Rapid Series Manual

Benzodiazepines-Series 10

What is this series about?

Benzodiazepines are sedative medications that are recommended for short term use in the treatment of anxiety and insomnia. For some time now, benzodiazepines are also routinely recommended and prescribed as adjuvant agents in the palliation of breathlessness. However, there is no evidence for or against benzodiazepines for the relief of breathlessness in people with advanced cancer and COPD. A systematic review highlighted that benzodiazepines cause more drowsiness as an adverse effect compared to placebo and suggested that benzodiazepines may be considered as a second- or third-line treatment, when opioids and non-pharmacological measures have failed to control breathlessness.

This phase IV pharmacovigilance study is uniquely examining real clinical experience when palliative care patients receive benzodiazepines as part of their dyspnoea management. This is very important data as it will not only enhance understanding of the reasons that clinicians choose to prescribe benzodiazepines but also examine the safety of the process.

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 digit number

ii) Medication number

The medication number for the Benzodiazepine series is **10**

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. 01/10/001

Time points

There are 3 main time points where data is required;

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

Other data collection points are:

1. Toxicity at unexpected time points (T_1 & T_2):
   - There can be up to three other times where toxicity can be recorded
   - 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

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

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.