Rapid Series Manual

Opioids for Symptomatic Breathlessness-Series 21

What is this series about?

Breathlessness can be a frightening and overwhelming problem that is difficult to treat. For many people, breathlessness remains when all the underlying causes of breathlessness have been optimally managed (chronic breathlessness). Breathlessness in these circumstances often occurs at rest or doing routine things like showering or preparing meals.

The prevalence of chronic breathlessness will continue to increase as the population ages because the chronic progressive diseases where breathlessness is common are increasing in prevalence. Nearly one half of all people experience distressing breathlessness during the last year of life.

This opioids for symptomatic breathlessness series is being relaunched and the CRF has now been reduced to three timepoints. T0, T1 and T2. This will make it easier for sites to participate in this series and significantly reduce the time it takes to complete the Case Report Form.

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 Opioids for Symptomatic Breathlessness Series is **21**

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. 01/21/001

Time points

There are 3 main time points where data is required:

1. Commencement of the medication (baseline) (T_0)
2. Day 2 symptomatic benefit assessment (T_1)
3. Day 7 – 14 symptomatic benefit assessment (T_2)

Other data collection points are:

1. Adverse event/harm at unexpected time points (T_1 & T_2):
   - There can be up to three other times where harms can be recorded (Adhoc A, B, & 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.

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: Oxycodone/naloxone Series

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

Adverse event assessment

Adverse events (or harms) 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.