Rapid Paediatrics Series Manual

Opioids for Paediatric Breathlessness-Series 34

What is this series about?

Breathlessness is a frequent symptom at the end of life for children with the prevalence of dyspnoea reported to range anywhere between 17 to 80% [Pieper et al 2018]. It is therefore essential to have reliable and well evidenced treatment approaches for this symptom. This does not currently exist with the few studies available only reporting the response of a small number of participants.
Low dose morphine or other opioid agents are in common clinical use to manage breathlessness at the end of life and warrant good evidence to guide prescribing. This Rapid series will look at the use of opioids for breathlessness to ascertain overall benefit; effectiveness vs. adverse effects and, potentially, allow a comparison between different opioids.

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 Opioids for Breathlessness series is **34**

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/**34**/001

Time points

There are 4 main time points where data is required;

1. Commencement of the medication (baseline) **(T0)**
2. Following first opioid dose for breathlessness **(T1)** either;
   -within 30-min following intravenous (bolus or infusion) or transmucosal dose OR
   -within 60-min following bolus subcutaneous dose OR
   -within 3-hours following oral dose or start of subcutaneous infusion

3. 24 hours after start of opioid for breathlessness symptomatic benefit assessment **(T2)**
4. 48 to 60 hours after opioid started for breathlessness **(T3)**

Other data collection points are:

1. Harm/adverse event at unexpected time points (T_1, T_2 & T_3,):
   - 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 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 series that is applicable to you.

References: Common Terminology Criteria for Adverse Events (CTCAE) Version 5.0
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