

# Technology/Clinical Practice Committee

## Evaluation Report 2008

Establishment of systems and processes for the introduction, monitoring and reporting of technologies and clinical practices at Southern Health



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## **EXECUTIVE SUMMARY**

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This is the first Evaluation Report of the Southern Health Technology/Clinical Practice Committee (TCPC) and consists of activities undertaken in 2008. This report includes background information and explanations of the outcome measures and will form the basis of a paper for publication in a peer reviewed journal. Future reports will be briefer, focusing only on outcomes and future planning based on results.

### **Definition of technologies and clinical practices**

Technologies and clinical practices (TCPs) are defined as therapeutic interventions (including prostheses; implantable devices; high cost pharmaceuticals; medical, surgical or other clinical procedures) or diagnostic procedures that are considered by a reasonable body of clinical opinion to be significantly different from existing clinical practice.

### **Establishment of new systems and processes at Southern Health**

With executive endorsement from Southern Health, the TCPC aimed to enhance the existing systems and processes by developing a framework that met the following needs of the organisation in the area of safe and appropriate introduction of technologies and clinical practices:

- Increased transparency in decision-making
- Clear decision-making criteria
- Timetables to allow sufficient time for the application and decision-making processes.

Subsequent to detailed analysis of best practice, and in line with the Victorian Department of Human Services (DHS) Guidance for TCPCs, a program was established for the development, implementation and evaluation of the following core components:

- Governance of the TCPC
- Application process for introduction or change of use of TCPs
- Decision-making for introduction or change of use of TCPs and subsequent review
- Monitoring and reporting of newly introduced TCPs
- Administration of the process
- Resources

These components have been piloted and refined based on feedback from applicants, support staff and TCPC members.

### **Audience for the evaluation**

The key audiences for the evaluation are the Southern Health TCPC, the Executive Management Team (EMT) and the Southern Health Board. Other stakeholders who may be interested in the results of this evaluation include the Australian Council of Healthcare Standards Surveyors, the DHS Health Technology Program and the Victorian Policy Advisory Committee on Clinical Practice and Technology (VPACT). It is planned that this evaluation report will be disseminated to these stakeholders on completion.

### **Evaluation plan**

The evaluation plan is presented in Appendix 1.

### **Conclusion**

This evaluation report highlights that the Southern Health TCPC achieved its aim of developing a framework that meets the needs of the organisation in the area of safe and appropriate introduction of TCPs. The evaluation also reveals areas of achievement and success as well as opportunities for improvement.

The updating of systems and processes for introduction of a new TCP complies with current best practice. In updating the systems and processes, the TCPC has achieved its aim of developing a framework that meets the needs of the organisation in the area of safe and appropriate introduction of TCPs. This achievement is reflected in recommendations by DHS to other health services and requests to utilise Southern Health resources and expertise.

Opportunities for improvement include further revision of the application form, enhancement of decision-making by increasing committee member attendance and applicant representation at committee meetings, encouragement of formal feedback from applicants and continuing data collection on the application process. Transparency of the TCPC processes will be improved by the inclusion of approved patient information on the Southern Health intranet.

In 2009 the TCPC will work towards streamlining the process of application by modularising the application forms and integrating them with documentation for other Southern Health Committees. The TCPC will also establish a review process for recently introduced TCPs at the conclusion of their two year restricted approval period. In partnership with other Victorian health services, the Southern Health TCPC hope to undertake a comparison of decision-making for new TCPs and contribute to the development of a database of this information to prevent duplication of applications reviewed in Victoria.

The Southern Health TCPC will continue to be transparent and accountable in all its processes and decision-making.

## **ESTABLISHMENT OF BEST PRACTICE**

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*Does the Southern Health Technology/Clinical Practice Program match current best practice?*

### **Evidence Mapping**

Prior to the establishment of the new systems and processes for introduction of TCPs at Southern Health, the TCPC Secretariat undertook a mapping exercise to establish national and international standards of best practice. Several guides to establishing a TCPC or TCP Program were identified. These came from Australian Capital Territory (ACT) Health, Australian Safety and Efficacy Register of New Interventional Procedures – Surgery (ASERNIP-S), New South Wales (NSW) Health, New Zealand National Health Committee and the Victorian Department of Human Services (DHS)<sup>1-5</sup>. The mapping exercise highlighted that the DHS guidance covered most of the key areas outlined by the other organisations with the exception of informing local consumer health councils and networks of applications received and their outcomes (*See Appendix 2*).

During 2008, the Southern Health TCPC attempted to meet all the criteria in the best practice map and also introduced the following additional components to the program:

- Declarations of conflict of interest by applicant and decision makers
- Publication of a decision summary to ensure transparency of decision-making
- Applications for change of use to an existing TCP
- Review of TCPs with restricted approval at the conclusion of two years to assess requirement for further monitoring

### **Summary**

The Southern Health TCP program complies with current best practice for the introduction of TCPs to a health service. The single exception to this is that we have not implemented a process for informing local consumer groups.

### **Action**

The TCPC will continue to maintain the current high standards and will consult with the Consumer Representative and the Southern Health Consumer Advisory Committee regarding communication with consumer groups.

## **GOVERNANCE**

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*Is the program transparent and accountable?*

### **Publication of systems and processes**

To ensure that the purpose and scope of the TCPC are transparent the Terms of Reference are made available on the internet [http://www.mihsr.monash.org/cce/pdf/tcpc\\_tor.pdf](http://www.mihsr.monash.org/cce/pdf/tcpc_tor.pdf). The Terms of Reference are authorised by the Chair of the TCPC and are due for review in January 2011.

To ensure transparency of decision-making, a detailed summary of the factors considered in applications for introduction of new TCPs and a brief summary of decisions regarding change of use of TCPs in current practice are also published on the internet.

This Evaluation Report will also be available on the TCPC webpage.

A suite of documents and resources to support the implementation of the updated systems and processes were developed in 2008 and made available on the TCPC webpage. Along with the Terms of Reference these include:

- Application protocol
- Application form for introduction of new TCPs
- Application form for change of use of TCPs in current practice
- Application form and instructions for submission to VPACT
- Patient information templates
- Finding the Evidence: Guide to the best available evidence to support introduction of New Technologies and Clinical Practices 2008 (Centre for Clinical Effectiveness workbook)
- Timetable of meeting dates and application deadlines
- Decision summaries for introduction of new TCPs
- Summary of decisions made about change of use applications
- Progress report template
- Patient outcomes audit template

To ensure that the TCPC is accountable the Terms of Reference stipulate that the committee will report to the Executive Management Team (EMT) and DHS detailing applications submitted, procedures approved, reviews of existing TCPs and monitoring of introduced TCPs. These reports are due every six months.

## Attendance at meetings

During 2008 the TCPC convened nine out of the twelve meetings scheduled. It is a requirement of the committee that a quorum of four members be present if any decisions are to be made. Every meeting held in 2008 achieved this.

Two meetings were cancelled in 2008 as there were no applications submitted and no business to discuss and one meeting was cancelled due to committee members being called away at short notice and a quorum was not available to meet.

**Table 1: TCPC member attendance 2008**

Role	Name	Meetings eligible in 2008	Meetings attended in 2008	Meetings where feedback was provided when unable to attend
Chair	A/Prof Richard King	9	9	Data collection incomplete in 2008
Secretary	Dr Claire Harris	9	9	
Executive Sponsor	A/Prof Wayne Ramsey	9	3	
Legal/Ethics	Ms Malar Thiagarajan	9	6	
Operational/Financial	Dr Cate Kelly	9	7	
Consumer Representative	Dr Beverley Castleman	9	7	
Nursing Representative	A/Prof Kylie Ward Ms Lynne Bickerstaff	9	KW – 3 LB – 1	
Surgery Representative	Mr Ton Tran	6	0	
Medical Representative	Prof Ian Meredith	6	0	

\*Ms Lynne Bickerstaff (LB) represented A/Prof Kylie Ward (KW)

## Reporting on Southern Health TCPC activities

As stated in the Terms of Reference the TCPC is required to operate within a reporting structure to ensure corporate and clinical governance. The TCPC is committed to reporting to EMT and DHS biannually. Reports contain details of applications submitted, approved and monitored.

To comply with the DHS requirements of six monthly reporting on all activities of Victorian Health Service TCPCs, the Southern Health TCPC drafted a formal report outlining new processes introduced for TCP applications. Decision summaries for all approved applications were also included. This was approved at the September meeting of the Southern Health EMT and forwarded to DHS in October.

Feedback received from Dr Paul Fennessy (Manager, Genetics and Health Technology Programs Branch) suggested that the report provided to DHS was informative and would be tabled at the next VPACT meeting (November 2008) for information and discussion.

Data for the July – December 2008 report are being collated and the report is due for submission in March 2009.

## Summary

Transparency and accountability of the TCPC and its processes was accomplished in 2008. However it was difficult for several of the committee members to attend all the meetings and one meeting was cancelled as a quorum was not available. This issue needs to be addressed during 2009.

## Action

Actions to address the inability of TCPC members to attend meetings include:

- Review of available dates and times, conflicting meetings, existing commitments, etc with change of meeting schedule if possible and/or change of membership
- Meetings where no applications are tendered will start half an hour later to accommodate member's availability
- Members unable to attend a meeting will be encouraged to provide feedback regarding agenda items at the time of an apology

## APPLICATIONS

*Is the application process and documentation being utilised? Are applicants happy with the process? Were all TCPs introduced at Southern Health captured in the application process?*

The Southern Health TCPC considers applications for the following:

- Introduction of a new TCP that has not been performed at Southern Health and requires external funding prior to implementation
- Introduction of a new TCP that has not been performed at Southern Health and can be implemented within existing funding
- Change of use of a TCP in current practice at Southern Health

VPACT provides an annual funding round to Victorian health services for the introduction of new TCPs where the cost of implementing is greater than \$250,000. The role of the Southern Health TCPC in this situation is to review and make recommendations on applications prior to submission to VPACT.

Applications for the introduction of a new TCP at Southern Health whether for VPACT or internal funding are considered based on the assessment of safety; effectiveness and cost effectiveness; operational requirements such as cost, capability and credentialing; considerations related to access, equity, legal and ethical issues; and review of patient information. The application forms require details in each of these categories.

The application process for a change of use to a TCP in current practice at Southern Health was introduced in October 2008 and is designed to identify potential risks for the patient, clinician and the organisation as a result of the change. This process is currently being piloted.

### TCP applications received

All applications to the TCPC are required to be submitted two weeks prior to the predetermined meeting dates. This allows time to follow up with applicants regarding any omissions in content as well as providing the TCPC members a week to review the application prior to the meeting. The application deadlines are posted on the TCPC web page.

During 2008 the TCPC reviewed fifteen applications; five for the 2008-09 VPACT funding round, five for the introduction of a new TCP, and five for the change of use of a current TCP.

Data has been collected to determine how many applications were received, submitted by the set timelines and completed correctly at first submission. This data is outlined in Table 2.

In 2008 two thirds (10/15) of the applications received were submitted on time however eight of the fifteen required further information and amendments.

**Table 2: Applications received in 2008**

Application	Submitted on time	Completed correctly	Approval		Comment
			Southern Health	DHS	
08001V*	✓	✓	✓	✓	Minor amendments made for format and presentation only – Submitted to DHS
08002V	✓		✓		Additional information was sought from applicants and amendments were required for format and presentation – Submitted to DHS
08003V	✓		✓	✓	
08004V	✓		✓		
08005V					Application lacked sufficient information for the TCPC to make a decision – Not submitted to DHS
08007N†	✓		✓	N/A	Amendments were required for content, format and presentation.
08010N	N/A	N/A	✓	N/A	This application was tabled at a meeting as a reinstatement of use and did not require a full application.
08012N	✓		✓	N/A	Amendments were required for content, format and presentation.
08013N	✓		✓	N/A	
08014N	✓			N/A	
COU 1#	✓	✓	✓	N/A	All completed satisfactorily.
COU 2		✓	✓		
COU 3	✓	✓	✓		
COU 4		✓	✓		
COU 5		✓	✓		

\* V = VPACT application, † N = Application for introduction of a new TCP, # COU = Application for change of use to TCP

## Satisfaction with the application process

2008 was a pilot phase for the new systems and processes introduced by the TCPC. To obtain feedback from applicants surveys were included with all application forms. Feedback was requested for 'content and wording' and 'format' of the application form, 'resources' provided for completion of the application form and 'assistance' available for the application process.

The TCPC received feedback from two of the eleven applicants who submitted an application for introduction of a new TCP in 2008. One applicant commented that the information on who to contact to complete various sections was useful. The applicant also felt that the space provided for answers in the application form confined the response able to be given and that all questions should not be tick boxes as applicants need room to answer via prose.

In addition to the feedback surveys, the TCPC convened a meeting in March 2008 for those who participated in the VPACT funding round. Items discussed at the meeting included internal timelines, the application form, the support process, other support/input/approval required, and sign off for applications. A number of suggestions for possible improvements were made.

Several changes were made for the 2009-10 VPACT funding round:

- Timelines revised
  - Application process brought forward to September
  - Deadlines introduced for contacting and receiving support from Coding, Clinical Information Management, the Centre for Clinical Effectiveness and Finance
  - Inclusion of instructions in the application form regarding deadlines for support services
- Sign off from Southern Health Finance Department required
- Invitation extended to EMT members to participate in the TCPC meetings when VPACT applications are discussed
- Consistency created between application forms for internal and external funding

Other changes suggested but not yet implemented include:

- Organising a 'library' of applications that would be ready to submit once the funding round had opened
- Informing other health services of Southern Health's earlier timelines for VPACT applications
- Utilising coding data for TCP Program evaluation

Change of use applications had the same feedback form attached. The TCPC received feedback from three of the five applications submitted. The feedback was positive and has been taken into consideration at each revision of the application form (Figure 1).

**Figure 1: Change of use form feedback received in 2008**

<p><b>'Content and wording'</b></p> <ul style="list-style-type: none"><li>▪ Pretty straight forward</li><li>▪ Easy to fill in</li><li>▪ No question included to ask if the TCP has TGA approval, does not ask if a similar device is in current use</li></ul> <p><b>'Format'</b></p> <ul style="list-style-type: none"><li>▪ Would be better to automatically populate the first few fields</li><li>▪ Very straight forward</li><li>▪ Tick boxes were easy, form is difficult to use as a word document</li></ul> <p><b>'Other Comments'</b></p> <ul style="list-style-type: none"><li>▪ Form does not ask purpose for the technology</li></ul>
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Feedback was also received from TCPC members regarding usability and formatting of the change of use application form. This resulted in the following amendments:

- Inclusion of the date for when the change of use was endorsed by the Head of Department/Unit
- Addition of 'increased scope' as an option for nature of change of use
- Revision of questions to incorporate Yes-No as the answer options
- Inclusion of endorsement by appropriate Executive Director (Acute, Continuing Care, Mental Health) for related expenses or additional resources
- Inclusion of a decision summary
- Inclusion of a text response for provision of a brief summary of the change of use

## Comparison of the Southern Health TCPC application process and decision-making with other health services

In 2008 DHS planned to invite all Victorian TCPCs to a meeting to discuss the application process for introduction of TCPs. It was hoped that the Southern Health TCPC would utilise this meeting to establish networks to share information and find out what applications other TCPCs had received, decisions they had made and how this compared to our own applications and decisions. No data for 2008 is available as the meeting was postponed and is due to take place in 2009.

## Capturing TCPs that were introduced into practice at Southern Health but not reviewed by the TCPC

To determine if the new TCPC systems and processes have been effective we have developed strategies to identify new technologies or clinical practices that have been introduced without approval from the Southern Health TCPC. These will be undertaken in 2009.

### Summary

The process and documentation have been revised during 2008 based on feedback and ongoing evaluation.

Timelines for submitting applications were met by most applicants in 2008 and although applications for change of use were completed correctly we found that applications for introduction of a TCP lacked information that committee members required to make an informed decision.

### Action

Further work is required in 2009 to compare our processes and decision-making with other health services as well as establishing methods of capturing the introduction of TCPs or changes to the current use of TCPs that are not approved by the Southern Health TCPC. The TCPC will also continue to revise the application form.

## DECISION-MAKING

### *Are processes and documentation for decision-making being utilised?*

Decision summaries were introduced into the TCPC decision making process in March 2008. Their aim is to provide transparency for Southern Health and external stakeholders on all decisions made by the TCPC for applications submitted.

The decision summary includes details about conflict of interest; safety, effectiveness, cost, clinical feasibility, patient information and consent, access and equity, legal and ethical implications, and conditions of approval.

Recommendations for approval are made with the following qualifications:

- Recommended: Approved with no further need for assessment
- Restricted Recommendation – Audit: Approval subject to implementation under audit conditions. Conditions are specific to the technology or clinical practice being introduced
- Restricted Recommendation – Clinical Trial: Endorsed, however approval subject to implementation in clinical trial with Southern Health Human Research and Ethics Committee approval.
- Restricted Recommendation – Operational Restrictions: Endorsed, however financial or operational restrictions apply
- Not Recommended

### Appropriate representation for decision-making

For introduction of new TCPs, the TCPC requires attendance by the Applicant, Department/Unit Head, Program Director and, if for a high cost pharmaceutical, the Chair and Executive Officer of the Southern Health Therapeutics Committee. To ensure there is an independent perspective an additional Program Director is invited to attend and contribute to the decision.

Change of use applications do not require representation at TCPC meetings.

In 2008, ten applications were received for introduction of a TCP at Southern Health, nine of which required representation at the TCPC meeting. The Chair decided that one application did not require support from the applicant as it was a reinstatement of use. Seven applications were represented by at least two people, while two were represented by only one person. Only one was attended by an independent Program Director.

**Table 3: Applicant attendance in 2008**

Attendance	Applications									
	08001V	08002V	08003V	08004V	08005V	08007N	08010N	08012N	08013N	08014N
Applicant (proxy)	✓	✓ <sup>†</sup>	(✓) <sup>†</sup>			✓	N/A	(✓)	(✓) <sup>†</sup>	
Head of Department/Unit (proxy)	✓			✓	✓		N/A			
Program Director (proxy)		✓	(✓)	✓	✓	✓	N/A			✓
Additional Program Director							N/A		✓	

\* 08010N – did not require representation as this was an application for reinstatement of practice, <sup>†</sup> Denotes that applicant was the Head of Department/Unit

### **Utilisation of decision summaries**

The TCPC utilised the decision summary for all applications submitted from March 2008, with the exception of the application for reinstatement of use. All applications reviewed for approval since March 2008 covered each criterion of the decision summary. Decision summaries for TCP applications can be found on the TCPC webpage <http://www.mihsr.monash.org/cce/shtcp.html>.

Decisions made regarding change of use of current TCPs are recorded on the application form and are also summarised on the TCPC webpage [http://www.mihsr.monash.org/cce/pdf/cou\\_summaryofdecisions2008.pdf](http://www.mihsr.monash.org/cce/pdf/cou_summaryofdecisions2008.pdf).

### **Informing applicants of decision-making outcomes**

The process for informing applicants of decisions was inconsistent prior to September 2008. Four applications have been submitted since September 2008 and an outcome letter was forwarded informing applicants of the due dates for reporting and any special conditions related to the application.

### **Compliance with conditions of approval**

Of the ten applications approved in 2008, notification was received that all conditions of approval had been met. Deadlines for compliance were not issued prior to September 2008. Adherence to deadlines will be audited in 2009.

### **Process of appeal for TCPC applications**

At the November 2008 meeting it was noted that the Southern Health TCPC did not have a process for appeal. A decision was made that all appeals should be directed to the Chief Executive of Southern Health. Applicants are made aware of this process when issued with the outcome letter of the TCPC meeting. The TCPC has published this process in the procedure protocol. There were no appeals in 2008.

### **Decision-making for review of TCPs introduced**

Newly introduced TCPs are monitored closely, however after some time will be considered to be "standard practice". The Southern Health TCPC has decided to review TCPs two years after introduction to assess the need for continued monitoring, restricted practice or special conditions.

All TCPs introduced prior to 2008 were reviewed; details are in the Monitoring and Reporting section below. A more formal review process for recently introduced TCPs will be implemented in 2009.

### **Summary**

The transparency of the TCPC decision-making process has improved with the introduction of the decision summary in 2008. Methods for documenting and communicating decisions and ensuring compliance have improved throughout the year. Participation by appropriate representatives in the decision-making process can still be improved

### **Action**

For 2009 the TCPC Administrator has revised the administration process and register of applications to address the following areas which require improvement from 2008 processes:

- Requesting attendance of an additional Program Director for all applications for introduction of a TCP
- Improving Applicant, Head of Department/Unit, Program Director attendance
- Sending of outcome letters following TCPC meeting that includes a due date for meeting special conditions of the application
- Collecting dates for when special conditions of applications are met by the applicant

## **MONITORING AND REPORTING**

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*Are monitoring and reporting processes being utilised? Are applicants happy with the process? Were patient outcomes as expected?*

Since January 2008 there have been considerable changes to the process of monitoring and reporting of new TCPs at Southern Health. These new processes are based on guidance provided by DHS. The TCPC Secretariat has developed data collection tools and a reporting template to assist Southern Health applicants.

Applicants are required to complete six monthly progress reports and patient outcome data spreadsheets for the periods January – June and July – December for a minimum of two years. Patient outcome data is requested in the proforma provided by the TCPC however if applicants already have a system in place they are free to forward patient outcome data in that format. Reporting data are collated by the TCPC Administrator and reports are prepared for the Southern Health EMT and DHS.

### **Applications requiring reporting in 2008**

In 2008 the TCPC requested reporting from applicants listed in Tables 4 and 5.

Progress reports were received by the due date from all applicants in the January – June period and from six of the nine applicants in the July – December reporting period.

The new TCP had not been implemented during the relevant reporting period for three of the approved applications. All but one completed the progress reports correctly. Two applicants did not submit a data collection spreadsheet. None of the applicants used their own patient outcome data collection tool.

**Table 4: January – June Reporting**

Applications	Received by Due Date 29/8/2008	Progress reporting template completed correctly	TCP patient outcome data spreadsheet utilised	Applicants own patient outcome data collection tool utilised
06001N	✓	✓	N/A	N/A
06004N	✓	✓	N/A	N/A
07007N	✓	N/A – no patients seen	N/A	N/A
08007N	✓	✓	✓	N/A

**Table 5: July – December Reporting**

Applications	Received by Due Date 27/2/2009	Progress reporting template completed correctly	TCP patient outcome data spreadsheet utilised	Applicants own patient outcome data collection tool utilised
06001N	✓	✓	✓	N/A
06004N	✗	✓	✓	N/A
07004N	✓	N/A – no patients seen	N/A	N/A
07007N	✗	N/A – no patients seen	N/A	N/A
08001V	✓	✓	✓	N/A
08003V	✗	✓	✓	N/A
08007N	✓	✓	✓	N/A
08012N	✓	N/A – no patients seen	N/A	N/A
08013N	✓	✓	✓	N/A

**Available data for comparison between original application and progress report data**

Table 6 compares the number of patients actually treated with the number expected at the time of application. It should be noted that expected number of procedures to be performed is estimated per year, while actual number of procedures performed is collected six monthly. Underperformance should take into consideration that not all TCPs were introduced at the beginning of reporting periods eg commencement of a procedure in October will impact on achieving expected number of performed procedures.

Some procedures exceeded the number expected and others did not reach the anticipated figure. No data were collected on the possible reasons for any discrepancies, so no firm conclusions can be drawn from this information.

There was one reported death, but this was not attributed to the procedure. The patient had neutropenia and thrombocytopenia due to myelodysplastic syndrome and died of sepsis of unknown origin. Six patients suffered adverse events including cerebral oedema, confusion and minor stroke, nosocomial infection, rejection of transplant and two unplanned readmissions post discharge. None of these adverse events were notified to the committee at the time.

**Table 6: Reporting data 2008**

Applications & Reporting Periods		Data					
		Patients		Procedures performed		Deaths	Other adverse events
		Referred	Treated	Expected (annual)	Actual (6 months)		
06001N	October 2006 – June 2008	14	14	25	14	1	0
	July – December 2008	4	4	25	4	0	0
06004N	January – June 2008	10	7	10-20	7	0	0
	July – December 2008	10	9	6-8	9	0	3
07004N	July – December 2008	0	0	2-3	0	0	0
07007N	January – June 2008	0	0	10-15	0	0	0
	July – December 2008	0	0	10-15	0	0	0
08001V	July – December 2008	4	2	12	2	0	3
08003V	July – December 2008	270	270	5760	270	0	0
08007N	January – June 2008	10	3	6-10	3	0	0
	July – December 2008	12	9	6	9	0	0
08012N	July – December 2008	0	0	50-70	0	0	0
08013N	July – December 2008	7	7	200	7	0	0

## Monitoring of TCP applications submitted to TCPC during 2001 – 2007

The TCPC undertook a review of all applications approved prior to 2008 and requested information from previous applicants regarding the current status of the TCP. The results are as follows:

**Table 7: Results of review of 2001 – 2007 TCP applications**

	VPACT	Internal funding	Total
Applications received	2	22	24
Applications approved	2	17	19
TCPs no longer in practice	0	4	4/19 (21%)
TCPs now considered to be routine practice	2	8	10/19 (53%)
TCPs still requiring monitoring and reporting	0	5	5/19 (26%)

### Satisfaction with the reporting process

The survey feedback forms were also included with all Progress Report templates. Feedback about the reporting process was requested for 'content and wording', 'format of the progress report' and 'format of the outcome spreadsheet' (Figure 2). Three responses were received and all highlighted the need for revision of the forms which were seen as repetitive and difficult to use.

**Figure 2: Reporting feedback received in 2008**

<p><b>'Content and wording'</b></p> <p>What worked well? Why?</p> <ul style="list-style-type: none"> <li>▪ Minimal experience in using thus far as no cases used the new procedure</li> <li>▪ Reasonably brief</li> </ul> <p>What didn't work well? Why?</p> <ul style="list-style-type: none"> <li>▪ The reporting of patients not treated was unexpected and therefore data had not been collected</li> <li>▪ Questions repetitive particularly when considering the outcome spreadsheet as well. The same thing is asked three times</li> </ul> <p>Should anything else be included?</p> <ul style="list-style-type: none"> <li>▪ I do not see why we have to report on patients that do not undergo the procedure</li> <li>▪ Additional measures specific to the TCP</li> </ul> <p>Should anything be excluded?</p> <ul style="list-style-type: none"> <li>▪ The repeated questions on infections and adverse outcomes, just one would do</li> </ul> <p><b>'Format of the progress report'</b></p> <p>What worked well? Why?</p> <ul style="list-style-type: none"> <li>▪ Reasonably brief</li> </ul> <p>What didn't work well? Why?</p> <ul style="list-style-type: none"> <li>▪ Fields to fill in are not very easy to use. Would suggest using radio buttons for Yes/No responses</li> <li>▪ Repeated questions</li> </ul> <p><b>'Format of the outcome spreadsheet'</b></p> <p>What worked well? Why?</p> <ul style="list-style-type: none"> <li>▪ Reasonably brief</li> </ul> <p>What didn't work well? Why?</p> <ul style="list-style-type: none"> <li>▪ There is no need to summarise the data on this form, when we have to do a separate report on this form</li> <li>▪ Some columns not relevant and were deleted, Formula didn't work on my computer so I re-did it</li> </ul> <p>How could we improve the format?</p> <ul style="list-style-type: none"> <li>▪ I have added some relevant outcome measures</li> </ul>
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### Summary

Overall, compliance with the proposed reporting schedule was satisfactory. Applicants correctly completed progress reports and all utilised the templates developed by the Secretariat. Some adverse events were identified in the routine data collection cycle but were not reported to the committee at the time of the incident.

### Action

In 2009 the TCPC will action suggestions made by applicants regarding progress reporting. The TCPC will continue to collect progress reports and outcome data on a six monthly basis in accordance with DHS requirements. The administrator will report on adverse events collected from the six monthly patient outcomes reporting, however the committee must address lack of reporting of adverse events as they arise.

## RESOURCES

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*Are resource documents and support systems being utilised?*

Southern Health staff from various disciplines are available to assist in the completion of applications. Resources are available from Health Information Services, Clinical Information Management, the Centre for Clinical Effectiveness, Medical Support Unit and Finance. These resources are advertised on the TCPC webpage and contact details are included in the application form.

### **Patient Information**

It is a requirement of the TCPC that all newly introduced TCPs have an evidence-based patient information sheet. To assist applicants, the TCPC initially developed a patient information template which was based on the Southern Health Human Research and Ethics Committee template. In consultation with the TCPC Consumer Representative, all research aspects of the template were removed and an amended version was made available on the TCPC webpage.

In September 2008 a decision was made to reformat the template to match a suite of patient information brochures purchased by Southern Health from the Royal Australasian College of Surgeons for surgical procedures. The previously approved patient information was reformatted and submitted to the Patient Information Committee for approval and uploading onto the Southern Health intranet.

It is planned that TCPC approved patient information will be available on the intranet in early 2009.

### **Applicant satisfaction with quality of resources**

Feedback provided by two applicants stated that staff from the Centre for Clinical Effectiveness were helpful in supporting the evidence component of their applications.

### **Applicant feedback regarding accessibility of resources**

No feedback was provided regarding the accessibility of the resources and support offered in 2008.

### **External requests for Southern Health TCP Program resources and expertise**

TCPC have been sought by the Peter McCallum Cancer Centre in Victoria and, on the recommendation of DHS, by Queensland Health and the South Eastern Sydney and Illawarra Area Health Service.

Queensland Health has also asked that the TCPC Executive Officer conduct a workshop on establishing a TCP Program in 2009.

### **Summary**

Due to the lack of feedback data, it is unclear whether or not the users of the Southern Health TCP Program found the resources and support useful. The Southern Health documents, processes and expertise are being sought by other health services and state health departments.

### **Action**

In 2009 the TCPC plan to continue to request and collect feedback from applicants regarding the usefulness of the TCPC resources.

The TCPC will also liaise with the Quality Unit to ensure that the TCPC approved patient information is uploaded onto the Southern Health intranet.

## REFERENCES

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1. VICTORIAN DEPARTMENT OF HUMAN SERVICES (2006) Guidance for Victorian Health Services to Establish Technology/Clinical Practice Committees. Melbourne, Victoria, Victorian Department of Human Services.
2. AUSTRALIAN SAFETY AND EFFICACY REGISTER OF NEW INTERVENTIONAL PROCEDURES General Guidelines for Assessing, Approving and Introducing New Procedures into a Hospital or Health Service. Royal Australian College of Surgeons.
3. NEW SOUTH WALES HEALTH (2005) Clinical Practice - Model Policy for Safe Introduction of New Interventional Procedures. North Sydney, NSW, NSW Health.
4. AUSTRALIAN CAPITAL TERRITORY HEALTH (2007) Policy: Introduction of new health technologies. Canberra, ACT, ACT Health.
5. NATIONAL HEALTH COMMITTEE (2005) Decision-Making about New Health Interventions: A Report to the New Zealand Minister of Health. New Zealand, National Health Committee New Zealand.

**Appendix 1: Evaluation Plan**

Components	Key evaluation questions	Success measures/indicators (What to measure)	Method of data collection and source (Where & how to find it)	When to be.....	
				Collected	Reported
Establishment of best practice	Does the SH TCP Program match current best practice?	Current best practice – Evidence Mapping	Revise mapping exercise of State/National/International Sources	End of establishment phase – 3 to 5 year intervals	
Governance	Is the process transparent and accountable?	Publication of TOR, procedure protocols, application deadlines, meeting dates	Review of TCPC website, Southern Health intranet	Annually	Annually
		Attendance at meetings	Attendance list	Monthly	Annually
		Feedback from TCPC re processes	TCPC meetings – review minutes	Annually	Annually
		Achieving reporting requirements (EMT/ DHS)	Reports sent	Biannually	Biannually
		Appropriateness of reporting to EMT & DHS	Feedback from EMT & DHS	Biannually	Biannually
Applications New TCPs	Has an application process and documentation in accordance with DHS requirements been established and is it being utilised?  Are applicants happy with the process?	Number of applications received	Audit of TCP register	Monthly	Annually
		Number of applications completed correctly at first submission	Audit of TCP register	Monthly	Annually
		Applicant satisfaction with application process	Audit application feedback forms	Monthly	Annually
		Number of VPACT applications approved by DHS	DHS feedback	Monthly	Annually
		Compliance with the Southern Health VPACT schedule	Audit VPACT timetable	Annually	Annually
		Comparison with other health services <ul style="list-style-type: none"> <li>▪ number of applications received</li> <li>▪ comparison of applications (same/different)</li> <li>▪ were the same decisions made</li> </ul>	Collect this information from the group that Paul Fennessey sets up	Annually	Annually
	Did we capture all TCPs introduced at Southern Health	Number of TCPs introduced at Southern Health that did not go through the TCPC process	Query unit managers and theatre Query enquiries received by Steven Anderson/Kevin Ericson Query high cost drug list produced by Pharmacy Query presentations made at the Southern Health State of Art Lectures and grand rounds Query Capital Expenditure “Unfunded Capital Expenditure budget process of prioritisation”	Quarterly	Annually
Applications	Has a change of use application	Number of applications received	Audit of TCP register	Monthly	Annually

Components	Key evaluation questions	Success measures/indicators (What to measure)	Method of data collection and source (Where & how to find it)	When to be.....	
				Collected	Reported
COU of existing TCPs	process and documentation been established and is it being utilised? Are applicants happy with the process?	Number of applications completed correctly at first submission	Audit of TCP register	Monthly	Annually
		Applicant satisfaction with COU application process	Audit application feedback forms	Monthly	Annually
Decision-making New TCPs	Have processes and documentation for decision-making been established and are they being utilised?	Appropriate representation at TCPC meetings to discuss applications	Audit of minutes for attendance by applicant/HOD/Program Director	Monthly	Annually
		Number of applications that the TCPC utilised the decision summary for	Audit of application folders	Monthly	Annually
		Number of decision summaries published on the website	Cross check applications with webpage	Monthly	Annually
		Number of applicants that complied with the conditions of approval and were received by the due date	Audit of TCP register	Monthly	Annually
		Number of outcome letters for approval for provisional use sent	Audit of TCP register	Monthly	Annually
		Number of applicants that appealed to the Chief Executive re the TCPC decision	Audit of TCP register	Monthly	Annually
Decision-making Review of approved TCPs	Have processes and documentation for decision-making for reviewed TCPs been established and are they being utilised?	Number of reviews that the TCPC utilised the decision summary for	Audit of application folders	Monthly	Annually
		Number of decision summaries published on the website	Cross check applications with webpage	Monthly	Annually
		Number of TCPs withdrawn after review	Audit of TCP register	Monthly	Annually
		Number of decisions made that were consistent with the evidence	Review of the evidence	Monthly	Annually
Monitoring and reporting for newly introduced TCPs	Have monitoring and reporting processes been established and are they being utilised?	Number of reports <ul style="list-style-type: none"> <li>▪ received</li> <li>▪ received by due date</li> <li>▪ received late</li> </ul>	Audit of TCP register	Biannually	Annually
		Number of applicants who used TCPC outcome spreadsheet	Audit of TCP register	Biannually	Annually
		Number of applicants who used their own outcome data collection tool	Audit of TCP register	Biannually	Annually
		Number of reporting templates completed correctly	Audit of TCP register	Biannually	Annually
	Are applicants happy with the process? Were patient outcomes as expected?	Applicant satisfaction with reporting processes	Audit application feedback forms	Biannually	Annually
		Number of procedures performed	Comparison between original	Biannually	Biannually

Components	Key evaluation questions	Success measures/indicators (What to measure)	Method of data collection and source ( <i>Where &amp; how to find it</i> )	When to be.....	
				Collected	Reported
		Referred versus treated Expected versus actual Deaths Other adverse events	applications and progress report data		
Resources	Has a support system and resource documents been developed and are these being utilised?	Number of applicants that utilised patient information template	Audit of application documents	Biannually	Annually
		Applicant satisfaction with quality and accessibility of resources	Audit application feedback forms	Monthly	Annually
		Feedback from resource providers	Via formal meeting or request feedback via email	Biannually	Annually
		Number of requests for use of resources/expertise externally	Audit of requests	Annually	Annually

## Appendix 2: Mapping Exercise

Best Practice Criteria Mapping for Southern Health Technology and Clinical Practice Program	Victorian DHS <sup>1</sup>	ASERNIP-S <sup>2</sup>	NSW Health <sup>3</sup>	ACT Health <sup>4</sup>	New Zealand <sup>5</sup>	Southern Health	
						Before	After
Principles underpinning the safe introduction of a TCP							
A TCP committee is established	✓	✓	✓	✓	✓	✓	✓
Any conflicts of interests are disclosed	✓	✓	✓				✓
Safety of new TCP is established							✓*
Evidence concerning a new TCP is robust and reliable	✓	✓	✓	✓	✓		✓
Resources required and future/recurring costs of the TCP are estimated as accurately as possible	✓	✓	✓	✓	✓		✓
Ethics procedures are in place to protect patients, clinicians and the community	✓	✓	✓		✓	✓	✓
Issues of access and equity are considered							✓*
Legislative requirements are met							✓*
Risk management procedures are in place	✓		✓	✓			✓
Patient information and informed consent procedures are established	✓	✓	✓			✓	✓
Evidence-based practice informs conditions and logistics for introduction	✓		✓	✓	✓		✓
Appropriate, credentialed and trained staff are in place for the introduction of the new TCP	✓	✓	✓	✓	✓	✓	✓
Appropriate clinical and physical infrastructure/facilities exist to support the introduction of new TCP	✓	✓	✓	✓	✓		✓
Recommendations for introduction have clearly noted conditions eg audit, clinical trial, operational restrictions							✓*
TCP committee responsibilities							
TCP committee meetings are held at regular intervals	✓						✓
There is a range of clinical disciplines represented on the TCP committee	✓	✓		✓	✓	✓	✓
There is a consumer representative on the TCP committee	✓					✓	✓
There are established criteria for assessment of applications to introduce a new TCP	✓					✓	✓
Clinical and financial effects of each TCP are considered at all levels and in all departments	✓						✓
Decisions of the committee are published to ensure transparency and accountability							✓*
A register of applications and approved procedures is maintained	✓		✓			✓	✓
Information about the TCP is disseminated and advice provided	✓	✓	✓		✓	✓	✓
Appropriate training is provided to all staff so that each TCP is performed (and all equipment is handled) safely	✓		✓			✓	✓
Determine processes for monitoring and reviewing existing TCP	✓		✓				✓
Monitor requirements for each approved TCP	✓	✓	✓	✓	✓		✓
Any adverse event occurring with an approved TCP is notified to the TCP committee	✓	✓	✓			✓	✓
The TCP committee operates within a reporting structure to ensure corporate and clinical governance	✓	✓				✓	✓
Six monthly reports are submitted to the state health department detailing applications, approved procedures, reviews of existing TCP and monitoring of introduced/referred TCP	✓		✓				✓
Six monthly reports are submitted to the health service executive	✓		✓				✓
TCP Application							
Clinician and/or unit making the application will receive endorsement from their departmental head	✓		✓			✓	✓
Completed application will be forwarded to the chair of the TCP committee or other nominated delegate	✓		✓			✓	✓
Reassessment of newly introduced TCPs at the end of the two year monitoring period							✓*
Local consumer health councils and networks will be informed of applications and of their outcomes			✓				✓
Resources							
Expertise in coding, data analysis, evidence review, finance and credentialing provided							✓*
Guide to finding the evidence of effectiveness of TCP to support the application							✓*
Template for Patient information brochure							✓*
Templates for data collection tools and reporting proformas							✓*

\* Additional items introduced by Southern Health