Rapid Paediatrics Series Manual
Methadone for Pain - Series 51

What is this series about?

Methadone is a long-acting lipid soluble synthetic opioid analgesic increasingly being used in paediatric palliative care. Methadone is generally used when other opioid analgesic agents have failed to achieve sufficient analgesia or are causing excessive side effects. Due to the presence of inactive metabolites with methadone it is well tolerated in renal failure and avoids the anti-analgesic or potentially hyper-analgesic metabolites seen with morphine. Efficacy is also maintained in stable liver disease. In this Rapid series we are collecting data at five timepoints. At baseline, 48hrs after first dose, 5 days, 10 days and 30 days after commencement of Methadone.

By collecting data for this series, you will be assisting us to better understand the attitudes and prescribing practices of paediatric palliative care physicians regarding the use of methadone in children in this cohort of patients. We thank you for your time in collecting data for this important work.

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

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 Methadone for Pain series is **51**
   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/**51**/001*

Time points

There are 5 main time points where data is required.
1. Commencement of Methadone (baseline) (T0)
2. 48hrs after baseline - symptomatic benefit assessment (T1)
3. 5 days after baseline symptomatic benefit assessment (T2)
4. 10 days after baseline – symptomatic benefit assessment (T3)
5. 30 days after baseline – symptomatic benefit assessment (T4)

Other data collection points are:
1. Toxicity/harm at unexpected time points (T_1, T_2, T_3 and T_4):
   - There can be up to three other times where harm/toxicity can be recorded (Adhoc a, b & c)
   - These pages can be left blank if there are no unexpected adverse events
2. Cessation of the Methadone
   - Complete this page if the Methadone 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.

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.

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.