Series Manual

Physiotherapy for Respiratory Deteriorations – Series 54

Background

Respiratory distress is one of the leading causes of parents presenting with their child to emergency healthcare facilities worldwide (Gibson, et al., 2021; Sannet et al., 2023). Respiratory symptoms in children with life-limiting and life-threatening conditions are common, recurrent and distressing (Craig, Henderson & Bluebond-Langner, 2015). Deteriorations in respiratory function occur for a multitude of reasons in these rare and complex patient groups, whether it be from the natural history of a child's primary condition or because of secondary complications of their clinical presentation. Contemporary research in paediatric neurodisability cohorts identify deterioration in respiratory status as being associated with significantly increased morbidity, impacting on quality of life, reduced participation and life expectancy (Proesmans, 2016; Troller & Small, 2019; Gibson, et al., 2021; Smith et al., 2022).

Physiotherapy is a common first-line strategy requested to relieve increased work of breathing with predominantly non-pharmaceutical interventions. Physiotherapists who are experienced working with paediatric patients with multiple co-morbidities, including complex neurodisabilities, can uniquely appreciate the nuances and interplay between altered respiratory mechanics, fatigability of the muscular respiratory system and the impact of impaired swallow or upper airway dysfunctions contributing to acute respiratory deteriorations (Proesmans, 2015; Marpole, et al., 2020). Therefore, choice of management strategy and response to deteriorations need to be individualised to patient and condition.

This multi-centre, international observational series aims to document current clinical practice and its impact as a non-pharmaceutical management strategy, through identifying key aspects of physiotherapy assessment that guide effective intervention selection for the respiratory management of acute deteriorations in children and young people with life-limiting conditions across various healthcare environments, including at home or community-based settings (such as hospices), as well as in acute health facilities.

Patient tracking

A password-protected log or spreadsheet should be developed in order to 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 IMPACCT Trials Coordination Centre (ITCC) and should be stored as per the participating site data management guidelines. The spreadsheet should also contain the date and time of the data entry at each time point.

Participant ID number	Patient name	Patient medical record number	Date of initial data entry	Time of data entry

Allocating a Participant ID (PID) number

The PID 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 2- or 3-digit number.

ii) Intervention number

The intervention number for the Physiotherapy for Respiratory Deteriorations is **54.**

iii) Participant number

This is a three-digit number starting with the first participant from 001, followed by 002, 003, and so on.

Therefore, the full patient ID number will be; ***Site identifier/intervention number/patient number***
e.g., **01/54/001**

Time points

There are 4 main time points where data is required.

1. Referral for respiratory physiotherapy (baseline) – (T_0)
2. First physiotherapy assessment and intervention – (T_1)
3. Second physiotherapy assessment and intervention (within 24-48hrs of initial physiotherapy review) – (T_2)
4. Third physiotherapy assessment and intervention (within 7-10 days of initial physiotherapy review) – (T_3)

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.

Other data collection points are:

1. Harm/adverse event at unexpected time points
   - There can be up to three other times where harm can be recorded (Ad hoc A, B and C)
   - These pages can be left blank if there are no unexpected harms/adverse events unrelated to the intervention of interest (physiotherapy).
2. Cessation of the intervention
   - Complete this page if the respiratory physiotherapy intervention of interest is ceased at any time during the data collection period for any reason (e.g. if no further physiotherapy intervention is indicated for ongoing.
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

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 case report form (Ad hoc A, B and C). Please also ensure that any local clinical incident policies and procedures are followed.

Data entry

The REDCap data entry link can be acquired by emailing **rapid@uts.edu.au** and requesting the link to the series that is applicable to you.