# Rapid Paediatrics Series Manual

# Cyclizine for Nausea and Vomiting-Series 31

## What is this series about?

Nausea and/or vomiting are common and distressing symptoms in children receiving palliative care. The aetiology for nausea and/or vomiting is often multifactorial in children with cancer or non-cancer conditions. Consideration of the most likely mechanism of these symptoms influences the approach to pharmacological symptom management, in addition to other patient factors, previous antiemetic history and the expected adverse effect profile. More often, there is a tendency for polypharmacy in the management of nausea and/or vomiting. Cyclizine, an antihistaminic antiemetic, is thought to be an important pharmacological option for children with central causes of nausea. However, there is limited existing data focussing on the use of cyclizine in paediatric palliative medicine.

The RAPID-Paediatric series seeks to establish the broad utility and toxicity of frequently used drugs in "real life" paediatric palliative care situations across the world. It is designed to minimise the workload for any individual site through multi-site collaboration and enable RAPID data collection relatively quickly and easily. In this study the data points are at baseline, 24 hours and 72 hours post baseline, to characterise and quantify the use, efficacy and adverse effect profile of cyclizine, in the hope to establish its broad utility.

## 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 |
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## 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 Cyclizine series is **31**

**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/**31**/001

## Time points

There are 3 main time points where data is required;

1. Commencement of the medication (baseline) (T0)
2. 24 hours after baseline - symptomatic benefit assessment (T1)
3. 72 hours after baseline symptomatic benefit assessment (T2)

## Other data collection points are:

1. Harm/adverse event at unexpected time points ($T_1$, and $T_{2,}$):
   - 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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*National Institutes of Health, National Cancer Institute*