Rapid Paediatrics Series Manual

Medicinal Cannabis-Series 43

What is this Series about?

Medicinal cannabis may be useful for managing treatment-resistant epilepsy, pain and other symptoms that can affect many patients in paediatric palliative care (PPC). However, the supporting evidence is very limited, and little is known about the most suitable doses of individual products.

It is unlikely that medicinal cannabis will be a first-line agent for the management of pain, nausea & vomiting or other specific symptoms, but it may have an adjuvant or complementary role in symptom management within palliative care.

This RAPID series seeks to capture information on the symptoms clinicians prescribe medicinal cannabis, whether it is being used as a first line treatment or as an adjuvant and what doses and formulations are being prescribed.

In this study the data collection time points are at baseline, day 7, day 14, day 28, 2 months, 3 months, and 6 months' post baseline. This is a reflection of the many conditions requiring a longer-term involvement from PPC services. We don't expect that every patient will have data collected for the full 6 months as it is likely that many children's life expectancy will be shorter than this. However, we would hope that each patient would have data collected for at least 28 days.

Patient tracking

A log or spreadsheet should be developed in order track the patient medical record number and the study ID number allocated to each patient when commenced on a medication/intervention. 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 or three digit number

ii) Medication number

The medication number for the Paediatric Medicinal Cannabis series is **43**

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/**43**/001

Time points

There are 7 main time points where data is required.

1. Commencement of the medication (baseline) **(T0)**
2. 7 days after baseline **(T1)**
3. 14 days post baseline **(T2)**
4. 28 days post baseline **(T3)**
5. 2 months post baseline **(T4)**
6. 3 months post baseline **(T5)**
7. 6 months post baseline **(T6)**

Other data collection points are:

1. Harm/adverse event at unexpected time points:
   - There can be up to three other times where harm can be recorded (Adhoc a, b & c)
   - These pages can be left blank if there are no harms/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 for subsequent data will be received.

Each medication/intervention of interest will have different time points for clinical benefit and adverse events according to its profile. Time points are determined by each Series subcommittee and are based on clinical experience and published product information.
For example: Paediatric Gabapentinoids series

- Harm is assessed at days 1, 14, 28, 6 weeks and 12 weeks after baseline
- Clinical benefit is assessed at days 1, 14, 28, 6 weeks and 12 weeks after baseline

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 (harms). 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 seriesthat is applicable to you.

References: Common Terminology Criteria for Adverse Events (CTCAE) Version 5.0
Published: November 27, 2017, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health, National Cancer Institute