Adverse Event Coding

Participant ID

_____

Adverse events, such falls, infections, and death, are common for patients in palliative care units due to their advanced illness. To circumvent unnecessary and burdensome reporting processes for site study personnel in this implementation study of an evidence-based Standard, we have refined the adverse event reporting processes to focus on systematically monitoring and reporting adverse effects - i.e., adverse events assessed by the principal site investigator as likely to be related to study processes or the new clinical processes to implement the Delirium Standard or new PCOC items.

Data collector

_____

Who did this AE occur for?

- ◯ Patient
- ◯ Family/Carer
- ◯ Clinician

Adverse event

- ◯ Fatigue (Patient/Family Carer)
- ◯ Falls (Patient)
- ◯ Increased distress (Patient/Family Carer/Staff)
- ◯ Agitation (RASS-PAL > 1)
- ◯ Sedation (RASS-PAL < -1)
- ◯ Physical harm (Patient/Family Carer)
- ◯ Complaints (Patient/Family Carer/Staff)
- ◯ COVID-19 Transmission (Patient/Family Carer/Staff)
- ◯ Verbal or physical aggression from a patient +/- injury (Staff)
- ◯ Increased workload (Staff)
- ◯ Breach of confidentiality (Patient/Family Carer/Staff)
- ◯ Other (Patient/Family Carer/Staff)

Start date of event

_____
(The date the event (or change of grade) started, first documented or first reported, whichever is earliest)

Grade

- ◯ Grade 1: Mild; asymptomatic or mild, intervention not indicated
- ◯ Grade 2: Moderate; minimal local or non-invasive intervention indicated
- ◯ Grade 3: Severe of medically significant but not immediately life threatening
- ◯ Grade 4: Life threatening consequences; urgent intervention indicated
- ◯ Grade 5: Death related to AE
- ◯ Unable to be graded

Serious event	◯ Yes ◯ No (Any adverse event/adverse reaction that results in death, is life-threatening, requires hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or is a congenital anomaly or birth defect.)
For a serious AE, please state who was notified and when	_____
Relationship to the MODEL-PC study or Delirium Standard care	◯ Unrelated ◯ Unlikely ◯ Possible ◯ Probably ◯ Definite ◯ Not possible
Action taken	◯ None ◯ Study intervention discontinued and no other treatment ◯ study intervention discontinued and other treatment ◯ Remedial drug therapy ◯ Hospitalisation (and SAE) ◯ Non drug treatment ◯ Not able to be determined ◯ Not applicable ◯ Other action
Specify action taken	_____
Outcome	◯ Resolved ◯ Change in grade ◯ Ongoing at end of study ◯ Death ◯ Unkown
Comments	_____