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Original Article

Patient-reported outcomes, postoperative pain and pain relief after day case surgery (POPPY): methodology for a prospective, multicentre observational study*

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Summary

Background In the UK, approximately 70% of surgical procedures are undertaken as day-cases. Little information exists about recovery from day-case surgery, yet international data highlights patients are at risk of developing significant longer-term health problems including chronic post-surgical pain and persistent postoperative opioid use. The Patient-reported Outcomes, Postoperative Pain and pain relief after daY case surgery (POPPY) study was a national prospective multicentre observational study, measuring short- and longer-term patient-reported outcomes, postoperative pain and pain relief after day-case surgery.

Methods This was a collaborative project led by resident anaesthetists under the Research and Audit Federation of Trainees umbrella. Adult day-case surgical patients were recruited on the day of surgery. Baseline data including patient characteristics; procedure details; pre-operative analgesic use; pre-existing pain; and quality of life scores were recorded. Patients were followed up through automated short message service messages. Short-term (postoperative days 1, 3 and 7) outcomes included: quality of recovery; pain severity; impact of pain on function; and analgesic use. Longer-term outcomes (postoperative day 97) included: quality of life; analgesic use; incidence of chronic post-surgical pain; and incidence persistent postoperative opioid use. Additional outcomes were completed by those patients with chronic post-surgical pain and persistent postoperative opioid use, with 30 patients recruited to a qualitative semi-structured interview study exploring postoperative expectations, recovery, postoperative pain and opioid use.

Results An embedded pilot study at four sites recruited 129 patients. Responses to the automated short message service were gained from 129 patients (100%) at day 1; 116 (89.9%) at day 3; 108 (83.7%) at day 7; and 77 (59.7%) at day 97 postoperatively. The pilot enabled refinement of the methods and processes before the national roll out.

Conclusion This paper outlines the methods for the POPPY study, the largest UK multicentre prospective observational study considering short- and longer-term outcomes following day-case surgery.

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Introduction

Approximately 70% of surgical procedures in the UK are carried out as day-cases [1]. This equates to 6 million day-case procedures performed annually [2]. While many day-case units successfully employ next day follow-up, meaningful longer-term assessment is lacking, despite recognition that full functional recovery may take several months [3].

Patient-reported outcome measures, such as the ability to return to usual activities and a good quality of life after surgery, are recognised as being of greater importance and value to patients and healthcare providers than traditional clinician-centred outcomes, such as morbidity and mortality [4–6]. Patient-reported outcome measures can provide a more thorough understanding of the impact interventions may have upon patients and lead to improved service delivery [7]. There is evidence that patients having day-case procedures develop longer-term health problems following surgery, including chronic post-surgical pain and persistent postoperative opioid use [8, 9].

Chronic post-surgical pain is defined as pain occurring or worsening at the site of surgery, or within relevant areas of innervation, persisting for more than 3 months after surgery [10]. It has a significant negative impact on quality of life, particularly if it has characteristics of neuropathic pain [8]. Inappropriate longer-term postoperative opioid use is also a significant public health concern [11, 12]. While there are several definitions for persistent postoperative opioid use in the literature, it is accepted that it represents any opioid use in opioid naïve patients, or an increase in use in opioid exposed or tolerant patients, at 3 months following surgery [13]. It can be postulated from international studies that chronic post-surgical pain and persistent postoperative opioid use may also be significant problems in UK patients having day-case surgery [14–16]. However, to date, little is known about the prevalence of these conditions in this population [13, 17].

This paper describes the methods for the Patient-reported Outcomes, Postoperative Pain and pain relief after daY case surgery (POPPY) study, a national prospective multicentre observational study measuring short- and longer-term patient-reported outcomes, postoperative pain and pain relief after day-case surgery, and presents the embedded pilot study data undertaken before national roll out.

Methods

The POPPY study was developed by the South West Anaesthesia Research Matrix (SWARM) committee, an anaesthesia, peri-operative medicine, pain and intensive care research network for resident doctors. It was selected as the fourth national Research and Audit Federation of Trainees (RAFT) project and represents collaborative work led by resident doctors in anaesthesia. The design was a prospective, multicentre, observational cohort study with an embedded pilot study, that had ethical approval. Sites were identified and recruited through the RAFT network, as well as advertising at conferences and through the NIHR portfolio scheme. Patients were recruited from hospitals across all four UK nations (see online Supporting Information Appendix S1), with the local principal investigator and associate principal investigators, being supported by their local trainee research networks. All sites provided capacity and capability confirmation in accordance with usual Health Research Authority requirements.

The study had two phases. Phase 1 involved participant recruitment and baseline data collection, delivered by local collaborators over a continuous 5-day period. Before surgery, data were collected following individual patient consent. Phase 2 collected patient-reported outcome measures on postoperative days 1, 3, 7 and 97 using a short message service (SMS)-prompted online system. At day 97, additional outcomes were evaluated for those patients reporting moderate/severe chronic post-surgical pain and persistent postoperative opioid use. A subgroup of patients that reported chronic post-surgical pain and persistent postoperative opioid use at day 97 completed a nested qualitative study exploring postoperative expectations, recovery, postoperative pain and opioid use. A summary of the study is shown in Fig. 1.

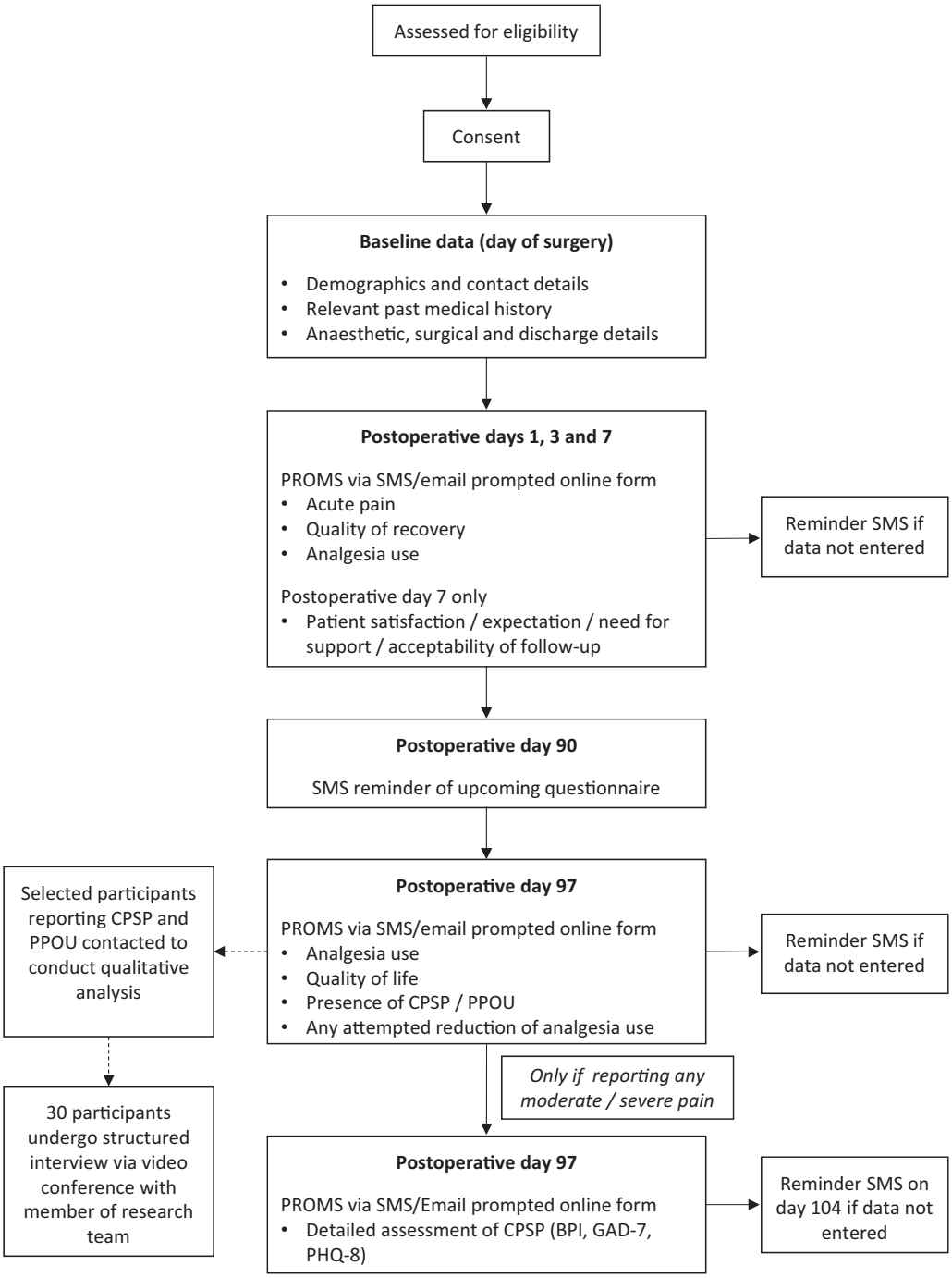

Figure 1 POPPY study flowchart. PROMS, patient-reported outcome measures; SMS, short message service; CPSP, chronic post-surgical pain; PPOU, persistent postoperative opioid use; BPI, Brief Pain Inventory; GAD-7, Generalised Anxiety Disorder Scale 7; PHQ-8, Patients Health Questionnaire 8.

The primary objectives of the POPPY study were to measure short and longer-term patient-reported outcomes (see Table 1) in UK patients having day-case surgery in relation to recovery, post-surgical pain and analgesic use. The short-term aims were to describe the quality of recovery in the first postoperative week and longer-term aims were to establish the prevalence of chronic post-surgical pain and persistent postoperative opioid use following day-case surgery. Secondary objectives were to identify patient, medication, anaesthetic and surgical characteristics

Table 1 Outcome measures and timing of data collection.

Outcome measure	Timing of data collection				
	Day 0	Day 1	Day 3	Day 7	Day 97
Baseline data	Yes				
QOR-15 score		Yes	Yes	Yes	
BPI-derived pain questions	Yes	Yes	Yes	Yes	
Functional pain score		Yes	Yes	Yes	
Analgesic use	Yes	Yes	Yes	Yes	Yes
Acceptability of SMS follow-up				Yes	
Patient satisfaction				Yes	
Need for additional help				Yes	
Chronic post-surgical pain incidence					Yes
Persistent postoperative opioid use incidence					Yes
EQ-5D-5L score	Yes				Yes
BPI score					Yes*
GAD-7 Score					Yes*
PHQ-8 Score					Yes*
Attempted reduction of opioid use					Yes*

*Conditional.
QOR-15, Quality of recovery 15; BPI, Brief Pain Inventory; SMS, short message service; EQ-5D-5L, 5-level EuroQol 5-dimensional questionnaire; GAD-7, Generalised anxiety disorder scale 7; PHQ-8, Patients Health Questionnaire 8.

associated with poor quality of recovery; to describe the acute pain and analgesic use of patients in the first postoperative week; to estimate patient need for further healthcare support in the first postoperative week; to determine the patient-reported acceptability of SMS-prompted follow-up; to determine the difference in quality of life between those patients with and without chronic post-surgical pain and how this relates to persistent postoperative opioid use; and to investigate the difficulty in reducing opioid use in patients with persistent postoperative opioid use.

Each hospital site selected a 5-day study period, during a predefined 4-week timeframe from 15 January to 9 February 2024. All adult patients (aged ≥ 18 y on the day of the operation) undergoing day-case surgery were screened for eligibility. Patients had to be able to read and understand English; have been booked for day-case surgery as defined by the National Day Surgery Delivery Pack [1] with an anaesthetist present; and the procedure must have involved ≥ 1 of the following modes of anaesthesia: sedation; regional anaesthesia; neuraxial anaesthesia; or general anaesthesia. We did not study patients with any of the following criteria: no access to a smartphone; lacking capacity for consent; prisoners; undergoing diagnostic and/or minimally invasive procedures (such as radiology, endoscopy or cardiology procedures); procedures related to obstetrics or ophthalmology; currently breast feeding; overnight hospital stay on the day of surgery (this included an unplanned overnight admission to hospital after surgery at day 0 only); and/or did not undergo a surgical procedure, as identified by the local research team on day 0 or day 1. The time-points for patient responses regarding unplanned admission were taken during day 1 and day 7 postoperative questions.

Methods for identifying patients varied according to individual recruiting sites depending on local resources and protocols. At some sites, members of the usual care team used operating theatre lists or electronic theatre management systems on the day of surgery. Other sites identified patients before the day of surgery at a pre-assessment clinic, with patient information sheets given or sent with appointment letters. Posters were displayed on admission wards to inform patients of the study.

All patients gave written informed consent and were able to withdraw from the study at any time; with data collected before withdrawal remaining eligible for analysis. Patients could decide not to reply to SMS contact at the specified time-points but were contacted by the automated system in accordance with the protocol, unless they specifically requested the study team to cease further communications. This option was facilitated by a withdrawal link included in each SMS. This directed patients to an online page allowing them to signify their intent to withdraw

from the rest of the study without affecting their ongoing care.

Data collection tools and outcomes were selected in accordance with existing evidence and best practice recommendations [18–21]. Complete details of collected variables, patient-facing questions and assessment tools can be found in online Supporting Information Appendix S2. At baseline, patients supplied: demographic data (including age, sex, ethnicity, postcode, ASA physical status and Rockwood frailty score); current treatment for anxiety or depression; smoking, alcohol or other drug dependency; surgical information (operation by specialty, severity and urgency); pain severity and chronicity, at the surgical site and elsewhere (0–10 scale, worst, average and now); analgesics taken within the last week; and the 5-level EuroQol 5-dimensional questionnaire (EQ-5D-5L) that evaluates quality of life across five domains (mobility; self-care; usual activities; pain/discomfort; and anxiety/depression) each scored from 1 (no problem) to 5 (unable to/extreme problems) [22]. Postoperatively, the local research team completed data entry, relating to whether the surgery took place; the method of anaesthesia used; whether the patient was discharged on the day of surgery; and the medications prescribed at discharge.

On days 1, 3 and 7 following SMS contact, patients completed a range of outcomes. Quality of Recovery-15 (QoR-15) scores were included to study early postoperative recovery; this scale is validated and psychometrically tested for use in patients having day-case procedures and covers five domains: emotional state; psychological support; pain; physical comfort; and physical independence, each rated from 0 to 10, giving a maximum score of 150, which would correlate with `excellent recovery´ [19, 23]. Pain severity questions were derived from the Brief Pain Inventory (BPI), in addition to patient-reported analgesic use [24]. The BPI is used commonly for assessment of chronic pain, and we used derived questions including pain `right now´; `on average in the last 24 hours´; and `at worst in the last 24 hours´, rated using an 11-point numerical scale. For outcomes taken up to and including day 7, the impact of pain on physical functioning was assessed using a five-level Likert scale of pain interference with usual activities, based on a published function pain assessment scale [24]. On postoperative day 7, data were also collected on the proportion of patients seeking further healthcare support following discharge; patient satisfaction with analgesia; and acceptability of the SMS follow-up method. The short-term follow-up period was chosen to be the first 7 postoperative days as this was deemed important to assess acute recovery, known to impact upon longer-term outcomes.

Following an SMS reminder sent at postoperative day 90 alerting patients to expect further contact, additional outcomes accessed by SMS contact were collected at postoperative day 97. All patients completed quality of life scores using the EQ-5D-5L and provided information on analgesic use, the presence of chronic post-surgical pain and chronic persistent postoperative opioid use. Day 97 was selected to assess longer-term outcomes, based on existing definitions of chronic post-surgical pain and persistent postoperative opioid use which stipulate a timeframe of 3 months after surgery as being significant [10, 25]. Follow-up beyond this timeframe was felt to be impractical, particularly as the study was using a novel methodology for outcome collection (SMS).

Analgesic data both at baseline and collected on day 97 were reported using drug name (selected from predefined list (see online Supporting Information Appendix S3) and frequency (selected from a predefined frequency option list)). Medications were categorised by the study team as simple analgesics; weak opioids; strong opioids; or other (e.g. amitriptyline or lidocaine plasters). For pre-operative and day 97 data collection, reported frequency of use was scored as: never = 0; less than once a week as needed = 1; more than once a week as needed = 2; daily as needed = 3; and regularly every day = 4. This timeframe was modified for the day 1, 3 and 7 time-points to reflect use in the preceding 24 h. At each time-point, weak and strong opioid scores were calculated by summing the total frequency score within each category. Chronic post-surgical pain was evaluated using the BPI pain severity scores at the site of surgery for average, worst and now (each 0–10) compared between baseline and day 97. Patients were categorised as having chronic post-surgical pain if any pain score at the site of surgery (average, worst or now) was ≥ 4 (out of 10) at day 97 (indicating moderate or severe pain [26]) and the day 97 composite pain score (of average pain, worst pain and current pain, range 0–30) was greater than the composite pain score at baseline. The analysis therefore considered chronic pain of moderate or worse severity. In accordance with the IMMPACT recommendations, patients with chronic post-surgical pain also completed questions from the modified short form BPI (including pain interference questions to investigate impact on physical functioning but with the body diagram and response to treatment sections removed); the Patient Health Questionnaire 8 (an eight-item screening questionnaire to assess the severity of depression in the preceding 2 weeks); and the Generalised Anxiety Disorder 7 questionnaire (a seven-item questionnaire to assess generalised anxiety disorder symptom frequency in the preceding 2 weeks [27, 28]).

Table 2 Pilot study response rate targets to enable proceeding to the main study.

	Green (possible with no changes to protocol ± close monitoring)	Amber (possible with changes)	Red (not possible)
All eligible patients			
Recruitment on day of surgery	> 50%	40–49%	< 39%
All recruited patients			
Day of surgery data completed	> 60%	40–59%	< 39%
Completion of day 1 data	> 60%	40–59%	< 39%
Completion of day 3 data	> 60%	40–59%	< 39%
Completion of day 7 data	> 60%	40–59%	< 39%
Completion of day 97 data	> 60%	40–59%	< 39%

For the purpose of determining persistent postoperative opioid use, opioid naïvety was determined for patients at baseline. If patients did not report prescribed opioids or reported opioid use with a frequency score of 0 at baseline, they were classified as opioid naïve. Persistent postoperative opioid use was calculated from the reported analgesic use at baseline and day 97. Persistent postoperative opioid use was defined in patients who were opioid naïve as any use of opioids at day 97, and in patients who were not opioid naïve as an increase in the strong opioid use score, and/or an increase in the weak opioid use score (if it did not coincide with a decrease in the strong opioid use score). For patients identified as having persistent postoperative opioid use, an additional question exploring whether they had difficulty in reducing analgesic use was completed.

A qualitative study was performed in a purposive sample of 30 patients who reported chronic post-surgical pain and/or persistent postoperative opioid use at postoperative day 97. Patient selection criteria included a requirement to have completed all outcomes at day 97 and predetermined primary criteria (including age, sex, pre-operative opioid use and pre-operative pain) and secondary criteria (ethnicity, region of the UK, anaesthetic and surgery type, postoperative pain and quality of recovery scores). Patients were telephoned by a researcher to discuss the qualitative study, arranging a time for a videoconference call. Virtual consent was obtained before the videoconference call and verbal consent was confirmed at the start of the interview. A semi-structured interview was conducted that explored the experiences of several aspects of the patient's day-case surgery journey including preparation for day-case surgery; pre-operative expectations; acute recovery (during the first postoperative week); longer-term recovery (after 3 months); postoperative pain; and opioid analgesic use (which medications were used and their duration) (online Supporting Information Appendix S4). Results will be reported according to the COREQ checklist [29].

An embedded pilot study was completed in July 2023 across four diverse sites to test the protocol of the POPPY study and to enhance the likelihood of its success on a larger scale. The pilot study data informed the design and conduct of the main study by testing the reliability and validity of the proposed study design, assessing patient drop-out rates and measuring the acceptability of the methodology. The reliability of the SMS-prompted data collection methods was also tested. The primary objectives of the pilot were to determine the proportion of patients who accepted the invitation to participate in the study and to determine how many patients received and completed the electronic follow-up invitations. These data were then compared with pre-determined response rates (see Table 2) to decide whether progression to the main study was possible.

A purpose-built secure online platform was used to collect and manage anonymised patient data at each participating centre. This platform, provided by NewcastlePROMS, enabled the input of anonymised patient data at baseline on the day of surgery and subsequent follow-up of patients using an automated SMS [30]. The platform has been used successfully in day-case units across England and is secure, in line with the UK Government's `Cyber Essentials´ scheme [31]. Following the recommendations of our patient and public involvement and engagement group, the system also enabled links to online forms to be emailed to patients. This facilitated the entering of data using a computer, laptop or tablet device to improve accessibility for patients who might have found data entry on a smartphone difficult. The primary means of contact with patients throughout the study period was via SMS.

Once patients had provided consent and been recruited, their pseudo-anonymised data were uploaded to

the NewcastlePROMS platform and linked to a unique patient identifier. The data collection system was tested extensively and developed in conjunction with our patient and public involvement and engagement group with the embedded pilot study informing refinements to the data entry process. We worked with our patient and public involvement and engagement group to improve response rates by adding an additional reminder SMS for the 3-month follow-up data on day 104 (see Fig. 1).

The full statistical analysis plan is available in online Supporting Information Appendix S5. To summarise, the aim was to recruit at least 6000 patients, from approximately 200 sites. Of the eligible patients, we expected follow-up response rates for short-term outcomes to be around 75% and longer-term outcomes to be around 50%, based on information from the pilot study (see below). A sample size of 6000 patients with a 95%CI was evaluated to allow estimated prevalence of chronic post-surgical pain and persistent postoperative opioid use with a marginal error of 1.3%. This recruitment target was realistic based on the recruitment numbers for comparable RAFT snapshot studies [32, 33] and data on current day-case surgery activity in the UK [2]. Patients, anaesthetic, medication use and surgical characteristics were summarised using appropriate descriptive statistics. The quality of recovery in the first postoperative week and prevalence of persistent postoperative opioid use and chronic post-surgical pain at day 97 are presented with 95%CIs.

Loss to follow-up was felt to potentially affect the estimated prevalence if data were not missing at random. This was evaluated by exploring missingness by baseline patient and surgical characteristics and accommodated using methods including joint copula modelling of retention and outcome [34]. Mixed effects regression models were used to identify patient, anaesthetic and surgical characteristics associated with chronic post-surgical pain and persistent postoperative opioid use, adjusting for geography as a random effect. Short-term outcomes are summarised descriptively and graphically, with regression models used to identify associations between variables of interest and the outcome, where appropriate. Quality of recovery analysis used a repeated measures model for days 1, 3 and 7.

Four UK sites participated in the pilot study (Rotherham NHS Foundation Trust, University Hospitals of Leicester NHS Trust, University Hospitals Plymouth NHS Trust and York and Scarborough Teaching Hospitals NHS Foundation Trust) recruiting 196 patients, 67 of whom were excluded (did not have the procedure, n = 11; local anaesthetic only, n = 2; not discharged on the day of surgery, n = 25; unknown if procedure was performed, n = 1; unknown if discharged on day of surgery, n = 28). A further seven patients chose to withdraw from the study over the course of the 97-day follow-up for the following reasons: no longer interested, n = 3; too difficult to complete, n = 1; no smartphone access, n = 1; too long to answer, n = 1; no reason, n = 1.

The pilot study methodology meant that patients were required to respond to data entry on day 1 to be eligible for the study. Data from four patients were removed beyond day 7 as these patients had an overnight stay in hospital within 7 days of surgery. This exclusion criterion was removed from the main POPPY study.

Of the 129 eligible patients, 129 (100%) responded to the automated SMS at day 1; 116 (90%) at day 3; 108 (84%) at day 7; and 77 (60%) at day 97. These results met predetermined green/amber/red criteria (see Table 2), which meant that following consultation with the study steering committee, it was possible to proceed to the national study.

Discussion

The POPPY study represents the most comprehensive exploration to date of patient-reported outcome measures following day-case surgery in the UK, with a particular focus on the prevalence of chronic post-surgical pain and persistent postoperative opioid use. Pilot data showed study feasibility and enabled the methods to be modified before national roll out, specifically adaptation of the exclusion criteria and inclusion of an additional SMS, with the aim of improving response rates, particularly at postoperative day 97.

Multiple studies have shown chronic post-surgical pain is very common. A population-based survey from Norway revealed a 18.3% prevalence of longer-term moderate to severe pain following surgery [35] and a recent observational study of 3121 European patients reported an incidence of moderate to severe chronic post-surgical pain of 11.8% at 12 months. Multivariable analysis of this cohort identified risk factors for chronic post-surgical pain as pre-operative chronic pain; proportion of time in severe pain on postoperative day 1; and orthopaedic procedures [36]. However, a variety of additional patient-, surgical-, anaesthetic- and pain-related risk factors have been identified with the field focusing on the development of risk prediction models [37].

Existing literature suggests that chronic post-surgical pain is not limited to major surgery or trauma. One study from the Netherlands found that 15.3% of 908 patients having day-case procedures reported moderate to severe pain one year postoperatively [15]. Yet data from the UK

about day-case patients are lacking. In the UK, the clinical significance of this problem was recognised by the National Institute for Academic Anaesthesia and James Lind Alliance in 2015, with the prevention of chronic pain after surgery identified as a top priority for anaesthesia research [38].

Research suggests that persistent postoperative opioid use is also a common and under-recognised problem. In one recent retrospective cohort study of over 340,000 patients having ambulatory surgery in Canada, 13% went on to develop persistent postoperative opioid use [9]. Opioid prescriptions at hospital discharge are frequently not patient- or procedure-specific, and over-prescription is a serious concern, contributing to the global opioid crisis [39–42]. An international study, including data from 25 countries, revealed that approximately 30% of patients were prescribed opioids at discharge following surgery [43]. The median discharge dose was 100 mg oral morphine equivalents, with patients consuming less than half the dose prescribed [43]. Over-prescribing of opioids after discharge continues, despite recent meta-analyses showing that these drugs add little to pain relief and increase adverse effects [44]. Using data from North America, a conservative extrapolation would suggest that more than 18,000 UK patients having day-case procedures are at risk of developing persistent postoperative opioid use annually, yet there is a paucity of data about day-case surgery in the UK to help us manage this risk [17]. As more complex day-case procedures are performed on patients with increasing comorbidities, the incidence of chronic post-surgical pain and persistent postoperative opioid use may increase further. An understanding of the current situation is imperative to enable us to track changes and develop interventions to reduce the incidence of these serious negative outcomes.

Day-case surgery represents an ever-growing area of clinical practice. The POPPY study will improve our understanding of this important patient population, including an appreciation of which surgical procedures are being performed currently in a day-case setting in the UK and understanding short- and longer-term outcomes. These data are key to improving patient care and patient experience.

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Supporting Information

Additional supporting information may be found online via the journal website.

Appendix S1. POPPY research sites.

Appendix S2. Variables, patient-facing questions and assessment tools.

Appendix S3. Analgesic dropdown list.

Appendix S4. Qualitative study interview schedule.

Appendix S5. Detailed statistical analysis plan.