UTS IMPACCT Trials Coordination Centre

Frequently Asked Questions (FAQs) – Additional information on the IMPACCT Rapid Program

Project title
UTS Rapid Program: A prospective observational study of palliative care and cancer symptom management interventions - understanding the burden of the adverse effects.

Project type
- Multi-centre
- Negligible risk

Previous ethical review
This project has received approval from ethical review bodies in 16 different countries including Australia, New Zealand, United Kingdom, China, Japan, Canada, USA, Uganda, India, Ireland, Germany, Poland, Singapore, Korea, Malaysia, Uruguay, Hong Kong, and Italy. In Australia the study has approval from the Hunter New England HREC which is a NHMRC accredited committee.

Project summary
Aims
1. To prospectively collect information on the benefits of medicines and interventions commonly used in palliative care and cancer symptom management

2. To prospectively collect information on the harms of medicines and interventions commonly used in palliative care and cancer symptom management

3. To prospectively collect information on any significant drug/drug interactions of medicines commonly used in palliative care and cancer symptom management

Background

Palliative and supportive care has sought to improve its evidence base for clinical prescribing in a number of ways. Although there are high quality phase III randomised, controlled trials being done on pharmacological interventions around the world, these are expensive and complex, particularly if run over multiple sites. A complementary way of taking forward an evidence base is to include consecutive cohort studies that describe the net clinical effects of the index medication.

The Palliative Care Clinical Studies Collaborative (PaCCSC) and Cancer Symptom Trials (CST) are Australian based clinical trials research groups. CST receives infrastructure funding from Cancer Australia. They are located within IMPACCT, Faculty of Health, UTS. Rigorously designed, double-blind, randomised controlled, multisite phase III studies conducted by the collaborative and multi-site quality improvement studies have shown that there is systematic under-reporting of medication toxicity in palliative and supportive care. In order to address this gap, a program examining the use of key interventions in the palliative and cancer populations has been developed.

Participant group(s)

In this process, the only people who will be included are those who are having the medication or intervention being studied for routine clinical indications initiated during the review period.

Method

The first intervention, a medication series, commenced in 2011, following the first protocol release, with one medication under study. The program expanded in 2016 to include a medication series across six symptom areas. In 2018 a symptom node for fatigue was added and in 2019 a further node was added for sleep. The program now have a total of eight symptom nodes:

1. Pain
2. Breathlessness
3. Gut dysfunction
4. Nausea
5. Cognitive and neurological disorders
6. Appetite and cachexia
7. Fatigue
8. Sleep

As well as the eight symptom nodes the program also have several other extraordinary series.

It is proposed to study one selected medication in each of the nodes concurrently, and one intervention series simultaneously, however a number of series can run concurrently as they arise with the only determinant being the internal resources available within the program convenor. A table of series to date is provided (Table 1). This is a continuous quality improvement program adding new series all the time.

Rapid Program Series Plan

Table 1 – Rapid Program Series

Symptom Nodes	Past series	Current series	Future planned series
Pain	• Pregabalin for neuropathic pain *(Sanderson, et.al. 2014; Sanderson, et.al. 2016)* • Gabapentin for neuropathic pain *(Clark,et.al. 2015)* • Amitriptyline for neuropathic pain • Oxycodone/Naloxone for Pain (Targin Deprescribing) (Clark et, al, 2019) • NSAIDS for Pain	• Methadone Full Conversion	• As may be determined by the investigators, participating sites, or the symptom node subcommittee
Breathlessness		• Benzodiazepines for breathlessness • Opioids for symptomatic breathlessness	• Breathlessness and allied health • As may be determined by the investigators, participating sites, or the symptom node subcommittee
Gut Dysfunction	• Macrogol for constipation	• Nursing Interventions for Constipation	• As may be determined by the investigators, participating sites, or the symptom node subcommittee
Nausea	• Metoclopramide for nausea *(Currow, et.al. 2012)*	• Ondansetron for Nausea and Vomiting	• Olanzapine for Nausea • As may be determined by the

	• Dexamethasone for appetite /nausea *(Hatano, et.al. 2016)* • Haloperidol for nausea *(Digges, et. al. 2017)* • Cyclizine for Nausea		investigators, participating sites, or the symptom node subcommittee
Cognitive and neurological disorders	• Haloperidol for delirium *(Crawford, et.al. 2013)*	• Midazolam for agitation • Mirtazapine for Depression • Antidepressants (Duloxetine/Citalopram/Escitalopram) for Depression	• As may be determined by the investigators, participating sites, or the symptom node subcommittee
Appetite and cachexia	• Anamorelin for Cachexia	• Mirtazapine for anorexia	• As may be determined by the investigators, participating sites, or the symptom node subcommittee
Fatigue	• Dexamethasone for Fatigue		• As may be determined by the investigators, participating sites, or the symptom node subcommittee
Sleep		• Temazepam for Insomnia • Melatonin for Insomnia • Mesothelioma Night Sweats	• As may be determined by the investigators, participating sites, or the symptom node subcommittee
Intervention Series	**Past Series**	**Present Series**	• **Future Planned Series**
Intervention	• Blood Transfusion *(To, et.al. 2017; To, et.al. 2016)* • Hypodermoclysis • Ascitic Taps	• Compression and Related Physical Therapies for Lymphoedema • Intrathecal Catheters for Pain	• Venting gastrostomies • Pleural fluid drainage • Pleurodesis • Endoluminal stents (vascular,

			gastrointestinal, thoracic) • As may be determined by the investigators, participating sites, or the symptom node subcommittee.
Special Interest Series	**Past Series**	**Present Series**	**Future Planned Series**
Special interest & post marketing series	• Tranexamic Acid for Bleeding • COVID-19 series • Telehealth Series • Gabapentin for Itch and Restless legs	• Medical Cannabis prescribing • Diuretics for Cancer Related Lymphoedema • Cefalexin for Urinary Tract Infections in Aged Care • Cefalexin for Soft Tissue/Wound Infections in Aged Care	• Immunotherapy • Mucositis • Home Oxygen • Deep Venous Thrombosis • Antibiotics in the last weeks of life • Aged Care Specific Series • As may be determined by the investigators and/or participating sites
Nursing Series	**Past Series**	**Present Series**	**Future Planned Series**
Nursing interventions	• Noisy Respiratory Secretions at End of Life	• Nursing interventions for Disorientation • Nursing interventions for constipation • Dressings for Malignant Subcutaneous Wounds	• Nursing Interventions for Pressure Areas • As may be determined by the investigators and/or participating sites

Data will be collected on the use of interventions and medications that are currently registered and their use in day-to-day practice. This means that the therapeutic benefit, harm, toxicity (drug/host), any significant drug/drug interactions can be prospectively collected by sites worldwide and consolidated into reports that will directly inform clinical practice. The results of the completed studies have been made available through publications (Table 1) and presentations, with all future studies being made rapidly available to back to clinicians.

Information will be collected by clinicians from each person under study at pre-determined timepoints. Generally, this is:

- Baseline (T0) - basic clinical data including broad diagnostic group, and basic clinical parameters (only if available) and demographic data (age, gender but not names or date of birth will be collected);
- A time point for clinical benefit (T1) – selected specifically for the study by the study committee
- A time to toxicity (T2) - a time point at which immediate and short term toxicities/harms will be collected.
- Adhoc data on toxicities/harms that occur at other timepoints will also collect.

Reasons for data missing at any of the standard data points is also collected. Data can be entered into REDCap via a computer or mobile phone. REDCap is a secure web-based encrypted database with the data being held at UTS. People could be followed for up to six weeks for some medications and interventions, although it is likely that the routine data points will be far sooner. No identifiable data will be collected.

Possible outcomes

The *primary outcome* is to evaluate the benefit and toxicity/harms of medications and interventions commonly used in palliative care and cancer symptom management.

The *secondary outcomes* are to:

- Describe the indications for medicines and interventions being used in palliative care and cancer symptom management.
- Document the frequency of prescribing of common medicines and interventions in palliative care and cancer symptom management.

This quality improvement program provides the opportunity to cost effectively study medications and interventions used in palliative care and cancer symptom management in a timely manner which will contribute to the evidence base and support clinical practice in the field both locally and internationally.

Project design

A prospective review of people consecutively commenced on the index medication/intervention for the index symptom to capture best clinical practice by capturing important clinical toxicities/harms and benefits.

Data collection techniques

Relevant data will be entered into REDCap by the medical officer caring for the patient or a paper-based Case Report Form will be completed by the medical officer and the data entered by a member of the clinical/research team. Data collection takes approximately three minutes at each time point (baseline, clinical benefit point, clinical toxicity point).

Data to be collected

Key patient demographic and high level clinical information will only include age, gender and a computer generated identification number. No additional pathology tests will be requested and minimal documentation of the available tests will be recorded.

The Rapid Program collects data based on routine clinical care, once a decision to prescribe a medication/intervention has been made by their treating clinician. It then attempts only to record systematically routine data and request the clinician rate this data using the NCI CTCAE or similar rating scale. The data collected are the benefits and any harms or side effects that are seen from the prescribing of the medication/intervention which should be routine clinical care for any patient commenced on any medication/intervention as part of their treatment regimen by the treating clinician.

Number of participants
Sites may indicate which series they would like to be involved with and it is requested that the sites collect at least three participants per site every few months.

Tasks participants complete
Participants are not required to complete any tasks as data is collected by the treating clinician during their routine clinical practice. No identifying data will be collected.

Analysis of results
Basic descriptive statistics will be used to determine rates of benefit and toxicity observed during the audit period.

Likely benefits of the project for the participants, institution and/or community
The Rapid program will allow the net clinical effect (therapeutic benefit/failure) to be identified and published on a regular basis in order to refine practice. Regular publication of the findings from each evaluation will include implications for practice as well at national pharmaceutical policies around the world.

Actual or potential risk associated with the project
There are no foreseen risks associated with this project.

Research personnel

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Other commonly asked questions

Consent

Will informed consent be obtained from participants?

No. Patients themselves are not approached for the purposes of this work. The UTS Rapid Program purely captures the clinician's routine clinical practice. All data collected is clinician reported data not patient reported data. The UTS Rapid Program meets all NHMRC guidelines for waiver of consent.

Data and privacy

Is there a requirement for the project to collect, use, or disclose individually identifiable or re-identifiable data of a personal nature about participants without their consent?

No.

Will individually identifiable data about participants be disclosed in the dissemination of research results?

No.

Conflicts of interest

Are any 'conflict of interest' issues likely to arise in relation to this research?

No.

Payments

Are there any payments made to sites, personnel or patients for participation?

No.

Dissemination plan

How will the results be disseminated?

Data will be collated as soon as a series is completed and publication of the results will be in peer reviewed journals. This will include the background to the medication/intervention (if a medication, its pharmacokinetic and pharmacodynamic properties, and its registered indications) and the way the intervention is used in palliative care. Benefits will be quantified as well as the toxicities/harms that were encountered. Although sites who contribute data to each series will be acknowledged, there will be no way of identifying individual patients or individual sites. Only grouped data will be presented and as the data is not identifiable there is no need to de-identify.

Current publications, presentations and posters can be seen below.

Publications

1. Agar MR, Quinn SJ, Crawford GB, Ritchie CS, Phillips JL, Collier A, Currow DC. (2016) Predictors of mortality for delirium in palliative care. J Palliat Med. doi: 10.1089/jpm.2015.0416

2. Clark, K, Quinn SJ, Doogue M, Sanderson C, Lovell M, Currow DC. (2015) Routine prescribing of gabapentin or pregabalin in supportive and palliative care: what are the comparative performances of the medications in a palliative care population? Support Care Cancer. 23(9):2517-20. doi: 10.1007/s00520-015-2837-z

3. Crawford GB, Agar M, Quinn SJ, Phillips J, Litster C, Michael N, Doogue M, Rowett D, Currow DC. (2013) Pharmacovigilance in Hospice/Palliative Care: Net Effect of Haloperidol for Delirium. Journal of Palliative Medicine, 16(11):1-7. doi: 10.1089/jpm.2013.0230

4. Currow DC, Vella-Brincat J, Fazekas B, Clark K, Doogue M, Rowett D. (2012) Pharmacovigilance in hospice/ palliative care: Rapid report of net clinical effect of metoclopramide. Journal of Palliative Medicine, 15(10):1071-5. doi: 10.1089/jpm.2012.0111

5. Currow DC, Rowett D, Doogue M, To THM, Abernethy AP. (2012) An international initiative to create a collaborative for pharmacovigilance in hospice and palliative care clinical practice. Journal of Palliative Medicine, 15(3):282–6. doi: 10.1089/jpm.2012.9605

6. Curtis N. Sessler, Mark S. Gosnell, Mary Jo Grap, Gretchen M. Brophy, Pam V. O'Neal, Kimberly A. Keane, Eljim P. Tesoro, and R. K. Elswick "The Richmond Agitation–Sedation Scale", American Journal of Respiratory and Critical Care Medicine, Vol. 166, No. 10 (2002), pp. 1338-1344. doi: 10.1164/rccm.2107138

7. Digges M, Hussein A, Wilcock A, Crawford GB, Boland JW, Agar MR, Sinnarajah A, Currow DC, Johnson MJ (2017) Pharmacovigilance in Hospice/Palliative Care: Net effect of haloperidol for nausea or vomiting. J Palliat Med. doi: 10.1089/jpm.2017.0159

8. Hatano Y, Moroni M, Wilcock A, Quinn S, Csikós Á, Allan SG, Agar M, Clark K, Clayton JM, Currow DC. (2016) Pharmacovigilance in hospice/palliative care: the net immediate and short-term effects of dexamethasone for anorexia. BMJ Supportive & Palliative Care, 6(3):331-7. doi: 10.1136/bmjspcare-2015-001037

9. Sanderson C, Quinn SJ, Agar M, Chye R, Clark K, Doogue M, Fazekas B, Lee J, Lovell MR, Rowett D, Spruyt O, Currow DC (2016) Pharmacovigilance in hospice/palliative care: net effect of pregabalin for neuropathic pain. BMJ Support Palliat Care. 6(3):323-30 . doi: 10.1136/bmjspcare-2014-000825

10. Sanderson C, Quinn S, Agar M, Chye R, Clark K, Doogue M, Fazekas B, Lee J, Lovell M, Rowett D, Spruyt O, Currow D. (2014) Pharmacovigilance in hospice/palliative care: net effect of gabapentin for neuropathic pain. BMJ Supportive & Palliative Care, 5(3):273-80 doi: 10.1136/bmjspcare-2014-000699

11. To T, LeBlanc TW, Eastman P, Neoh K, Agar MR, To LB, Rowett D, Vandersman Z, Currow DC. (2017) The Prospective Evaluation of the Net Effect of Red Blood Cell Transfusions in Routine Provision of Palliative Care. J Palliat Med. doi: 10.1089/jpm.2017.0072.

12. To TH, To LB, Currow DC. (2016) Can we detect transfusion benefits in palliative care patients? J Palliat Med. doi: 10.1089/jpm.2016.0073.

13. Clark K, Byrne P, Hunt J, Rowett D, Watts G, Lovell M, Currow D,(2019) Pharmacovigilance in Hospice/Palliative Care: De-Prescribing Combination Controlled Release Oxycodone-Naloxone

14. Hunt J, Brown L, Fazekas B, Doogue M, Rowett D, Luckett T, Morgan D, Reed-Cox K, Sheehan C, Tuffin P, Currow D: Evaluation of the RAPID Program: A Cross-Sectional Survey of International Site Investigators. Letter to Editor J Palliat Med:

15. Investigating the benefits and harms of hypodermoclysis of patients in palliative care: A consecutive cohort study Meera R Agar, Sungwon Chang, Ingrid Amgarth-Duff, Maja V Garcia, Jane Hunt, Jane L Phillips, Aynharan Sinnarajah and Robin Fainsinger

16. Pharmacovigilance in hospice / palliative care: net effect of amitriptyline or nortriptyline on neuropathic pain. UTS/IMPACCT rapid program Authors: Akram Hussein, Madeline Digges, Sungwon Chang, Matt Doogue, Debra Rowett, Meera Agar, Aynharan Sinnarajah, Andrew Wilcock, Danielle Kain, Simon Allan, Jason W Boland, David Currow.

17. Seah D, Wilcock A, Chang S, Sousa MS, Sinnarajah A, Teoh CO, Allan S, Chye R, Doogue M, Hunt J, Agar M, Currow D. (2022) Paracentesis for cancer-related ascites in palliative care: An international, prospective cohort study. Palliative Medicine.

18. McNeill R, Boland JW, Wilcock A, Sinnarajah, A, Currow DC. Non-steroidal anti-inflammatory drugs for pain in hospice/palliative care: an international pharmacovigilance study. BMJ Supportive and Palliative Care. 2023 Jan; 0: 1-9. doi: 10.1136/spcare-2022-004154. PMID:36720587

Presentations

1. Devilee L, Participating in palliative care clinical research: RAPID makes it easy. PCNA Conference April, 2014

2. Devilee L, Cosic C. Participating in palliative care clinical research: RAPID makes it easy. SAPC State Conference June 2014

3. Devilee L, New Evidence from Palliative Care Clinical Trials. Palliative Care Conference, Brisbane. November 2016

4. Currow, D., Rowett, D., Doogue, M., Brown, L., Raymond, B. Using everyday practice to inform and develop an evidence base for future practice – applying the RAPID Pharmacovigilance methodology in palliative care PCNA Conference May 2018

5. Clark, K. De-Prescribing Combination Controlled Release Oxycodone-Naloxone Oceania Conference 2019

6. Hunt, J., Brown, L., Phillips, J., Currow, D., Doogue, M., Rowett, D., Hosie, A., Nursing Interventions for Noisy Respiratory Secretions at End of Life PCNA Conference 2020.

7. McNeill R, Prael G, Hunt J, Chang S, Wilcock A, Dunwoodie D, Lau C, Morgan N, Iupati S, Currow D, Phyo Y. UTS Rapid Program – Results of the cyclizine for nausea and vomiting series. NSW Cancer Conference 2022.

8. Ingham G, Seah D, Prael G, Urban K, Brown L, Hunt J, Phyo Y. UTS Rapid Program – Dexamethasone for Fatigue. ANZSPM Conference 2022.

9. Currow, D, Rowett, D, Doogue, M, Hunt, J, Phyo Y, Brown, L. UTS Rapid Program. 12th International Seminar of the European Palliative Care Research Centre 2022.

Posters

1. Linda Brown (formerly Devilee), D. Rowett, M. Doogue & D. Currow on behalf of the Palliative Care Clinical Studies Collaborative (PaCCSC). The real world effects of prescribing in palliative care: RAPID. Poster presented at the European Association for Palliative Care (EAPC) 15th World Congress, May 2017, Madrid Spain.

2. Currow, D., Rowett, D., Doogue, M., Brown, L., Hunt, J. Pharmacovigilance in hospice / palliative care. National Medicines Symposium, Canberra Convention Centre, May/June 2018

3. Currow, D., Rowett, D., Doogue, M., Brown, L., Phillips, J., & Hunt, J. Rapid Program - Nursing Interventions in Palliative Care. Oceanic Palliative Care Conference, Perth, November 2019

4. Hunt J, Brown L, Fazekas B, Doogue M, Rowett D, Luckett T, Morgan D, Reed-Cox K, Sheehan C, Tuffin P, Currow D: Evaluation of the RAPID Program EAPC World Research Congress 2020

5. Currow, D., Rowett, D. Doogue, M., Brown, L., Agar, M., Hunt, J. Seah, D. Variations in practice: paracentesis in malignant ascites.

6. Hunt J, Currow D, Brown L, Doogue M, Rowett D, Sheehan C. UTS Rapid Program- A prospective observational study of palliative care and cancer symptom management interventions - understanding the burden of the adverse effects., 60th ASMR National Scientific Conference. November 2021

7. Seah D, Chang S, Rowett D, Doogue M, Brown L, Agar M, Hunt J, Currow D. Rapid Program– Effectiveness of Paracentesis for malignant ascites at different time points. EAPC 2021

8. Seah D, Chang S, Rowett D, Doogue M, Brown L, Agar M, Hunt J, Currow D. Variations in Practice; Paracentesis in malignant ascites. EAPC 2021

9. Seah D, Rowett D, Doogue M, Brown L, Agar M, Hunt J, Currow D, Chang S. Rapid Program– Effectiveness of Paracentesis for malignant ascites at different time points. OPCC 2021

10. R. McNeill, J. Hunt, D. Currow, M. Doogue, D. Rowett, T. Nguyen, S. Chang, Y. Phyo. Pharmacovigilance in hospice/palliative care: Net effect of cyclizine for nausea and vomiting. OPCC 2021

11. Sheehan C, Rowett D, Doogue M, Hunt J, Brown L, Phyo Y. UTS Rapid Program. NSW Cancer Conference 2022

12. Seah D, Wilcock A, Chang S, Sousa MS, Sinnarajah A, Teoh CO, Allan S, Chye R, Doogue M, Hunt J, Agar M, Currow D. Benefits and harms in cancer related paracentesis: A multisite prospective palliative care study. NSW Cancer Conference 2022.

13. Seah D, Wilcock A, Chang S, Sousa MS, Sinnarajah A, Teoh CO, Allan S, Chye R, Doogue M, Hunt J, Agar M, Currow D. Variation in cancer related paracentesis: A palliative care prospective observational study. NSW Cancer Conference 2022.

14. Drake R, Hunt J, Herbert A, Hynson J, Currow D, Doogue M, Phillips M, Cossich M, Rowett D, Mherekumombe M. The University of Technology Sydney RAPID Paediatric Program – Understanding Medication Efficacy and Burden of Adverse Effects. ISPPS 2022

15. Drake R, Hunt J, Herbert A, Hynson J, Currow D, Doogue M, Phillips M, Cossich M, Rowett D, Mherejumombe M, Brown L. UTS Rapid Paediatric Palliative Care and Cancer Symptom Management Program. 12th International Seminar of the European Palliative Care Research Centre 2022.

16. Agar M, Chang S, Amgarth-Duff I, Garcia M, Hunt J, Phillips J, Sinnarajah A, Fainsinger R. UTS Rapid Program – Results of the Hypodermoclysis Series. 12th International Seminar of the European Palliative Care Research Centre 2022.

17. R. McNeill, J. Hunt, D. Currow, M. Doogue, D. Rowett, L. Brown. UTS Rapid Program – Results of the Cyclizine for Nausea and Vomiting Series. 12th International Seminar of the European Palliative Care Research Centre 2022.

18. Currow, D., Rowett, D., Doogue, M., Brown, L., Agar, M., & Hunt, J., Seah, D. Variations in practice: paracentesis in malignant ascites. 12th International Seminar of the European Palliative Care Research Centre 2022.

19. Sheehan C, Currow D, Rowett D, Doogue M, Brown L, Phyo Y. UTS Rapid Program. PaCCSC and CST Annual Research Forum 2023.

20. Drake R, Prael G, Hunt J, Chang S, Phyo Y, Herbert A, Mott C, Hynson J, Phillips M, Cossich M, Mherekumombe M, Kim MS, Chong PH, Molin-Friis S, Abitz M, Bernada M, Avery M, Doogue M, Rowett D, Currow D. UTS Rapid Paediatric Palliative Care and Cancer Symptom Management Program. PaCCSC and CST Annual Research Forum 2023.

21. McNeill R, Boland J, Wilcock A, Sinnarajah A, Currow D. UTS Rapid Program – Results of the Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) for Pain series. PaCCSC and CST Annual Research Forum 2023.

22. Ingham G, Seah D, Urban K, Phyo Y, Hunt J, Tuffin P. UTS Rapid Program - Dexamethasone For Fatigue. PaCCSC and CST Annual Research Forum 2023.

23. McNeill R, Prael G, Hunt J, Chang S, Wilcock A, Dunwoodie D, Lau C, Morgan N, Iupati S, Currow D, Phyo Y. UTS Rapid Program – Results of the cyclizine for nausea and vomiting series. PaCCSC and CST Annual Research Forum 2023.

24. Agar M, Chang S, Amgarth-Duff I, Garcia M, Hunt J, Phillips J, Sinnarajah A, Fainsinger R. UTS Rapid Program – Results of the Hypodermoclysis Series. PaCCSC and CST Annual Research Forum 2023.

25. Power JL, Brown L, Phyo Y, Sheehan C, Rowett D, Morgan D, Doogue M, Tuffin P, Drake R. Participating in the Rapid program can assist Australian sites meet accreditation standards. PaCCSC and CST Annual Research Forum 2023.