)

Complications post- Alteplase administration are most likely to occur within the first 24 hours. Close monitoring is paramount for early detection of life-threatening complications. Minimum monitoring requirement includes:

- Continuous cardiac monitoring.
- Other vital observations should be performed following **Table 1** below.
- BP monitoring can be performed using an automatic or manual BP measuring device post- Alteplase administration. ¹¹ Care must be taken when placing the BP cuff to prevent skin trauma and avoid placing the cuff on the arm with an invasive device on the cubital fossa, such as peripheral intravenous cannula (PIVC).

Other monitoring or care requirements include:

- Strict fluid balance. Maintain euvolemia. Use non-dextrose containing intravenous fluid only, if required.
- Keep the patient 'Nil by Mouth' (NBM) until swallowing status is established, ideally within four (4) hours of arrival at hospital (e.g. patient passes 'Acute Screening of Swallowing in Stroke/ TIA' (ASSIST), or cleared by the Speech Pathologist)⁷.
- Assess for signs of bleeding hourly, i.e. wounds, IV access, venepuncture sites, gums, etc.
- Maintain head-of-bed elevation at least 30°.
- Limit physical handling of the patient to minimise risk of bruising/bleeding:
 - o Strict bed rest for 24 hours. Provide regular pressure area care.
 - o Falls prevention plans in place, including continence care.
 - DO NOT shave for 24 hours.
 - Use swabs/ spray for oral hygiene. DO NOT use toothbrush for the first 24 hours.
- Refrain from performing invasive procedures within 24 hours post- Alteplase
 administration where possible, such as insertion of NGT or IDC, intramuscular
 injection, and removal of invasive devices, such as drains.
 Should the clinical needs arise for the insertion of NGT and/or IDC, insert using the
 smallest tube size possible and ample of lubricant to minimise risk of trauma and
 bleeding. IDC should only be inserted for urinary retention.
- Leave second IV cannula insitu for blood sampling, if required.
- If arterial or venous puncture is required, apply direct pressure to the puncture site for at least 20 minutes. Consider using compression device, if required.
- CT scan or other brain imaging should be repeated at 24 hours postadministration of Alteplase.

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Medications that affect blood coagulation, including anticoagulants or antiplatelet agents <u>MUST NOT</u> be given within 24 hours post- Alteplase administration until further directed by the treating Stroke physician/ Neurologist.

Table 1

Observations	Frequency
BP, HR, RR, cardiac	All of the listed observations must be attended to following the
rhythm, SpO ₂ and GCS	frequency below:
	15 minutely for 2 hours.
	• Half (½) hourly for 4 hours.
	Hourly for 4 hours.
	2 Hourly for 12 hours.
	4 Hourly until reviewed by treating team.
	Observations are then continued as per the patient's clinical status,
	but no less frequently than every 4 hours.
Temperature	Every 4 hours (report any temperature ≥38.0°C) ⁷ .
Blood Glucose Level	Every 6 hours (report BGL >10mmol/L) for 72 hours, regardless of
(BGL)	diabetes status ⁷ .

6.6. Notifiable or Reportable Events

The infusion of alteplase must be ceased. An urgent medical review and full set of observations must be completed for the following issues:

- Severe allergic, or anaphylactoid reactions, including rash, urticarial, angioedema, and bronchospasm.
- Signs of bleeding, including melena, hematemesis, haemoptysis, haematuria and altered level of consciousness (LOC) which may indicate intracranial haemorrhage.

The event(s) must be clearly documented in the patient healthcare record, and consider completing incident report (IMS+), if appropriate.

Other issues which require urgent clinical review include:

- Persistent hypertension SBP >180mmHg and/or DBP >105 mmHg.
- Hypotension SBP < 100 mmHg.
- Neurological deterioration new or worsening weakness, decreased level of consciousness, pupillary abnormalities.
- Extensive bruising and new haemorrhage, including hematemesis and melaena.
- New tachycardia greater than 100 beats/minute.
- Nausea and vomiting.
- Fever (≥38.0 °C).
- Hypoglycaemia or hyperglycaemia (BGL >10mmol/L).

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6.7. Complications management post - Alteplase administration

Escalation of patient's deterioration must be in accordance <u>SESLHDPR/697 - Management of the Deteriorating ADULT inpatient (excluding maternity)</u>¹², or as per ED escalation processes if the patient remains in ED.

6.7.1. Intracranial Haemorrhage (ICH)

The most serious of complications is ICH, which should be suspected following the commencement of Alteplase if there is any acute neurological change. The following signs MAY BE secondary to ICH, but note that none are specific:

- Acute decreased level of consciousness
- New or worsening headache. Note that headache is common in stroke and is not specific in isolation.
- Nausea and/or vomiting. Note that some strokes are associated with nausea/vomiting and this is also non-specific.
- Seizures.
- New or worsening neurological deficits.
- New hemianopia.
- Pupillary changes.
- Hypertension (acute).
- Bradycardia.
- Cardiac arrhythmias (new).
- Respiratory rate and pattern changes.

The following should be performed if ICH is suspected:

- Discontinue Alteplase infusion immediately and escalate as per <u>SESLHDPR/697</u>

 Management of the <u>Deteriorating ADULT inpatient (excluding maternity)</u>¹², or per ED escalation processes if the patient remains in ED. Notify the treating Neurologist/ Stroke Physician.
- Commence resuscitation measures as clinically indicated, including airway and breathing support, supplemental oxygen therapy (for SpO₂ < 94%), increase head-of-bed elevation to at least 30°, etc.
- Urgent head CT scan.
- Management of elevated blood pressure (as per <u>Section 6.8</u>).
- Request for urgent bloods, including FBC, Coagulations (PT, aPTT, and fibrinogen).
- Consider referral for ICU, if required.
- Monitor vital signs and GCS at least every 15 minutes.

If ICH is confirmed, the medical officer must (in consultation with the treating Stroke Physician):

Continue actions as above.

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- Chase results of fibrinogen, Hb, PT, aPTT and platelet count.
- Consider the administration of cryoprecipitate and/or fresh frozen plasma (FFP) and/or prothrombin complex (Prothrombinex ®)¹³.
- Consider Neurosurgical consult, if required.
- Consider a repeat CT scan to assess progression of the ICH.

6.7.2. Systemic Haemorrhage

Management of systemic haemorrhage will be dependent on the location and extent/ severity of the haemorrhage, such as whether the haemorrhage can be managed with direct pressure.

The following should be considered as indications of systemic haemorrhage:

- Epistaxis, and/or haemoptysis.
- Petechiae, purpura.
- Bleeding from intravenous access sites.
- Anaemia or drop in Hb (more than 10g/L within 24 hours)¹⁴.
- Intraabdominal bleeding: tachycardia, hypotension, pallor or restlessness, complaints of lower back and/or abdominal and/or chest pain, abdominal distension and generalised tenderness, decreased urine output, new bruising, weakness or dysaesthesia in the lower extremities, haematuria, melena, and hematemesis.
- Intrathoracic bleeding: hypoxia, increased work of breathing, tachypnoea, decreased blood pressure, pulsus paradoxus, tachycardia, elevated jugular venous pressure, distant heart sound, increased pulse pressure, and cardiac arrest.

The following should be performed if systemic haemorrhage is suspected:

- Discontinue Alteplase infusion immediately and escalate as per <u>SESLHDPR/697</u> <u>Management of the Deteriorating ADULT inpatient (excluding maternity)</u>¹², or as per ED escalation processes if the patient remains in ED. Notify the treating Neurologist/ Stroke Physician.
- Apply direct pressure to any external bleeding sites.
- Commence resuscitation measures as clinically indicated, including airway and breathing support, supplemental oxygen therapy (for SpO₂ < 94%).
- Management of elevated blood pressure (as per Section 6.8).
- Request for urgent bloods, including FBC, Coagulations (PT, aPTT, fibrinogen).
- Consider referral for ICU, if required.
- Monitor vital signs and GCS at least every 15 minutes.

If systemic haemorrhage is confirmed, the medical officer must (in consultation with the admitting Stroke Physician):

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- Continue actions as above.
- Chase results of fibrinogen, Hb, PT, aPTT and platelet count.
- Consider the administration of cryoprecipitate and/or fresh frozen plasma (FFP) and/or prothrombin complex (Prothrombinex ®). Also, consider the use of recombinant Factor VII therapy ¹³.
- Consider General Surgery/ Cardiothoracic Surgery/ Vascular Surgery consult, if required.
- If bleeding persists in spite of the above measures, then in consultation with the Haematologist.

6.7.3. Allergic or anaphylactoid reactions

Allergic or anaphylactoid reactions may occur following the administration of Alteplase due to the active substance of Alteplase, including gentamicin. ⁹ Angioedema represents the most common hypersensitivity reactions which risk may be enhanced by the concomitant treatment with Angiotensin-converting enzyme (ACE) inhibitors. Patient receiving Alteplase should be monitored for angioedema during and for up to 24 hours after infusion.⁹

Clinical signs are often new or worsening dysphagia and hemilingual (ipsilateral to side of hemiplegia) tongue swelling, wheezy or persistent cough, difficulty in breathing, vomiting and abdominal pain. Progression to the entire tongue and oropharyngeal swelling may occur.

If angioedema occurs the following treatment is recommended:

- Discontinue Alteplase infusion immediately and escalate as per <u>SESLHDPR/697</u> <u>Management of the Deteriorating ADULT inpatient (excluding maternity)</u>¹² Notify the treating Neurologist/ Stroke Physician.
- Commence resuscitation measures as clinically indicated, including airway and breathing support, supplemental oxygen therapy (for SpO₂ < 94%) and/or early intubation (consult ICU).
- Consider administration of second-generation anti-histamine and/or selective H2receptor antagonist, e.g. Ranitidine.
- Consider steroid therapy, e.g. Hydrocortisone 100mg IV stat and repeat every 6 hours until resolution.
- Consider nebulised Adrenaline 5mL (1:1000).
 NB: Intramuscular and intravenous Adrenaline use should be reserved to extreme cases due to the increasing risk of ICH secondary to a rapid rise in blood pressure.

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6.8. Blood pressure management

Strict Blood Pressure param	Strict Blood Pressure parameters must be maintained prior to and following Alteplase treatment.				
Blood Pressure (mmHg)	Treatment				
Pre -Thrombolysis	As per local preference				
SBP > 185 and/or DBP > 110	 Labetalol 10 – 20 mg IV bolus. Doses may be repeated at 5-minute interval if BP remains above the target range. Maximum dose: 300mg in 24 hours (do not use if HR <60bpm). OR Metoprolol 5 mg IV bolus over 2-3 minutes. Doses may be repeated at 5-minute interval if BP remains above the target range. Maximum dose: 20 mg (contraindicated in 2nd & 3rd degree AV block, asthma). OR Hydralazine 5 mg IV bolus over 1-2 minutes. Doses may be repeated at 20-minute interval. Maximum dose: 20 mg. 				
	ALERT: If target BP is not achieved, DO NOT administer Alteplase.				
During/ After Thrombolysis	,				
Monitor BP	Frequency outlined above in Section 6.5				
SBP > 180 and/or DBP > 105	Labetalol 10 – 20 mg IV bolus. Doses may be repeated at 5-minute interval if BP remains above the target range. Maximum dose: 300mg in 24 hours (do not use if HR <60bpm). OR				
	1. Metoprolol 5 mg IV bolus over 2-3 minutes. Doses may be repeated at 5-minute interval if BP remains above the target range. Maximum dose: 20 mg (contraindicated in 2 nd & 3 rd degree AV block, asthma). OR 2. Liverplanies 5 mg IV below ever 1.2 minutes. Doses may be				
	Hydralazine 5 mg IV bolus over 1-2 minutes. Doses may be repeated at 20-minute interval. Maximum dose: 20 mg.				

- The above medications can only be given in PRN doses in a ward environment. If infusions are required then admission to a HDU is necessary.
- If BP is not controlled with the above treatment and Alteplase infusion is still running, then pause it until BP is controlled. This **MUST** only be undertaken in consultation with the treating Neurologist.
- If BP **not controlled** by the above options, use:
 - Labetalol infusion as the first line intervention, this must be undertaken in Coronary care, HDU or ICU where available.

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 Switching to Sodium Nitroprusside infusion may be considered if Labetalol is not able to achieve the target BP.

7. DOCUMENTATION

Documentation of the neurological deficit and performance results should be completed on the National Institutes of Health Stroke Scale - NIHSS Scoring Sheet (AMR110.057) and/or in Electronic Medical Record (eMR) prior to the administration of Alteplase, at 24 hours and 90 days (3 months) post Alteplase.

8. AUDIT

Monitor through ims+ and death reviews.

9. REFERENCES

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- Monthly Index of Medical Specialties, 2022. <u>Actilyse</u>. [ebook] MIMS Australia. eMIMSplus
- 10. South Eastern Sydney Local Health District, 2021. <u>SESLHDPR/343 Bare Below the Elbows Hand Hygiene</u>.
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- 14. Rajkomar A, McCulloch C, Fang M. <u>Low Diagnostic Utility of Rechecking Hemoglobins Within 24 Hours in Hospitalized Patients</u>. The American Journal of Medicine. 2016;129(11):1194-1197.
- 15. Australian and New Zealand Living Clinical Guidelines for Stroke Management Chapter 3 of 8: Acute medical and surgical management Reperfusion therapy.

10. VERSION AND APPROVAL HISTORY

Date	Version No.	Author and approval notes		
April 2009	Draft	Written by SESIAHS rt-PA working party, approved by Emergency Services Committee (March 2009) Approved by CE at Clinical Council (April 2009)		
November 2009	0	E Browne Manager Neurosciences/Spinal/Rehabilitation Clinical Stream – modified to include definitions of Category A stroke units in SESIAHS and stroke physicians.		
July 2010	1	SESIH Area Drug Committee revision to use approved drug terminology and remove unacceptable abbreviations		
September 2010	2	P Smollen Clinical Stream Manager - removed abbreviations. Policy reviewed and approved by SESIAHS Stroke Group (September 2010).		
December 2012	3	L Horvat - Clinical Stream Nurse Manager Medicine, Emergency and Critical Care. Policy reviewed and approved by SESLHD Stroke Working Group; Drug and Quality Use Medicines Committee; and Emergency Services Stream Committee (December 2012).		
January 2013	3	Approved by James Mackie, Director Medicine Clinical Stream		
September 2015	4	K.Thomsett – Clinical Stream Nurse Manager Medicine. Added Neurovascular consultant to list of those who could review head CT, page 5. Policy reviewed and approved by SESLHD Stroke Working Group (September 2015) and Emergency Services Clinical Stream (July 2015). Content endorsed by Executive Sponsor		
November 2015	4	Endorsed by SESLHD DQUMC.		
August 2020	5	Minor review - revised by: R.Lim, NSW Telestroke CNC, B. van Galen, NSW Telestroke NE Reviewed by: Prof K. Butcher, Director of Clinical Neurology (POWH), A. Bailey, Stroke NP (POWH), E. Casey, Neurology A/CNC (SGH). Minor review approved by Executive Sponsor included updates to references and hyperlinks; terminologies and wordings to provide clarity; hospital classifications on their capacities in providing stroke care as per National Stroke Foundation Framework; roles and responsibilities (Section 4) to provide clarity; minor changes to the definitions (Section 5); update on the information for patient eligibility (section 6.2) for Alteplase administration; monitoring of BP can be performed using either manual or automatic oscillometric device post-Alteplase; additional signs of bleeding post-Alteplase; pharmacological interventions for blood pressure management are updated to include Labetalol; appendices updated to reflect current NSF Frameworks regarding 'Recommended		

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		Hospital Stroke Services' (Appendix 3), and 'Features of Hospital Stroke Services' (Appendix 4). The flow chart has also been updated.
September 2020	5	Draft for Comment period.
September 2020	5	Processed by Executive Services prior to submission to Quality Use of Medicines Committee.
November 2020	5	Approved by Quality Use of Medicines Committee. Published by Executive Services.
November 2022	6	Minor review by J. Li Clinical Pharmacist – POWH. Updated hyperlinks of current policies and references throughout the procedure; NSW Health - Medication Handling in NSW Public Health Facilities (PD2022_032) Removed reference to appendix 5 as it was not included in the previous version
		Added section 6.3 Prescribing Alteplase Alteplase must be prescribed on the National Inpatient Medication Chart (NIMC) or electronic Medication Administration Record (MAR) in accordance with NSW Health - Medication Handling in NSW Public Health Facilities (PD2022_032)³. The powerplan of "Alteplase for Acute Stroke" must be selected when prescribing on MAR.
		Added the following to Table 1 – Blood Glucose Level (BGL) frequency for 72 hours, regardless of diabetes status ⁷ .
		Updated reference number 1 - Australian Product Information - ACTILYSE (alteplase) powder for injection. Revised on 9th November 2021.
		Updated reference 7 as it was reviewed in 2021 and added 'Living' to the title
		Update reference 9 as it was reviewed in 2022
		Updated reference 12 to <u>SESLHDPR697 - Management of the</u> <u>Deteriorating ADULT inpatient, excluding maternity</u> ¹² .
February 2023	6.1	Approved by Executive Sponsor. Formatting by SESLHD-Policy team.
March 2023	6.2	Approved by SESLHD Drug and Therapeutics Committee with amendments.
12 May 2025	6.3	Minor review, added the following:
		8. AUDIT Monitor through ims+ and death reviews
		9. Reference 15. Australian and New Zealand Living Clinical Guidelines for Stroke Management - Chapter 3 of 8: Acute medical and surgical management - Reperfusion therapy. Rewording-6.2 Note key time-of-onset metrics: Patients are potentially eligible for alteplase within 4.5 hours after the onset of stroke symptoms, or (in the presence of appropriate cerebral perfusion parameters as determined by the Stroke physician) up to 9 hours after the time the

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	patient was last known to be well, or from the midpoint of sleep for patients who wake with stroke symptoms ⁷ . 6.2.15 Added - Emergent placement of NGT prior to thrombolysis is almost never required. 6.2.17 removal of actual or estimated Local policy replaced with local process section 4 and 6. Approved at SESLHD Drug and Therapeutics Committee.
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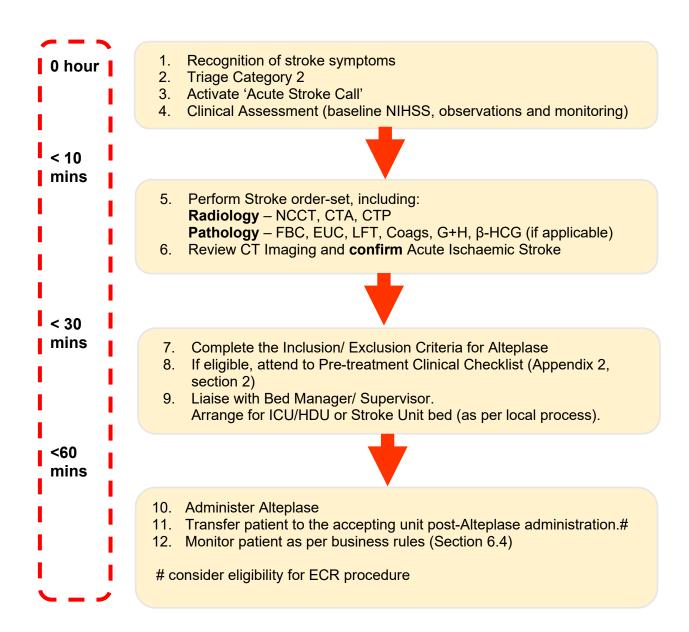


Alteplase (Recombinant Tissue Plasminogen Activator) in Adult Acute Ischaemic Stroke – Management of

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Appendix 1: Flowchart - use of Alteplase (rt-PA) in Acute Ischaemic Stroke

Alteplase administration: within 4.5 hours, and up to 9 hours after the onset of stroke symptoms or last known to be well, or from the midpoint of sleep for patients who wake up with stroke symptoms, and when deemed clinically appropriate by Stroke physician. Aim for 'door-to-needle' time within 60 minutes, if applicable.



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Alteplase (Recombinant Tissue Plasminogen Activator) in Adult Acute Ischaemic Stroke – Management of SESLHDPR/236

Appendix 2: SESLHD Form - <u>Administration of Recombinant Tissue Plasminogen Activator</u> (<u>Alteplase</u>) for the treatment of <u>Acute Ischaemic Stroke</u>

	ANN Health		FAMILY NAME	MRN				
	NSW	South Eastern Sydney Local Health District	GIVEN NAME		□ MALE □	FEMAL	E	'
	Facility:		D.O.B//	/ M.O.				
			ADDRESS					
		IISTRATION OF RECOMBINANT JE PLASMINOGEN ACTIVATOR						
	ı	LASE) FOR THE TREATMENT OF	LOCATION / WARD					
	A	CUTE ISCHAEMIC STROKE	COMPLETE ALL DETAI	LS OR AFFIX F	PATIENT LABE	HERE		
10058	Urgent	t CT Brain Scan ordered Pre-treatment NIHS	SS Score:	Date:			_	
	1. Compl	ete the inclusion/ Exclusion Criteria Chec	klist:					
SES	Inclusion	Criteria (must be 'Yes' to be eligible)				Yes	No	
	Clinically d	definite ischaemic stroke causing measurable	le/disabling neurological defic	it				,
	Onset of st	troke symptoms less than 4.5 hours prior to imaging	treatment commencement Al	ND/OR eviden	ce of			
	Age ≥ 18	years						
	Exclusion	Criteria (must be 'No' to be eligible)	~)		Yes	No	
0	Evidence o	of acute intracranial bleeding on CT scan	: 0					
	Major trau	ma, stroke or myocardial infarction in previou	s 3 months	5				
0 D	Hereditary	or acquired bleeding disorder or severe hep-	atic disease					
- NO WRITING	Minorora	apidly improving stroke symptoms with norma	al stroke imaging	<i>→</i>				
2828. O WF	Symptoms	suggestive of subarachnoid haemorrhage, e	ven with normal CT scan					
- NG	Infective e	ndocarditis	S. 7. O.					
loles Punched as per AS2828.1: 2019 BINDING MARGIN - NO WRITING	Uncontrolle despite ac	ed hypertension: Systolic BP > 185mmHg ar ute treatment (see Section 5 of this form for a	nd/or Diastolic BP > 110mmH acute treatment)	g on repeated	measures,			∄₽₽
Holes Punched BINDING MAI	Prothromb	oin time > 15 seconds or INR ≥ 1.7, if on ar	nticoagulant (i.e. Warfarin)					PLASMINGEN ACTIVATOR (ALTEPLASE) I TREATMENT OF ACUTE ISCHAEMIC STRO
D Pu	APTT > 35	seconds in patients treated with heparin dur	ing preceding 48 hours					ME TO
Hole BIN	Therapeuti	ic doses of Low molecular weight heparin (e.	g. enoxaparin) during precedi	ng 24 hours				TOPA
	Low platele	et count (< 100 x 10%/L and/or active bleeding	1)					FAC
0	Potential I	Exclusion Criteria (Discretion of Treating I	Neurologist/ Stroke Physici	an)		Yes	No	HE T
	Time last	seen well > 4.5 hours (able to still treat if in	naging favourable)					SOF
	Previous i	ntracranial haemorrhage						HALA AL
	Arterial pur	ncture at a non-compressible site in the previ	ious 7 days (risk/benefit based	d on severity)				MEN N
	Gastrointe	estinal or urinary tract haemorrhage in previ	ious 21 days (risk/benefit ba	sed on severi	ty)			LAS
	Major surg	gery in previous 14 days (the risk of bleeding	ng decreases every day post	op)				SEE SEE
	Current use of oral anticoagulant, e.g. apixaban, rivaroxaban, or dabigatran (excluding antiplatelet agents)						Might have	
	Hypersensitivity to gentamicin							RTHE
	Blood glucose < 2.8 mmol/L or > 22.2 mmol/L (correct BGL to exclude stroke mimics)							
	Pregnancy	у						
		with POTENTIAL exclusion criteria must whether to treat.	be discussed with the Ne	urologist who	o will make th	ie		S
11120	Completed	d by: Name:	1	Designation: _				SES110.058
S@168ES	Signature:	:		Date:/_	/	_		0.05
98		NO	WRITING			Page	1 of 8	

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Alteplase (Recombinant Tissue Plasminogen Activator) in Adult Acute Ischaemic Stroke – Management of

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	Health	FAMILY N	IAME			MRN	
NSW	South Eastern Sydney Local Health District	GIVEN NAME			☐ MALE ☐ FEMALE		
Facility		D.O.B		_//	M.O.		
		ADDRESS	S				
	NISTRATION OF RECOMBINANT UE PLASMINOGEN ACTIVATOR						
	LASE) FOR THE TREATMENT OF	LOCATIO	N/W	ARD]
	CUTE ISCHAEMIC STROKE	CC	OMP	LETE ALL DETAILS O	R AFFIX P	ATIENT LABEL HERE	
2. Comp	lete Pre-Treatment Clinical Checklist						
	lark all blood requests as URGENT.						
Do not n	eed to wait for blood results to commence			nless on warfarin			
	Clinical Variables	Y	es		Resu	lt	
2 x 18 Ga	uge cannulas inserted	-					
FBC		-					
JEC		-					
	cose level						
	on profile (include Factor Xa if on apixaban, an, or fondaparinux.)			\$	5		
Group and	d hold (for potential Endovascular Clot Retrie	val		×,O	2		(
Pregnanc	y test, if applicable			10	. 4		
	eight (kg) – actual weight if possible. Use weight only if unable to weigh.			50, XX			BINDING MARGIN - NO WRITING
IDC only t	to be inserted for urinary retention	<	1				6
Blood Pre	ssure within the limit of	20.	,	.('()'			ĀR
SBP < 18	5 and DBP < 110	(0)		See Section 5 of th BP (SBP > 185mm)	nis form for	Management of elevated	SE .
(manage Alteplase)	BP aggressively to avoid delays in starting the	e		Bi (SBi > 103iiiiii	ng or DDI	- Homming)	š
3. Drug	Administration						¥
3.1	Drug Presentation						=
3.1	Alteplase						ดิ
	50mg pack: 1 x 50mg vial of Alteplase (dry	powder)	and	1 x 50 mL vial of ster	ile water fo	or injections	
	10mg pack: 1 x 10mg vial of Alteplase (dry	powder) a	and	1 x 10mL vial of steri	le water fo	r injections.	(
	The reconstituted solution contains Alteplas	e 1mg/ml	L.				
32	Drug Dose						
0.2	Refer to dosage schedule on page 5						
	Total dose 0.9mg/kg (maximum dose 90 m	ng) infuse	d inti	ravenously over 60 n	ninutes wit	h:	
	- 10% of total dose administered as a bo	lus over 1	1 min	ute, followed imme	diately by.		
	- Remaining 90% infusion over 1 hour v	ia syringe	driv	er or controlled infus	ion device		
	 Medical Officer to chart bolus and infus 	ion doses	befo	ore leaving the patier	nt.		SES
	3 Reconstitution						\$1100
1.	 Refer to the Alteplase package insert f 	or detaile	d ins	structions in reconstit	utina Alteo	lase.	05
	Insert transfer cannula (provided with a on the stopper.						
	Empty the sterile water into the Altepla foaming upon reconstitution occurs, le					plase cake. If slight	
	- Mix by gently swirling or inverting the	vial. DO N	ют	SHAKE.			
	- Use separate syringes to draw the bol	us and inf	fusio	n dose for administra	ation.		
	- Use immediately after reconstitution vi	a a dedic	atad	IV cappula			l

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		FAMILY NAME		MRN		
Health South Eastern Sydney		GIVEN NAME		☐ MALE ☐ FEMALE	1	
Local Health District	Local Health District				1	
Facility:	D.O.B/ M.O. ADDRESS			1		
ADMINISTRATION OF RECOMBINANT					-	
TISSUE PLASMINOGEN AC		LOCATION / WARD			1	
(ALTEPLASE) FOR THE TREATMENT OF COMPLETE ALL DETAILS OR AFFIX PATIENT LABEL HERE COMPLETE ALL DETAILS OR AFFIX PATIENT LABEL HERE						
5. Guidelines for Blood Pressure Management in Patients Receiving Thrombolytic Therapy						
	-					
Strict blood pressure parameters mus	t be maintained	prior to and following Alteplase t	reatment:			
Blood Pressure (mmHg)		Treatment]	
Pre-Thrombolysis		As per local prefe	erence			
		10 – 20 mg IV bolus. Dose may b is above the target range.	e repeated	at 5-minute intervals if		
	Maximum	dose: 300mg in 24 hours (do not	use if HR <	60bpm).		
		OR	,			
		I 5 mg IV bolus over 2-3 minutes. BP remains above the target rang		be repeated at 5-minute		
SBP > 185 and/or DBP > 110	Maximum dose: 20 mg (contraindicated in 2 nd & 3 nd degree AV block, asthma).					
	 Hydralazine 5 mg IV bolus over 1-2 mins. Dose may be repeat at 20- minute intervals if BP remains above the target range. 					
	l	dose: 20 mg			NG Pun	
					Holes Punched as	
	ALERT: If targ	et BP is not achieved, DO NOT ad	dminister Al	teplase.	RG	
During / After Thrombolysis	×				N - A	
Monitor BP	Frequency as outlined above in Section 4.1 of this form					
		10 – 20 mg IV bolus. Dose may be a above the target range.	e repeated	at 5-minute intervals if	Holes Punched as per AS2828.1: 2018 BINDING MARGIN - NO WRITING	
	Maximum	dose: 300mg in 24 hours (do not u	use if HR <	80bpm).	6 9	
		OR				
SBP > 180 and/or DBP > 105		I 5 mg IV bolus over 2-3 minutes. BP remains above the target rang		be repeated at 5-minute	0	
	Maximum	dose: 20 mg (contraindicated in 2ª	™ & 3™ deg	ree AV block, asthma).		
	2. Hydralazi	ne 5 mg IV bolus over 1-2 mins. D	ose may b	e repeat at 20- minute		
	ge.					
	Maximum dose: 20 mg					
The above medications can only be given as PRN bolus doses in a ward environment. If infusions are required then admission to a HDU is necessary O O O O O O O O O O O O O						
If BP is not controlled with the above treatment and Alteplase infusion is still running, then pause the infusion until BP is controlled. This MUST only be undertaken in consultation with the treating Neurologist.					110058	
a If DD not controlled by the above entires use:						
If BP not controlled by the above options, use: Labetalol infusion as the first line intervention. This must be undertaken in Coronary Care, HDU or						

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the target BP.

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Switching to Sodium Nitroprusside infusion may be considered if Labetalol is not able to achieve

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Mik Health	FAMILY NAME	MRN		
NSW South Eastern Sydney Local Health District	GIVEN NAME	☐ MALE ☐ FEMALE		
Facility:	D.O.B// M.O.			
- domey.	ADDRESS			
ADMINISTRATION OF RECOMBINANT				
(ALTEPLASE) FOR THE TREATMENT OF	LOCATION / WARD			
ACUTE ISCHAEMIC STROKE	COMPLETE ALL DETAILS OR AFFIX PATIENT LABEL HERE			

Alteplase Dosage Schedule for Acute Ischaemic Stroke

(Ideally use patient's actual body weight)

Patient actual body weight is 90 kg. The total dose will be 81mg. The Alteplase order (reconstituted to 1mg/mL) will be:

- IV bolus (10% total dose): 8.1mL (8.1 mg)
- IV Infusion (90% of total dose): 72.9mL (72.9mg)

Patient		Vol. of 1mg/	ImL Alteplase	Patient	0	Vol. of 1mg	/1mL Alteplase
Weight (kg)	Total dose @ 0.9mg/kg (mg)	10% Bolus (mL)	90% Infusion (mL)	Weight (kg)	Total dose @ 0.9mg/kg (mg)	10% Bolus (mL)	90% Infusion (mL)
40	36	3.6	32.4	70	63	6.3	56.7
41	36.9	3.7	33.2	O71	63.9	6.4	57.5
42	37.8	3.8	34	72	64.8	6.5	58.3
43	38.7	3.9	34.8	73	65.7	6.6	59.1
44	39.6	4	35.6	74	66.6	6.7	59.9
45	40.5	4.1	36.4	75	67.5	6.8	60.7
46	41.4	4.1	37.3	76	68.4	6.8	61.6
47	42.3	4.2	38.1	77	69.3	6.9	62.4
48	43.2	4.3	38.9	78	70.2	7	63.2
49	44.1	4.4	39.7	79	71.1	7.1	64
50	45	4.5	40.5	80	72	7.2	64.8
51	45.9	4.6	41.3	81	72.9	7.3	65.6
52	46.8	4.7	42.1	82	73.8	7.4	66.4
53	47.7	4.8	42.9	83	74.7	7.5	67.2
54	48.6	4.9	43.7	84	75.6	7.6	68
55	49.5	5	44.5	85	76.5	7.7	68.8
56	50.4	5	45.4	86	77.4	7.7	69.7
57	51.3	5.1	46.2	87	78.3	7.8	70.5
58	52.2	5.2	47	88	79.2	7.9	71.3
59	53.1	5.3	47.8	89	80.1	8	72.1
60	54	5.4	48.6	90	81	8.1	72.9
61	54.9	5.5	49.4	91	81.9	8.2	73.7
62	55.8	5.6	50.2	92	82.8	8.3	74.5
63	56.7	5.7	51	93	83.7	8.4	75.3
64	57.6	5.8	51.8	94	84.6	8.5	76.1
65	58.5	5.9	52.6	95	85.5	8.6	76.9
66	59.4	5.9	53.5	96	86.4	8.6	77.8
67	60.3	6	54.3	97	87.3	8.7	78.6
68	61.2	6.1	55.1	98	88.2	8.8	79.4
69	62.1	6.2	55.9	99	89.1	8.9	80.2
				≥100	90	9	81
			NO WEIT	INC			Page 5 of 0

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Appendix 3: Recommended Hospital Stroke Services 6

Comprehensive Stroke Centre (CSC)

CSCs have highly specialised resources and personnel available (24 hours a day, seven days a week). These services are located in large, tertiary referral services which see high volumes of stroke patients (usually over 350 annual admissions) including the most complex presentations. In addition to all PSC capabilities, CSCs offer endovascular thrombectomy and neurosurgery (24/7/365), along with links to other specialist services such as cardiology, palliative care and rehabilitation. These services have a leadership role in establishing partnerships with other local hospitals for supporting stroke care services (e.g. formal networks, specialist education and clinical advice including outreach visits or telemedicine links) and leading clinical research.

CSC's must be located strategically across Australia to ensure the greatest equity of access to highly specialised interventions. CSC's should have sufficient dedicated stroke bed numbers to ensure stroke patients access SU early and remain for over 90% of their acute stay. CSCs will normally have a minimum of eight dedicated stroke beds in their stroke unit for centres admitting 350 stroke patients annually increasing proportionally to around 22 stroke beds for services that see >1000 stroke admissions. Recommended bed numbers are for acute stroke units only (not combined acute/rehabilitation units) with the actual capacity of a CSC stroke unit dependent on local factors including referral patterns, case mix, access to further rehabilitation services and the efficiency of repatriation to the health network of origin when patients have been transferred in for thrombectomy. CSC's should take a lead in coordinating stroke care across their local health district.

Primary Stroke Centre (PSC)

All services with 75 stroke patients or more per year should have PSC capability.

These services have a dedicated SU with clinicians who have stroke expertise; written stroke protocols for emergency services, provide hyperacute stroke treatments and rehabilitation. PSCs should have well organised systems to link emergency services (e.g. pre-notification and code stroke alert systems with direct transport to CT scanner on ambulance stretcher); rapid brain imaging and reporting including advanced imaging (for possible referral to CSC for endovascular thrombectomy); ability to offer thrombolytic therapy 24/7 (either via onsite specialist or supported by telemedicine); protocols to transfer appropriate patients to a CSC as needed (e.g. for neurointerventional or neurosurgical services, including transfers back for ongoing care); strong links with rehabilitation services to ensure early assessment and transfer (if not co-located) and secondary prevention services. Depending on local factors (previous and existing services, geography etc.) these services may be supported by telestroke, or may have some of the additional elements of comprehensive stroke services and/or responsibility for regional coordination of stroke services.

General Hospital

Hospitals admitting less than 75 stroke patients per annum may not have sufficient demand to justify specialised in-hospital resources such as a stroke unit, clinicians with stroke expertise or advanced neuroimaging and should be bypassed by ambulance services when stroke is suspected –this is especially the case for outer metropolitan or regional centres within approximately 1 hour transport time from a primary stroke centre (PSC) or comprehensive stroke centre (CSC). However, regional and larger rural hospitals who are not bypassed due to geography and local factors should have links, ideally including telestroke, to a PSC or CSC to facilitate initial assessment, thrombolysis and, if on-site provision is not feasible, transfer for further treatment and stroke unit care. Suspected stroke patients who self-present to hospitals without access to acute stroke therapy or have a stroke while in such a hospital should be immediately transferred to a stroke-capable hospital.

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Alteplase (Recombinant Tissue Plasminogen Activator) in Adult Acute Ischaemic Stroke -Management of

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Appendix 4: Features of Hospital Stroke Services

Element of service	Comprehensive Stroke Centre	Primary Stroke Centre	General Hospital (in regional and rural settings where not bypassed)
Receive pre-notification and prepare to rapidly accept potential stroke patient from pre-hospital services	✓	✓	✓
Coordinated emergency department systems (includes use of validated screening tools; agreed triage categories; rapid imaging; rapid referral and involvement of stroke team, protocols for IV thrombolysis and ECR intervention/transfer)	✓ including code stroke activation and possible direct transport to CT	✓ including code stroke activation and possible direct transport to CT	✓ initial assessment and thrombolysis via telestroke followed by transfer
Stroke unit	✓	✓	×
Rapid access to onsite CT brain (24/7) including CT perfusion and aortic arch to cerebral vertex angiography	4	4	✓ plain CT ✓/× CTP/CTA highly preferable
Delivery of intravenous thrombolysis	√24/7#	√24/7#	✓ With telestroke support followed by transfer
On-site endovascular stroke therapy	√24/7#	Optional¥	×
On-site neurosurgical services (e.g. for hemicraniectomy due to large middle cerebral artery infarcts)	✓	Optional¥	*
Ability to provide acute monitoring (telemetry and other physiological monitoring) for at least 72 hours	✓	✓	×
Acute stroke team (see Table 3)	✓	✓	Optional
Dedicated stroke coordinator position	√	√	Optional
Dedicated medical lead	√ ^	✓	×
Access to HDU / ICU (for complex patients)	✓	✓	×
Rapid (within 48 hours) Transient Ischaemic Attack (TIA) assessment clinics/services (including early access to carotid and advanced brain imaging)	1	4	initial assessment and referral
Use of telestroke services for acute assessment and treatment	√ (providing advice)	Optional (if required for 24/7 service)	✓
Standardised processes that ensure ALL stroke patients are assessed for rehabilitation. This includes use of standardised tools to determine individual rehabilitation needs and goals (ideally within 48 hours of admission).	1	1	√*
Coordination with rehabilitation service providers (this should include a standardised process, and/or a person, used to assess suitability for further rehabilitation).	✓	✓	Optional*
Routine involvement of patients and carers	✓	✓	✓
Routine use of guidelines, care plans and protocols	✓	✓	✓
Regular data collection and stroke specific quality improvement activities	✓	✓	Optional
Access and collaboration with other specialist services (cardiology, palliative care, vascular)	✓	Optional onsite	Referral
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[#] reperfusion therapies provided 24/7, 365 days/year onsite (including via telemedicine for thrombolysis)

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[¥] requires clear transfer arrangements to services with this capacity if not available onsite

[^] Dedicated medical lead who has primary focus on stroke (stroke service director)
* Patients should be transferred out for further specialist care including stroke unit care after acute assessment and initial treatment. Patients may be assessed and accepted back for rehabilitation following acute therapy at stroke centre.