

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)

INTRODUCTION

Over 80% of patients report pain after surgical procedures, and opioids are widely used to manage postoperative pain.¹ While often effective for acute pain, opioids can be

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 Precriptions 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 over prescription 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 Precriptions 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

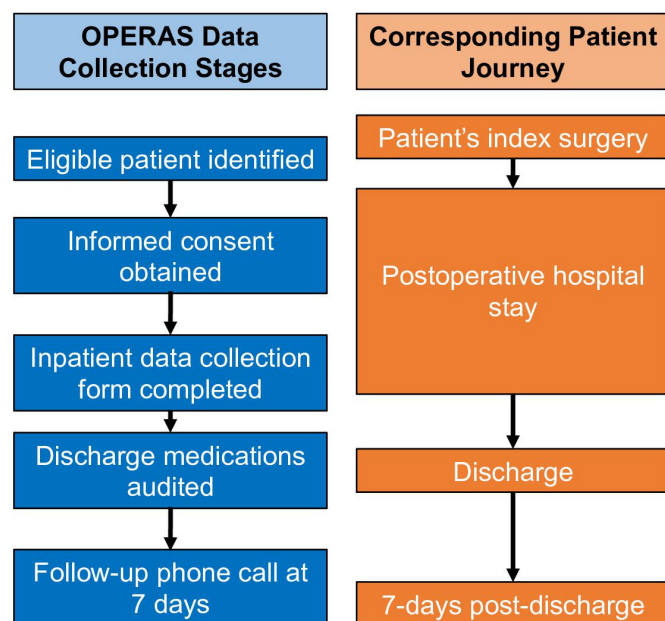


Figure 1 OPERAS data collection process and corresponding patient journey. OPERAS, Opioid PrEscRiptions and usage After Surgery.

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 R^2 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

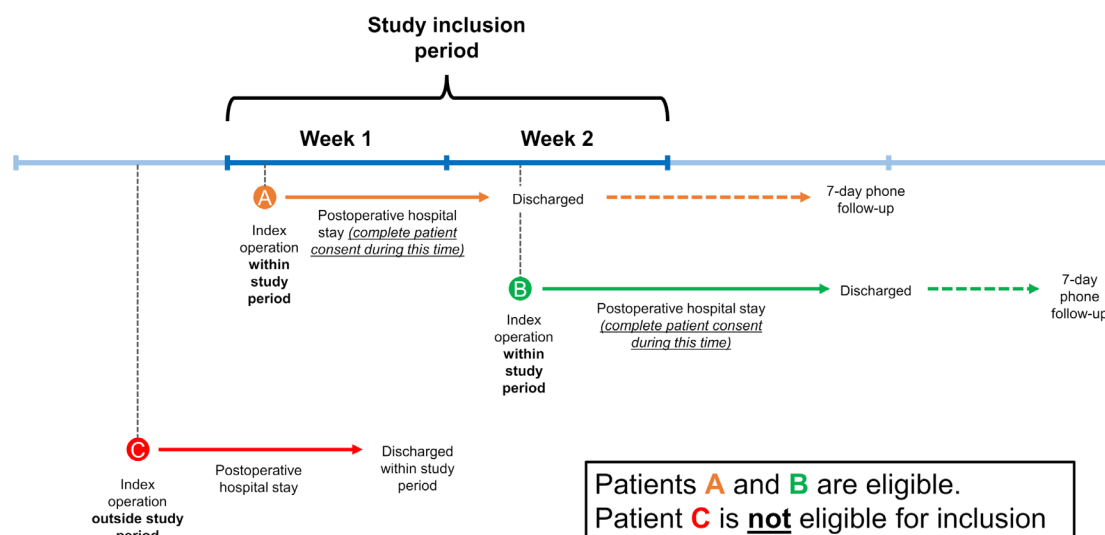


Figure 2 Patient eligibility based on timing of index operation and discharge.

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.² 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 over prescription 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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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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