28 January 2021

Dear Chief Medical Officer

For Attention: Tenecteplase supply shortage

We have been informed by Boehringer Ingelheim, the producer of tenecteplase, that there is an international shortfall in supply of this agent. This shortfall will have a significant impact on New Zealand until approximately October 2021 when production should catch up to international demand.
The shortfall has been caused by two issues:

1) COVID-19 has changed the balance between thrombolysis and Primary Coronary Intervention (PCI) for some patients with ST Elevation Myocardial Infarction (STEMI), and
2) A practice transition (including many New Zealand DHBs) from alteplase to tenecteplase as the preferred thrombolytic agent for ischaemic stroke.

Use of tenecteplase in New Zealand is currently as follows:

- Out-of-hospital thrombolysis for STEMI – this is administered by ambulance paramedics under a standing order in the community and is particularly important for non-urban patients who cannot reach a PCI service within 90 minutes.
- In-hospital thrombolysis for STEMI – particularly in rural and provincial hospitals that do not have cardiac catheter laboratories.
- ANZACS-QI reports 486 patients received thrombolysis for STEMI presentations between July 2019 and June 2020. 1 in 3 (175) had lysis administered prehospital compared to 1 in 6 the prior year (July 2018-June 2019).
- Thrombolysis for ischaemic stroke - this is an unlicenced use of tenecteplase. However it is becoming commonly accepted practice internationally especially prior to clot retrieval. 14 DHBs have now changed to this medicine and, based on the thrombolysis registry data, we predict around 500 Tenecteplase treatments this year if nothing else changes.
- Massive pulmonary embolus – this is also an unlicenced indication for Tenecteplase, however 9 DHBs have indicated that they are using it for this indication.

Supply state:
Last year the pharmaceutical company distributed 1500 doses of tenecteplase to DHBs. DHBs in turn supply St John and Wellington Free ambulance. This amount represents an approximate doubling from two years previously and while there may have been some stockpiling relating to COVID-19, this predominantly reflects the change in use for stroke. We are informed that New Zealand can expect at best 600 more doses, but possibly as few as 400 more doses to be available between now and October. This does not include stock currently held by DHBs and ambulances. If our current national rate of use does not change, this stock will last us until the end of April at which stage we will no longer have access to tenecteplase.

Alternative medicines:
The alternative medicine which is licenced for all indications is alteplase. There is no supply issue for alteplase, however it is much more challenging to use in hospital and almost impossible to safely use in the community. Pharmac has investigated alternative tenecteplase suppliers and has informed us that they have been unsuccessful.

Recommendations:

- It is our view that the highest priority for tenecteplase use should be for out-of-hospital treatment of patients with STEMI. If we can restrict the predicted supply to only this indication, there is a reasonable chance that we can get through without compromising treatment for this group.
- To achieve this, we need to stop using tenecteplase for all other indications as a matter of immediate urgency.

Hence we suggest:

1) Please prioritise existing stock supplies to support use of tenecteplase for out-of-hospital STEMI thrombolysis.
2) Please use alteplase as the thrombolytic of choice for massive pulmonary embolus.
3) Please use alteplase as the thrombolytic of choice for ischaemic stroke.
4) Please use alteplase as the thrombolytic of choice for STEMI in hospitals.
5) Urgently review stock held in DHBs and ambulances to inform predictions more accurately.
6) Introduce a system to monitor use and redistribute stock across the country to support priority use.
7) Please consider removing tenecteplase stocks from DHB areas other than hospital pharmacies.
8) Please put aside out-of-date tenecteplase and do not dispose of it in case we need to make a considered decision to administer out-of-date tenecteplase.

We ask that you ensure these recommendations are disseminated to the relevant people in your organisation.

We acknowledge the need for clear communication and training and support for clinical users in order to minimise safety and efficacy issues. Points (2) and (3) should be able to be achieved swiftly given most DHBs have used alteplase for these indications until relatively recently.

This information is being sent to all Chief Medical Officers, DHB chief pharmacists, Ambulance services, DHB stroke teams via the National Stroke Network, DHB Cardiology services via the National Cardiac Network and Cardiac Society, and Emergency Medicine Specialists via the Australasian College of Emergency Medicine.

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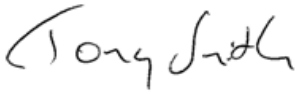
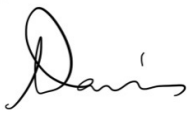
Michael Williams
Chair, New Zealand Committee, Cardiac Society of Australia and New Zealand



Tony Smith
Medical Director, St John Ambulance



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