PaCCSC
Palliative Care Clinical Studies Collaborative

Annual Research Forum 2013

20th March 2013

Flinders University receives funding for the PaCCSC project under the National Palliative Care Program and is supported by the Australian Government Department of Health and Ageing
WELCOME TO THE ANNUAL RESEARCH FORUM 2013: Professor David Currow

INVITED SPEAKER: Associate Professor Janette Vardy
Experiences in clinical trials – the good, the bad and the ugly.
Janette Vardy, MD, FRACP, PhD is a staff medical oncologist working as a clinician researcher at the Sydney Cancer Centre, and is a senior lecturer at the University of Sydney, Australia. She graduated medicine with honors from the University of Newcastle, Australia. She received the Margaret Dunn Resident of the Year award in 1999 and completed internal medicine and specialty training in Medical Oncology, obtaining a Fellowship from the Royal Australasian College of Physicians in 2002. From 2003-2006 she completed a Clinical Research Fellowship at the Princess Margaret Hospital in Toronto and a PhD in Clinical Epidemiology at the University of Toronto under the supervision of Dr Ian Tannock.

Upon returning to Australia in 2007 she received a Cancer Institute New South Wales fellowship which has enabled her to establish a research program in cancer survivorship at the Sydney Cancer Centre. Her primary area of research is in cognitive function and fatigue in cancer survivors. For this work she has received two Young Investigator Awards (ASCO, MASCC), a PhD scholarship and an ASCO Career Development Award.

More recently she has commenced work on establishing trials investigating the benefits of exercise in cancer patients. She is co-chair of the International Cognition and Cancer Task Force, and chair of the Scientific Advisory Committee for the Psycho-Oncology Co-operative Group, Australia.

Cluster randomised trial of clinical pathways for managing symptoms in people with cancer.
<table>
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<tr>
<th>Time</th>
<th>Event Description</th>
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| 11.00 | **NEW STUDY PRESENTATION:** Katherine Clark*, Jane Phillips, Irene Higgins, Brian Kelly, Naomi Byfieldt, Peter Saul, Lisa Shaw, Malcolm Green.  
A stepped wedge randomised trial of implementation of an observation chart for the dying part of usual care for people dying in acute hospitals: promoting optimal care as usual practice. |
| 11.30 | **NEW STUDY PRESENTATION:** Thang Huynh*, Rajesh Aggarwal*, Meera Agar  
Gabapentin for refractory cough in advanced cancer. |
| 12.00 | **NEW STUDY DISCUSSION (no presentation, for discussion only):** Jennifer Philip, Brian Le, Odette Spruyt, Michelle Gold  
An audit of the management of refractory cancer pain in the post ketamine era. |

**Member Presentations**

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<th>Time</th>
<th>Event Description</th>
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| 12.15 | **MEMBER PRESENTATION:** Tracey Bullen  
The use of an emergency medication kit (EMK) in palliative care community practice. |
| 12.30 | **LUNCH**                                                                                                  |
| 1.15  | **MEMBER PRESENTATION:** David Currow, Peter Allcroft, Tim To, Sue Haynes, Aileen Mowat, Aine Greene*  
The role of peripheral opioid receptors in modulating breathlessness. An *in vivo* placebo controlled, cross over, double blind study of naloxone and methylnaltrexone on breathlessness during exercise in people with chronic obstructive pulmonary disease. |
| 1.30  | **MEMBER PRESENTATION:** Geoff Mitchell*, Jane Nikles, Sue-Ann Carmont, Janet Hardy, Phillip Good, Meera Agar, Katherine Clark, Carol Douglas, Rohan Vora, David Currow  
Overview of N-of-1 study suite – lessons learned from three aggregated N-of-1 trials. |
| 1.45  | **MEMBER PRESENTATION:** Natasha Michael*, Clare OCallaghan, Josephine Clayton, Karla Gough, Annabel Pollard, Odette Spruyt, Mei Krishnasamy  
Utilising the Medical Research Council Framework for Complex Interventions to develop and test a cancer specific Advance Care Planning Intervention |
| 2.00  | **MEMBER PRESENTATION:** Paul Tait*, John Gray, Paul Hakendorf, Belinda Morris, David Currow, Debra Rowett  
Community pharmacists: a forgotten resource for palliative care. |
| 2.15  | **MEMBER PRESENTATION:** Katherine Clark  
A multi-site cluster randomised controlled trial comparing the severity of constipation symptoms experienced by palliative care patients receiving usual care compared to those diagnosed and managed according to the underlying |
pathophysiology.
“Management of constipation in palliative care” – FAQ’s

2.35  PaCCSC Website Launch
        Linda Devilee, Belinda Fazekas
        Overview of the new website

2.50  AFTERNOON TEA

3.15  MEMBER PRESENTATION:
        Naomi Byfieldt
        Learning’s from the Critical Appraisal Workshop – 12th December 2012

3.30  MEMBER PRESENTATION:
        Belinda Fazekas
        Monitoring PaCCSC studies – improving quality.

3.45  MEMBER PRESENTATION:
        Janet Hardy
        A two stage trial of antiemetic therapy in patients with cancer and nausea not related to anticancer therapy – FAQ’s

4.05  MEMBER PRESENTATION:
        Natasha Michael*, Jo Phipps-Nelson, Michael Bramwell, Fran Gore, Mei Krishnasamy
        PANCare - Development and testing of a state wide comprehensive care planning service to facilitate care at home for patients with pancreatic cancer.

4.20  CLOSE PRESENTATIONS

* Denotes presenter

4.30 – MAB Meeting and Site Coordinator Meeting (See Meeting Agenda’s for more information)
6.00 – Close
Flinders University receives funding for the PaCCSC project under the National Palliative Care Program and is supported by the Australian Government Department of Health and Ageing.
Cluster randomised trial of clinical pathways for managing symptoms in people with cancer

**Investigator/s**

**Collaborating partners**
- PaCCSC only
- Other trial groups, specify: PoCoG (Psycho-oncology Co-operative Research Group), ImPaCCT (Improving Palliative Care through Clinical Trials)
- Pharmaceutical companies, specify__________________________________

**Background and rationale (including key papers):**
Cancer symptoms exact a heavy economic burden, both on patients themselves and the Australian health system. Despite the availability of evidence-based guidelines and pathways, their use is limited in the absence of targeted and tailored implementation strategies (1). A range of healthcare system, provider and consumer factors contribute to this, leading to healthcare disparities. Clinical pathways give step-by-step instructions on how to implement evidence-based assessment and management along with a framework for evaluation. Best-practice clinical pathways, providing guidance to both patients and clinicians, have been shown to result in cost-effective improvements in patient outcomes (2, 3).

Most people with advanced cancer present with multiple physical symptoms, and their psychosocial concerns also need consideration. People with cancer at earlier stages may also present with symptoms and also suffer adverse effects from active treatment. Assessment and management should be patient-centred; determining an overall symptom profile for each person and developing a coordinated assessment and management plan, rather than considering each symptom in isolation or from a purely biomedical perspective. Treating one symptom may benefit another (e.g. treating anxiety also improves breathlessness), and one treatment may target more than one symptom (e.g. opioids for pain and dyspnoea); there may also be cumulative adverse effects from multiple treatments (4). Accurate assessment of symptom burden requires a detailed history, consideration of personal circumstances and co-morbidities, as well as involvement of the patient in shared decision-making regarding their priorities and the treatment goals. Assessing and managing co-occurring symptoms within a person-centred model will be a distinguishing characteristic of the proposed study, building on the unique collaboration proposed between oncology, palliative care and psychosocial researchers.

**Study objectives:**

**Aim**
To evaluate the capacity of multiple harmonised clinical pathways to provide cost-effective symptom relief and improvement to quality of life in people with cancer.

**Null hypothesis**
Assessment and management of cancer symptoms in accordance with multiple harmonised clinical pathways will have no impact on symptom relief or quality of life.

**Primary outcome measure**
The primary outcome will be quality of life at 6 weeks, as measured by the FACT-G overall score (5).
QOL has been chosen to provide a common unit of measurement for disparate impacts on multiple symptoms.

**Secondary outcome measure/s**
- Screening measures for each symptom (administered at each patient visit)
- Overall symptom burden (e.g. Edmonton Symptom Assessment Scale; ESAS (6)) at 2, 4 and 6 weeks.
- Impact on unpaid carers as measured by the Carer Experience Scale (CES) (7) at 2, 4 and 6 weeks.
- QOL as measured by the FACT-G overall score and each of its domains at 2 and 4 weeks.

**Study population:**

**Inclusion criteria**
1. Age ≥18 years
2. Cancer of any type and stage
3. Patients receiving treatment at palliative care and oncology departments - outpatients only?
4. Screen positive for one or more symptom for which a clinical pathway is available; candidates may include: pain, anxiety, depression, dyspnoea, delirium, constipation, nausea, vomiting, mucositis.

**Exclusion criteria**
- Patients who have received more than 2 treatment sessions of their most recent symptom management regime

**Any recruitment issues of note:**
A major potential benefit of clinical pathways is to ease transitions and coordination between settings and providers. To test this potential, we might plan to recruit patients receiving concurrent care or transitioning (e.g. between oncology and palliative care).

**Investigational plan:**

**Overall study design**
A multi-centre longitudinal stepped-wedge cluster randomised trial with treatment centre as unit of randomisation will be undertaken to formally evaluate the pathways. A particularly attractive feature of the stepped wedge design is that all clusters (centres) receive the intervention (unlike in a parallel design) and the intervention will not be withdrawn from any clusters (unlike a standard crossover trial) (see Table 1) (8). Expressions of interest have been obtained from 14 NSW treatment centres including regional and rural centres, demonstrating capacity to attain the target number of clusters. Each recruitment period will last 3 months. A new cohort of approximately 10 patients (diagnosed with cancer, over 18 who have attended no more than 2 treatment sessions of their most recent treatment regime) will be recruited at each centre at each period, complete touch screen assessments each time they attend clinic, complete outcome measures at 2, 4 and 6 weeks and then leave the study. Centres will be stratified by metropolitan versus non-metropolitan setting, and randomised within strata by the programme statistician (CI Xuan) as to when they begin training.

**Table 1. Stepped-wedge design for Training and Intervention (interven) across 14 centres over time**

<table>
<thead>
<tr>
<th>Period</th>
<th>Centre 1 &amp; 2</th>
<th>Centre 3 &amp; 4</th>
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<td></td>
<td>Control</td>
<td>Control</td>
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<tr>
<td>1</td>
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<td>2</td>
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<td>9</td>
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<td>Centres 5&amp;6</td>
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<td>Centres 7&amp;8</td>
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<td>Centres 9&amp;10</td>
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<td>Centres 11&amp;12</td>
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<tr>
<td>Centres 13&amp;14</td>
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**Treatment arms**

**Intervention:** Symptom screening at every visit and follow-up assessment and management based on harmonized clinical pathways as required.

**Control:** Usual care, variable by site.

**Intervention/s**

Medical and nursing teams will be trained in using the clinical pathways and provided with associated documentation and resources. Screening will occur utilising the most effective method that can be integrated into local conditions in a sustainable and cost effective way. One option available will be via touch-screen computers such as QUICATOUCH (CI Clover) (9). Where scores are at or above the cut-off, an alert will automatically be sent to the patient’s physician via an email, notifying them that further assessment and management is indicated in accordance with the pathway(s). Staff will then log on to a password-protected website to retrieve data and follow the clinical pathway based on results from screening and subsequent, more detailed assessment. Patients and families will be provided with a consumer version of the relevant pathways. Clinical staff (and with the patient’s permission their GP) will receive a summary report of screening data and a copy will be placed in the patient’s file. The study nurse co-ordinators will facilitate the screening process, and document the management plan, referral and uptake, for those patients identified with symptoms or needs. Adherence to clinical pathways will be monitored via checklists completed by treating clinicians. We will work with participating centres to maintain and monitor implementation of screening and pathways.

**Sample size estimate**

Sample size was calculated based on a 2-sided t-test with type I error 0.05 to detect a minimally important difference in the FACT-G of 4 points, assuming a standard deviation of 15. The cluster design increases the sample size by a design factor of 2.7, assuming an intra-cluster correlation of 0.05 (the correlation between patients’ scores within centre) and 126 patients per centre at 14 sites. Allowing for 10% dropout, a total sample size of 1,764 yields 90% power. A small simulation study using mixed models and stepped wedge longitudinal clustered data confirmed this power approximation.

**Statistical analysis plan**

Linear mixed models will be used to model all continuous outcomes while accounting for the clustering and longitudinal design; allow for testing differences between groups in pattern over time as well as at specific time points.

**Health economic analysis**

A cost-utility analysis will be conducted to evaluate the incremental costs and consequences of clinical pathways relative to usual care. Outcomes will be valued using quality adjusted life years (QALYs) based on utility scores derived from the total FACT-G QOL score (5). FACT-G QOL scores will
be converted into utility scores using published algorithms (10, 11). Cancer also has a considerable impact on informal caregivers’ QOL (12). Consequently, the preference-based Carer Experience Scale (CES) will be used to evaluate the effect of the intervention on unpaid carers (7). Participants will also be asked for permission to link their survey responses to health service utilisation data. Most data can be accessed through the Centre for Health Record Linkage (to which we have low-cost access through the University of Sydney Cancer Network membership), and from Commonwealth datasets (e.g. Medicare; PBS). Variables include: The ARDRG code (which provides a way of grouping episodes of care in a hospital according to clinical characteristics and resource use); number of hospitalizations; length of hospital stays; number of emergency dept visits; outpatient visits; psychology/psychiatry visits; non-hospital Medicare services such as the number of GP visits; health insurance status; medication usage; number of Cancer Care Case conferences; and Chronic Disease Management Items. The primary outcome measure for the cost-utility study will be the incremental cost per QALY. As economic data may be skewed, confidence intervals will be estimated with bootstrap methods (13). Sensitivity analysis will examine the effect of any assumptions, and determine which cost components drive the results.

Ethics, including any perceived/real issues with ethics approval
Ethics approval has been granted by the Cancer Institute NSW HREC for piloting of the clinical pathway for cancer pain. The pathways are intended to change practice only insofar as this deviates from current evidence-based care.

Other trials or initiatives with which this proposed study links
Participation in this study and other PaCCSC studies on symptom assessment and management (e.g. delirium and constipation) would be incompatible, and a decision would need to be made as to how to handle this.

Equipment or other resources required to conduct the study
Equipment requirements at each site are limited to touch-screen computers for symptom screening. Collaboration with IT departments at each site will be needed to integrate computerized screening into local systems. Substantial costs will be incurred in enabling screening data to be streamed to a central site. The team plans to submit to the Cancer Institute NSW Program Grant Translational Research scheme (closes 28 June 2010) and/or NHMRC Partnership (closes 30th April and 6th Aug) schemes for funding.

References


A stepped wedge randomised trial of implementation of an observation chart for the dying part of usual care for people dying in acute hospitals: promoting optimal care as usual practise

Investigator/s
Katherine Clark*
Jane Phillips
Irene Higgins
Brian Kelly
Naomi Byfieldt
Peter Saul
Lisa Shaw
Malcolm Green

Collaborating partners
☐ PaCCSC only
☐ Other trial groups, specify__________________
☐ Pharmaceutical companies, specify__________________

Background and rationale (including key papers):
A lack of an agreed standard of care for people dying in acute hospitals:
Despite the fact that most deaths occur in acute settings, many such settings do not have agreed approaches in place to ensure that quality care is provided for the imminently dying. As a result, hospital deaths are often identified as less than satisfactory by both relatives and health care providers, with the care delivered often in stark contrast to what people facing imminent death have defined as a good death. In summary, some attributes of a good death as described by people imminently facing death include:
1). Provision of pain and symptom management;
2). Preservation of a person’s dignity;
3). Family’s presence and a sense of support for the family;
4). Transparent Communication with the person and their family particularly around the timing of death and what is to be expected.

However actual reports of hospital deaths suggest that deaths are often remarkable to poor symptom control and limited communication.
Our own observations support the published literature. We recently completed an audit of teaching hospital deaths to retrospectively examine if the care actually delivered would have addressed four distinct issues that have been identified as important to people facing imminent death, namely communication, monitoring of symptoms, adequately addressing symptoms and minimisation of the burden of care.
The results identified the following:
1). In the hospitals where the deaths occurred there is no standard approach to documenting that death is imminent with very little detail to elaborate what people’s wishes were around the care they received;
2) Very few people had symptoms monitored but 50% had usual vital signs continued. This is despite the fact that pain scores are considered a routine observation on this chart;
3). The lack of documentation around people’s expectations and their experiences made it very difficult to understand why medications were ordered and administered;
4) 40% of people had investigations after death had been diagnosed as imminent.

An alternative model of care is required that adopts a principle of quality health care i.e. health care delivery that is safe, readily accessible to those who require it, effective and aligns with
people’s expectations.

**State-wide audit of care of the dying**

Improving care of the dying has been identified as a matter of importance to NSW Health. As a baseline to identify areas for improvement, the NSW Health Clinical Excellence Commission asked the LHD to report on their perceived capacity to care for dying people, with this report highlighting the absence of agreed approaches to caring for the dying.

This is not to suggest that there are initiatives in place to try and improve the situation. That is not to say there are not attempts to improve care nationally and internationally. The most discussed and commonly adopted approach is the use of pathways for the dying. Of these, the most popular is the Liverpool Pathway for the Dying, an approach designed to guide health professional’s care for people identified as dying. In summary, the Liverpool Pathway is implemented once agreement is reached by health professionals caring for the person with the pathway template inserted in the medical record, replacing usual in-patient notes. Whilst this approach has been widely adopted, the fact that evidence-base that supports it is poor is inescapable. So far, two high-quality systematic reviews have highlighted that the pathway is not evidenced-based with most of the published data that supports the pathway’s use based on case reports. The association of the Liverpool Pathway with the use of sedation has prompted some observers to question the safety of the Liverpool Pathway in inexperienced hands. As a result, in the United Kingdom there have been calls from both professional and community bodies to review the safety of this approach.

**Routine observations to improve identification of problems requiring a timely response**

Ensuring that people are observed and regularly monitored in order to identify when it is necessary to respond to changes in their condition is accepted as best practice in acute hospitals. An example of such a system is the NSW Health “Between the flags” program. This system has adopted colour coded charts for recording people’s vital signs allowing for easy visual recognition of deterioration. Changes in people’s vital signs prompt clinical reviews with the urgency of the clinical review based on the severity of the problem. Alongside mandatory training in the use of the charts for all health professionals, the charts are accompanied by educational manuals. As well as a standard adult observation chart which focuses mostly on vital signs (blood pressure,
temperature, pulse, respiratory rate, oxygen saturations, pain), there are other charts for specific populations including maternity services and paediatrics.

**An observation chart for the dying**

Routine observations of people’s vital signs and implementation of timely and appropriate responses based on these observations is considered best practice to improve the safety of people’s hospital experiences. There is no reason that care of the dying should be different. To achieve this, a simple track and trigger chart based on validated tools that measure elements that families have identified as important aspects of quality care of their dying relatives has been developed. Once a person has been identified by the hospital-team caring for this person, they are either switched to this observation chart or the chart is added to existing observations to ensure that symptoms most likely to bother people are observed for. The chart uses numerical analogue scores to measure pain, breathing problems, agitation, nausea and family distress with the tools adopted for this chart being the same as those recommended by the Department of Health and Aged funded Australian Palliative Care Clinical Outcomes Collaborative. This means that the observations selected are:

1. Partially validated for use in the terminally ill in an Australian context
2. Already in everyday use in palliative care services across Australia.

As well as being standard palliative care observations, there is research that supports that changes in numerical scores are clinically meaningful for people. Furthermore, the numerical analogue scores allow specific calling criteria to be defined improving the capacity of staff to mobilise extra support. The family of dying people also might require assistance with the observation chart requiring families to be regularly reviewed ensuring ongoing interactions with not only the patient but also the patient and their family, another issue currently seen as lacking in acute care. Supporting the everyday use of the observation chart will be an accompanying manual that wherever possible will summarise evidence-based approaches to managing common problems at the end of life. Where the evidence is less robust, consensus opinion from an expert working party of palliative care clinicians sought to identify the optimal approaches to problems.

**Proposal**

This study will adopted a randomized, stepped-wedge approach to investigate if the process of integrating an observation chart for the dying:

1. Improves health professional’s self-assessed competency and capacity when faced with the care of dying people in acute hospital situations.
2. Improves the relatives of the person who has died perception of the quality of death experienced in an acute hospital situation.

**Study objectives:**

**Aim**

The primary aim of this project is to evaluate whether the implementation an evidence-based observation chart supported by a structured education program and accompanying manual improves:

1. Staff’s attitude and competencies when caring for people in the last 24-48 hours of life in acute medical inpatient units.
2. Family’s perception of the quality of care delivered to dying people in acute hospitals

**Null hypothesis**

- Issues identified as important to people are not better addressed when a routine observation chart is integrated into usual practice compared to currently accepted practice in acute hospitals;
- The perception of the relatives of the dying person regarding the quality of care is no different when usual care is delivered compared to when the observation chart for the dying is incorporated in to the care plan;
Health care professionals will not find care of the dying less stressful when they understand what observations are applicable to dying people.

**Primary outcome measure**
The primary outcomes of interest are staff attitudes and competency and family perceptions of the quality of care.

**Staff:**
Changes in attitudes before and after implementation of the observation chart and the education package towards caring for dying people on acute medical wards will be assessed using the validated 7-item Thanatophobia scale.

Changes in ability to provide effective care for a dying patient will be measured before and after the implementation of the education package and chart using the Self-efficacy in palliative care scale. For this study, only the sections on communication and patient management will be administered making this a 16-item questionnaire.

**Relatives:**
Families’ experiences will be assessed by the completion of the Quality of Death and Dying (QODD) questionnaire. This 31-item tool will be completed one month after death. The bereaved family will be approached approximately one month after the death of their family member and asked if they would complete the questionnaire. A research nurse will organise a time and place that is convenient for the family to assist them with this. The nurse helping the family also makes it possible to ensure that the completion of the tool does not evoke significant distress. The nurse’s presence makes it possible to expedite contact with either a pastoral care worker or social worker if necessary.

**Secondary outcome measure/s**
- The costs of delivering care before and after implementation of the chart will be assessed. This will be undertaken by comparing the difference between ordering of investigations before and after the implementation of the chart
- The differences in prescribing before and after implementation of the chart and attendant education will be compared.
- The number of complaints regarding the care of dying people
- The completeness with the chart is utilised

**Study population:**

**Inclusion criteria**
- People identified as dying as per usual practice in acute hospital settings which may include one or more of the following:
  - As indicated on a MOLST tool
  - Entry in the inpatient medical record that states this person is likely to shortly die
  - Completion of a DNR order
- Admitting clinician agrees that this person is imminently dying

**Exclusion criteria**
- Aim of management is treating a reversible disorder

**Any recruitment issues of note:**

**Investigational plan:**

**Overall study design**
A stepped wedge design is proposed with the participating sites allocated in a random fashion to commence training and implementation for sites randomly assigned. The study will be conducted as two discrete components:
a) Training of the medical and nursing staff in the use of the observation chart;
b) Real care of dying people when they have been identified as dying and have been placed on the Observation Chart for the Dying.

The design for this randomised study is a stepped wedge cluster design, a type of crossover design in which different clusters i.e. the 4 clinical sites are crossed over in one direction only, from Control to Training then Intervention as outlined in table 1 below. (reference)

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<thead>
<tr>
<th>Study Population and participating sites</th>
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<tr>
<td>The study will be conducted in four acute medical wards across NSW.</td>
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<tr>
<td>1). Health professionals</td>
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<tr>
<td>The nursing and resident medical staff of four acute medical wards will receive a structured education program focusing on improving diagnosing death and providing care to a person who is imminently dying. This will be supported by an information manual. Before and after completing the education program, staff will be invited to complete two questionnaires designed to consider their attitudes towards caring for dying patients and their self-assessed competencies.</td>
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<tr>
<td>2). Families of people diagnosed as dying</td>
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<tr>
<td>Relatives of people identified as dying will be approached to ascertain if they would comment on their impression of the care offered to their relative in the final hours to days of life at a discrete time point after their relatives’ death.</td>
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<th>Study Processes</th>
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<tr>
<td>a) Training of the medical and nursing staff in the use of the observation chart;</td>
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<tr>
<td>b) Real care of dying people when they have been identified as dying and have been placed on the Observation Chart for the Dying.</td>
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<tr>
<td>c) Follow up with family following the death of the patient.</td>
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<th>Interventions</th>
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<td>1. A structured education program will be delivered to the nursing and medical staff involved in the day-to-day care of dying inpatients on general medical wards. This will be based on best evidence and aligned with the manual being developed to support the observation chart. The education package will be developed by palliative care experts (medical and nursing) and will be reviewed by independent experts. Topics covered will include managing pain, anxiety and breathing problems at the end of life, approaching distressed families, communication skills.</td>
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| 2. Implementation of the already developed Observation Chart for the Dying. This chart is aligned in appearance with the NSW standard observation chart which is itself a track and trigger chart developed with the purpose of identifying deteriorating patients and responding appropriately. The main difference between this chart and the newly developed observation chart of the dying is the different vital signs identified as necessary to ensure the vital signs of dying patients are observed for and when necessary responded to appropriately. Based on the
literature, this includes pain, anxiety and breathing problems. Charting these signs is undertaken with numerical analogue scores, an approach supported in the literature as objective and repeatable. This chart is commenced when people have been identified as likely to die in the next 24-48 hours after all reversible causes of deterioration have been considered according to usual practice. The main difference between commencement of the observation chart for the dying and usual care is that usual care is associated with cessation of other observations.

The nominated next of kin identified from medical records will be contacted by the research team 6 weeks after the person’s death and asked to participate in an interview to complete the Quality of Death and Dying (QODD) questionnaire regarding their families of people who died.

**Outcomes and measure**

The primary outcomes of interest are staff attitudes and competency and family perceptions of the quality of care.

**Staff outcomes:**

- Changes in attitudes before and after implementation of the observation chart and the education package towards caring for dying people on acute medical wards will be assessed using the validated 7-item Thanatophobia scale.
- Changes in ability to provide effective care for a dying patient will be measured before and after the implementation of the education package and chart using the Self-efficacy in palliative care scale. For this study, only the sections on communication and patient management will be administered making this a 16-item questionnaire.

**Family outcomes:**

- Families’ experiences will be assessed by the completion of the Quality of Death and Dying (QODD) questionnaire. This 31-item tool will be completed one month after death. The bereaved family will be approached approximately one month after the death of their family member and asked if they would complete the questionnaire. A research nurse will organise a time and place that is convenient for the family to assist them with this. The nurse helping the family also makes it possible to ensure that the completion of the tool does not evoke significant distress. The nurse’s presence makes it possible to expedite contact with a social worker if necessary.

**Other outcomes:**

- The costs of delivering care before and after implementation of the chart will be assessed. This will be undertaken by comparing care post-implementation of the chart with baseline data collected before implementation of the chart in terms of investigations, clinical reviews undertaken.
- The differences in prescribing before and after implementation of the education program and chart.
- Whether there is any difference in the number of IIMS made around the care of dying people reports
- Improvement in quality of death as assessed by the HNE death audit proforma with the death reviews undertaken by an independent auditor such as those engaged by clinical governance units
- Repeat CEC QSA

**Sample size estimate**

This will depend upon the pilot

**Statistical analysis plan**

Pending based on pilot data
**Health economic analysis**  
Pending, based on pilot data

**Ethics, including any perceived/real issues with ethics approval**  
Pilot proposal submitted to HNE HREC as low risk application

**Other trials or initiatives with which this proposed study links**
- Pilot study
- Other PaCCSC studies that are examining evidence-based approaches to managing symptoms such as noisy breathing, breathlessness, nausea and delirium
- HNE LHD, NSW Health commitment to improving end of life care

**Equipment or other resources required to conduct the study**  
The main requirement of this study will be sufficient human resources to ensure completion
Gabapentin for refractory cough in life-limiting disease

Investigator/s  Dr Thang Huynh*, Dr Rajesh Aggarwal*, Dr Meera Agar (Liverpool Hospital, NSW)

Collaborating partners  
- PaCCSC only
- Other trial groups, Dr Nicole Ryan – Researcher, Hunter Medical Research Institute, Newcastle NSW
- Pharmaceutical companies

Background and rationale (including key papers):
A recent positive RCT by Ryan et al (2012) showed that Gabapentin was effective in treating chronic idiopathic refractory cough. We aim to:
1) undertake pilot study to establish the feasibility of trial design and recruitment rates
2) develop a phase III protocol
to evaluate whether Gabapentin is effective and well-tolerated in our population of palliative patients with refractory chronic cough due to underlying disease.
If the pilot study is successful, we aim to proceed to full RCT and also will submit for NHMRC funding.

Key papers

- RCT of gabapentin (n=32) vs placebo (n=30) in non-palliative care population.
- Outpatient adults with idiopathic chronic cough (longer than 8 weeks) from John Hunter Hospital, Newcastle over a 2-year recruitment period
- Gabapentin escalation to 1800mg/day, continued for 8 weeks then weaned
- Gabapentin significantly improved cough-specific quality of life compared with placebo according to Leicester Cough Questionaire (LCQ)
  - Gabapentin Mean change in LCQ score +2.5 (SD 3.3) vs Placebo Mean change in LCQ score +1.1 (SD 4.7). [95% CI of 0.56 to 3.04, p=0.004]
- Significant Cough frequency reduction (coughs/hr)
  - Gabapentin -22.5 vs Placebo -4.3 [95% CI of -51.75 to -2.88, p=0.028]

- Good summary of current validated tools used in cough studies. Also brief discussion of currently used antitussive agents. Non-palliative care population

- 17 eligible studies reviewed but overall, an absence of credible evidence to make recommendations for cough in cancer.

- Cohort analysis of 35 patients (Non-palliative care) commenced on gabapentin for chronic cough. Gabapentin 600mg bd for 4 weeks
- Mean reduction of cough VAS severity score of 2.8/10. \(p=0.0001\).
- Only used a component of the complete LCQ

- Gabapentin 100-900mg/day effective in chronic cough. N=28

**Study objectives:**
To determine in patients with life-limiting disease with refractory cough, whether Gabapentin can:
- reduce duration, severity and frequency of cough
- improve cough-specific Quality of Life

**Null hypothesis**
Gabapentin in patients with life-limiting disease, does not improve:
- persistent cough
- cough-specific Quality of Life
- cough severity and frequency

**Primary outcome measure**
Leicester Cough Monitor (LCM) : 24 hour recording
- Cough frequency
Leicester Cough Questionnaire (LCQ)
- Cough severity and cough specific QOL
Visual analogue scale (VAS)
  - Cough severity
Gabapentin toxicity Assessment (RAPID Pharmacovigilance Study)

**Secondary outcome measure/s**
QOL Questionnaire (SF-36)
Brief Pain Inventory (BPI)
VAS for Breathlessness
Cough Diary

**Study population:**

**Inclusion criteria**
Malignant and non-malignant patients (>18yrs age) with life-limiting illness with symptomatic refractory cough
Able to swallow tablets
Definition of refractory cough
- cough>4 weeks duration prior to trial
- must have had investigation and treatment for reversible causes
- Negative response to previous use of opioids/other traditional anti-tussives
No change in baseline opioid dose for >48 hours prior to study commencing. (Similar to Ketamine Study)

**Exclusion criteria**
Patients already on Gabapentin / Pregabalin
Contraindication to gabapentin or placebo ingredients
Evidence of acute chest infection (i.e purulent sputum, active fever/sweats/chills)
- Respiratory tract infection in past 1 month
Current smokers but not ex-smokers
Patients on ACE Inhibitors with cough
Patients with significant renal failure (Cr>150 or eGFR<30mL/min)
Documented brain metastases Why?
Acute delirium
Unable to provide consent
Estimated prognosis <4 weeks (?) as per PAP Score

**Any recruitment issues of note:**
Study accrual rate uncertain
Confounding factors – opioids and methadone
Prevalence of refractory cough is relatively low.
Setting ? inpatient PCU vs. outpatient/community

**Investigational plan:**

**Overall study design**
Pilot Study – Small RCT with 10 patients in each arm

**Treatment arms**
Gabapentin vs. inactive placebo

**Intervention/s**
5 days of up-titration (200mg bd, 400mg bd, 600mg bd every 2nd day), 4 weeks on maximum tolerated dose, 5 days down-titration

**Assessments**

<table>
<thead>
<tr>
<th>Days</th>
<th>Measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>LCM (coughs/hr), LCQ, VAS for cough, BPI, VAS for SOB, SF36</td>
</tr>
<tr>
<td>5</td>
<td>LCM (coughs/hr)</td>
</tr>
<tr>
<td>10</td>
<td>LCM (coughs/hr)</td>
</tr>
<tr>
<td>14</td>
<td>LCM (coughs/hr), LCQ, VAS for cough, BPI, VAS for SOB, SF36</td>
</tr>
<tr>
<td>28</td>
<td>LCM (coughs/hr), LCQ, VAS for cough, BPI, VAS for SOB, SF36</td>
</tr>
<tr>
<td>35</td>
<td>LCM (coughs/hr), LCQ, VAS for cough, BPI, VAS for SOB, SF36</td>
</tr>
</tbody>
</table>

Review of cough diary and record of toxicity score at Days 5, 14 and 28.

**Sample size estimate**
Pilot study - 5 – 10 in each arm
Full RCT – 55 in each arm assuming similar results to Ryan 2010 trial
i.e. Effect size LCQ change active arm 2.5 (SD 3.3)
and LCQ change Placebo arm 1.1 (SD 4.7)

**Statistical analysis plan**
Collaborator Dr Wei Xuan, Statistician Ingham Institute for Medical Research
ANCOVA-type model to examine differences between groups during treatment.

**Health economic analysis**
Resource use: other meds for cough, admissions
Impacts: reduction in cough, toxicities of gabapentin, impacts on sleep esp. if nocturnal cough and hence daytime function

**Ethics, including any perceived/real issues with ethics approval**
Gabapentin widely used for neuropathic pain in Palliative and chronic pain population.
Already one published positive study showing effect of Gabapentin at higher doses in idiopathic refractory cough with minimal side effects.
Retention rates – RCTs in patients with life-limiting illnesses
Placebo arm essential in absence of comparator arm of proven benefit
Clinicians perceived role for methadone in cough management
Duration of study and burden of longer study
<table>
<thead>
<tr>
<th>Other trials or initiatives with which this proposed study links</th>
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<tbody>
<tr>
<td>No</td>
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<table>
<thead>
<tr>
<th>Equipment or other resources required to conduct the study</th>
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<tbody>
<tr>
<td>LCM monitor – Device with microphone that can do 24hrs monitoring for patients cough and LCM software for interpretation. (Enquiries being made to Sergio Matos in regards to cost and accessibility)</td>
</tr>
<tr>
<td>Compounding Pharmacy or Pharmaceutical Company supply of active vs. placebo</td>
</tr>
<tr>
<td>Research nurse for data collection</td>
</tr>
<tr>
<td>Statistician</td>
</tr>
</tbody>
</table>
An audit of the management of refractory cancer pain in the post ketamine era

Investigator/s:
Jennifer Philip,
Brian Le,
Odette Spruyt,
Michelle Gold

Collaborating partners
☒ PaCCSC only
☐ Other trial groups, specify________________
☐ Pharmaceutical companies, specify________________

Background and rationale (including key papers):
Following the publication of Australian data which revealed that ketamine was no more effective than placebo for the management of refractory cancer pain, many clinicians have reviewed their practice. There are few rigorous data to inform the management of refractory cancer pain using other strategies, so clinicians are making decisions based upon small trials, case series, expert opinion and anecdotes. There is a need to understand current practice and to evaluate, using standardized measures, the response and toxicity of such analgesic interventions. These data may be used to inform future randomized controlled trials of analgesic measures for this patient population.

Study objectives:
Aim: Primary aim: to document the current management of refractory pain in palliative care population
Secondary aims: to undertake a standardized method of evaluation of:
- Analgesic response to the interventions
- Toxicity associated with the interventions.

Null hypothesis N/A

Primary outcome measure
- The documented chosen therapeutic intervention

Secondary outcome measure/s for 3 days
- Pain scores
- Opioid doses last 24 hours (oral morphine equivalents)
- Toxicity measures
- Medication changes

Study population:
Inclusion criteria
- The presence of refractory pain in the setting of cancer, where refractory is defined as:
  - Average pain score on BPI of at least 3 in past 24 hours
  - If nociceptive pain (LANS <12) have received opioids and at least NSAID+/- paracetamol +/− corticosteroids for at least 48 hours unless specifically contraindicated by side effects or intolerance
  - AND / OR If neuropathic pain (LANS ≥12) have received opioids and at least one
antidepressant +/- anticonvulsant for at least 48 hours unless specifically contraindicated by side effects or intolerance
- AND be deemed to have refractory pain by the treating clinicians whereby an additional analgesic measure is required

Exclusion criteria
- Cognitive impairment as determined by the treating clinician such that unable to rate pain levels

Any recruitment issues of note:
Discussion around:
- Definition of refractory
- Length of time to monitor

Investigational plan:
Overall study design

Baseline measures:
- Details of pain including: site, presumed aetiology (eg bone pain, radicular pain, peripheral neuropathy, maybe other features??)
  - The Edmonton Classification System for Cancer Pain (ECS-CP)
  - Pain score
  - LANSS score
  - Opioid doses last 24 hours; record as baseline and breakthrough doses
  - Toxicity measures (as per ketamine toxicity assessment form and Nudesc)
  - Decision of therapy; please include as much detail as you are able to.
    o Opioid dose change: Please specify _____________
    o Opioid rotation: Details
    o Other drug dose change: Please specify
    o Ceased medication: Please list
    o Added medication 1: Details (drug name, dose, route)
    o Added medication 2: Details (drug name, dose, route)
    o Added medication 3: Details (drug name, dose, route)
  - Reason why this chosen
    o Change 1 Reason:
    o Change 2 Reason:
    o Etc

Please use this space to explain other factors important in your decision, eg renal impairment, other co-morbidities, previously documented drug allergy or intolerance.

Measures at Day 1:
- Pain score
- Opioid doses last 24 hours; record as baseline and breakthrough doses
- Toxicity measures
- Medication changes

Measures at Day 2:
- Pain score
- Opioid doses last 24 hours; record as baseline and breakthrough doses
- Toxicity measures
- Medication changes

Measures at Day 3:
- Pain score
- Opioid doses last 24 hours; record as baseline and breakthrough doses
- Toxicity measures
- Medication changes

<table>
<thead>
<tr>
<th>Treatment arms</th>
<th>N/A</th>
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<tbody>
<tr>
<td>Intervention/s</td>
<td>N/A</td>
</tr>
<tr>
<td>Sample size estimate</td>
<td>approx. 200</td>
</tr>
<tr>
<td>Statistical analysis plan</td>
<td>simple descriptive statistics</td>
</tr>
<tr>
<td>Health economic analysis</td>
<td>N/A</td>
</tr>
<tr>
<td>Ethics, including any perceived/real issues with ethics approval</td>
<td>No. Likely to require ethics approval unlike pharmacovigilance as measuring pain scores, but of note, no other patient direct data.</td>
</tr>
<tr>
<td>Other trials or initiatives with which this proposed study links</td>
<td>Is follow up from ketamine study and survey Will give baseline data on future analgesic studies, ie what is the usual practice and what should be next evaluated.</td>
</tr>
<tr>
<td>Equipment or other resources required to conduct the study</td>
<td>Study nurse monitoring</td>
</tr>
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</table>
PaCCSC
Palliative Care Clinical Studies Collaborative

Annual Research Forum 2013

Member Presentations
The use of an emergency medication kit (EMK) in palliative care community practice

Authors (Full list, * marks corresponding author)
Dr Tracey Bullen*, Kate Maher, Dr John Rosenberg, Brad Smith

Brief overview of the study (include basic methodology)
Previous studies evaluating the use of EMKs with palliative care patients indicate it increases the number of home deaths and decreases the number of unscheduled nursing visits as symptoms are relieved within a shorter period of time. However, the caregiver experience of EMKs in the home has not been assessed directly in this context to date.

Newly admitted patient-caregiver dyads to the community palliative care service will be recruited. They will be supplied with an EMK containing a medication diary and medicines that are frequently used to address common symptoms that can arise unexpectedly, such as pain or breathlessness. Caregivers will be asked to complete a questionnaire at admission, three and six months post recruitment to determine the impact of the intervention on their perceptions of self efficacy to provide care.

The aims of the study are as follows:
1. To determine if the provision of emergency medication packs in the patient’s home reduces inpatient admission and unscheduled emergency home visits.
2. To evaluate the impact of EMKs upon caregiver self efficacy.

What worked well/is working well
1. CNC screening for eligible patients (55% of all patients met eligibility criteria)
2. Completion of audit forms when kits are accessed
3. 100% recruitment participation rate of eligible patient/carer dyads

What didn’t work well/isn’t working well
1. Strict supervision of the recruitment process is required to ensure consent forms are returned in a timely fashion.

Results (if available)/future directions
1. To date 47 dyads have been recruited since the trial commenced in November 2012.
2. 20 patients recruited have died, 70% did so in their preferred place of death. 61% of deceased patients died at home.

Prevalence survey:
3. 27% response rate (49/179) of email invitations sent.
4. 60% of respondents from community services indicated they do not utilize emergency medication kits (EMK)
5. 88% of respondents felt an EMK would improve patient care and that 58% of respondents felt current practice in obtaining parenterals required improvement.

Future directions
6. There is a need to improve medication management and assess the impact upon patients and caregivers across services. Researching this practice change across multiple sites in a larger scale trial is warranted.

What would you do differently next time
The role of peripheral opioid receptors in modulating breathlessness. An in vivo placebo controlled, cross over, double blind study of naloxone and methylnaltrexone on breathlessness during exercise in people with chronic obstructive pulmonary disease.

**Authors**
David Currow, Peter Allcroft, Tim To, Sue Haynes Aileen Mowat, Aine Greene*.

**Brief overview of the study**
Recent work from the United States has demonstrated that a person’s own (endogenous) opioids help to modulate the feeling of dyspnoea in people with COPD while exercising. [Mahler 2009] This double blind, crossover study was conducted on 17 participants with moderate to severe COPD. Their maximal exercise tolerance on both speed and inclination on a treadmill were calculated for each participant. On separate days before exercising to 75% of maximal exercise tolerance for as long as possible, participants were randomly administered either intravenous normal saline or intravenous naloxone, an opioid antagonist that has central and peripheral actions.

When participants were administered naloxone, they were markedly more breathless with no change in work effort demonstrated when compared to normal saline. This strongly supports a role for endogenous opioids in reducing the subjective sensation of dyspnoea. More recently, methylnaltrexone, an opioid antagonist that does not cross the blood-brain barrier has become available. In routine clinical practice, the aim of combining methylnaltrexone with an opioid agonist such as morphine or oxycodone is to reduce the peripheral effects of opioids (specifically constipation) while ensuring that central effects (analgesia) continue.

By adding a methylnaltrexone arm to the experiment by Mahler, important questions about the relationship between opioids and the modulation of dyspnoea by peripheral opioid receptors (especially in the large airways) can be answered:

1. Does the blockade of peripheral opioid receptors lessen the impact of opioids in modulating the sensation of dyspnoea during exertion?

**What has worked or is working well**
The inter-relationships between the nursing teams across the 3 departments
Support from biomedical engineering who set up our computer program, advised us on equipment and devised a pole to support respiratory tubing.
The Palliative Care medical team members who volunteer for our roster every Friday afternoon.
We get access to respiratory patients for our other respiratory studies.
Bringing the patients into the unit for their eligibility medical

**What is problematic**
The study commencement was protracted as we had little control over equipment and room availability
Borrowing equipment for prolonged periods of time due to budget constraints.
Palliative Care research team members working in the cardiology department. We feel like the cuckoo being in someone else’s nest.
Transporting our equipment across the hospital.
Working with interdepartmental staff dynamics leading to conflict in respiratory and cardiology
The ongoing need to feed egos
We only have access to the room one afternoon per week
Agreement from a host referring who then starts recruiting to competing studies without
telling us.

<table>
<thead>
<tr>
<th>What would be done differently next time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Have the head of Cardiology and the Respiratory Scientist on the protocol as investigators so they had ownership of the study.</td>
</tr>
<tr>
<td>Purchase some of the necessary equipment</td>
</tr>
<tr>
<td>Run the study on healthy volunteers</td>
</tr>
</tbody>
</table>
## Overview of N-of-1 study suite – lessons learned from three aggregated N-of-1 trials

<table>
<thead>
<tr>
<th>Authors (Full list, * marks corresponding author)</th>
</tr>
</thead>
</table>

### Brief overview of the study (include basic methodology)

N-of-1 studies are individualized multi-cycle, placebo-controlled, double-blind studies, assessed by validated treatments of effect. They are usually used to determine if a treatment works in an individual. However, they can be aggregated to determine a population level treatment of effect, and require a fraction of the sample size of an RCT. Few n-of-1 studies have been completed, so in addition to answering clinical question, it is important to evaluate n-of-1 trials as a method, particularly to assess when they are most appropriate. We have completed three trials – methylphenidate (MPH) in fatigue, pilocarpine drops in dry mouth, and paracetamol for people on stable doses of opioids. Bayesian statistics were used to assess outcomes.

### What worked well/is working well

For MPH, the use of a dose finding study informed the study design. The sample size target was exceeded. It was possible to identify individuals who responded to the test treatment, and those who were made worse by them. However, the study may have lacked the power to identify predictors of response.

### What didn’t work well/isn’t working well

Powered for a clinical effect. In future, consider power study to identify characteristics of responders and non-responders. Time taken to get regulatory requirements in place in different states is extraordinary.

### Results (if available)/future directions

Population effect not significant, but eight patients had important positive effects and one had definite harm from MPH, all hidden within the population results. Future directions – opportunity to explore pharmacogenetics with future trials identifying responders and non-responders.

### What would you do differently next time

Consider changing the question to one identifying responders, and adjust sample size accordingly. Lengthen time of study to reflect major complexity in managing a trial of Schedule 8 drugs in multiple jurisdictions.
Utilising the Medical Research Council Framework for Complex Interventions to develop and test a cancer specific advance care planning intervention

<table>
<thead>
<tr>
<th>Authors</th>
<th>Natasha Michael*, Clare O’Callaghan, Mei Krishnasamy, Karla Gough, Odette Spruyt, Annabel Pollard, Josephine Clayton</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brief overview of the study</td>
<td>To test the feasibility of the intervention to improve satisfaction with treatment decision making and experience of care for patients with advanced cancer and their carers. Phase 1 – Constructivist research, grounded theory, vignette technique, semi – structured interviews, focus groups Phase 2 – mixed methods: patient, carer, physician and system based outcomes</td>
</tr>
<tr>
<td>What worked well/is working well</td>
<td>Development / utilization of innovative method. Conceptual model First article - Supportive Care and Cancer, second being written up for Social Science and Medicine Findings from Phase 1 - secured funding for Phase 2. – Peter Mac Foundation Grant. Recruitment progressing well Collaborative links within / outside of organisation Extending skill sets of research staff</td>
</tr>
<tr>
<td>What didn’t work well/isn’t working well</td>
<td>Research governance routine practice / sustainability</td>
</tr>
<tr>
<td>Results (if available)/future directions</td>
<td>ACP is an individualized, yet dynamic and shared process in cancer patient’s minds, discussions and actions; characterized by variations in actualizing, relinquishing and/or rejecting its individual components. systematic review, RCT</td>
</tr>
<tr>
<td>What would you do differently next time</td>
<td>Clarify governance issues early Less cautious in progressing work, ethics submissions</td>
</tr>
</tbody>
</table>
Community Pharmacists: A Forgotten Resource for Palliative Care

**Authors** (Full list, * marks corresponding author)
Paul Tait*, John Gray, Paul Hakendorf, Belinda Morris, David Currow, Debra Rowett

**Brief overview of the study** (include basic methodology)
- To identify factors that influence the supply of medicines through community pharmacies for symptom control within the terminal phase.
- A survey was used to determine the types of medicines community pharmacies stock, the expiry date of this stock, awareness of palliative patients and basic demographic characteristics of pharmacies.
- Surveys distributed by post, to 455 community pharmacies in SA.

**What worked well/is working well**
- Sending survey in paper form with reply paid envelope
- Surveying all pharmacies across SA

**What didn’t work well/isn’t working well**
- In simplifying the survey, we enquired about a single strength for each medicine. This may have skewed data.

**Results (if available)/future directions**
- Each pharmacy stocked a median of 3 medicines (range 0 to 12) from the list
- One in 8 pharmacies had none of the 13 medicines listed
- One in 5 pharmacies reported learning about the palliative status of a patient through another health practitioner.
- Palliative care services and government agencies need to develop new strategies for better access to medicines for palliative patients

**What would you do differently next time**
- It would be useful to know the actual stock holdings of each stock item
- We would ask what factors motivate the pharmacy to hold the stock.
A multi-site cluster randomised controlled trial comparing the severity of constipation symptoms experienced by palliative care patients receiving usual care compared to those diagnosed and managed according to the underlying pathophysiology.

“Management of constipation in palliative care” – FAQ’s

| Authors (Full list, * marks corresponding author) |
| Conjoint Professor Katherine Clark |

| Brief overview of the study (include basic methodology) |
| A cluster randomised controlled trial of an algorithmic approach to the diagnosis and management of constipation in palliative care versus standard current clinical care. |

| Intervention Units: 7 day assessment period to sub-categorise participants (diagnostic testing) and collect pre-intervention data. |
| Once Assessment period complete, participants will commence the two-week intervention period. Laxative medications will be changed based on the sub-category allocation, participants will be provided with exercises, toileting routine and positioning. All participants will complete an intervention diary. |

| Usual Practice Units: 14 day study period with participants taking their usual laxative medication and recording bowel habits in a daily diary. |
| At the end of the 14 day period, all participants are offered the opportunity to participate in the ‘sub-study’ in which the diagnostic tests are performed and the results provided to their GP. |

| What worked well/is working well |
| It’s new, and has never been investigated in this way in this population. |
<br>The usual practice sites are going better with recruitment due to the fact that it is really a matter of completing questionnaires. |
<br>Intervention sites investigate the underlying cause and provide targeted treatments depending upon cause. |

| What didn’t work well/isn’t working well |
| Overall recruitment is slower than expected. |
<br>Participants report that the number of questionnaires is burdensome. |

| Results (if available)/future directions |
| Increase recruitment. |
<br>Total recruitment to date (3rd March 2013): 59 randomised, 42 completed |
<br>Total needed: 295 randomised, 210 completed. |

| What would you do differently next time |
| Incorporate individual questionnaires into participant diaries. |
## Learning’s from the Critical Appraisal Workshop – 12th December 2012

<table>
<thead>
<tr>
<th><strong>Presenter</strong></th>
<th>Ms Naomi Byfieldt</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Brief overview</strong></td>
<td>Ms Angela Hipwell &amp; I were fortunate to be awarded the “Study Staff Award” which enabled us to attend the Critical Appraisal Workshop in Melbourne in December 2012. Attendance at the workshop aimed to provide us with the ability to review and appraise research articles.</td>
</tr>
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</table>

### What worked well/is working well

The presenter, Narinder was fantastic. She provided a well-paced presentation of the workshop material allowing time for clarification and questions.

I particularly liked the hands on part of the workshop where we put into practice what we were being taught. The simple methods that Narinder showed us (such as how to compare samples) were probably what I found most helpful.

### What didn’t work well/isn’t working well

Having access to the online course is a great opportunity; however actually having time to do the online course is proving especially difficult.

### Future directions

At this point, no idea! I’d like to be able to set some time aside to do the online course before my access is deactivated!

### What would you do differently next time

I think there was a lot squeezed into the one day workshop, and whilst I would be hesitant to suggest breaking it up into a 2 day session, I think perhaps the content could be reviewed so that people don’t leave at the end of the day with a sore head!
### Monitoring PaCCSC studies – improving quality

<table>
<thead>
<tr>
<th>Authors (Full list, * marks corresponding author)</th>
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<tbody>
<tr>
<td>Belinda Fazekas</td>
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<table>
<thead>
<tr>
<th>Brief overview of the study (include basic methodology)</th>
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<tbody>
<tr>
<td>PaCCSC undertakes an innovative and complete monitoring process. The review of files is targeted at specific data elements and has involved not only coordinating site staff but also study staff from recruiting sites.</td>
</tr>
</tbody>
</table>

Three studies have been examined; ketamine, octreotide and risperidone to see if the monitoring process improves the quality of subsequent recruitment.

<table>
<thead>
<tr>
<th>What worked well/is working well</th>
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</thead>
<tbody>
<tr>
<td>Monitoring of the ketamine and octreotide studies is now complete and specifically used site staff to monitor other sites; did this process result in reducing the quality of the data at their own sites in subsequent monitoring?</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>What didn’t work well/isn’t working well</th>
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<tbody>
<tr>
<td>The risperidone study is still recruiting but a specific issue identified during early monitoring resulted in a strategy aimed at reducing the errors related to dosing. Has the introduction of this strategy made a difference?</td>
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</table>

<table>
<thead>
<tr>
<th>Results (if available)/future directions</th>
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<tbody>
<tr>
<td>Some preliminary information about the process of monitoring and if the strategies and training have resulted in improvements will be discussed.</td>
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</table>

<table>
<thead>
<tr>
<th>What would you do differently next time</th>
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<tbody>
<tr>
<td>For discussion.</td>
</tr>
</tbody>
</table>
**A two-stage trial of antiemetic therapy in patients with cancer and nausea not related to anticancer therapy**

**Authors** (Full list, * marks corresponding author)
Professor Janet Hardy*, Director of Palliative Care, Mater Health Services (Brisbane)
Professor Patsy Yates (QUT)

**Brief overview of the study** (include basic methodology)
**Study 1** is a randomised open label study of guideline-driven targeted antiemetic therapy versus single agent antiemetic therapy (haloperidol)

**Study 2** is a two arm randomised controlled double blind study of levomepromazine versus placebo with rescue antiemetics (best supportive care) in patients with refractory nausea. Patients who participant in Study 1 may also be eligible for Study 2 if their nausea has not resolved

**What worked well/is working well**
- Study 1 – 125 patients have been recruited to date (30/01/2013) with 95 having completed the trial
- Study 1 is short and easy to undertake
- The high rate of response in study 1 supporting a focused approach to antiemetic therapy

**What didn’t work well/isn’t working well**
- Frequently asked question: the principal investigators will present a list of queries that have been received from sites and present the responses
- Response definition and eligibility criteria will be clarified

**Results (if available)/future directions**
- Strategies for completing study 2

**What would you do differently next time**
- Avoid multiple amendments
**PANCare - Development and testing of a state wide comprehensive care planning service to facilitate care at home for patients with pancreatic cancer**

**Authors** (Full list, * marks corresponding author)
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**Brief overview of the study (include basic methodology)**
Draws on international recommendations that have identified key factors to enable patients to die in their preferred place of death.

- Strong commissioning and clinical leadership
- Clearly defined access to 24hr cover
- Use of state / nationally recognised drivers
- Flexible budgets and care packages
- nationally recognised tools or their local equivalent
- facilitators and coordination of care across boundaries
- Training to support staff delivering end of life care

**Endpoints include:**
- Identification of essential elements of model that is transferrable across Victorian Integrated Cancer Services (ICS) and beyond.
- Development of a robust palliative care night nursing service that is feasible and sustainable within existing structures and processes of care
- Demonstrating the potential of the night nursing service to: Manage symptoms overnight, minimising the associated patient / carer distress, avoid unplanned hospital presentations,
- Development of an evidence based training program for community palliative care teams
- Health economic evaluation

**What worked well/is working well**
Secured funding agreement
Miles stones ahead of target