

## Decision Summary

<b>Meeting Date</b>	Friday 17 October, 2008		
<b>Application #</b>	08012N		
<b>Title of TCP</b>	Trisodium Citrate Catheter Locking Solution		
<input type="checkbox"/> New TCP	<input checked="" type="checkbox"/> Substitute/replacement for existing	<input type="checkbox"/> Extended use of existing	<input type="checkbox"/> Other
Tunneled dialysis access catheters (often referred to as Permcaths) have an unacceptably high rate of thrombosis, occlusion and infection. Currently catheters are "locked" between uses with a heparin solution to provide anticoagulation. The proposed change introduces the use of Trisodium Citrate 46.7% as the locking solution for anticoagulation and antimicrobial activity.			
<b>CONFLICT OF INTEREST DECLARATION</b>			
<b>Applicant</b>	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	No conflict of interest	
<b>Committee</b>	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	No conflict of interest from any TCPC members or invitees present	
<b>SAFETY</b>			
<input checked="" type="checkbox"/> Safer than current practice	<input type="checkbox"/> Equivalent to current practice	<input type="checkbox"/> Less safe than current practice	
Systemic anticoagulation, often seen with 'flushing through' of heparin, is highly unlikely with trisodium citrate due to the dose administered and the rapid rate of metabolism resulting in spontaneous reversal of action within minutes.			
<b>EFFECTIVENESS</b>			
High quality evidence?	Yes		
Consistent, clinically important benefit?	Findings consistent across several sub-analyses		
Applicable to Southern Health?	Yes		
There is high quality evidence demonstrating that Trisodium Citrate Catheter Locking Solution is more effective at preventing infection than heparin and reduces use of rescue thrombolytic therapy.			
<b>COST</b>			
Expected cost for 50 patients per year is \$15,000. Expected savings due to reduced rates of bacteraemia is \$406,000 (based on \$35,000 per bacteraemic episode). Outlay to be borne by Pharmacy budget. This will be offset by savings in antimicrobials.			
<b>CLINICAL FEASIBILITY</b>			
Resource implications	Adequate resources are available to perform these procedures		
Credentialing and competency assurance undertaken	Training of staff is underway		
This procedure is feasible at Southern Health, existing staff are undertaking training, no additional resources will be required.			
<b>ISSUES RELATED TO ACCESS &amp; EQUITY AND LEGAL &amp; ETHICAL IMPLICATIONS</b>			
All expected referrals can be treated within current systems and funding arrangements. There is no need for additional patient information. Previous restriction to 50 patients pa imposed by Therapeutics Committee to be removed. All eligible patients can be treated. Trisodium citrate to be implemented across all Southern Health sites to ensure all patients have access. Widespread rollout can occur following successful piloting of processes at MMC Clayton.			
<b>Final decision by the Southern Health Technology/Clinical Practice Committee</b>			
<input type="checkbox"/>	<b>Recommended:</b> Approved with no further need for assessment.		
<input checked="" type="checkbox"/>	<b>Restricted Recommendation – Audit:</b> Approval subject to implementation under audit conditions. Conditions are specific to the technology.		
<input type="checkbox"/>	<b>Restricted Recommendation – Clinical Trial:</b> Endorsed, however approval subject to implementation in clinical trial with Southern Health Human Research and Ethics Committee approval.		
<input type="checkbox"/>	<b>Restricted Approval – Operational Restrictions:</b> Endorsed, however financial or operational restrictions apply.		
<input type="checkbox"/>	<b>Not Recommended</b>		
Conditions			
<ul style="list-style-type: none"> <li>▪ Implementation strategies to be undertaken to facilitate appropriate administration and successful uptake at all sites.</li> <li>▪ Baseline data on current rates of infection to be determined from routinely collected data and reported to TCPC.</li> <li>▪ Data to be collected on all patients receiving Trisodium Citrate and reports provided to TCPC at six monthly intervals for two years</li> <li>▪ Adverse events to be reported immediately to TGA and TCPC</li> </ul>			
Progress Reporting Due Dates			
	Due date of first progress report (Oct – Dec 2008)	27 February 2009	

	Due date of second progress report (Jan – Jun 2009)	28 August 2009
	Due date of third progress report (Jul – Dec 2009)	26 February 2010
	Due date of fourth progress report (Jan – Jun 2010)	27 August 2010
	Due date of fifth progress report (Jul – Oct 2010)	25 February 2011

SH Policy	Quality and Risk Management	ACHS	Leadership and Management
Reviewer	Director, Centre for Clinical Effectiveness	Last review date	January 2008
Authoriser	Chair, Technology/Clinical Practice Committee	Next review date	August 2010

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