

BMJ Open Opioid PrEscRiptions and usage After Surgery (OPERAS): protocol for a prospective multicentre observational cohort study of opioid use after surgery

TASMAN Collaborative

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ABSTRACT

Introduction Postoperative pain is common and frequently addressed through opioid analgesia. This practice must balance the benefits of achieving adequate pain relief against the harms of adverse effects such as opioid-induced ventilatory impairment and opioid use disorder. This student and trainee-led collaborative study aims to investigate and compare the prescription versus consumption of opioids at 7 days postdischarge after common surgical procedures and their impact on patient-reported outcomes regarding postoperative pain.

Methods and analysis This is a prospective multicentre observational cohort study of surgical patients in Australia, Aotearoa New Zealand and select international sites, conducted by networks of students, trainees and consultants. Consecutive adult patients undergoing common elective and emergency general, orthopaedic, gynaecological and urological surgical procedures are eligible for inclusion, with follow-up 7 days after hospital discharge. The primary outcome will be the proportion of prescribed opioids consumed by patients at 7 days postdischarge. Secondary outcomes will include patient-reported quality of life and satisfaction scores, rate of non-opioid analgesic use, rate of continuing use of opioids at follow-up, rates of opioid prescription from other sources and hospital readmissions at 7 days postdischarge for opioid related side-effects or surgery-related pain. Descriptive and multivariate analyses will be conducted to investigate factors associated with opioid requirements and prescription-consumption discrepancies.

Ethics and dissemination OPERAS has been approved in Australia by the Hunter New England Human Research Ethics Committee (Protocol 2021/ETH11508) and by the Southern Health and Disability Ethics Committee (2021 EXP 11199) in Aotearoa New Zealand. Results will be submitted for conference presentation and peer-reviewed publication. Centre-level data will be distributed to participating sites for internal audit.

Trial registration number ANZCTR (ID: ACTRN12621001451897p)

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This is a prospective, multicentre, collaborative study, which will capture a wide range of clinical practices and patient experiences on an international scale.
- ⇒ Integration of a rigorous follow-up escalation plan will maximise successful participant follow up.
- ⇒ The use of 2-week snapshot data collection periods will optimise data quality, encourage complete follow-up and minimise selection bias, but 7-day follow-up may lead to recall bias of patient experiences during the first week postdischarge.
- ⇒ This study is an observational study and will have limited ability to identify causal relationships pertaining to opioid prescription postdischarge and patient outcomes.

addictive and are associated with numerous side effects and serious sequelae such as death secondary to opioid-induced ventilatory impairment.² Opioid-related adverse drug events have been found to affect up to 10.6% of patients, associated with a 2.9% increase in absolute mortality and a 1.6-day increase in length of stay for index hospitalisation.³ The over prescription of opioids after common surgical procedures is a recognised contributor to the opioid crisis.⁴ In particular, opioids prescribed to previously opioid-naïve patients after surgery create the potential risk of developing long-term dependence.⁵ The USA leads the world in per person opioid prescribing, but both Australia and Aotearoa New Zealand are ranked among the top 10 countries. The many non-fatal health consequences of opioid use disorder contribute to an annual cost of >\$1 trillion in North America alone.⁶

The causes of opioid misuse are complex and multifactorial, and this is further complicated by challenges in postoperative prescribing.⁷ Opioid over prescription is associated with increased risk of opioid overdose,



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prolonged opioid use and diversion of unused opioids into the community.⁴ Prolonged duration of opioid use has been identified as the strongest predictor of misuse.⁸ However, under prescribing of analgesia can lead to undertreatment of pain, pain-related readmissions and delayed surgical recovery.¹ Various resources at the hospital, national and international level aim to provide guidance on safe perioperative opioid use in adults.^{2 9} Specific preoperative interventions and evidence-based recommendations for analgesia prescribing at time of hospital discharge have the potential to improve pain control while reducing the risk of opioid over prescription.¹⁰

Given the significance and challenges of postoperative opioid prescribing, Opioid PrEscRiptions and usage After Surgery (OPERAS) is an international prospective collaborative study that aims to investigate and compare the prescription versus consumption of opioids after common surgical procedures and their impact on patient-reported outcomes. OPERAS will address key gaps in the literature by prospectively incorporating patient-reported outcomes, and by providing a snapshot of current post-surgical opioid prescribing patterns on a global scale.

METHODS

This protocol is described according to relevant items of the SPIRIT checklist (Standard Protocol Items: Recommendations for Interventional Trials).¹¹ The complete approved study protocol is provided in online supplemental appendix A.

Study objectives

The primary aim is to quantify the amount of opioid medication prescribed at hospital discharge after common surgical procedures and to identify the proportion of opioid prescription medication consumed by patients within 7 days postdischarge. The secondary aims are to describe the variations in opioid prescription and consumption by procedure and specialty, quantify the impact of the amount of analgesia prescribed on patient-reported satisfaction with pain relief after discharge, determine the rate of ongoing opioid use at 7 days, identify risk factors for opioid consumption and overprescription at 7 days and describe the use of ancillary analgesia postdischarge after surgery. Data on patient comorbidities will also be recorded.

Study design

This is a prospective, multicentre, observational cohort study that will be delivered under the umbrella of the Trials and Audit in Surgery by Medical Students in Australia and Aotearoa New Zealand (TASMAN) Collaborative, supported by the Clinical Trials Network Australia and New Zealand (CTANZ). The study will also be facilitated in Australia and Aotearoa New Zealand through other state and national student and trainee networks. This model of collaborative research has been previously described in detail.^{12 13}

Box 1 Operas data collection forms

OPERAS data collection is divided into four forms.

1. Inpatient data: this form is completed prospectively during the patient's index hospitalisation and includes demographic and procedure specific information such as type of procedure, American Society of Anesthesiologists status, comorbidities and complications during the admission.
2. Discharge opioids: this form is completed at discharge and includes details regarding the patient's discharge opioid medications, including type, dose, route and quantity supplied.
3. Follow-up medication: this form is completed during the structured follow-up interview on day 7 after discharge, using the OPERAS telephone interview follow-up script and includes information about pain management since discharge, such as quantity of opioids consumed, adverse effects experienced or requirements for further analgesia.
4. Patient-reported pain and satisfaction outcomes: this form is also completed during the structured follow-up interview on day 7 after discharge using the OPERAS telephone interview script and includes the EQ-5D-HL Health Questionnaire as well as further questions about patient satisfaction with postoperative pain management.

OPERAS, Opioid PrEscRiptions and usage After Surgery.

Data collection team structure will consist of students, junior doctors, registrars and pharmacists collecting data and acting as hospital leads with responsibility for obtaining necessary local approvals and overseen by a supervising consultant. Prospective data will be collected from inpatient clinical records and a standardised patient telephone interview 7 days postdischarge (box 1).

Study setting

Any hospital that performs surgery will be eligible to participate. Each hospital may contribute data in up to six predetermined 2-week data collection periods between April and September 2022. All eligible patients operated within the recruitment period will be approached. Study participants will be monitored through their admission and prospective data collection will be completed (figure 1). Participants will subsequently be followed up at 7 days after discharge from hospital.

Patient recruitment periods

- Period 1: 4 April 2022 to 17 April 2022.
 Period 2: 2 May 2022 to 15 May 2022.
 Period 3: 30 May 2022 to 12 June 2022.
 Period 4: 27 June 2022 to 10 July 2022.
 Period 5: 25 July 2022 to 7 August 2022.
 Period 6: 22 August 2022 to 4 September 2022.

Study recruitment and power calculation

Based on the POSTVenTT (POST operative Variability in anaemia Treatment and Transfusion) study and recent multispecialty collaborative studies, approximately 55 hospitals in Australia and Aotearoa New Zealand and 3000 patients are expected to be eligible.^{12 14 15} We anticipate more than 75% recruitment based on the results of a pilot single-centre study utilising telephone interviews.¹⁶

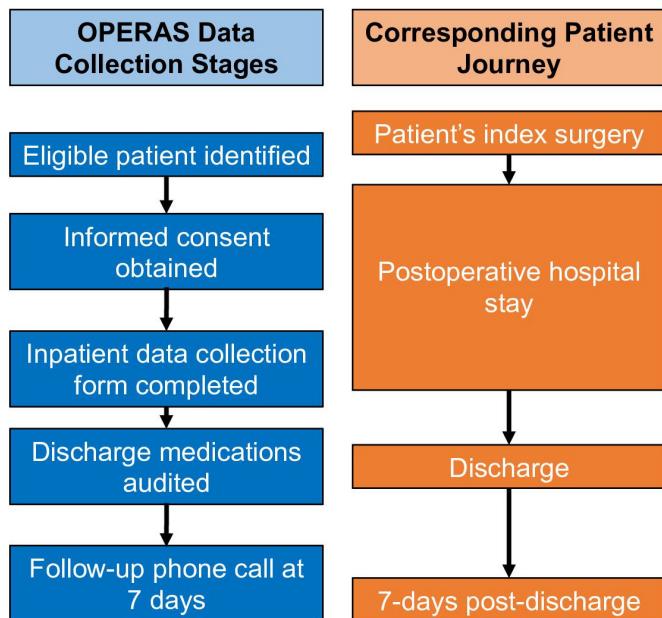


Figure 1 OPERAS data collection process and corresponding patient journey. OPERAS, Opioid PrEscRiptions and usage After Surgery.

A sample size calculation was performed per the methods of Riley *et al*^{17 18} with the assumption that 56% of patients are discharged with opioids,⁸ with a median of 150 (IQR 135–225) Oral Morphine Equivalents (OME)¹⁹ and an estimated multivariable linear regression model R² value of 0.47 based on a previous study.¹⁹ For 36 candidate variables, the resulting minimum sample size is 852. Further details are provided in the online supplemental appendix.

Data collection and management

All data will be collected prospectively and stored online through a secure Research Electronic Data Capture (REDCap) web server hosted by the Hunter Medical Research Institute (HMRI).²⁰ All data uploaded and stored in REDCap are encrypted. No patient-identifiable information will be uploaded, and anonymised data will be pooled with no surgeon-specific analysis. A full list of data points collected is provided in online supplemental appendix B.

Eligibility criteria

The following criteria must be met for inclusion in the study:

1. *Age:* 18 years or above.
2. *Procedure:* Common general surgical, orthopaedic, gynaecological and urological procedures, listed in online supplemental appendix C. Procedures can be performed using any surgical approach, including open, laparoscopic and robotic surgery.
3. *Urgency:* Patients undergoing elective (planned) or emergency (unplanned) surgery.
4. *Discharge status:* Patients discharged home or to non-healthcare settings.

Patients who fulfil any of the following criteria will be excluded from the study:

1. *Medication-assisted treatment of opioid dependence (MATOD):* Patients currently on MATOD including methadone, suboxone or buprenorphine.
2. *Discharge status:* Patients discharged to rehabilitation (including inpatient rehabilitation service), nursing or supported care services, or another hospital or not discharged. Patients discharged to hospice or with palliative intent.
3. *Procedures:* Procedures not included in the full list of common surgical procedures (online supplemental appendix C), including diagnostic procedures, for example, endoscopy and diagnostic laparoscopy (without appendicectomy). Palliative procedures as determined preoperatively and explicitly stated in the medical record or consent form. Procedure and specialty-specific exclusions are outlined in online supplemental appendix C.
4. *Extent of surgery:* Multivisceral resections (defined as operations involving two or more distinct procedures of the gastrointestinal, hepatopancreatobiliary, genitourinary or gynaecological systems, eg, hysterectomy with colorectal resection).
5. *Return to theatre:* Patients may not be included in the study more than once, therefore patients returning to theatre due to complications following earlier surgery will be excluded if they have already participated following their index procedure.

Participant informed consent process

All eligible patients anticipated to be discharged during the study inclusion periods will be approached during their inpatient stay to obtain written informed consent to participate in the study (figure 2). Collaborators will explain the purpose of the study, advise patients to expect a phone call at 7 days postdischarge, and confirm their preferred contact number.

Follow-up

Participants will be contacted by telephone call at 7 days postdischarge from the hospital. A script outlining the follow-up phone call questions to be asked during this interview will be provided to data collectors to minimise variance (online supplemental appendix D). The telephone call will confirm if the prescribed medication was dispensed from a pharmacy, total opioid consumption, need for repeat analgesia prescriptions and where these were sourced, satisfaction scores regarding pain management, contact with the health system for uncontrolled pain or opioid related side effects and quality of life as measured by the EQ-5D-5L tool (online supplemental appendix E). As trialled in a pilot single-centre study, wherever possible a number identified mobile will be used to contact participants and a text will be sent prior to the call to explain the source and purpose of the call, in order to maximise response rates.¹⁶ There will be up to three attempts to contact the participants on day 7, followed by

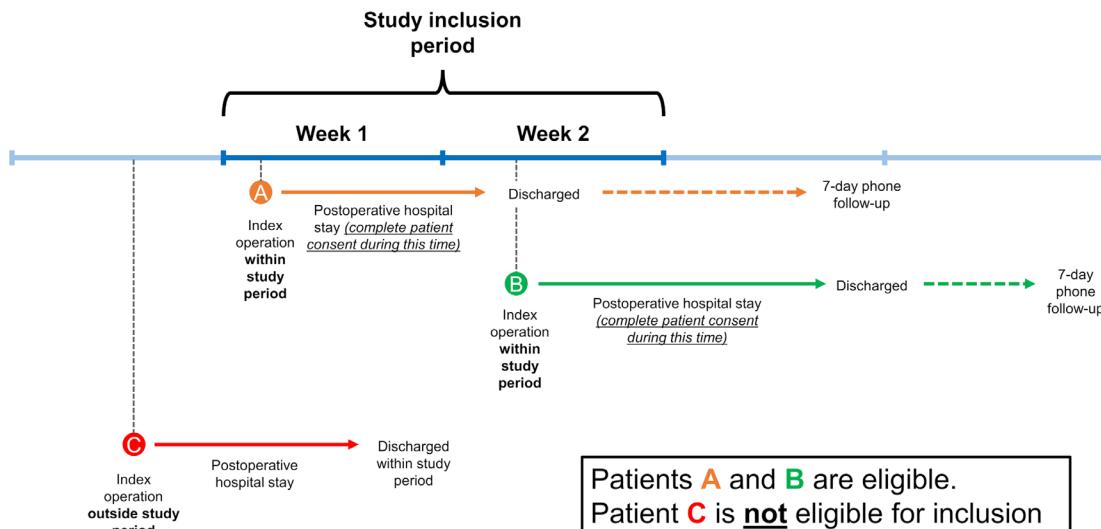


Figure 2 Patient eligibility based on timing of index operation and discharge.

up to three further attempts over 3 days up to day 10 days postdischarge. If unsuccessful, the participant will be lost to follow-up (online supplemental appendix F).

Outcomes

The primary outcome is the proportion of prescribed opioids in oral morphine equivalent (OMEs) that have been consumed by 7 days postdischarge. This will be calculated using conversion ratios defined by the Australian and New Zealand College of Anaesthetists (ANZCA) Faculty of Pain Medicine.²¹ Secondary outcomes include patient-reported outcomes (eg, quality of life, postoperative pain, adequacy of pain relief prescribed), consumption of non-opioid analgesics (eg, paracetamol, non-steroidal anti-inflammatory drugs (NSAIDs)), rate of continuing use of opioids at follow-up, rates of opioid prescription from other sources and hospital readmissions at 7 days postdischarge for opioid-related side-effects or surgery-related pain.

Other outcome variables

Potentially confounding factors will be collected for the purposes of risk-adjusted analyses in the data analysis (online supplemental appendix B). These include patient demographics (age, sex and ethnicity), as well as American Society of Anesthesiologists (ASA) physical status, comorbid disease, contraindications to opioids or NSAIDs, smoking and alcohol status, length of hospital stay and opioid consumption in the 24 hours prior to discharge. Data will also be collected on procedure type, indication, urgency, duration, postoperative complications (as defined by the Clavien-Dindo classification) and referrals to acute pain services.²²

Statistical analysis

Use of multimodal analgesia and avoidance of long-acting opioids for acute postoperative pain will be assessed.⁹ Descriptive statistics (rates of events and proportions) followed by multivariate regression models will be used

to identify association between quantity of prescribed opioids to consumed opioids; with risk adjustment for eligible factors determined *a priori* including age, sex, smoking status, alcohol use, cancer, obesity, ASA physical status, elective versus emergency surgery and patient-reported pain scores. Mixed-effects models, where the hospital comprises the random effect, will be used. No direct comparisons between individual hospitals will be undertaken, however comparisons across nations and health systems may be performed. A planned subgroup analysis will be completed of patients taking preoperative opioids.

Confounding factors for increased or decreased opioid use will be used to generate risk adjusted models for outcomes, particularly the proportion and amount of prescribed opioids in OME doses that have been consumed by 7 days postdischarge from common surgical procedures. Normally distributed data will be reported as mean (SD), and non-normally distributed data as median (IQR). Independent samples t-tests or analysis of variance for normally distributed variables, Mann-Whitney U and Kruskal-Wallis tests for non-normally distributed continuous or ordinal variables and χ^2 tests for categorical variables will be used for comparisons. A multivariable, multilevel regression model will be used to assess the association between quantity of prescribed opioids to consumed opioids. Risk factors for unused opioids at 7 days, requirements for further analgesia and pain-related readmissions within 7 days will also be investigated.

Study delivery and quality assurance

OPERAS will be coordinated by an Australian and Aotearoa New Zealand steering committee with the support of a scientific advisory group and CTANZ. Existing national student and trainee-led collaborative research networks will enable effective dissemination of the study in participating regions. The accuracy and completeness of data will be ensured using strategies demonstrated by

past collaborative studies: a local consultant will supervise data collection by mini teams of collaborators (students and trainees) at each site, and online education modules will provide training in assessment of outcome measures, eligibility criteria and data collection.¹⁵

Patient and public involvement

The development of the research question and outcome measures are based on the findings of a pilot study of postoperative patient experiences and opioid use after discharge.¹⁶ No formal patient and public involvement process was utilised in the development of this protocol. Patient and public representatives may be consulted in future translation and dissemination of study results in partnership with stakeholders.

ETHICS AND DISSEMINATION

Ethical approval has been sought according to the requirements at each participating centre. Evidence of local governance approval at each site will be a prerequisite to gaining access to the REDCap database prior to data collection. In Australia, OPERAS has been approved by the Hunter New England Human Research Ethics Committee (2021/ETH11508), and in Aotearoa New Zealand from the Southern Health and Disability Ethics Committee (2021 EXP 11199). Results will be submitted for conference presentation and peer-review publication. Centre-level data will be distributed to participating sites for internal audit.

DISCUSSION

Postoperative opioid use remains a significant public health issue, however data on postdischarge prescription, consumption and its relationship with patient-reported outcomes are lacking. Several factors are likely contributing to variability in opioid prescribing, including challenges in research translation and limited awareness of national and international resources and guidelines among prescribers.^{9 23} Given increasing recognition of disparities in access to pain relief internationally, there is a need for a multinational approach to examine this issue.^{24 25} OPERAS will characterise postoperative discharge opioid prescription practices in Australia, Aotearoa New Zealand and internationally, and provide insight into patient-reported experiences of postoperative pain on discharge from hospital. The results of this study will provide a more accurate understanding of patients' opioid requirements after common surgical procedures and assist in identifying strategies to minimise opioid overprescription and its associated harms.

OPERAS is among the first student and trainee-led prospective, multicentre, observational collaborative studies designed and undertaken in Australia and Aotearoa New Zealand, emulating well-established models of collaborative research that have conducted several large international cohort studies.¹² OPERAS will build on the success of emerging international and Australian and Aotearoa

New Zealand collaborative studies such as POSTVenTT.¹⁴ OPERAS will provide a valuable opportunity for students and trainees to develop their research skills, with a particular emphasis on obtaining informed consent from patients for research, telephone follow-up, management and leadership skills and further development of collaborative research capacity throughout Australia and Aotearoa New Zealand.

Data collection is limited to 2-week snapshot periods and this approach is likely to enhance data quality, encourage complete follow-up and minimise selection bias as evidenced by previous successful collaborative studies.^{15 26} This will facilitate collaboration across multiple international sites and amass a significant sample size. Additionally, rigorous escalation plans involving in-person participant recruitment, multiple contact attempts and multiple communication avenues, are in place to maximise data completeness from telephone follow-up calls. Limitations will include the accuracy of the data collected at the 7-day follow-up, which are subject to recall bias. Loss to follow-up will likely be correlated with outcomes of interest and is likely to be a limitation of a telephone follow-up data collection approach. Variables have been chosen in consultation with an expert panel to maximise accuracy of results and high levels of data completion. Finally, this study is an observational study and will have limited ability to identify causal relationships pertaining to opioid prescription postdischarge and patient outcomes.

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Contributors The OPERAS Steering Committee, Scientific Advisory Group, and representatives from TASMAN contributed to the drafting of this manuscript. The OPERAS Steering Committee and Scientific Advisory Group supervised the protocol design and final manuscript. All listed collaborators meet required criteria and no others have been omitted. PP is the guarantor.

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Competing interests None declared.

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Correction: *Opioid PrEscRiptions and usage After Surgery (OPERAS): protocol for a prospective multicentre observational cohort study of opioid use after surgery*

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This article has been corrected since it was published online. The author by-line has been updated from 'TASMAN Collaborative Project Management Group' to 'TASMAN Collaborative'.

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Appendix A: OPERAS Study Protocol

OPERAS Study Protocol Version 2.0.8 – 28th February 2022



OPERAS Study

Opioid PrEscrptions and Usage After Surgery

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

Study protocol version 2.0.8
28th February 2022



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OPERAS Study Protocol Version 2.0.8 – 28th February 2022

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Amendments

Amendment	Date	Protocol Version	Summary
	1/12/21	2.0.6	Change in Scientific Advisory Committee personnel, additional trainee-led collaborative networks included, and data collection instrument harmonized with patient telephone call script.
	28/1/22	2.0.7	Addition of student pharmacists and pharmacists as data collectors and members of mini teams. Addition of Steering Committee personnel.
	28/2/22	2.0.8	Changes made in response to peer review of protocol including; • Addition of previously omitted data point (date of last opioid medication use) and inclusion of the analysis of this datapoint as a secondary study outcome • Amendments to reflect current pharmacology and nomenclature • Correction of typographical errors/clarification of text

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Steering Committee

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Scientific Advisory Group

Name	Position	Twitter
Peter Pockney	Associate professor and consultant colorectal surgeon	@Ppockney
Luke Peters	Clinical teaching fellow and SET trainee	
David Watson	Professor and consultant oesophagogastric surgeon	@CtanZDavid
Deborah Wright	Senior lecturer and consultant colorectal surgeon	@scalpel_deborah
Amanda Dawson	Associate professor and consultant general surgeon	
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Nicholas Lightfoot	Consultant anaesthetist	
Jennifer Martin	Professor of clinical pharmacology and physician	
Rachel Sara	Consultant anaesthetist and pain specialist	
Arnab Banerjee	Senior lecturer and consultant anaesthetist	

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Collaborative Partners

CTANZ	The logo for the Royal Australasian College of Surgeons features a stylized blue 'S' icon followed by the text 'Royal Australasian College of Surgeons' in a serif font.
VERITAS	The logo for VERITAS features the word 'VERITAS' in a large, serif, black font. Below the letter 'T' is a small silhouette of a person holding a torch. Smaller text below the main title includes 'EX SCIENTIA ET COLLABORARE INNOVATUS'.
SPARTANS	The logo for HUNTER SPARTANS features a circular graphic divided into four quadrants: red at the top, grey at the bottom, and blue on the left and right. To the right of the graphic, the word 'HUNTER SPARTANS' is written in a serif font, with 'STUDENT, PREVOCATIONAL AND REGISTRAR TRIALS AND AUDIT NETWORK' in smaller text below.
STRIVEWA	The logo for STRIVE WA features a stylized graphic of three people in orange, yellow, and blue. To the right, the word 'STRIVE WA' is written in a serif font, with 'Student Research Initiative' in smaller text below.
STARCSA	The logo for STARC SA features a stylized graphic of three people in blue, orange, and green. Below the graphic, the word 'STARC SA' is written in a serif font.
STORCC	The logo for STORCC features a stylized graphic of a sailboat on water. Below the graphic, the word 'STORCC' is written in a bold, sans-serif font, with 'SURGICAL TRAINEE ORGANISATION FOR RESEARCH - CENTRAL COAST' in smaller text below.
STRATA	The logo for STRATA features a stylized graphic of the outline of New Zealand in blue. Below the graphic, the word 'STRATA' is written in a bold, sans-serif font, with 'SURGICAL TRAINEE RESEARCH, AUDIT & TRIALS AOTEAROA' in smaller text below.

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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

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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 duration of use of opioid analgesics in the first 7 days after discharge
5. 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/actual prescription duration. Comparisons will be made across states/countries, specialties, and common operations.

When?

Prospectively over a four-month period in 2022.

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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.

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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, evaluate 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, student pharmacists, junior doctors, trainees, registrars, pharmacists, and supervising consultants (**Figure 1**) Data will be collected prospectively on patients being discharged following major surgery (included procedures in **Appendix A**).

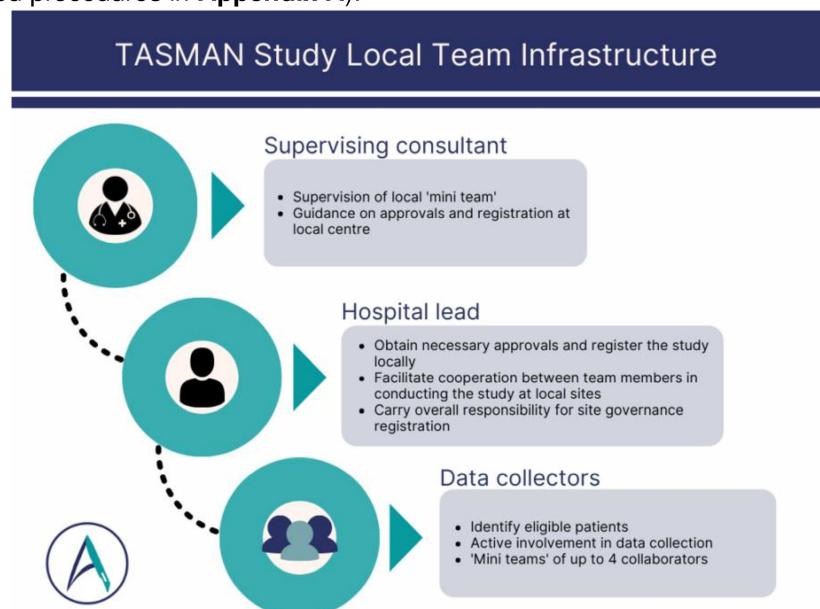


Figure 1: Mini-team structure

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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 being discharged after 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, e) when they last took opioid analgesia, and f) 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.

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The exclusion criteria is as follows:

- Paediatric patients (below 18 years of age)
- On the opiate replacement program (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:



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- 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
- Whether the participant is still using opioid analgesics at the day 7 post-discharge follow up

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 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

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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 database 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).

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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



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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.

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Collaborator role descriptions are as follows:

1. **Local supervising consultant/attending/pharmacist:** provide guidance for approval processes, facilitate communication within the hospital, and mentor and facilitate medical students, student pharmacists, 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

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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/1rbAuUMGOQ7ZcZmlJe2IUJGTmJV9MqY3leQsOMnVTkzA/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

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- Included ileocolic resection, total colectomy, subtotal colectomy, extended hemicolectomy, left hemi-colectomy, right hemicolecction, 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

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Appendix B: Data Dictionary

Inpatient data points:

Baseline Demographic Data Fields	Required data (definition/comment)
Data collection period	<ol style="list-style-type: none"> 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
American Society of Anesthesiologists (ASA) physical status	I, II, III, IV, V
Body Mass Index (BMI)	Height, weight, BMI (calculator)
Underlying comorbidities (select all that apply)	<ul style="list-style-type: none"> • Myocardial Infarction (MI) or Congestive Heart Failure (CHF) • Peripheral Vascular Disease (PWD) • Cerebrovascular Accident (CVA) or Transient Ischaemic Attack (TIA) • Peptic Ulcer Disease • Diabetes Mellitus (Type 1 or Type 2). • Chronic Kidney Disease (CKD) Estimated Glomerular Filtration Rate (eGFR) <60/ml/min/1.73m², dialysis or post kidney transplant, or uraemia. • Liver Disease • Cancer (active, remission) • None of the Above <p><i>Definitions for Diabetes Mellitus: Uncomplicated is defined as medically managed and no end-organ damage</i></p>

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	<i>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</i>
Relative or absolute contraindication to opioids	Yes/No Allergy Renal impairment Severe respiratory disease Previous adverse event Previous opioid use disorder/opioid misuse Concurrent benzodiazepine use (Free text option)
Relative or absolute contraindication to Non-Steroidal Anti-Inflammatory Drugs (NSAIDS)	Yes/No Previous GI bleeding/ulcer Allergy Renal impairment NSAID responsive asthma
Substance use	<ul style="list-style-type: none"> • Smoking (never, ex-smoker >12 months, ex-smoker <12 months, current) • Vaping (never, ex-vaper >12 months ago, ex-vaper <12 months ago, 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.

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In-patient analgesia data points	
Referral to Acute Pain Service: <i>(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).</i>	Yes/No
Last 24h AND at discharge analgesia data points - collect from discharge record (if day-case, immediate postoperative consumption).	
Opioid medication consumed in the last 24 hours of hospitalization (see protocol page 22-24 for brand names)	<p>Type of medication (select all that apply): (Morphine, Tramadol, Oxycodone, Fentanyl, Codeine, Buprenorphine, Pethidine, Hydromorphone, Tanpentadol, Dextropropoxyphene ± other)</p> <p>For each medication used specify: Formulation: Slow-release/immediate release/both Route: Oral (PO)-Tablet/PO-liquid/Transdermal or Topical patch / Sublingual/Subcutaneous or intramuscular/Intravenous Dose (per tablet/patch/injection) (mcg/mg/mL) Total amount consumed/prescribed (amount, units: mcg/mg/mL) Frequency of dosing: Once daily (od) / Twice daily (bd) / Three times daily (tds) / Four times daily (qds) / As required (PRN)/ Continuous delivery</p>
Discharge paracetamol advised	Yes/No
Discharge NSAIDs advised	Yes/No
Discharge medications for neuropathic pain such as gabapentinoids (e.g., pregabalin, gabapentin)	Yes/No
Discharge medications for neuropathic pain such as tricyclic antidepressants (e.g., amitriptyline and serotonin noradrenaline reuptake inhibitors (SNRIs) (e.g. venlafaxine))	Yes/No
Discharge opioid prescription	Yes/No
If yes, please specify drug/amount/route:	

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<p>Morphine (Kapanol, MS Mono)</p> <p><u>Brand names</u></p> <p><i>Immediate release morphine</i></p> <ul style="list-style-type: none"> • RA-Morph® • Sevredol® • Anamorph <p><i>Sustained/modification release morphine</i></p> <ul style="list-style-type: none"> • MORPHINE MR APOTEX • MS Contin • Momex SR • Morphine MR Mylan • m-Eslon SR® • Kapanol • LA-Morph® • Arrow-Morphine LA® • MS Mono 	<p>Prescribed: Yes/No</p> <p>Formulation: Slow-release/immediate release/both</p> <p>Dose: ____ (mcg/mg/mL)</p> <p>Route: ____</p> <p>Frequency of dosing: ____</p> <p>Total number of doses consumed/prescribed: ____</p>
<p>Tramadol (Tramal, Tramedo, Zydol)</p> <p><u>Brand names</u></p> <p><i>Immediate release morphine</i></p> <ul style="list-style-type: none"> • Tramal • Tramedo • Zydol <p><i>Sustained/modification release morphine</i></p> <ul style="list-style-type: none"> • Tramal SR • Tramedo SR • Zydol SR • Tramahexal SR <p><i>Tramadol with paracetamol</i></p> <ul style="list-style-type: none"> • Zaldair 	<p>Prescribed: Yes/No</p> <p>Formulation: Slow-release/immediate release/both</p> <p>Combined pill with paracetamol: Y/N</p> <p>Dose: ____ (mcg/mg/mL)</p> <p>Route: ____</p> <p>Frequency of dosing: ____</p> <p>Total number of doses consumed/prescribed: ____</p>
<p>Oxycodone (Endone, Novacodone, OxyContin, OxyNorm, Proladone, Targin)</p> <p><u>Brand names</u></p> <p><i>Immediate release</i></p> <ul style="list-style-type: none"> • Endone • OxyNorm • OxyNorm liquid <p><i>Controlled release</i></p> <ul style="list-style-type: none"> • Novacodone • OxyContin With Naloxone • Targin 	<p>Prescribed: Yes/No</p> <p>Formulation: Slow-release/immediate release/both</p> <p>Dose: ____ (mcg/mg/mL)</p> <p>Route: ____</p> <p>Frequency of dosing: ____</p> <p>Total number of doses consumed/prescribed: ____</p>
<p>Fentanyl (Abstral, Fentora, Actiq, Denpax, Durogesic, Dutran, Fenpatch)</p> <p><u>Brand names</u></p> <p><i>Patch</i></p> <ul style="list-style-type: none"> • Denpax, • Durogesic, • Dutran, • Fenpatch <p><i>Oral</i></p> <ul style="list-style-type: none"> • Abstral • Fentora • Actiq 	<p>Prescribed: Yes/No</p> <p>Formulation: Slow-release/immediate release/both</p> <p>Dose: ____ (mcg/mg/mL)</p> <p>Route: ____</p> <p>Frequency of dosing: ____</p> <p>Total number of doses consumed/prescribed: ____</p>

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<p>Codeine (Panadeine forte, Actacode Linctus, Aspalgan, Nurofen Plus, Ibudeine)</p> <p><u>Brand names</u></p> <p><i>Codeine only</i></p> <ul style="list-style-type: none"> • Codeine Phosphate • <i>Codeine with Aspirin</i> • Aspalgan • <i>Codeine with Ibuprofen</i> • Brufen Plus, • Nurofen Plus • Ibuprofen/Codeine • Ibudeine <p><i>Codeine with paracetamol</i></p> <ul style="list-style-type: none"> • Panamax Co • Panadeine Forte • Codalgin Forte, • Codapane Forte, • Comfarol Forte, • Prodeine Forte 	<p>Prescribed: Yes/No Formulation: Slow-release/immediate release/both Combined pill with paracetamol: Yes/No Combined pill with NSAIDs: Yes/No Dose: ____ (mcg/mg/mL) Route: ____ Frequency of dosing: ____ Total number of doses consumed/prescribed: ____</p>
<p>Buprenorphine (Bupredermal, Norspan, Temgesic)</p> <p><u>Brand names</u></p> <p><i>Oral</i></p> <ul style="list-style-type: none"> • Temgesic • <i>Patch</i> • Bupredermal • Norspan 	<p>Prescribed: Yes/No Formulation: Slow-release/immediate release/both Dose: ____ (mcg/mg/mL) Route: ____ Frequency of dosing: ____ Total number of doses consumed/prescribed: ____</p>
<p>Pethidine</p>	<p>Prescribed: Yes/No Formulation: Slow-release/immediate release/both Dose: ____ (mcg/mg/mL) Route: ____ Frequency of dosing: ____ Total number of doses consumed/prescribed: ____</p>
<p>Hydromorphone (Dilaudid, Jurnista)</p> <p><u>Brand names</u></p> <p><i>Immediate release</i></p> <ul style="list-style-type: none"> • Dilaudid • <i>Controlled release</i> • Jurnista 	<p>Prescribed: Yes/No Formulation: Slow-release/immediate release/both Dose: ____ (mcg/mg/mL) Route: ____ Frequency of dosing: ____ Total number of doses consumed/prescribed: ____</p>
<p>Tapentadol (Palexia)</p> <p><u>Brand names</u></p> <p><i>Immediate release</i></p> <ul style="list-style-type: none"> • Palexia IR • <i>Controlled release</i> • Palexia SR 	<p>Prescribed: Yes/No Formulation: Slow-release/immediate release/both Dose: ____ (mcg/mg/mL) Route: ____ Frequency of dosing: ____ Total number of doses consumed/prescribed: ____</p>
<p>Dextropropoxyphene (Di-Gesic, Doloxene)</p>	<p>Prescribed: Yes/No Formulation: Slow-release/immediate release/both</p>

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	Dose: ____ (mcg/mg/mL) Route: ____ Frequency of dosing: ____ Total number of doses consumed/prescribed: ____
Other opioid prescribed	Prescribed: Yes/No Formulation: Slow-release/immediate release/both Dose: ____ (mcg/mg/mL) Route: ____ Frequency of dosing: ____ Total number of doses consumed/prescribed: ____
Safety net ((29))	Information provided about safe disposal of surplus opioids Yes/No

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	Yes/No
If no: Confirm participant withdrawn from study at their request	Withdrawn: Yes/No
Medication-related	
If discharge opiate prescription = Yes	
Did you take your hospital -prescribed opioids	Yes/No
If Yes, what was the date you last took opioid medication	Date
Quantity of opioids taken from hospital prescription (<i>if liquid, quantify mLs consumed</i>)	Only to fill in relevant medications
Morphine	Number of tablets remaining from hospital prescription: ____ (tablets)
Tramadol	Number of tablets remaining from hospital prescription: ____ (tablets)

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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)
Dextropropoxyphene	Number of tablets remaining from hospital prescription: ____ (tablets)
Other opioid 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 medications prescribed with the opioids (e.g. cyclizine, metoclopramide, ondansetron) prescribed?	Yes/No
For all	
During the first week after your	Yes/No

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discharge, did you use paracetamol (panadol) to manage your post-surgical pain?	
During the first week after your discharge, did you use NSAIDs (ibuprofen, naproxen, celecoxib, diclofenac, etc.) to manage your post-surgical pain?	Yes/No
Did you use any nerve pain medications like gabapentin, pregabalin, amitriptyline, venlafaxine, ketamine or clonidine to help with pain in the last week?	Yes – Gabapentinoid (e.g. gabapentin, pregabalin) Yes – Tricyclic antidepressant (e.g. amitriptyline) Yes – Serotonin noradrenaline reuptake inhibitors (e.g. venlafaxine) Yes – NMDA antagonists (e.g. ketamine) Yes – A2 agonists (e.g. clonidine) No
Did you seek medical help for your pain i.e., requesting increased pain relief or additional pain relief prescriptions? For example – from a GP, an urgent care facility (GP access), the Emergency Dept at the hospital (A&E), your surgeon?	Yes – GP Yes – Urgent care/Emergency department Yes – Readmission to hospital Yes – Surgeon Yes – Other No
If yes - other:	Where?
If you did seek medical help, did you receive additional opioids i.e. a repeat prescription	Yes/No
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?	eso
If yes – name of medication	Name Dose / can't recall How many consumed / can't recall
Did you seek medical help for side effects of your pain medication? For example – from a GP, an urgent care	Yes - GP Yes - Urgent care/Emergency department Yes - Readmission to hospital

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facility (GP access), the Emergency Dept at the hospital (A&E), your surgeon?	Yes – Other No
For the 3 months prior to your admission, were you using any routine pain relieving 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) Opioids (tramadol, codeine, sevredol, oxycodone etc)
Patient-reported pain and satisfaction outcomes	
<u>EQ-5D-5L + EQ-VAS:</u> Under each heading, please tick the ONE box that best describes your health TODAY:	<u>EQ - 5D</u>
MOBILITY	<ol style="list-style-type: none"> I have no problems in walking about I have slight problems in walking about I have moderate problems in walking about I have severe problems in walking about I am unable to walk about
SELF-CARE	<ol style="list-style-type: none"> I have no problems washing or dressing myself I have slight problems washing or dressing myself I have moderate problems washing or dressing myself I have severe problems washing or dressing myself I am unable to wash or dress myself
USUAL ACTIVITIES (e.g. work, study, housework, family or leisure activities)	<ol style="list-style-type: none"> I have no problems doing my usual activities I have slight problems doing my usual activities I have moderate problems doing my usual activities I have severe problems doing my usual activities I am unable to do my usual activities
PAIN / DISCOMFORT	<ol style="list-style-type: none"> I have no pain or discomfort I have slight pain or discomfort I have moderate pain or discomfort I have severe pain or discomfort I have extreme pain or discomfort
ANXIETY / DEPRESSION	<ol style="list-style-type: none"> I am not anxious or depressed I am slightly anxious or depressed

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	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 about managing pain from your doctor or nurse before discharge?	Yes/No/Can't recall
Did you receive information, advice or education on how to dispose of excess opioid medications?	Yes/No/Can't recall
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)



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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, appendectomy, 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-naïve 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>



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- 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>

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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 <ul style="list-style-type: none"> • 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) <ul style="list-style-type: none"> • Grade IVa - single-organ dysfunction (including dialysis) • Grade IVb - multi-organ dysfunction
Grade V	Death of the patient

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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

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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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Appendix B: OPERAS Data Dictionary

Supplementary Table 1: OPERAS study inpatient data collection form

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
American Society of Anaesthesiologists (ASA) physical status	I, II, III, IV, V
Body Mass Index (BMI)	Height, weight, BMI (calculator)
Underlying comorbidities (select all that apply)	<ul style="list-style-type: none"> ● 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) (Estimated Glomerular Filtration Rate (eGFR) <60/ml/min/1.73m², dialysis or post kidney transplant, or uraemia. ● Liver Disease ● Cancer (active, remission) ● None of the Above <p><i>Definitions for Diabetes Mellitus: Uncomplicated is defined as medically managed and no end-organ damage</i> <i>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</i></p>
Relative or absolute contraindication to opioids	Yes / No Allergy Renal impairment Severe respiratory disease Previous adverse event Previous opioid use disorder/ opioid misuse Concurrent benzodiazepine use (Free text option)
Relative or absolute contraindication to non-steroidal anti-inflammatory drugs (NSAIDs)	Yes / No Previous GI bleeding/ulcer Allergy

	Renal impairment NSAID responsive asthma
Substance use	Smoking (never, ex-smoker >12 months, ex-smoker <12 months, current) Vaping (never, ex-vaper >12 months, ex-vaper <12 months, current) Alcohol consumption (standard drinks/week)
Operative data points	
Surgical procedure	See <i>Appendix 4 + free-text entry for additional procedural details</i>
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:	Yes / No <i>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.</i>
Last 24h AND at discharge analgesia data points - collect from discharge record (if day-case, immediate postoperative consumption).	
Opioid 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, Tapentadol, Dextropropoxyphene ± other) For each medication used specify: Formulation: Slow-release/immediate release/both Route: Oral (PO)/PO liquid/transdermal patch/IV/other Total amount consumed in the last 24 hours (amount, units: mcg/mg)
Discharge paracetamol advised	Yes / No
Discharge NSAIDs advised	Yes / No
Discharge medications for neuropathic pain such as gabapentinoids (e.g., pregabalin, gabapentin)	Yes / No
Discharge medications for neuropathic pain such as tricyclic antidepressants (e.g. amitriptyline) and serotonin noradrenaline reuptake inhibitors (e.g. venlafaxine)	Yes / No
Discharge opioid prescription	Yes / No
<i>If yes, please specify drug/ amount/ route:</i>	

Morphine (Kapanol, MS Mono)	<p><i>Prescribed:</i> Yes/No <i>Formulation:</i> Slow-release/immediate release/both <i>Dose per tablet:</i> ____ (mg) <i>Overall dose</i> <i>Route:</i> PO/other <i>Frequency of dosing:</i> once daily (od) / twice daily (bd) / three times a day (tds) / four times a day (qid) / as required (PRN) <i>Total number of pills prescribed:</i> ____</p> <p><i>Brand names</i></p> <p><i>Immediate release morphine</i></p> <ul style="list-style-type: none"> ● RA-Morph® ● Sevredol® ● Anamorph <p><i>Sustained/modified release morphine</i></p> <ul style="list-style-type: none"> ● MORPHINE MR APOTEX ● MS Contin ● Momex SR ● Morphine MR Mylan ● m-Eslon SR® ● Kapanol ● LA-Morph® ● Arrow-Morphine LA® ● MS Mono
Tramadol (Tramal, Tramedo, Zydol)	<p><i>Prescribed:</i> Yes/No <i>Formulation:</i> Slow-release/immediate release/both <i>Combined pill with paracetamol:</i> Yes/No <i>Dose:</i> ____ (mg) <i>Route:</i> PO/other <i>Frequency of dosing:</i> od / bd / tis / qid / PRN <i>Total number of pills prescribed:</i> ____</p> <p><i>Brand names</i></p> <p><i>Immediate release morphine</i></p> <ul style="list-style-type: none"> ● Tramal ● Tramedo ● Zydol <p><i>Sustained/modified release morphine</i></p> <ul style="list-style-type: none"> ● Tramal SR ● Tramedo SR ● Zydol SR ● Tramahexal SR <p>Tramadol with paracetamol</p> <ul style="list-style-type: none"> ● Zaldair
Oxycodone (Endone, Novacodone, OxyContin, OxyNorm, Proladone, Targin)	<p><i>Prescribed:</i> Yes/No <i>Formulation:</i> Slow-release/immediate release/both <i>Dose:</i> ____ (mg OR mg/5ml) <i>Route:</i> PO/PO liquid/other <i>Frequency of dosing:</i> od / bd / tis / qid / PRN <i>Total number of pills prescribed:</i> ____</p> <p><i>If liquid - total volume</i></p> <p><i>Brand names</i></p> <p><i>Immediate release</i></p> <ul style="list-style-type: none"> ● Endone ● OxyNorm ● OxyNorm liquid <p><i>Controlled release</i></p> <ul style="list-style-type: none"> ● Novacodone ● OxyContin <p>With Naloxone</p>

	<ul style="list-style-type: none"> ● Targin
Fentanyl (Abstral, Fentora, Actiq, Denpax, Durogesic, Dutran, Fenpatch)	<p><i>Prescribed: Yes/No</i> <i>Formulation: Slow-release/immediate release/both</i> <i>Dose: ____ (mcg)</i> <i>Route: Transdermal patch/other</i> <i>Frequency of dosing: od / bd / tis / qid / PRN / continuous delivery</i> <i>Total number of pills prescribed: ____</i></p> <p>Brand names</p> <p><i>Patch</i></p> <ul style="list-style-type: none"> ● Denpax, ● Durogesic, ● Dutran, ● Fenpatch <p><i>Oral</i></p> <ul style="list-style-type: none"> ● Abstral ● Fentora ● Actiq
Codeine (Panadeine forte, Actacode Linctus, Aspalgan, Nurofen Plus, Ibudeine)	<p><i>Prescribed: Yes/No</i> <i>Formulation: Slow-release/immediate release/both</i> <i>Combined pill with paracetamol: Y/N</i> <i>Combined pill with NSAIDs: Y/N</i> <i>Dose: ____ (mg)</i> <i>Route: PO/other</i> <i>Frequency of dosing: od / bd / tis / qid / PRN</i> <i>Total number of pills prescribed: ____</i></p> <p>Brand names</p> <p><i>Codeine only</i></p> <ul style="list-style-type: none"> ● Codeine Phosphate <p><i>Codeine with Aspirin</i></p> <ul style="list-style-type: none"> ● Aspalgan <p><i>Codeine with Ibuprofen</i></p> <ul style="list-style-type: none"> ● Brufen Plus, ● Nurofen Plus ● Ibuprofen/Codeine ● Ibudeine <p><i>Codeine with paracetamol</i></p> <ul style="list-style-type: none"> ● Panamax Co ● Panadeine Forte ● Codalgin Forte, ● Codapane Forte, ● Comfarol Forte, ● Prodeine Forte
Buprenorphine (Bupredermal, Norspan, Temgesic)	<p><i>Prescribed: Yes/No</i> <i>Formulation: Slow-release/immediate release/both</i> <i>Dose: ____ (mcg)</i> <i>Route: SL/patch/other</i> <i>Frequency of dosing: od / bd / tis / qid / PRN / continuous delivery</i> <i>Total number of pills prescribed: ____</i></p> <p>Brand names</p> <p><i>Oral</i></p> <ul style="list-style-type: none"> ● Temgesic <p><i>Patch</i></p> <ul style="list-style-type: none"> ● Bupredermal ● Norspan

Pethidine	<p><i>Prescribed: Yes/No</i></p> <p><i>Formulation: Slow-release/immediate release/both</i></p> <p><i>Dose: ____ (mg)</i></p> <p><i>Route: PO/other</i></p> <p><i>Frequency of dosing: od / bd / tis / qid / PRN</i></p> <p><i>Total number of pills prescribed: ____</i></p>
Hydromorphone (Dilaudid, Jurnista)	<p><i>Prescribed: Yes/No</i></p> <p><i>Formulation: Slow-release/immediate release/both</i></p> <p><i>Dose: ____ (mg)</i></p> <p><i>Route: PO/other</i></p> <p><i>Frequency of dosing: od / bd / tis / qid / PRN</i></p> <p><i>Total number of pills prescribed: ____</i></p> <p>Brand names</p> <p><i>Immediate release</i></p> <ul style="list-style-type: none"> ● Dilaudid <p><i>Controlled release</i></p> <ul style="list-style-type: none"> ● Jurnista
Tapentadol (Palexia)	<p><i>Prescribed: Yes/No</i></p> <p><i>Formulation: Slow-release/immediate release/both</i></p> <p><i>Dose: ____ (mg)</i></p> <p><i>Route: PO/other</i></p> <p><i>Frequency of dosing: od / bd / tis / qid / PRN</i></p> <p><i>Total number of pills prescribed: ____</i></p> <p>Brand names</p> <p><i>Immediate release</i></p> <ul style="list-style-type: none"> ● Palexia IR <p><i>Controlled release</i></p> <ul style="list-style-type: none"> ● Palexia SR
Other opioid prescribed	<p>Name: _____</p> <p><i>Prescribed: Yes/No</i></p> <p><i>Formulation: Slow-release/immediate release/both</i></p> <p><i>Dose: ____ (mg) per tablet</i></p> <p><i>Route: PO/other</i></p> <p><i>Frequency of dosing: od / bd / tis / qid / PRN</i></p> <p><i>Total number of pills prescribed: ____</i></p>
Safety net ((39))	Information provided about safe disposal of surplus opioids Yes/No

Supplementary Table 2: OPERAS study follow up data collection form

7-day follow up data points	Required data (definition / comment)
Information provided and verbal consent obtained	Yes / No
<i>If no: Confirm participant withdrawn from study at their request</i>	<i>Withdrawn Yes/No</i>
<i>Medication-related</i>	
<i>If discharge opioid prescription = Yes</i>	
Did you take your hospital-prescribed opioids	Yes / No
If yes, what was the date you last took opioid medication?	Date
Quantity of opioids taken from hospital prescription (<i>if liquid, quantify mLs consumed</i>)	<i>Only to fill in relevant medications</i>
Morphine	<i>Number of tablets remaining from hospital prescription: _____ (tablets) or _____mL</i>
Tramadol	<i>Number of tablets remaining from hospital prescription: _____ (tablets) or _____mL</i>
Oxycodone	<i>Number of tablets remaining from hospital prescription: _____ (tablets) or _____mL</i>
Fentanyl	<i>Number of tablets remaining from hospital prescription: _____ (tablets) or _____mL</i>
Codeine	<i>Number of tablets remaining from hospital prescription: _____ (tablets) or _____mL</i>
Buprenorphine	<i>Number of tablets remaining from hospital prescription: _____ (tablets) or _____mL</i>
Pethidine	<i>Number of tablets remaining from hospital prescription: _____ (tablets) or _____mL</i>
Hydromorphone	<i>Number of tablets remaining from hospital prescription: _____ (tablets) or _____mL</i>
Tapentadol	<i>Number of tablets remaining from hospital prescription: _____ (tablets) or _____mL</i>
Other opioid prescribed	<i>Number of tablets remaining from hospital prescription: _____ (tablets) or _____mL</i>
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 medications (e.g. cyclizine, metoclopramide, ondansetron) prescribed with the opioids?	Yes / No
<i>For all</i>	
During the first week after your discharge, did you use paracetamol (panadol) to manage your post-surgical pain?	Yes / No
During the first week after your discharge, did you use NSAIDs (ibuprofen, naproxen, celecoxib, diclofenac, etc) to manage your post-surgical pain?	Yes / No
Did you use any nerve pain medications like gabapentin, pregabalin, amitriptyline, venlafaxine, ketamine or clonidine to help with pain in the last week?	Yes – gabapentinoid Yes – tricyclic antidepressant Yes - serotonin noradrenaline reuptake inhibitors Yes - NMDA antagonists Yes – A2 agonists No
Did you seek medical help for your pain i.e. requesting increased pain relief or additional pain relief prescriptions?	Yes - GP Yes - Urgent care/Emergency department Yes - Readmission to hospital Yes – Surgeon Yes - other No
If yes - other:	Where?
If you did seek medical help, did you receive additional opioids i.e. a repeat prescription	Yes / No
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?	Yes - Family/friends/own stock No
If yes:	Name Dose / can't recall How many consumed / can't recall
Did you seek medical help for side effects of your pain medication?	Yes - GP Yes - Urgent care/Emergency department Yes - Readmission to hospital Yes – Surgeon No
For the 3 months prior to your admission, were you using any routine pain-relieving 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) Opioids (tramadol, codeine, oxycodone, sevredol etc)

<i>Patient-reported pain and satisfaction outcomes</i>	
EQ-5D-5L + EQ-VAS: <i>Under each heading, please tick the ONE box that best describes your health TODAY</i>	EQ - 5D
MOBILITY	<ol style="list-style-type: none"> 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	<ol style="list-style-type: none"> 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)	<ol style="list-style-type: none"> 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	<ol style="list-style-type: none"> 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	<ol style="list-style-type: none"> 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?	Yes/No/ can't recall
Did you receive information, advice or education on how to dispose of excess opioid medications?	Yes/No/can't recall
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: Included Procedures by Specialty

Supplementary Table 3: OPERAS study list of 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.)
	Appendectomy	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 Yes/No or colostomy formed Yes/No 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 D: OPERAS Study Patient Follow up Phone Call Script

**OPERAS Follow-up telephone interview script:**

Good afternoon/morning/evening Mr/Mrs/title (as listed on file) participant's name.

My name is _____, and I am a _____ (e.g., researcher medical student or role as appropriate) and I am calling on behalf of the OPERAS study team. You may remember we discussed a study about medicine prescriptions for pain relief after surgery while you were in hospital 1 week ago. Is now a good time to talk?

Before we start, can I confirm you're still happy to participate in this study?

If yes, start questionnaire, if no, thank participant and end call. Record participant as withdrawn from study at their request

We will start by asking a series of questions about the medicines you have used to help with pain after your return home from hospital

Can I ask if you have used any medicines for pain since you left hospital?

If Yes, ask questions 1 – 11. If No, go to question 12 and continue from there.

1. Did you take your hospital-prescribed opioid pain-relief medications? (give examples of prescribed medications here e.g. sevredol). If answer no, go to Qu 8. If yes, ask Qu 2 and on
2. How many tablets of _____ did you take through the course of the week? (Please go through the list of medications this patient was prescribed and calculate the quantity consumed in number of tablets OR mls)
3. Were you prescribed any other opioid medications I have missed?
(Take this opportunity to answer any questions about what medications may or may not count as opioids – this study includes weak opioids such as tramadol and codeine).
4. What was the date you last consumed your opioid medication?
5. While you have been at home, have you had any of the following side-effects?
Nausea or vomiting
Drowsiness
Itching
Dizziness
Constipation
 - a. If they said yes to any of the above, ask them: can you please describe on a scale of 0 to 10, 0 being none at all and 10 being extreme, how severe these side effects were?
6. Were you prescribed any laxatives, that is medications to help pass bowel motions easier, or anti-sickness medications? (You may use cyclizine, metoclopramide,



ondansetron or appropriate anti-emetics as examples to give examples to the patient, lactulose, coloxyl, senna are examples of laxatives).

7. Did you receive information, advice or education on how to dispose of excess opioid medications?
8. If you took your opioid medication and are no longer taking them, have you returned your unused opioids to the pharmacy? (Yes - pharmacy, No - disposed of in rubbish, No - not disposed of) (Question necessary only if patient has not taken opioids for >1 day or specifies they have stopped taking medication).

For all patients:

9. Did you use paracetamol/panadol to manage pain during the last week?
10. Did you use any non-steroidalals like ibuprofen, naproxen, or celecoxib (insert common trade names i.e. nurofen to help with pain in the last week)?
11. Did you use any nerve pain medications like gabapentin, pregabalin, or amitriptyline to help with pain in the last week?
12. Did you seek medical help for pain relief? This includes your GP, urgent care or the emergency department, the ward you were in at the hospital, or your surgeon.
 - a. If Yes, did you receive any additional medicines?
 - b. If yes, were they the same dose, higher dose, or lower dose? (You may ask the patient to check their containers or prescription to compare).
13. Did you get any pain relief medications from any other sources? For example, from friends or family, or that you already had at home? Anything you tell us here will not be passed on to anyone else, and we do not want to know anyone's name.
 - a. If yes, do you know the name, dose and how many you have used?
14. Did you seek any medical help for side effects from your pain medication? If so, was this the GP, urgent care, the emergency department, the ward you were in at the hospital, or your surgeon.? (Clarify if they were readmitted).
15. For the past 3 months prior to your admission, were you using any routine pain killer medications?
 - a. If yes, how many days per week?
 - b. If yes, what medications were you using (tick boxes which apply)?

The next series of questions will ask you about your quality of life after surgery.

16. We are trying to find out what you think about your health. I will explain what to do as I go along, but please interrupt me if you do not understand something or if things are not clear to you. There are no right or wrong answers. We are interested only in your personal view.



17. First, I am going to read out some questions. Each question has a choice of five answers. Please tell me which answer best describes your health TODAY.
18. Do not choose more than one answer in each group of questions. (Note to interviewer: first read all five options for each question. Then ask the respondent to choose which one applies to him/herself. Repeat the question and options if necessary. Mark the appropriate box under each heading. You may need to remind the respondent regularly that the timeframe is TODAY)

EQ-5D DESCRIPTIVE SYSTEM

19. First, I would like to ask you about MOBILITY. Would you say that:
1. You have no problems in walking about?
 2. You have slight problems in walking about?
 3. You have moderate problems in walking about?
 4. You have severe problems in walking about?
 5. You are unable to walk about?
20. Next, I would like to ask you about SELF-CARE. Would you say that:
1. You have no problems washing or dressing yourself?
 2. You have slight problems washing or dressing yourself?
 3. You have moderate problems washing or dressing yourself?
 4. You have severe problems washing or dressing yourself?
 5. You are unable to wash or dress yourself?
21. Next, I would like to ask you about USUAL ACTIVITIES, for example work, study, housework, family or leisure activities. Would you say that:
1. You have no problems doing your usual activities?
 2. You have slight problems doing your usual activities?
 3. You have moderate problems doing your usual activities?
 4. You have severe problems doing your usual activities?
 5. You are unable to do your usual activities?
22. Next, I would like to ask you about PAIN OR DISCOMFORT. Would you say that:
1. You have no pain or discomfort?
 2. You have slight pain or discomfort?
 3. You have moderate pain or discomfort?
 4. You have severe pain or discomfort?
 5. You have extreme pain or discomfort?
23. The next question we would like to ask is regarding your mental health and wellbeing and may be sensitive. Is this okay to discuss?

If prompted for the reason for the question: we are asking this question to get a holistic perspective of your overall health, including mental health and mood to investigate whether opioids impact on these aspects of your life. If yes: go to Q24, if no go to Q25



24. Finally, I would like to ask you about ANXIETY OR DEPRESSION. Would you say that:

1. You are not anxious or depressed?
2. You are slightly anxious or depressed?
3. You are moderately anxious or depressed?
4. You are severely anxious or depressed?
5. You are extremely anxious or depressed?

EQ-5D VAS

25. Now, I would like to ask you to say how good or bad your health is TODAY. I would like you to picture in your mind a vertical line that is numbered from 0 to 100. (Note to interviewer: if interviewing face-to-face, please show the respondent the VAS line.)

- a. "100 at the top of the line means the best health you can imagine."
- b. 0 at the bottom of the line means the worst health you can imagine."

26. I would now like you to tell me the point on this line where you would put your health TODAY. (Note to interviewer: mark the line at the point indicating the respondent's health today)

The next questions are about what has happened to you since you left hospital one week ago

27. On a scale of 0 to 100, 0 being none of the time and 100 being all of the time, how often were you in **severe** pain in the last week?

28. Did you remember receiving any information, advice, or education about managing your pain from your doctor or nurse before being discharged from hospital?
Yes/No/Can't recall

29. In your opinion, was the amount of pain medication you received when leaving hospital too little, just right or too much to manage your pain during this week?

30. On a scale of 0 to 10, 0 being extremely dissatisfied and 10 being extremely satisfied, how satisfied were you with the results of your pain treatment over the past week?

Thank you for your time. Do you have any questions?

If anything we have discussed has brought up any bad feelings and you'd like to talk to someone further, I can recommend some resources for you.

For Australia: Lifeline Australia 13 11 14, for Aotearoa New Zealand: Lifeline Aotearoa 0508 828 865

Appendix E: EQ-5D-5L Health Questionnaire

Under each heading, please tick the ONE box that best describes your health TODAY.

MOBILITY

- I have no problems in walking about
- I have slight problems in walking about
- I have moderate problems in walking about
- I have severe problems in walking about
- I am unable to walk about

SELF-CARE

- I have no problems washing or dressing myself
- I have slight problems washing or dressing myself
- I have moderate problems washing or dressing myself
- I have severe problems washing or dressing myself
- I am unable to wash or dress myself

USUAL ACTIVITIES (e.g. work, study, housework, family or leisure activities)

- I have no problems doing my usual activities
- I have slight problems doing my usual activities
- I have moderate problems doing my usual activities
- I have severe problems doing my usual activities
- I am unable to do my usual activities

PAIN / DISCOMFORT

- I have no pain or discomfort
- I have slight pain or discomfort
- I have moderate pain or discomfort
- I have severe pain or discomfort
- I have extreme pain or discomfort

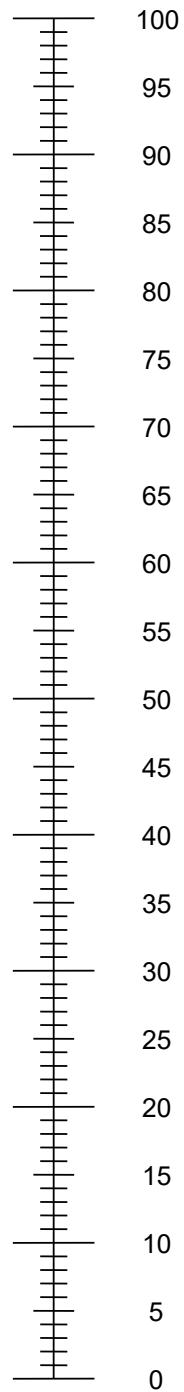
ANXIETY / DEPRESSION

- I am not anxious or depressed
- I am slightly anxious or depressed
- I am moderately anxious or depressed
- I am severely anxious or depressed
- 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 mark an X on the scale to indicate how your health is TODAY.
- Now, write the number you marked on the scale in the box below.

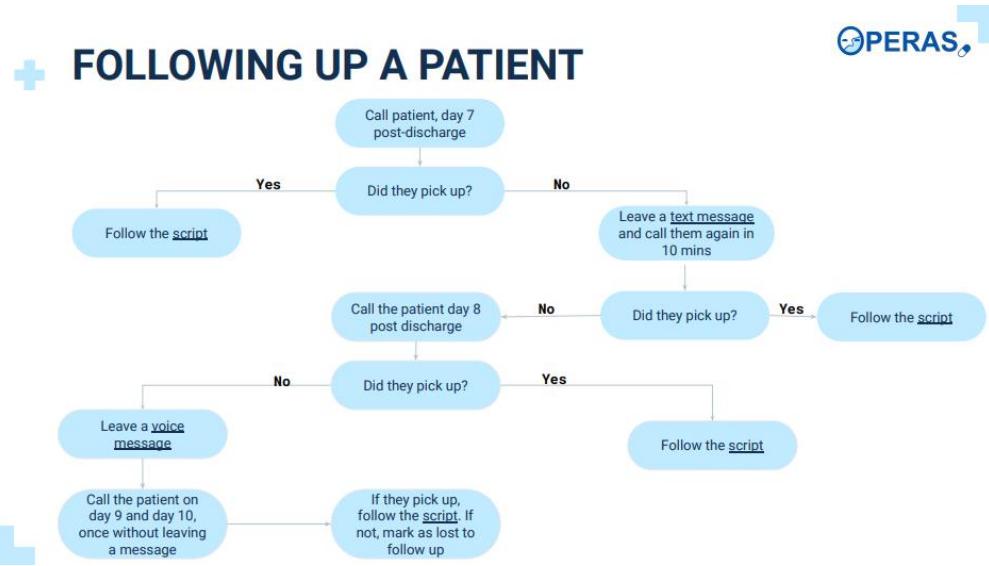
YOUR HEALTH TODAY =

The best health
you can imagine



The worst health
you can imagine

Appendix F: Patient Follow Up Procedure



*Script refers to the OPERAS follow-up telephone interview script (Appendix

Appendix A: OPERAS Study Protocol

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OPERAS Study

Opioid PrEscrptions and Usage After Surgery

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

Study protocol version 2.0.8
28th February 2022



TASMAN

Website: <https://anzsurgsoc.org/tasman/>

General email: operas.tasman@gmail.com

REDCap queries:

Twitter: @TASMANCollab

Coordinating Investigator: Associate Professor Peter Pockney
Hunter Medical Research Institute, Newcastle, NSW, Australia

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Amendments

Amendment	Date	Protocol Version	Summary
	1/12/21	2.0.6	Change in Scientific Advisory Committee personnel, additional trainee-led collaborative networks included, and data collection instrument harmonized with patient telephone call script.
	28/1/22	2.0.7	Addition of student pharmacists and pharmacists as data collectors and members of mini teams. Addition of Steering Committee personnel.
	28/2/22	2.0.8	Changes made in response to peer review of protocol including; • Addition of previously omitted data point (date of last opioid medication use) and inclusion of the analysis of this datapoint as a secondary study outcome • Amendments to reflect current pharmacology and nomenclature • Correction of typographical errors/clarification of text

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Steering Committee

Name	Training stage	Twitter
Aya Basam	4 th year medical student, Melbourne, AUS	@AyaBasam
Lorane Gaborit	3rd year medical student, Canberra, AUS	@LoraneGaborit
Sarah Goh	3 rd year medical student, Melbourne, AUS	
Aiden Jabur	Medical student, AUS	
Isabella Ludbrook	Resident medical officer, Hunter New England, AUS	@isabella_lud
Laure Taher Mansour	5 th year medical student, Adelaide, AUS	@LaureMansour8
Chui Foong (Kelly) Ong	Final year medical student, Melbourne, AUS	@foong_ong
Melissa Park	4 th year medical student, Newcastle, AUS	@melissapar_k
Upasana Pathak	2 nd year medical student, Canberra, AUS	@Upasanaa5
Kyle Raubenheimer	Junior medical officer, Perth, AUS	@kyle.raube
Venesa Siribaddana	4th year medical student, Newcastle, AUS	@VenesaS2000
Chris Varghese	5th year medical student, Auckland, NZ	@chrisvarghese98
Cameron Wells	PhD candidate, Auckland, NZ	@drcamwells
William Xu	5th year medical student, Auckland, NZ	@williamxu_98

Scientific Advisory Group

Name	Position	Twitter
Peter Pockney	Associate professor and consultant colorectal surgeon	@Ppockney
Luke Peters	Clinical teaching fellow and SET trainee	
David Watson	Professor and consultant oesophagogastric surgeon	@CtanZDavid
Deborah Wright	Senior lecturer and consultant colorectal surgeon	@scalpel_deborah
Amanda Dawson	Associate professor and consultant general surgeon	
Nagendra Dudi-Venkata	General surgical SET trainee	@surgnags
Nicholas Lightfoot	Consultant anaesthetist	
Jennifer Martin	Professor of clinical pharmacology and physician	
Rachel Sara	Consultant anaesthetist and pain specialist	
Arnab Banerjee	Senior lecturer and consultant anaesthetist	

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Collaborative Partners

CTANZ	
VERITAS	
SPARTANS	
STRIVEWA	
STARCSA	
STORCC	
STRATA	

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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

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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 duration of use of opioid analgesics in the first 7 days after discharge
5. 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/actual prescription duration. Comparisons will be made across states/countries, specialties, and common operations.

When?

Prospectively over a four-month period in 2022.

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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.

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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, evaluate 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, student pharmacists, junior doctors, trainees, registrars, pharmacists, and supervising consultants (**Figure 1**) Data will be collected prospectively on patients being discharged following major surgery (included procedures in **Appendix A**).

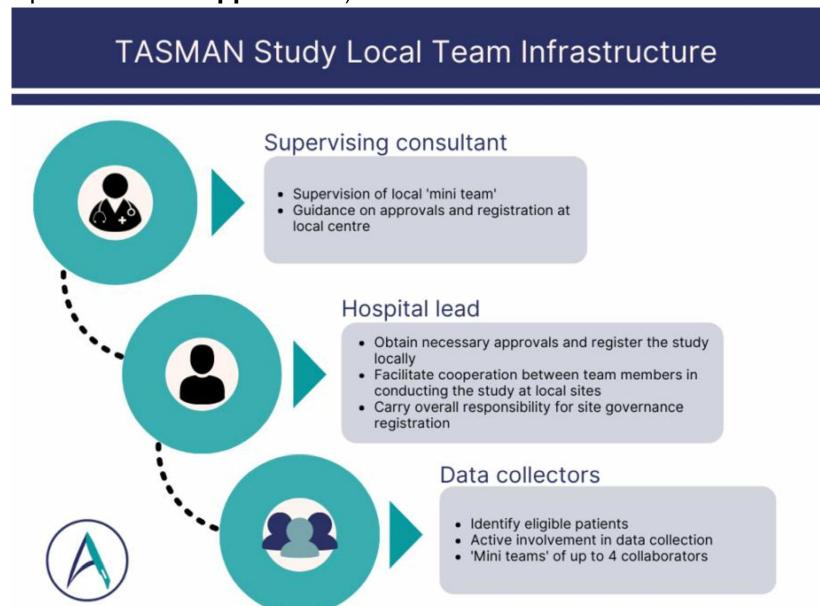


Figure 1: Mini-team structure

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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 being discharged after 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, e) when they last took opioid analgesia, and f) 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.

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The exclusion criteria is as follows:

- Paediatric patients (below 18 years of age)
- On the opiate replacement program (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:



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- 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
- Whether the participant is still using opioid analgesics at the day 7 post-discharge follow up

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 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

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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 database 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).

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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



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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.

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Collaborator role descriptions are as follows:

1. **Local supervising consultant/attending/pharmacist:** provide guidance for approval processes, facilitate communication within the hospital, and mentor and facilitate medical students, student pharmacists, 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

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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/1rbAuUMGOQ7ZcZmlJe2IUJGTmJV9MqY3leQsOMnVTkzA/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

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- Included ileocolic resection, total colectomy, subtotal colectomy, extended hemicolectomy, left hemi-colectomy, right hemicolecction, 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

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Appendix B: Data Dictionary

Inpatient data points:

Baseline Demographic Data Fields	Required data (definition/comment)
Data collection period	<ol style="list-style-type: none"> 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
American Society of Anesthesiologists (ASA) physical status	I, II, III, IV, V
Body Mass Index (BMI)	Height, weight, BMI (calculator)
Underlying comorbidities (select all that apply)	<ul style="list-style-type: none"> • Myocardial Infarction (MI) or Congestive Heart Failure (CHF) • Peripheral Vascular Disease (PWD) • Cerebrovascular Accident (CVA) or Transient Ischaemic Attack (TIA) • Peptic Ulcer Disease • Diabetes Mellitus (Type 1 or Type 2). • Chronic Kidney Disease (CKD) Estimated Glomerular Filtration Rate (eGFR) <60/ml/min/1.73m², dialysis or post kidney transplant, or uraemia. • Liver Disease • Cancer (active, remission) • None of the Above <p><i>Definitions for Diabetes Mellitus: Uncomplicated is defined as medically managed and no end-organ damage</i></p>

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	<i>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</i>
Relative or absolute contraindication to opioids	Yes/No Allergy Renal impairment Severe respiratory disease Previous adverse event Previous opioid use disorder/opioid misuse Concurrent benzodiazepine use (Free text option)
Relative or absolute contraindication to Non-Steroidal Anti-Inflammatory Drugs (NSAIDS)	Yes/No Previous GI bleeding/ulcer Allergy Renal impairment NSAID responsive asthma
Substance use	<ul style="list-style-type: none"> • Smoking (never, ex-smoker >12 months, ex-smoker <12 months, current) • Vaping (never, ex-vaper >12 months ago, ex-vaper <12 months ago, 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.

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In-patient analgesia data points	
Referral to Acute Pain Service: <i>(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).</i>	Yes/No
Last 24h AND at discharge analgesia data points - collect from discharge record (if day-case, immediate postoperative consumption).	
Opioid medication consumed in the last 24 hours of hospitalization (see protocol page 22-24 for brand names)	<p>Type of medication (select all that apply): (Morphine, Tramadol, Oxycodone, Fentanyl, Codeine, Buprenorphine, Pethidine, Hydromorphone, Tanpentadol, Dextropropoxyphene ± other)</p> <p>For each medication used specify: Formulation: Slow-release/immediate release/both Route: Oral (PO)-Tablet/PO-liquid/Transdermal or Topical patch / Sublingual/Subcutaneous or intramuscular/Intravenous Dose (per tablet/patch/injection) (mcg/mg/mL) Total amount consumed/prescribed (amount, units: mcg/mg/mL) Frequency of dosing: Once daily (od) / Twice daily (bd) / Three times daily (tds) / Four times daily (qds) / As required (PRN)/ Continuous delivery</p>
Discharge paracetamol advised	Yes/No
Discharge NSAIDs advised	Yes/No
Discharge medications for neuropathic pain such as gabapentinoids (e.g., pregabalin, gabapentin)	Yes/No
Discharge medications for neuropathic pain such as tricyclic antidepressants (e.g., amitriptyline and serotonin noradrenaline reuptake inhibitors (SNRIs) (e.g. venlafaxine))	Yes/No
Discharge opioid prescription	Yes/No
If yes, please specify drug/amount/route:	

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<p>Morphine (Kapanol, MS Mono)</p> <p><u>Brand names</u></p> <p><i>Immediate release morphine</i></p> <ul style="list-style-type: none"> • RA-Morph® • Sevredol® • Anamorph <p><i>Sustained/modification release morphine</i></p> <ul style="list-style-type: none"> • MORPHINE MR APOTEX • MS Contin • Momex SR • Morphine MR Mylan • m-Eslon SR® • Kapanol • LA-Morph® • Arrow-Morphine LA® • MS Mono 	<p>Prescribed: Yes/No</p> <p>Formulation: Slow-release/immediate release/both</p> <p>Dose: ____ (mcg/mg/mL)</p> <p>Route: ____</p> <p>Frequency of dosing: ____</p> <p>Total number of doses consumed/prescribed: ____</p>
<p>Tramadol (Tramal, Tramedo, Zydol)</p> <p><u>Brand names</u></p> <p><i>Immediate release morphine</i></p> <ul style="list-style-type: none"> • Tramal • Tramedo • Zydol <p><i>Sustained/modification release morphine</i></p> <ul style="list-style-type: none"> • Tramal SR • Tramedo SR • Zydol SR • Tramahexal SR <p><i>Tramadol with paracetamol</i></p> <ul style="list-style-type: none"> • Zaldair 	<p>Prescribed: Yes/No</p> <p>Formulation: Slow-release/immediate release/both</p> <p>Combined pill with paracetamol: Y/N</p> <p>Dose: ____ (mcg/mg/mL)</p> <p>Route: ____</p> <p>Frequency of dosing: ____</p> <p>Total number of doses consumed/prescribed: ____</p>
<p>Oxycodone (Endone, Novacodone, OxyContin, OxyNorm, Proladone, Targin)</p> <p><u>Brand names</u></p> <p><i>Immediate release</i></p> <ul style="list-style-type: none"> • Endone • OxyNorm • OxyNorm liquid <p><i>Controlled release</i></p> <ul style="list-style-type: none"> • Novacodone • OxyContin With Naloxone • Targin 	<p>Prescribed: Yes/No</p> <p>Formulation: Slow-release/immediate release/both</p> <p>Dose: ____ (mcg/mg/mL)</p> <p>Route: ____</p> <p>Frequency of dosing: ____</p> <p>Total number of doses consumed/prescribed: ____</p>
<p>Fentanyl (Abstral, Fentora, Actiq, Denpax, Durogesic, Dutran, Fenpatch)</p> <p><u>Brand names</u></p> <p><i>Patch</i></p> <ul style="list-style-type: none"> • Denpax, • Durogesic, • Dutran, • Fenpatch <p><i>Oral</i></p> <ul style="list-style-type: none"> • Abstral • Fentora • Actiq 	<p>Prescribed: Yes/No</p> <p>Formulation: Slow-release/immediate release/both</p> <p>Dose: ____ (mcg/mg/mL)</p> <p>Route: ____</p> <p>Frequency of dosing: ____</p> <p>Total number of doses consumed/prescribed: ____</p>



<p>Codeine (Panadeine forte, Actacode Linctus, Aspalgan, Nurofen Plus, Ibudeine)</p> <p><u>Brand names</u></p> <p><i>Codeine only</i></p> <ul style="list-style-type: none"> • Codeine Phosphate • Codeine with Aspirin • Aspalgan • Codeine with Ibuprofen • Brufen Plus, • Nurofen Plus • Ibuprofen/Codeine • Ibudeine <p><i>Codeine with paracetamol</i></p> <ul style="list-style-type: none"> • Panamax Co • Panadeine Forte • Codalgin Forte, • Codapane Forte, • Comfarol Forte, • Prodeine Forte 	<p>Prescribed: Yes/No Formulation: Slow-release/immediate release/both Combined pill with paracetamol: Yes/No Combined pill with NSAIDs: Yes/No Dose: ____ (mcg/mg/mL) Route: ____ Frequency of dosing: ____ Total number of doses consumed/prescribed: ____</p>
<p>Buprenorphine (Bupredermal, Norspan, Temgesic)</p> <p><u>Brand names</u></p> <p><i>Oral</i></p> <ul style="list-style-type: none"> • Temgesic • Patch • Bupredermal • Norspan 	<p>Prescribed: Yes/No Formulation: Slow-release/immediate release/both Dose: ____ (mcg/mg/mL) Route: ____ Frequency of dosing: ____ Total number of doses consumed/prescribed: ____</p>
<p>Pethidine</p>	<p>Prescribed: Yes/No Formulation: Slow-release/immediate release/both Dose: ____ (mcg/mg/mL) Route: ____ Frequency of dosing: ____ Total number of doses consumed/prescribed: ____</p>
<p>Hydromorphone (Dilaudid, Jurnista)</p> <p><u>Brand names</u></p> <p><i>Immediate release</i></p> <ul style="list-style-type: none"> • Dilaudid • Controlled release • Jurnista 	<p>Prescribed: Yes/No Formulation: Slow-release/immediate release/both Dose: ____ (mcg/mg/mL) Route: ____ Frequency of dosing: ____ Total number of doses consumed/prescribed: ____</p>
<p>Tapentadol (Palexia)</p> <p><u>Brand names</u></p> <p><i>Immediate release</i></p> <ul style="list-style-type: none"> • Palexia IR • Controlled release • Palexia SR 	<p>Prescribed: Yes/No Formulation: Slow-release/immediate release/both Dose: ____ (mcg/mg/mL) Route: ____ Frequency of dosing: ____ Total number of doses consumed/prescribed: ____</p>
<p>Dextropropoxyphene (Di-Gesic, Doloxene)</p>	<p>Prescribed: Yes/No Formulation: Slow-release/immediate release/both</p>

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	Dose: ____ (mcg/mg/mL) Route: ____ Frequency of dosing: ____ Total number of doses consumed/prescribed: ____
Other opioid prescribed	Prescribed: Yes/No Formulation: Slow-release/immediate release/both Dose: ____ (mcg/mg/mL) Route: ____ Frequency of dosing: ____ Total number of doses consumed/prescribed: ____
Safety net ((29))	Information provided about safe disposal of surplus opioids Yes/No

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	Yes/No
If no: Confirm participant withdrawn from study at their request	Withdrawn: Yes/No
Medication-related	
If discharge opiate prescription = Yes	
Did you take your hospital -prescribed opioids	Yes/No
If Yes, what was the date you last took opioid medication	Date
Quantity of opioids taken from hospital prescription (<i>if liquid, quantify mLs consumed</i>)	Only to fill in relevant medications
Morphine	Number of tablets remaining from hospital prescription: ____ (tablets)
Tramadol	Number of tablets remaining from hospital prescription: ____ (tablets)

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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)
Dextropropoxyphene	Number of tablets remaining from hospital prescription: ____ (tablets)
Other opioid 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 medications prescribed with the opioids (e.g. cyclizine, metoclopramide, ondansetron) prescribed?	Yes/No
For all	
During the first week after your	Yes/No

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discharge, did you use paracetamol (panadol) to manage your post-surgical pain?	
During the first week after your discharge, did you use NSAIDs (ibuprofen, naproxen, celecoxib, diclofenac, etc.) to manage your post-surgical pain?	Yes/No
Did you use any nerve pain medications like gabapentin, pregabalin, amitriptyline, venlafaxine, ketamine or clonidine to help with pain in the last week?	Yes – Gabapentinoid (e.g. gabapentin, pregabalin) Yes – Tricyclic antidepressant (e.g. amitriptyline) Yes – Serotonin noradrenaline reuptake inhibitors (e.g. venlafaxine) Yes – NMDA antagonists (e.g. ketamine) Yes – A2 agonists (e.g. clonidine) No
Did you seek medical help for your pain i.e., requesting increased pain relief or additional pain relief prescriptions? For example – from a GP, an urgent care facility (GP access), the Emergency Dept at the hospital (A&E), your surgeon?	Yes – GP Yes – Urgent care/Emergency department Yes – Readmission to hospital Yes – Surgeon Yes – Other No
If yes - other:	Where?
If you did seek medical help, did you receive additional opioids i.e. a repeat prescription	Yes/No
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?	eso
If yes – name of medication	Name Dose / can't recall How many consumed / can't recall
Did you seek medical help for side effects of your pain medication? For example – from a GP, an urgent care	Yes - GP Yes - Urgent care/Emergency department Yes - Readmission to hospital

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facility (GP access), the Emergency Dept at the hospital (A&E), your surgeon?	Yes – Other No
For the 3 months prior to your admission, were you using any routine pain relieving 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) Opioids (tramadol, codeine, sevredol, oxycodone etc)
Patient-reported pain and satisfaction outcomes	
<u>EQ-5D-5L + EQ-VAS:</u> Under each heading, please tick the ONE box that best describes your health TODAY:	<u>EQ - 5D</u>
MOBILITY	<ol style="list-style-type: none"> I have no problems in walking about I have slight problems in walking about I have moderate problems in walking about I have severe problems in walking about I am unable to walk about
SELF-CARE	<ol style="list-style-type: none"> I have no problems washing or dressing myself I have slight problems washing or dressing myself I have moderate problems washing or dressing myself I have severe problems washing or dressing myself I am unable to wash or dress myself
USUAL ACTIVITIES (e.g. work, study, housework, family or leisure activities)	<ol style="list-style-type: none"> I have no problems doing my usual activities I have slight problems doing my usual activities I have moderate problems doing my usual activities I have severe problems doing my usual activities I am unable to do my usual activities
PAIN / DISCOMFORT	<ol style="list-style-type: none"> I have no pain or discomfort I have slight pain or discomfort I have moderate pain or discomfort I have severe pain or discomfort I have extreme pain or discomfort
ANXIETY / DEPRESSION	<ol style="list-style-type: none"> I am not anxious or depressed I am slightly anxious or depressed

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	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 about managing pain from your doctor or nurse before discharge?	Yes/No/Can't recall
Did you receive information, advice or education on how to dispose of excess opioid medications?	Yes/No/Can't recall
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)



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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, appendectomy, 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-naïve 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>



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- 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>

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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 <ul style="list-style-type: none"> • 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) <ul style="list-style-type: none"> • Grade IVa - single-organ dysfunction (including dialysis) • Grade IVb - multi-organ dysfunction
Grade V	Death of the patient

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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

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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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Appendix B: OPERAS Data Dictionary

Supplementary Table 1: OPERAS study inpatient data collection form

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
American Society of Anaesthesiologists (ASA) physical status	I, II, III, IV, V
Body Mass Index (BMI)	Height, weight, BMI (calculator)
Underlying comorbidities (select all that apply)	<ul style="list-style-type: none"> ● 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) (Estimated Glomerular Filtration Rate (eGFR) <60/ml/min/1.73m², dialysis or post kidney transplant, or uraemia. ● Liver Disease ● Cancer (active, remission) ● None of the Above <p><i>Definitions for Diabetes Mellitus: Uncomplicated is defined as medically managed and no end-organ damage</i> <i>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</i></p>
Relative or absolute contraindication to opioids	Yes / No Allergy Renal impairment Severe respiratory disease Previous adverse event Previous opioid use disorder/ opioid misuse Concurrent benzodiazepine use (Free text option)
Relative or absolute contraindication to non-steroidal anti-inflammatory drugs (NSAIDs)	Yes / No Previous GI bleeding/ulcer Allergy

	Renal impairment NSAID responsive asthma
Substance use	Smoking (never, ex-smoker >12 months, ex-smoker <12 months, current) Vaping (never, ex-vaper >12 months, ex-vaper <12 months, current) Alcohol consumption (standard drinks/week)
Operative data points	
Surgical procedure	See <i>Appendix 4 + free-text entry for additional procedural details</i>
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:	Yes / No <i>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.</i>
Last 24h AND at discharge analgesia data points - collect from discharge record (if day-case, immediate postoperative consumption).	
Opioid 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, Tapentadol, Dextropropoxyphene ± other) For each medication used specify: Formulation: Slow-release/immediate release/both Route: Oral (PO)/PO liquid/transdermal patch/IV/other Total amount consumed in the last 24 hours (amount, units: mcg/mg)
Discharge paracetamol advised	Yes / No
Discharge NSAIDs advised	Yes / No
Discharge medications for neuropathic pain such as gabapentinoids (e.g., pregabalin, gabapentin)	Yes / No
Discharge medications for neuropathic pain such as tricyclic antidepressants (e.g. amitriptyline) and serotonin noradrenaline reuptake inhibitors (e.g. venlafaxine)	Yes / No
Discharge opioid prescription	Yes / No
<i>If yes, please specify drug/ amount/ route:</i>	

Morphine (Kapanol, MS Mono)	<p><i>Prescribed:</i> Yes/No <i>Formulation:</i> Slow-release/immediate release/both <i>Dose per tablet:</i> ____ (mg) <i>Overall dose</i> <i>Route:</i> PO/other <i>Frequency of dosing:</i> once daily (od) / twice daily (bd) / three times a day (tds) / four times a day (qid) / as required (PRN) <i>Total number of pills prescribed:</i> ____</p> <p><i>Brand names</i></p> <p><i>Immediate release morphine</i></p> <ul style="list-style-type: none"> ● RA-Morph® ● Sevredol® ● Anamorph <p><i>Sustained/modified release morphine</i></p> <ul style="list-style-type: none"> ● MORPHINE MR APOTEX ● MS Contin ● Momex SR ● Morphine MR Mylan ● m-Eslon SR® ● Kapanol ● LA-Morph® ● Arrow-Morphine LA® ● MS Mono
Tramadol (Tramal, Tramedo, Zydol)	<p><i>Prescribed:</i> Yes/No <i>Formulation:</i> Slow-release/immediate release/both <i>Combined pill with paracetamol:</i> Yes/No <i>Dose:</i> ____ (mg) <i>Route:</i> PO/other <i>Frequency of dosing:</i> od / bd / tis / qid / PRN <i>Total number of pills prescribed:</i> ____</p> <p><i>Brand names</i></p> <p><i>Immediate release morphine</i></p> <ul style="list-style-type: none"> ● Tramal ● Tramedo ● Zydol <p><i>Sustained/modified release morphine</i></p> <ul style="list-style-type: none"> ● Tramal SR ● Tramedo SR ● Zydol SR ● Tramahexal SR <p>Tramadol with paracetamol</p> <ul style="list-style-type: none"> ● Zaldair
Oxycodone (Endone, Novacodone, OxyContin, OxyNorm, Proladone, Targin)	<p><i>Prescribed:</i> Yes/No <i>Formulation:</i> Slow-release/immediate release/both <i>Dose:</i> ____ (mg OR mg/5ml) <i>Route:</i> PO/PO liquid/other <i>Frequency of dosing:</i> od / bd / tis / qid / PRN <i>Total number of pills prescribed:</i> ____</p> <p><i>If liquid - total volume</i></p> <p><i>Brand names</i></p> <p><i>Immediate release</i></p> <ul style="list-style-type: none"> ● Endone ● OxyNorm ● OxyNorm liquid <p><i>Controlled release</i></p> <ul style="list-style-type: none"> ● Novacodone ● OxyContin <p>With Naloxone</p>

	<ul style="list-style-type: none"> ● Targin
Fentanyl (Abstral, Fentora, Actiq, Denpax, Durogesic, Dutran, Fenpatch)	<p><i>Prescribed: Yes/No</i> <i>Formulation: Slow-release/immediate release/both</i> <i>Dose: ____ (mcg)</i> <i>Route: Transdermal patch/other</i> <i>Frequency of dosing: od / bd / tis / qid / PRN / continuous delivery</i> <i>Total number of pills prescribed: ____</i></p> <p>Brand names</p> <p><i>Patch</i></p> <ul style="list-style-type: none"> ● Denpax, ● Durogesic, ● Dutran, ● Fenpatch <p><i>Oral</i></p> <ul style="list-style-type: none"> ● Abstral ● Fentora ● Actiq
Codeine (Panadeine forte, Actacode Linctus, Aspalgan, Nurofen Plus, Ibudeine)	<p><i>Prescribed: Yes/No</i> <i>Formulation: Slow-release/immediate release/both</i> <i>Combined pill with paracetamol: Y/N</i> <i>Combined pill with NSAIDs: Y/N</i> <i>Dose: ____ (mg)</i> <i>Route: PO/other</i> <i>Frequency of dosing: od / bd / tis / qid / PRN</i> <i>Total number of pills prescribed: ____</i></p> <p>Brand names</p> <p><i>Codeine only</i></p> <ul style="list-style-type: none"> ● Codeine Phosphate <p><i>Codeine with Aspirin</i></p> <ul style="list-style-type: none"> ● Aspalgan <p><i>Codeine with Ibuprofen</i></p> <ul style="list-style-type: none"> ● Brufen Plus, ● Nurofen Plus ● Ibuprofen/Codeine ● Ibudeine <p><i>Codeine with paracetamol</i></p> <ul style="list-style-type: none"> ● Panamax Co ● Panadeine Forte ● Codalgin Forte, ● Codapane Forte, ● Comfarol Forte, ● Prodeine Forte
Buprenorphine (Bupredermal, Norspan, Temgesic)	<p><i>Prescribed: Yes/No</i> <i>Formulation: Slow-release/immediate release/both</i> <i>Dose: ____ (mcg)</i> <i>Route: SL/patch/other</i> <i>Frequency of dosing: od / bd / tis / qid / PRN / continuous delivery</i> <i>Total number of pills prescribed: ____</i></p> <p>Brand names</p> <p><i>Oral</i></p> <ul style="list-style-type: none"> ● Temgesic <p><i>Patch</i></p> <ul style="list-style-type: none"> ● Bupredermal ● Norspan

Pethidine	<p><i>Prescribed: Yes/No</i></p> <p><i>Formulation: Slow-release/immediate release/both</i></p> <p><i>Dose: ____ (mg)</i></p> <p><i>Route: PO/other</i></p> <p><i>Frequency of dosing: od / bd / tis / qid / PRN</i></p> <p><i>Total number of pills prescribed: ____</i></p>
Hydromorphone (Dilaudid, Jurnista)	<p><i>Prescribed: Yes/No</i></p> <p><i>Formulation: Slow-release/immediate release/both</i></p> <p><i>Dose: ____ (mg)</i></p> <p><i>Route: PO/other</i></p> <p><i>Frequency of dosing: od / bd / tis / qid / PRN</i></p> <p><i>Total number of pills prescribed: ____</i></p> <p>Brand names</p> <p><i>Immediate release</i></p> <ul style="list-style-type: none"> ● Dilaudid <p><i>Controlled release</i></p> <ul style="list-style-type: none"> ● Jurnista
Tapentadol (Palexia)	<p><i>Prescribed: Yes/No</i></p> <p><i>Formulation: Slow-release/immediate release/both</i></p> <p><i>Dose: ____ (mg)</i></p> <p><i>Route: PO/other</i></p> <p><i>Frequency of dosing: od / bd / tis / qid / PRN</i></p> <p><i>Total number of pills prescribed: ____</i></p> <p>Brand names</p> <p><i>Immediate release</i></p> <ul style="list-style-type: none"> ● Palexia IR <p><i>Controlled release</i></p> <ul style="list-style-type: none"> ● Palexia SR
Other opioid prescribed	<p>Name: _____</p> <p><i>Prescribed: Yes/No</i></p> <p><i>Formulation: Slow-release/immediate release/both</i></p> <p><i>Dose: ____ (mg) per tablet</i></p> <p><i>Route: PO/other</i></p> <p><i>Frequency of dosing: od / bd / tis / qid / PRN</i></p> <p><i>Total number of pills prescribed: ____</i></p>
Safety net ((39))	Information provided about safe disposal of surplus opioids Yes/No

Supplementary Table 2: OPERAS study follow up data collection form

7-day follow up data points	Required data (definition / comment)
Information provided and verbal consent obtained	Yes / No
<i>If no: Confirm participant withdrawn from study at their request</i>	<i>Withdrawn Yes/No</i>
<i>Medication-related</i>	
<i>If discharge opioid prescription = Yes</i>	
Did you take your hospital-prescribed opioids	Yes / No
If yes, what was the date you last took opioid medication?	Date
Quantity of opioids taken from hospital prescription (<i>if liquid, quantify mLs consumed</i>)	<i>Only to fill in relevant medications</i>
Morphine	<i>Number of tablets remaining from hospital prescription: _____ (tablets) or _____mL</i>
Tramadol	<i>Number of tablets remaining from hospital prescription: _____ (tablets) or _____mL</i>
Oxycodone	<i>Number of tablets remaining from hospital prescription: _____ (tablets) or _____mL</i>
Fentanyl	<i>Number of tablets remaining from hospital prescription: _____ (tablets) or _____mL</i>
Codeine	<i>Number of tablets remaining from hospital prescription: _____ (tablets) or _____mL</i>
Buprenorphine	<i>Number of tablets remaining from hospital prescription: _____ (tablets) or _____mL</i>
Pethidine	<i>Number of tablets remaining from hospital prescription: _____ (tablets) or _____mL</i>
Hydromorphone	<i>Number of tablets remaining from hospital prescription: _____ (tablets) or _____mL</i>
Tapentadol	<i>Number of tablets remaining from hospital prescription: _____ (tablets) or _____mL</i>
Other opioid prescribed	<i>Number of tablets remaining from hospital prescription: _____ (tablets) or _____mL</i>
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 medications (e.g. cyclizine, metoclopramide, ondansetron) prescribed with the opioids?	Yes / No
<i>For all</i>	
During the first week after your discharge, did you use paracetamol (panadol) to manage your post-surgical pain?	Yes / No
During the first week after your discharge, did you use NSAIDs (ibuprofen, naproxen, celecoxib, diclofenac, etc) to manage your post-surgical pain?	Yes / No
Did you use any nerve pain medications like gabapentin, pregabalin, amitriptyline, venlafaxine, ketamine or clonidine to help with pain in the last week?	Yes – gabapentinoid Yes – tricyclic antidepressant Yes - serotonin noradrenaline reuptake inhibitors Yes - NMDA antagonists Yes – A2 agonists No
Did you seek medical help for your pain i.e. requesting increased pain relief or additional pain relief prescriptions?	Yes - GP Yes - Urgent care/Emergency department Yes - Readmission to hospital Yes – Surgeon Yes - other No
If yes - other:	Where?
If you did seek medical help, did you receive additional opioids i.e. a repeat prescription	Yes / No
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?	Yes - Family/friends/own stock No
If yes:	Name Dose / can't recall How many consumed / can't recall
Did you seek medical help for side effects of your pain medication?	Yes - GP Yes - Urgent care/Emergency department Yes - Readmission to hospital Yes – Surgeon No
For the 3 months prior to your admission, were you using any routine pain-relieving 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) Opioids (tramadol, codeine, oxycodone, sevredol etc)

<i>Patient-reported pain and satisfaction outcomes</i>	
EQ-5D-5L + EQ-VAS: <i>Under each heading, please tick the ONE box that best describes your health TODAY</i>	EQ - 5D
MOBILITY	<ol style="list-style-type: none"> 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	<ol style="list-style-type: none"> 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)	<ol style="list-style-type: none"> 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	<ol style="list-style-type: none"> 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	<ol style="list-style-type: none"> 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?	Yes/No/ can't recall
Did you receive information, advice or education on how to dispose of excess opioid medications?	Yes/No/can't recall
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: Included Procedures by Specialty

Supplementary Table 3: OPERAS study list of 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.)
	Appendectomy	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 Yes/No or colostomy formed Yes/No 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 D: OPERAS Study Patient Follow up Phone Call Script

**OPERAS Follow-up telephone interview script:**

Good afternoon/morning/evening Mr/Mrs/title (as listed on file) participant's name.

My name is _____, and I am a _____ (e.g., researcher medical student or role as appropriate) and I am calling on behalf of the OPERAS study team. You may remember we discussed a study about medicine prescriptions for pain relief after surgery while you were in hospital 1 week ago. Is now a good time to talk?

Before we start, can I confirm you're still happy to participate in this study?

If yes, start questionnaire, if no, thank participant and end call. Record participant as withdrawn from study at their request

We will start by asking a series of questions about the medicines you have used to help with pain after your return home from hospital

Can I ask if you have used any medicines for pain since you left hospital?

If Yes, ask questions 1 – 11. If No, go to question 12 and continue from there.

1. Did you take your hospital-prescribed opioid pain-relief medications? (give examples of prescribed medications here e.g. sevredol). If answer no, go to Qu 8. If yes, ask Qu 2 and on
2. How many tablets of _____ did you take through the course of the week? (Please go through the list of medications this patient was prescribed and calculate the quantity consumed in number of tablets OR mls)
3. Were you prescribed any other opioid medications I have missed?
(Take this opportunity to answer any questions about what medications may or may not count as opioids – this study includes weak opioids such as tramadol and codeine).
4. What was the date you last consumed your opioid medication?
5. While you have been at home, have you had any of the following side-effects?
Nausea or vomiting
Drowsiness
Itching
Dizziness
Constipation
 - a. If they said yes to any of the above, ask them: can you please describe on a scale of 0 to 10, 0 being none at all and 10 being extreme, how severe these side effects were?
6. Were you prescribed any laxatives, that is medications to help pass bowel motions easier, or anti-sickness medications? (You may use cyclizine, metoclopramide,



ondansetron or appropriate anti-emetics as examples to give examples to the patient, lactulose, coloxyl, senna are examples of laxatives).

7. Did you receive information, advice or education on how to dispose of excess opioid medications?
8. If you took your opioid medication and are no longer taking them, have you returned your unused opioids to the pharmacy? (Yes - pharmacy, No - disposed of in rubbish, No - not disposed of) (Question necessary only if patient has not taken opioids for >1 day or specifies they have stopped taking medication).

For all patients:

9. Did you use paracetamol/panadol to manage pain during the last week?
10. Did you use any non-steroidalals like ibuprofen, naproxen, or celecoxib (insert common trade names i.e. nurofen to help with pain in the last week)?
11. Did you use any nerve pain medications like gabapentin, pregabalin, or amitriptyline to help with pain in the last week?
12. Did you seek medical help for pain relief? This includes your GP, urgent care or the emergency department, the ward you were in at the hospital, or your surgeon.
 - a. If Yes, did you receive any additional medicines?
 - b. If yes, were they the same dose, higher dose, or lower dose? (You may ask the patient to check their containers or prescription to compare).
13. Did you get any pain relief medications from any other sources? For example, from friends or family, or that you already had at home? Anything you tell us here will not be passed on to anyone else, and we do not want to know anyone's name.
 - a. If yes, do you know the name, dose and how many you have used?
14. Did you seek any medical help for side effects from your pain medication? If so, was this the GP, urgent care, the emergency department, the ward you were in at the hospital, or your surgeon.? (Clarify if they were readmitted).
15. For the past 3 months prior to your admission, were you using any routine pain killer medications?
 - a. If yes, how many days per week?
 - b. If yes, what medications were you using (tick boxes which apply)?

The next series of questions will ask you about your quality of life after surgery.

16. We are trying to find out what you think about your health. I will explain what to do as I go along, but please interrupt me if you do not understand something or if things are not clear to you. There are no right or wrong answers. We are interested only in your personal view.



17. First, I am going to read out some questions. Each question has a choice of five answers. Please tell me which answer best describes your health TODAY.
18. Do not choose more than one answer in each group of questions. (Note to interviewer: first read all five options for each question. Then ask the respondent to choose which one applies to him/herself. Repeat the question and options if necessary. Mark the appropriate box under each heading. You may need to remind the respondent regularly that the timeframe is TODAY)

EQ-5D DESCRIPTIVE SYSTEM

19. First, I would like to ask you about MOBILITY. Would you say that:
1. You have no problems in walking about?
 2. You have slight problems in walking about?
 3. You have moderate problems in walking about?
 4. You have severe problems in walking about?
 5. You are unable to walk about?
20. Next, I would like to ask you about SELF-CARE. Would you say that:
1. You have no problems washing or dressing yourself?
 2. You have slight problems washing or dressing yourself?
 3. You have moderate problems washing or dressing yourself?
 4. You have severe problems washing or dressing yourself?
 5. You are unable to wash or dress yourself?
21. Next, I would like to ask you about USUAL ACTIVITIES, for example work, study, housework, family or leisure activities. Would you say that:
1. You have no problems doing your usual activities?
 2. You have slight problems doing your usual activities?
 3. You have moderate problems doing your usual activities?
 4. You have severe problems doing your usual activities?
 5. You are unable to do your usual activities?
22. Next, I would like to ask you about PAIN OR DISCOMFORT. Would you say that:
1. You have no pain or discomfort?
 2. You have slight pain or discomfort?
 3. You have moderate pain or discomfort?
 4. You have severe pain or discomfort?
 5. You have extreme pain or discomfort?
23. The next question we would like to ask is regarding your mental health and wellbeing and may be sensitive. Is this okay to discuss?

If prompted for the reason for the question: we are asking this question to get a holistic perspective of your overall health, including mental health and mood to investigate whether opioids impact on these aspects of your life. If yes: go to Q24, if no go to Q25



24. Finally, I would like to ask you about ANXIETY OR DEPRESSION. Would you say that:

1. You are not anxious or depressed?
2. You are slightly anxious or depressed?
3. You are moderately anxious or depressed?
4. You are severely anxious or depressed?
5. You are extremely anxious or depressed?

EQ-5D VAS

25. Now, I would like to ask you to say how good or bad your health is TODAY. I would like you to picture in your mind a vertical line that is numbered from 0 to 100. (Note to interviewer: if interviewing face-to-face, please show the respondent the VAS line.)

- a. "100 at the top of the line means the best health you can imagine."
- b. 0 at the bottom of the line means the worst health you can imagine."

26. I would now like you to tell me the point on this line where you would put your health TODAY. (Note to interviewer: mark the line at the point indicating the respondent's health today)

The next questions are about what has happened to you since you left hospital one week ago

27. On a scale of 0 to 100, 0 being none of the time and 100 being all of the time, how often were you in **severe** pain in the last week?

28. Did you remember receiving any information, advice, or education about managing your pain from your doctor or nurse before being discharged from hospital?
Yes/No/Can't recall

29. In your opinion, was the amount of pain medication you received when leaving hospital too little, just right or too much to manage your pain during this week?

30. On a scale of 0 to 10, 0 being extremely dissatisfied and 10 being extremely satisfied, how satisfied were you with the results of your pain treatment over the past week?

Thank you for your time. Do you have any questions?

If anything we have discussed has brought up any bad feelings and you'd like to talk to someone further, I can recommend some resources for you.

For Australia: Lifeline Australia 13 11 14, for Aotearoa New Zealand: Lifeline Aotearoa 0508 828 865

Appendix E: EQ-5D-5L Health Questionnaire

Under each heading, please tick the ONE box that best describes your health TODAY.

MOBILITY

- I have no problems in walking about
- I have slight problems in walking about
- I have moderate problems in walking about
- I have severe problems in walking about
- I am unable to walk about

SELF-CARE

- I have no problems washing or dressing myself
- I have slight problems washing or dressing myself
- I have moderate problems washing or dressing myself
- I have severe problems washing or dressing myself
- I am unable to wash or dress myself

USUAL ACTIVITIES (e.g. work, study, housework, family or leisure activities)

- I have no problems doing my usual activities
- I have slight problems doing my usual activities
- I have moderate problems doing my usual activities
- I have severe problems doing my usual activities
- I am unable to do my usual activities

PAIN / DISCOMFORT

- I have no pain or discomfort
- I have slight pain or discomfort
- I have moderate pain or discomfort
- I have severe pain or discomfort
- I have extreme pain or discomfort

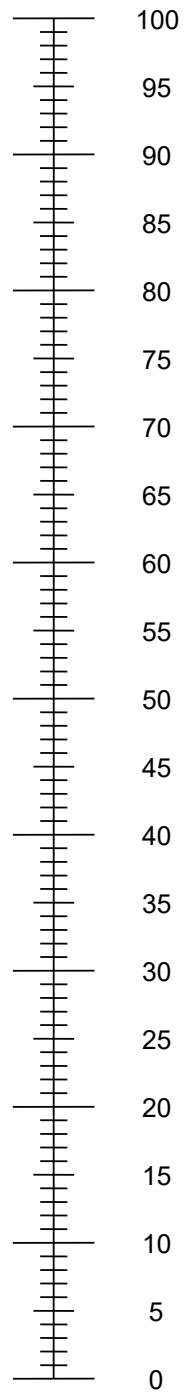
ANXIETY / DEPRESSION

- I am not anxious or depressed
- I am slightly anxious or depressed
- I am moderately anxious or depressed
- I am severely anxious or depressed
- 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 mark an X on the scale to indicate how your health is TODAY.
- Now, write the number you marked on the scale in the box below.

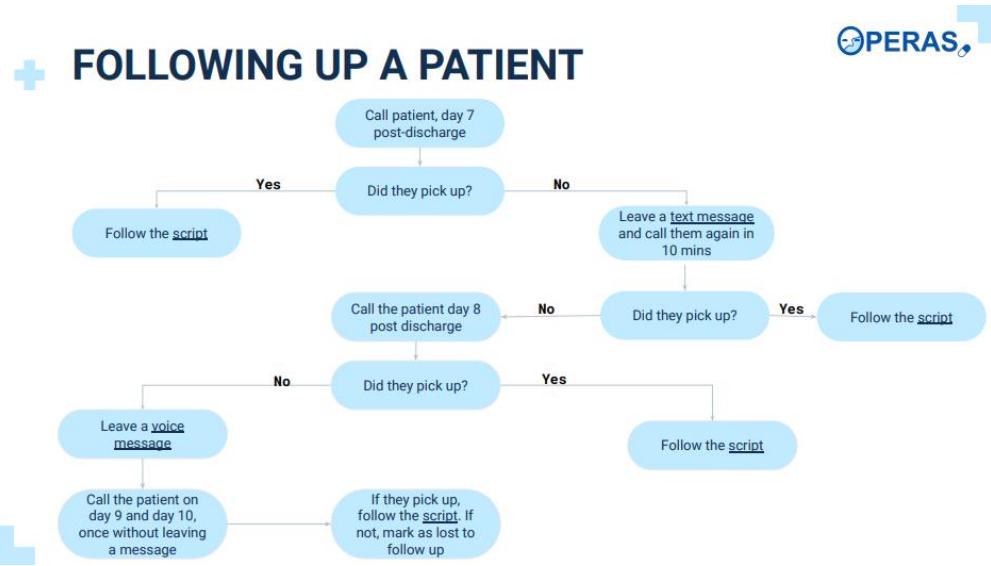
YOUR HEALTH TODAY =

The best health
you can imagine



The worst health
you can imagine

Appendix F: Patient Follow Up Procedure



*Script refers to the OPERAS follow-up telephone interview script (Appendix