

OPERAS Case Report Form (CRF)

Use with Appendix (Data Dictionary) to help data collection.

Unique ID									
Data Collection Period									
Baseline demographics									
Date of birth	__/__/____	Gender	<input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Other	Weight (kg)	__-__-__ (1dp)	Height (m)	__-__-__ (2dp)	OR BMI (if known)	__-__
Ethnicity	<input type="checkbox"/> European <input type="checkbox"/> Māori <input type="checkbox"/> Pacific Peoples <input type="checkbox"/> Asian <input type="checkbox"/> Middle Eastern <input type="checkbox"/> Latin American <input type="checkbox"/> African <input type="checkbox"/> Aboriginal or Torres Strait Islander <input type="checkbox"/> Other (specify): []			Underlying co-morbidities (Tick all that apply)	<input type="checkbox"/> Myocardial Infarction or Congestive Heart Failure <input type="checkbox"/> Peripheral vascular disease <input type="checkbox"/> Cerebrovascular Accident or Transient Ischaemic Attack <input type="checkbox"/> Peptic ulcer disease <input type="checkbox"/> Diabetes Mellitus (Type 1 or 2) <input type="checkbox"/> Chronic Kidney Disease (CKD) (eGFR < 60ml/min/1.73m ² , dialysis or post kidney transplant, or uraemia) <input type="checkbox"/> Liver disease <input type="checkbox"/> Cancer (active/remission) <input type="checkbox"/> None of the above				
ASA Physical Status	<input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV <input type="checkbox"/> V				Smoking status	<input type="checkbox"/> Current <input type="checkbox"/> Ex-smoker (>12 mths) <input type="checkbox"/> Ex-smoker (<12 mths) <input type="checkbox"/> Never <input type="checkbox"/> Unknown status			
Any relative or absolute contraindications to opioid use? (select all that apply)	<input type="checkbox"/> Allergy <input type="checkbox"/> Renal impairment <input type="checkbox"/> Severe respiratory disease <input type="checkbox"/> Previous adverse event <input type="checkbox"/> Previous opioid use disorder / opioid misuse <input type="checkbox"/> Concurrent benzodiazepine use <input type="checkbox"/> Other (specify): [] <input type="checkbox"/> None			Vaping status		<input type="checkbox"/> Current <input type="checkbox"/> Ex-vaper (>12 mths) <input type="checkbox"/> Ex-vaper (<12 mths) <input type="checkbox"/> Never <input type="checkbox"/> Unknown status			
Any relative or absolute contraindication to NSAID use? (select all that apply)	<input type="checkbox"/> Previous GI bleeding / ulcer <input type="checkbox"/> Allergy <input type="checkbox"/> Renal impairment <input type="checkbox"/> NSAID-responsive asthma <input type="checkbox"/> Other (specify): [] <input type="checkbox"/> None				Alcohol consumption (standard drinks/week)	<input type="checkbox"/> Non-drinker (0) <input type="checkbox"/> Light (1-5) <input type="checkbox"/> Moderate (6-10) <input type="checkbox"/> Heavy (11+) <input type="checkbox"/> Unknown status			
Intraoperative data fields									
Procedure	See Appendix A for list of operation types (in protocol and on REDCap)								
Surgical approach	<input type="checkbox"/> Laparoscopic <input type="checkbox"/> Open <input type="checkbox"/> Laparoscopic converted to open <input type="checkbox"/> Robotic <input type="checkbox"/> Arthroscopic <input type="checkbox"/> Vaginal			If relevant	<input type="checkbox"/> Unilateral <input type="checkbox"/> Bilateral <input type="checkbox"/> Total <input type="checkbox"/> Partial <input type="checkbox"/> Reverse				
				Indication	<input type="checkbox"/> Malignancy <input type="checkbox"/> Benign				
				Urgency	<input type="checkbox"/> Emergency <input type="checkbox"/> Elective				
Duration of procedure	__ mins		Complications during in patient stay (Clavien Dindo)				<input type="checkbox"/> None <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III-V		
Date of admission	__/__/____	Date of procedure	__/__/____	Date of discharge	__/__/____	Referral to acute pain service for difficulty managing pain (excludes routine referrals)			<input type="checkbox"/> Yes <input type="checkbox"/> No
Opioids given in 24h prior to discharge									
For each medication, please record the generic name , formulation (slow release (SR) vs immediate release (IR)), dose (mg/mcg per pill/ tablet/ patch per 24hrs/ concentration per 1ml), route , total amount consumed in the 24 hours prior to discharge									
Opioid 1	See protocol for generic names	Formulation	<input type="checkbox"/> SR <input type="checkbox"/> IR	Route		Total dose consumed	__mg/mcg		
Opioid 2	See protocol for generic names	Formulation	<input type="checkbox"/> SR <input type="checkbox"/> IR	Route		Total dose consumed	__mg/mcg		
Opioid 3	See protocol for generic names	Formulation	<input type="checkbox"/> SR <input type="checkbox"/> IR	Route		Total dose consumed	__mg/mcg		
Opioid 4	See protocol for generic names	Formulation	<input type="checkbox"/> SR <input type="checkbox"/> IR	Route		Total dose consumed	__mg/mcg		
Opioid 5	See protocol for generic names	Formulation	<input type="checkbox"/> SR <input type="checkbox"/> IR	Route		Total dose consumed	__mg/mcg		
Discharge analgesia									
Discharge paracetamol advised or prescribed	Yes/No	Discharge NSAIDs advised or prescribed	Yes/No	Discharge gabapentinoids for neuropathic pain prescribed	Yes/No				
Discharge tricyclic antidepressants or SNRIs for neuropathic pain prescribed	Yes/No	Discharge opioid(s) prescribed	Yes/No	(if opioid prescribed) Information provided about safe disposal of surplus opioids?	Yes/No				
For each discharge medication, please record the generic name , formulation (slow release (SR) vs immediate release (IR)), dose (mg/mcg per pill/ tablet/ patch per 24hrs/ concentration per 1ml), route , frequency , and total number of pills/ liquid/ tablets/ injectable volume prescribed									
Opioid 1	See protocol for generic names	Form.	<input type="checkbox"/> SR <input type="checkbox"/> IR	Dose of medication		Route		Freq.	Total amount prescribed
Opioid 2	See protocol for generic names	Form.	<input type="checkbox"/> SR <input type="checkbox"/> IR	Dose of medication		Route		Freq.	Total amount prescribed
Opioid 3	See protocol for generic names	Form.	<input type="checkbox"/> SR <input type="checkbox"/> IR	Dose of medication		Route		Freq.	Total amount prescribed
Opioid 4	See protocol for generic names	Form.	<input type="checkbox"/> SR <input type="checkbox"/> IR	Dose of medication		Route		Freq.	Total amount prescribed
Opioid 5	See protocol for generic names	Form.	<input type="checkbox"/> SR <input type="checkbox"/> IR	Dose of medication		Route		Freq.	Total amount prescribed
7-day follow-up									
For follow-up please ensure to follow the phone follow up script to complete this section. If the patient is not reachable on day 7, please continue to reach out to the patient as per the flow chart on the REDCap data collection form before marking as lost-to-follow up									
Date of follow up	__/__/____	Patient consent for follow up	Y/N	Used opioid medication?	Y/N	Date of last opioid use	__/__/____		
For each opioid medication listed in the section 'Discharge analgesia', please confirm the generic name , and the amount consumed by the patient at 7-day follow up . If a patient is prescribed oral pills, this can be recorded by the number of pills consumed									
Opioid 1		Amount of medication consumed		Opioid 2		Amount of medication consumed			
Opioid 3		Amount of medication consumed		Opioid 4		Amount of medication consumed			

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Opioid 5			Amount of medication consumed								
Any of the following side effects? 0 (none) – 10 (extreme)		Nausea or vomiting	___/10	Drowsiness	___/10	Itching	___/10	Dizziness	___/10	Constipation	___/10
Prescribed laxatives on discharge?	Y/N	Prescribed antiemetics on discharge?	Y/N	Paracetamol use since discharge	Y/N	NSAID use since discharge	Y/N	Nerve pain medication use since discharge	Y/N		Y/N
Sought additional medical care for pain relief after discharge?	<input type="checkbox"/> Yes – GP <input type="checkbox"/> Yes – Urgent care/Emergency department <input type="checkbox"/> Yes – Direct surgeon contact <input type="checkbox"/> Yes – Readmission to hospital <input type="checkbox"/> Yes – other (specify []) <input type="checkbox"/> No			Were any additional medications prescribed/used?	Y/N	Were any additional opioids prescribed/used?	Y/N	What was the dose compared to discharge prescription	<input type="checkbox"/> Lower <input type="checkbox"/> The same <input type="checkbox"/> Higher <input type="checkbox"/> Other medication		
Pain relief from other sources?	Y/N	Was this pain relief an opioid?	Y/N	Name of opioid used (if relevant)		Dose of opioid used (if relevant)		Quantity of opioid used (if relevant)			
Sought additional medical care for side effects of your pain medication?	<input type="checkbox"/> Yes – GP <input type="checkbox"/> Yes – Urgent care/Emergency department <input type="checkbox"/> Yes – Direct surgeon contact <input type="checkbox"/> Yes – Readmission to hospital <input type="checkbox"/> Yes – other (specify []) <input type="checkbox"/> No			For 3 months prior to readmission, were you using pain killers routinely?	Y/N	No. of days/week pain relief was used?		Medication used	<input type="checkbox"/> Paracetamol <input type="checkbox"/> NSAID <input type="checkbox"/> Opioid <input type="checkbox"/> Other		
EQ-5D-5L Quality of Life											
Mobility	<input type="checkbox"/> No problems walking about <input type="checkbox"/> Slight problems walking about <input type="checkbox"/> Moderate problems walking about <input type="checkbox"/> Severe problems walking about <input type="checkbox"/> Unable to walk about		Self-care	<input type="checkbox"/> No problems washing or dressing self <input type="checkbox"/> Slight problems washing or dressing self <input type="checkbox"/> Moderate problems washing or dressing self <input type="checkbox"/> Severe problems washing or dressing self <input type="checkbox"/> Unable to wash or dress self			Usual activities e.g. work, study, leisure	<input type="checkbox"/> No problems doing usual activities <input type="checkbox"/> Slight problems doing usual activities <input type="checkbox"/> Moderate problems doing usual activities <input type="checkbox"/> Severe problems doing usual activities <input type="checkbox"/> Unable to do usual activities			
Pain or discomfort	<input type="checkbox"/> No pain or discomfort <input type="checkbox"/> Slight pain or discomfort <input type="checkbox"/> Moderate pain or discomfort <input type="checkbox"/> Severe pain or discomfort <input type="checkbox"/> Extreme pain or discomfort		Anxiety or depression	<input type="checkbox"/> Not anxious or depressed <input type="checkbox"/> Slightly anxious or depressed <input type="checkbox"/> Moderately anxious or depressed <input type="checkbox"/> Severely anxious or depressed <input type="checkbox"/> Extremely anxious or depressed			Health today on a scale of 0 (lowest) -100 (highest)	___/100			
Other patient-reported questions											
% of time in severe pain since discharge	___/100%	Did the patient receive information/ advice/ education about managing pain from their doctor/ nurse before discharge?			Y/N	Did the patient receive information/ advice/ education about how to dispose of excess opioids?			Y/N		
Opinion on amount of pain medication received			<input type="checkbox"/> Too little <input type="checkbox"/> Just right <input type="checkbox"/> Too much			Satisfaction with pain treatment during first week post-discharge (0: extremely dissatisfied, 10: extremely satisfied)			___/10		