Australasian College
for Emergency Medicine

Statement on Intravenous Thrombolysis for Ischaemic Stroke

Document review

Timeframe for review:	Every five years, or earlier if required
Next review to be completed:	November 2030
Content owner:	EM Standards and Endorsement Committee
Approval authority:	Council of Advocacy, Practice and Partnerships
Accessibility:	Public [website]

Revision history

Version	Date	Pages revised / Brief explanation of revision
V6	Nov-2025	Review of clinical recommendation and context of care

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1. Scope

This statement applies to all emergency departments (EDs) in Australia and Aotearoa New Zealand that evaluate and manage patients with acute stroke.

2. Clinical Position

Intravenous thrombolysis is an intervention for acute stroke which, administered to selected patients early after symptom onset, may increase the odds of a better functional outcome. Thrombolysis for acute stroke increases the risk of intracranial haemorrhage and confers no mortality benefit.

3. Evidence

Due to uncertainty on the efficacy of intravenous thrombolysis as an intervention for acute stroke, in 2016 ACEM commissioned an independent systematic evidence review.[1] It found that intravenous thrombolysis as an intervention for acute stroke, administered to selected patients within three hours of symptom onset, may increase the odds of a better functional outcome while increasing the risk of intracranial haemorrhage and conferring no mortality benefit. The review raised concerns about the quality of many of the included studies.

The situation is now more complex, with endovascular clot retrieval (ECR) widely utilised, and continued debate over the role of intravenous thrombolysis. New research has focused on extending the eligibility criteria for thrombolysis beyond 4.5 hours using specialised neuroradiology protocols to identify patients most likely to benefit, and on the role of thrombolysis for those undergoing ECR.

Current evidence for thrombolysis in the extended window mirrors the findings of earlier literature, with evidence of improved functional outcome being at the cost of increased symptomatic intracranial haemorrhage and with no mortality benefit[2] The number of patients in these studies with a confirmed onset time >4.5h is small, with most studies enrolling more patients with an unknown time of onset, or wake-up stroke. Studies excluded patients planned for ECR.

A recent meta-analysis showed that ECR alone failed to reach the threshold of non-inferiority compared to thrombolysis + ECR[3] though a further study suggests the result may be limited to those presenting early.[4] There are no randomised evidence to guide the use of thrombolysis in patients presenting beyond 4.5h who are planned for ECR.[5]

4. Stroke Pathways

Many larger centres now have pathways which can be activated from the pre-hospital setting or triage to allow early involvement of stroke / neurology teams, to expedite imaging and facilitate hyperacute stroke therapy (thrombolysis and/or ECR).

In many regional and rural settings, access to care involves patient transfer to centres that can provide imaging and specialist input. The time taken to transfer may impact a patient's eligibility for treatment. Use of telemedicine may reduce the duration and number of transfers required and may help to reduce this inequity of access to care.

Acute stroke pathways result in significant utilisation of healthcare resources. Impacts of this may be felt in ambulance and radiology services, in the ED and in intensive care units. ACEM is concerned about the increased demand that extension of the eligibility criteria for thrombolysis places on healthcare resources. Local protocols should consider the impact that resource utilisation would have on patients with other time-critical presentations.

5. Recommendations

5.1 Clinical Environment

Thrombolysis should be undertaken in a setting with appropriate infrastructure, facilities and network support[6] (for example, via telemedicine) including:

- Access to an interdisciplinary acute care team with expert knowledge of stroke management, who are trained in delivery of thrombolysis and monitoring of patients receiving thrombolytic therapy.
- A streamlined acute stroke assessment workflow (including ambulance pre-notification, stroke team response and direct transport from triage to radiology) to minimise treatment delays, and protocols available to guide medical, nursing and allied health acute phase management.
- Immediate access to imaging facilities and staff trained to interpret images.
- Access to a specialist stroke unit for ongoing care.
- Routine data collected in a central register[7] to allow monitoring, benchmarking and improvement of patient outcomes.

5.2 Informed Consent

The patient and family/whānau/carers should be involved in the decision to give thrombolysis whenever possible and the discussion of risk and benefit documented in the medical record. Every effort should be made to contact a patient's representative if the patient does not have capacity to consent for themselves. Consent information should be structured to enable layperson understanding of the key clinical issues and risks associated with the therapy. Informed consent is vital to any decision about the use of thrombolytic therapy in stroke.

Issues to be discussed with the patient (and/or family/whānau/carer), tailored to their clinical situation, may include:

- Thrombolysis provides no mortality benefit.
- Numbers needed to treat (NNT) to achieve functional independence, as measured by modified Rankin Scale (mRS) outcome of 0-1, is 10 (i.e. 10 patients needed treatment for one additional good functional outcome, 95%CI 19 to 6). However, NNT to achieve functional independence, as measured by mRS outcome of 0-2, is 13 (95%CI 29 to 8).
- Treatment has a risk of causing a symptomatic intracranial haemorrhage (sICH), with numbers needed to harm (NNTH) being 42 (i.e. 42 patients needed treatment for one to experience sICH), and 122 for risk of death from sICH. It should be acknowledged that there is wide variation in the literature regarding the NNTH with the confidence intervals ranging from 119 to 13 for sICH and 830 to 30 for death.
- There is disagreement about the strength of the evidence.

Clinicians should follow local health department policies regarding consent for emergency treatment in patients who are unable to consent for themselves.

5.3 Future Considerations

ACEM believes that developing pathways for regional, rural and remote communities to access timely acute stroke assessment, intervention and specialist stroke unit care is vital and advocates for the use of technology, including telehealth, to ensure equity in these communities. Cost effectiveness analyses will be important in defining models of care that provide the best balance of equity and value for money.

ACEM notes that the independent review on stroke thrombolysis raised concerns about the quality of evidence and strongly supports replication research into stroke thrombolysis i.e. further placebo-controlled clinical trials and use of registry data to reduce the current uncertainty.

6. References

1. Upton D, Upton P, Busby-Grant J, Norton M. (2016) Systematic Review of Intravenous Thrombolysis in Acute Ischemic Stroke. University of Canberra, Health Research Institute.

2. Gunkan, A., et al., Thrombolysis for Ischemic Stroke Beyond the 4.5-Hour Window: A Meta-Analysis of Randomized Clinical Trials. Stroke, 2025. 56(3): p. 580-590.

3. Majoie, C.B., et al., Value of intravenous thrombolysis in endovascular treatment for large-vessel anterior circulation stroke: individual participant data meta-analysis of six randomised trials. Lancet, 2023. 402(10406): p. 965-974.

4. Kaesmacher, J., et al., Time to Treatment With Intravenous Thrombolysis Before Thrombectomy and Functional Outcomes in Acute Ischemic Stroke: A Meta-Analysis. JAMA, 2024. 331(9): p. 764-777.

5. Berge, E., et al., European Stroke Organisation (ESO) guidelines on intravenous thrombolysis for acute ischaemic stroke. Eur Stroke J, 2021. 6(1): p. I-LXII.

6. Stroke Foundation. Australian and New Zealand Living Clinical Guidelines for Stroke Management. Available at: https://informme.org.au/en/Guidelines/Clinical-Guidelines-for-Stroke-Management. Accessed [23 September 2025 Chapter 3: Acute medical and surgical management].

7. Australian Stroke Clinical Registry. Available at: https://auscr.com.au. Accessed 10 October 2025.