Rapid Series Manual - Medicinal Cannabis-Series 19

What is this series about?

There is wide public interest in the role of medicinal cannabis in cancer care generally, and palliative care in particular. Despite this substantial interest many clinicians in palliative care remain wary of prescribing medicinal cannabis. They cite concerns about the lack of evidence underpinning the role of medicinal cannabis, concerns about the potential for adverse effect and the unconventional way by which cannabis came to be listed as a medicine in many jurisdictions including Australia.

This RAPID series of Medicine Cannabis in Palliative Care will address some of these concerns by establishing a significant database of real-time monitoring of patients prescribed cannabis who receiving palliative care. These data will capture the benefits or effects, as well as adverse effects seen for patients. Specifically, all patients attending palliative care services who are prescribed medicinal cannabis for any indication will have a series of outcomes documented (1) at time of prescription, and (2) at subsequent standardised follow up times. Outcomes of interest include evidence of effects upon symptoms such as pain, appetite, nausea, sleep and upon overall quality of life. In addition, data will be collected around any evidence of adverse effects such as sedation, confusion and other potential side effects. The doses of cannabis and of other medications prescribed for symptom relief will be collected.

This important study will enable prospective monitoring of a medication that is already available and where the evidence underpinning its use is limited. Australian palliative care services are uniquely placed to contribute to this real-time data monitoring and reporting project with potential to inform practice worldwide.

Patient tracking

A log or spreadsheet should be developed in order to track the patient medical record number and the study ID number allocated to each patient when medication/intervention commenced. This spreadsheet will be the only link between the data collected and the identity of the patient and remains the property of the participating site. This information should not be shared with the Palliative Care Clinical Studies Collaborative (PaCCSC). The spreadsheet should also contain the date and time of the data entry at each time point.

Patient PID	Patient name	Patient medical record number	Date of initial data entry	Time of data entry

Allocating Patient ID number

a) The ID number for each set of data collected is a composite number built up using a series of three codes.

i) Site identifier.

This is the number allocated to each participating site as a two digit number

ii) Medication/intervention number

The number for the Medical Cannabis Series is **19.**

iii) Patient number

This is usually a three digit number e.g. **001**

Therefore the full patient ID number will be;

Site identifier/medication number/patient number e.g. 01/19/001

Time points

There are four main time points where data is required;

1. Commencement of the medical cannabis (baseline) (T_0)
2. 7 days post commencement of medicinal cannabis (T_1)
3. Day 14 assessment of benefit/toxicity (T_2)
4. Time to expected toxicity (if any)

Other data collection points are:

1. Date and time of death
    a. Enter the date and time of death when known.
    b. If the date of death is entered during the data collection period, the investigator will no longer receive prompts to complete the remaining data.

Each medication/intervention of interest will have different time points for clinical benefit and harms according to its profile. Time points are determined by each Series subcommittee and are based on clinical experience and published product information.

For example: Oxycodone/naloxone Series

- Harm is assessed at both days 1 and 3
- Clinical benefit is assessed at both days 1 and 3

Other data collection points are:

1. Toxicity at unexpected time point - there can be up to three other times where toxicity can be recorded (Adhoc A, B and C).
  • These pages can be left blank if there are no unexpected adverse events
2. Cessation of the medication
  • Complete this page if the medication/intervention of interest is ceased at any time during the data collection period for any reason
3. Date of death
  • Enter the date of death if/when known
  • If the date of death is entered during the data collection period no further prompts will be received.

Adverse event assessment

Adverse events (or toxicities) are assessed using a standard scale from the National Cancer Institute Criteria for Adverse Events (NCI CTCAE). The NCI uses a scale between 1 and 5 ranging from mild to serious (resulting in death) symptoms or sequelae. The NCI criteria are provided as a reference document which is supplied separately and should be referred to for any events recorded is association with the patient's clinical course.

Each medication/intervention has a number of pre-populated expected adverse events (toxicities). These are listed at each time point, and the NCI grade is described and provided for easy reference. A grade should be provided for each listed adverse event.

If unexpected adverse events occur at any other time, either before or after any pre-determined time point, these should be recorded in the unexpected adverse event section of the CRF. Up to three other time points can be recorded.

Data entry

Login can be acquired by emailing **RAPID@uts.edu.au** and requesting the login to the series that is applicable to you.