| | |
|---|---|
| **Participant ID** | |

| | |
|---|---|
| **Initials of person entering data** | |

| | |
|---|---|
| **Staff email** | |

CONFIDENTIAL CASE REPORT FORM

**INTRATHECAL CATHETER FOR PAIN MANAGEMENT**
**Series No: 36**

IMPACCT Trials Coordination Centre (ITCC)
UTS Rapid Program

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

| **Baseline ($T_0$) – Just prior to commencement of procedure** | |
|---|---|
| **Date of Assessment** | DD/MM/YYYY |
| **Time of Assessment (24hr clock)** | HH:MM |

**Demographics** *(please tick)*

**Gende**r ○ Male ○ Female ○ Other

| **Age (yrs)** | | **Weight (kg)** | | **Height (cm)** | |
|---|---|---|---|---|---|

| **Tick ✓** | **Primary life limiting illness** *(please choose only one)* |
|---|---|
| | Advanced cancer – please specify type of cancer:_____ |
| | Neurodegenerative disease |
| | 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?** *(Please tick ✓ all that apply)* | | | |
|---|---|---|---|
| **Tick ✓** | | **Tick ✓** | |
| | Myocardial Infarction (history, not ECG changes only) | | Hemiplegia |
| | Congestive Cardiac Failure | | Moderate or Severe Renal Disease |
| | Peripheral Vascular Disease (includes aortic aneurysm ≥ 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) | | |

| **Laboratory Tests** (in the last 7 days - only if available) | | |
|---|---|---|
| **Test** | **Value** | **Date of test** |
| WCC ($10^9$/L) | | DD/MM/YYYY |
| CRP | | DD/MM/YYYY |
| Platelets (x $10^9$/L) | | DD/MM/YYYY |
| INR (International Normalised Ratio) | | DD/MM/YYYY |
| APTT | | DD/MM/YYYY |
| CrCl (mL/min) | | DD/MM/YYYY |
| Albumin (g/dL) | | DD/MM/YYYY |

| **Is patient on any anticoagulant or anti-platelet agent?** |
|---|
| ○ **Yes** ○ **No** *(Please go on to the next question - Symptom Severity)* |

**If YES, how long was this withheld before insertion of catheter**

| | |
|---|---|
| **No. of days withheld** | |
| **Name of medication** | |

**SYMPTOM SEVERITY**

**How would your patient rate their *distress due to pain* out of 10 currently?** *(Circle number in the box)*

0 = no distress at all  5 = moderate distress  10 = worst possible distress

| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Not reported |
|---|---|---|---|---|---|---|---|---|---|---|---|

No distress  Moderate distress  Worst possible distress

**Please rate patient's *pain* at its *worst in the last 24 hours*** *(Circle number in box that best describes their pain)*

0 = no pain at all  5 = moderate pain  10 = worst possible pain

| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Not reported |
|---|---|---|---|---|---|---|---|---|---|---|---|

No pain  Moderate pain  Worst possible pain

**Please rate your patient's *pain right now*** *(Circle number in box that best describes their pain)*

0 = no pain at all  5 = moderate pain  10 = worst possible pain

| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Not reported |
|---|---|---|---|---|---|---|---|---|---|---|---|

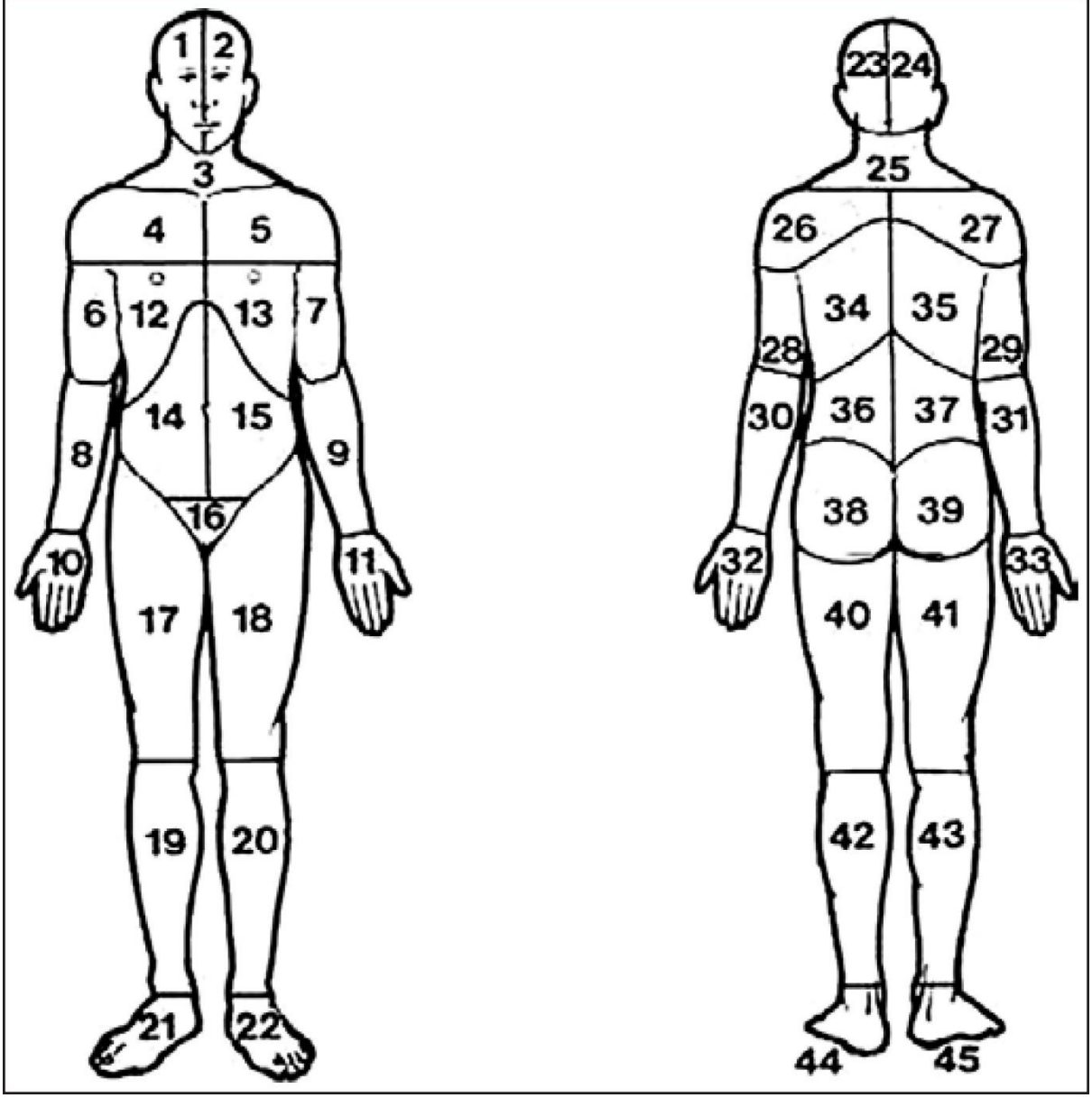
No pain  Moderate pain  Worst possible pain

**Please rate your patient's *psychological/spiritual distress*** *(Circle number in box that best describes their level of distress)*

| 0 = absent | 1 = mild | 2 = moderate | 3 = severe | 4 = not recorded/ assessed |
|---|---|---|---|---|

| **Tick ✓** | **Please tick the type/s of pain that are being targeted by the intrathecal intervention** *(Tick all that apply)* |
|---|---|
| | **Nociceptive superficial somatic pain** (Pain initiated by activation of nociceptors in the skin or other superficial tissue; it is sharp, well-defined, and clearly located) |
| | **Nociceptive deep somatic pain** (occurs when stimuli activate pain receptors deeper in the body including tendons, joints, bones, and muscles) |
| | **Nociceptive visceral pain** (occurs when pain receptors in the pelvis, abdomen, chest, or intestines are activated) |
| | **Neuropathic** (caused by damage or disease affecting the somatosensory nervous system) |

**Please circle the numbers on the diagram where pain is present**




**Please list patient's baseline opioids – both regular and PRN (as needed)**

| Name | Total daily dose (mg/mcg) | Route |
|---|---|---|
| | | |
| | | |
| | | |
| | | |
| | | |

| **Other Concurrent Medications patient is taking (classes of drugs)** *(Tick all that apply)* | | | | |
|---|---|---|---|---|
| **Tick ✓** | | **Class of Drug** | **Generic Name** | **Daily Dose** |
| **Yes** | **No** | | | |
| | | Steroids | | |
| | | Tricyclic antidepressants | | |
| | | Benzodiazepines | | |
| | | NMDA antagonists – Ketamine, Dextromethorphan | | |
| | | SSRIs | | |
| | | Alpha 2 agonists - Clonidine | | |
| | | Paracetamol | | |
| | | NSAIDS | | |
| | | Baclofen | | |
| | | Anticonvulsants including gabapentinoids | | |
| | | Antipsychotics | | |
| | | Lignocaine/mexiletine | | |
| | | Other – e.g. medicinal cannabis. Please specify here: _____ | | |

| **Tick ✓** | | **Indication/s for intrathecal catheter** |
|---|---|---|
| **Yes** | **No** | |
| | | Sub optimal pain relief despite appropriate use of multimodal analgesia |
| | | Intolerable side-effects of medication doses needed to alleviate severe pain |
| | | Patient has undergone a successful trial of intrathecal opioids and/or local anaesthetic |
| | | Poor prognosis of only a few months |

| **Tick ✓** | | **Test dose of intrathecal medication** |
|---|---|---|
| **Yes** | **No** | |
| | | Was a test dose of intrathecal medication given?<br>If YES, what medications were administered in the test dose?<br>_____ |
| | | Was the test dose successful in reducing pain levels? |
| | | Were there any adverse effects from the test dose?<br>If YES, please specify: _____ |

| Tick ✓ | What type of device was used? |
|---|---|
| | Intrathecal catheter connected to an implanted pump |
| | Tunnelled intrathecal catheter connected directly to an external pump |
| | Tunnelled intrathecal catheter connected to external pump via subcutaneous port |
| | Intrathecal catheter (non-tunnelled) connected to an external pump |

| Tick ✓ | | Was an initial bolus dose given today prior to starting the pump? |
|---|---|---|
| **Yes** | **No** | *If yes, please specify medication and dose below.* |
| | | *If no, please go to next question.* |

**Please specify medication and dose**

| Tick ✓ | NAME | DOSE (in mg/mcg) |
|---|---|---|
| | Bupivacaine | |
| | Ropivacaine | |
| | Morphine | |
| | Hydromorphone | |
| | Baclofen | |
| | Clonidine | |
| | Other - please specify: | |
| | Other - please specify: | |

| Yes | No | Was a prophylactic antibiotic given at the time of intrathecal catheter insertion? |
|---|---|---|
| | | |

**What medications were commenced in the pump at time of the procedure?**

| Tick ✓ | NAME | Concentration | Infusion rate (mg/mcg/hour) | Bolus dose prescribed |
|---|---|---|---|---|
| | Bupivacaine | | | |
| | Ropivacaine | | | |
| | Morphine | | | |
| | Hydromorphone | | | |
| | Baclofen | | | |
| | Clonidine | | | |
| | Other -please specify: _____ | | | |
| | Other - please specify: _____ | | | |

## $T_0$- Baseline Symptoms/Harm Assessment – Prior to insertion of intrathecal catheter *(Please grade all harms; indicate that each harm has been assessed by ticking the square box next to each)*

☐ **Nausea**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. Loss of appetite without alteration in eating habits
2. Oral intake decreased without significant weight loss, dehydration or malnutrition
3. Inadequate oral caloric or fluid intake; tube feeding, TPN, or hospitalization

☐ **Vomiting**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. Intervention not indicated
2. Outpatient IV hydration; medical intervention indicated
3. Tube feeding, TPN, or hospitalization indicated
4. Life-threatening consequences
5. Death

☐ **Constipation**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No symptom ○ Not reported

*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

☐ **Confusion**

○ 1 ○ 2 ○ 3 ○ 4 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. Mild disorientation
2. Moderate disorientation; limiting instrumental ADL
3. Severe disorientation; limiting self-care ADL
4. Life-threatening consequences; urgent intervention indicated

☐ **Somnolence/Drowsiness**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. Mild but more than usual drowsiness or sleepiness
2. Moderate sedation; limiting instrumental ADL
3. Obtundation or stupor
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **Dizziness**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. Mild unsteadiness or sensation of movement
2. Moderate unsteadiness or sensation of movement; limiting instrumental ADL
3. Severe unsteadiness or sensation of movement; limiting self-care ADL

☐ **Pruritus**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1.Mild or localized; topical intervention indicated
2. Widespread and intermittent; skin changes from scratching (e.g., edema, papulation, excoriations, lichenification, oozing/crusts); oral intervention indicated; limiting instrumental ADL
3. Widespread and constant; limiting self-care ADL or sleep; systemic corticosteroid or immunosuppressive

☐ **Falls (within the past week)**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. Minor with no resultant injuries; intervention not indicated
2. Symptomatic; noninvasive intervention indicated
3. Hospitalization indicated; invasive intervention indicated

☐ **Other harms (*only if applicable - can be related or unrelated to intervention*)**

*Please specify other harm here:* _____

○ Mild ○ Moderate ○ Severe ○ Ungradable

☐ **Additional other harms (*only if applicable - can be related or unrelated to intervention*)** *Please specify additional other harm here:* _____

○ Mild ○ Moderate ○ Severe ○ Ungradable

| **Tick ✓** | **Which symptom/harm is the most troublesome?** *(Tick one only)* |
|---|---|
| | Nausea |
| | Vomiting |
| | Constipation |
| | Confusion |
| | Somnolence/Drowsiness |
| | Dizziness |
| | Pruritus |
| | Falls |
| | Other harm |
| | Additional other harm |
| | Not applicable |

# $T_1$ –72 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 *(continue to complete $T_1$)* |
| | Died *(record date of death below)* |
| | Not able to be contacted / located |
| | Too unwell |
| | Other |

| | |
|---|---|
| **Date of Death*** | DD/MM/YYYY |

***End survey here***

| **What medications/s have been given in the pump in the last 24hours?** | | | | |
|---|---|---|---|---|
| **Tick ✓** | **NAME** | **Concentration** | **Infusion rate** (mg/mcg/hour) | **Bolus dose prescribed** |
| | Bupivacaine | | | |
| | Ropivacaine | | | |
| | Morphine | | | |
| | Hydromorphone | | | |
| | Baclofen | | | |
| | Clonidine | | | |
| | Other -please specify: _____ | | | |
| | Other - please specify: _____ | | | |

| | |
|---|---|
| **How long has the patient been on this dose** (hours) | |

| **Tick ✓** | | **Have there been any interruptions to the infusion since baseline due to a hardware problem?** (E.g. catheter accidentally dislodged/removed, issues with the pump that caused pump failure or stall, an issue with the gripper needle if an external device, or catheter kinking or disconnection) |
|---|---|---|
| **Yes** | **No** | |
| | | If YES, please explain interruption here: |

**SYMPTOM SEVERITY**

**How would your patient rate their *distress due to pain* out of 10 currently?**
*(Circle number in the box)*

0 = no distress at all  5 = moderate distress  10 = worst possible distress

| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Not reported |
|---|---|---|---|---|---|---|---|---|---|---|---|

No distress  Moderate distress  Worst possible distress

**Please rate patient's *pain* at its *worst in the last 24 hours*** *(Circle number in box that best describes their pain)*

0 = no pain at all  5 = moderate pain  10 = worst possible pain

| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Not reported |
|---|---|---|---|---|---|---|---|---|---|---|---|

No pain  Moderate pain  Worst possible pain

**Please rate your patient's *pain right now*** *(Circle number in box that best describes their pain)*

0 = no pain at all  5 = moderate pain  10 = worst possible pain

| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Not reported |
|---|---|---|---|---|---|---|---|---|---|---|---|

No pain  Moderate pain  Worst possible pain

**Please rate your patient's *psychological/spiritual distress*** *(Circle number in box that best describes their level of distress)*

| 0 = absent | 1 = mild | 2 = moderate | 3 = severe | 4 = not recorded/ assessed |
|---|---|---|---|---|

| **Tick ✓** | **Clinical Global Impression (CGI)**<br>**Global improvement:** *(Clinician to rate total improvement compared to patient's condition at admission to the project, how much has he changed?)* |
|---|---|
| | 0 = Not assessed |
| | 1 = Very much improved |
| | 2 = Much improved |
| | 3 = Minimally improved |
| | 4 = No change |
| | 5 = Minimally worse |
| | 6 = Much worse |
| | 7 = Very much worse |

**Efficacy index:** Rate this on the basis of **drug effect only**.
Select the terms below which best describe the degrees of therapeutic effect and side effects and record the number in the box where the 2 items intersect.
(E.g. If therapeutic effect is rated as 'moderate' and side effects are judged 'do not significantly interfere with patients functioning' the score = 6)

| | | **Side effects** | | | |
|---|---|---|---|---|---|
| | | **None** | **Do not significantly interfere with patients functioning** | **Significantly interfere with patients functioning** | **Outweighs therapeutic effect** |
| **Therapeutic effect** | **Marked - Vast improvement. Complete or nearly complete remission of all symptoms** | 01 | 02 | 03 | 04 |
| | **Moderate - Decided improvement. Partial remission of symptoms** | 05 | 06 | 07 | 08 |
| | **Minimal. Slight improvement which doesn't alter status of care of patient** | 09 | 10 | 11 | 12 |
| | **Unchanged or worse** | 13 | 14 | 15 | 16 |
| | **Not assessed = 00** | | | | |
| **Record Efficacy Index Score here** | | | | | |

## $T_1$ – Harm/Toxicity Assessment

*(Please grade all harms/toxicities regardless of whether they are attributable to the medication of interest or not; indicate that each harm has been assessed by ticking the square box next to each)*

☐ **Nausea**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. Loss of appetite without alteration in eating habits
2. Oral intake decreased without significant weight loss, dehydration or malnutrition
3. Inadequate oral caloric or fluid intake; tube feeding, TPN, or hospitalization

☐ **Vomiting**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. Intervention not indicated
2. Outpatient IV hydration; medical intervention indicated
3. Tube feeding, TPN, or hospitalization indicated
4. Life-threatening consequences
5. Death

☐ **Constipation**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No symptom ○ Not reported

*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

☐ **Confusion**

○ 1 ○ 2 ○ 3 ○ 4 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. Mild disorientation
2. Moderate disorientation; limiting instrumental ADL
3. Severe disorientation; limiting self-care ADL
4. Life-threatening consequences; urgent intervention indicated

☐ **Somnolence/Drowsiness**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. Mild but more than usual drowsiness or sleepiness
2. Moderate sedation; limiting instrumental ADL
3. Obtundation or stupor
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **Dizziness**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. Mild unsteadiness or sensation of movement
2. Moderate unsteadiness or sensation of movement; limiting instrumental ADL
3. Severe unsteadiness or sensation of movement; limiting self-care ADL

☐ **Pruritus**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. Mild or localized; topical intervention indicated
2. Widespread and intermittent; skin changes from scratching (e.g., edema, papulation, excoriations, lichenification, oozing/crusts); oral intervention indicated; limiting instrumental ADL
3. Widespread and constant; limiting self-care ADL or sleep; systemic corticosteroid or immunosuppressive

☐ **Falls (within the past 72 hours)**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. Minor with no resultant injuries; intervention not indicated
2. Symptomatic; noninvasive intervention indicated
3. Hospitalization indicated; invasive intervention indicated

☐ **Bleeding at insertion site**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. Minimal bleeding identified on clinical exam; intervention not indicated
2. Moderate bleeding; medical intervention indicated
3. Transfusion indicated; invasive intervention indicated
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **Infection (skin)**

○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. –
2. Localized; local intervention indicated; oral intervention indicated (e.g., antibiotic, antifungal, or antiviral)
3. IV antibiotic, antifungal, or antiviral intervention indicated; invasive intervention indicated
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **Infection (meningitis)**

○ 3 ○ 4 ○ 5 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. –
2. –
3. IV antibiotic, antifungal, or antiviral intervention indicated; invasive intervention indicated; focal neurologic deficit
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **Urinary retention**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. Urinary, suprapubic or intermittent catheter placement not indicated; able to void with some residual
2. Placement of urinary, suprapubic or intermittent catheter placement indicated; medication indicated
3. Elective invasive intervention indicated; substantial loss of affected kidney function or mass
4. Life-threatening consequences; organ failure; urgent operative intervention indicated
5. Death

☐ **Headache**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. Post-lumbar puncture: transient headache; postural care indicated
2. Post-lumbar puncture: persistent moderate symptoms; blood patch indicated
3. Severe symptoms; medical intervention indicated
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **Sensory deficits**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. Mild; intervention not indicated
2. Moderate; limiting instrumental ADL
3. Severe; limiting self-care ADL

☐ **Motor deficits**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. Minor; intervention not indicated
2. Moderate; limiting instrumental ADL
3. Severe; limiting self-care ADL

☐ **Other harms (*only if applicable - can be related or unrelated to intervention*)**

*Please specify other harm here:* _____

○ Mild ○ Moderate ○ Severe ○ Ungradable

☐ **Additional other harms (*only if applicable - can be related or unrelated to intervention*)** *Please specify additional other harm here:* _____

○ Mild ○ Moderate ○ Severe ○ Ungradable

| **Tick ✓** | **Which symptom/harm is the most troublesome?** *(Tick one only)* |
|---|---|
| | Nausea |
| | Vomiting |
| | Constipation |
| | Confusion |
| | Somnolence/Drowsiness |
| | Dizziness |
| | Pruritus |
| | Falls |
| | Bleeding at insertion site |
| | Infection (skin) |
| | Infection (meningitis) |
| | Urinary retention |
| | Headache |
| | Sensory deficit |
| | Motor deficit |
| | Other harm |
| | Additional other harm |
| | Not applicable |

**If a harm/toxicity scored 3 or more, please complete this set of questions from the Naranjo modified checklist** *(Tick 'yes', 'no', or 'don't know' for each question below) (If the symptom was present at baseline and grading remains unchanged the Naranjo questions are not required to be answered.)*

| | Yes | No | Don't know |
|---|---|---|---|
| 1. Did the adverse reaction appear after the suspected drug was given? | | | |
| 2. Did the adverse reaction improve when the drug was discontinued, or a specific antagonist was given? | | | |
| 3. Are there alternative causes (other than the drug) that could on their own have caused the reaction? | | | |
| 4. Did the patient have a similar reaction to the same or similar drug in any previous exposure? | | | |
| 5. Was the adverse event confirmed by any objective evidence? | | | |

## Post harms assessment

| Tick ✓ | | What is the intended treatment based on today's assessment? *(Tick all that apply)* |
|---|---|---|
| | | No change to medication of interest/continue current dose |
| | | Medication of interest dose reduced - please specify new dose here: _____ |
| | | Medication of interest increased - please specify new dose here: _____ |
| | | Medication of interest ceased |
| **Yes** | **No** | Has an intervention/medication been added to treat a specific harm/toxicity? If yes, please specify medication here: _____ |
| | | |

| **Based on the assessment today has the harm resolved?** |
|---|
| ○ Yes ○ No ○ Not applicable |

| $T_2$ – 7 days post Baseline | |
|---|---|
| **Date of Assessment** | DD/MM/YYYY |
| **Time of Assessment (24hr clock)** | HH:MM |

| Tick✓ | $T_2$: Assessed/Not assessed reason |
|---|---|
| | Assessed today *(continue to complete $T_2$)* |
| | Died *(record date of death below)* |
| | 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 7 days after baseline assessment.*

| |
|---|
| |

| **What medications/s have been given in the pump in the last 24hours?** | | | | |
|---|---|---|---|---|
| **Tick ✓** | **NAME** | **Concentration** | **Infusion rate** (mg/mcg/hour) | **Bolus dose prescribed** |
| | Bupivacaine | | | |
| | Ropivacaine | | | |
| | Morphine | | | |
| | Hydromorphone | | | |
| | Baclofen | | | |
| | Clonidine | | | |
| | Other -please specify: _____ | | | |
| | Other - please specify: _____ | | | |

| **How long has the patient been on this dose** (hours) | |
|---|---|

| **Tick ✓** | | **Have there been any interruptions to the infusion since baseline due to a hardware problem?** (E.g. catheter accidentally dislodged/removed, issues with the pump that caused pump failure or stall, an issue with the gripper needle if an external device, or catheter kinking or disconnection) |
|---|---|---|
| **Yes** | **No** | |
| | | If YES, please explain interruption here: |

**SYMPTOM SEVERITY**

**How would your patient rate their *distress due to pain* out of 10 currently?**
*(Circle number in the box)*

0 = no distress at all  5 = moderate distress  10 = worst possible distress

| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Not reported |
|---|---|---|---|---|---|---|---|---|---|---|---|

No distress  Moderate distress  Worst possible distress

**Please rate patient's *pain* at its *worst in the last 24 hours*** *(Circle number in box that best describes their pain)*

0 = no pain at all  5 = moderate pain  10 = worst possible pain

| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Not reported |
|---|---|---|---|---|---|---|---|---|---|---|---|

No pain  Moderate pain  Worst possible pain

**Please rate your patient's *pain right now*** *(Circle number in box that best describes their pain)*

0 = no pain at all  5 = moderate pain  10 = worst possible pain

| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Not reported |
|---|---|---|---|---|---|---|---|---|---|---|---|

No pain  Moderate pain  Worst possible pain

**Please rate your patient's *psychological/spiritual distress*** *(Circle number in box that best describes their level of distress)*

| 0 = absent | 1 = mild | 2 = moderate | 3 = severe | 4 = not recorded/ assessed |
|---|---|---|---|---|

| **Tick ✓** | **Clinical Global Impression (CGI)**<br>**Global improvement:** *(Clinician to rate total improvement compared to patient's condition at admission to the project, how much has he changed?)* |
|---|---|
| | 0 = Not assessed |
| | 1 = Very much improved |
| | 2 = Much improved |
| | 3 = Minimally improved |
| | 4 = No change |
| | 5 = Minimally worse |
| | 6 = Much worse |
| | 7 = Very much worse |

**Efficacy index:** Rate this on the basis of **drug effect only**.
Select the terms below which best describe the degrees of therapeutic effect and side effects and record the number in the box where the 2 items intersect.
(E.g. If therapeutic effect is rated as 'moderate' and side effects are judged 'do not significantly interfere with patients functioning' the score = 6)

| | | Side effects | | | |
|---|---|---|---|---|---|
| | | **None** | **Do not significantly interfere with patients functioning** | **Significantly interfere with patients functioning** | **Outweighs therapeutic effect** |
| **Therapeutic effect** | **Marked - Vast improvement. Complete or nearly complete remission of all symptoms** | 01 | 02 | 03 | 04 |
| | **Moderate - Decided improvement. Partial remission of symptoms** | 05 | 06 | 07 | 08 |
| | **Minimal. Slight improvement which doesn't alter status of care of patient** | 09 | 10 | 11 | 12 |
| | **Unchanged or worse** | 13 | 14 | 15 | 16 |
| | **Not assessed = 00** | | | | |
| **Record Efficacy Index Score here** | | | | | |

## $T_2$ – Harm/Toxicity Assessment

*(Please grade all harms/toxicities regardless of whether they are attributable to the medication of interest or not; indicate that each harm has been assessed by ticking the square box next to each)*

☐ **Nausea**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. Loss of appetite without alteration in eating habits
2. Oral intake decreased without significant weight loss, dehydration or malnutrition
3. Inadequate oral caloric or fluid intake; tube feeding, TPN, or hospitalization

☐ **Vomiting**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. Intervention not indicated
2. Outpatient IV hydration; medical intervention indicated
3. Tube feeding, TPN, or hospitalization indicated
4. Life-threatening consequences
5. Death

☐ **Constipation**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No symptom ○ Not reported

*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

☐ **Confusion**

○ 1 ○ 2 ○ 3 ○ 4 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. Mild disorientation
2. Moderate disorientation; limiting instrumental ADL
3. Severe disorientation; limiting self-care ADL
4. Life-threatening consequences; urgent intervention indicated

☐ **Somnolence/Drowsiness**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. Mild but more than usual drowsiness or sleepiness
2. Moderate sedation; limiting instrumental ADL
3. Obtundation or stupor
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **Dizziness**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. Mild unsteadiness or sensation of movement
2. Moderate unsteadiness or sensation of movement; limiting instrumental ADL
3. Severe unsteadiness or sensation of movement; limiting self-care ADL

☐ **Pruritus**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. Mild or localized; topical intervention indicated
2. Widespread and intermittent; skin changes from scratching (e.g., edema, papulation, excoriations, lichenification, oozing/crusts); oral intervention indicated; limiting instrumental ADL
3. Widespread and constant; limiting self-care ADL or sleep; systemic corticosteroid or immunosuppressive

☐ **Falls (since $T_1$)**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. Minor with no resultant injuries; intervention not indicated
2. Symptomatic; noninvasive intervention indicated
3. Hospitalization indicated; invasive intervention indicated

☐ **Bleeding at insertion site**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. Minimal bleeding identified on clinical exam; intervention not indicated
2. Moderate bleeding; medical intervention indicated
3. Transfusion indicated; invasive intervention indicated
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **Infection (skin)**

○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. –
2. Localized; local intervention indicated; oral intervention indicated (e.g., antibiotic, antifungal, or antiviral)
3. IV antibiotic, antifungal, or antiviral intervention indicated; invasive intervention indicated
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **Infection (meningitis)**

○ 3 ○ 4 ○ 5 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. –
2. –
3. IV antibiotic, antifungal, or antiviral intervention indicated; invasive intervention indicated; focal neurologic deficit
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **Urinary retention**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. Urinary, suprapubic or intermittent catheter placement not indicated; able to void with some residual
2. Placement of urinary, suprapubic or intermittent catheter placement indicated; medication indicated
3. Elective invasive intervention indicated; substantial loss of affected kidney function or mass
4. Life-threatening consequences; organ failure; urgent operative intervention indicated
5. Death

☐ **Headache**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. Post-lumbar puncture: transient headache; postural care indicated
2. Post-lumbar puncture: persistent moderate symptoms; blood patch indicated
3. Severe symptoms; medical intervention indicated
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **Sensory deficits**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. Mild; intervention not indicated
2. Moderate; limiting instrumental ADL
3. Severe; limiting self-care ADL

☐ **Motor deficits**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom ○ Not reported

| |
|---|
| *NCI Criteria*<br>1. Minor; intervention not indicated<br>2. Moderate; limiting instrumental ADL<br>3. Severe; limiting self-care ADL |

☐ **Other harms (*only if applicable - can be related or unrelated to intervention*)**

*Please specify other harm here:* _____

○ Mild ○ Moderate ○ Severe ○ Ungradable

☐ **Additional other harms (*only if applicable - can be related or unrelated to intervention*)** *Please specify additional other harm here:* _____

○ Mild ○ Moderate ○ Severe ○ Ungradable

| **Tick ✓** | **Which symptom/harm is the most troublesome?** *(Tick one only)* |
|---|---|
| | Nausea |
| | Vomiting |
| | Constipation |
| | Confusion |
| | Somnolence/Drowsiness |
| | Dizziness |
| | Pruritus |
| | Falls |
| | Bleeding at insertion site |
| | Infection (skin) |
| | Infection (meningitis) |
| | Urinary retention |
| | Headache |
| | Sensory deficit |
| | Motor deficit |
| | Other harm |
| | Additional other harm |
| | Not applicable |

**If a harm/toxicity scored 3 or more, please complete this set of questions from the Naranjo modified checklist** *(Tick 'yes', 'no', or 'don't know' for each question below) (If the symptom was present at baseline and grading remains unchanged the Naranjo questions are not required to be answered.)*

| | Yes | No | Don't know |
|---|---|---|---|
| 1. Did the adverse reaction appear after the suspected drug was given? | | | |
| 2. Did the adverse reaction improve when the drug was discontinued, or a specific antagonist was given? | | | |
| 3. Are there alternative causes (other than the drug) that could on their own have caused the reaction? | | | |
| 4. Did the patient have a similar reaction to the same or similar drug in any previous exposure? | | | |
| 5. Was the adverse event confirmed by any objective evidence? | | | |

## Post harms assessment

| Tick ✓ | | What is the intended treatment based on today's assessment? *(Tick all that apply)* |
|---|---|---|
| | | No change to medication of interest/continue current dose |
| | | Medication of interest dose reduced - please specify new dose here: _____ |
| | | Medication of interest increased - please specify new dose here: _____ |
| | | Medication of interest ceased |
| **Yes** | **No** | Has an intervention/medication been added to treat a specific harm/toxicity? |
| | | If yes, please specify medication here: _____ |

| **Based on the assessment today has the harm resolved?** |
|---|
| ○ Yes ○ No ○ Not applicable |

## $T_3$ – On discharge from hospital

*(Whenever that occurs – may be before $T_2$)*

| | |
|---|---|
| **Date of Assessment** | DD/MM/YYYY |
| **Time of Assessment (24hr clock)** | HH:MM |

| Tick ✓ | $T_3$: Assessed/Not assessed reason |
|---|---|
| | Assessed today *(continue to complete $T_3$)* |
| | Died *(record date of death below)* |
| | Not able to be contacted / located |
| | Too unwell |
| | Other |

| | |
|---|---|
| **Date of Death*** | DD/MM/YYYY |

***End survey here***

**What medications/s have been given in the pump in the last 24hours?**

| Tick ✓ | NAME | Concentration | Infusion rate (mg/mcg/hour) | Bolus dose prescribed |
|---|---|---|---|---|
| | Bupivacaine | | | |
| | Ropivacaine | | | |
| | Morphine | | | |
| | Hydromorphone | | | |
| | Baclofen | | | |
| | Clonidine | | | |
| | Other -please specify: _____ | | | |
| | Other - please specify: _____ | | | |

| | |
|---|---|
| **How long has the patient been on this dose** (hours) | |

| Tick ✓ | | **Have there been any interruptions to the infusion since baseline due to a hardware problem?** (E.g. catheter accidentally dislodged/removed, issues with the pump that caused pump failure or stall, an issue with the gripper needle if an external device, or catheter kinking or disconnection) |
|---|---|---|
| **Yes** | **No** | |
| | | If YES, please explain interruption here: |

**SYMPTOM SEVERITY**

**How would your patient rate their *distress due to pain* out of 10 currently?** *(Circle number in the box)*

0 = no distress at all  5 = moderate distress  10 = worst possible distress

| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Not reported |
|---|---|---|---|---|---|---|---|---|---|---|---|

No distress  Moderate distress  Worst possible distress

**Please rate patient's *pain* at its *worst in the last 24 hours*** *(Circle number in box that best describes their pain)*

0 = no pain at all  5 = moderate pain  10 = worst possible pain

| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Not reported |
|---|---|---|---|---|---|---|---|---|---|---|---|

No pain  Moderate pain  Worst possible pain

**Please rate your patient's *pain right now*** *(Circle number in box that best describes their pain)*

0 = no pain at all  5 = moderate pain  10 = worst possible pain

| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Not reported |
|---|---|---|---|---|---|---|---|---|---|---|---|

No pain  Moderate pain  Worst possible pain

**Please rate your patient's *psychological/spiritual distress*** *(Circle number in box that best describes their level of distress)*

| 0 = absent | 1 = mild | 2 = moderate | 3 = severe | 4 = not recorded/ assessed |
|---|---|---|---|---|

| **Tick ✓** | **Clinical Global Impression (CGI)**<br>**Global improvement:** *(Clinician to rate total improvement compared to patient's condition at admission to the project, how much has he changed?)* |
|---|---|
| | 0 = Not assessed |
| | 1 = Very much improved |
| | 2 = Much improved |
| | 3 = Minimally improved |
| | 4 = No change |
| | 5 = Minimally worse |
| | 6 = Much worse |
| | 7 = Very much worse |

**Efficacy index:** Rate this on the basis of **drug effect only**.
Select the terms below which best describe the degrees of therapeutic effect and side effects and record the number in the box where the 2 items intersect.
(E.g. If therapeutic effect is rated as 'moderate' and side effects are judged 'do not significantly interfere with patients functioning' the score = 6)

| | | Side effects | | | |
|---|---|---|---|---|---|
| | | **None** | **Do not significantly interfere with patients functioning** | **Significantly interfere with patients functioning** | **Outweighs therapeutic effect** |
| **Therapeutic effect** | **Marked - Vast improvement. Complete or nearly complete remission of all symptoms** | 01 | 02 | 03 | 04 |
| | **Moderate - Decided improvement. Partial remission of symptoms** | 05 | 06 | 07 | 08 |
| | **Minimal. Slight improvement which doesn't alter status of care of patient** | 09 | 10 | 11 | 12 |
| | **Unchanged or worse** | 13 | 14 | 15 | 16 |
| | **Not assessed = 00** | | | | |
| **Record Efficacy Index Score here** | | | | | |

## $T_3$ – Harm/Toxicity Assessment

*(Please grade all harms/toxicities regardless of whether they are attributable to the medication of interest or not; indicate that each harm has been assessed by ticking the square box next to each)*

☐ **Nausea**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. Loss of appetite without alteration in eating habits
2. Oral intake decreased without significant weight loss, dehydration or malnutrition
3. Inadequate oral caloric or fluid intake; tube feeding, TPN, or hospitalization

☐ **Vomiting**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. Intervention not indicated
2. Outpatient IV hydration; medical intervention indicated
3. Tube feeding, TPN, or hospitalization indicated
4. Life-threatening consequences
5. Death

☐ **Constipation**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No symptom ○ Not reported

*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

☐ **Confusion**

○ 1 ○ 2 ○ 3 ○ 4 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. Mild disorientation
2. Moderate disorientation; limiting instrumental ADL
3. Severe disorientation; limiting self-care ADL
4. Life-threatening consequences; urgent intervention indicated

☐ **Somnolence/Drowsiness**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. Mild but more than usual drowsiness or sleepiness
2. Moderate sedation; limiting instrumental ADL
3. Obtundation or stupor
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **Dizziness**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. Mild unsteadiness or sensation of movement
2. Moderate unsteadiness or sensation of movement; limiting instrumental ADL
3. Severe unsteadiness or sensation of movement; limiting self-care ADL

☐ **Pruritus**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1.Mild or localized; topical intervention indicated
2. Widespread and intermittent; skin changes from scratching (e.g., edema, papulation, excoriations, lichenification, oozing/crusts); oral intervention indicated; limiting instrumental ADL
3. Widespread and constant; limiting self-care ADL or sleep; systemic corticosteroid or immunosuppressive

☐ **Falls (since $T_2$)**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. Minor with no resultant injuries; intervention not indicated
2. Symptomatic; noninvasive intervention indicated
3. Hospitalization indicated; invasive intervention indicated

☐ **Bleeding at insertion site**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. Minimal bleeding identified on clinical exam; intervention not indicated
2. Moderate bleeding; medical intervention indicated
3. Transfusion indicated; invasive intervention indicated
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **Infection (skin)**

○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. –
2. Localized; local intervention indicated; oral intervention indicated (e.g., antibiotic, antifungal, or antiviral)
3. IV antibiotic, antifungal, or antiviral intervention indicated; invasive intervention indicated
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **Infection (meningitis)**

○ 3 ○ 4 ○ 5 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. –
2. –
3. IV antibiotic, antifungal, or antiviral intervention indicated; invasive intervention indicated; focal neurologic deficit
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **Urinary retention**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. Urinary, suprapubic or intermittent catheter placement not indicated; able to void with some residual
2. Placement of urinary, suprapubic or intermittent catheter placement indicated; medication indicated
3. Elective invasive intervention indicated; substantial loss of affected kidney function or mass
4. Life-threatening consequences; organ failure; urgent operative intervention indicated
5. Death

☐ **Headache**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. Post-lumbar puncture: transient headache; postural care indicated
2. Post-lumbar puncture: persistent moderate symptoms; blood patch indicated
3. Severe symptoms; medical intervention indicated
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **Sensory deficits**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. Mild; intervention not indicated
2. Moderate; limiting instrumental ADL
3. Severe; limiting self-care ADL

☐ **Motor deficits**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. Minor; intervention not indicated
2. Moderate; limiting instrumental ADL
3. Severe; limiting self-care ADL

☐ **Other harms (*only if applicable - can be related or unrelated to intervention*)**

*Please specify other harm here:* _____

○ Mild ○ Moderate ○ Severe ○ Ungradable

☐ **Additional other harms (*only if applicable - can be related or unrelated to intervention*)** *Please specify additional other harm here:* _____

○ Mild ○ Moderate ○ Severe ○ Ungradable

| **Tick ✓** | **Which symptom/harm is the most troublesome?** *(Tick one only)* |
|---|---|
| | Nausea |
| | Vomiting |
| | Constipation |
| | Confusion |
| | Somnolence/Drowsiness |
| | Dizziness |
| | Pruritus |
| | Falls |
| | Bleeding at insertion site |
| | Infection (skin) |
| | Infection (meningitis) |
| | Urinary retention |
| | Headache |
| | Sensory deficit |
| | Motor deficit |
| | Other harm |
| | Additional other harm |
| | Not applicable |

| **If a harm/toxicity scored 3 or more, please complete this set of questions from the Naranjo modified checklist.** *(Tick 'yes', 'no', or 'don't know' for each question below) (If the symptom was present at baseline and grading remains unchanged the Naranjo questions are not required to be answered.)* |
|---|

| | **Yes** | **No** | **Don't know** |
|---|---|---|---|
| 1. Did the adverse reaction appear after the suspected drug was given? | | | |
| 2. Did the adverse reaction improve when the drug was discontinued, or a specific antagonist was given? | | | |
| 3. Are there alternative causes (other than the drug) that could on their own have caused the reaction? | | | |
| 4. Did the patient have a similar reaction to the same or similar drug in any previous exposure? | | | |
| 5. Was the adverse event confirmed by any objective evidence? | | | |

## Post harms assessment

| **Tick ✓** | | **What is the intended treatment based on today's assessment?** *(Tick all that apply)* |
|---|---|---|
| | | No change to medication of interest/continue current dose |
| | | Medication of interest dose reduced - please specify new dose here: _____ |
| | | Medication of interest increased - please specify new dose here: _____ |
| | | Medication of interest ceased |
| **Yes** | **No** | Has an intervention/medication been added to treat a specific harm/toxicity? |
| | | If yes, please specify medication here: _____ |

| **Based on the assessment today has the harm resolved?** |
|---|
| ○ Yes ○ No ○ Not applicable |

## Treatment Cessation (only complete this page if the intrathecal catheter is removed at any point during the study period)

| **Date of Assessment (treatment cessation)** | DD/MM/YYYY |
|---|---|

| **Tick ✓** | **Treatment was ceased (related to intrathecal catheter)** |
|---|---|
| | Symptom resolved - please indicate date symptom resolved: DD/MM/YYYY |
| | Symptom continued unchanged |
| | Symptom/s worsened - please record Pain Score below. |

**Please rate your patient's *pain right now*** *(Circle number in box that best describes their pain)*

0 = no pain at all  5 = moderate pain  10 = worst possible pain

| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Not reported |
|---|---|---|---|---|---|---|---|---|---|---|---|

No pain  Moderate pain  Worst possible pain

| **Tick ✓** | **Treatment was ceased (related to other reasons)** |
|---|---|
| | Harm/toxicity |
| | Patient unable to take medication - please specify: _____ _____ |
| | Other - please specify: _____ |

| **What treatment did you subsequently initiate following the removal of the intrathecal catheter?** |
|---|
| |

# Ad hoc A - Unscheduled Harm/Toxicity Assessment

| **Date of Assessment** | DD/MM/YYYY |
|---|---|

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

☐ **Nausea**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. Loss of appetite without alteration in eating habits
2. Oral intake decreased without significant weight loss, dehydration or malnutrition
3. Inadequate oral caloric or fluid intake; tube feeding, TPN, or hospitalization

☐ **Vomiting**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. Intervention not indicated
2. Outpatient IV hydration; medical intervention indicated
3. Tube feeding, TPN, or hospitalization indicated
4. Life-threatening consequences
5. Death

☐ **Constipation**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No symptom ○ Not reported

*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

☐ **Confusion**

○ 1 ○ 2 ○ 3 ○ 4 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. Mild disorientation
2. Moderate disorientation; limiting instrumental ADL
3. Severe disorientation; limiting self-care ADL
4. Life-threatening consequences; urgent intervention indicated

☐ **Somnolence/Drowsiness**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. Mild but more than usual drowsiness or sleepiness
2. Moderate sedation; limiting instrumental ADL
3. Obtundation or stupor
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **Dizziness**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. Mild unsteadiness or sensation of movement
2. Moderate unsteadiness or sensation of movement; limiting instrumental ADL
3. Severe unsteadiness or sensation of movement; limiting self-care ADL

☐ **Pruritus**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. Mild or localized; topical intervention indicated
2. Widespread and intermittent; skin changes from scratching (e.g., edema, papulation, excoriations, lichenification, oozing/crusts); oral intervention indicated; limiting instrumental ADL
3. Widespread and constant; limiting self-care ADL or sleep; systemic corticosteroid or immunosuppressive

☐ **Falls (within the past 72 hours)**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. Minor with no resultant injuries; intervention not indicated
2. Symptomatic; noninvasive intervention indicated
3. Hospitalization indicated; invasive intervention indicated

☐ **Bleeding at insertion site**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. Minimal bleeding identified on clinical exam; intervention not indicated
2. Moderate bleeding; medical intervention indicated
3. Transfusion indicated; invasive intervention indicated
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **Infection (skin)**

○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. –
2. Localized; local intervention indicated; oral intervention indicated (e.g., antibiotic, antifungal, or antiviral)
3. IV antibiotic, antifungal, or antiviral intervention indicated; invasive intervention indicated
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **Infection (meningitis)**

○ 3 ○ 4 ○ 5 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. –
2. –
3. IV antibiotic, antifungal, or antiviral intervention indicated; invasive intervention indicated; focal neurologic deficit
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **Urinary retention**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. Urinary, suprapubic or intermittent catheter placement not indicated; able to void with some residual
2. Placement of urinary, suprapubic or intermittent catheter placement indicated; medication indicated
3. Elective invasive intervention indicated; substantial loss of affected kidney function or mass
4. Life-threatening consequences; organ failure; urgent operative intervention indicated
5. Death

☐ **Headache**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. Post-lumbar puncture: transient headache; postural care indicated
2. Post-lumbar puncture: persistent moderate symptoms; blood patch indicated
3. Severe symptoms; medical intervention indicated
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **Sensory deficits**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. Mild; intervention not indicated
2. Moderate; limiting instrumental ADL
3. Severe; limiting self-care ADL

☐ **Motor deficits**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. Minor; intervention not indicated
2. Moderate; limiting instrumental ADL
3. Severe; limiting self-care ADL

☐ **Other harms (*only if applicable - can be related or unrelated to intervention*)**

*Please specify other harm here:* _____

○ Mild ○ Moderate ○ Severe ○ Ungradable

☐ **Additional other harms (*only if applicable - can be related or unrelated to intervention*)** *Please specify additional other harm here:* _____

○ Mild ○ Moderate ○ Severe ○ Ungradable

| **Tick ✓** | **Which symptom/harm is the most troublesome?** *(Tick one only)* |
|---|---|
| | Nausea |
| | Vomiting |
| | Constipation |
| | Confusion |
| | Somnolence/Drowsiness |
| | Dizziness |
| | Pruritus |
| | Falls |
| | Bleeding at insertion site |
| | Infection (skin) |
| | Infection (meningitis) |
| | Urinary retention |
| | Headache |
| | Sensory deficit |
| | Motor deficit |
| | Other harm |
| | Additional other harm |
| | Not applicable |

**If a harm/toxicity scored 3 or more, please complete this set of questions from the Naranjo modified checklist.** *(Tick 'yes', 'no', or 'don't know' for each question below) (If the symptom was present at baseline and grading remains unchanged the Naranjo questions are not required to be answered.)*

| | Yes | No | Don't know |
|---|---|---|---|
| 1. Did the adverse reaction appear after the suspected drug was given? | | | |
| 2. Did the adverse reaction improve when the drug was discontinued, or a specific antagonist was given? | | | |
| 3. Are there alternative causes (other than the drug) that could on their own have caused the reaction? | | | |
| 4. Did the patient have a similar reaction to the same or similar drug in any previous exposure? | | | |
| 5. Was the adverse event confirmed by any objective evidence? | | | |

# Ad hoc B - Unscheduled Harm/Toxicity Assessment

| **Date of Assessment** | DD/MM/YYYY |
|---|---|

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

☐ **Nausea**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. Loss of appetite without alteration in eating habits
2. Oral intake decreased without significant weight loss, dehydration or malnutrition
3. Inadequate oral caloric or fluid intake; tube feeding, TPN, or hospitalization

☐ **Vomiting**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. Intervention not indicated
2. Outpatient IV hydration; medical intervention indicated
3. Tube feeding, TPN, or hospitalization indicated
4. Life-threatening consequences
5. Death

☐ **Constipation**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No symptom ○ Not reported

*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

☐ **Confusion**

○ 1 ○ 2 ○ 3 ○ 4 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. Mild disorientation
2. Moderate disorientation; limiting instrumental ADL
3. Severe disorientation; limiting self-care ADL
4. Life-threatening consequences; urgent intervention indicated

☐ **Somnolence/Drowsiness**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. Mild but more than usual drowsiness or sleepiness
2. Moderate sedation; limiting instrumental ADL
3. Obtundation or stupor
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **Dizziness**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. Mild unsteadiness or sensation of movement
2. Moderate unsteadiness or sensation of movement; limiting instrumental ADL
3. Severe unsteadiness or sensation of movement; limiting self-care ADL

☐ **Pruritus**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. Mild or localized; topical intervention indicated
2. Widespread and intermittent; skin changes from scratching (e.g., edema, papulation, excoriations, lichenification, oozing/crusts); oral intervention indicated; limiting instrumental ADL
3. Widespread and constant; limiting self-care ADL or sleep; systemic corticosteroid or immunosuppressive

☐ **Falls (within the past 72 hours)**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. Minor with no resultant injuries; intervention not indicated
2. Symptomatic; noninvasive intervention indicated
3. Hospitalization indicated; invasive intervention indicated

☐ **Bleeding at insertion site**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. Minimal bleeding identified on clinical exam; intervention not indicated
2. Moderate bleeding; medical intervention indicated
3. Transfusion indicated; invasive intervention indicated
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **Infection (skin)**

○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. –
2. Localized; local intervention indicated; oral intervention indicated (e.g., antibiotic, antifungal, or antiviral)
3. IV antibiotic, antifungal, or antiviral intervention indicated; invasive intervention indicated
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **Infection (meningitis)**

○ 3 ○ 4 ○ 5 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. –
2. –
3. IV antibiotic, antifungal, or antiviral intervention indicated; invasive intervention indicated; focal neurologic deficit
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **Urinary retention**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. Urinary, suprapubic or intermittent catheter placement not indicated; able to void with some residual
2. Placement of urinary, suprapubic or intermittent catheter placement indicated; medication indicated
3. Elective invasive intervention indicated; substantial loss of affected kidney function or mass
4. Life-threatening consequences; organ failure; urgent operative intervention indicated
5. Death

☐ **Headache**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. Post-lumbar puncture: transient headache; postural care indicated
2. Post-lumbar puncture: persistent moderate symptoms; blood patch indicated
3. Severe symptoms; medical intervention indicated
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **Sensory deficits**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. Mild; intervention not indicated
2. Moderate; limiting instrumental ADL
3. Severe; limiting self-care ADL

☐ **Motor deficits**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. Minor; intervention not indicated
2. Moderate; limiting instrumental ADL
3. Severe; limiting self-care ADL

☐ **Other harms (*only if applicable - can be related or unrelated to intervention*)**

*Please specify other harm here:* _____

○ Mild ○ Moderate ○ Severe ○ Ungradable

☐ **Additional other harms (*only if applicable - can be related or unrelated to intervention*)** *Please specify additional other harm here:* _____

○ Mild ○ Moderate ○ Severe ○ Ungradable

| **Tick ✓** | **Which symptom/harm is the most troublesome?** *(Tick one only)* |
|---|---|
| | Nausea |
| | Vomiting |
| | Constipation |
| | Confusion |
| | Somnolence/Drowsiness |
| | Dizziness |
| | Pruritus |
| | Falls |
| | Bleeding at insertion site |
| | Infection (skin) |
| | Infection (meningitis) |
| | Urinary retention |
| | Headache |
| | Sensory deficit |
| | Motor deficit |
| | Other harm |
| | Additional other harm |
| | Not applicable |

**If a harm/toxicity scored 3 or more, please complete this set of questions from the Naranjo modified checklist.** *(Tick 'yes', 'no', or 'don't know' for each question below) (If the symptom was present at baseline and grading remains unchanged the Naranjo questions are not required to be answered.)*

| | Yes | No | Don't know |
|---|---|---|---|
| 1. Did the adverse reaction appear after the suspected drug was given? | | | |
| 2. Did the adverse reaction improve when the drug was discontinued, or a specific antagonist was given? | | | |
| 3. Are there alternative causes (other than the drug) that could on their own have caused the reaction? | | | |
| 4. Did the patient have a similar reaction to the same or similar drug in any previous exposure? | | | |
| 5. Was the adverse event confirmed by any objective evidence? | | | |

# Ad hoc C - Unscheduled Harm/Toxicity Assessment

| **Date of Assessment** | DD/MM/YYYY |
|---|---|

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

☐ **Nausea**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. Loss of appetite without alteration in eating habits
2. Oral intake decreased without significant weight loss, dehydration or malnutrition
3. Inadequate oral caloric or fluid intake; tube feeding, TPN, or hospitalization

☐ **Vomiting**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. Intervention not indicated
2. Outpatient IV hydration; medical intervention indicated
3. Tube feeding, TPN, or hospitalization indicated
4. Life-threatening consequences
5. Death

☐ **Constipation**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No symptom ○ Not reported

*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

☐ **Confusion**

○ 1 ○ 2 ○ 3 ○ 4 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. Mild disorientation
2. Moderate disorientation; limiting instrumental ADL
3. Severe disorientation; limiting self-care ADL
4. Life-threatening consequences; urgent intervention indicated

☐ **Somnolence/Drowsiness**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. Mild but more than usual drowsiness or sleepiness
2. Moderate sedation; limiting instrumental ADL
3. Obtundation or stupor
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **Dizziness**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. Mild unsteadiness or sensation of movement
2. Moderate unsteadiness or sensation of movement; limiting instrumental ADL
3. Severe unsteadiness or sensation of movement; limiting self-care ADL

☐ **Pruritus**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. Mild or localized; topical intervention indicated
2. Widespread and intermittent; skin changes from scratching (e.g., edema, papulation, excoriations, lichenification, oozing/crusts); oral intervention indicated; limiting instrumental ADL
3. Widespread and constant; limiting self-care ADL or sleep; systemic corticosteroid or immunosuppressive

☐ **Falls (within the past 72 hours)**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. Minor with no resultant injuries; intervention not indicated
2. Symptomatic; noninvasive intervention indicated
3. Hospitalization indicated; invasive intervention indicated

☐ **Bleeding at insertion site**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. Minimal bleeding identified on clinical exam; intervention not indicated
2. Moderate bleeding; medical intervention indicated
3. Transfusion indicated; invasive intervention indicated
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **Infection (skin)**

○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. –
2. Localized; local intervention indicated; oral intervention indicated (e.g., antibiotic, antifungal, or antiviral)
3. IV antibiotic, antifungal, or antiviral intervention indicated; invasive intervention indicated
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **Infection (meningitis)**

○ 3 ○ 4 ○ 5 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. –
2. –
3. IV antibiotic, antifungal, or antiviral intervention indicated; invasive intervention indicated; focal neurologic deficit
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **Urinary retention**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. Urinary, suprapubic or intermittent catheter placement not indicated; able to void with some residual
2. Placement of urinary, suprapubic or intermittent catheter placement indicated; medication indicated
3. Elective invasive intervention indicated; substantial loss of affected kidney function or mass
4. Life-threatening consequences; organ failure; urgent operative intervention indicated
5. Death

☐ **Headache**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. Post-lumbar puncture: transient headache; postural care indicated
2. Post-lumbar puncture: persistent moderate symptoms; blood patch indicated
3. Severe symptoms; medical intervention indicated
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **Sensory deficits**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. Mild; intervention not indicated
2. Moderate; limiting instrumental ADL
3. Severe; limiting self-care ADL

☐ **Motor deficits**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom ○ Not reported

*NCI Criteria*
1. Minor; intervention not indicated
2. Moderate; limiting instrumental ADL
3. Severe; limiting self-care ADL

☐ **Other harms (*only if applicable - can be related or unrelated to intervention*)**

*Please specify other harm here: _____*

○ Mild ○ Moderate ○ Severe ○ Ungradable

☐ **Additional other harms (*only if applicable - can be related or unrelated to intervention*)** *Please specify additional other harm here: _____*

○ Mild ○ Moderate ○ Severe ○ Ungradable

| **Tick ✓** | **Which symptom/harm is the most troublesome?** *(Tick one only)* |
|---|---|
| | Nausea |
| | Vomiting |
| | Constipation |
| | Confusion |
| | Somnolence/Drowsiness |
| | Dizziness |
| | Pruritus |
| | Falls |
| | Bleeding at insertion site |
| | Infection (skin) |
| | Infection (meningitis) |
| | Urinary retention |
| | Headache |
| | Sensory deficit |
| | Motor deficit |
| | Other harm |
| | Additional other harm |
| | Not applicable |

**If a harm/toxicity scored 3 or more, please complete this set of questions from the Naranjo modified checklist.** *(Tick 'yes', 'no', or 'don't know' for each question below) (If the symptom was present at baseline and grading remains unchanged the Naranjo questions are not required to be answered.)*

| | Yes | No | Don't know |
|---|---|---|---|
| 1. Did the adverse reaction appear after the suspected drug was given? | | | |
| 2. Did the adverse reaction improve when the drug was discontinued, or a specific antagonist was given? | | | |
| 3. Are there alternative causes (other than the drug) that could on their own have caused the reaction? | | | |
| 4. Did the patient have a similar reaction to the same or similar drug in any previous exposure? | | | |
| 5. Was the adverse event confirmed by any objective evidence? | | | |

# APPENDIX

**Calculation of oral Morphine Equivalent Daily Dose (oMEDD)**
**oMEDD (mg) = Current Opioid Dose x Conversion factor**

| CURRENT OPIOID | | CONVERSION FACTOR | PROPRIETARY NAMES |
|---|---|---|---|
| **ORAL (SWALLOWED) PREPARATIONS** *Note: Modified release formulations are marked MR* | | | |
| Morphine | mg/day | 1 | Anamorph, Kapanol (MR), MS Contin (MR), MS Mono (MR), Ordine, Sevredol |
| Oxycodone | mg/day | 1.5 | Endone, OxyContin (MR), OxyNorm, Targin (MR) |
| Hydromorphone | mg/day | 5 | Dilaudid, Jurnista (MR) |
| Codeine | mg/day | 0.13 | Aspalgin, Codalgin, Panadeine, Panadeine Forte, Mersyndol, Nurofen Plus, others |
| Dextropropoxyphene | mg/day | 0.1 | Di-Gesic, Doloxene |
| Tramadol | mg/day | 0.2 | Durotram-XR (MR) , Tramal, Tramadol SR (MR), Zydol, Zydol SR (MR), others |
| Tapentadol | mg/day | 0.3 | Palexia-SR (MR), Palexia-IR |
| **SUBLINGUAL PREPARATIONS** | | | |
| Buprenorphine | mg/day | 40 | Suboxone, Subutex, Temgesic |
| **RECTAL PREPARATION** *Note: Absorption from rectal administration is highly variable* | | | |
| Oxycodone | mg/day | 1.5 | Proladone |
| **TRANSDERMAL PREPARATIONS** | | | |
| Buprenorphine | mcg/hr | 2 | Norspan |
| Fentanyl | mcg/hr | 3 | Denpax, Durogesic, Dutran, Fenpatch, Fentanyl Sandoz |
| **PARENTERAL PREPARATIONS** | | | |
| Morphine | mg/day | 3 | DBL morphine sulphate injection, DBL morphine tartrate injection |
| Oxycodone | mg/day | 3 | OxyNorm FI |
| Hydromorphone | mg/day | 15 | Dilaudid FI, Dilaudid-HP FI |
| Codeine | mg/day | 0.25 | Codeine phosphate injection USP |
| Pethidine | mg/day | 0.4 | Pethidine injection BP |
| Fentanyl | mcg/day | 0.2 | DBL fentanyl injection, Sublimaze |
| Sufentanil | mcg/day | 2 | |

**Reference: Faculty of Pain Medicine Australia and New Zealand College of Anaesthetists.**