

Ms Tania SHELBY-JAMES

TM Shelby-James¹, DC Currow¹, D Rowett,² J Plummer³, G Gourlay³, S Eckermann⁴, A Abernethy^{1,5}.

¹Department of Palliative and Supportive Services, Flinders University, Bedford Park SA, ²Drug and Therapeutic Information Service, Repatriation General Hospital, Daw Park SA, ³Pain Management Unit, Flinders Medical Centre, Bedford Park, SA, ⁴Flinders Centre for Clinical Change and Health Care Research, Flinders University, Bedford Park SA, ⁵Duke University Medical Centre, Durham, NC, USA.

Palliative Care Clinical Studies Collaborative PaCCSC

Abstract:

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, pharmacoeconomics, 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
- Octreotide for inoperable bowel obstruction
- Megesterol 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.