Palliative Care Clinical Research, Calvary and PaCCSC

Calvary

Continuing the Mission of the Sisters of the Little Company of Mary
Linda Brown, National Manager – Palliative Care Clinical Studies Collaborative (PaCCSC)

The mutually beneficial relationship between Calvary and PaCCSC to conduct high quality clinical research and build research capacity in palliative care
Calvary – Commitment to Palliative & End of Life Care Research

- Launch of new palliative and end of life care research institute by LCMHC on 30/11/2017
- Recognition that quality health care depends on high quality research
- Capacity and expertise to conduct research and change palliative care practice globally

- www.calvarypallcareresearch.org.au
Calvary – Challenges in Palliative & End of Life Care Research

Population and perceptions:

• Very unwell, frail, multiplicity and complexity of treatments/needs
• Need for sensitive and individualised approach
• Communication and how best to communicate with all involved
Calvary – Challenges in Palliative & End of Life Care Research

Capacity building:

- Research is not just the domain of academics
- Embedded
- Used as a tool to answer everyday clinical questions that arise from practice
- Build minds
Calvary/PaCCSC: A mutually beneficial relationship

Calvary sites recruiting to PaCCSC Phase 3 clinical trials since 2008

- Calvary Health Care Kogarah
- Calvary Mater Newcastle
- Calvary Public Hospital Bruce: Clare Holland House
Calvary’s recruitment to PaCCSC trials

- Ketamine for cancer pain
- Octreotide for bowel obstruction
- Risperidone/Haloperidol for delirium
- Megestrol for anorexia
- MOP (Morphine for chronic breathlessness)
- Sertraline for breathlessness
- Can Less Be Better (constipation)
- Nausea Studies 1, 2 and 3
- The BEAMS study (Breathlessness, Exertion And Morphine Sulfate) (OPEN to recruitment)
- Melatonin for delirium (OPEN to recruitment)
Calvary/PaCCSC: A mutually beneficial relationship

Calvary sites are currently recruiting to the PaCCSC RAPID Quality Improvement Program

- Calvary Health Care Kogarah (Top 3 recruiter for one de-prescribing series)
- Calvary Mater Newcastle (Top 2 recruiter at all time points for Haloperidol/Delirium series)
- Calvary North Adelaide Hospital
- Calvary Health Care Bethlehem
RAPID - an international collaboration studying the benefits and harms of medicines and other interventions used in palliative care

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RAPID - Overview

• **Rapid** aims to have a large number of sites around the world contributing a small amount of data (multiple series now open)

• **Rapid** engagement of clinicians to lead series subcommittees

• **Rapid** data collection (online, web-based, now using an App)

• **Rapid** analysis of these data (access to experts such as statisticians)

• **Rapid** reporting findings to clinicians (members of each series subcommittee are invited to draft the series results publication)

• **Rapid** influence on clinical practice
RAPID – Engagement
Phase IV - RAPID Pharmacovigilance Sites

**CANADA**
- Bruyere Continuing Care
- Capital Health Integrated Palliative Care Service
- Foothills Hospital Calgary
- Fraser Health
- Grey Nun’s Hospital
- Hamilton Health Sciences
- Providence Health Care

**UK**
- Bradford Royal Infirmary
- Dove House Hospice
- Haywards House Macmillan Specialist Palliative Care
- Humber NHS Foundation Trust
- Kings College London
- Leeds Teaching Hospital
- Lindsey Lodge Hospice
- Marie Curie Hospice
- Peninsula Acute Hospitals NHS
- St. Catherine’s Hospice
- St. Gemma’s Hospice
- St. James’s Hospital
- St. Leonard’s Hospice
- Sue Ryder Leckhampton Court Hospice
- Teeside Hospice
- Wheatfield’s Hospice Trust

**USA**
- Duke University
- Four Seasons Hospice
- Mayo Clinic Rochester
- San Diego Hospice
- University of California
- University of New Mexico

**IRAN**
- Tehran University

**INDIA**
- Bangalore Institute of Oncology
- Bhagwati Mahavir Cancer Hospital & Research Centre

**POLAND**
- St. Lazarus Hospice

**GERMANY**
- University of Munich

**ITALY**
- Maria Teresa Chiantore Seraglio Hospice

**HUNGARY**
- Pecs Medical School

**FINLAND**
- Tampere University Hospital

**HONG KONG**
- Haven of Hope Hospital
- Our Lady of Maryknoll Hospital

**TAIWAN**
- Hospice Palliative Care Centre Taipei

**JAPAN**
- National Cancer Center Hospital East
- Seirei Hamamatsu Hospital
- Seirei Mikoda Hospital

**SINGAPORE**
- National Cancer Centre
- Singapore General Hospital
- Singapore Palliative Care Service

**MALAYSIA**
- Hospis Malaysia Kuala Lumpur

**CHINA**
- West China Fourth Hospital of Sichuan University

**NEW ZEALAND**
- Archway Hospice
- Auckland Palliative Care
- Mercy Hospice
- North Shore Hospice

**AUSTRALIA**
- Barwon Health
- Brisbane Hospital
- Broken Hill Palliative Care
- Calvary Health Care Kogarah
- Calvary Mater Newcastle
- Calvary North Adelaide
- Gold Coast Hospital
- Greenough Hospital
- Hope Health Care
- Ilawarra Palliative Care
- Ipswich Hospital
- Liverpool Hospital
- Melbourn Palliative Care Service
- Modbury Hospital
- Monash Palliative Care Unit
- Orange Health Service
- Peter MacCallum Cancer Centre
- Port Kembla Hospital
- Prince Charles Hospital
- Prince of Wales Hospital
- Redcliffe Hospital
- Royal Adelaide Hospital
- Royal Albury Hospital
- Royal Brisbane Hospital
- Royal Hobart Hospital
- Royal Melbourne Hospital
- Royal North Shore Hospital
- Sacred Heart Hospice
- Sir Charles Gairdner Hospital

**AUSTRALIA (cont.)**
- South West Health Warrnambool
- Southern Adelaide Palliative Services
- St. Vincent’s Hospital Brisbane
- St. Vincent’s Hospital Melbourne
- Sunshine Coast Hospital
- Tasmanian Palliative Care Service
- The Alfred Hospital
- The Austin Hospital
- The Queen Elizabeth Hospital
- Wantirna Palliative Care
- Westmead Hospital
- Woburn Jewish Private Hospital
RAPID - Data collection

- Data points – each series has three data points
- T0 – date of the intervention commencing (baseline)
- T1 – date of time point 1 clinical benefit
- T2 – date of time point 2 toxicities
- Ad hoc toxicity reporting at any time up to 14 days after baseline
- Automatic reminder emails are triggered for T1 & T2 based on data entered for T0
RAPID - Data collection

- Gender
- Age (but not DOB)
- Primary life limiting illness
- Phase (PCOC)
- Lab tests (if available)
- Charlson Comorbidity Index
- AKPS – functional status
- Symptom Severity Score according to NCI Criteria
- Dose
- Frequency
- Route of administration
- Toxicities – Naranjo check list
RAPID - Data analysis

- Once the series reaches the required sample size the series is closed.
- Data collection remains open for another 2-4 weeks approximately
- Database is closed
- Data is downloaded and tabulated
- Then provided to the team biostatistician
- Results form the basis for the publication
RAPID - Reporting to clinicians

• By quantifying the net clinical effects – clinical benefits and clinical harms – of medications and other interventions routinely used in palliative care practice the program helps clinicians:
  – To use the right drugs/intervention
  – In the right patients
  – And reduce potential harm to patients
RAPID - Influence on clinical practice

• Standardisation of clinical assessment
  – evaluates both benefits and harms from a range of interventions (both medication and non-pharmacological)
  – records events in a consistent and systematic way
  – provides feedback on practice in a standardised way
  – compares practices across the world

• Less tangible outcomes
  – participating sites adopt a questioning culture
  – harms as well as benefits become routine questions
  – provides an avenue to participate in clinical research without the normal significant resource implications
  – allows for individual and team learning
  – part of an international research network
RAPID – Examples of Series

Medications:
• Haloperidol/delirium; haloperidol/nausea & vomiting
• Pregabalin/pain; gabapentin/pain
• Amitriptyline/pain
• Midazolam/agitation
• Cyclizine/nausea
• Dexamethasone/appetite
• Mirtazipine/appetite
• Benzodiazepines/breathlessness
• Macrogol/constipation

Non-pharmacological interventions:
• Hypodermoclysis;
• Ascitic taps;
• Blood transfusions;
Please email if you want to know more:

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Thank you