Dear PaCCSC Members

As I sit here and pen my introduction to this newsletter I ask myself where has the first three months of 2017 gone? Since our return from the festive season the Collaborative hasn’t just been in play mode, it has been in fast forward, and the heady pace of activities is unlikely to abate any time soon.

At the top of the priority list has been the conduct of our signature event of the year, the PaCCSC Annual Research Forum. This year was the 8th Forum held in successive years in Sydney. As a national network, the Forum presents all members with the opportunity to come together, face to face, to continue to build on our combined strengths, add further work to the program of clinical research, discuss new ideas and initiatives, and welcome newcomers alike. This years Forum also included the 10th Year of PaCCSC celebration. Louise has pulled together a snapshot of the Forum and associated activities across the two days including some stellar photographs. My sincere thanks to every member of PaCCSC who attended the Forum and makes the event such a melting pot of ideas, networking opportunities and celebration. The event would not run so smoothly were it not for Louise’s extraordinary event management capabilities and for this I am very very grateful.

Early in February a very important announcement was made by the Chair of the PaCCSC Management Advisory Board, Emeritus Professor Lloyd Sansom AO. In an email circular to all members Professor Sansom announced that Professor David Currow, PaCCSC Chief Investigator, has accepted a new position as Professor of Palliative Medicine in the Faculty of Health, University of Technology Sydney (UTS). David commenced in this role early this month and between February and 30 June, 2017, the Palliative Care Clinical Studies Collaborative will transition from its current academic home at Flinders University to its new location at UTS.

The move by PaCCSC to UTS presents an exceptional opportunity to leverage off the excellence, wisdom and capacity developed since the Collaborative commenced in 2006 and to expand into the areas of chronic disease, aged care and health services research. Over the past 10 years, PaCCSC has positioned itself internationally as the most significant research network in the generation of evidence from clinical trials in palliative care. This position has been afforded because of the vision, leadership and dedication of every member of the Collaborative; from those that contribute to PaCCSC governance, the site investigators who drive clinical research locally and the organisational capacity within the national office.

During PaCCSC transition it will be ‘business as usual’ and the national office will be working tirelessly to ensure a smooth transition of the Collaborative’s program of research and team to UTS.

Some of the PaCCSC studies will continue to be sponsored by Flinders University including: BEAMS; OPRA and CADET. All new studies will however commence under the auspice of UTS. We look forward to this next chapter in the life of the Collaborative.

A number of PaCCSC members have been appointed into new roles since late 2016. Peter Martin has taken up a new role as Professor of Clinical Communication and End of Life Care at Deakin University; Jennifer Philip has taken up a new role as Chair Palliative Medicine at the Victorian Comprehensive Cancer Centre; Meera Agar is the Chair of the COSA Geriatric Oncology Group; Peter Allcroft has agreed to continue in his role as the PaCCSC representative at COSA; the national office has had a one month visit from a Japanese Palliative Care Clinical Trials Nurse, Noriko Fujiwara; SAPS were recognised in the SA Health Awards; and Debra Rowett was the recipient of the Fred J Boyd Award. Congratulations to all these individuals and sites for these achievements. More information is contained herein.

Another individual I would like to personally acknowledge and thank is Belinda Fazekas, the PaCCSC National Project Officer, who celebrated 10 years of service with the Collaborative in late 2016. Belinda has been a key contributor to the success of the Collaborative over her 10 years of full time service. She was integral in the establishment of many of the operational procedures that PaCCSC has in place today and has been a driving force in study implementation, recruitment, trials administration and study closure.

I hope you enjoy this 30th Issue of the PaCCSC newsletter.

Regards

Linda Brown (formerly Devilee)
National Manager
The 8th Annual Research Forum 2 March 2017 was held at the Rydges Hotel Sydney International Airport. Our membership and attendance at the Forum is ever increasing, with over 70 delegates in attendance this year, and for the first time ever we received more expressions of interest to present than we could accommodate in one day program. The increasing growth in numbers and interest in bringing new ideas to the forum is encouraging and demonstrates the increasing awareness of the importance of clinical research activity in palliative care. The more knowledge awareness gained, the more new study ideas arise.

We invited two guest speakers this year, with a different structure than past years including a panel discussion. Professor Richard Head, Chair Scientific Committee, presented about the statistical landscape from a non-statistician point of view. Professor Tim Shaw of University of Sydney led the presentation and panel discussion about implementation and translational research concepts.

New studies are integral to PaCCSC and our future work, so naturally there were several new study proposals presented for which members of the Trials Management Committee are requested to evaluate as a way of determining future support from PaCCSC.

Other presentations included results of the Phase III Megestrol vs Dexamethasone vs Placebo trial and the PERT 1 Pilot study, and international presentations including one from New Zealand, and two presentations from our Japanese delegates from JORTC, who have become regulars at the Forum!

A special mention must go to our Session Chairs – Louise Welch, Peter Eastman and Jenny Philip for keeping the day to time, an often underestimated task but greatly appreciated by those in the know!

Being a national Collaborative, the opportunity of having the PaCCSC governance committee members all in the same location presented once again an optimal time to hold our extended face to face committee meetings, which were all held on Friday 3rd March.
PaCCSC News

This year the Forum was extended to mark the anniversary of ten years of operations at the close of presentations on 2nd March! Special guests for this event included UTS Vice Chancellor Professor Attila Brungs, Dean of Faculty of Health Professor John Daly, Director of Research Strategy and Engagement in Faculty of Health Justine Waters, Associate Dean Research Faculty of Health Professor Fiona Brooks, and many more. This was a fantastic opportunity to celebrate the past ten years with Flinders University, but also herald new beginnings at the future academic home of PaCCSC at the University of Technology Sydney.

Emeritus Professor Lloyd Sansom, Chair Management Advisory Board, kicked off proceedings with a very motivating and genuine speech reflecting on the first 10 years of the collaborative and looking forward to the next ten years.

Vice Chancellor Professor Attila Brungs publicly welcomed PaCCSC to the UTS family, stressing the values held by UTS and the mutually beneficial relationship this would be for PaCCSC and UTS.

Finally our Chief Investigator Professor David Currow reflected on the journey from the very first idea and how it grew into the Collaborative we know today. The achievements of PaCCSC are many, but are thanks to the hard work of so many groups and individuals.
PaCCSC News

News from the palliative care community worldwide

**Belinda Fazekas—10 years of service**

The PaCCSC National Project Officer, Belinda Fazekas, this year celebrates 10 years of service at PaCCSC. Belinda was one of the first staff employed on the PaCCSC project when it commenced in 2006. She has been integral in building systems and processes that underpin the operations of PaCCSC and her work continues to underpin the success of the Collaborative. Congratulations Belinda.

**PaCCSC Visitor—Noriko Fujiwara MS, RN, CNS, CCRP**

“I am a member of Japanese Organization for Research and Treatment of Cancer (JORTC) as a research nurse and a certified nurse specialist of Palliative care. So I had really wanted to learn how to manage clinical trials and the role of research nurses in palliative care field. It was a really great honor to visit PaCCSC. I really appreciate them providing me a great support to have a wealth of experience. This experience will help me in the future and I will try to do my best to conduct high quality research of palliative care field in Japan.” - Noriko Fujiwara

Noriko has studied at the University of Osaka, University of Tokyo, University of California San Diego Extension, and University of Texas MD Anderson Cancer Center, before her visiting fellowship at PaCCSC. Noriko is also involved in local and international clinical research communities, including the Japanese Society of Clinical Trials and Research (JSCTR), the International Association of Clinical Research Nurses (IACRN) and the Clinical Trial Nurse Special Interest Groups in the US and Japan.

Noriko was a pleasure to have in our office, and we will be welcoming her back at the Annual Research Forum on 2nd March in Sydney. We hope Noriko has learned and benefited from her time in Adelaide with us and look forward to future engagement.

**Professor Peter Martin—New Role at Deakin University**

Barwon Health Clinical Director Palliative Care Services Dr Peter Martin has been appointed as Professor of Clinical Communication and End of Life Care at Deakin University School of Medicine. Peter will maintain a clinical practice at Barwon Health, and will be developing a number of different areas in his new academic role at Deakin University. Peter’s extensive experience and expertise in clinical communication and palliative care will play an integral role in developing communication curriculum.

Peter has also become the Australian National Representative for the International Association for Communication in Healthcare (EACH) and chairs the policy/practice sub-group (pEACH). Find out more about this group at www.each.eu/practice.

**New Chair of the COSA Geriatric Oncology Group**

Professor Meera Agar has been elected as new Chair of the COSA Geriatric Oncology Group, taking over from Professor Christopher Steer who has led the group since its beginning in 2007. The Geriatric Oncology Group is the only Australian collaboration dedicated to cancer care in older adults.
Professor Jennifer Philip—New Chair of Palliative Medicine, Victorian Comprehensive Cancer Centre

Professor Jennifer Philip, Deputy Director, Palliative Medicine at St Vincent’s Hospital Melbourne (and also the PaCCSC Site Investigator for the same hospital) has been appointed to the new role of Chair, Palliative Medicine at the Victorian Comprehensive Cancer Centre (VCCC) as part of the Leaders in Cancer Strategy through the University of Melbourne and St Vincent’s Hospital Melbourne. There was an international search conducted, but the most suitable candidate happened to be close to home.

“This is still a relatively new area of clinical care. There is enormous scope for research and training, and to forge new ideas and directions in palliative care research. More broadly, we want to spark conversations about how we live fully and die well.” - Professor Jenny Philip

The position was announced on 13th January 2017 on the Victorian Comprehensive Cancer Centre’s website www.victorianccc.org.au, and the position is effective immediately from that date.

SAPS recognised in SA Health Awards

Southern Adelaide Palliative Services has been named winner of the Research/Education in Patient/Consumer Safety Award in recognition of 10 years’ research into the management of breathlessness. SAPS are a vital recruiting site for PaCCSC studies, and well-deserving of such an award. Congratulations SAPS team.

Dr Peter Allcroft, SA Health Chief Executive Vickie Kaminski, Vera Margitanovic, Urska Cosic, Aine Greene.

Debra Rowett 2016 Recipient Fred J Boyd Award

Congratulations are also in order for Professor Debra Rowett for receiving the Fred J Boyd Award from the Society of Hospital Pharmacists of Australia (SHPA) in Perth. This award is given to an individual who has made outstanding contributions to hospital pharmacy in Australia and is awarded annually. Professor Debra Rowett is a member of the PaCCSC Scientific Committee as a pharmacy expert.

Debra Rowett receiving award from SHPA President Professor Michael Dooley

PaCCSC Membership

PaCCSC actively encourages membership to extend the underlying knowledge of the Collaborative, to broaden the scope of the trials being conducted, and to prioritise subsequent studies which, among other funding streams, continue to seek competitive category one funding.

Benefits of membership include attendance at the PaCCSC Research Forum, held annually early in the calendar year, receipt of quarterly newsletters, and voting rights for full and associate members.

To learn more about membership and the different levels, please click here. You will be directed to the PaCCSC website.
### PaCCSC 8th Annual Research Forum—Program 2017

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<thead>
<tr>
<th>Time</th>
<th>Activity</th>
<th>Presenter/Institution</th>
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<tbody>
<tr>
<td>8.00am</td>
<td>Registrations Open</td>
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<tr>
<td>9.15-9.25am</td>
<td>Opening Address</td>
<td>Professor David Currow, PaCCSC Chief Investigator</td>
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<tr>
<td>9.25-10.10</td>
<td>Phase III Study Results - Randomised, double blind control trial of megestrol acetate, dexamethasone and placebo in the management of anorexia in people with cancer.</td>
<td>Professor David Currow, PaCCSC Chief Investigator</td>
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<td>10.10-10.40</td>
<td>A pilot study of intravenous ketamine for major depressive disorder in palliative care patients with advanced life limiting illness (Australia Asia-Pacific Clinical Oncology Development (ACORD) Workshop Project.)</td>
<td>Dr Wei Lee, Prince of Wales Hospital, NSW</td>
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<td>10.40-11.00</td>
<td>Morning Tea</td>
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<td>11.00-11.40</td>
<td>Contemporary issues on the statistical landscape</td>
<td>Professor Richard Head, Invited Speaker, University of South Australia</td>
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<td>11.40-12.20</td>
<td>A prospective, randomised, cross-over trial of the efficacy and side effect profile of gabapentin, gamma-linolenic acid, independently and in combination, in the management of uremic pruritus in patients with End Stage Kidney Disease: a pilot study</td>
<td>Dr Frank Brennan, St George Hospital, NSW</td>
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<td>12.20-1.00</td>
<td>Phase II (pilot) cluster randomised controlled trial of a multi-component multi-disciplinary non-pharmacological intervention to prevent delirium for hospitalised people with advanced breast cancer.</td>
<td>Dr Annmarie Hosie, University of Technology Sydney</td>
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<td>1.00-1.40</td>
<td>Lunch</td>
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<td>1.40-2.20</td>
<td>Invited Speaker and Panel Discussion</td>
<td>Professor Tim Shaw, Invited Speaker, University of Sydney</td>
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<td>2.20-2.50</td>
<td>Intranasal fentanyl versus placebo for treatment of episodic breathlessness in advanced non-malignant terminal diseases, a pilot study.</td>
<td>Dr Salina Lupati, Te Omanga Hospice, New Zealand</td>
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<td>2.50-3.10</td>
<td>Does harmonica playing improve dyspnoea in patients with moderate to severe Chronic Obstructive Pulmonary Disease? A randomised study.</td>
<td>Dr Peter Allcroft, Southern Adelaide Palliative Services</td>
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<td>3.10-3.40</td>
<td>A randomised phase 2 feasibility trial of morphine for dyspnoea in patients with interstitial lung disease.</td>
<td>Dr Yoshinobu Matsuda, Kinki-Chuo Chest Medical Center, Osaka, Japan</td>
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<td>3.40-4.00</td>
<td>Afternoon Tea</td>
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<td>4.00-4.15</td>
<td>Pancreatic enzyme replacement therapy (PERT 1). A pilot randomised placebo controlled trial comparing creon with placebo with follow-on treatment for all participants with PERT.</td>
<td>Dr Wendy Muircroft, Southern Adelaide Palliative Services</td>
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<td>4.15-4.30</td>
<td>JORTC PALOB: Efficacy of addition of duloxetine for neuropathic cancer pain refractory to opioids and gabapentinoids: a double-blind, randomised, placebo controlled trial.</td>
<td>Dr Hiromichi Matsuoka, JORTC</td>
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<td>4.30-4.45</td>
<td>Challenges in interpreting Randomised Controlled Trial data for patients and clinical decision making</td>
<td>Professor Geoffrey Mitchell, General Practise and Palliative Care, University of Queensland</td>
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<td>4.45-5.00</td>
<td>Inter-rate agreement in evaluation of abdominal radiographs for faecal shadowing</td>
<td>Professor Katy Clark, Northern Sydney Local Health Network</td>
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<td>5.00pm</td>
<td>Close Presentations</td>
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<td>5.00-6.30</td>
<td>10 Year Anniversary Networking Drinks</td>
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### Upcoming Meeting Dates

**Management Advisory Board Strategic Planning Day:** 12th May 2017

**Scientific Committee:** TBC August/September

**Publications Sub-Committee:** TBC August/September
Pilot and Phase 4 Study Updates

If you would like to be involved in any of the studies below or have a new study idea please contact the PaCCSC office at: paccsc@flinders.edu.au

RAPID Update

The RAPID Pharmacovigilance initiative being conducted by PaCCSC, aims to establish the clinical effect of common medicines used for symptom control in palliative care practice.

Five medication series are now complete with the sixth medication series – **amitriptyline for neuropathic pain** currently open. This series is making excellent progress with data recorded for 37 completed patients. The current intervention series on **hypodermoclysis** is well over the halfway mark, with data for 59 completed patients.

In 2016, an expansion to the current program was initiated and as a result six medication/indication series have been developed on the symptom nodes of pain, breathlessness, gastro-intestinal symptoms, nausea, cognitive disorders and loss of appetite/anorexia. It is proposed to run these six series concurrently:

1. Oxycodone/Naloxone for pain
2. Benzodiazepines for breathlessness
3. Macrogol (Movicol) for constipation
4. Cyclizine for nausea
5. Midazolam for agitation
6. Mirtazapine for appetite

The macrogol (movicol) for constipation series and the oxycodone/naloxone for pain series are in the piloting phase at several sites across the globe. The case report forms for the remaining series are currently in the process of being developed. It is anticipated that these series will be open for data collection later in 2017.

If you would like more information on the RAPID Pharmacovigilance program please refer to www.caresearch.com.au/paccsc or contact Rhiannon Vince rhiannon.vince@flinders.edu.au if your service is interested in participating.

An Australasian perspective on the curative treatment of patients with pancreatic cancer, supportive care, and future directions for management—Wendy Muircroft

*The management of patients with pancreatic cancer requires an individualised approach and the support of a multidisciplinary team to accurately stage patients and determine their suitability for curative treatment. Guidelines have been developed in Australasia to define the operability for patients who have been diagnosed with pancreatic cancer. This is supported by advances in pancreatic cancer genetics, which show potential for developing targeted therapies for pancreatic cancer. Both surgery and targeted therapies aim to extend the overall survival of patients. Patients who are cured of their cancer may live with permanent changes in gut anatomy and physiology leading to distressing symptoms that may not be addressed. Patients who cannot be cured of pancreatic cancer may have supportive care issues that are often complex, and a strategic approach to manage these needs for patients with pancreatic cancer is underdeveloped in Australasia. Supportive care services need to be in a position to adapt patient care as the evidence base develops.*

For the full article, refer to [ecancer.org](http://ecancer.org)

CADET Study—re-opens to recruitment

The CADET: CAncer Dexamethasone Trial (CADET) Part 1: A multi-centre single-arm, feasibility study of oral dexamethasone in the management of cancer-related pain study, has re-opened to recruitment following a revision of the eligibility criteria and protocol amendment. The sample size: 20 participants; the study status is: Open to recruitment with an estimated close date: 31 December 2017.

The study is open at four sites: Sacred Heart, Southern Adelaide Palliative Services, Royal Melbourne Hospital & Barwon Health. Good Luck with recruitment everyone!
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PaCCSC Phase III Study Updates

Nausea Study 3 — successfully CLOSED

Title: A randomised, controlled, double blind study of oral methotrimeprazine versus oral haloperidol in patients with cancer and nausea not related to anticancer therapy (Nausea Study 3)

Study aims: To assess the efficacy of oral methotrimeprazine versus oral haloperidol in patients with cancer and nausea not related to anticancer treatment.

Nausea Study 3 is an RCT similar in design to Study 2. It is a parallel 2 arm study designed to determine the efficacy of regular oral methotrimeprazine (currently used off licence in palliative care) against one of the PBS listed antiemetics (haloperidol) found to be efficacious in study 1.

The first participant was recruited on 26th March 2015. Seven sites across QLD, NSW, Vic and SA recruited participants to the study. Recruitment to the study closed on 24/02/2017 and on Wednesday 1st March 2017 an email from the Chief Investigator, Professor Janet Hardy announced the successful obtainment of the study sample size and formally closed the study. Professor Hardy thanked all the participating sites and their teams for the hard work in recruiting and completing patients on the study. Formal closure procedures are now underway via the QUT Project Office.

A total of 121 participants were randomised to the study and 105 of these participants completed intervention. The final Data Safety Monitoring Committee meeting for Nausea Study 3 will be held on 28th April 2017, with a study activity report, lists of adverse events and protocol violations to be provided for review.

The close of the Nausea 3 study takes the total number of phase III clinical trials sponsored and completed by PaCCSC to be successfully closed to 8 studies. Thank you to all sites for their commitment to Nausea Study 3.

BEAMS

The BEAMS study has now opened at 16 sites with WA soon to come on board. Ten sites have randomised at least one participant. SAPS lead the randomisation tally with 21 out of a total 34.

PaCCSC has placed advertisements with LungNet as a means to attract direct interest from people with COPD with approval from the Ethics Committee. The advertisement is on both the LungNet website and was circulated via direct email. This advertisement has produced approximately 60 direct participant queries with the central office referring patients to their nearest recruiting site.

There has been quite a bit of interest already from these patients with COPD, and it has been worthwhile to give these individuals the opportunity to make first contact. We hope all recruiting sites are following up these referrals and they are being subsequently recruited to the study.

Melatonin Study Funded

Study Title: Randomised double blind placebo controlled phase III trial of oral melatonin for the prevention of delirium in hospitalised advanced cancer patients.

Under Professor Meera Agar as lead investigator, this study has been successful in gaining competitive grant funding from Cancer Australia for three years, through the 2016 Priority-driven Collaborative Cancer Research Scheme. The process for opening the study across a number of recruiting sites has now begun with the study officially opening to recruitment by the end of April. Fortnightly study team meetings are being conducted to keep study initiation progressing and Julie Wilcock is assisting with many of the initiating activities.

Congratulations to Meera and the investigator team on being awarded funding to take this important study forward.
Recent Publications by members of the PaCCSC Site Investigator Team

If you have published a paper in the last three months, please write to us and let us know!


