

Participant ID	
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Initials of person entering data	
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Staff email	
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CONFIDENTIAL CASE REPORT FORM
**Nursing Interventions for Constipation
Series 33**

IMPACCT Trials Coordination Centre (ITCC)
UTS IMPACCT Rapid Program

The case report form (CRF) is to be completed in compliance with
ITCC Standard Operating Procedures (SOP)

TABLE OF CONTENTS	PAGE NO.
T₀-Baseline	2
T₁ – 24 hours post baseline	6

Does this patient have a bowel obstruction?
<input type="radio"/> No <input type="radio"/> Yes (patient excluded from study)

References:
Common Terminology Criteria for Adverse Events (CTCAE). Version 5.0. Published: November 27, 2017. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES National Institutes of Health, National Cancer Institute
Bristol Stool Chart Distributed with the kind permission of Dr K. W. Heaton; formerly reader in Medicine at the University of Bristol. Reproduced as a service to the medical profession by Norgine Ltd. ©2017

(T₀) - Baseline Assessment

Date of Assessment	DD/MM/YYYY
Time of Assessment (24-hour clock)	HH:MM

Demographics

Gender (please tick) Male Female Non binary

Age (yrs)		Weight (kg)		Height (cm)	
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Tick ✓	Primary life limiting illness (please choose only one)
	Advanced cancer – please specify type of cancer: _____
	End stage renal failure
	Hepatic failure
	Neurodegenerative disease
	Cardiac failure
	Respiratory failure
	Other - Please specify: _____

Tick ✓	Palliative Care Phase
	1. Stable Phase: The person's symptoms are adequately controlled by established management. Further interventions to maintain symptom control and quality of life have been planned.
	2. Unstable Phase: The person experiences the development of a new problem or a rapid increase in the severity of existing problems either of which requires an urgent change in management or emergency treatment.
	3. Deteriorating Phase: The person experiences a gradual worsening of existing symptoms or the development of new but expected problems. These require the application of specific plans of care and regular review but not urgent or emergency treatment.
	4. Terminal Care Phase: Death is likely in a matter of days and no acute intervention is planned or required.

Tick ✓	Australian Modified Karnofsky Performance Scale (AKPS)
	100 - Normal; no complaints; no evidence of disease
	90 - Able to carry on normal activity; minor sign of symptoms of disease
	80 - Normal activity with effort; some signs or symptoms of disease
	70 - Cares for self; unable to carry on normal activity or to do active work
	60 - Requires occasional assistance but is able to care for most needs
	50 - Requires considerable assistance and frequent medical care
	40 - In bed more than 50% of the time
	30 - Almost completely bedfast
	20 - Totally bedfast and requiring extensive nursing care by professionals and/or family
	10 - Comatose or barely rousable
	0 - Dead
	Not able to determine

Charlson Comorbidity Index - Does the patient have any of the following?			
Tick ✓	<i>(Please tick all that apply)</i>	Tick ✓	<i>(Please tick all that apply)</i>
	Myocardial Infarction (history, not ECG changes only)		Hemiplegia
	Congestive Cardiac Failure		Moderate or Severe Renal Disease
	Peripheral Vascular Disease (includes aortic aneurysm \geq 6 cm)		Diabetes (with end organ damage)
	Cerebrovascular Disease (CVA with mild or no residual or TIA)		Any Tumour
	Dementia		Leukaemia (acute or chronic)
	Chronic Pulmonary Disease		Lymphoma
	Connective Tissue Disease		Moderate or Severe Liver Disease
	Peptic Ulcer Disease		Metastatic Solid Tumour
	Mild Liver Disease (without portal hypertension, includes chronic hepatitis)		AIDS (not just HIV positive)
	Diabetes (without organ damage) (excludes diet-controlled alone)		

Tick ✓	Place of Care <i>(please tick)</i>
	Inpatient Acute Hospital
	Inpatient Hospice/Palliative Care Unit
	Community
	Residential Aged Care Facility/Nursing Home
	Other; Please specify here. _____

Tick ✓	What reasons have led to the intervention? <i>(tick 'yes' or 'no' to all)</i>	
Yes	No	
		Patient triggered
		Nurse triggered
		Commenced on opioids
		Ondansetron or other 5HT3 Antagonist
		No bowel action for 2 days
		No bowel action for 3 or more days
		Less than 3 bowel movements a week








Tick ✓	What is the dominant underlying mechanism of constipation symptoms in the opinion of the care team <i>(please tick only one)</i>
	Functional (Constipation for which there is no obvious physical, biochemical, or iatrogenic causes for)
	Medication induced
	Metabolic (e.g. hypercalcemia, hypothyroid)
	Neurological (e.g. Autonomic neuropathy, Multiple sclerosis, Parkinson's disease, Spinal cord injury)
	Psychological (e.g. depression)
	Others (e.g. dehydration, poor oral intake, reduced mobility): Please specify here: _____

How many days since patient had a bowel motion? (circle number in box)

1	2	3	4	5	6	7	8	9	10	Unsure
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DESCRIPTION OF LAST BOWEL MOTION

BRISTOL STOOL CHART- Which picture best describes patient's last bowel motion?

	Type 1	Separate hard lumps	SEVERE CONSTIPATION
	Type 2	Lumpy and sausage like	MILD CONSTIPATION
	Type 3	A sausage shape with cracks in the surface	NORMAL
	Type 4	Like a smooth, soft sausage or snake	NORMAL
	Type 5	Soft blobs with clear-cut edges	LACKING FIBRE
	Type 6	Mushy consistency with ragged edges	MILD DIARRHEA
	Type 7	Liquid consistency with no solid pieces	SEVERE DIARRHEA

Please circle type below;

Type 1	Type 2	Type 3	Type 4	Type 5	Type 6	Type 7	Not recorded
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Baseline T₀ – Nursing Intervention Commencement

Target Symptom Severity

Constipation

1 2 3 4 5 Ungradable

NCI Criteria

1. Occasional or intermittent symptoms; occasional use of stool softeners, laxatives, dietary modification, or enema
2. Persistent symptoms with regular use of laxatives or enemas; limiting instrumental ADL
3. Obstipation with manual evacuation indicated; limiting self-care ADL
4. Life-threatening consequences; urgent intervention indicated
5. Death

What oral aperients is patient actually taking at this point in time:

Name of Laxative	Current Dose	Frequency. E.g. TDS, BD, Daily PRN

Tick ✓		What intervention/treatment regimen is being commenced today: (tick yes or no to all)												
Yes	No	New additional oral aperients that patient is to commence today: please specify dose, frequency of laxative. E.g. TDS, BD, Daily, Stat, PRN												
		<table border="1"> <thead> <tr> <th>Name of medication</th> <th>Dose</th> <th>Frequency of dose. E.g. TDS, BD Daily</th> </tr> </thead> <tbody> <tr> <td>1.</td> <td></td> <td></td> </tr> <tr> <td>2.</td> <td></td> <td></td> </tr> <tr> <td>3.</td> <td></td> <td></td> </tr> </tbody> </table>	Name of medication	Dose	Frequency of dose. E.g. TDS, BD Daily	1.			2.			3.		
Name of medication	Dose	Frequency of dose. E.g. TDS, BD Daily												
1.														
2.														
3.														
		Rectal intervention: Suppositories <input type="checkbox"/> Softening suppository <input type="checkbox"/> Stimulant suppository												
		Rectal intervention: Enema <input type="checkbox"/> Microlax <input type="checkbox"/> Fleet <input type="checkbox"/> Other; please specify; _____												
		Were there any other additional nonpharmacological actions suggested/commenced: e.g. increase fluid intake, increase fibre intake, regular exercise? Please specify here: _____												

Baseline Symptom/Harm Assessment (Please grade all harms; indicate that each harm has been assessed by ticking the square box next to each)

Abdominal pain

1 2 3 Ungradable No symptom

NCI Criteria

1. Mild pain
2. Moderate pain; limiting instrumental ADL
3. Severe pain; limiting self-care ADL

Diarrhoea

1 2 3 4 5 Ungradable No symptom

NCI Criteria

1. Increase of <4 stools per day over baseline; mild increase in ostomy output compared to baseline
2. Increase of 4 - 6 stools per day over baseline; moderate increase in ostomy output compared to baseline; limiting instrumental ADL
3. Increase of >=7 stools per day over baseline; hospitalisation indicated; severe increase in ostomy output compared to baseline; limiting self-care ADL
4. Life-threatening consequences; urgent intervention indicated
5. Death

Bloating

1 2 Ungradable No symptom

NCI Criteria

1. No change in bowel function or oral intake
2. Symptomatic, decreased oral intake; change in bowel function

Nausea

1 2 3 Ungradable No symptom

NCI Criteria

0. Nil

1. loss of appetite without alteration in eating habits

2. Oral intake decreased without significant weight loss.

3. Inadequate caloric or fluid intake; tube feeding, TPN or hospitalisation indicated.

Vomiting

1 2 3 4 5 Ungradable No symptom

NCI Criteria

1. 1-2 episodes (separated by > 5 minutes) in 24 hours

2. 3-5 episodes (separated by > 5 minutes) in 24 hours

3. >=6 episodes (separated by > 5 minutes) in 24 hours; tube feeding, TPN or hospitalisation indicated

4. Life threatening consequences: urgent intervention indicated

5. Death

Other (if exists) (*e.g. straining when going to toilet to open bowels*)

1 2 3 Ungradable

NCI Criteria

1. Mild

2. Moderate

3. Severe

Additional other (if exists)

1 2 3 Ungradable

NCI Criteria

1. Mild

2. Moderate

3. Severe

T₁ – 24 hours post Baseline

Date of Assessment

DD/MM/YYYY

Time of Assessment (24hr clock)

HH:MM

Tick ✓	T ₁ : Assessed/Not assessed reason
	Assessed today (<i>continue to complete T₁</i>) OR
	Died (<i>record date of death below</i>)
	Not able to be contacted / located
	Too unwell
	Other

Date of Death*

DD/MM/YYYY

***End survey here**

Please provide reason if today's assessment is not 24 hours after baseline.
(e.g., weekend)

If treatment was not administered as recorded at baseline, please provide a reason below.

Tick ✓ Was there any benefit from the intervention? (tick 'yes' or 'no')

Yes No

Number of times a bowel action has been passed in the last 24 hours.

BRISTOL STOOL CHART- Which picture best describes patient's last bowel motion?



Type 1 Separate hard lumps

SEVERE CONSTIPATION



Type 2 Lumpy and sausage like

MILD CONSTIPATION



Type 3 A sausage shape with cracks in the surface

NORMAL



Type 4 Like a smooth, soft sausage or snake

NORMAL



Type 5 Soft blobs with clear-cut edges

LACKING FIBRE



Type 6 Mushy consistency with ragged edges

MILD DIARRHEA



Type 7 Liquid consistency with no solid pieces

SEVERE DIARRHEA

Please circle type below;

Type 1	Type 2	Type 3	Type 4	Type 5	Type 6	Type 7	Not recorded
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Target Symptom Severity

Constipation

1 2 3 4 5 Ungradable

NCI Criteria

1. Occasional or intermittent symptoms; occasional use of stool softeners, laxatives, dietary modification, or enema
2. Persistent symptoms with regular use of laxatives or enemas; limiting instrumental ADL
3. Obstipation with manual evacuation indicated; limiting self-care ADL
4. Life-threatening consequences; urgent intervention indicated
5. Death

T₁ - Symptom/Harm Assessment (Please grade all harms; indicate that each harm has been assessed by ticking the square box next to each)

Abdominal pain

1 2 3 Ungradable No symptom

NCI Criteria

1. Mild pain
2. Moderate pain; limiting instrumental ADL
3. Severe pain; limiting self-care ADL

Diarrhoea

1 2 3 4 5 Ungradable No symptom

NCI Criteria

1. Increase of <4 stools per day over baseline; mild increase in ostomy output compared to baseline
2. Increase of 4 - 6 stools per day over baseline; moderate increase in ostomy output compared to baseline; limiting instrumental ADL
3. Increase of ≥7 stools per day over baseline; hospitalization indicated; severe increase in ostomy output compared to baseline; limiting self-care ADL
4. Life-threatening consequences; urgent intervention indicated
5. Death

Bloating

1 2 Ungradable No symptom

NCI Criteria

1. No change in bowel function or oral intake
2. Symptomatic, decreased oral intake; change in bowel function

Nausea

0 1 2 3

NCI Criteria

4. Nil
5. loss of appetite without alteration in eating habits
6. Oral intake decreased without significant weight loss.
7. Inadequate caloric or fluid intake; tube feeding, TPN or hospitalisation indicated.

Vomiting

- 0 1 2 3 4 5

NCI Criteria

6. Nil
7. 1-2 episodes (separated by > 5 minutes) in 24 hours
8. 3-5 episodes (separated by > 5 minutes) in 24 hours
9. >=6 episodes (separated by > 5 minutes) in 24 hours; tube feeding, TPN or hospitalization indicated
10. life threatening consequences: urgent intervention indicated
11. Death

Other (if exists) (e.g. straining when going to toilet to open bowels)

- 1 2 3 Ungradable

NCI Criteria

1. Mild
2. Moderate
3. Severe

Additional other (if exists)

- 1 2 3 Ungradable

NCI Criteria

1. Mild
2. Moderate
3. Severe

What is the intended treatment based on today's assessment?

Tick ✓	Medication and treatment changes <i>(Tick all that apply)</i>
	No change to constipation treatment regimen/continue current dose of aperient
	Aperients dose decreased: Please specify dose here: _____
	Aperient dose increased: Please specify dose here: _____
	Aperient ceased.
	New additional aperient commenced: Please specify here: _____
	Further investigations needed: e.g. X-ray, blood tests
	Patient sent to GP for review
	Patient sent to emergency department

Based on the assessment today has the constipation resolved?

- Yes No Partial resolution