

Palliative Care Clinical Studies Collaborative (PaCCSC)



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Abstract

PALLIATIVE CARE CLINICAL STUDIES COLLABORATIVE
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Background: The Australian Government Department of Health and Ageing, under the National Palliative Care Strategy has provided funding for a national multi-site palliative care clinical studies research collaborative (PaCCSC). The collaborative aims to improve the quality of information for clinical decision making and through this also increase access to key medicines for symptom control in the community. PaCCSC includes key opinion leaders experienced in palliative care clinical study methodology and experts in clinical research, complemented by experts in clinical pharmacology, pharmacoconomics, biostatistics, clinical study methodology and health policy.

Methods: Under the direction of a national Trials Management Committee protocols for six priority medicines are currently being developed for randomised double blinded phase III studies:
•Risperidone for delirium
•Ketamine for complex pain
•Ketorolac for cancer pain
•Oxycodone for inoperable bowel obstruction
•Megestrol acetate for anorexia
•Ondansetron for cholestatic itch
This will be complemented by additional pharmacovigilance studies and consumer impact statements focusing on the symptoms of interest.

Results: The collaborative has initiated recruitment of all six studies within the *a priori* defined timeframe, however the development of a multi-site research collaborative of palliative care services has been challenging. This presentation will describe the establishment, governance structure and management processes of the collaborative and achievements to date.

Conclusion: PaCCSC will allow palliative care to more formally explore efficacy, effectiveness and safety of key medicines within Australia for registration and subsidy applications. At the same time, it is going to allow palliative care clinical researchers from across the country to work collaboratively on the development and implementation of clinical studies, protocols and publications of rigorous, adequately powered randomised studies.

Policy context – palliative care

A key aim under the National Palliative Care Strategy and National Palliative Care Program is to improve equity of access and increase the ability of all clinicians to improve the provision of palliation in the place of patient's choice

Policy context – medicines

Australia's National Medicines Policy integrates the Policy on Quality Use of Medicines and provides a framework to achieve appropriate medication use and improved health outcomes

National Medicines Policy has four central objectives

- Timely access to and affordable cost of medicines
- Appropriate standards of quality, safety, efficacy
- Quality use of medicines
- Maintaining a responsible and viable medicines industry

The *Essential Drugs in Palliative Care Survey* was completed by members of the Australian New Zealand Society for Palliative Medicine and this survey provided the initial list of medications for consideration by the PCMWG.

Good PD, Cavenagh JD, Currow DC, Woods DA, Tuffin PH, Ravenscroft PJ. 'What are the essential medications in palliative care? A survey of Australian Palliative care doctors.' *Aust Fam Phys* 2006;35:261-4.

Development of PaCCSC

What has been done

In June 2006 the Australian Government provided seed funding to support the development of the Palliative Care Clinical Studies Collaborative. The Palliative Care Clinical Studies Collaborative or PaCCSC is a collaborative network of researchers from around Australia who have joined forces to facilitate the generation of the scientific evidence to support the registration of medicines on the Pharmaceutical Benefits Scheme (PBS).

Activities being undertaken

- A feasibility phase for PaCCSC for rigorously designed and performed prospective, clinical studies
- Phase 3 clinical studies
- Phase 4 pharmacovigilance studies

Phase 3 Sites

- WA Centre for Cancer & Palliative Care, Western Australia
- Peter MacCallum Cancer Institute, Victoria
- Sydney Cancer Centre, New South Wales
- Liverpool Palliative Care Services, New South Wales
- School of Nursing/CPCRE QUT & Mater Health, Queensland
- Southern Adelaide Palliative Services & Flinders University, South Australia

Phase 4 Sites

- Central Adelaide, South Australia
- Launceston, Tasmania
- North Sydney, New South Wales
- Nambour, Queensland

PaCCSC research agenda

- For the first round of studies several priority medications have been chosen:
- ketamine – uncontrolled pain
- ketorolac – refractory pain
- risperidone – delirium
- megestrol acetate – loss of appetite
- octreotide – bowel obstruction
- ondansetron – cholestatic itch

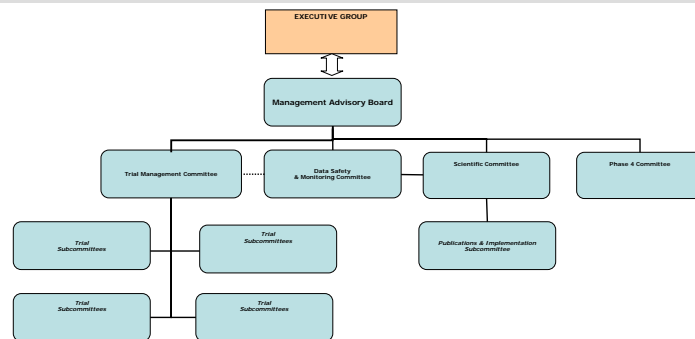
PaCCSC Governance

- Management Advisory Board
Chair - Professor Felix Bochner
- Trial Management Committee
Chair – Professor Janet Hardy
- Scientific Committee
Chair – Professor Lindon Wing
- Trial Subcommittee Chairs
Dr Odette Spruyt
Dr Meera Agar
Professors Janet Hardy
A/Professor Paul Glare
Professor David Currow



PaCCSC Palliative Care Clinical Studies Collaborative

PaCCSC organisational structure



Progress to date

- First round of PaCCSC partners established
- Priority medications to be studied determined
- Governance established
- Infrastructure established
- Protocols for the first round of studies under development
- Feasibility audit nearing completion

Funding



Flinders University receives funding for PaCCSC from the Australian Government Department of Health and Ageing under the National Palliative Care Program.

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