EXECUTIVE SUMMARY

A search for systematic reviews and randomised controlled trials published during February was conducted. A total of 21 publications including 15 systematic reviews and 6 randomised controlled trials on surgery and surgery-related issues were identified. Of particular interest in the search results this month were orthopaedic procedures (of the hip, knee, spine and extremities) and cardiovascular (in particular stenting) procedures.

There were no new surgery-related Australian or New Zealand clinical practice guidelines published in February 2018.

The Therapeutic Goods Administration (TGA) issued a safety alert for a photopheresis system among recent reports of venous thromboembolism, including pulmonary embolism, associated with its use in the US. Medsafe in New Zealand updated its advice and recommendations for a prior safety alert on heater-cooler units used during cardiac surgery with regard to their risk of infection with non-tuberculous mycobacterium species.

There were no device recalls reported in New Zealand.

There were no new items added to the Australian Medicare Benefits Schedule (MBS).

Two Australian clinical trials were identified; one large bariatric surgery register and another on the safety of autologous cord blood cells in hypoplastic left heart syndrome patients during surgery.
BACKGROUND

The purpose of this monthly publication is to provide a high-level summary of developments within surgical practice to inform the Australian and New Zealand surgical Fellowship. This includes peer reviewed publications, technological alerts, regulatory information and relevant reports published by the Australian and New Zealand governments.

On 6 March 2018 a search for peer reviewed literature published between 1 February and 28 February 2018 was conducted. The purpose of this search was to identify surgery, and surgery-related publications, with a focus on the highest levels of evidence available:

- Systematic Reviews
- Randomised Controlled Trials (RCT)

Quality appraisal of select publications has been conducted. The reviewed publications were chosen due to the potential interest across the field of surgery. Interpretation of the appraisal, study implementation, results and their implications to surgical practice is at the discretion of the reader.

Full listing of Systematic Review and RCT literature identified in February has been collated per surgical specialty.
A total of 15 systematic reviews were identified from February 2018, three have been chosen by clinicians to highlight developments of potential interest. The conclusions published in each respective abstract are quoted below (the full abstracts can be accessed by clicking the citation).

A quality appraisal was performed evaluating the conduct and content of each review. Overall confidence in the study outcomes resultant from this appraisal are indicated in the respective graphics below (details in Table 1).


**Conclusion:** Asymptomatic bacteriuria is not a contraindication for arthroplasty, and the practice of routine preoperative screening for and treatment of asymptomatic bacteriuria should not be continued.


**Conclusion:** Our review found that PMRT [postmastectomy radiation therapy] for patients who underwent immediate implant-based breast reconstruction led to higher risks of reconstruction failure, overall complications, and capsular contracture. However, it is still the standard adjuvant therapy for mastectomy patients who have opted for immediate implant-based breast reconstruction.

**Laparoscopic left lateral hepatic sectionectomy was expected to be the standard for the treatment of left hepatic lobe lesions: A meta-analysis. Z. Liu, et al. (2018) Medicine (Baltimore) 97 (7): e9835**

**Conclusion:** LLLHS [laparoscopic left lateral hepatic sectionectomy] has an advantage in the hospital stay, blood loss, and total morbidity. It is an ideal method for LLHS surgery.
Table 1: ‘A MeaSurement Tool to Assess systematic Reviews’ appraisal of highlighted systematic reviews

<table>
<thead>
<tr>
<th>AMSTAR 2 appraisal domains</th>
<th>ZHANG et al</th>
<th>PU et al</th>
<th>LIU et al</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Did the research questions and inclusion criteria for the review include the components of PICO?</td>
<td>Green</td>
<td>Green</td>
<td>Green</td>
</tr>
<tr>
<td>2. Did the report of the review contain an explicit statement that the review methods were established prior to conduct of the review and did the report justify any significant deviations from the protocol?</td>
<td>Red</td>
<td>Red</td>
<td>Green</td>
</tr>
<tr>
<td>3. Did the review authors explain their selection of the study designs for inclusion in the review?</td>
<td>Red</td>
<td>Red</td>
<td>Green</td>
</tr>
<tr>
<td>4. Did the review authors use a comprehensive literature search strategy?</td>
<td>Green</td>
<td>Green</td>
<td>Green</td>
</tr>
<tr>
<td>5. Did the review authors perform study selection in duplicate?</td>
<td>Red</td>
<td>Red</td>
<td>Green</td>
</tr>
<tr>
<td>6. Did the review authors perform data extraction in duplicate?</td>
<td>Red</td>
<td>Red</td>
<td>Green</td>
</tr>
<tr>
<td>7. Did the review authors provide a list of excluded studies and justify the exclusions?</td>
<td>Red</td>
<td>Red</td>
<td>Green</td>
</tr>
<tr>
<td>8. Did the review authors describe the included studies in adequate detail?</td>
<td>Yellow</td>
<td>Red</td>
<td>Red</td>
</tr>
<tr>
<td>9. Did the review authors use a satisfactory technique for assessing the risk of bias (RoB) in individual studies that were included in the review?</td>
<td>Green</td>
<td>Green</td>
<td>Green</td>
</tr>
<tr>
<td>10. Did the review authors report on the sources of funding for the studies included in the review?</td>
<td>Red</td>
<td>Red</td>
<td>Green</td>
</tr>
<tr>
<td>11. If meta-analysis was performed did the review authors use appropriate methods for statistical combination of results?</td>
<td>NA</td>
<td>NA</td>
<td>Red</td>
</tr>
<tr>
<td>12. If meta-analysis was performed did the review authors assess the potential impact of RoB in individual studies on the results of the meta-analysis or other evidence synthesis?</td>
<td>NA</td>
<td>NA</td>
<td>Red</td>
</tr>
<tr>
<td>13. Did the review authors account for RoB in individual studies when interpreting/ discussing the results of the review?</td>
<td>Green</td>
<td>Green</td>
<td>Green</td>
</tr>
<tr>
<td>14. Did the review authors provide a satisfactory explanation for, and discussion of, any heterogeneity observed in the results of the review?</td>
<td>NA</td>
<td>NA</td>
<td>Red</td>
</tr>
<tr>
<td>15. If they performed quantitative synthesis did the review authors carry out an adequate investigation of publication bias (small study bias) and discuss its likely impact on the results of the review?</td>
<td>NA</td>
<td>NA</td>
<td>Green</td>
</tr>
<tr>
<td>16. Did the review authors report any potential sources of conflict of interest, including any funding they received for conducting the review?</td>
<td>Green</td>
<td>Green</td>
<td>Green</td>
</tr>
</tbody>
</table>

Green cells correspond to a ‘yes’, red to a ‘no’, and, yellow to a ‘partial’.
NA: not applicable.
SYSTEMATIC REVIEWS

Cardiothoracic Surgery
No systematic reviews were identified during the February search period.

General Surgery
• Laparoscopic left lateral hepatic sectionectomy was expected to be the standard for the treatment of left hepatic lobe lesions: A meta-analysis. Z. Liu, et al. (2018) Medicine (Baltimore) 97 (7): e9835

Neurosurgery
No systematic reviews were identified during the February search period.

Orthopaedic Surgery

Otolaryngology Head & Neck Surgery
No systematic reviews were identified during the February search period.

Paediatric Surgery
No systematic reviews were identified during the February search period.

Plastic & Reconstructive Surgery

Urology
No systematic reviews were identified during the February search period.

Results continued over page
SYSTEMATIC REVIEWS (continued)

Vascular Surgery

RANDOMISED CONTROLLED TRIALS

A total of six randomised controlled trials (RCTs) were identified from February 2018. One RCT was chosen from these results to highlight a development of interest. The conclusion published by the study abstract is included below; the full abstract and clinical trial listing can be accessed by clicking the links below:


Conclusion: Among patients who received 5 days of rivaroxaban prophylaxis after total hip or total knee arthroplasty, extended prophylaxis with aspirin was not significantly different from rivaroxaban in the prevention of symptomatic venous thromboembolism. (Funded by the Canadian Institutes of Health Research; ClinicalTrials.gov number, NCT01720108).)

The RCT conducted by Anderson et al was assessed using the ‘Revised Cochrane risk of bias tool for randomised trials (RoB 2.0)’ appraisal tool.

Table 2: Quality appraisal of highlighted RCT

<table>
<thead>
<tr>
<th>Risk of bias arising from randomisation process</th>
<th>Risk of bias due to deviations from intended interventions</th>
<th>Risk of bias due to missing outcome data</th>
<th>Risk of bias in measurement of the outcome</th>
<th>Risk of bias in selection of the reported results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Some concerns</td>
<td>Low risk</td>
<td>Low risk</td>
<td>Low risk</td>
<td>Low risk</td>
</tr>
</tbody>
</table>

As a result of this appraisal it was determined that the review was at a low risk of bias for the majority of domains, see Table 2 above. An exception was the risk of bias arising from the randomisation process. Concerns were identified regarding the lack of transparency in the concealment of the allocation sequence. Additional, areas for note include the authors state that the recruitment of the patients frequently occurred post operatively, thus the trial population did not consist of an entire inception cohort treated in accordance with a standardised protocol. As such the absolute event rates of thromboembolic or bleeding complications associated with each of the two prophylaxis methods could not be calculated.

A free video summarising the outcomes of this study has been produced by the study publisher, the New England Journal of Medicine. Click the image below to access this summary.
RANDOMISED CONTROLLED TRIALS

Cardiothoracic Surgery
No RCTs were identified during the February search period.

General Surgery
No RCTs were identified during the February search period.

Neurosurgery
No RCTs were identified during the February search period.

Orthopaedic Surgery

Otolaryngology Head & Neck Surgery
No RCTs were identified during the February search period.

Paediatric Surgery
No RCTs were identified during the February search period.

Plastic & Reconstructive Surgery
No RCTs were identified during the February search period.

Urology

Vascular Surgery
DEVICES

New Zealand

No device recalls were reported during February on the NZ Medsafe Online Recall Database.

One alert was identified for February regarding heat-cooler units used during cardiac surgery. This alert titled 'Update - Heater-cooler units used during cardiac surgery: risk of infection with Nontuberculous Mycobacterium (NTM) species – advice and recommendations' is a follow up to the one issued on the 11th of July 2017. Two new key points have been added:

- NTM infection should be considered in patients who have undergone surgery where heater-cooler units have been used, who present with symptoms of an infection, but conventional cultures are negative and the patients do not respond to antibiotic treatment.

- Patients who have undergone certain types of cardiac surgery will be contacted, along with their medical practitioners, and informed of the need to be vigilant regarding possible NTM infection.

Australia

The TGA issued a safety alert in February for the CELLEX® Photopheresis System by Therakos, Inc. The device can be used to treat cutaneous T-cell lymphoma and patients with graft versus host disease. The alert notes that the FDA is evaluating recent reports of venous thromboembolism, including pulmonary embolism, in patients who received autologous immune cell therapy with the System. It also states that the TGA has received 13 reports about the device since 2009; mainly in relation to components breaking, leaking or being missing.

Four items were removed from the MBS, effective February 2018. The descriptor of one item (900 73341) was amended. All ceased items and the amended item were for pathology services. No new items were added to the MBS.
CLINICAL TRIALS

Two Australian clinical trials were identified as ‘recruiting’ for the search period. Information contained by the Clinicaltrials.gov website on the respective trials can be accessed by clicking their respective trial numbers. No trials were identified for New Zealand for the same time period.

<table>
<thead>
<tr>
<th>NCT #</th>
<th>Title</th>
<th>Sponsor</th>
<th>Study Type</th>
<th>Estimated enrolment</th>
<th>Estimated completion date</th>
</tr>
</thead>
<tbody>
<tr>
<td>NCT03441451</td>
<td>The Bariatric Surgery Registry</td>
<td>Monash University</td>
<td>Case series</td>
<td>250,000</td>
<td>December 2025</td>
</tr>
<tr>
<td>NCT03431480</td>
<td>Safety of autologous cord blood cells in hypoplastic left heart syndrome patients during Norwood Heart Surgery</td>
<td>Murdoch Children’s Research Institute</td>
<td>Case series</td>
<td>12</td>
<td>December 2020</td>
</tr>
</tbody>
</table>

CLINICAL PRACTICE GUIDELINES

No new Australian or New Zealand Clinical Practice Guidelines were published within the search period.

REGULATORY INFORMATION

No new Australian or New Zealand Government information was published within the search period.
INTERNATIONAL SURGICAL DEVICE REGULATION NEWS

The Americas

The US Food and Drug Administration (FDA) will implement updates to its Global Unique Device Identification Database (GUDID) in Spring and Summer 2018. The GUDID updates will include new file data elements, record accessibility and premarket submission and supplement number details.

The US FDA has updated its 510(k) Refuse to Accept and Premarket Approval acceptance policies for combination product submissions.

Brazilian medical device market regulator ANVISA has officially extended applicability of the Medical Device Single Audit Program (MDSAP) to domestic manufacturers as well as other companies based in South America.

Europe

Additional information on Eudamed (the European Database for Medical Devices) including; information on devices, manufacturers, importers, sponsors, authorised representatives, notified bodies, certificates and field safety notices, will now be publically available.

Uptake of a Unique Device Identification system in markets beyond the US is set to increase with European regulators currently undertaking a major project implementation. A guidance document is due for publication by the European Commission in March 2018.

Asia

The China Food and Drug Administration (CFDA) will develop medical device standards covering risk management, quality control and clinical trials. Devices covered included medical robots, active implantable products, medical software, positron emission tomography–magnetic resonance imaging (PET-MRI) devices as well as radiation therapy products.

The CFDA is also planning to launch a two-track in-country testing pathway for medical devices:
1. CFDA testing which is free, and,
2. Commission testing which is potentially faster but requires a fee.

Africa

No developments to report.

Oceania

No developments to report.
Method

This horizon scanning report was performed in accordance with a standardised methodology. Further information regarding this method, or the content reported herein can be obtained by emailing: research.evaluation@surgeons.org

Disclaimer

This report is a short, rapidly completed, ‘state of play’ document. It provides current information to alert surgeons of the advent and potential impact of recently published evidence (including interventions, procedures, programs, or systems), and issues relating to surgical practice. This report is not a comprehensive systematic review and is an overview of recently available information.

This report is based on information available at the time of writing and cannot be expected to cover all publications.

This report should not be considered a definitive statement on the safety, effectiveness or cost-effectiveness of the health technology covered.

This report is not intended to be used as medical advice or to diagnose, treat, cure, or prevent any disease, nor should it be used for therapeutic purposes or as a substitute for a health professional’s advice.

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