Review of new technologies or clinical practices (TCPs) for reclassification as standard practice

This process is to determine whether a recently introduced TCP can now be classified as standard practice at Monash Health or if it requires further monitoring and reporting. The review will take place two years after introduction of the TCP or earlier by request from the relevant Department Head.

**Background** *(to be completed by TCPC)*

<table>
<thead>
<tr>
<th>Title of Technology/Clinical Practice</th>
<th>Laparoscopic Sleeve Gastrectomy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Program</td>
<td>Surgery</td>
</tr>
<tr>
<td>Department/Unit</td>
<td>UGI/HPB</td>
</tr>
</tbody>
</table>

**Brief summary of TCP**

Laparoscopic gastric sleeving is a new, alternative surgical intervention for obesity. Surgery has been shown to be more effective than diet and exercise. The main surgical treatment for obesity at Monash Health is gastric banding; however this has limitations including wear and tear on the prosthesis and lack of an exit strategy for the patient. Sleeve gastrectomy is a bariatric procedure that involves a subtotal resection of the gastric fundus and body to create a tubular gastric conduit. Weight loss occurs due to a mechanical (gastric volume restriction) and hormonal (neurohormonal manipulation) mechanism. The technique involves:

- Mobilising the greater curve of stomach
- Dividing the stomach using stapling devices over a calibration tube
- Optional oversewing of the staple line with reattachment of omentum.

**Reason for original application**

- Safety
- Effectiveness
- Cost Effectiveness

**Brief summary of supporting evidence**

A systematic review performed on 26 studies (23 RCTs) led the author to conclude that surgery is more effective than conventional management. Certain procedures produce greater weight loss, but data are limited. The evidence on safety is even less clear. Due to limited evidence and poor quality of the trials, caution is required when interpreting comparative safety and effectiveness. (1)

LSG has morbidity and effectiveness positioned between the LAGB and the LRYGB/ORYGB for data up to 1 year. As obesity is a lifelong disease, longer term comparative effectiveness data are most critical, and are yet to be determined. (2)

Weight loss and loss of feeling of hunger after 1 year and 3 years are better after SG than GB. GERD is more frequent at 1 year after SG and at 3 years after GB. The number of re-operations is important in both groups, but the severity of complications appears higher in SG. (3)

References:


**Results of Monitoring and Reporting** *(to be completed by Department Head)*

<table>
<thead>
<tr>
<th>Reporting period</th>
<th>Patients</th>
<th>Procedures Performed</th>
<th>Successful outcomes</th>
<th>Deaths</th>
<th>Adverse Events</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Referred</td>
<td>Expected</td>
<td>Actual</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Year 1</td>
<td>14</td>
<td>14</td>
<td>14</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Year 2</td>
<td>20</td>
<td>20</td>
<td>20</td>
<td>0</td>
<td>1</td>
</tr>
</tbody>
</table>

**Summary of Results**

The key features that make sleeve stand out, when compared to lap band is:

- Reduced number of post op visits thereby reducing outpatient load
- Higher patient satisfaction
- Better weight loss in the short term (needs on going follow up to validate for long term)
- Low re intervention rate

Only one patient had developed wound dehiscence and gastric fistulation following open sleeve gastrectomy. This patient had had extensive previous failed bariatric procedures and was a revisional operation. He was managed conservatively.

**Name of clinician who undertook the procedures?**

**Number of procedures undertaken?**

*Note: More than one clinician involved in each procedure*
Review Form (to be completed by Department Head)

Sites TCP is in current use
- [ ] Clayton
- [ ] Moorabbin
- [ ] Dandenong
- [ ] Casey
- [ ] Kingston
- [x] Other

If the TCP does not apply to all sites please explain why
Specialists/Services related to TCP only available at Clayton.

What is the volume (per annum) required for maintaining skills in this TCP? 7-11 cases

1. Are there any conflicts of interest to declare regarding the ongoing use of this TCP at Monash Health? 
   (This includes any financial or other benefits received from groups that have a vested interest eg manufacturers, distributors, etc.) Please see the Monash Health Conflict of Interest Protocol.
   If Yes, please provide details.

2. Has the TCP been used in any way other than that described in the original application? (eg different patient group, clinical indications, sites, practitioners credentialed, etc)
   If Yes, please outline the differences and list reasons for the variance from the application.

3. Has any new data been published in the research literature since the introduction of this TCP?
   If Yes, please provide references and a brief description of outcomes

4. Are the rates of successful outcomes and adverse events published in the literature different to data collected for Monash Health patients?
   If Yes, please explain differences and provide a possible reason for this?

5. Has the TCP performed differently to the expectation outlined in the original application in relation to operational outcomes? (eg different length of stay, use of associated services, cost of staff or consumables, unforseen outcomes, etc)
   If Yes, please outline the differences and list reasons for the variance from the application.

6. Will there be an increase in resource use and/or ongoing costs if the TCP is introduced as standard practice? (Consider staffing and salaries, administration, specialist medical practitioners, nursing, allied health, pharmacy, theatre, intensive care, imaging, pathology, special consumables, dietary supplements, outpatient services, organisational overheads.)
   If Yes, please compare current and future costs with details of the relevant items listed above and how the costs will be met. If there is an increase in resource use and/or ongoing costs approval is required by the relevant Executive Director.

7. Will any change to the current department/unit procedures list be required to incorporate the TCP if it is introduced as standard practice? (ie for credentialing and scope of practice)
   If Yes, has the appropriate Program Director been notified? [ ] Yes [ ] No

8. Do any additional staff require training and credentialing if the TCP is introduced as standard practice? (Consider if credentialing and competency assurance is required by staff to ensure safe implementation)
   If Yes, please list those persons who will be credentialed and how/where they will be trained.

9. Will the TCP go through any internal reviews such as Clinical Review Panel
   If Yes, please note the outcome/s of the review/s.

10. The current patient information materials will require amendment if the TCP is introduced as standard practice. Please attach the amended patient information brochure.

11. Has the TCP gone through any internal reviews such as Clinical Review Panel
    If Yes, please note the outcome/s of the review/s.

Additional Comments
nil

Name of appropriate Program Director
Paul Cashin

Name of appropriate Executive Director (Acute, Continuing Care, Mental Health, Medical Services and Quality)
Alan Saunder

Name of appropriate Business Manager
Peter Choma
I declare that the Program Director has received and approved a copy of this completed review  
Date  25.11.2015

I declare that the Executive Director has received and approved a copy of this completed review  
Date  30.11.2015

I declare that the appropriate Business Manager has received and approved a copy of this completed review and is satisfied that the ongoing expenses related to use of this TCP can be met within current budgets  
Date  30.11.2015

Name  
Department  UGI/HPB
Phone  Email  

For any questions please contact:
Ms Gillian Yap at gillian.yap@monashhealth.org

Decision

☑ Approved as standard practice at Monash Health
☐ Approved with conditions for continued monitoring (see below)
☐ Not Approved for continued use at Monash Health

There are no conditions to this approval.
**Review of new technologies or clinical practices (TCPs) for reclassification as standard practice**

This process is to determine whether a recently introduced TCP can now be classified as standard practice at Monash Health or if it requires further monitoring and reporting. The review will take place two years after introduction of the TCP or earlier by request from the relevant Department Head.

For submission deadlines and meeting dates please see [Meeting Dates](#).

If you need assistance to complete any of the review questions please contact:

**Evidence of Effectiveness**
Angela Melder (Centre for Clinical Effectiveness)
Phone: 9594 7575 Email: angela.melder@monashhealth.org

**Coding**
Ross Major (Health Information Services)
Phone: 9594 1382 Email: ross.major@monashhealth.org

**Current Bed Utilisation and Financial Impact**
Ben Kuppe (Clinical Information Management)
Phone: 9594 3782 Email: ben.kuppe@monashhealth.org

**Credentialing and Scope of Practice**
Richard Nasra (Medical Workforce Unit)
Phone: 9594 2750 Email: richard.nasra@monashhealth.org

### Background (to be completed by TCPC)

<table>
<thead>
<tr>
<th>Title of Technology/Clinical Practice</th>
<th>Lucas 2 external chest compression system</th>
</tr>
</thead>
<tbody>
<tr>
<td>Program</td>
<td>Specialty Medicine</td>
</tr>
<tr>
<td>Department/Unit</td>
<td>Monash Heart</td>
</tr>
</tbody>
</table>

**Brief summary of TCP**
The Lucas chest compression system performs automated, external cardiac compressions on adult patients who have suffered acute circulatory arrest, and who require prolonged cardiac compressions to maintain circulation during resuscitation attempts including advanced cardiac life support, cardiac catheterisation laboratory procedures and commencement of extracorporeal membrane oxygenation (ECMO).

Reason for original application

- [x] Safety  [x] Effectiveness  [ ] Cost Effectiveness

**Brief summary of supporting evidence**
The evidence included retrospective case studies and hospital reports on the safety and effectiveness of the device. It was concluded that the LUCAS device was suitable during cardiac catheterisation and intervention, and ensures systemic blood pressure in most patients without life-threatening injuries.

### Results of Monitoring and Reporting (to be completed by Department Head)

<table>
<thead>
<tr>
<th>Reporting period</th>
<th>Patients</th>
<th>Procedures Performed</th>
<th>Successful outcomes</th>
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<tr>
<td></td>
<td>Referred</td>
<td>Treated</td>
<td>Expected</td>
<td>Actual</td>
<td></td>
</tr>
<tr>
<td>Year 1</td>
<td>2</td>
<td>5</td>
<td>2</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Year 2</td>
<td>4</td>
<td>5</td>
<td>4</td>
<td>1</td>
<td>3</td>
</tr>
</tbody>
</table>

**Summary of Results**
Out of the 6 patients on whom this device was used, 5 died eventually. All of the 6 patients presented with ST elevation MI with cardiogenic shock. No adverse events were encountered in all the patients (eg details of successful outcomes, other outcomes, adverse events, etc)

**Name of clinician who undertook the procedures?**

<table>
<thead>
<tr>
<th>XX</th>
<th>XX</th>
<th>XX</th>
<th>XX</th>
</tr>
</thead>
</table>

**Number of procedures undertaken?**

<table>
<thead>
<tr>
<th>XX</th>
<th>XX</th>
<th>XX</th>
<th>XX</th>
</tr>
</thead>
</table>

**Review Form (to be completed by Department Head)**

**Sites TCP is in current use**

- [ ] Clayton
- [ ] Moorabbin
- [ ] Dandenong
- [ ] Casey
- [ ] Kingston
- [ ] Other

If the TCP does not apply to all sites please explain why

Only Monash Medical Centre Clayton site has a cardiac catheterisation laboratories where emergency cardiac catheterisation procedures are undertaken.

**What is the volume (per annum) required for maintaining skills in this TCP?**

1

**1. Are there any conflicts of interest to declare regarding the ongoing use of this TCP at Monash Health?** *(This includes any financial or other benefits received from groups that have a vested interest eg manufacturers, distributors, etc.) Please see the Monash Health Conflict of Interest Protocol.*

If Yes, please provide details.
2. Has the TCP been used in any way other than that described in the original application? (eg different patient group, clinical indications, sites, practitioners credentialed, etc)
   If Yes, please outline the differences and list reasons for the variance from the application.

3. Has any new data been published in the research literature since the introduction of this TCP?
   If Yes, please provide references and a brief description of outcomes

4. Are the rates of successful outcomes and adverse events published in the literature different to data collected for Monash Health patients?
   If Yes, please explain differences and provide a possible reason for this

5. Has the TCP performed differently to the expectation outlined in the original application in relation to operational outcomes? (eg different length of stay, use of associated services, cost of staff or consumables, unforseen outcomes, etc)
   If Yes, please outline the differences and list reasons for the variance from the application.

6. Will there be an increase in resource use and/or ongoing costs if the TCP is introduced as standard practice? (Consider staffing and salaries, administration, specialist medical practitioners, nursing, allied health, pharmacy, theatre, intensive care, imaging, pathology, special consumables, dietary supplements, outpatient services, organisational overheads.)
   If Yes, please compare current and future costs with details of the relevant items listed above and how the costs will be met. If there is an increase in resource use and/or ongoing costs approval is required by the relevant Executive Director.

7. Will any change to the current department/unit procedures list be required to incorporate the TCP if it is introduced as standard practice? (ie for credentialing and scope of practice)
   If Yes, has the appropriate Program Director been notified? Yes No

8. Do any additional staff require training and credentialing if the TCP is introduced as standard practice? (Consider if credentialing and competency assurance is required by staff to ensure safe implementation)
   If Yes, please list those persons who will be credentialed and how/where they will be trained.

9. The current patient information materials will require amendment if the TCP is introduced as standard practice. Please attach the amended patient information brochure.

10. Has the TCP gone through any internal reviews such as Clinical Review Panel
    If Yes, please note the outcome/s of the review/s.

### Additional Comments

<table>
<thead>
<tr>
<th>Name of appropriate Program Director</th>
<th>Prof Julian Smith</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of appropriate Executive Director</td>
<td></td>
</tr>
<tr>
<td>Name of appropriate Business Manager</td>
<td>Mr Ying Chan</td>
</tr>
</tbody>
</table>

☐ I declare that the Program Director has received and approved a copy of this completed review Date 26.04.2016
☐ I declare that the Executive Director has received and approved a copy of this completed review Date
☐ I declare that the appropriate Business Manager has received and approved a copy of this completed review and is satisfied that the ongoing expenses related to use of this TCP can be met within current budgets Date 26.04.2016

<table>
<thead>
<tr>
<th>Name</th>
<th>Monash Heart</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phone</td>
<td></td>
</tr>
<tr>
<td>Fax</td>
<td></td>
</tr>
<tr>
<td>Email</td>
<td></td>
</tr>
</tbody>
</table>

### Decision

☐ Approved as standard practice at Monash Health
☐ Approved with conditions for continued monitoring (see below)
☐ Not Approved for continued use at Monash Health

### Criteria of Approval

This procedure is approved for use in the catheterisation laboratory to avoid radiation exposure and in the emergency department for prolonged resuscitation.

### FEEDBACK

We would appreciate any comments regarding this form and how we can improve this reporting process.
Review of new technologies or clinical practices (TCPs) for reclassification as standard practice

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**Background**

*To be completed by TCPC*

<table>
<thead>
<tr>
<th>Title of Technology/Clinical Practice</th>
<th>Extracorporeal shockwave lithotripsy for renal tract stones</th>
</tr>
</thead>
<tbody>
<tr>
<td>Program</td>
<td>Surgery</td>
</tr>
<tr>
<td>Department/Unit</td>
<td>Urology</td>
</tr>
<tr>
<td>Brief summary of TCP</td>
<td>Establishment of new out patient service at Monash Health</td>
</tr>
<tr>
<td>Reason for original application</td>
<td>☑ Safety, ☑ Effectiveness</td>
</tr>
<tr>
<td>Brief summary of supporting evidence</td>
<td>Lithotripsy has been used in millions of patients over the last 36 years. The centralised service at St Vincents Hospital has not served the Monash population well and the latest machines allow cost effective treatment for both ureteric and renal stones without the need for anaesthesia.</td>
</tr>
</tbody>
</table>

**Results of Monitoring and Reporting**

*To be completed by Department Head*

<table>
<thead>
<tr>
<th>Reporting period</th>
<th>Patients</th>
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<tbody>
<tr>
<td></td>
<td>Referred</td>
<td>Treated</td>
<td>Expected</td>
<td>Actual</td>
<td></td>
</tr>
<tr>
<td>Year 1</td>
<td>222</td>
<td>197</td>
<td>200</td>
<td>227</td>
<td>70%</td>
</tr>
<tr>
<td>Year 2</td>
<td>250</td>
<td>215</td>
<td>240</td>
<td>255</td>
<td>70%</td>
</tr>
</tbody>
</table>

**Summary of Results**

Overall success rate of treatments is 70% (may take multiple treatments). This is comparable with world literature. There have been minimal adverse results - 3 haematomas. There have been a number of patients requiring ureteric stents, but literature suggests 10-20% may develop steinstrasse. Our results are comparable. (eg details of successful outcomes, other outcomes, adverse events, etc)

Name of clinician who undertook the procedures? Philip McCahy 200

Name of clinician who undertook the procedures? Shekib Shahbaz 150

**Review Form**

*To be completed by Department Head*

Sites TCP is in current use

- Clayton
- Moorabbin
- Dandenong
- Casey
- Kingston
- Other

If the TCP does not apply to all sites please explain why

What is the volume (per annum) required for maintaining skills in this TCP? 50

NO YES

1. Are there any conflicts of interest to declare regarding the ongoing use of this TCP at Monash Health? *(This includes any financial or other benefits received from groups that have a vested interest eg manufacturers, distributors, etc.) Please see the Monash Health Conflict of Interest Protocol.*

   If Yes, please provide details.

2. Has the TCP been used in any way other than that described in the original application? *(eg different patient group, clinical indications, sites, practitioners credentialed, etc)*

   If Yes, please outline the differences and list reasons for the variance from the application.

3. Has any new data been published in the research literature since the introduction of this TCP?

   If Yes, please provide references and a brief description of outcomes

4. Are the rates of successful outcomes and adverse events published in the literature different to data collected for Monash Health patients?

   If Yes, please explain differences and provide a possible reason for this?

5. Has the TCP performed differently to the expectation outlined in the original application in relation to operational outcomes? *(eg different length of stay, use of associated services, cost of staff or consumables, unforeseen outcomes, etc)*
6. Will there be an increase in resource use and/or ongoing costs if the TCP is introduced as standard practice? (Consider staffing and salaries, administration, specialist medical practitioners, nursing, allied health, pharmacy, theatre, intensive care, imaging, pathology, special consumables, dietary supplements, outpatient services, organisational overheads.)

If Yes, please compare current and future costs with details of the relevant items listed above and how the costs will be met. If there is an increase in resource use and/or ongoing costs approval is required by the relevant Executive Director.

7. Will any change to the current department/unit procedures list be required to incorporate the TCP if it is introduced as standard practice? (ie for credentialing and scope of practice)

If Yes, has the appropriate Program Director been notified?  □ Yes □ No

8. Do any additional staff require training and credentialing if the TCP is introduced as standard practice? (Consider if credentialing and competency assurance is required by staff to ensure safe implementation)

If Yes, please list those persons who will be credentialed and how/where they will be trained.

9. Will any change to the current department/unit procedures list be required to incorporate the TCP if it is introduced as standard practice? (for credentialing and scope of practice)

If Yes, has the appropriate Program Director been notified?

Yes  □ No

10. The current patient information materials will require amendment if the TCP is introduced as standard practice. Please attach the amended patient information brochure.

11. Has the TCP gone through any internal reviews such as Clinical Review Panel

If Yes, please note the outcome/s of the review/s.

Additional Comments

Name of appropriate Program Director: Alan Sauder
Name of appropriate Executive Director: Bernadette Comitti
Name of appropriate Business Manager: Peter Choma

☑ I declare that the Program Director has received and approved a copy of this completed review

Date: 30/11/2016

☑ I declare that the Executive Director has received and approved a copy of this completed review

Date: 30/11/2016

☑ I declare that the appropriate Business Manager has received and approved a copy of this completed review and is satisfied that the ongoing expenses related to use of this TCP can be met within current budgets

Date: 30/11/2016

For any questions please contact:
TCPC Executive Officer on TCPC@monashhealth.org

Decision

☑ Approved as standard practice at Monash Health

☑ Approved with conditions for continued monitoring (see below)

☐ Not Approved for continued use at Monash Health

Conditions of Approval

• There are no conditions to this approval. No further reporting to the Technology/Clinical Practice Committee is required.

This hard copy may not be the latest version of this document. Please see the Monash Health Policy and Protocol intranet site for current policies, protocols and guidelines.
Review of new technologies or clinical practices (TCPs) for reclassification as standard practice

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### Background (to be completed by TCPC)

**Title of Technology/Clinical Practice**

N14-0-3 Drug eluting Stents and balloons

**Program**

DI and vascular surgery

**Department/Unit**


di and vascular surgery

**Brief summary of TCP**

Drug eluting technology for peripheral and fistula percutaneous revascularisation

**Reason for original application**

- Safety
- Effectiveness
- Cost Effectiveness

**Brief summary of supporting evidence**

This TCPC application was intended as a method for safe introduction to Monash health of a well established TGA approved technology

### Results of Monitoring and Reporting (to be completed by Department Head)

**Reporting period**

<table>
<thead>
<tr>
<th>Reporting period</th>
<th>Patients</th>
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<td>Expected</td>
<td>Actual</td>
<td></td>
</tr>
<tr>
<td>Year 1</td>
<td>11</td>
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<td>11</td>
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</tr>
<tr>
<td>Year 2</td>
<td>36</td>
<td>36</td>
<td>36</td>
<td>36</td>
<td>0</td>
</tr>
</tbody>
</table>

**Summary of Results**

Nil adverse events (eg details of successful outcomes, other outcomes, adverse events, etc)

**Name of clinician who undertook the procedures?**

see above

**Number of procedures undertaken?**

see above

### Review Form (to be completed by Department Head)

**Sites TCP is in current use**

- Clayton
- Dandenong
- Other

If the TCP does not apply to all sites please explain why

No angi facilities at other sites procedure only performed at Dandenong and Clayton

**What is the volume (per annum) required for maintaining skills in this TCP?**

It is the same technique as in standard angioplasty so no additional volume required

### Conflicts of Interest

1. Are there any conflicts of interest to declare regarding the ongoing use of this TCP at Monash Health? (This includes any financial or other benefits received from groups that have a vested interest eg manufacturers, distributors, etc.) Please see the Monash Health Conflict of Interest Protocol.
   
   If Yes, please provide details.

2. Has the TCP been used in any way other than that described in the original application? (eg different patient group, clinical indications, sites, practitioners credentialed, etc)
   
   If Yes, please outline the differences and list reasons for the variance from the application.

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   If Yes, please provide references and a brief description of outcomes

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7. Will any change to the current department/unit procedures list be required to incorporate the TCP if it is introduced as standard practice? (ie for credentialing and scope of practice)
   If Yes, has the appropriate Program Director been notified?  
   Yes  No

8. Do any additional staff require training and credentialing if the TCP is introduced as standard practice? (Consider if credentialing and competency assurance is required by staff to ensure safe implementation)
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9. The current patient information materials will require amendment if the TCP is introduced as standard practice. Please attach the amended patient information brochure.

10. Has the TCP gone through any internal reviews such as Clinical Review Panel
    If Yes, please note the outcome/s of the review/s.

Additional Comments

Name of appropriate Program Director  Mr Al Saunder, Prof Richard King
Name of appropriate Executive Director  Martin Keogh
Name of appropriate Business Manager  Peter Choma

☐ I declare that the Program Director has received and approved a copy of this completed review  Date  24/11/16
☐ I declare that the Executive Director has received and approved a copy of this completed review  Date  24/11/16
☐ I declare that the appropriate Business Manager has received and approved a copy of this completed review and is satisfied that the ongoing expenses related to use of this TCP can be met within current budgets  Date  24/11/16

Name  
Department  DI
Phone  
Fax  
Email  

For any questions please contact:
TCPC Executive Officer on TCPC@monashhealth.org

Decision

☐ Approved as standard practice at Monash Health
☐ Approved with conditions for continued monitoring (see below)
☐ Not Approved for continued use at Monash Health

Conditions of Approval
- There are no conditions to this approval. No further reporting to the Technology/Clinical Practice Committee is required.

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Please see the Monash Health Policy and Protocol intranet site for current policies, protocols and guidelines