OPERAS Study

Opioid PrEscRiptions and Usage After Surgery

An international, multi-centre study of the prescription and usage of opioids after common surgical procedures

Study protocol version 2.0.6
1 December 2021

TASMAN
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Table of Contents

Amendments

Amendment	Date	Protocol Version	Summary
	1/12/21	2.06	Change in Scientific Advisory Committee personnel, additional trainee-led collaborative networks included, and data collection instrument harmonized with patient telephone call script.

Steering Committee

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Peter Pockney	Associate professor and consultant colorectal surgeon	@Ppockney
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Jennifer Martin	Professor of clinical pharmacology and physician	
Rachel Sara	Consultant anaesthetist and pain specialist	
Arnab Banerjee	Senior lecturer and consultant anaesthetist	

Collaborative Partners

CTANZ	Royal Australasian College of Surgeons
VERITAS	VERITAS EX SCIENTIA ET COLLABORARE INNOVATUS
SPARTANS	HUNTER SPARTANS STUDENT, PREVOCATIONAL AND REGISTRAR TRIALS AND AUDIT NETWORK
STRIVEWA	STRIVE WA Student Research Initiative
STARCSA	STARC SA
STORCC	STORCC SURGICAL TRAINEE ORGANISATION FOR RESEARCH - CENTRAL COAST
STRATA	STRATA SURGICAL TRAINEE RESEARCH, AUDIT & TRIALS AOTEAROA

Study Delivery Timeline

Dates	Description
1 August 2021	OPERAS Study Launch
10 January 2022	First Hospital Lead REDCap Accounts Generated (then on a rolling twice-weekly basis for all new PIs) - Tuesdays and Fridays
24 January 2022	First Collaborator REDCap Accounts Generated (then on a rolling twice-weekly basis for all new collaborators – Tuesday and Fridays)
4 April 2022 - 17 April 2022	Study Period 1 - Data Collection Period (capture new intern prescribing practices)
2 May - 15 May 2022	Study Period 2 - Data Collection Period (all centres)
30 May 2022 - 12 June 2022	Study Period 3 - Data Collection Period (all centres)
27 June 2022 - 10 July 2022	Study Period 4 - Data Collection Period (all centres)
7 August 2022	REDCap Database Locked, Final Data Submission Deadline
August - September 2022	Data Analysis
October 2022	Planned Dissemination of Results

Executive Summary

To assess the consumption of opioid analgesia after common surgical procedures in comparison to what is prescribed.

Primary aim:

To quantify the amount of opiate medication prescribed at hospital discharge after surgery and identify the proportion of prescription medication consumed by patients at 7-days post-discharge.

Secondary aims:

1. Describe variations in opioid prescription and consumption by procedure and specialty
2. Quantify the impact of postoperative opioid prescription on patient-reported outcome measures
3. Identify risk factors for opioid consumption and over-prescription at 7-days
4. Describe the use of ancillary analgesic use post-discharge after common procedures

Who?

Patients undergoing common general, orthopaedic, urological, and gynaecological surgical procedures (summarised in ***[Appendix A]***).

What?

Data will be collected on opioids prescribed and consumed after common surgical procedures including type, form, dose, route, intended prescription length. Comparisons will be made across states/countries, specialties, and common operations.

When?

Prospectively over a four-month period in 2022.

Introduction

Pain relief is considered a fundamental right in medicine. With over 80% of patients reporting pain after surgical procedures (1,2), adequate postoperative analgesia is essential to patient care (1,3). However, pain management is complex and requires the consideration of many factors including the specific surgical procedure, patients' needs and their perceived analgesic control (4).

Opioid prescriptions for non-cancer related indications, including postoperative reasons, have been increasing in recent years (1,5). While often effective for acute pain, opioids are addictive and have numerous side effects, the most serious being respiratory depression (6). In the United States, there are 530 opioid-related deaths every week and the opioid epidemic has been recognised as a public health emergency (7,8). The many nonfatal health consequences of opioid abuse and addiction in Australia contribute to an annual cost of $15.7 billion (9). In Australia, opioid-related deaths in adults between 15-64 years of age have increased by 3.8% per year since 2007 (10). In New Zealand, the figures are similar, with the rate of opioid-related deaths increasing by one third in total from 2001 to 2012 (11).

Globally, the over prescription of opioids after common surgical procedures is a well recognised contributor to the opioid epidemic (12), including in Australia (13,14). Opioid initiation post-surgical hospital visit leads to chronic use in a small but significant proportion of patients (15). Similarly, there are a wide variety of reasons for overprescribing (16,17). Awareness of opioid prescription practices locoregionally can advise targeted interventions to change prescribing patterns and reduce the overprescribing of postoperative discharge opioids (18).

The aim of this prospective multi-centre cohort study is to describe the correlation between discharge opioid prescriptions to consumption by patients after common surgical procedures and the impact on patient-reported outcomes.

Methods

1. Study Aims

The primary aim of the OPERAS study is to quantify the amount of opiate medication prescribed at hospital discharge after surgery and identify the proportion of prescription medication consumed by patients at 7-days post-discharge. The secondary aims will be to describe the variations in opioid prescriptions and consumptions by procedure and specialty, quantify the impact of quantity of analgesia on patient-reported satisfaction, identify risk factors for opioid consumption and over-prescription at 7-days, and to describe the use of ancillary analgesia after post-discharge after common procedures.

2. Study Design

OPERAS is a snapshot, international, multi-centre, prospective observational study of discharge opioid prescription and consumption. This study will adapt the student- and trainee-led collaborative research model used by EuroSurg (19) and STARSurg (20) to an Australian and NZ context.

'Mini-teams' of collaborators will participate at each hospital, with a range of members including medical students, junior doctors, trainees, registrars, and supervising consultants (**Figure 1**) Data will be collected prospectively on patients being discharged following major surgery (included procedures in **Appendix A**).

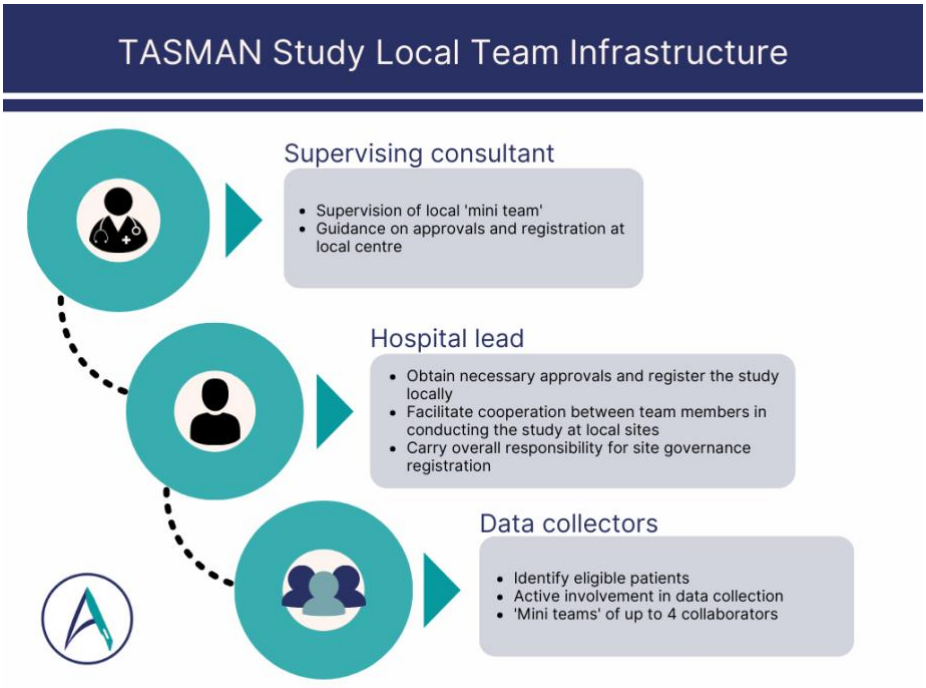

Figure 1: Mini-team structure

3. Setting

OPERAS is open to any hospital/site in Australia and New Zealand that performs major inpatient and day-case surgical procedures. All participating centres will be required to register the study according to local regulations, evidence of which must be uploaded onto REDCap prior to commencement of data collection from each respective site. It may be necessary to obtain formal research ethics approval in some participating countries.

4. Project Timeline

Collaborators at each participating centre will prospectively collect data for all patients discharged following a major surgical procedure meeting the inclusion criteria for their given surgical specialty over 1 or more 2-week periods across 2 months in April-May 2022:

1. **Period 1**: 4 April 2022 - 17 April 2022 (+7-day follow-up post-discharge)
2. **Period 2**: 2 May 2022 - 15 May 2022 (+7-day follow-up post-discharge)
3. **Period 3**: 30 May 2022 - 12 June 2022 (+7-day follow-up post-discharge)
4. **Period 4**: 27 June 2022 - 10 July 2022 (+7-day follow-up post-discharge)

Each period will have 14 consecutive days of patient recruitment. All eligible patients having their index operation within the recruitment period will be approached for inclusion. Consented patients will be monitored through their admission and prospective clinical data collection will be completed. They will subsequently be followed up 7 days after discharge from hospital.

If the patient is not discharged within the study period they can be excluded.

When patients are contacted via telephone call at 7-days post-day of discharge, we will confirm a) if the prescribed medication was picked up, b) total analgesia consumption, c) need for analgesic medication refills, d) readmission to hospital for uncontrolled pain or opioid related side effects, and e) satisfaction scores regarding pain management. The provisional deadline for entering new patients to REDCap will be 13 June 2022, this will be reviewed throughout.

5. Patients

Patients must fulfill all the following criteria to be included in the study:

- Adult patients (greater than or including 18 years of age)
- Acute or elective surgery
- Operated on within the pre-specified study periods
- Undergoing a surgery within the inclusion criteria (**Appendix A**) [to analyse procedure specific pain management]
- Discharged to home/community/usual residence
- Able and willing to provide independent informed consent

All eligible patients must be approached to avoid selection bias.

The exclusion criteria is as follows:

- Paediatric patients (below 18 years of age)
- On the opiate replacement programme (on methadone, suboxone, buprenorphine)
- Patients discharged to hospice or with palliative intent
- Patients discharged to rehabilitation (including inpatient rehabilitation service), nursing or supported care services, or another hospital, or not discharged should be excluded
- Diagnostic procedures, e.g., endoscopy, diagnostic laparoscopy (without appendicectomy)
- Multivisceral resections (defined as operations involving ≥ 2 distinct procedures of the gastrointestinal, hepatopancreatobiliary, genitourinary, or gynaecological systems e.g. hysterectomy with colorectal resection or any other operation where multiple eligible procedures are included) [to ensure the included standard procedures are internally consistent]
- Each individual patient should only be included once in the OPERAS study. Return to theatre during the same admission is regarded as a complication and should not form a duplicate entry onto REDCap.

6. Participant consent

Patient reported outcomes are routinely collected via follow up phone calls post-discharge, as recommended by local hospital protocols and adherence to Enhanced Recovery After Surgery (ERAS) guidelines (21,22).

Eligible patients during the study inclusion periods will be identified through hospital theatre lists or procedure lists. All eligible patients will be approached in the pre-admissions clinic or as an inpatient by data collectors to provide information about the study and the participant information sheet. Data collectors will then return to obtain written informed consent for participation in the study at a later time while the patient is still an inpatient. If participants indicate they would like more time to consider participation, they can confirm participation when contacted post-discharge. The participant information sheet makes clear that participants do not have to give a reason to decline to be involved in the study, and their decision will not affect the care they receive.

Data collectors will discuss the purpose of the phone call and how the information will be used before completing the consent form with patients, as well as answer any questions raised in the process. Eligible patients will be encouraged to consult with friends, family, and other medical professionals before making their decision. They will also be given the opportunity to contact research team members outside of their clinical care team during the recruitment process, with details for further contact listed on the patient information sheet. Follow-up phone calls will be aided via a transcript to aid data collectors in ensuring consistent information is obtained from patients.

7. Outcomes and variables

The primary outcome is the proportion and amount (morphine equivalent doses) of prescribed opiates that are consumed at 7-days post-discharge.

Secondary outcomes include:

- Patient reported outcomes, e.g., quality of life via EQ5D-5L, postoperative pain, adequacy of pain relief prescribed
- Rates of opioid prescription and consumption through primary care at 7-days post-discharge
- Requirement for further analgesia, hospital readmissions at 7-days post-discharge for opiate-related side-effects or pain related to surgical pathology/procedure

Audit standard outcomes:

- Are opioids prescribed in a down-titrating manner post-surgery?
- Are opioid prescription durations similar between procedures (i.e. opioid prescriptions post discharge should be guided by duration of pain anticipated to be at severity requiring an opioid).
- Describe use of slow-release opioids by specialty, procedure, and prescriber level.
- Proportion of short-acting versus long-acting opioid prescriptions.
- Appropriate use of ancillary analgesia post-discharge

Additional data will be collected on patient demographics and comorbidities, preoperative diagnosis, procedure-specific details, post-operative in-patient analgesia 24 hours prior to discharge, and post-operative complications. This additional data will be collected to enable risk adjustment of outcomes. Without appropriately adjusting for risk factors, it is likely that any findings would be biased and unable to be appropriately analysed on a national and international scale.

Further detail is detailed in the case report forms and data dictionary outlined in **Appendix B**. Data will be collected to align with relevant audit standards found in **Appendix C**.

8. Opioid-data recording

If patients are prescribed opiates at discharge, the agent, total dose in mg, and route of administration will be collected (type, dose, frequency of dosing, route, total number of pills prescribed, immediate vs. sustained/extended-release formulations (common brand names described in **Appendix B**).

Oral morphine equivalent (OME) doses will be calculated as per the ANZCA guidelines (23). Opioid conversions will be completed by the analysis team. Conversion functionality will occur automatically within the REDCap database. An appendix of included opioids (both ‘weak’ and ‘strong’ can be found in **Appendix B**). The Faculty of Pain medicine calculator at Faculty of Pain http://www.opioidcalculator.com.au/ will be used.

9. Data collection and storage

Data collection will be done via two distinct phases. Firstly, patient demographic and in-patient variables (diagnosis/procedure/analgesia) will be collected from routine clinical records by data collectors. Secondly, 7-day follow-up will be conducted through a phone call by data collectors. Data collectors will ask pre-specified questions (**Appendix B**) regarding analgesia prescription, use, and patient-reported satisfaction.

Collection and storage during study

Data will be collected on paper proforma forms and stored in a securely locked location at each site. Forms will not be accessed by anyone other than study collaborators. Each site will maintain records of which participant is recruited into the study and their unique REDCap identifier. These records will be held onsite according to local hospital protocols, with access limited to the local data collection team.

Participant data will not be shared between centres other than that which is uploaded to the REDCap database. Each collaborator will have their own unique login which will only give them access to the participant data for which they are responsible, as recorded in their REDCap 'Data Access Group'. This means that no hospital or health-service identifying information will be recorded in the data collection instrument (i.e. no surgeon name, hospital name, location) and data collectors will only be able to view records from within their own sites (aka their Data Access Group) within the database.

Data submitted to the secure online REDCap database will be deidentified and will not be able to be linked back to individual patients in any way. The REDCap will be hosted by Hunter Medical Research Institute in Newcastle, NSW, Australia. Appropriate data storage, management, and removal policies are in place.

Following uploading of the data to the REDCap database, paper records at each centre will be permanently destroyed. Data stored on the secure online database will be deidentified as described above, and will not be able to be linked to individual patients in any way.

Use

Only deidentified data will be used during analysis. Data from the anonymous REDCap database will be used for analysis to generate scientific manuscripts. No identifiable data will be distributed or shared.

Storage after study and disposal

Data will be retained for 15 years in an anonymized form, after which it will be permanently deleted. Data held on the centralised REDCap database will be destroyed after a period of 3 years, in keeping with local guidelines in Australia. No data will be stored in an identifiable form.

Data linkage and re-use

As data will be prospectively collected for the purposes of this study, re-use of existing data is not relevant. No data linking will be done. This data will not contribute to any registry or databank.

Data completeness

REDCap will be used to calculate % completeness of required fields. For successful inclusion in the study, collaborators will need to obtain **>95% data completeness** for all required fields. This will be separated into >95% completeness for inpatient data fields, and >95% completeness for patient follow-up survey where the patient is able to be contacted. If patients are not able to be reached by phone then they will be marked as lost to follow up and the 95% threshold will be applied to the inpatient variables only. These inpatient variables may still be included in analyses pertaining to inpatient data.

In order to maximise successful participant follow up, the following phone call escalation plan will be used:

1. Participants will be called on day 7 post discharge (including weekends and public holidays).

2. If the participant does not respond to the phone call, they will be called again after a 10 minute interval and a text message sent indicating the reason for the call and requesting the participant to notify the team of a convenient time for a follow up call or to reply to opt out of further calls.

3. The participant will then be called at the nominated convenient time.

4. If no response is received, further attempts to contact the patient will be made every day until day 10 post discharge at which point they will be lost to follow up. Overall, this allows 7-10 days for follow up.

10. Analysis plan

Descriptive statistics will be used to characterise the quantity of prescribed and consumer opioids in oral morphine equivalents (OME); these data will be stratified by procedure. Normally distributed data will be reported as mean (standard deviation (SD), and non-normally distributed data as median (interquartile range (IQR)). Independent *t*-tests or ANOVAs for normally distributed variables, Mann-Whitney U and Kruskal-Wallis tests for non-normally distributed continuous or ordinal variables, and chi-squared tests for categorical variables will be used for comparisons.

Multivariable, multilevel, mixed-effects linear regression model will be conducted to assess the association between quantity of prescribed opioids to consumed opioids; this will be risk-adjusted for confound factors such as age, sex, smoking status, alcohol use, cancer, obesity, ASA grade, elective vs emergency surgery, and patient reported pain scores.

Risk factors for unused opiates at 7-days, requirements for further analgesia, and pain-related readmissions within 7-days will also be investigated using a multivariable, mixed effects logistic regression model. Hospitals will comprise the random effect in the above multivariable models.

No comparisons of data will be completed between individual sites and no site-identifying geographical comparisons will be undertaken. However, regional differences at the state- and country-level will be made to describe variations in practice. Funnel plots may be used to show variations of outcomes by centre, but this will be centre de-identified. P-value < 0.05 is considered significant.

A planned subgroup analysis will be completed of patients taking preoperative opiates.

No previous literature has established minimal clinically important differences in OME dose of opioid consumption. The PANSAID trial by Thybo et al., considered a difference of 10 mg of morphine to be minimally clinically significant (26). Based on pilot data and unpublished work that this study is based on, there was a mean difference of -17.4 OME with a standard error of 2.8 (SD 4.2). Howard et al., found in United States cohort of elective or emergent inpatient or outpatient general, vascular or gynaecological surgery, median 150 (IQR 135 - 225) OME, equivalent to 30 pills (27-45) was prescribed compared to a median 45 (IQR 5-125) OME, equivalent to 9 pills (IQR 1-25) consumed; this represents a 70% discrepancy in postoperative opioid prescription to consumption (27). We estimate that a discrepancy of >25% would be clinically relevant. A formal power calculation was not performed

for this observational study due to the overall goal of characterising postoperative, discharge opioid prescription practices in Australia and New Zealand.

11. Local governance and ethical approval

As part of the process of obtaining site-specific approval (SSA) for inclusion in this study, hospital leads will identify a consultant surgeon to provide overarching supervision and responsibility for the study at that site. Where there are multiple mini-teams within a site, each mini-team will have a supervising consultant. Additionally, as part of the SSA hospital leads will inform all relevant surgeons about the OPERAS study and provide an opportunity for questions and discussion.

The hospital lead with supervision from a consultant/ attendant supervisor is responsible for obtaining necessary local approvals (e.g., audit approval, service evaluation, research ethics committee or institutional review board approval) at each site. This is an investigator-led, non-commercial study, which requires no changes to normal patient care and only routinely available non-identifiable data will be collected. No patient identifiable data will be uploaded or stored on the REDCap database.

In New Zealand, Health and Disability Ethics Committees (HDEC) will be approached for national ethical approval with locality assessments and approvals at each DHB prior to the commencement of the study. In Australia, ethical approval will be sought from National Mutual Acceptance Scheme (NMA). Individual patient informed consent will be sought from each patient while they are an inpatient.

It is compulsory to have a consultant supervisor who is able to guide and advise how you may register the study at your hospital, and what approvals will be required. These must be added to the REDCap database as evidence of approvals. You may also seek advice from your local audit department or get in touch with the TASMAN for further advice.

12. Authorship and mini-teams

All research outputs from the OPERAS study will be authored as per the National Research Collaborative (NRC) authorship guidelines (28). All collaborators will be listed as PubMed-citable collaborators within the TASMAN Collaborative in accordance with the roles defined below (so long as the minimum requirements for authorship are met).

A local supervising consultant/attending and a maximum of four additional collaborators will be identified per specialty, making a total of five collaborators per specialty at each participating site. Additional mini-teams can participate at the same site if they are part of different surgical specialties. One consultant/attending may supervise more than one mini-team. Additional collaborators may be allowed in certain cases, such as at particularly high-volume centres, only after discussion with, and at the discretion of, the TASMAN Steering Group.

To be credited with authorship, all collaborators must provide a valid ORCID identifier (https://orcid.org/register) which will be used to generate authorship lists for all papers.

Collaborator role descriptions are as follows:

1. **Local supervising consultant/attending:** provide guidance for approval processes, facilitate communication within the hospital, and mentor and facilitate medical students, junior doctors and registrars in conducting the study at your local site. They have overall responsibility for the site governance registration and should support data collection. Only one person can fulfil this role. Minimum requirements for authorship include:
    - Sponsorship of local study registration, and responsibility to ensure local collaborators act in accordance with local governance guidelines.
    - Successful completion of data collection at a centre which meets the criteria for inclusion within the OPERAS dataset.
    - Facilitation of local result presentation and support of appropriate local interventions.

    Sponsorship through the audit approval / project registration process by a consultant does not constitute authorship, nor does inclusion of a consultants' patients alone in the audit serve sufficient for authorship.

2. **Hospital lead:** this role can be fulfilled by a medical student, junior doctor, trainee or the consultant supervisor/PI (as above). Prior experience in collaborative research is recommended but not essential. Additional support can be sought from TASMAN. They will be the single lead point of contact for data collection at each site and will liaise with the local PI and TASMAN. You must be responsive to communication from the PI, governance bodies, and TASMAN.
    - Primary person responsible in obtaining local approvals for conduct of the OPERAS Study (e.g., registration of the audit, seeking permission to upload data to REDCap).
    - Successful completion of data collection at a centre which meets the criteria for inclusion within the OPERAS dataset.

3. **Local collaborators**: A team of up to four data collectors per specialty, per centre, although this may be adjusted based on the anticipated caseload with express permission from the TASMAN steering committee). Minimum requirements for authorship on OPERAS publications include:
    - Compliance with local audit approval processes and data governance policies.
    - Active involvement in data collection over at least one data collection period at a centre which meets the criteria for inclusion within the OPERAS dataset.
    - Collaboration with the hospital leads to ensure that the audit results are reported back to the audit office / clinical teams.

Criteria for site inclusion within OPERAS

- Successful in obtaining all relevant local approvals for conduct of the OPERAS Study
- Have completed the site survey
- Successful data collection of at least one eligible patient per period for each site
- Individual sites must also ensure
    1. They obtain **>95% data completeness** for all required fields

2. All data has been uploaded by the specified database closure deadline

Should these criteria not be met, the contributing mini-team and any data they contribute may not be included in the final study, and they may be removed from any authorship lists. You are advised to get in touch with us as soon as possible so we may support you with ensuring your site is able to successfully collect data towards the OPERAS Study.

Further details regarding authorship categories i.e. steering committee roles, writing groups, data analysis and management groups, and scientific advisory groups can be found under the TASMAN Authorship Policy v.1.0 (15.05.2021) found here: https://docs.google.com/document/u/2/d/1rbAuUMGOQ7ZcZmlJe2IUJGTmJV9MqY3IeQsOMnVTkzA/edit.

For guidance relating to mini-team setup and audit registration, please contact your local principal investigator (PI). If you would be interested in signing up as a PI for a new centre not currently involved, or for any general enquiries regarding the protocol, please contact us via email (operas.tasman@gmail.com) or Twitter (@TASMANCollab)

13. Expected outputs

Unit level data for comparison will be fed back to collaborators to support local service improvement (upon request). This project will be submitted for presentation at national and international conferences. Manuscript(s) will be prepared following close of the project.

Appendix A: Included Procedures by Specialty

General Surgery

- Cholecystectomy
  - Laparoscopic or open
  - Includes subtotal cholecystectomies
  - Excludes cholecystectomy in conjunction with other major surgical procedures (e.g. Whipple's, colonic resections etc.)
- Appendicectomy
  - Laparoscopic or open
  - Excludes patients with pseudomyxoma peritonei
  - If planned associated cecectomy or right hemicolectomy, include under colonic resection group
- Inguinal hernia repair
  - Laparoscopic or open
  - Mesh or no mesh
- Colon resection with or without stoma
  - Laparoscopic or open or converted

    - Included ileocolic resection, total colectomy, subtotal colectomy, extended hemi-colectomy, left hemi-colectomy, right hemicolectomy, transverse colectomy, sigmoid colectomy/Hartmann's procedure, anterior resection, panproctocolectomy, completion proctectomy
    - Ileostomy formed Y/N or colostomy formed Y/N
    - Abdominoperineal resections and any colorectal resection resecting the anorectal complex are excluded
- Antireflux surgery (Nissen fundoplication)
    - Open or laparoscopic
- Sleeve gastrectomy
    - Open or laparoscopic

Orthopaedic Surgery

- Total shoulder arthroplasty/reverse shoulder arthroplasty
    - Total vs reverse
    - Open vs arthroscopic
- Rotator cuff repair/labral repair
- ACL repair
- Hip arthroplasty
    - Indication should be for arthritis, neck of femur fractures are excluded
    - Total vs partial
    - Robotic vs conventional
- Knee arthroplasty
    - Total vs partial
    - Robotic vs conventional

Gynaecology

- Hysterectomy
    - Abdominal (open), laparoscopic, vaginal
    - Benign and malignant indications
    - Exclude multivisceral resections or pelvic exenteration
- Oophorectomy and/or Salpingectomy
    - Unilateral or bilateral

Urology

- Prostatectomy
    - Open/robotic/laparoscopic
- Cystectomy
- Nephrectomy
    - Partial or total

Appendix B: Data Dictionary

Inpatient data points:

Baseline Demographic Data Fields	Required data (definition/comment)
Data collection period	1. **Period 1**: 4 April 2022 - 17 April 2022 2. **Period 2**: 2 May 2022 - 15 May 2022 3. **Period 3**: 30 May 2022 - 12 June 2022 4. **Period 4**: 27 June 2022 - 10 July 2022
Age	Years (whole years at the time of operation)
Gender	Male / Female / Other
Ethnicity	European Māori Pacific Peoples Asian Middle Eastern Latin American African Aboriginal or Torres Strait Islander Other Not reported
ASA	I, II, III, IV, V
BMI	Height, weight, BMI (calculator)
Underlying comorbidities (select all that apply)	• Myocardial Infarction (MI) or Congestive Heart Failure (CHF) • Peripheral Vascular Disease (PVD) • Cerebrovascular Accident (CVA) or Transient Ischaemic Attack (TIA) • Peptic Ulcer Disease • Diabetes Mellitus (Type 1 or Type 2). • Chronic Kidney Disease (CKD) (eGFR <60/ml/min/1.73m^2, dialysis or post kidney transplant, or uraemia. • Liver Disease • Cancer (active, remission) • None of the Above *Definitions for Diabetes Mellitus: Uncomplicated is defined as medically managed and no end-organ damage* *Definitions for Liver Disease: Mild defined as chronic hepatitis or cirrhosis without portal hypertension; Moderate defined as cirrhosis and portal hypertension but no variceal*

	bleeding history; Severe defined as cirrhosis and portal hypertension with variceal bleeding history
Relative or absolute contraindication to opioids	Y/N Allergy Renal impairment Severe respiratory disease Previous adverse event Previous addiction/ abuse Concurrent benzodiazepine use (Free text option)
Relative or absolute contraindication to NSAIDS	Y/N Previous GI bleeding/ulcer Allergy Renal impairment NSAID responsive asthma
Substance use	● Smoking (never, ex-smoker >12 months, ex-smoker <12 months, current) ● Alcohol consumption (standard drinks/week)
Operative data points	
Surgical procedure	See ***Appendix A*** + *free-text entry for additional procedural details*
Indication for surgery	Malignancy / Benign
Urgency	Emergency/elective
Duration procedure (mins)	Minutes (from knife-to-skin to closure of skin)
Complications while as an **inpatient** (Clavien-Dindo grade)	None I II IIIa/IIIb/IVa/IVb
Length of stay (LOS)	Total number of nights spent in hospital after operation (collect retrospectively if operation occurred prior to study period but discharge occurred within study period.) Therefore discharge on the day of surgery is considered LOS: 0. Discharge for the day immediately following surgery is considered LOS: 1.
In-patient analgesia data points	
Referral to Acute Pain Service:	Y / N

(This excludes referrals that are routine in postoperative care, only enter Yes, if non-routine acute pain service input was required due to difficulty managing analgesia).	
Last 24h AND at discharge analgesia data points - collect from discharge record (if day-case, immediate postoperative consumption).	
Opiate medication consumed in the last 24 hours of hospitalization (see protocol page 19-21 for brand names)	**Type of medication (select all that apply)** (Morphine, Tramadol, Oxycodone, Fentanyl, Codeine, Buprenorphine, Pethidine, Hydromorphone, Tanpentadol, Dextropropoxyphene ± other) **For each medication used specify:** Formulation: *Slow-release/immediate release/both* Route: PO/PO liquid/epidermal patch/IV/other Total amount consumed in the last 24 hours (amount, units: mcg/mg)
Discharge paracetamol advised	Y / N
Discharge NSAIDs advised	Y / N
Discharge medications for neuropathic pain such as gabapentinoids (e.g., pregabalin, gabapentin)	Y / N
Discharge medications for neuropathic pain such as tricyclic antidepressants (e.g., amitriptyline)	Y / N
Discharge opioid prescription	Y / N
If yes, please specify drug/amount/route:	
Morphine (Kapanol, MS Mono) *Brand names* *Immediate release morphine* • *RA-Morph®* • *Sevredol®* • *Anamorph* *Sustained/modified release morphine* • *MORPHINE MR APOTEX* • *MS Contin* • *Momex SR* • *Morphine MR Mylan* • *m-Eslon SR®* • *Kapanol* • *LA-Morph®* • *Arrow-Morphine LA®* • *MS Mono*	*Prescribed: Y/N* *Formulation: Slow-release/immediate release/both* *Dose per tablet: ___ (mg)* *Overall dose* *Route: PO/other* *Frequency of dosing: od / bd / tis / qid / PRN* *Total number of pills prescribed: ____* *If liquid - total volume ____ mL*
Tramadol (Tramal, Tramedo, Zydol)	*Prescribed: Y/N* *Formulation: Slow-release/immediate release/both*

Brand names *Immediate release morphine* • Tramal • Tramedo • Zydol *Sustained/modified release morphine* • Tramal SR • Tramedo SR • Zydol SR • Tramahexal SR Tramadol with paracetamol • Zaldair	*Combined pill with paracetamol: Y/N* *Dose: ___ (mg)* *Route: PO/other* *Frequency of dosing: od / bd / tis / qid / PRN* *Total number of pills prescribed: ____*
Oxycodone (Endone, Novacodone, OxyContin, OxyNorm, Proladone, Targin) Brand names *Immediate release* • Endone • OxyNorm • OxyNorm liquid *Controlled release* • Novacodone • OxyContin *With Naloxone* • Targin	*Prescribed: Y/N* *Formulation: Slow-release/immediate release/both* *Dose: ___ (mg OR mg/5ml)* *Route: PO/PO liquid/other* *Frequency of dosing: od / bd / tis / qid / PRN* *Total number of pills prescribed: ____* *If liquid - total volume ____ mL*
Fentanyl (Abstral, Fentora, Actiq, Denpax, Durogesic, Dutran, Fenpatch) Brand names *Patch* • Denpax, • Durogesic, • Dutran, • Fenpatch *Oral* • Abstral • Fentora • Actiq	*Prescribed: Y/N* *Formulation: Slow-release/immediate release/both* *Dose: ___ (mg)* *Route: Epidermal patch/other* *Frequency of dosing: od / bd / tis / qid / PRN* *Total number of pills prescribed: ____*
Codeine (Panadeine forte, Actacode Linctus, Aspalgin, Nurofen Plus, Ibudeine) Brand names *Codeine only* • Codeine Phosphate *Codeine with Aspirin* • Aspalgin *Codeine with Ibuprofen* • Brufen Plus, • Nurofen Plus • Ibuprofen/Codeine • Ibudeine *Codeine with paracetamol* • Panamax Co • Panadeine Forte • Codalgin Forte, • Codapane Forte, • Comfarol Forte,	*Prescribed: Y/N* *Formulation: Slow-release/immediate release/both* *Combined pill with paracetamol: Y/N* *Combined pill with NSAIDs: Y/N* *Dose: ___ (mg)* *Route: PO/other* *Frequency of dosing: od / bd / tis / qid / PRN* *Total number of pills prescribed: ____*

• Prodeine Forte	
Buprenorphine (Bupredermal, Norspan, Temgesic) Brand names *Oral* • Temgesic *Patch* • Bupredermal • Norspan	*Prescribed: Y/N* *Formulation: Slow-release/immediate release/both* *Dose: ___ (mg)* *Route: PO/patch/other* *Frequency of dosing: od / bd / tis / qid / PRN* *Total number of pills prescribed: ____*
Pethidine	*Prescribed: Y/N* *Formulation: Slow-release/immediate release/both* *Dose: ___ (mg)* *Route: PO/other* *Frequency of dosing: od / bd / tis / qid / PRN* *Total number of pills prescribed: ____*
Hydromorphone (Dilaudid, Jurnista) Brand names *Immediate release* • Dilaudid *Controlled release* • Jurnista	*Prescribed: Y/N* *Formulation: Slow-release/immediate release/both* *Dose: ___ (mg)* *Route: PO/other* *Frequency of dosing: od / bd / tis / qid / PRN* *Total number of pills prescribed: ____*
Tapentadol (Palexia) Brand names *Immediate release* • Palexia IR *Controlled release* • Palexia SR	*Prescribed: Y/N* *Formulation: Slow-release/immediate release/both* *Dose: ___ (mg)* *Route: PO/other* *Frequency of dosing: od / bd / tis / qid / PRN* *Total number of pills prescribed: ____*
Dextropropoxyphene (Di-Gesic, Doloxene)	*Prescribed: Y/N* *Formulation: Slow-release/immediate release/both* *Dose: ___ (mg)* *Route: PO/other* *Frequency of dosing: od / bd/ tis / qid / PRN* *Total number of pills prescribed: ____*
Other opiate prescribed	*Prescribed: Y/N* *Formulation: Slow-release/immediate release/both* *Dose: ___ (mg) per tablet* *Route: PO/other* *Frequency of dosing: od / bd / tis / qid / PRN* *Total number of pills prescribed: ____*
Safety net ((29))	Information provided about safe disposal of surplus opioids Y/N

Follow-up data points

Briefly explain to patients what an opioid is and some examples of medications which are opioids.

7-day follow up data points	**Required data (definition / comment)**
Information provided and verbal consent obtained	Y/N
Medication-related	
If discharge opiate prescription = Y	
Did you take your **hospital-**prescribed opiates	Y/N
Quantity of opiates taken from **hospital prescription** (*if liquid, quantify mLs consumed)*	*Only to fill in relevant medications*
Morphine	*Number of tablets remaining from hospital prescription: ____ (tablets)*
Tramadol	*Number of tablets remaining from hospital prescription: ____ (tablets)*
Oxycodone	*Number of tablets remaining from hospital prescription: ____ (tablets) or ___mL*
Fentanyl	*Number of tablets remaining from hospital prescription: ____ (tablets) or ___ (patches)*
Codeine	*Number of tablets remaining from hospital prescription: ____ (tablets)*
Buprenorphine	*Number of tablets remaining from hospital prescription: ____ (tablets) or ___ (patches)*
Pethidine	*Number of tablets remaining from hospital prescription: ____ (tablets)*
Hydromorphone	*Number of tablets remaining from hospital prescription: ____ (tablets)*
Tapentadol	*Number of tablets remaining from hospital prescription: ____ (tablets)*
Other opiate prescribed	*Number of tablets remaining from hospital prescription: ____ (tablets)*

While you've been at home have you had any of the following side effects? Please circle "0" if no; if yes, please circle the one number that best shows the severity of each:	0 (none) - 10 (extreme)
Nausea/vomiting	
Drowsiness	
Itching	
Dizziness	
Constipation	
Were laxatives (e.g. laxsol) or anti-sickness with the opioids (e.g. cyclizine, metoclopramide, ondansetron) prescribed?	Y/N
For all	
During the first week after your discharge, did you use **paracetamol** (panadol) to manage your post-surgical pain?	Y/N
During the first week after your discharge, did you use **NSAIDs** (ibuprofen, naproxen, celecoxib, diclofenac, etc) to manage your post-surgical pain?	Y/N
Did you use any nerve pain medications like gabapentin, pregabalin, or amitriptyline to help with pain in the last week?	Y/N
Did you seek medical help for your pain i.e., requesting increased pain relief or additional pain relief prescriptions? This includes GP, urgent care or the emergency department, the ward you were in at the hospital, or your surgeon.	Y/N
~~If yes - other:~~	~~Where?~~

If you did seek medical help, did you receive additional opiates i.e. a repeat prescription	Y/N
If yes, was the dose:	Higher The same Lower
Did you get any pain relief medications from any other sources? For example, from friends or family, or that you already had at home?	Y/N
If yes – name, dose, quantity	
Did you seek medical help for side effects of your pain medication?	Y - GP Y - Urgent care/Emergency department Y - Readmission to hospital N
For the past 3 months prior to your admission, were you using any routine pain killer medications?	No Yes: 1 / 2 / 3 / 4 / 5 / 6 / 7 days per week
If yes:	Tick all that apply: **Paracetamol** (panadol), **NSAIDs** (ibuprofen, naproxen, celecoxib, diclofenac, etc) **Weak opioids** (tramadol, codeine, etc) **Strong opioids** (sevredol, oxycodone etc)
Patient-reported pain and satisfaction outcomes	
EQ-5D-5L + EQ-VAS: *Under each heading, please tick the ONE box that best describes your health TODAY*	EQ - 5D
MOBILITY	1. I have no problems in walking about 2. I have slight problems in walking about 3. I have moderate problems in walking about 4. I have severe problems in walking about 5. I am unable to walk about
SELF-CARE	1. I have no problems washing or dressing myself 2. I have slight problems washing or dressing myself 3. I have moderate problems washing or dressing myself

	4. I have severe problems washing or dressing myself 5. I am unable to wash or dress myself
USUAL ACTIVITIES (e.g. work, study, housework, family or leisure activities)	1. I have no problems doing my usual activities 2. I have slight problems doing my usual activities 3. I have moderate problems doing my usual activities 4. I have severe problems doing my usual activities 5. I am unable to do my usual activities
PAIN / DISCOMFORT	1. I have no pain or discomfort 2. I have slight pain or discomfort 3. I have moderate pain or discomfort 4. I have severe pain or discomfort 5. I have extreme pain or discomfort
ANXIETY / DEPRESSION	1. I am not anxious or depressed 2. I am slightly anxious or depressed 3. I am moderately anxious or depressed 4. I am severely anxious or depressed 5. I am extremely anxious or depressed
We would like to know how good or bad your health is TODAY. This scale is numbered from 0 to 100. 100 means the best health you can imagine. 0 means the worst health you can imagine. Please indicate on the scale to indicate how your health is TODAY	0 (worst health imaginable) - 100 (best health imaginable)
How often were you in **severe pain** in the first week after discharge?	0% (none of the time) - 100% (all of the time)
Did you receive information, advice, or education managing pain from your doctor or nurse before discharge?	Y/N
The amount of pain medication I received was:	Too little Just right Too much
Circle the one number that best shows how **satisfied** you were with the results of your pain treatment in the first week after discharge	0 (extremely dissatisfied) - 10 (extremely satisfied)

Appendix C: Relevant audit standard

The following audit standard data were used to inform the development of the OPERAS protocol.

Hospital opioid stewardship programs in Australia and New Zealand are highly variable, with clinicians mostly relying on site-specific guidelines and advice.

There are no specific Australasian guidelines for opioid prescription following cholecystectomy, appendicectomy, inguinal hernia repair, mastectomy, bimalleolar ankle fracture ORIF, distal radius fracture ORIF, total shoulder arthroplasty, total hip arthroplasty, total knee arthroplasty, anterior cruciate ligament reconstruction, rotator cuff tear repair, and abdominal/laparoscopic/vaginal hysterectomy (30–32).

Some key principles have been identified regarding postoperative analgesia in general.

From ANZCA, Position statement on the use of slow-release opioid preparations in the treatment of acute pain. Accessed at: blob:https://www.anzca.edu.au/9b47a506-ee4f-48de-b8c2-ceb78ad97fae

- Slow-release opioids are not recommended for use in the management of patients with acute pain.
- In most patients, pain intensity will decrease reasonably rapidly over a few days. In order to minimise the risk of opioid-related adverse effects, the patient's opioid doses must also decrease over this time.
- When opioids are used for acute pain, especially for discharge or in the community, the quantity prescribed should be based on the expected duration of pain which is severe enough to require an opioid.
- In postoperative or post-traumatic patients with prolonged pain states, it may sometimes be useful to introduce a slow-release opioid in a previously opioid-naive individual on a temporary basis after careful reassessment. Consideration should then be given to opioids with the least sedative (and therefore respiratory depressant) effect. In establishing an appropriate dose, time to steady state should also be considered. As daily opioid requirements may vary considerably in the acute pain setting, the dose should be frequently assessed and reduced appropriately. Communication with the primary service (including rehabilitation services) or general practitioner about the temporary basis of this prescription is essential.
- The planning of weaning and ceasing the opioid remains the responsibility of the person who initiated it. The need for discharge opioids should be assessed. Appropriate instructions should be conveyed to the patient about opioid weaning as well as timely formal communication to junior medical staff and/or the patient's general practitioner about discontinuation of these medications in a planned time frame.

From RACGP, Prescribing drugs of dependence in general practice, Part A Clinical governance framework. Accessed at: https://www.racgp.org.au/FSDEDEV/media/documents/Clinical%20Resources/Guidelines/Drugs%20of%20dependence/Prescribing-drugs-of-dependence-in-general-practice-Part-A.pdf

- Registrars are permitted to supply opioid analgesic continuation therapy provided there is a plan to reduce and cease all opioid analgesia within a fortnight for most surgery, but up to 6 weeks for joint replacement or thoracotomy is undertaken

From Australian Prescriber, Management of postsurgical pain in the community. Accessed at: https://www.nps.org.au/australian-prescriber/articles/management-of-postsurgical-pain-in-the-community

- When considering management of postsurgical pain in the community;
    - Opioid doses should be titrated
    - Opioids should be weaned at a rate that matches the resolution of the pain
    - Short-acting opioids should be used in preference over long-acting opioids to manage post-surgical pain

Outside the Australian and New Zealand context, the RCA Faculty of Pain Medicine provide detailed pre and post operative recommendations, including discharge planning.

From RCA Faculty of Pain Medicine, Surgery and Opioids Best Practice Guidelines 2021. Accessed at: https://fpm.ac.uk/sites/fpm/files/documents/2021-03/surgery-and-opioids-2021_4.pdf

- postoperative recommendations regarding discharge planning:
    - Immediate-release opioids are preferred in the management of postoperative pain (to decrease risk of respiratory impairment and long term continuation), when simple analgesics such as paracetamol or NSAIDs are not effective enough to allow the achievement of agreed functional goals.
    - Advice on medicine self administration: On discharge, patients must be advised how to self- administer medicines safely, wean analgesics, dispose of unused analgesic medications and of the dangers of driving/operating machinery while taking opioid medicines. The dangers of mixing opioids with alcohol and other illicit drugs that increase risk of harm should be communicated. A patient leaflet should be provided to reinforce these messages.
    - Local protocols for the prescription of discharge medications after surgery (“TTOs”) should be developed to minimise the chances of subsequent inappropriate opioid use. Ideally this should be managed between the hospital and primary care.
    - The hospital discharge letter must explicitly state the recommended opioid dose, amount supplied and planned duration of use.
    - Identification of patients for de-escalation of opioids: Some painful conditions, such as osteoarthritis of the knee, may require surgical procedures to treat pain and improve function. Patients with these conditions may be taking opioid medications before surgery. These opioids should be gradually withdrawn, where possible, after surgery.
    - Medicine review post discharge: Guidance should be given about necessary medicine review following discharge from hospital. Usually, 5 days and no more than 7 days medication should be prescribed.

See also RCA Guidelines for the provision of anaesthesia services for inpatient pain management 2020. Accessed at: https://www.rcoa.ac.uk/sites/default/files/documents/2020-02/GPAS-2020-11-Pain.pdf

Appendix D: Clavien-Dindo Grading of Surgical Complications

Grade	Definition
Grade I	Any deviation from the normal postoperative course not requiring surgical, endoscopic or radiological intervention. This includes the need for certain drugs (e.g., antiemetics, antipyretics, analgesics, diuretics and electrolytes), treatment with physiotherapy and wound infections that are opened at the bedside
Grade II	Complications requiring drug treatments other than those allowed for Grade I complications; this includes blood transfusion and total parenteral nutrition (TPN)
Grade III	Complications requiring surgical, endoscopic or radiological intervention ● Grade IIIa - intervention not under general anaesthetic ● Grade IIIb - intervention under general anaesthetic
Grade IV	Life-threatening complications: this includes CNS complications (e.g. brain haemorrhage, ischaemic stroke, subarachnoid haemorrhage) which require intensive care, but excludes transient ischaemic attacks (TIAs) ● Grade IVa - single-organ dysfunction (including dialysis) ● Grade IVb - multi-organ dysfunction
Grade V	Death of the patient

Appendix E: American Society of Anesthesiologists (ASA) Classification

ASA Class	Definition
I	A normally healthy patient
II	A patient with mild systemic disease
III	A patient with severe systemic disease
IV	A patient with severe systemic disease that is a constant threat to life
V	A moribund patient who is not expected to survive without the operation
VI	A declared brain-dead patient whose organs are being removed for donor purposes

Appendix F: Patient identification recommendations

To capture all eligible patients within the study period the patient identification process will be as follows:

1. 2-week inclusion period:
    a. Theatres lists will be prospectively screened for a 2-week period to identify patients undergoing eligible procedures. This patient will be kept track of using a patient identification key (spreadsheet with study ID, procedure, and corresponding patient identifier (MRN or NHI equivalent))
2. Patients identified during this 2-week inclusion period will be followed up by data collectors. At 7-days post-discharge, a phone-call will be made to collect data on analgesic usage and pain control. Consent for inclusion into the study will be made while they are an inpatient or at follow-up as per local ethical requirements. No data on patients will be collected before consent is confirmed.

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