Thrombolysis with Alteplase for Acute Ischaemic Stroke at Blacktown Hospital - Procedure

<table>
<thead>
<tr>
<th>DocumentID:</th>
<th>PROC20042</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alternative Title:</td>
<td>N/A</td>
</tr>
<tr>
<td>Creator Corporate Name:</td>
<td>Western Sydney Local Hospital Network</td>
</tr>
<tr>
<td>Author:</td>
<td>BURDUSEL Camelia</td>
</tr>
<tr>
<td>Department Address:</td>
<td>Stroke, Rehabilitation &amp; Aged Care Services - Blacktown Hospital</td>
</tr>
<tr>
<td>Author Position:</td>
<td>Clinical Nurse Consultant Stroke/Rehabilitation</td>
</tr>
<tr>
<td>Author Contact:</td>
<td>9881 7061</td>
</tr>
<tr>
<td>Author Email:</td>
<td><a href="mailto:camelia_burdusel@wsahs.nsw.gov.au">camelia_burdusel@wsahs.nsw.gov.au</a></td>
</tr>
<tr>
<td>Contributor:</td>
<td>Prof Richard LINDLEY, Geriatric Medicine</td>
</tr>
<tr>
<td>Endorsement:</td>
<td>General Manager - Blacktown Mt Druitt Hospital</td>
</tr>
<tr>
<td>Publisher:</td>
<td>Western Sydney Local Hospital Network</td>
</tr>
<tr>
<td>Subject:</td>
<td>Hyperacute fibrinolytic treatment for acute ischaemic stroke</td>
</tr>
<tr>
<td>Keywords:</td>
<td>Thrombolysis; Acute Ischaemic Stroke; Alteplase</td>
</tr>
<tr>
<td>Description:</td>
<td>Provision of hyperacute treatment with recombinant tissue plasminogen activator (rt-PA) of patients presenting with acute ischaemic stroke within a therapeutic window of 4.5 hours at Blacktown Hospital.</td>
</tr>
<tr>
<td>Version History:</td>
<td>Release 2 - Version 3.0</td>
</tr>
<tr>
<td>Category:</td>
<td>Chronic, Complex and Aged Care</td>
</tr>
<tr>
<td>ClassificationID:</td>
<td>Procedure (PROC)</td>
</tr>
<tr>
<td>Date Created:</td>
<td>01/Mar/2010</td>
</tr>
<tr>
<td>Date Modified:</td>
<td>01/May/2012</td>
</tr>
<tr>
<td>Date Valid From:</td>
<td>31/May/2012</td>
</tr>
<tr>
<td>Date Valid To:</td>
<td>01/Aug/2013</td>
</tr>
<tr>
<td>Date Issued:</td>
<td>01/Aug/2012</td>
</tr>
<tr>
<td>IdentifierID:</td>
<td>(0)</td>
</tr>
<tr>
<td>Identifier Number:</td>
<td>N/A</td>
</tr>
<tr>
<td>TRIM File Number:</td>
<td>WS11/135</td>
</tr>
<tr>
<td>TRIM Record Number:</td>
<td>WSPP12/32</td>
</tr>
<tr>
<td>Availability:</td>
<td>Online: Yes, Via Stores Request: No, Hosprint Print Request: No</td>
</tr>
<tr>
<td>Key Contact:</td>
<td>Belle Mangan Director Corporate Governance 9845 7285 <a href="mailto:belle.mangan@swahs.health.nsw.gov.au">belle.mangan@swahs.health.nsw.gov.au</a></td>
</tr>
<tr>
<td>AudienceID:</td>
<td>Western Sydney Employees (1)</td>
</tr>
<tr>
<td>------------</td>
<td>-----------------------------</td>
</tr>
<tr>
<td>LanguageID:</td>
<td>English (1)</td>
</tr>
<tr>
<td>Relation:</td>
<td>Thrombolysis for Acute Ischaemic Stroke with Intravenous Alteplase at Westmead Hospital - PROC20084</td>
</tr>
</tbody>
</table>
Thrombolysis with Alteplase for Acute Ischaemic Stroke at Blacktown Hospital

Date Created: March 2010
Last Updated: May 2012
**Purpose**

The scope of this Procedure is to offer clear guidance for administration of Alteplase, the only approved intravenous thrombolytic for stroke to patients presenting to Blacktown Hospital – Emergency Department (ED) with acute ischaemic stroke within 4.5 hours from onset of symptoms, which constitutes the currently approved therapeutic window.

**Intended Audience**

Medical and nursing personnel involved in the thrombolysis treatment either in Emergency Department, High Dependency Unit or Acute Stroke Unit. It may also apply to the Radiology Department, Pathology, Patient Flow Management and Allied Health personnel.

**Expected outcomes**

There is an expectation that the suitable candidate for thrombolysis will be rapidly assessed and will receive Alteplase within the 4.5-hour therapeutic window. It is also expected that the Alteplase treatment will be administered in a safe and efficient manner to improve potential of the patient’s neurological recovery. All involved departments, including ED, Radiology, Pathology, Intensive Care, Stroke Service and Patient Flow Service will do their utmost to ensure the rapidity of assessment, treatment, monitoring and transfer within the prescribed time.

**Definitions**

Thrombolysis can be defined as the rescue strategy of rapid re-canalization of the blocked vessel by using a drug which accelerates the body’s fibrinolytic system.


The thrombolytic agent currently approved at Blacktown Hospital is the Alteplase (Actylase®). Based on the evidence, intravenous Alteplase is beneficial for selected patients but should be delivered in well equipped and skilled emergency departments and / or stroke care units with adequate expertise and infrastructure for monitoring, rapid assessment and investigation for acute stroke patients. Collaboration between clinicians in pre-hospital emergency services, emergency medicine, neurology and neuroradiology is recommended to foster prompt identification of potentially eligible patients, expert patient selection along with audit and quality improvement initiatives (Levy, 2009) “

**Recommendations:**

A. Intravenous Alteplase in acute ischemic stroke should only be undertaken in patients satisfying inclusion / exclusion criteria.

B. Intravenous Alteplase should be given as early as possible in carefully selected patients with acute ischemic stroke as the effect size of thrombolysis is time-dependent.
C. Intravenous Alteplase should be given under the authority of a physician trained and experienced in acute stroke management.

D. Thrombolysis should only be undertaken in a hospital setting with appropriate infrastructure, facilities and network support.

E. A minimum set of de-identified data from all patients treated with thrombolysis should be recorded in a central register to allow monitoring, review, comparison and benchmarking of key outcome.


Procedure Statement

Thrombolysis treatment is offered at Blacktown Hospital 24 hours a day; seven days a week to patients with acute ischemic stroke presenting within 4.5 hours from symptoms’ onset and who fulfil the selection criteria (see Appendix 1 - tick-box sheet for inclusion / exclusion criteria).

Thrombolysis with Alteplase is not to be performed at Mt Druitt Hospital. However, if a patient fulfils the criteria and it is reasonable to believe that the treatment could be performed within 4.5 hours from symptoms’ onset, the patient may be transferred to Blacktown Emergency Department (ED) by ambulance (20 minutes driving). Senior Registrar in ED Mt Druitt should contact the Stroke Consultant on call for the day and also the ED Consultant in Blacktown ED.

Procedure

The potential candidate will be initially assessed by the Triage nurse. Patients who are considered eligible should be given a category 2 classification. Triage nurse will inform the Senior ED Registrar directly as rapidity of treatment is essential.

The treatment is administered in the Emergency Department in one of the Resuscitation bays by the ED Consultant in conjunction with the Stroke Consultant on call for the day between 8am and midnight. Between midnight and 8am when the ED Consultant may not be available it is up to the Stroke Consultant on call to either go in or give the authority to go ahead if she/he feels there is enough information to do so on the phone. In this case ED Registrar will administer the treatment (see Appendix 2 -Thrombolysis Clinical Pathway).

Patients under the age of 70 years are to be admitted and receive thrombolysis under one of the Neurology Consultants. Patients over the age of 70 years are to be admitted and receive thrombolysis under one of the Geriatric Medicine Consultants.

The neurological deficit will be measured with the NIHSS Scale (see Appendix 3 for NIHSS and NIHSS Description). The total score will be documented in the provided form and in the patient’s medical record.
The **Code Thrombolysis** will be activated by the Senior ED Registrar via the Switchboard (9) and all consultants in Neurology & Geriatrics, Radiology, the ICU Registrar, the Bed Manager and the Stroke CNC will be informed that a potential candidate for treatment is present in ED.

The potential candidate will have a brain CT as soon as possible and the report of this CT should be available within 30 minutes during working hours. Contact the CT Radiographer on ext 48244 or # 7598. After hours a verbal report may be obtained by calling I-TeleRad in Melbourne on 1800 009 945.

The Stroke Consultant on call will contact the ED immediately. The other Stroke Consultants who may be available in the hospital grounds will offer their assistance to ED toward rapid patient assessment and treatment implementation.

Written consent will be obtained from the patient or a family member by the ED Consultant or Stroke Consultant on call (see Appendix 4 for **Basic facts about thrombolysis that could be used for obtaining consent**).

Consent can be obtained over the phone and documented as such by a senior MO in ED. If the patient cannot sign the consent and relative / responsible person is not available, the treatment may be given without consent as an emergency procedure.

The dose to be infused, as a bolus and continuous IV infusion will be calculated by the ED Consultant or Stroke Consultant and ordered on the medication chart as separate orders and documented in the patient’s medical record (see Appendix 5 for **Dosage**).

At least two doses (50mg x 4 vials) of Alteplase will be available in the ED medication cupboard. Further 50mg x 2 vials will be available in the After Hours cupboard and a small stock will be available in the Pharmacy Department.

*The ICU Consultant on call will be contacted by the ED Consultant or Stroke Consultant, as soon as practical after the decision to proceed to thrombolysis has been made to request that a bed be made available in the HDU.* As soon as the IV infusion finishes and a bed is made available, the thrombolysed patient will be transferred to the High Dependency Unit (HDU) for continuous monitoring. The patient is **NOT to be routinely transferred to another hospital.**

If the stroke occurs while the patient is already in the hospital, the team, Registrar (in-hours) or Medical Registrar on call (after hours) and stroke consultant, either Neurology or Geriatrics Medicine (depending on age of patient) should be contacted immediately.

If the patient is assessed after initial evaluation as a potential candidate for thrombolysis, arrangement needs to be made by the Registrar for completion of the inclusion / exclusion criteria, urgent CT brain, full set of bloods and early notification to ED Senior Doctor of potential thrombolysis candidate.
If the patient meets all criteria and CT brain shows no haemorrhage, the Senior ED doctor should be re-contacted to request urgent transfer to ED for thrombolysis, this being the appropriately prepared and resourced department to provide the treatment in a safe and rapid manner.

Once the patient is in ED with plan to proceed with thrombolysis, the procedure should be commenced as soon as possible and the usual clinical pathway should be followed from that point.

If the CT shows a haemorrhage or other pathology, the Stroke Consultant should advise regarding appropriate management.

The Bed Manager will be notified via Code Thrombolysis but may be also contacted on ext. 48203 or # 7507.

Blood pressure parameters will be decided for each individual patient by the Stroke Consultant in conjunction with the ICU Consultant. Parameters should not exceed 185mmHg systolic and 110mmHg diastolic. Medication to treat blood pressure which is outside parameters will be ordered on the medication chart.

If signs of intracranial haemorrhage (ICH) occur while in HDU, the ICU Consultant will contact the Stroke Consultant for further management decisions. Neurosurgical advice will be sought if necessary. Blood Bank service (24 hours) is available if the need arises (ext. 48210 / 48377).

The thrombolysed patient will stay in the HDU for 24 hours and will have a repeat brain CT 24 hours post-treatment. After that and if stable, the patient may be transferred to the Acute Stroke Unit (ASU).

While in the ASU the patient will be monitored 4th hourly for the rest of admission. Allied Health professionals will perform their initial functional assessment within 24 hours. Physical activities & exercises will be started and increased gently pending on the patient’s condition.

Stroke patients receiving thrombolysis should be considered high risk for falling and adequate preventive measures should be implemented to avoid that.

Stroke patients admitted and thrombolysed at Blacktown Hospital will be entered in a national audit program either the Safe Implementation of Thrombolysis in Stroke (SITS) Registry for treatment evaluation, national and international audit and/or the Thrombolysis Implementation Project (TIPS).

**Monitoring**

1. Monitor baseline BP, HR, RR, SaO2, Temp, BSL, GCS, Cranial Nerves, NIHSS, skin inspection.
   - If BP >185/110mmHg, thrombolysis is not recommended.
   - If blood pressure rises above 185mmHg systolic or over 110mmHg diastolic, check the patient’s neurological condition and inform the Medical Officer.
2. Monitor vital signs as follows:

- 15 minute intervals for first 2 hours then
- ½ hourly for the next 6 hours, then
- hourly until 24 hours after treatment

⚠️ **Attention!!!**

**DO NOT** use arterial line for invasive BP monitoring. Use non-invasive monitoring – pay special attention to the fitting of BP cuff. Unwrap the cuff between measurements, when not in use. Check often for any bruises that may develop under the cuff. Automated blood pressure machines often inflate the cuff to high pressures and this can cause arm bruising.

⚠️ **Attention!!!**

**Sudden drastic changes in BP may indicate ICH or other major systemic bleeding.** If this occurs, stop the infusion immediately and inform the medical officer.

3. Monitor neurological function using the GCS, as above. Inform the medical officer if there is evidence of neurological deterioration. **STOP** the infusion immediately if neurological deficits worsen or if patient becomes haemodynamically unstable and inform the medical officer.

⚠️ **Attention!!!**

The most common signs of ICH include:

- Decreased level of consciousness
- Changes in motor function examination
- New headache
- Increased blood pressure

4. Avoid insertion or removal of indwelling catheters, removal of intravenous cannulas, intramuscular injections, shaving or any other invasive procedures during the first 24 hours following the infusion. Venipunctures should be performed carefully and **ONLY** as required.

5. Assess skin and oral integrity before, during and after Alteplase administration. If peripheral bleeding is detected, apply pressure until the bleeding stops to prevent haematoma formation.

6. Avoid toothbrushes, mouth washes or soft sponge to prevent oral trauma within the first 24 hours post thrombolysis.

7. Observe and report to medical officer any signs of bleeding (e.g. in the eyes, sputum, vomit, urine, skin, PR, PV).

8. Do not administer antiplatelet therapy for at least 24 hours after the completion of treatment, and ideally only after the second CT scan, performed at 24-48 hours has excluded intracranial haemorrhage.
9. Ensure patient safety is maintained to avoid potential trauma or falls.

10. Explain the reasons for the monitoring and treatment to patient and family members in addition to the usual information about stroke.

**Administration**

- Treatment must be prescribed by a physician specialised in Geriatric Medicine / Neurology or ED Consultant (See contraindications and special warnings / precautions for use).
- Alteplase is to be ordered on the medication chart. ED assessment & administration form should be used as a guide only.
- The recommended dose is 0.9 mg Alteplase/kg body weight (to a maximum of 90mg total dose) infused intravenously over 60 minutes, with 10% of the total dose administered as an initial intravenous bolus over 1-2 minutes and the remaining 90% total dose infused over the following hour (see Appendix 6 for Alteplase / Action / Preparation & Administration). Alteplase must not be mixed with any other drug. Intravenous infusion is best administered via Agilia volumat MC pump. The initial IV bolus is best administered manually.
- Treatment with Alteplase must be started within 4.5 hours of the symptoms’ onset.

**Side effects and adverse reactions**

- Compared to other indications patients with acute ischaemic stroke treated with Alteplase has a markedly increased risk of intracranial haemorrhage as the bleeding occurs predominantly into the infarcted area.
- The most frequent adverse reaction associated with Alteplase is bleeding which may result in a fall in haematocrit and/or haemoglobin values. The type of bleeding associated with thrombolytic therapy can be divided into two broad categories:
  - **Internal bleeding**, involving the gastrointestinal, genitourinary tracts, retroperitoneal sites, parenchymatous organs or central nervous system
  - **Superficial / Surface bleeding**, observed mainly at invaded or disturbed sites (e.g. venipuncture sites, arterial punctures, sites of recent surgical intervention)

- Should serious bleeding in a critical location (intracranial, gastrointestinal, retroperitoneal, and pericardial) occurs, Alteplase therapy should be discontinued immediately.
- Peripheral bleeding at venipuncture sites, recent abrasions, shaving nicks and gingival oozing are common but these factors may indicate the patient is at increased risk of ICH.
- Allergic reactions occur in about 2.5% (angi-oedema, tongue oedema, etc) that has sometimes been associated with current angiotensin converting enzyme inhibitor (ACE-I) treatment (e.g. Captopril).
**Risk Rating**

**Critical**

- The procedure should be reviewed every 12 months as it is a new service offered by Blacktown Hospital, one not yet widely available in Australia (<3% of suitable candidates). Research projects are underway worldwide and protocols may need modifications pending to the outcome of new research result.

- Non-compliance with this procedure may lead to patients suitable for thrombolysis not receiving the treatment and therefore not benefiting the chance of potential neurological improvement.

**Implementation Plan**

**Resources required**

The stroke thrombolysis service is being implemented within existing resources by a planned education and training program.

**Nursing** monitoring will need the following resources:

As the procedure is started in one of the Resuscitation bay, nursing ratio should be 1:2. In case of staff shortage the ED NUM may request extra nursing staff as appropriate.

The potential need of a bed in the HDU will be communicated with the Patient Flow Unit by the Clinical NUM in ED. When the infusion is completed or during treatment, the patient will be transferred to the HDU. If staff not available that particular day, the ICU/HDU NUM may request extra nursing staff.

After 24 hours of continuous monitoring in HDU the patient will be transferred to the ASU, nursing ratio 1:4. The ASU NUM will ensure that there is enough, appropriately skilled nursing staff. The nurse working in the ASU will not be required to act as Team Leader in that evening and night shift.

Based on the experience from other hospitals in Sydney and NSW, it is predicted that the number of patients receiving thrombolysis for acute ischaemic stroke is unlikely to be more than 10-12 per year therefore the need for extra resources will be limited/ occasional.

**Monitoring compliance**

The ED and the ASU/Stroke Service will collect KPIs such as the number of thrombolysed patients, timing from symptoms onset to Triage door, timing from door to needle, near misses, NIHSS scores, Rankin score at 90 days, etc.
Each case will be reviewed during and immediately after the procedure and then at 6 weeks and 3 months. The whole service will be evaluated by the BMDH Stroke Service at 6 and 12 months.

The Thrombolysis Procedure at Blacktown Hospital will be reviewed within 12 months. The Procedure is the result of extensive consultation between clinicians.

It is worth mentioning that the thrombolysis for acute ischaemic stroke is already offered at Westmead (2005) and Nepean (2007) Hospitals and the drug itself (Alteplase) was approved for use in the SWAHS by the Area Drug Committee in December 2009.

**Education Notes**

On-going education will be provided for medical, nursing and allied health staff by the BMDH Stroke Service either as regular lectures, in-services or written material (see Stroke Book no 4 – Reading package for nurses involved in the thrombolysis treatment, available in the Intranet). Online education could be find at:

- [www.strokecenter.org](http://www.strokecenter.org)
- [www.thecochranelibrary.com](http://www.thecochranelibrary.com)
- etc…

**Appendix 1**

**Thrombolysis with Alteplase for Acute Ischaemic Stroke at Blacktown - Inclusion / Exclusion Criteria - tick-box**

**Inclusion Criteria**

All boxes must be “YES”

<table>
<thead>
<tr>
<th>Y</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ] Yes</td>
<td>[ ] No</td>
</tr>
<tr>
<td>[ ] Yes</td>
<td>[ ] No</td>
</tr>
<tr>
<td>[ ] Yes</td>
<td>[ ] No</td>
</tr>
<tr>
<td>[ ] Yes</td>
<td>[ ] No</td>
</tr>
</tbody>
</table>
Age 18 or greater
Discuss with Stroke Consultant ASAP
Consent. TGA approved treatment < 4.5 hours from stroke onset can be given to patient unable to consent if no relatives available and all other criteria satisfied

### Exclusion Criteria

<table>
<thead>
<tr>
<th>Y</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evidence of acute or chronic intracranial bleeding on CT.</td>
<td></td>
</tr>
<tr>
<td>History of previous stroke or serious head trauma within the past 3 months.</td>
<td></td>
</tr>
<tr>
<td>Clinical presentation suggestive of subarachnoid haemorrhage, even if initial CT is normal.</td>
<td></td>
</tr>
<tr>
<td>Seizure at stroke onset.</td>
<td></td>
</tr>
<tr>
<td>History of suspected intracranial haemorrhage, aneurysm, arteriovenous malformation, intracranial neoplasm or history of intracranial or spinal surgery.</td>
<td></td>
</tr>
<tr>
<td>History of significant bleeding disorder over the past 6 months.</td>
<td></td>
</tr>
<tr>
<td>Known haemorrhagic diathesis, severe hepatic disease or, patient receiving oral anticoagulants with INR &gt;1.3.</td>
<td></td>
</tr>
<tr>
<td>Administration of heparin within 48 hours preceding stroke onset with an elevated APTT at presentation.</td>
<td></td>
</tr>
<tr>
<td>Administration of low molecular weight heparin within 48 hours preceding</td>
<td></td>
</tr>
<tr>
<td>Presumed septic embolus, diagnosis of bacterial endocarditis or pericarditis.</td>
<td></td>
</tr>
<tr>
<td>Documented ulcerative gastrointestinal disease over the last 3 months</td>
<td></td>
</tr>
<tr>
<td>Major surgery or significant trauma (eg CABG or head trauma) within the past 3 months.</td>
<td></td>
</tr>
<tr>
<td>Recent (within 10 days) obstetric delivery, organ biopsy, puncture of a non-compressible blood vessel, or traumatic (&gt;2 minutes) cardio-pulmonary resuscitation.</td>
<td></td>
</tr>
<tr>
<td>Pregnancy or lactation</td>
<td></td>
</tr>
<tr>
<td>Known thrombocytopenia (&lt;100 x 10^9/L)</td>
<td></td>
</tr>
<tr>
<td>Hypoglycaemia &lt; 2.8mmol/L</td>
<td></td>
</tr>
<tr>
<td>Hyperglycaemia &gt; 22.0mmol/L</td>
<td></td>
</tr>
</tbody>
</table>
### Relative Exclusion Criteria

- Uncontrolled baseline hypertension: Systolic BP >185mmHg or Diastolic BP >110mmHg, or aggressive (iv) management required to reduce BP to these limits.
- Menstruation (rt-PA has been given safely, but patient may need blood transfusion)
- Proliferative diabetic retinopathy
- Age < 18 years or > 80 years
- Microscopic haematuria on urinalysis (think of Subacute Bacterial Endocarditis)
Appendix 2

Thrombolysis for Acute Ischaemic Stroke

Clinical Pathway

Triage Nurse Assessment

- Alert Senior Registrar in ED of potential ischaemic stroke - Thrombolysis / Category 2

Criteria for immediate exclusion

- Significant dementia or marked dependency for ADLs
- Significant surgery <2 weeks
- Anticoagulated with Warfarin / Heparin / Hemodialysis / bleeding disorders / myelosuppressive therapy

If yes
- Exit Pathway
  + Discuss with Stroke Consultant

If not
- Exit Pathway
  + Discuss with Stroke Consultant

Onset of symptoms definitely within 4.5 hours

If wake up event, consider onset as occurring from time last seen perfectly well.
If witnessed and patient unclear on timing, take onset as occurring from time last seen perfectly well.

Focused Neurological Exam

Use NIH Stroke Scale (see page 3 & 4) for clinically definite stroke

- If potential candidate at this stage, notify Stroke Consultant on call.
- Call switch on 9 and ask to send notification on CODE THROMBOLYSIS

Order CT Brain-rule out bleed
Call Radiology on 48244 / #7598
Obtain URGENTLY full set of bloods including FBC, U&E, LT, Triage and Coag
Call Pathology on 48210 / 48377 and explain

Focused systemic exam and Vital Signs

- Any physical evidence that would contraindicate rt-PA or suggest stroke mimic?
- Any evidence of trauma / laceration from fall?
  If yes, clinically assess hips and pelvis for occult fractures.

Go through inclusion / exclusion criteria

- See detailed sheet tick-box (page 1)

Estimate weight (kg) and work out the dosage from dosing schedule

- See detailed administration sheet (page 2)

If meet all of the above criteria and brain imaging reported. Discuss with Stroke Consultant on call, obtain consent and start the thrombolysis

Notify Bed Manager on 48203 / #7507 and discuss with ICU Registrar to provide bed in the HDU
### Appendix 3

#### National Institute of Health Stroke Scale - NIHSS (Modified)

<table>
<thead>
<tr>
<th>Category</th>
<th>Definition</th>
<th>NIHSS</th>
<th>Score</th>
<th>Category</th>
<th>Definition</th>
<th>NIHSS</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOC</td>
<td>Alert</td>
<td>0</td>
<td>0</td>
<td>LOC Questions</td>
<td>Both Qs correct</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Drowsy</td>
<td>1</td>
<td>1</td>
<td></td>
<td>One Q correct</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Stuporous</td>
<td>2</td>
<td>2</td>
<td></td>
<td>Both Qs incorrect</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Coma</td>
<td>3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LOC Commands</td>
<td>Obeys both correctly</td>
<td>0</td>
<td>0</td>
<td>Best Gaze</td>
<td>Obeys both correctly</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Obeys one correctly</td>
<td>1</td>
<td>1</td>
<td></td>
<td>Obeys one correctly</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Both incorrect</td>
<td>2</td>
<td>2</td>
<td></td>
<td>Both incorrect</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Visual</td>
<td>No visual field loss</td>
<td>0</td>
<td>0</td>
<td>Facial Paralysis</td>
<td>Normal facial movements</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Partial hemianopia</td>
<td>1</td>
<td>1</td>
<td></td>
<td>Minor paralysis</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Complete hemianopia</td>
<td>2</td>
<td>2</td>
<td></td>
<td>Partial paralysis</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Bilateral hemianopia</td>
<td>3</td>
<td>3</td>
<td></td>
<td>Complete palsy</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Motor L arm</td>
<td>Normal</td>
<td>0</td>
<td>0</td>
<td>Motor R arm</td>
<td>Normal</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Drift</td>
<td>1</td>
<td>1</td>
<td></td>
<td>Drift</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Some efforts against gravity</td>
<td>2</td>
<td>2</td>
<td></td>
<td>Some efforts against gravity</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td></td>
<td>No effort against gravity</td>
<td>3</td>
<td>3</td>
<td></td>
<td>No effort against gravity</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td></td>
<td>No movement</td>
<td>4</td>
<td>4</td>
<td></td>
<td>No movement</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Untestable (explain)</td>
<td>9</td>
<td>9</td>
<td></td>
<td>Untestable (explain)</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>Motor L leg</td>
<td>Normal</td>
<td>0</td>
<td>0</td>
<td>Motor R leg</td>
<td>Normal</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Drift</td>
<td>1</td>
<td>1</td>
<td></td>
<td>Drift</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Some efforts against gravity</td>
<td>2</td>
<td>2</td>
<td></td>
<td>Some efforts against gravity</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td></td>
<td>No effort against gravity</td>
<td>3</td>
<td>3</td>
<td></td>
<td>No effort against gravity</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td></td>
<td>No movement</td>
<td>4</td>
<td>4</td>
<td></td>
<td>No movement</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Untestable (explain)</td>
<td>9</td>
<td>9</td>
<td></td>
<td>Untestable (explain)</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>Limb Ataxia</td>
<td>No ataxia</td>
<td>0</td>
<td>0</td>
<td>Sensory</td>
<td>Normal</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Present in one limb</td>
<td>1</td>
<td>1</td>
<td></td>
<td>Partial loss</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Present in two limbs</td>
<td>2</td>
<td>2</td>
<td></td>
<td>Dense loss</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Best language</td>
<td>No aphasia</td>
<td>0</td>
<td>0</td>
<td>Dysarthria</td>
<td>Normal articulation</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Mild to moderate aphasia</td>
<td>1</td>
<td>1</td>
<td></td>
<td>Mild to moderate dysarthria</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Severe aphasia</td>
<td>2</td>
<td>2</td>
<td></td>
<td>Near unintelligible or worse</td>
<td>2</td>
<td></td>
</tr>
</tbody>
</table>
NIH Stroke Scale Instructions & Definitions (short-form)
If in doubt use the full version (provided in the Thrombolysis folder)

<table>
<thead>
<tr>
<th>Level of Consciousness</th>
<th>LOC Commands</th>
<th>LOC Questions</th>
<th>Visual</th>
<th>Best Gaze</th>
<th>Extinction &amp; Inattention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Choose one response if there are obstacles to full evaluation (endotracheal tube, language barrier, orotracheal trauma/bandages). 1 – Not Alert: but arousable by minor stimulation to obey, answer or respond. 2 – Not Alert: requires repeated stimulation to attend; strong or painful stimulation to move. 3 – Unresponsive: responds only with motor reflex or unresponsive, flaccid and areflexic.</td>
<td>Open &amp; close the eyes. Grip &amp; release with the non-paretic hand. Give credit for an unequivocal attempt not completed due to weakness. Use pantomime if necessary. Physical impediments, trauma, amputation give one-step command. Only first attempt scored.</td>
<td>Ask for birthday (year, month and day). No partial credit for close response. Aphasic or stuporous patients score 2. If unable to speak due to other reason than aphasia (intubation, trauma, severe dysarthria, language barrier) score 1. Don’t give cues.</td>
<td>Test visual fields (upper &amp; lower quadrants) by confrontation, using finger counting or visual threat. If unilateral blindness or enucleation, the other eye is scored. Clear-cut asymmetry score 1. If extinction on double simultaneous stimulation, score 1. Blindness for any other cause score 3.</td>
<td>Test only horizontal eye movements. Score voluntary or reflexive eye movements. Test for pre-existing ocular trauma, bandages, blindness, visual fields or acuity deficits with reflexive movements. Test aphasic pts. 1 – Partial gaze palsy: abnormal in one or both eyes but, forced deviation or total gaze paresis is not present. 2 – Forced deviation: or total gaze paresis not overcome by the oculocephalic manoeuvre.</td>
<td>Score only sensory loss due to stroke. Test pinprick on many areas: arm (not hands), legs, trunk, face. Stuporous or aphasic patient score 1 or 0. Brainstem stroke with bilateral sensory loss score 2. If non-responding, coma or quadriplegic score 2. 1 – Mild-to moderate loss: pinprick is less sharp or is dull on affected side, or loss of superficial pain. 2 – Severe –to total sensory loss: pt not aware of being touched in the face, arm and leg.</td>
</tr>
</tbody>
</table>
Place arm in appropriate position: if sitting, extend arms 90°. If supine 45°, palms down. Use pantomime but not noxious stimuli. Test each limb, starting with the non-parietic arm.

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>No drift: limb holds 90° (or 45°) for full 10 sec.</td>
</tr>
<tr>
<td>1</td>
<td>Drift: drift down before full 10 seconds.</td>
</tr>
<tr>
<td>2</td>
<td>Some effort against gravity: limb cannot get or maintain 90° or 45°, drift down, some effort against gravity.</td>
</tr>
<tr>
<td>3</td>
<td>No effort against gravity: limb falls rapidly.</td>
</tr>
<tr>
<td>4</td>
<td>No movement</td>
</tr>
</tbody>
</table>

UN – Amputation or joint fusion. Explain………..

Place leg in appropriate position at 30°. Always tested supine. Use pantomime and gesture for aphasic pts but not noxious stimuli. Test each leg, start with the non-paretic one.

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>No drift: leg holds 30° position for full 5 sec.</td>
</tr>
<tr>
<td>1</td>
<td>Drift: leg falls by the end of 5 sec but does not hit bed.</td>
</tr>
<tr>
<td>2</td>
<td>Some effort against gravity: leg falls to bed by 5 seconds, but some effort against gravity.</td>
</tr>
<tr>
<td>3</td>
<td>No effort against gravity: leg falls to bed immediately.</td>
</tr>
<tr>
<td>4</td>
<td>No movement</td>
</tr>
</tbody>
</table>

UN – Amputation or joint fusion. Explain………..

Name some objects; read some sentences. Intubated pt may write. If blind ask to identify objects by touch, repeat and produce speech.

1 – Mild-to moderate aphasia: some loss of fluency or comprehension, limited reduction of speech and expression, difficult conversation.

2 – Severe aphasia: all communication is through fragmentary expression, need for inference, questioning, guessing, minimal information exchange

3 – Mute, Global aphasia: no usable speech or auditory comprehension, coma, stuporous.

Ask to read or repeat words (attached list). Do not tell patient why he / she is tested.

1 – Mild-to moderate dysarthria: slurred some words

2 – Severe dysarthria: slurred to unintelligible words, anarthria/mute

UN – Intubated or other physical barriers. Explain…………..

Test for unilateral cerebella lesion. Test with eyes open. Perform finger-nose-finger and heel-shin tests on both sides. Ensure vision is intact. Score absent ataxia in paralysed or pts who don’t understand instructions. Score ataxia present only if out of proportion to weakness. Only amputation or joint fusion is scored untestable. Explain…………..

> You know how. Down to earth. I got home from work. Near the table in the dining room. They heard him speak on the radio last night.

> Mama; tip-top ; fifty-fifty ; thanks ; huckleberry ; baseball player.

> Glove ; cactus ; key ; feather ; armchair hammock.

(Rengachary & Lin, 2004)

Appendix 4

For Medical Officers
Facts regarding Thrombolysis with Alteplase for the treatment of Acute Ischaemic Stroke. Information that can be used in obtaining consent.

- The process of cerebral infarction may take several hours to complete, creating a time window during which it may be possible to restore blood supply to the ischaemic area of the brain and interrupt or reverse the process. If this is achieved through thrombolytic therapy, it may minimize subsequent neurological deficit, disability and secondary complications.

- Unfortunately, many people have a poor outcome after a stroke. One year after a stroke, about a third of people have died and a further third have some disability. New stroke treatments such as thrombolysis with Alteplase are therefore important advances in stroke medicine.
- Alteplase treatment has risks and benefits similar to a major surgical operation. If given according to the protocol, the treatment has been shown, in clinical practice to have net benefit and improved clinical outcome.

- For every 10 people treated, one more will be alive and independent- even after taking into account the bleeding risk discussed below.

- The main risk is bleeding either in the brain or other organs. Bleeding in the brain causing symptoms occurs in about 6 per 100 people treated, that in some cases can be fatal.

- Allergic reactions occur in about 2.5% (angi-oedema, tongue oedema, etc) that has sometimes been associated with current angiotensin converting enzyme inhibitor (ACE-I) treatment (e.g. Captopril).

- Careful monitoring of the patient in the next 24 hours should identify early these important complications.

References


Appendix 5

Dosage of Alteplase (Actylase®)

Alteplase must be ordered on the medication chart; bolus dose and the remaining infusion as separate orders. This is a guiding tool only.

Patients weight measured:  
Patients weight estimated:  

Calculate dose of Alteplase (Actilyse) required (0.9mg/Kg). Maximum 90mg total dose.

- Total Dose required (mg)  
- 10% Bolus dose required (mg)  
- 90% remaining infusion(mg)  

<table>
<thead>
<tr>
<th>Body weight in Kg</th>
<th>TOTAL DOSE (mg) at 0.9mg/kg</th>
<th>Bolus dose (mg) 10% of total calculated dose</th>
<th>Infusion dose (mg) 90% to be given over 60 minutes</th>
</tr>
</thead>
<tbody>
<tr>
<td>45</td>
<td>40.5</td>
<td>4.0</td>
<td>36.5</td>
</tr>
<tr>
<td>50</td>
<td>45</td>
<td>4.5</td>
<td>40.5</td>
</tr>
<tr>
<td>55</td>
<td>49.5</td>
<td>4.9</td>
<td>44.6</td>
</tr>
<tr>
<td>60</td>
<td>54</td>
<td>5.4</td>
<td>48.6</td>
</tr>
<tr>
<td>65</td>
<td>58.5</td>
<td>5.8</td>
<td>52.7</td>
</tr>
<tr>
<td>70</td>
<td>63</td>
<td>6.3</td>
<td>56.7</td>
</tr>
<tr>
<td>75</td>
<td>67.5</td>
<td>6.7</td>
<td>60.8</td>
</tr>
<tr>
<td>80</td>
<td>72</td>
<td>7.2</td>
<td>64.8</td>
</tr>
<tr>
<td>85</td>
<td>76.5</td>
<td>7.6</td>
<td>68.9</td>
</tr>
</tbody>
</table>

When Alteplase (Actilyse®) is reconstituted, using the provided water in the Alteplase (Actilyse®) box, the solution is 1mg per mL.
Appendix 6

Alteplase / Action / Preparation & Administration

Alteplase is a serine protease that has the property of fibrin enhanced conversion of plasminogen to plasmin. Alteplase produces minimal conversion of plasminogen in the absence of fibrin; and when introduced into the systemic circulation, Alteplase binds to fibrin in a thrombus and converts the entrapped plasminogen to plasmin. This initiates local fibrinolysis with minimal systemic effects. Alteplase is produced by recombinant DNA technique using a Chinese hamster ovary cell-line. The pH of the reconstituted solution is 7.3 +/- 0.5.

Indications

Used in the treatment of ischaemic stroke. Treatment must be prescribed by a physician specialised in Geriatrics Medicine or Neurology or ED Consultant, following the guidelines for inclusion / exclusion.

Significant drug interaction

Reperfusion of ischaemic area may induce cerebral oedema in the infarcted zone. Due to an increased haemorrhagic risk, treatment with platelet aggregation inhibitors should not be initiated within the first 24 hours following thrombolysis with Alteplase.

Prescription

Medical officer should prescribe Alteplase on the medication chart. The exact dose of bolus and remaining infusion should be specified as separate orders on Once-Only medication chart and documented in the Medical Record. One 100mL bag of Sodium Chloride 0.9% Solution for priming the line should be ordered on the IV fluid chart.

Presentation

Alteplase (Actylase®) 50mg vial (in off-white lyophilised powder/cake)
Dose

0.9mg/kg body weight (to a maximum of 90mg) given as:

- 10% of total dose as a bolus injection over 1-2 minute, then
- Remaining 90% as an infusion over 60 minutes
- The reconstituted solution is 1mg per mL (see below - reconstitution)

Dose Calculation

The calculation formula is as follows;

- **Total dose (mg)** = No. of kg x 0.9
- **10 % bolus (mg)** = Total dose ÷ 10
- **90% remaining solution (mg)** = Total amount - bolus

Eg. Patient weight is 80kg
Total dose is 80kg x 0.9mg = 72mg
10% bolus is 72mg ÷ 10 = 7.2mg
Remaining 90% Alteplase solution is 72mg - 7.2mg = 64.8mg

Reconstitution

- If the patient weighs more than 50kg there should be 2 vials of Alteplase reconstituted
- Reconstitute each vial of Alteplase 50mg with 50mL Sterile Water for injection (supplied with drug) using transfer cannula provided
- The reconstituted solution is 1mg per mL
- Avoid agitation; ensure Alteplase powder dissolves by inverting the vial slowly
- From one of the vials withdraw the pre-calculated bolus dose using a 10mL syringe. 10% Bolus dose is to be administered intravenously over 1-2 minutes (see below – procedure)
- Take the 90% remaining solution and add it into the pre-assembled burette (see bellow-procedure)

Procedure for Administration

A. Required equipment

- Agilia volumat MC Pump (or similar pump)
- Volumat line
- In-line Buretrol (burette) extension set
- Sodium Chloride solution 0.9% 100mL bag – for priming the lines and flush
- Antiseptic swabs
- Gloves

B. **Attaching Pump & Lines**
   - Insert the burette line spike into the Sodium Chloride 0.9% solution bag adaptor
   - Close on/off clamp
   - Attach the volumat line to the burette line by inserting the volumat line spike into the burette line adaptor
   - Close on/off clamp
   - Open the air vent at the top of the volumat filter/chamber.

C. **Priming the lines**
   - Open on/off clamp of burette line
   - Fill burette chamber with 30 mL Sodium Chloride 0.9% Solution from the 100 mL bag
   - Close the on/off clamp
   - Prime the line
   - Control flow of Sodium Chloride 0.9% Solution with the on/off clamp from the volumat line
   - Insure that no air bubbles are trapped into the lines
   - Close the volumat line on/off clamp
   - Insert the volumat line into the Agilia volumat MC pump
   - Check the patency of the IV cannula by injecting a 1-2 mL of Sodium Chloride 0.9% solution (flush)
   - If patent attach the volumat line to the IV cannula

D. **Adding Alteplase to the Burette**
   - Using aseptic technique add the pre-calculated and already prepared Alteplase solution to the burette via the Luer activated valve after swabbing with antiseptic
   - Open airway slide clamp

E. **Giving the bolus dose**
   - Check the pre-calculated bolus available in a 10mL syringe
   - Use the additive port of the volumat line after swabbing with antiseptic
   - Inject the Alteplase bolus over 1-2 minutes

F. **Starting the Alteplase infusion**
   - As soon as the bolus is injected open the on/off clamp of the volumat line
   - Dial the dose volume (mL) to be infused over 60 minutes
Press start

Monitor closely for signs of allergic reaction:
- SOB, Skin rush, swollen tongue, ↑Temp

Monitor every 15 minutes:
- BP, HR, RR, SaO2, Temp + GCS

When the infusion finishes add 20mL of Sodium Chloride 0.9% solution into the burette and through the lines to ensure that no amount of Alteplase remain in the line

If required, further Sodium Chloride 0.9% solution may be added to the line

Storage & Shelf life

- 36 months
- Chemical and physical in-use stability of the reconstituted solution has been demonstrated for 24 hours at 2 - 8°C and 8 hours at 25°C.
- From a microbiological point of view, the product should be used immediately.
- Do not store above 25°C. Protect from light. Store in the original package.

References


The Internet Stroke Center (18/02/2010). *Cellular injury during ischemia*. [www.strokecenter.org](http://www.strokecenter.org)


### Version History

<table>
<thead>
<tr>
<th>Date of Issue</th>
<th>Document Version</th>
<th>Change Details</th>
<th>Author</th>
</tr>
</thead>
<tbody>
<tr>
<td>May 2012</td>
<td>Version 3</td>
<td>Changed therapeutic window from 3 hours to 4.5 hours Added: in-hospital stroke pathway / procedure</td>
<td>CNC Camelia Burdusel Prof Richard Lindley</td>
</tr>
</tbody>
</table>