

Participant ID

Initials of person entering data

Staff email

CONFIDENTIAL CASE REPORT FORM

Methadone Full Conversion Series 18

Palliative Care Clinical Studies Collaborative (PaCCSC)

RAPID Pharmacovigilance in Palliative Care

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

Demographics**Gender:** Male Female**Age: years** Weight (*kg*) Estimated UndeterminedHeight (*cm*) Estimated Undetermined**Primary life limiting illness (tick one)** Advanced metastatic cancer End stage renal failure Hepatic failure Neurodegenerative disease AIDS Cardiac failure Respiratory failure Other

Please specify Other Life limiting Illness _____

Palliative Care Phase? Stable Unstable Deteriorating Terminal

1, Stable: 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.

Australian Modified Karnofsky Performance Scale (AKPS) (circle one)

100	Normal; no complaints; no evidence of disease
90	Able to carry on normal activity; minor signs of symptoms
80	Normal activity with effort; some signs of symptoms or 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 of his 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

Laboratory tests *within the last 14 days* (fill those available)

Test	Value
Serum albumin	
C-reactive protein (CRP)	
Calculated creatinine clearance (CCr) or eGFR	
Haemoglobin - Hb	
QTc from ECG	

Charlson Comorbidity Index: *(Conditions-tick all that apply)*

- Myocardial infarct
- Congestive cardiac failure
- Peripheral vascular disease
- Cerebrovascular disease
- Dementia
- Chronic pulmonary disease
- Connective tissue disease
- Ulcer disease
- Mild liver disease
- Diabetes Hemiplegia
- Moderate or severe renal disease
- Diabetes with end organ damage

- Any tumour
- Leukaemia
- Lymphoma
- Moderate or severe liver disease
- Metastatic solid tumour
- AIDS

Edmonton classification system for Cancer Pain

For each of the following, tick the response that is most appropriate based on your clinical assessment of the patient.

1. Mechanism of Pain

- No No pain syndrome
- Nc Any nociceptive combination of visceral and/or bone or soft tissue pain
- Ne Neuropathic pain syndrome with or without any combination of nociceptive pain
- Nx Insufficient information to classify

2. Incident Pain

- Io No incident pain
- Ii Incident pain present
- Ix Insufficient information to classify

3. Psychological Distress

- Po No psychological distress
- Pp Psychological distress present
- Px Insufficient information to classify

4. Addictive Behaviour

- Ao No addictive behaviour
- Aa Addictive behaviour present
- Ax Insufficient information to classify

5. Cognitive Function

- Co No impairment. Patient able to provide accurate present and past pain history unimpaired
- Ci Partial impairment. Sufficient impairment to affect patient's ability to provide accurate present and/or past pain history
- Cu Total impairment. Patient unresponsive, delirious or demented to the stage of being unable to provide any present and past pain history
- Cx Insufficient information to classify.

ECS-CP profile: N__ I__ P__ A__ C__ (combination of the five responses, one for each category)

To-Baseline – medication commencement**Baseline Assessment Date** (*dd/mm/yyyy*) **Symptom Severity Score****Pain**

Please score pain out of 10.

0 = no pain and 10 = worst/severe/disabling pain

 1 **2** **3** **4** **5** **6** **7** **8** **9** **10** **Reason for commencement of methadone (tick all that apply)**

- Poor pain control
- Intolerance to current opioids (*please specify adverse reactions below)
- Very high doses of other opioids
- Poor renal function
- Other- please specify below: _____

***If cessation is due to adverse drug reaction, please indicate the relevant adverse reaction below:** Nausea Drowsiness Somnolence Confusion Myoclonus If 'Other' reason please specify here: _____**Dosing of methadone commenced ATC (around the clock)**Dose of methadone commenced (*mg*) Time of first dose (*please use 24hr time*) Frequency of dose (*e.g. 4th hourly, 6th hourly*) Calculated target dose (*mgs/24hrs if available*)

Route of administration

 Oral Injectable Both**How many opioids is patient currently taking?** **0** **1** **2** **3** **4** **5** **6**

Baseline Toxicity Assessment

Drowsiness

1 2 3 4 5 ungradable no symptom

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

Nausea

1 2 3 ungradable no symptom

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 indicated

Confusion

1 2 3 4 5 ungradable no symptom

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
5. Death

Myoclonus

1 2 3 4 5 ungradable no symptom

NCI Criteria

1. Mild; asymptomatic or mild symptoms
2. Moderate; minimal; local or non-invasive intervention indicated
3. Severe or medically significant but not immediately life threatening
4. Life threatening consequences; urgent intervention indicated
5. Death

Anxiety

1 2 3 4 5 ungradable no symptom

NCI Criteria

1. Mild symptoms; intervention not indicated
2. Moderate symptoms; limiting instrumental ADL
3. Severe symptoms; limiting self-care ADL; hospitalization not indicated
4. Life-threatening; hospitalization indicated
5. Death

Restlessness

1 2 3 ungradable no symptom

NCI Criteria-

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

Respiratory Depression (RR<8/min)

1 2 3 4 5 ungradable no symptom

NCI Criteria-

1. Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated
2. Moderate; minimal; local or non-invasive intervention indicated; limiting age-appropriate instrumental ADL
3. Severe or medically significant but not immediately life-threatening; hospitalisation or prolongation of existing hospitalisation indicated; disabling; limiting self-care ADL
4. Life-threatening consequences; urgent intervention indicated
5. Death

Other (if exists)

Please specify other toxicity here _____

Other toxicity grade here:

1 2 3 4 5 Ungradable

Additional other (if exists)

Please specify additional other toxicity here _____

Additional other toxicity grade here

1 2 3 4 5 Ungradable

Which toxicity is the most troublesome?

- Drowsiness
- Nausea
- Confusion
- Myoclonus
- Anxiety
- Restlessness
- Respiratory Depression
- Other
- Additional other

T1-Final Assessment (---)**T1 Assessment Date** (dd/mm/yyyy)**Reason for final assessment**

- Stable dose for 7 days Discharge Death

T₁: Assessed/Not assessed reason

- Assessed today (continue to complete T₁) OR
 Died
 Not able to be contacted / located
 Too unwell
 Other

Date of Death**Symptom Severity Score****Pain** = Grade worst pain experienced in last 24 hours

Please score pain out of 10.

0 = no pain and 10 = worst/severe/disabling pain

- 0** **1** **2** **3** **4** **5** **6** **7** **8** **9** **10** **ungradable**

Dosing related to methadone:

Final Dose per day/24hrs	Unit	Route	Frequency	Not applicable
				<input type="checkbox"/>

How many days on stable dose?

How many opioids is patient currently taking?

0 1 2 3 4 5 6

Please record below all opioids used within 24 hours, prior to commencement of methadone:

Opioid Name	Immediate release	Sustained release	Dose	Unit (e.g. mg,)	Route (e.g. sub cut, oral, buccal)	PRN	Regular	Number of doses in last 24hrs
	<input type="radio"/>	<input type="radio"/>				<input type="radio"/>	<input type="radio"/>	
	<input type="radio"/>	<input type="radio"/>				<input type="radio"/>	<input type="radio"/>	
	<input type="radio"/>	<input type="radio"/>				<input type="radio"/>	<input type="radio"/>	
	<input type="radio"/>	<input type="radio"/>				<input type="radio"/>	<input type="radio"/>	
	<input type="radio"/>	<input type="radio"/>				<input type="radio"/>	<input type="radio"/>	
	<input type="radio"/>	<input type="radio"/>				<input type="radio"/>	<input type="radio"/>	

Laboratory tests *within the last 14 days* (fill those available)

Test	Value
Serum albumin	
C-reactive protein (CRP)	
Calculated creatinine clearance (CCr) or eGFR	
Haemoglobin - Hb	
QTc from ECG (post starting methadone) within the last 14 days	

Toxicity Assessment**Drowsiness**

1 2 3 4 5 ungradable no symptom

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

Nausea

1 2 3 ungradable no symptom

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 indicated

Confusion

1 2 3 4 5 ungradable no symptom

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
5. Death

Myoclonus

1 2 3 4 5 ungradable no symptom

NCI Criteria

1. Mild; asymptomatic or mild symptoms
2. Moderate; minimal; local or non-invasive intervention indicated
3. Severe or medically significant but not immediately life threatening
4. Life threatening consequences; urgent intervention indicated
5. Death

Anxiety

1 2 3 4 5 ungradable no symptom

NCI Criteria

1. Mild symptoms; intervention not indicated
2. Moderate symptoms; limiting instrumental ADL
3. Severe symptoms; limiting self-care ADL; hospitalization not indicated
4. Life-threatening; hospitalization indicated
5. Death

Restlessness

1 2 3 ungradable no symptom

NCI Criteria-

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

Respiratory Depression (RR<8/min)

1 2 3 4 5 ungradable no symptom

NCI Criteria-

1. Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated
2. Moderate; minimal; local or non-invasive intervention indicated; limiting age-appropriate instrumental ADL
3. Severe or medically significant but not immediately life-threatening; hospitalisation or prolongation of existing hospitalisation indicated; disabling; limiting self-care ADL
4. Life-threatening consequences; urgent intervention indicated
5. Death

Other (if exists)

Please specify other toxicity here _____

Other toxicity grade here:

1 2 3 4 5 Ungradable

Additional other (if exists)

Please specify additional other toxicity here _____

Additional other toxicity grade here

1 2 3 4 5 Ungradable

Which toxicity is the most troublesome?

- Drowsiness
- Nausea
- Confusion
- Myoclonus
- Anxiety
- Restlessness
- Respiratory Depression
- Other
- Additional other

If there were any toxicities, were any given a grade of 3 or more?

Yes No Not applicable

Key questions derived from the Naranjo modified check list

(Only complete this section if any toxicity on the previous page is 3 or greater)

1. Did the adverse reaction appear after the methadone was started?

- Yes
- No
- Don't know

2. Did the adverse reaction improve when the methadone was discontinued or a specific antagonist was given?

- Yes
- No
- Don't know

3. Are there alternative causes (other than methadone) that could on their own have caused the reaction?

- Yes
- No
- Don't know

4. Was the reaction more severe when the dose was increased, or less severe when the dose decreased?

- Yes
- No
- Don't know

5. Did the patient have a similar reaction to methadone or similar drug in any previous exposure?

- Yes
- No
- Don't know

6. Was the adverse event confirmed by any objective evidence?

- Yes
- No
- Don't know

What is the intended treatment based on the assessment today?

- No change to Methadone/continue current dose
- Methadone ceased
- Methadone dose reduced
- Methadone dose increased (please specify new dose)
- Medication to treat a specific toxicity added (please specify below)

If medication to treat a specific toxicity has been added please specify here:

If Methadone dose increased please specify total new dose/24hrs here (mgs)

Medication Cessation (complete this page at any time the medication of interest is ceased)

Date of assessment

dd/mm/yyyy

Medication was ceased (related to indication of interest):

- Symptom resolved
- Symptom continued unchanged
- Symptom worsened
- Symptom resolved - date of resolution (dd/mm/yyyy) _____
- Symptom worsened - Grade (NCI) _____

Medication was ceased (related to other reasons):

- Toxicity
- Patient unable to take medication
- Other

Please specify the other reason medication was ceased

Please specify the patient's inability to take medication

Unscheduled Toxicity Assessment (a)

(Please list any toxicities that occur any time regardless of whether they are attributable to the medication of interest or not.)

Date of assessment (dd/mm/yyyy)

Was there any toxicity?

Yes No (end survey here)

Was there any benefit?

yes no

Symptoms of interest

Drowsiness

1 2 3 4 5 ungradable no symptom

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

Nausea

1 2 3 ungradable no symptom

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 indicated

Confusion

1 2 3 4 5 ungradable no symptom

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
5. Death

Myoclonus

1 2 3 4 5 ungradable no symptom

NCI Criteria

1. Mild; asymptomatic or mild symptoms
2. Moderate; minimal; local or non-invasive intervention indicated
3. Severe or medically significant but not immediately life threatening
4. Life threatening consequences; urgent intervention indicated
5. Death

Anxiety

1 2 3 4 5 ungradable no symptom

NCI Criteria

1. Mild symptoms; intervention not indicated
2. Moderate symptoms; limiting instrumental ADL
3. Severe symptoms; limiting self-care ADL; hospitalization not indicated
4. Life-threatening; hospitalization indicated
5. Death

Restlessness

1 2 3 ungradable no symptom

NCI Criteria-

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

Respiratory Depression (RR<8/min)

1 2 3 4 5 ungradable no symptom

NCI Criteria-

1. Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated
2. Moderate; minimal; local or non-invasive intervention indicated; limiting age-appropriate instrumental ADL
3. Severe or medically significant but not immediately life-threatening; hospitalisation or prolongation of existing hospitalisation indicated; disabling; limiting self-care ADL
4. Life-threatening consequences; urgent intervention indicated
5. Death

Other (if exists)

Please specify other toxicity here _____

Other toxicity grade here:

1 2 3 4 5 Ungradable

Additional other (if exists)

Please specify additional other toxicity here _____

Additional other toxicity grade here

1 2 3 4 5 Ungradable

Which toxicity is the most troublesome?

- Drowsiness
- Nausea
- Confusion
- Myoclonus
- Anxiety
- Restlessness
- Respiratory Depression
- Other
- Additional other

If there were any toxicities, were any given a grade of 3 or more?

Yes No Not applicable

What is the intended treatment based on the assessment today?

- No change to methadone, continue current dose
- Methadone ceased due to toxicity
- Methadone dose reduced
- Methadone dose increased (please specify new dose below)
- Medication to treat a specific toxicity added (please specify below)

If methadone increased please specify total new dose/24hrs here

If medication to treat a specific toxicity has been added please specify here:

Key questions derived from the Naranjo modified check list

(Only complete this section if any toxicity on the previous page is 3 or greater)

1. Did the adverse reaction appear after the methadone was started?

- Yes
- No
- Don't know

2. Did the adverse reaction improve when the methadone was discontinued or a specific antagonist was given?

- Yes
- No
- Don't know

3. Are there alternative causes (other than methadone) that could on their own have caused the reaction?

- Yes
- No
- Don't know

4. Was the reaction more severe when the dose was increased, or less severe when the dose decreased?

- Yes
- No
- Don't know

5. Did the patient have a similar reaction to methadone or similar drug in any previous exposure?

- Yes
- No
- Don't know

6. Was the adverse event confirmed by any objective evidence?

- Yes
- No
- Don't know

Unscheduled Toxicity Assessment (b)

Please list any toxicities that occur any time regardless of whether they are attributable to the medication of interest or not.

Date of assessment(dd/mm/yyyy)

Was there any toxicity?

Yes No (end survey here)

Was there any benefit?

Yes No

Symptoms of interest

Drowsiness

1 2 3 4 5 ungradable no symptom

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

Nausea

1 2 3 ungradable no symptom

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 indicated

Confusion

1 2 3 4 5 ungradable no symptom

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
- 5.Death

Myoclonus

1 2 3 4 5 ungradable no symptom

NCI Criteria

1. Mild; asymptomatic or mild symptoms
2. Moderate; minimal; local or non-invasive intervention indicated
3. Severe or medically significant but not immediately life threatening
4. Life threatening consequences; urgent intervention indicated
5. Death

Anxiety

1 2 3 4 5 ungradable no symptom

NCI Criteria

1. Mild symptoms; intervention not indicated
2. Moderate symptoms; limiting instrumental ADL
3. Severe symptoms; limiting self-care ADL; hospitalization not indicated
4. Life-threatening; hospitalization indicated
5. Death

Restlessness

0 1 2 3 ungradable no symptom

NCI Criteria-

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

Respiratory Depression (RR<8/min)

1 2 3 4 5 ungradable no symptom

NCI Criteria-

1. Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated
2. Moderate; minimal; local or non-invasive intervention indicated; limiting age-appropriate instrumental ADL
3. Severe or medically significant but not immediately life-threatening; hospitalisation or prolongation of existing hospitalisation indicated; disabling; limiting self-care ADL
4. Life-threatening consequences; urgent intervention indicated
5. Death

Other (if exists)

Please specify other toxicity here _____

Other toxicity grade here:

1 2 3 4 5 Ungradable

Additional other (if exists)

Please specify additional other toxicity here _____

Additional other toxicity grade here

1 2 3 4 5 Ungradable

Which toxicity is the most troublesome?

- Drowsiness
- Nausea
- Confusion
- Myoclonus
- Anxiety
- Restlessness
- Respiratory Depression
- Other
- Additional other

If there were any toxicities, were any given a grade of 3 or more?

- Yes No Not applicable

What is the intended treatment based on the assessment today?

- No change to Methadone/continue current dose
- Methadone ceased
- Methadone dose reduced
- Methadone dose increased (please specify new dose)
- Medication to treat a specific toxicity added (please specify below)

If medication to treat a specific toxicity has been added please specify here:

If Methadone dose increased please specify total new dose/24hrs here (mgs)

Key questions derived from the Naranjo modified check list

(Only complete this section if any toxicity on the previous page is 3 or greater)

1. Did the adverse reaction appear after the methadone was started?

- Yes
- No
- Don't know

2. Did the adverse reaction improve when the methadone was discontinued or a specific antagonist was given?

- Yes
- No
- Don't know

3. Are there alternative causes (other than methadone) that could on their own have caused the reaction?

- Yes
- No
- Don't know

4. Was the reaction more severe when the dose was increased, or less severe when the dose decreased?

- Yes
- No
- Don't know

5. Did the patient have a similar reaction to methadone or similar drug in any previous exposure?

- Yes
- No
- Don't know

6. Was the adverse event confirmed by any objective evidence?

- Yes
- No
- Don't know

Unscheduled Toxicity Assessment (c)

Please list any toxicities that occur any time regardless of whether they are attributable to the medication of interest or not.

Date of assessment (dd/mm/yyyy)

Was there any toxicity?

Yes No (end survey here)

Was there any benefit?

Yes No

Symptoms of interest

Drowsiness

1 2 3 4 5 ungradable no symptom

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

Nausea

1 2 3 ungradable no symptom

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 indicated

Confusion

1 2 3 4 5 ungradable no symptom

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
5. Death

Myoclonus

1 2 3 4 5 ungradable no symptom

NCI Criteria

1. Mild; asymptomatic or mild symptoms
2. Moderate; minimal; local or non-invasive intervention indicated
3. Severe or medically significant but not immediately life threatening
4. Life threatening consequences; urgent intervention indicated
5. Death

Anxiety

1 2 3 4 5 ungradable no symptom

NCI Criteria

1. Mild symptoms; intervention not indicated
2. Moderate symptoms; limiting instrumental ADL
3. Severe symptoms; limiting self-care ADL; hospitalization not indicated
4. Life-threatening; hospitalization indicated
5. Death

Restlessness

1 2 3 ungradable no symptom

NCI Criteria-

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

Respiratory Depression (RR<8/min)

1 2 3 4 5 ungradable no symptom

NCI Criteria-

1. Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated
2. Moderate; minimal; local or non-invasive intervention indicated; limiting age-appropriate instrumental ADL
3. Severe or medically significant but not immediately life-threatening; hospitalisation or prolongation of existing hospitalisation indicated; disabling; limiting self-care ADL
4. Life-threatening consequences; urgent intervention indicated
5. Death

Other (if exists)

Please specify other toxicity here _____

Other toxicity grade here:

1 2 3 4 5 Ungradable

Additional other (if exists)

Please specify additional other toxicity here _____

Additional other toxicity grade here

 1 2 3 4 5 Ungradable**Which toxicity is the most troublesome?**

- Drowsiness
- Nausea
- Confusion
- Myoclonus
- Anxiety
- Restlessness
- Respiratory Depression
- Other
- Additional other

If there were any toxicities, were any given a grade of 3 or more?

 Yes No Not applicable**What is the intended treatment based on the assessment today?**

- No change to Methadone/continue current dose
- Methadone ceased
- Methadone dose reduced
- Methadone dose increased (please specify new dose)
- Medication to treat a specific toxicity added (please specify below)

If medication to treat a specific toxicity has been added please specify here:

If Methadone dose increased please specify total new dose/24hrs here (mgs)

Key questions derived from the Naranjo modified check list

(Only complete this section if any toxicity on the previous page is 3 or greater)

1. Did the adverse reaction appear after the methadone was started?

- Yes
- No
- Don't know

2. Did the adverse reaction improve when the methadone was discontinued or a specific antagonist was given?

- Yes
- No
- Don't know

3. Are there alternative causes (other than methadone) that could on their own have caused the reaction?

- Yes
- No
- Don't know

4. Was the reaction more severe when the dose was increased, or less severe when the dose decreased?

- Yes
- No
- Don't know

5. Did the patient have a similar reaction to methadone or similar drug in any previous exposure?

- Yes
- No
- Don't know

6. Was the adverse event confirmed by any objective evidence?

- Yes
- No
- Don't know