Sterilization in Australia

Volume 38 No. 1

Print Post Approved
PP255003/01725

Sterilization in Australia

Official Journal of Sterilizing Research & Advisory Council (NSW) Inc.

S.R.A.C.A. NSW Inc. Committee -

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Sterilization in Australia is published 3 times per year on behalf of the Sterilizing Research and Advisory Council of Australia NSW Incorporated.
The views expressed in any article are not necessarily those of the S.R.A.C.A. NSW Incorporated, nor are any products advertised given any official backing or endorsement by the Council.

Sterilization in Australia is Print Post Approved PP255003/01725

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PO Box M71 Missenden Road, Camperdown NSW 2050

Web Address: www.sracansw.org.au
ISSN number 0725.7066
Electronic on-line version ISSN1444-8476
ABN 85 914 815 703

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Contents -

President's Report

Welcome to the first edition of the Sterilization in Australia Journal for 2018
Volume 38 NO.1

Our committee met in January for our planning day and from that day our calendar of events for 2018 has been developed and is available on the website, in addition has been placed in this journal.

For our members to access the journal on line the password is sent to you when you renew your membership or join as a new member.

Click on Exclusive member's login at the top of the webpage.
Username: **member**
Password: **$rac@nsw16**

Our website is very user friendly and we have encouraged our members to access our website more frequently for information on up and coming events.

It is with great sadness that I announce our President George Papadopoulos has decided to resign from the SRACA NSW committee affective from June 2018. George has been an active member of the NSW SRACA for over 20 years George has held many executive roles over those years and is currently in the president's role. I would like to take the time to thank George for his service to our state SRACA. George has been a valued committee member and will be sadly missed by us all. We wish him all the very best for his future and we hope you enjoy the time with your young family.

At our planning day we decided to try Saturdays for our workshops as requested by our members as it is not always easy to be able to get away from our workplace during the week.

Saturday March 10th we held our very first bring a friend open day it was a truly successful day. The evaluation sheets were all very positive and the members and associated members that attended thoroughly enjoyed the day, especially understanding and looking at the bylaws. The members stated they really felt their input was valued and had the opportunity to help and see changes being made.

The HE_023 Standards committee have been working on the public comments and the revised AS/NZS 4187 should be soon available, watch this space.

The FSRACA National Conference in September 12-14th 2018 at Sydney Luna Park is quickly approaching, the program is available in Draft and it will be available on the FSRACA Website as we speak, just Google FSRACA and click on the webpage to view the program. You will find there is something for everyone. If you live in NSW please do not miss this educational and trade display opportunity as it only comes around every 18 years to our state. So please make a big effort to support our state by attending the national conference in 2018.

Our next event will be Saturday 23rd of June 2018 at RPAH Scot Skirving Lecture Theatre.

President's Report... continued

The following positions are declared vacant and nominations are sought according to the Constitutions & Bylaws.

- President - George Papadopoulos
- Treasurer - Leanne Burns
- Committee - Tracey Worthington
- Committee - David Bellamy
- Committee - 2 vacant positions.

Nomination forms will need to be submitted according to the constitution and Bylaws.

The nomination form will be emailed/mailed to members along with the program & a meeting agenda. Or you can access them from our website google NSW SRACA and click on the link. We will provide an educational presentation, the annual meeting, elections & catering, this is free to all members & associate members. You are welcome to join our society on the day.

This will be your last opportunity to win one of 5x registration scholarships for the National conference in Sydney Luna Park in September. These are not transferrable.

Enjoy this Journal and we hope to see you all at our workshop on Saturday 23rd June 2018 at RPAH.

Regards
Lynne Noring
Vice President NSW SRACA

SRACA NSW open day and Workshop

Hello Members and associate members.

On March 10th 2018 we had our first workshop for the year. We decided to make it an open day for members and associated members and to bring a friend at no cost.

The workshop was held on a Saturday because many of our members stated it is very hard to be able to take time away from work to attend our workshops.

The workshop was held at Royal Prince Alfred Hospital in the Large Conference Room at the Kerry Packer Education Centre.
We started the day with registration at 8:30am. We were welcomed by George Papadopoulos the President of NSW SRACA.

Lynne Noring started her presentation with the purpose of the NSW SRACA, Lynne asked the members what they thought the purpose was, and when the slide was revealed the members new exactly what the purpose was.
The purpose is:

- To promote the sharing of knowledge, research and investigation
- To enhance opportunities for education and training of the principles and practices of reprocessing of Reusable Medical Devices in Health Service Organisations.
- To provide access to knowledge and information on current standards and best practice through Conferences, workshops and networking.
- To control infection and microbiological contamination in Health Service Organisations and community services through research and education
- To represent the professional interest of our members of the association.

Lynne then went into her Presentation of NSW SRACA **The Past**.

- **When & why did our society begin?** In 1961 a microbiologist was invited to speak in a conference at Melbourne on Centralizing Sterilization Services in Great Britain. He was also invited to Visit the newly built Sterilizing Department at RPAH in Sydney on his way. From that Visit he was asked to attend a meeting at Crown Street Women's hospital to discuss problems associated with sterilizing and to share knowledge and experiences and to encourage education.
- **The founders of our society**. After this meeting there was many very enthusiastic people interested in starting a sterilizing society in NSW. A meeting date was set and word had been spread far & wide.
- **The inaugural meeting**. Took place in 1962 at Balmain & District hospitals at 8pm at night. There were representatives from 25 city hospitals and 2x country hospitals, the Australian Atomic energy commission (Lucas heights).The NSW hospitals commission, the public works department and the Leichardt Council.
- **The first executive members and committee members were**:
- **President** Dr D. Childs Superintendent RPAH
- **Snr Vice President** Mr K. Boylan , Secretary & CEO Balmain & district Hospital
- **Vice President** Mr J Bell CSSD supervisor –Sutherland Hospital
- **Secretary** SR N Spence, Theatre Supervisor Balmain & District Hospital
- **Education Officer** Mr Frank Hebbard CSSD Supervisor RPAH
- **Director of Research** SR Mary Anthony Theatre Supervisor St Vincent's Hospital

SRACA NSW open day and Workshop... continued

- **Publicity Officer** SR Arthur CSSD Supervisor repat General Hospital Concord
- **Liaison Officer** Mr Buckingham Public works dept. Engineering Health Section
- **The writing of the constitution took place and the society began**.

Unfortunately an accurate record of these meetings could not be obtained as all earlier records had been destroyed in a fire at Balmain Hospital in 1966 These are the personal files obtained and made available by Miss Spence & Mr Hebbard.

- **The first sterilising technology Certificate** - Preparation for the lecture notes started in 1967 by a subcommittee of SRACA committee members the lecture notes were in reference to the Principles and Methods of Sterilisation in Health Sciences by John Perkins. The first course commenced in June 1969 there was 55 students that attempted the course, 47 completed the course and 43 successfully passed the course. The Sterilising Technology course was successfully attended year after year and rolled out by the NSW health commission and NSW SRACA. Then in 1990 the sterilising industry saw a change and the first Sterilising Certificate graduation took place with the lecture notes written together by TAFE, SRACA NSW and The Department of Health.
- **The Launching of the First Sterilising Journal was in March 1981**. The honorary Kevin Stewart who at the time was the Minister of Health, Kevin stated that was with great pleasure to be able to endorse the National Journal of Sterilization Research & Advisory Council of Australia it's launching marked another Milestone in the development of the Councils Activities. **The first Co-editors of the Journal was none other than Mr Anthony (Tony) Mercieca & Mr Jonathan Milligan**. Tony & Jonathan both contributed a great deal with research, education and sharing knowledge over the years they were both on the SRACA committee and they are both regarded as the gurus of sterilising and rightly so.
- **The Australian Federation of Sterilizing & disinfection** was formalized in March 1977 this was a giant step forward in consolidating the knowledge and expertise of membership in all Australian States and to acknowledge that there is strength in professional unity.
- **October 1987 Hosplan** with the help of Tony Mercieca wrote the very first Code of Sterilizing Practice.
- **April 20th 1994** saw the Launch of the first Australian standard for Sterilizing and disinfection again another milestone assisted by our society.

In Conclusion

Much water has past under the bridge since 1962 but as SRACA NSW enters its 57th year a debt of gratitude must be recognised for the work and dedication of our pioneers of our Council and other enthusiastic members who have taken up the reins and moved the society forward. There have been so many people that have been so devoted to this wonderful society we have. This would be a timely reminder to all of us involved in Sterilising that we indeed are a profession and that we should live up to the heritage of those who had the spirit to progress our profession more than 57 years ago.

Cindy Shaw then took over and did an excellent presentation on NSW SRACA in its **present** state and what our plans are for the immediate future please see Cindy's presentation attached.

David Bellamy brought us into the **Future** using modern technology and social media. Please see David's excellent presentation Attached.

Cindy then did an overview on the constitution and bylaws and how changes can be made and how these changes are accepted. Cindy explained to the members & associate members that after morning tea we will put the constitution & the bylaws on the screen and we can work through each point and make necessary changes.

After morning tea as Cindy stated we worked through the constitution & the by-laws going through each point. Kim Beard our minute's secretary made track changes when all members were happy with the change.

You could clearly see the members really enjoyed being part of this process as everyone one in the room were making positive comments to these changes.

We informed the members the next process is, we will need to go back to the executive committee maybe some rewording would be applied and it would be placed onto website and emailed in draft for all members to see. No changes will take place

SRACA NSW open day and Workshop... continued

until acceptance at the next AGM in June.

We than broke for lunch and some of the members requested a tour of RPAH sterilising department which was granted.

After lunch we had the general meeting and then questions & answer time.

We drew 5x registration scholarships and the winner's names and a group photo will be in this journal.

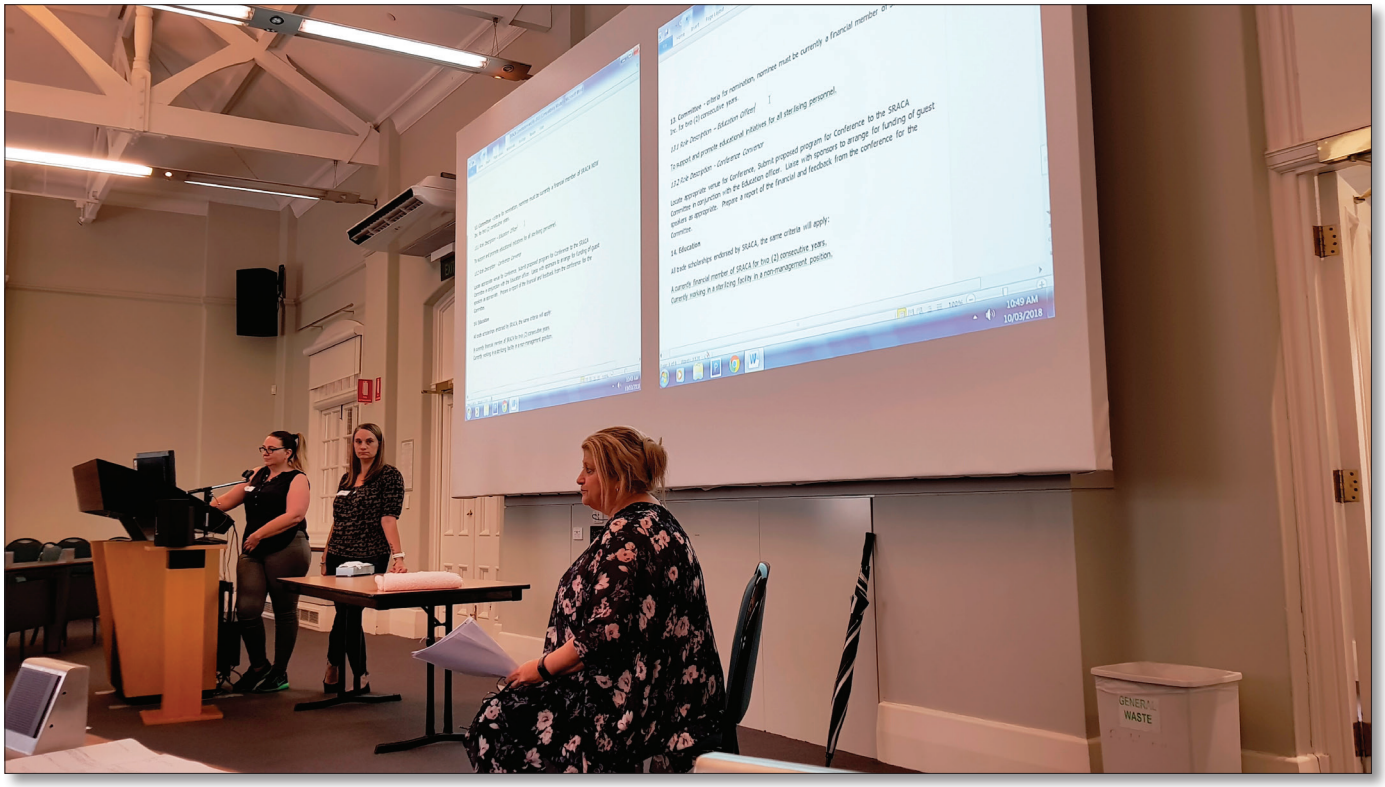
The evaluation forms were very positive and the members stated how much they enjoyed being included in the constitution and bylaws.

The members thoroughly enjoyed the day and learnt so much about our society and will now utilise the website more frequently.

The next Annual General Meeting will be June 23rd 2018 again on a Saturday at Royal Prince Alfred Hospital Kerry Packer Education Centre Large Conference room.

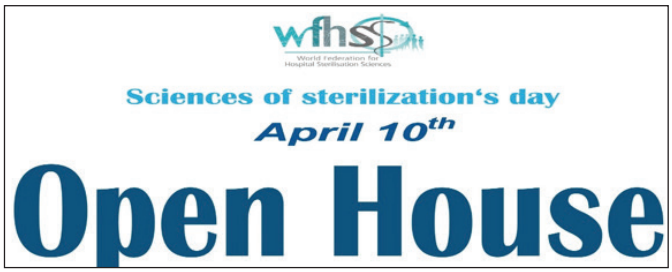
Come along to this meeting. This will be your last chance to win one of 5 registration Scholarships to The FSRACA National Conference SEPTEMBER 12-14 2018 at Luna Park.

SRACA NSW open day and Workshop... continued



World CSSD Day

Hello members & associate Members,



Once again on April 10th 2018 Sterilizing Services Departments around the world celebrated World sterilization open day.

This day needs to be marked on your calendar and well planned to display our service to our health care facilities. It is our golden opportunity to be recognised and let our health care facilities understand what we do, how we do it and why we do it. I have heard for many years SSD'S complaining that our service goes unrecognised and unappreciated, so here we have this chance to make that change. So we need to all get together nationally to make this event something to look forward to and celebrate our Sterilizing services each year.

This year we did not disappoint we had many hospitals in NSW celebrate our World Open Day in many different ways , we all opened the doors of our departments or put together a display in the main foyers or cafeterias of our healthcare facilities.

Fairfield Hospital the manager Barbara Flaherty encouraged her staff to help in planning their event. The staff at Fairfield SSD took great pride in showing the hospital what they do in their department. They had plenty of hospital staff participation by initiating SSD oriented quizzes with guessing competitions, demonstrations of wrapping techniques and wrapping

World CSSD Day... continued

competitions. The cutting of a cake with the hospital executive unit. Well done Barbara and Fairfield SSD team great effort.

Some displayed presentations of the hospitals past cleaning, packing and sterilising techniques and passed through to new technology going from manual and ultrasonic cleaning only to washer disinfector cleaning. From ETO sterilising to Hydrogen peroxide sterilising. They even managed to show some old hot air sterilising methods when needles and syringes were reusable. They demonstrated old operating techniques to robotic operating techniques and how we clean and sterilise these Reusable medical devises. This was displayed using screens placed around the hospitals foyers. It was well received by all they passed through the foyer that day from executive staff, doctors, nursing staff, & visitors.

And thank you to our associated members our wonderful trade that also got involved in the way of banner displays and hand hygiene give a ways.

It was a great day had by all as you can see by some of the photos sent to our Sterilizing journal editor.

Please get on board and ensure you all mark on your calendar for next year 10th of April 2019 World Sterilizing Open day and make it the biggest and best event on the yearly health calendar. It can only happen if you all make the effort to make it happen by celebrating. Get your staff involved and plan your display.

Thank you to this year's participants and we are looking forward to seeing even more displays next year.

Lynne Noring
Vice President NSW SRACA

World CSSD Day RPA Hospital

Certificate III - Sterilisation Services

Certificate III in Sterilisation Services

TAFE NSW Course No: HLT37015-01V01
National Course Code: HLT37015
Nominal Hours: 455

Course structure and units

This course includes 14 units. Use the links below to go to your online learning resources for each unit.

BSBFLM312 – Contribute to team effectiveness

BSBINM301 – Organise workplace information

CHCCOM005 – Communicate and work in health or community services

CHCDIV001 – Work with diverse people

BSBADM311– Maintain business resources

HLTINF001 – Comply with infection prevention and control policies and procedures

HLTSTE001 – Clean and disinfect reusable medical devices

HLTSTE002 – Inspect and pack reusable medical devices

HLTSTE003 – Sterilise loads HLTSTE004 – Manage sterile stock

HLTSTE005 – Care for reusable medical devices

HLTSTE006 – Chemically disinfect reusable medical devices

HLTWHS001 – Participate in workplace health and safety

HLTWHS005 – Conduct manual tasks safely

wsi.tafensw.edu.au

For full details on TAFE NSW fees and money matters please visit our website: wsi.tafensw.edu.au/fees

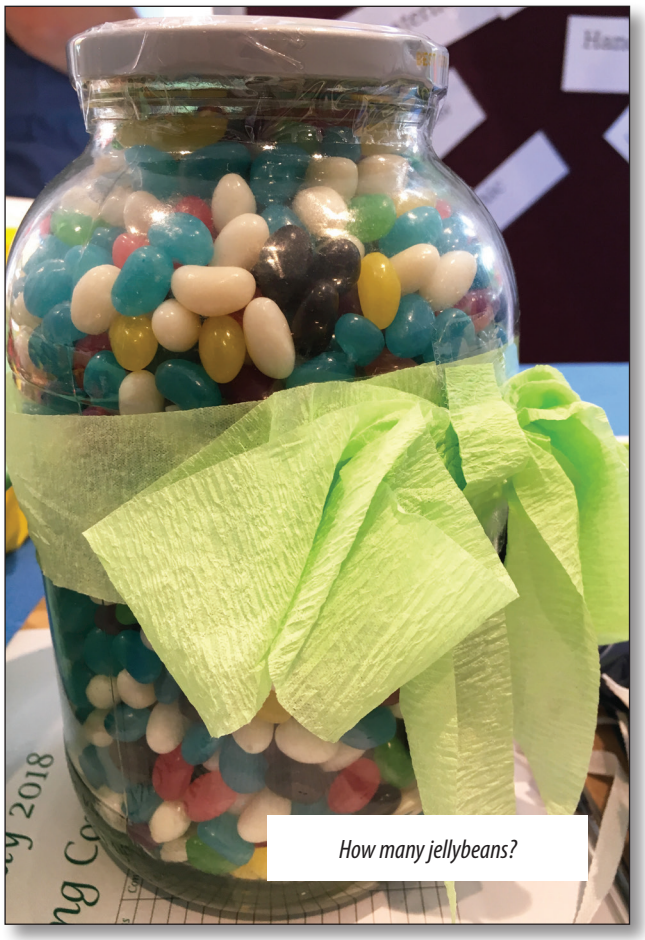
World CSSD Fairfield Hospital

CSSD Staff enjoying the celebrations

CSSD Staff sharing information

World CSSD Fairfield Hospitald... continued

Showcase in the Fields Café on Campus at Fairfield Hospital



How many jellybeans?

YUMMY!

World CSSD Campbelltown Hospital

'The World Federation for Hospital Sterilisation Sciences invited Australia to help celebrate the 'Sciences of Sterilisations' Day' on April 10th.

The Campbelltown Hospital CSSD displayed images of the valuable work involved in the process of reusable medical devices.

The display was open to staff, visitors and patients. Many were interested to learn about the complexity of instruments used in surgical procedures.

Some were surprised to learn that a Certificate III in Sterilising Services is a TAFE qualification, which complements competency based training in a Hospital CSSD.

The CSSD team were happy to interact and share their knowledge on the day. Processes, chemical indicators, documentation, education and accountability were discussed in detail.

A big thankyou to the partners in sterilising, who provided token give-a-ways and also to the CSSD team for assisting with the display and their dedicated expertise in the Sterilising industry.

World CSSD Campbelltown Hospital... continued

SRACA NSW Annual AGM

SRACA NSW ANNUAL GENERAL MEETING PROGRAM

DATE : 23rd June, 2018
TIME : 9:00 Registration
VENUE: RPA Hospital
Scot Skirving Lecture Theatre
COST: Free for Financial Members
$80.00 for Non Members
RSVP: 16th June 2018
Cynthia.Shaw@health.nsw.gov.au OR
Tracey.Worthington@health.nsw.gov.au

9:00 Registration

9:20 Welcome & Update on National Conference

9:30 Benoit Kergrohen— GAS Monitoring in the CSSD Environment

10:00 Morning Tea

10:20 AGM and Election of Office Bearers

11:00 Lynn Rapley—Nursing Unit Manager RN ACGEN Endoscopy: new consensus statements/storage/biofilm/ alcohol usage/ATP & bioburden testing and…….. the GAP Analysis

11:50 FSRACA National Conference lucky draw x 5

12:00 Lunch

13:00 Close

Public Carpark in Hospital Street @$12.00 per day

On Street parking meters

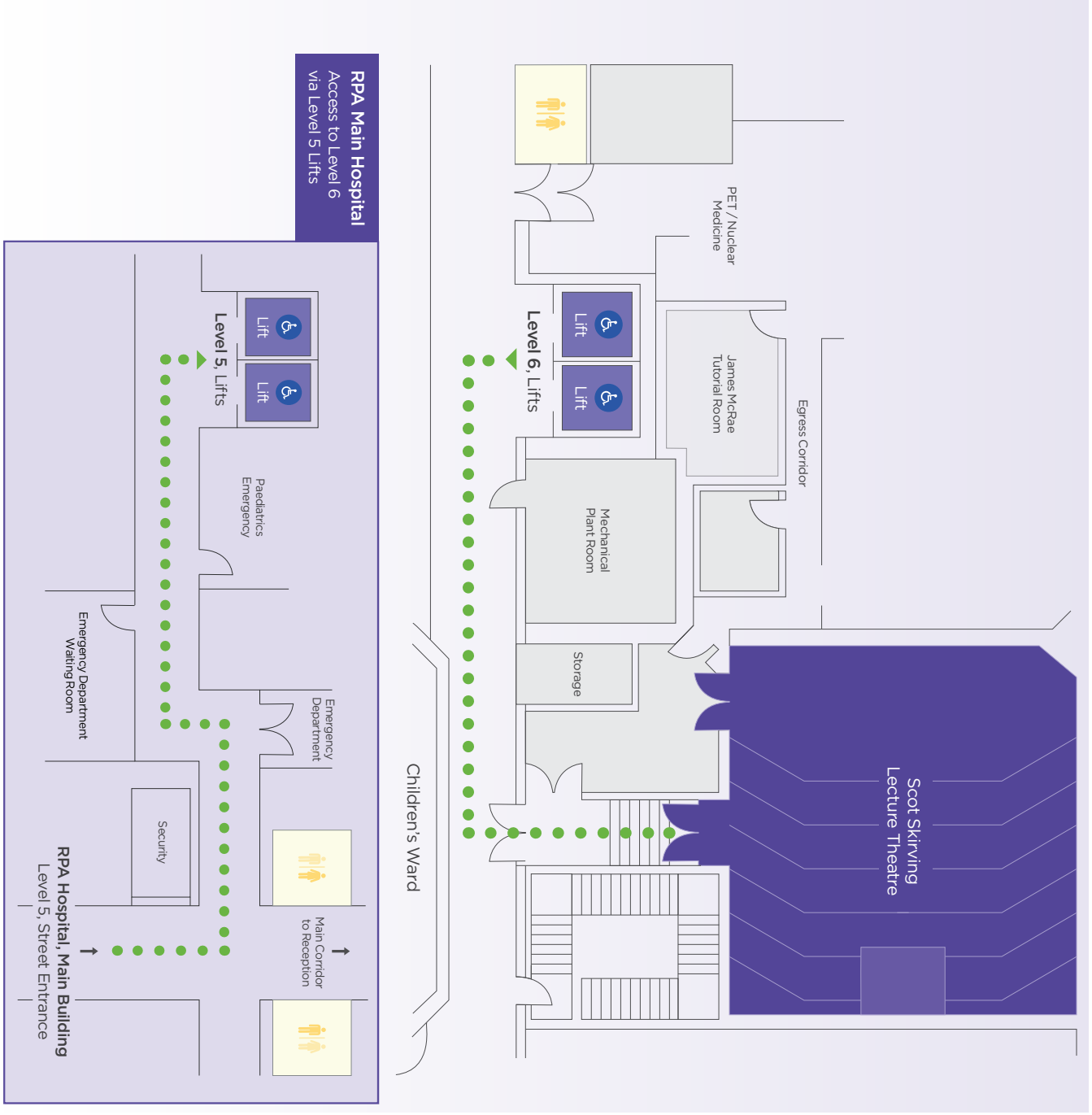
*New Members will be accepted on the day however will be subject to acceptance at the July 2018 executive committee meeting, as per the NSW SRACA Constitution

SRACA NSW Annual AGM... continued

Kerry Packer Education Centre
Level 6
Scot Skirving Lecture Theatre

Note: Access via RPA Main Hospital, Level 5 Lifts (Main Street Entrance)

Health
Sydney Local Health District



SRACA NSW Annual AGM... continued

S.R.A.C.A. (N.S.W.) Inc.

ABN: 85 914 815 703

P.O. Box M71
Missenden Road
CAMPERDOWN NSW 2050
11TH MAY 2018

NOTICE OF THE ANNUAL GENERAL MEETING TO BE HELD AT 10.00AM ON JUNE 23rd 2018 AT ROYAL PRINCE ALFRED HOSPITAL, SCOT SKIRVING LECTURE THEATRE

AGENDA

1. PRESENT
2. APOLOGIES
3. ACCEPTANCE OF PREVIOUS MINUTES
4. BUSINESS ARISING FROM MINUTES
5. CORRESPONDENCE PERTAINING TO AGM
6. BUSINESS ARISING FROM THE CORRESPONDENCE
7. REPORTS
   a) PRESIDENT
   b) SECRETARY
   c) TREASURER
8. ELECTION OF OFFICE BEARERS FOR 2018-2019
9. NOTICES OF MOTION
10. GENERAL BUSINESS – Pertaining to the AGM

IN ORDER TO ORGANISE CATERING, MEMBERS ARE REQUESTED TO RSVP BY FRIDAY 18/06/2018

Cynthia Shaw (02) 9515 7304
Cynthia.shaw@health.nsw.gov.au

SRACA NSW Annual AGM... continued

ELECTION OF OFFICERS 2018-2019

The following positions are to be declared vacant and nominations for a period of two years are sought in accordance with the Constitution and By Laws of the association.

President	-	George Papadopoulos
Treasurer	-	Leanne Burns
Committee	-	Tracey Worthington
	-	David Bellamy
	-	Vacant Position

Those members who are vacating Office are eligible and may be available for re-election.

WRITTEN NOMINATIONS MUST BE RECEIVED BY THE SECRETARY 7 DAYS PRIOR TO THE ANNUAL GENERAL MEETING.

******ONLY FULL MEMBERS WHO HAVE CURRENT MEMBERSHIP, (WITH A MINIMUM OF 2 FULL YEARS CONTINUOUS MEMBERSHIP) ARE ELIGIBLE FOR NOMINATION (AS PER CONSTITUTION)******

Return completed forms to:

Cynthia Shaw
The Honorary Secretary
S.R.A.C.A. (NSW) Inc.
P.O. Box M71
Missenden Road
CAMPERDOWN NSW 2050
Fax: (02) 9515 8120

THE NOMINATION FORM BELOW MAY BE PHOTOCOPIED

NOMINATION FORM FOR THE ELECTION OF COUNCIL OFFICERS AND COMMITTEE 2018-2019

I _____being a fully paid up member of the Sterilising Research and Advisory Council of Australia (NSW) Inc. nominate:

Name_____for the position of_____

Signature_____Nomination Seconded by_____

Signature of person nominated accepting the nomination_____

TGA - March 2018

Australian Government
Department of Health
Therapeutic Goods Administration

Medical Devices Safety Update

Volume 6, Number 2, March 2018

In this Issue

Preventable alarm issues remain a major source of adverse event reports

Failure to generate alarms, inaudible alarms, or failure to trigger alarms continue to be major sources of adverse event reports received by the TGA.

One Australian hospital, in consultation with the TGA, recently undertook a review into its use of cardiotocographs (CTGs) following the death of a foetus.

The review found that a number of these devices in use at the facility had their alarms disabled.

A TGA investigation noted that a number of CTG devices on the market could have their default alarm settings to off or disabled. This would mean that if a situation warranting clinical attention developed, no clinical alarms would be generated to warn the clinician.

The TGA is continuing to investigate this issue and encourages hospitals and health professionals to review and test alarm generation capability and settings of all devices monitoring life-critical function.

Advice for health workers and facilities

Health workers and facilities should:

- regularly test alarms on devices that monitor critical physiological parameters
- review the alarm settings of devices periodically to ensure they are correct and suit your needs
- review training and educational opportunities available to staff regarding alarms
- increase staff awareness of the implications of muting alarms and changing alarm settings
- avoid exclusive reliance on audio alarms
- be aware that some manufacturers have factory default alarms set to “off” or “technical alarms only” – these could cause a risk to users and patients if not reviewed
- be aware that issues can happen due to a defect with the device, especially with the speakers, an incorrect alarm setting, users muting the device or setting it off accidentally
- report any missed alarms or adverse events to the TGA.

Advice for manufacturers and sponsors

Manufacturers and sponsors should:

- check that the default settings of their devices are designed and tested from the perspective of safety and that it needs to conform to Essential Principles.
- review the ability of users to mute alarms permanently
- report alarm-related issues to TGA
- ensure their post-market process appropriately trigger corrective and preventative action and correct any issues early
- ensure corrective action and recalls address all devices, not just newly manufactured units.

Medical Devices Safety Update is the medical devices safety bulletin of the Therapeutic Goods Administration (TGA)

TGA Health Safety Regulation

Review into cochlear implants and magnetic resonance imaging safety

The TGA has received a number of adverse event reports relating to cochlear implants and magnetic resonance imaging procedures.

Cochlear implants are small electronic devices that are used to stimulate the auditory nerve to provide a sense of sound to someone with profound hearing loss.

A cochlear implant has multiple parts including external parts consisting of a microphone and auditory processor as well as a transmitter. Other parts of the implant are located under the skin, including the receiver. The electrode or electrode array is inserted into the cochlea and stimulates the auditory (hearing) nerve. Magnets in both the internal and external parts of the implant allow them to connect and remain in place.

The TGA had received 18 Device Incident Reports relating to MRI safety and cochlear implants as of 9 March 2018. These reports concerned issues relating to the device's internal magnet dislodgement and reversal, subsequent surgeries to replace magnets, and pain and discomfort experienced by patients undergoing MRI while the internal device magnet is in situ.

Magnets in both the external and internal components of cochlear implants hold them in place.

TGA actions

The TGA sought advice from the Advisory Committee on Medical Devices in February 2017 regarding the risks associated with MRI scans and patients with cochlear implants.

A post market review was conducted on all cochlear implants supplied in Australia to assess the current procedures and advice related to MRI scans and cochlear implants.

The TGA is currently working with sponsors of cochlear Implants to update the Instructions for Use and associated product materials. The materials provided with the cochlear implant should address and advise users and clinicians about the risks when having an MRI scan with a cochlear implant.

Any decision to authorise an MRI scan remains a medical decision balancing the risk of damage to the implant and possible pain and discomfort against the benefit of information provided by the scan.

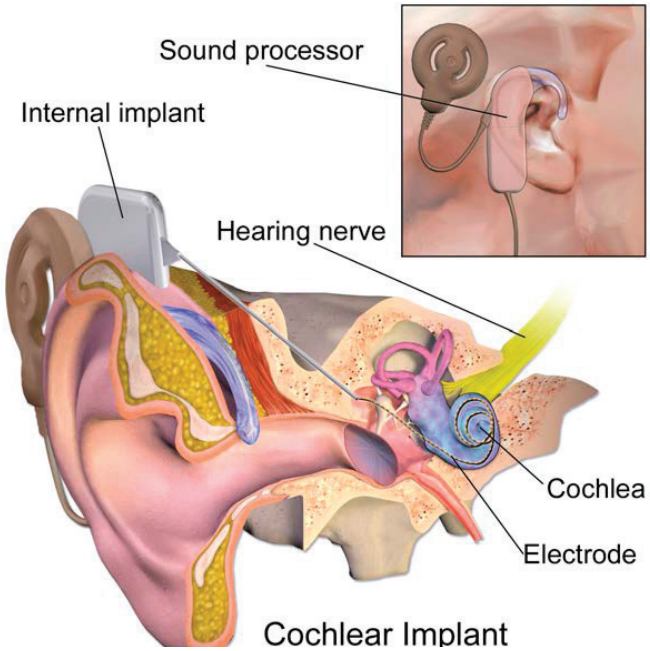


Image created by Blausen.com staff and published under Creative Commons licence. "Medical gallery of Blausen Medical 2014". WikiJournal of Medicine 1 (2). DOI:10.15347/wjm/2014.010. ISSN 2002-4436. Own work, CC BY 3.0.

TGA - March 2018... continued

NHS cylinder alert

The United Kingdom's National Health Service (NHS) has issued a safety alert about risks associated with newer designs of oxygen cylinders.

The TGA has received reports relating to fire, leakage and broken valves and regulators but none for the reported UK issues.

The NHS said insights from local investigations prompted the following advice for facilities to focus on: prioritising training for staff groups and clinical areas where the risk is high; reinforcing theoretical training with regular opportunities to practise operating the cylinder controls; linking safe operation of cylinder controls with other key safety issues, including fire hazards and how long a full cylinder will last; and placing laminated guides close to the point of use.

Recent safety alerts

Below are TGA safety alerts relating to medical devices published since the last edition of *Medical Devices Safety Update*.

Rite Aid Mini Digital Temple Touch Thermometer: Recall - potential risk of harm for children who access the button battery

Puritan Bennett 980 Series Ventilator: New suspension - Medtronic Puritan Bennett 980 Series Ventilator

Therakos Cellex Photopheresis System: Update: Therakos Cellex Photopheresis System Safety advisory – risk of blood clots

TGA actions after review into urogynaecological surgical mesh implants: Update - Stress Urinary Incontinence (SUI) mid-urethral slings

What to report? Please report adverse events, as well as near misses

The TGA encourages the reporting of any suspected adverse event or potential adverse event relating to a medical device. Adverse events can involve actual harm to a patient or caregiver, or a near miss that may have resulted in harm.

Some issues relating to medical devices that may lead to adverse events and prompt you to report include:

- mechanical or material failure
- design issues
- labelling, packaging or manufacturing deficiencies
- software deficiencies
- device interactions
- user/systemic errors

Suspected adverse events or near misses can be reported directly to the TGA:

- **online** at www.tga.gov.au (click 'Report a problem')
- **by emailing** iris@tga.gov.au
- **by mail** to IRIS, TGA, PO Box 100, Woden ACT 2606
- **by fax** to 02 6203 1713

For more information about reporting, visit www.tga.gov.au or contact the TGA's Medical Devices Branch on 1800 809 361.

For the latest information from the TGA, subscribe to the TGA Safety Information email list via the TGA website

For correspondence or further information about Medical Devices Safety Update, contact the TGA's Medical Devices Branch at iris@tga.gov.au or 1800 809 361

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TGA - May 2018

Australian Government
Department of Health
Therapeutic Goods Administration

Medical Devices Safety Update

Volume 6, Number 3, May 2018

In this issue

How the TGA uses Australian joint replacement registry data

The information generated by the Australian Orthopaedics Association National Joint Replacement Registry has been an important tool for post-market vigilance and monitoring and for decisions regarding inclusion of medical devices on the Australian Register of Therapeutic Goods (ARTG).

The Australian Orthopaedics Association National Joint Replacement Registry (AOANJRR) has been operating since 1999. Every October the registry publishes an annual report for the previous year, alongside several supplementary reports. The 2017 annual report undertook analysis on 1,237,576 joint replacement procedures (545,831 hip, 653,480 knee and 38,265 shoulder).[1] Registry information is also available through a web portal.

The annual reports contain information about the types and reasons for revision procedures and identify implant combinations that have higher-than-anticipated rates of revision. The information is a resource for orthopaedic surgeons, implant manufacturers, researchers and regulatory agencies such as the TGA.

A joint replacement procedure triggers data collection including: patient identifying details; consulting surgeon; reason for surgery; and the type of implant, including individual implant components. If the procedure is a revision the type of revision and reason for revision are recorded. Although patient identifiers are collected, they are only used to ensure the integrity of the data and to reconcile revision information with the original operation. In case of a problem, it is best for the patient to be contacted by a medical practitioner.

Why is it so useful?

The AOANJRR reports are useful for a variety of reasons including:

- The 'opt-out' method of enrolment leads to a virtually complete data set.
- A wide variety of analysis options are available.
- The data set allows calculation of Cumulative Percent Revision (Kaplan-Meier survivorship).
- Revision rates can be broken down among particular patient populations, for example: primary diagnoses; gender; age; use of cement; type of implant; implant models; etc.
- The reasons for the primary procedures and types of revision procedures can be taken into account.

Focus on outliers

The TGA's focus has been on implants that are revision rate outliers. An implant may be having a higher-than-expected rate of revision for many reasons. These must be considered before contemplating regulatory action.

In 2006 the TGA established a process for the investigation of an implant 'identified' as having a higher-than-expected rate of revision:

1. The sponsor/manufacturer of the implant is requested to make a submission relating to the safety and performance of the implant.

Medical Devices Safety Update is the medical devices safety bulletin of the Therapeutic Goods Administration (TGA)

TGA Health Safety Regulation

TGA - May 2018... continued

2. A group of orthopaedic experts considers the information from the AOANJRR and the manufacturer. The expert group advises the TGA about safety, performance and benefits that may compensate for the high risk of revision.
3. The TGA considers all the evidence and the expert advice and makes a regulatory decision. The action taken could be a recall, hazard alert, safety alert and/or cancellation, or taking no action if it is appropriate.

In 2017 the registry 'identified' 130 implant combinations:[1]

- All 130 implant combinations have been investigated by the TGA.
- 53 implant combinations are in the category 'identified and still used'
- 77 implant combinations are in the category 'identified and no longer used'
  - 32 of these 77 implant combinations were withdrawn from the market after some form of TGA intervention.

TGA intervention is not restricted to recall or product cancellation. The TGA has also intervened in instances where the implant continues to be used, for instance by ensuring that clear advice is provided about the use indications and contraindications of particular implants.

The outcomes of the interventions are published on the TGA website (www.tga.gov.au). The Australian Orthopaedic Association and surgeons who used the implants that are subject to regulatory outcomes are notified individually by the sponsor of the implant.

Other uses

The TGA also uses registry information to check the revision rate of implants that are the subject of a Device Incident Report .

We have also used registry information in the assessment of applications for new implants. In some cases, the TGA has used AOANJRR reports on clinically equivalent implants to compensate for a lack of sufficient clinical evidence about a new device.

REFERENCE

1. Australian Orthopaedic Association National Joint Replacement Registry. Hip Knee and Shoulder Arthroplasty: 2017 Annual Report. Adelaide: AOA, 2017 - available from https://aoanjrr.sahmri.com/annual-reports-2017.

Focus on skills for vacuum-assisted births

The safe use of devices in vacuum-assisted births relies on careful patient selection, good technique, and the setting of appropriate procedural limits, all within a robust clinical governance framework.

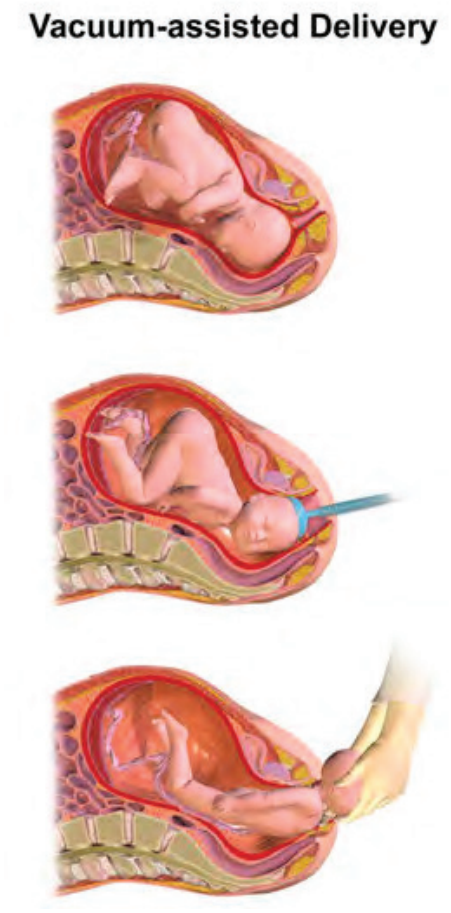
There is a reported increase in clinical acceptance and use of medical devices in vacuum-assisted deliveries and so far the TGA has not received any serious injury reports related to their use. However, device sponsors and clinical experts have been calling for more attention to be paid to appropriate training, supervision and credentialing as vacuum-assisted deliveries, like all similar procedures, are not free of potentially serious risks.

NSW's Clinical Excellence Commission (CEC) addressed many of the issues in a 2014 report, *Vacuum Assisted Births – Are We Getting it Right? A focus on subgaleal haemorrhage.*[1] The report found vacuum delivery was not without risk with injuries in about 5 per cent of deliveries. Complications include subgaleal haemorrhage, which is potentially life threatening and occurs in approximately 1 in 300 cases.[2]

After analysing data collected by NSW Health's Incident Information Management System, the CEC report concluded:

> *Management of the second stage of labour can be challenging. With respect to vacuum assisted births, clinicians need to appreciate that while the incidence of maternal trauma is reduced compared with forceps, neonatal trauma occurs in approximately 1 in 15 babies. While such trauma is mostly minor, potentially fatal complications such as subgaleal haemorrhage do occur.*
>
> *It is evident from the review of cases that clinicians may perceive that the use of vacuum devices do not require the same level of rigour with respect to training, supervision and*

TGA - May 2018... continued



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credentialing, as other forms of assisted birth. The prerequisites for instrumental vaginal birth need to be fulfilled and documented. There must be adequate maternal effort such that a clinician needs to question the use of vacuum devices where there is profound maternal exhaustion or where a neuraxial block (e.g. epidural) significantly inhibits the mother's expulsive efforts. Vacuum devices should not be used for births less than 36+0 weeks gestation and never before 34+0 weeks gestation. However, if a vacuum assisted birth is to be performed at 36+0 weeks gestation a consultant should be present to provide direct supervision. Professionally determined procedural limits must be adhered to and documented.

Many cases reviewed in this report indicate that clinician supervision, skill and knowledge are variable across the system. In particular, it would appear that some clinicians do not possess the full range of obstetric skills that would permit alternative options to effect birth safely. Professional obstetrical and gynaecological bodies recognise the need for clinicians to be skilled in both forceps and vacuum assisted births early in their career development. Such skills require appropriate training, supervision and credentialing.

Instrumental vaginal birth continues to have a role in modern obstetrics. It is recognised that forceps births are associated with an increase in maternal trauma. However, this report would indicate that the risk of neonatal trauma in vacuum assisted births is not fully appreciated. It is important for clinicians to recognise those elements of safe instrumental vaginal birth that are critical to minimising harm to both mothers and babies.

These conclusions echo similar findings in a 2010 Cochrane review, Instruments for assisted vaginal delivery:[3]

There is a recognised place for forceps and all types of ventouse in clinical practice. The role of operator training with any choice of instrument must be emphasised. The increasing risks of failed delivery with the chosen instrument from forceps to metal cup to hand-held to soft cup vacuum, and trade-offs between risks of maternal and neonatal trauma identified in this review need to be considered when choosing an instrument.

REFERENCES

1. Vacuum Assisted Births – Are We Getting it Right? A focus on subgaleal haemorrhage. Clinical Excellence Commission 2014. http://www.cec.health.nsw.gov.au/__data/assets/pdf_file/0010/258247/c-f-report-vacuum-assisted-births-are-we-getting-in-right.pdf (accessed 10 May 2018)
2. Prevention, Detection and Management of Subgaleal Haemorrhage in the Newborn. The Royal Australian and New Zealand College of Obstetricians and Gynaecologists. 2015; C-Obs 28. https://www.ranzcog.edu.au/RANZCOG_SITE/media/RANZCOG-MEDIA/Women's%20Health/Statement%20and%20guidelines/Clinical-Obstetrics/Prevention-detection-and-management-of-Subgaleal-Haemorrhage-(C-Obs-28)-Review-November-2015.pdf?ext=.pdf (accessed 10 May 2018)
3. Instruments for assisted vaginal delivery. O'Mahony F, Hofmeyr GJ, Menon V. www.cochrane.org/CD005455/PREG_instruments-for-assisted-vaginal-delivery (accessed 10 May 2018)

TGA reviews product safety of ventilators

The TGA is undertaking a product safety review into ventilators being used in the intensive care or high-level care environments.

The TGA's review covers ventilators that are used in high-care hospital settings for long-term therapy of intubated patients. Such long-term use will normally be associated with integral or separate humidifiers. It does not include ventilators used only for transport or in home settings.

The review will initially examine 18 of the more commonly used ventilators, but more may be added over time.

TGA has requested that sponsors of ventilators provide the following information:

- evidence that the ventilators meet the ventilation delivery and monitoring specifications published in the Instructions For Use, which should include evidence that the breathing circuits recommended for use with this ventilator are valid
- for ventilators that are intended for use with paediatric patients, a clear clinical justification and validation of why tidal volume delivery specifications are acceptable and safe
- post-market data
- which breathing circuits are suitable for use with the ventilator.

The information requested is undergoing review and any regulatory action resulting from the review will be published.

The TGA advises that the devices can continue to be used while the product safety review is being conducted.

More information about the review and the products included is available on the TGA website.

What to report? Please report adverse events, as well as near misses

The TGA encourages the reporting of any suspected adverse event or potential adverse event relating to a medical device. Adverse events can involve actual harm to a patient or caregiver, or a near miss that may have resulted in harm.

Some issues relating to medical devices that may lead to adverse events and prompt you to report include:

- mechanical or material failure
- design issues
- labelling, packaging or manufacturing deficiencies
- software deficiencies
- device interactions
- user/systemic errors

Suspected adverse events or near misses can be reported directly to the TGA:

- **online** at www.tga.gov.au (click 'Report a problem')
- **by emailing** iris@tga.gov.au
- **by mail** to IRIS, TGA, PO Box 100, Woden ACT 2606
- **by fax** to 02 6203 1713

For more information about reporting, visit www.tga.gov.au or contact the TGA's Medical Devices Branch on 1800 809 361.

For the latest information from the TGA, subscribe to the TGA Safety Information email list via the TGA website

For correspondence or further information about Medical Devices Safety Update, contact the TGA's Medical Devices Branch at iris@tga.gov.au or 1800 809 361

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National Conference

LUNA PARK - SYDNEY

Save the date

12-14 September 2018

JUGGLING PRIORITIES

Risk

Challenges

CIRCUS

Innovation

Up Date

Compliance

Standards

FSRACA

Applying for a Research Grant

Sterilizing Research Advisory Council of Australia

Expression of interest for The Sterilizing Industry

Applying for a Research Grant

FEDERATION STERILIZING RESEARCH ADVISORY COUNCIL OF AUSTRALIA

INVITE ALL FINANCIAL MEMBERS OF SRACA to apply for a research grant of up to $1400.00

This package includes;

- Information
- Guidelines
- Application form

You can request your package from your State Secretary, or download from your State or Federal website.

Applying for a Research Grant ... continued

Purpose

To provide financial assistance, to promote research and develop skills to ensure the sterilizing industry is contributing to quality patient care.

Value
Maximum $1,400.00

1. Selection criteria

- Financial assistance will be considered for projects which would be relevant and beneficial to both the applicant and those involved in the field of sterilization.

2. Eligibility

- Highly developed written and oral skills
- State SRACA membership number and proof you are a current active member.
- Be a full member of a state SRACA and have been a member of a state SRACA for a minimum of two years immediately prior to submitting an application
- Be currently employed in the field of sterilization and have been employed in the field of sterilization for a minimum of two years immediately prior to submitting an application
- Has attended SRACA meetings and educational activities during the two years immediately prior to submitting an application.
- Be actively involved in his/her state SRACA. Active involvement is considered to include but is not limited to:-
  Willingness to serve on SRACA committee or sub-committee
  Promotion of SRACA activities
- Applicants shall submit information about any application for funding from an alternative source/s for the same purpose.
- Only one research grant will be awarded annually.

3. Application Guidelines

- Application forms are available from both FSRACA and SRACA State secretaries
- Applicants should submit a completed type written application form
- Comprehensive Curriculum Vitae, which show details of work and education qualifications.
- Full details of the project, including the objectives, the methodology of the research, the outcome and how the research can enhance sterilization and the estimated or actual budget.
- The proposed project must have commenced within 12 months from receipt of the research grant.
- Within four weeks of completing the research project the recipient will need to submit a type written report outlining the project
- The recipient of a FSRACA grant shall:

  Be prepared to speak on the funded project at FSRACA and /or SRACA meetings, conferences or workshops

Applying for a Research Grant ... continued

- The report may be published in the "Sterilization in Australia" Journal or in an appropriate national professional Journal at the discretion of the editor.
- The recipient will submit progress reports to FSRACA if requested to do so.
- Papers and reports shall not be returned to the grant recipient by FSRACA committee.
- Projects involving human bioethics shall show proof of permission by the people and/or organization/s concerned.
- The grant may fund all or part of the project
- The grant will be available only once to any individual.

4. *Selection*

- Completed application forms together with all supporting documentation shall be submitted to the Secretary of the state SRACA of which the applicant is a member, by 31 December each year.
- The state SRACA committee will determine whether eligibility requirements (as set out in this document) have been met.
- All applications will be forwarded by SRACA to the FSRACA Secretary together with a State committee recommendation.
- The applications shall be assessed at a meeting of the FSRACA committee.
- The decision of FSRACA committee shall be final and binding on all matters.
- Confidentiality of the selection process shall be upheld by all those involved.
- The names of successful applicants, together with an outline of project and funds granted, will be published in the minutes of FSRACA meeting.

5. *Publication*

- Grant recipients shall retain copyright of all papers/reports submitted to FSRACA

6. *Financial Considerations*

- Applicant shall submit a statement of proposed expenditure for the proposed project.
- FSRACA committee reserves the right to cancel the grant and request return of any monies granted should the recipient fail to pursue the purpose for which the grant was awarded.

7. *Alternative Funding*

- FSRACA financial grants are conditioned upon the applicant informing FSRACA at any time should funding received exceed the total cost of the project.
- FSRACA committee reserves the right to request the return of monies over and above full funding.

Applying for a Research Grant ... continued

Application form
(Please circle your title)
Title Ms, Miss, Mrs, Mr., Dr

Surname _____

Given Names _____

Address _____

_____**Post code**_____

Email address _____

Phone number. _____

Current occupation and years of experience _____

_____

Amount of Funding requested $_____
I have/have not made application to alternative sources for funding **YES/NO**
If YES from whom and what support has been requested/granted: _____

_____

If funding is granted I _____ agree to abide by the terms and Conditions of FSRACA "Guidelines for Financial Grants"
SIGNATURE: _____ **DATE**_____

_____

OFFICE USE ONLY

Received by _____**State SRACA Secretary on** _____
State SRACA comments regarding eligibility (as per financial grant guidelines)

_____

_____

SIGNED: _____**POSITION**:_____**DATE**:_____

Received by FSRACA Secretary on _____**DATE:**_____

Presented to FSRACA meeting on _____ **DATE:** _____

FSRACA Action: _____

_____

SIGNED: _____**POSTION:**_____**DATE:**_____

Attachments

- **Current SRACA Membership**
- **Curriculum Vitae**
- **2 x Professional Referees**
- **Proposed Project**
- **Budget Plan**

Applying for a Research Grant ... continued

Applicant_____

1= Criteria not met

5= Criteria fully met

Criteria Rating Comment

1. Documentary evidence. (Circle correct answer)

- Current membership and active member State group YES/NO
- Two relevant references supplied YES/NO
- Curriculum Vitae supplied YES/NO
- Project details YES/NO
- Budget Plan YES/NO

2. Essential Qualifications supplied YES/NO

3. Communication skills

- Written 1,2,3,4,5
- Oral 1,2,3,4,5

Summary_____

_____

_____

_____

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(Circle the correct answer)

Approved/not approved

Amount granted $_____

Signature_____Date_____

2018 NSW SRACA Calendar of Events

STERILIZING RESEARCH & ADVISORY COUNCIL OF AUSTRALIA

AGM

- 23th June 2018—Royal Prince Alfred Hospital

General Meeting

- 10th March 2018 Royal Prince Alfred Hospital
- 10th November 2018 Hornsby RSL

National Conference

- 12-14th September 2018 Luna Park Sydney

Executive Committee Meetings

- 26th February 2018
- 19th March 2018
- 23rd April 2018
- 23rd June 2018
- 30th July 2018
- 27th August 2018
- 24th September 2018
- 29th October 2018
- 26th November 2018

WORLD CSSD DAY

- 10th April 2018

January 2018

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February 2018

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March 2018

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April 2018

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May 2018

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June 2018

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July 2018

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August 2018

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September 2018

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October 2018

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November 2018

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December 2018

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30	31					

Please note dates and venues are subject to change due to venue availability

S.R.A.C.A. (NSW) Inc.
Membership Application/Renewal

Renewals Due December Annually- NOW DUE

Sterilizing Research & Advisory Council of Australia (NSW)

NEW MEMBERSHIP/RENEWALS

MEMBERSHIP COMMENCES: 1st January each year and is valid till 31st December of the same year

TITLE_____SURNAME_____GIVEN NAME_____

HOSPITAL/COMPANY_____

POSTAL ADDRESS_____

POSTCODE_____STATE_____PHONE NO_____

EMAIL_____

Please tick Membership Type

FULL Membership renewal includes Journal	$50	☐	$50.00
NEW Membership includes Journal & Joining fee	$50 + $5 Joining fee	☐	$55.00
ASSOCIATE Membership includes Journal	$50	☐	$50.00
SUBSCRIPTION to Journal Only (Overseas incl. postage)	$60	☐	$60.00

TOTAL PAYMENT ENCLOSED $_____

TOTAL PAYMENT BANK DEPOSIT $_____

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Return to
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PO Box M71
Missenden Road
CAMPERDOWN NSW 2050
Email: sracansw@gmail.com

RENEWAL MEMBERSHIPS ONLY CAN BE DONE VIA EFT:
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BSB: 032096
Account: 871850
Reference: Company/Facility Name or Member Name
Please send or Email Application Form


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OF AUSTRALIA