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ORIGINAL ARTICLE

Status quo of pain-related patient-reported outcomes and perioperative pain management in 10,415 patients from 10 countries: Analysis of registry data

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Abstract

Background: Postoperative pain is common at the global level, despite considerable attempts for improvement, reflecting the complexity of offering effective pain relief. In this study, clinicians from Mexico, China, and eight European countries evaluated perioperative pain practices and patient-reported outcomes (PROs) in their hospitals as a basis for carrying out quality improvement (QI) projects in each country.

Methods: PAIN OUT, an international perioperative pain registry, provided standardized methodology for assessing management and multi-dimensional PROs on the first postoperative day, in patients undergoing orthopaedic, general surgery, obstetric & gynaecology or urological procedures.

Results: Between 2017 and 2019, data obtained from 10,415 adult patients in 105 wards, qualified for analysis. At the ward level: 50% (median) of patients reported worst pain intensities ≥7/10 NRS, 25% spent ≥50% of the time in severe pain and 20–34% reported severe ratings for pain-related functional and emotional interference. Demographic variables, country and surgical discipline explained a small proportion of the variation in the PROs, leaving about 88% unexplained. Most treatment processes varied considerably between wards. Ward effects accounted for about 7% and 32% of variation in PROs and treatment processes, respectively.

Conclusions: This comprehensive evaluation demonstrates that many patients in this international cohort reported poor pain-related PROs on the first postoperative day. PROs and treatments varied greatly. Most of the variance of the PROs could not be explained. The findings served as a basis for devising and implementing QI programmes in participating hospitals.

Author names are listed in the acknowledgement section.

Significance: In preparation for quality improvement projects, we comprehensively evaluated pain-related patient-reported outcomes (PROs) and treatment practices of 10,415 adult patients spanning 10 countries. PROs were generally poor. Demographics, country and surgical discipline explained a small proportion of variation for the PROs, about 88% remained unexplained. Treatment practices varied considerably between wards. Ward effects accounted for about 7% and 32% of variation in PROs and treatment processes, respectively. Future studies will aim to identify treatments which are associated with improved outcomes.

1 | INTRODUCTION

For the past decades, clinicians, basic scientists, clinical researchers and policy makers have attempted to improve perioperative pain management and outcomes at local, national and international levels (Stamer et al., 2020). Attempts include developing and implementing clinical practice guidelines, improving methods for administering analgesics, establishing structures within hospitals of teams providing specialized pain care, advocacy and policy making and creating tools for teaching health care providers and patients about pain and its management (Brennan et al., 2007; Gilron et al., 2019). Despite these extensive efforts, postoperative pain is still common and undertreated at the global level (Walters et al., 2016). The considerable attempts carried out reflect the complexity of offering effective and harm-free pain relief rather than a lack of trying to improve it (Schug et al., 2020).

Patient registries offer a system for collecting standardized information about care processes and outcomes across multiple sites in the clinical routine (Kabore et al., 2020). The findings can be used to reveal variability in treatment practices and outcomes and to identify targets for improvement. Variability is described as 'deviation of clinical practice from the best locally available, evidence-based, targeted approaches' (Lenert et al., 2019). It is commonly accepted that patients should receive care based on the best available scientific knowledge and it should not vary inconsistently from clinician to clinician or from place to place (Institute of Medicine Committee on Quality of Health Care in, 2001). Conversely, when patterns of care are widely divergent, clinical outcomes suffer (Richards, 2009). Registry findings can facilitate public reporting, prospective research and quality improvement (QI) in terms of professional development and improving service (Nelson et al., 2016).

PAIN OUT is an international registry and research network offering healthcare providers a platform for standardized assessment, feedback and benchmarking of perioperative pain management and pain-related patient-reported outcomes (PROs) in the clinical routine (www.pain-out.eu). Clinicians from Mexico, China, and the leadership of the European Pain Federation (EFIC) approached PAIN OUT with the intention of carrying out QI projects addressing perioperative pain in their country/Europe. As the first step in this process, teams from hospitals in each country carried out baseline evaluation of PROs and care. This was followed by developing, implementing and evaluating tools for improving perioperative pain management, tailored to each country. This is the first publication from these projects and the focus is on descriptive analysis of findings at baseline. Its objectives include: (1) describing patient's pain experience using multi-dimensional outcomes; (2) evaluating the use of evidence-based pain management techniques which are largely independent of surgery type and are recommended for most patients undergoing surgery as part of a multi-modal treatment approach (Chou et al., 2016; Joshi & Machi, 2019; Rawal, 2016; Schug et al., 2020) and (3) examining the contributors to variability in the PROs and treatment processes by analysing the proportion of explained variance related to patient demographics, surgical discipline, country and ward. Follow-up publications are being prepared to describe findings from the quality improvement projects and further analysis of the data from the cohort.

2 | METHODS

2.1 | Study design and setting

This was an observational, cross-sectional study in which data about pain management and PROs was collected from hospitals in México, China, Belgium, Italy, Ireland, France, the Netherlands, Spain, Serbia and Switzerland. Principal Investigators (PIs) were recruited through a call published in each country. PIs in each hospital could be anaesthesiologists, surgeons or nurses willing to participate in a 2 year project, and with availability of staff for collecting data. Ethical approval was obtained from the Institutional Review Board (IRB) in each hospital. PAIN

OUT coordinated the projects in each country together with a local leader. The trial was overseen by a Steering Committee, led by PAIN OUT, 1–2 representatives from each country and the European Pain Federation (EFIC).

The PAIN OUT methodology for auditing perioperative pain on the first post-operative day (POD1) has been described (Rothaug et al., 2013; Zaslansky et al., 2015). The methodology is registered with the US National Library of Medicine (ClinicalTrials.gov NCT02083835).

2.2 | Eligibility criteria

Patients could be enrolled if they fulfilled the following inclusion criteria: (1) were 18 years or older; (2) on POD1 and returned to the ward from surgery for at least 6 h; and (3) consented to take part in a survey assessing pain-related outcomes related with their surgery. Consent could be written or oral, depending on the requirements of local IRBs. Patients were approached once by a trained surveyor during the first day after surgery. Patients undergoing surgery as outpatients were not enrolled.

2.3 | Data collection

2.3.1 | Clinical and demographic items obtained for each patient

Surveyors abstracted demographic and clinical data items from the patient's medical record including gender, year of birth, weight and height, whether opioids were administered before admission, the types of analgesics administered perioperatively, type of anaesthesia and surgery (using the International Classification of Disease procedure codes, ICD-9). Lastly, whether there was a record that a member of staff assessed pain at least once after the patient returned to the ward since surgery.

2.3.2 | Pain-related patient-reported outcomes

We used the International Pain Outcomes Questionnaire (IPO-Q) (Rothaug et al., 2013). The questionnaire consists of 13 questions evaluating four outcome domains and they include: (a) intensity of pain (worst, least pain, time spent in severe pain); (b) interference of pain with activities (changing position in bed, taking a deep breath or coughing, getting out of bed, sleep) and with emotional well-being (anxiety and helplessness); (c) side effects (nausea, drowsiness, itch, dizziness); and (d) perception of care (whether patients would have liked more pain treatment than they received, were satisfied with pain treatment and received information about pain treatment options). Patients were also asked whether they used or received non-pharmacological interventions for pain. The IPO-Q offers a list of interventions to choose from, including *psychological* modalities, e.g. distraction, relaxation, meditation or *physical* modalities, e.g. a cold pack, TENS or acupuncture. Patients were requested to make all their evaluations with regards to their pain since surgery. Lastly, patients were also asked about the existence and severity of a persistent painful condition lasting 3 months before surgery. The questionnaire's psychometric properties have been validated in English and translated, using standardized methodology, into 29 languages. To reduce interviewer bias, patients completed the questionnaire independently with no assistance from family, staff or surveyor. If a patient requested help, the surveyor could assist.

2.3.3 | Study surveyors, data management and storage

In each hospital, study surveyors, medical or nursing students, nurses, or anaesthesia residents, not involved in patients' care, underwent training for recruiting patients and collecting the demographic and clinical data. Training involved reading a manual outlining the standard operating procedures, completing a quiz, review and feedback on initial datasets collected. Surveyors entered the data into a web-based, password secure portal where each dataset was given a unique, anonymous code. There was no link between this code, the patient's name or the medical record from which the data were obtained. Data quality was evaluated at different phases, including the standardized training of surveyors, range and consistency checks when entering data into the repository and additional plausibility checks after the data were downloaded for analysis. The PAIN OUT database is hosted and maintained by Jena University Hospital, Germany.

2.4 | Statistical analysis

2.4.1 | General approach

First, we assessed the proportion of patients whose outcomes exceeded pre-specified thresholds of the continuous PROs in the IPO-Q. Second, we analysed the proportion of patients receiving pharmacological and non-pharmacological techniques and which are largely independent of surgery type and recommended for most patients undergoing surgery (Chou et al., 2016; Joshi &

Machi, 2019; Rawal, 2016; Schug et al., 2020). These included:

1. Receipt of information about pain treatment options
2. Administering at least one non-opioid analgesic perioperatively (paracetamol or a non-steroidal anti-inflammatory drug [NSAID], or metamizole. The latter is commonly used for treating post-operative pain in some of the participating countries (Hearn et al., 2016))
3. Infiltrating the surgical wound intra-operatively, independent of medication type
4. Assessing and recording pain by a member of staff at least once since returning to the ward after surgery
5. Patients reporting whether they used a non-pharmacological intervention
6. Patients reporting worst pain ≥7/10 and receiving an opioid (Alexander et al., 2019). To evaluate whether there was an association between the patient's report of severe pain and treatment practices on the ward.

Though regional anaesthesia is procedure-specific, it is regarded an integral technique in many guidelines (Wu & Raja, 2011), we, thus, include findings about the frequency it was employed.

2.4.2 | Sample selection

A surgical discipline was included in the analysis if ≥500 datasets were entered into the registry for that discipline. A ward was included if it contributed ≥30 valid data sets for the selected surgical disciplines. A data set was considered as valid if the patient inclusion criteria were met and if it included a reading for 'worst pain since surgery'.

2.4.3 | Determining thresholds for the PROs

Using 'computed ABC Analysis' (Ultsch & Lötsch, 2015), we determined variable-specific thresholds for the continuous items in the IPO-Q. This data-driven technique divides patient ratings into three subsets, which can be interpreted in line with the commonly used categories in the pain literature (Mendoza et al., 2004) namely, a sensation which is *severe* (A), *moderate* (B) and *mild-none* (C). The ABC-analysis offers statistically valid definitions of the thresholds and cut-offs for single PROs. The ABC-analysis was performed within 1000 sub-samples within each of the surgical disciplines and in 1000 sub-samples with balanced patient numbers for the surgical disciplines. For every sub-sample, the A-B Limit (cut-off: severe vs. moderate) and the B-C Limit (cut-off: moderate vs. mild-none) were recorded. The most frequent Numerical Rating Scale (NRS) ratings for A-B- and B-C limits over the 1000 sub-sampling steps were recorded. The mode of the discipline-specific A-B-Limits and the balanced sub-samples were used as cut-offs in the current publication. Here we report the percentage of patients who provided severe ratings, 'A', for each of the continuous variables in the IPO-Q. Supplement 1 describes the approach and thresholds in more detail.

2.4.4 | Descriptive analysis

The main focus of this paper is the analysis of ward-level PROs and treatment processes. Consequently, for each ward, we calculated the percentage of patients with ratings above variable-specific thresholds for the continuous PROs (as described in Section 2.4.3 'Determining thresholds for the PROs') as well as the percentages for dichotomous PROs, treatment processes and demographic variables. We used descriptive statistics for the whole cohort and also stratified by the major surgical disciplines. We, thus, report the median percentage and the first (Q_1) and third quartiles (Q_3) for each variable. For the sake of completeness, we also report absolute frequencies and percentages, irrespective of single ward analysis, for the whole cohort and within the disciplines. The continuous demographic variables, duration of surgery, time between end of the surgery and time of the survey were analysed in a similar manner. Here, medians for each ward were obtained and descriptive statistics (median, Q_1, Q_3) were used in conjunction with stratification by the major surgical disciplines.

Absolute frequencies and percentages for the administration of the three classes of non-opioid analgesics (paracetamol, NSAIDs, metamizol) stratified by country and perioperative phase (pre-operative, intraoperative, PACU and ward) were also calculated. We report the median (Q_1 and Q_3) of all doses administered on the ward for the most frequently administered non-opioid analgesics and opioids. For the non-opioid analgesics, we also report cumulative daily doses administered perioperatively. Structural variables for hospitals are reported as absolute frequencies and percentages.

2.4.5 | Mixed models

Linear mixed models were used to assess the amount of explained variation in the continuous PROs. For the 'wish for more pain treatment' variable and all the treatment process variables, we used generalized linear mixed models with a logit binomial link function. The approach is described in Supplement 2. Briefly, we

iteratively tested if the inclusion of random intercepts for wards, countries and disciplines as well as the inclusion of demographic variables (age, sex, pre-existing pain) as fixed effects significantly improved the model fit. The proportion of explained variance components from the variables included in the final models is given in percent.

A data analysis and statistical plan was written and shared by email with all prospective authors before the data were accessed. The number of valid datasets for all the outcomes is listed in Supplement 3. For the analysis, we used R (Version 3.6.3, Vienna, Austria [R Core Team, 2020]) and R-Studio (Version 1.2.5003, R-Studio Inc.). We followed the RECORD guidelines (Benchimol et al., 2015) for preparing the manuscript.

3 | RESULTS

3.1 | Recruitment of hospitals and patients

Between 2017 and 2019, study surveyors approached 13,083 patients, of whom 10,415 from 105 surgical wards, in 64 hospitals, qualified for the analysis (Figure 1 and Table 1). Structural data of the participating hospitals included the following: 90% ($n = 55$) were publically run, one was financed by an insurance company and one was by a religious organization. In 40% ($n = 25$) of hospitals the number of beds was <500; in 26% ($n = 16$) it was 500–1000; in 21% ($n = 13$) it was 1000–2000, and in 13% ($n = 8$) the number of beds was >2000. Teaching status: 73% ($n = 45$) were university-based, 25% ($n = 16$) were teaching but non-university, and one was not a teaching hospital. Structural data were missing for tewo hospitals.

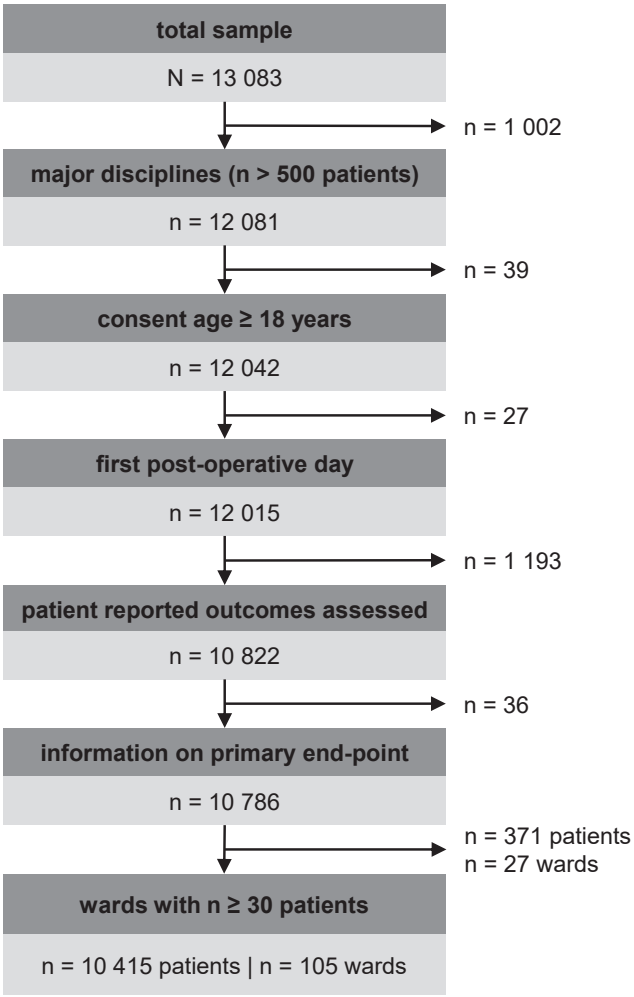

FIGURE 1 Study flow chart.

3.2 | Description of the patient cohort and details on the surgical procedures

Patient demographics and pre-hospital admission pain-related information are listed in Table 2 for the whole cohort and by discipline. Additional information is provided in Supplement 3.1. The three most common surgical procedures in each of the disciplines in the cohort were: (1) *General surgery*: laparoscopic cholecystectomy, laparoscopic gastroenterostomy, laparoscopic vertical (sleeve) gastrectomy; (2) *Orthopaedic surgery*: total hip or knee replacement and open reduction of fracture with internal fixation; (3) *Obstetrics and Gynaecology*: Caesarean delivery, laparoscopic total abdominal hysterectomy, excision or destruction of lesion of uterus; (4) *Urology*: complete nephrectomy, radical prostatectomy, transurethral removal of obstruction from the ureter and renal pelvis. See also Supplement 3.2.

3.3 | Patient reported outcomes

Below we present descriptive statistics at the ward-level and as they apply across the whole cohort. Results are reported as median frequency and first and third quartiles between the single wards. Figure 2-I presents similar information for each of the surgical disciplines. Detailed results for the PROs are shown in Supplement 3.3.

Of all patients, 48.7% (35.3–57.1) across the wards reported worst pain ≥7/10 and 24.3% (18.6–33.3) reported being in severe pain for over 50% of the time since surgery. Patients reported pain interference ratings (moving in bed, sleeping, taking a deep breath or coughing) and negative affect (anxiety, helplessness) above the thresholds with a frequency of 20–33.6%. Of all patients, 66.4% (48.2–83.3) got out of bed on POD1.

TABLE 1 Number of hospitals, wards and patients for each of the participating countries, discipline and the whole cohort

Country	Complete cohort			General surgery		Orthopaedics And Traumatology		Obstetrics And Gynaecology		Urology	
	Hospitals	Wards	Patients	Wards	Patients	Wards	Patients	Wards	Patients	Wards	Patients
Belgium	2	3	198	1	73	0	0	2	125	0	0
China	12	24	2520	7	885	11	1059	6	576	0	0
France	5	6	627	1	69	4	432	1	126	0	0
Ireland	4	7	422	2	74	4	291	0		1	57
Italy	4	6	620	2	279	1	81	1	62	2	198
México	9	12	1492	6	831	4	454	1	76	1	131
Netherlands	10	18	1701	9	740	7	827	1	86	1	48
Serbia	8	13	1268	6	686	3	278	2	163	2	141
Spain	7	10	1080	6	642	4	438	0	0	0	0
Switzerland	3	6	487	2	187	3	213	1	87	0	0
Sum:	64	105	10,415	42	4466	41	4073	15	1301	7	575

The frequency of side-effects (drowsiness, dizziness, itch, nausea) above the threshold ranged between 9.3 and 26.8%. The frequency for dis-satisfaction with pain treatment was 17.4% (12.5–23.5), and 22.0% (13.7–29.1) would have liked more pain treatment than they received.

3.4 | Treatment processes

Below we present findings for the treatment process at the ward level and as they apply across the whole cohort. Results are reported as median frequency and first and third quartiles between the single wards. Figure 2-II presents similar information for each of the surgical disciplines. See Supplement 3.4 for additional information.

Of all patients, 56.5% (44.6–74.8) reported that they received information about treatment options. Pain was assessed in 98.5% (88–100) of patients, with some outliers. The surgical wound was infiltrated in 8.7% (0.9–28) of patients. Across the cohort, 59% (29–75) of patients who reported worst pain intensity ≥7/10 NRS received a systemic opioid.

The frequency for using a non-pharmacological intervention was 28% (18.1–40.2) of these patients, 42.8% reported use of one and 23.2% of two interventions. The most frequent interventions were distraction-based, reported by 25.1% of patients or a physical modality, in the form of a cold pack, in 8.1% of the cohort.

Regional anaesthesia (any form) was administered to 26% (8.4–58.3) of patients. Spinal anaesthesia was the technique used most often in 10.4% (1.4–39.4) of patients across the cohort. Patient-Controlled Analgesia (PCA) in PACU and/or ward was used by 6.1% (0–25.7) of patients.

3.5 | Non-opioid analgesics and opioids administered on the ward and perioperatively

On the ward, 94.7% (83.5–98.3) of patients were administered a non-opioid analgesic. Of these, the majority of patients, 57%, received one and 38% received two non-opioids. Paracetamol was the most commonly used non-opioid, administered with a frequency of 65% (6–95). NSAIDs were the second most commonly administered non-opioid, administered to 57.5% (34.4–78.8) patients across the wards. The use of metamizole was restricted to five countries in the cohort. In these countries, 12.2% (0.7–40.2) of patients across wards received this medication. Doses for the non-opioids administered perioperatively and on the ward are summarized in Table 3. The large variability in the non-opioid classes administered

TABLE 2 Patient demographics and general information about surgery. The absolute frequency and percentage of valid data entries are listed in the first column

Variable	Unit	Whole cohort	General surgery	Orthopaedics & traumatology	Obstetrics & Gynaecology	Urology
		Median [Q_1 Q_3]	Median [Q_1 Q_3]	Median [Q_1 Q_3]	Median [Q_1 Q_3]	Median [Q_1 Q_3]
Age	Years	56.0	54.5	62.5	45.0	65.0
[n = 10,362, 99.5%]		[51.0 64.5]	[51.1 60.9]	[52.0 68.0]	[36.0 49.5]	[62.5 65.3]
Sex: male	%	45.1	46.0	47.0	0.0	69.6
[n = 10,372, 99.6%]		[30.2 54.8]	[38.1 55.7]	[42.9 52.5]	[0.0 0.0]	[67.4 79.6]
Comorbidity[a]: any	%	66.7	69.1	65.6	39.7	80.8
[n = 10,354, 99.4%]		[43.4 80.2]	[48.1 86.3]	[43.5 76.7]	[27.7 68.2]	[75.6 85.9]
Pre-existing chronic pain: yes	%	32.5	28.7	62.1	11.9	17.5
[n = 10,323, 99.1%]		[20.9 52.5]	[21.2 37.0]	[40.4 82.5]	[6.5 24.4]	[15.3 31.5]
Pre-existing chronic pain: intensity	NRS	6.0	6.0	7.0	5.8	5.5
[n = 4072, 98.1%]		[5.0 7.0]	[5.0 7.0]	[6.0 7.5]	[4.8 6.6]	[4.8 7.3]
Opioid before admissions: yes	%	1.8	3.3	6.4	0.0	0.0
[n = 9512, 91.3%]		[0.0 7.0]	[0.0 5.2]	[0.0 13.5]	[0.0 0.0]	[0.0 0.7]
Duration of surgery	h:mm	1:45	1:48	1:40	1:30	1:57
[n = 10,182, 97.8%]		[1:23 2:00]	[1:23 2:09]	[1:25 1:55]	[1:02 1:45]	[1:40 2:45]
Time to survey[b]	hh:mm	22:47	22:43	22:23	23:31	23:55
[n = 9371, 90.0%]		[21:45 24:43]	[21:40 24:25]	[21:46 24:27]	[21:42 25:21]	[22:12 24:33]

[a]Related to management of acute pain.

[b]Hours from end of surgery until the patient filled in the questionnaire.

during the different perioperative phases and in the different participating countries is shown in Figure 3 (see also Supplement 3.5).

A systemic opioid was administered to 48.8% (25–68.6) of patients across the wards. The intravenous route was used in 57.9% (n = 2867/4954) and the oral route in 40.7% (n = 2015/4954) of these patients. Median daily doses of the most frequently administered systemic opioids were: 10 mg for oxycodone (10–20 mg, n = 1892), 100 mg for tramadol (100–200 mg, n = 1454) and 10 mg for morphine (5–19 mg, n = 527).

3.6 | Sources of variance

3.6.1 | Patient-reported outcomes

Surgical discipline and country explained a range of 0.0–13.6% and 0.0–6.6% of the variance for the single PROs, respectively (see Figure 4a). Ward effects accounted for a median of 7.0% (range: 3.1–11.2%) of the variance. Demographic variables (age, sex, pre-existing pain) explained a range of 0.2–4.7% of the variance. The majority of the variance, a median of 88.2% (range: 77.2–91.8%) was unexplained. See also Supplement 4.1.

3.6.2 | Treatment processes

Ward effects accounted for a median of 32.1% (range: 11.6–52.0%) of the variance (see Figure 4b). Country and discipline explained a median of 18.9% (range: 0.0–80.0%) and 0.0% (range: 0.0–5.7%) of the variance, respectively. Percentages of explained variance resulting from demographic variables ranged between 0.0 and 2.7%. A median of 39.5% (range: 6.4–75.0%) of the variance was unexplained. See also Supplement 4.2.

4 | DISCUSSION

This study evaluated multi-dimensional PROs and perioperative pain treatment practices in 10,415 patients undergoing procedures related to four surgical disciplines, in 64 hospitals, across eight European countries, México and China. The purpose of these evaluations was to study

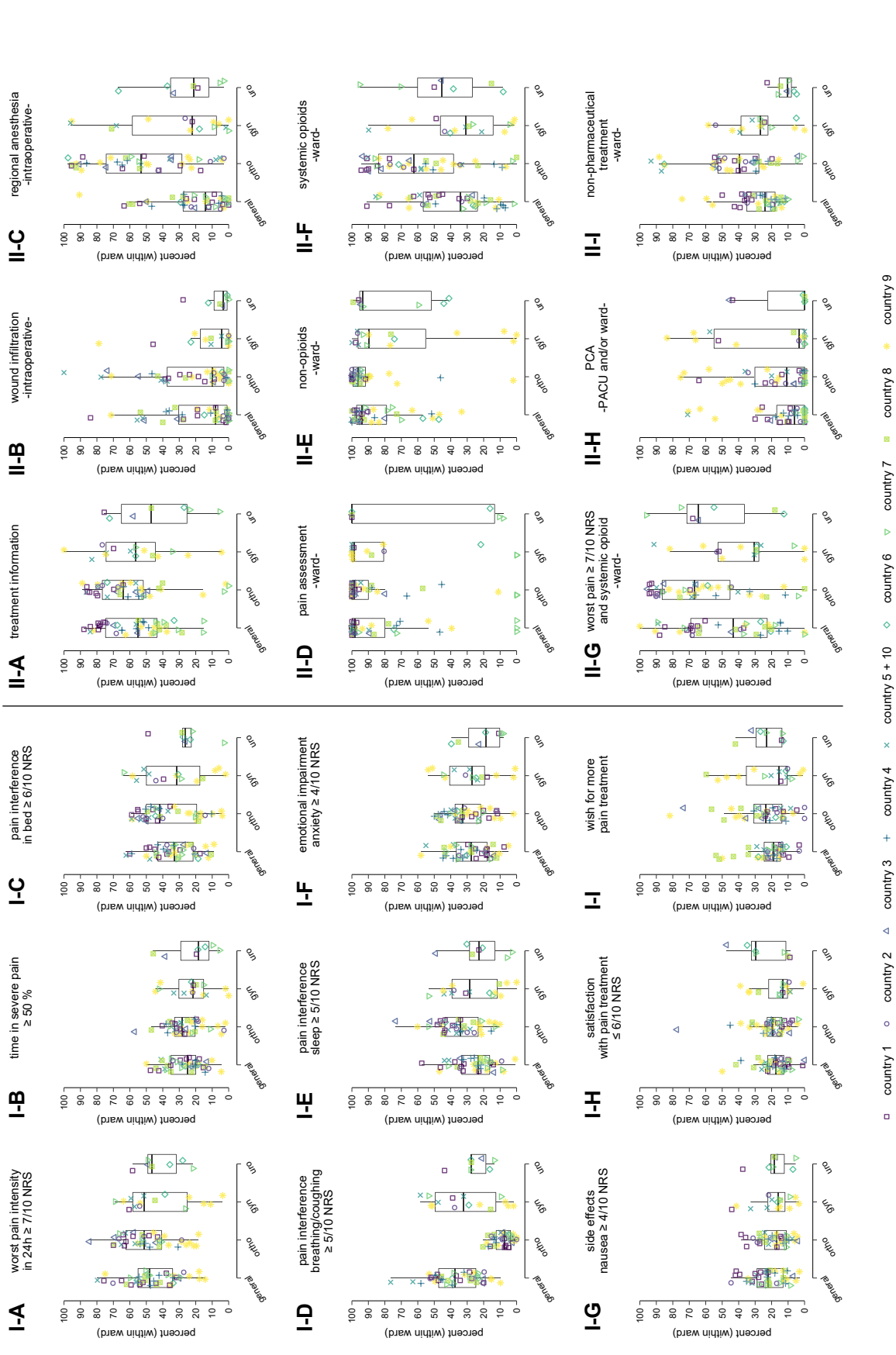

FIGURE 2 Summary of the single ward analysis by discipline. Figure 2-I depicts the patient reported outcomes and Figure 2-II treatment processes. Each data point refers to summarized data from a single ward; the different symbols represent the different countries. The boxplots summarize the results for general surgery (general), orthopaedics and traumatology (ortho), obstetrics and gynaecology (gyn) and urology (uro). The median is marked by the horizontal line inside the box and the ends of the box are the 1st and 3rd quartiles.

TABLE 3 The most frequently administered non-opioid analgesics are shown as cumulative doses (intraoperative, PACU, ward) and doses administered on the ward. Median doses, including first (Q_1) and third quartile (Q_3) and the number of analysed doses are displayed

	Cumulative			Ward		
Medication	**Median**	**[Q1–Q3]**	***n***	**Median**	**[Q1–Q3]**	***N***
Paracetamol	3000	[2000–4000]	5991	2000	[1200–3000]	5468
Metamizole	3000	[2000–5000]	2231	2500	[2000–4000]	1541
Ketorolac	60	[30–90]	2452	60	[30–90]	1513
Diclofenac	100	[75–150]	1113	100	[75–50]	821
Parecoxib	40	[40–80]	1214	80	[40–80]	741
Flurbiprofen	100	[50–150]	917	147	[100–243]	414
Ketoprofen	160	[100–300]	889	160	[100–200]	487

current treatment practices and pain-related PROs as a basis for finding targets for interventions when planning quality QI projects in participating hospitals. We found considerable variability in the PROs between wards. Approximately half of patients reported worst pain intensities ≥7/10 NRS and about a quarter spent over half of the first day after surgery in severe pain. Up to a third of patients reported that pain interfered considerably with activities in and out of bed and with their emotional well-being. Side-effects, such as nausea and drowsiness, affected up to a quarter of patients. Approximately 20% of patients reported low levels of satisfaction with pain care. Finally, just over 20% of patients would have liked to receive more pain treatment than they did. The emerging picture confirms and supports findings obtained from national and international surveys (Fletcher et al., 2008; Meissner et al., 2015).

We sought to identify gaps in practice in this mixed surgical cohort and carried this out by evaluating the proportion of patients receiving interventions recommended for most patients undergoing surgery. We found considerable variation within each discipline. Non-opioid analgesics are effective for managing post-operative pain and thus, clinicians should routinely incorporate them into multi-modal analgesic regimens, administering them on a regular basis (Chou et al., 2016). In the current cohort, paracetamol was the most commonly used non-opioid, its cumulative daily dose was generally lower than the recommended 4 g for acute pain management (Schug et al., 2020). Despite its widespread use, concerns have been expressed that paracetamol may be ineffective for treating moderate to severe pain related to surgery (Abdel Shaheed et al., 2021). NSAIDs, more effective for managing pain compared with paracetamol alone (Moore et al., 2015), were administered less frequently. Combining at least two different non-opioid classes confers better analgesia than when either medication is administered alone (Martinez et al., 2017), however, only 38% of patients received such care. Patients should receive some form of local or regional anaesthesia, as this is effective for controlling movement-evoked pain (Shanthanna et al., 2021). Wound infiltration is simple to carry out and inexpensive (Stamenkovic et al., 2021). The infrequent use of wound infiltration was not explained by frequent use of regional anaesthesia. For example, orthopaedic patients rarely received femoral blocks or TAP blocks in general surgery and obstetrics. Pain assessment was carried out in the majority of patients but in light of the high percentage of patients reporting severe pain (intensity and duration) and interference, assessments may have been ineffective. Pain assessments have been under intense scrutiny, regarded as a 'regulatory nuisance' (Levy et al., 2018). Yet, due to the considerable variability in patients' responses to pain and to analgesics, assessment, whatever form it takes, is the primary means for tailoring care to individual patients so that it might be effective and safe (Gerbershagen et al., 2013). Offering information to patients is a strong recommendation but the evidence is weak (Chou et al., 2016). It may represent a starting point for QI as it has been associated with improved outcomes (Garduño-López et al., 2021). Lastly, approximately a third of the cohort reported using non-pharmacological interventions. The majority were psychological modalities (e.g. distraction), whereas physical modalities (e.g. cold packs) were offered to a minority of patients. Though the concept of multi-modal analgesia is widely accepted, its implementation in clinical practice is generally disappointing (Shanthanna et al., 2021). In our study, this is reflected by the large variability of implementing treatments across the wards and that the PROs were unfavourable.

Opioids were administered sparingly on POD1, with only 59% (29–75) of patients reporting severe pain receiving an opioid. When an opioid was administered, it was mostly as a single dose for the entire post-operative day. Similar findings have been described (Gerbershagen et al., 2013). Opioids are still the mainstay for treating moderate to severe acute pain, within a multi-modal treatment regimen (Alexander et al., 2019) and when adhering to safe prescribing practices (Levy et al., 2021). It is

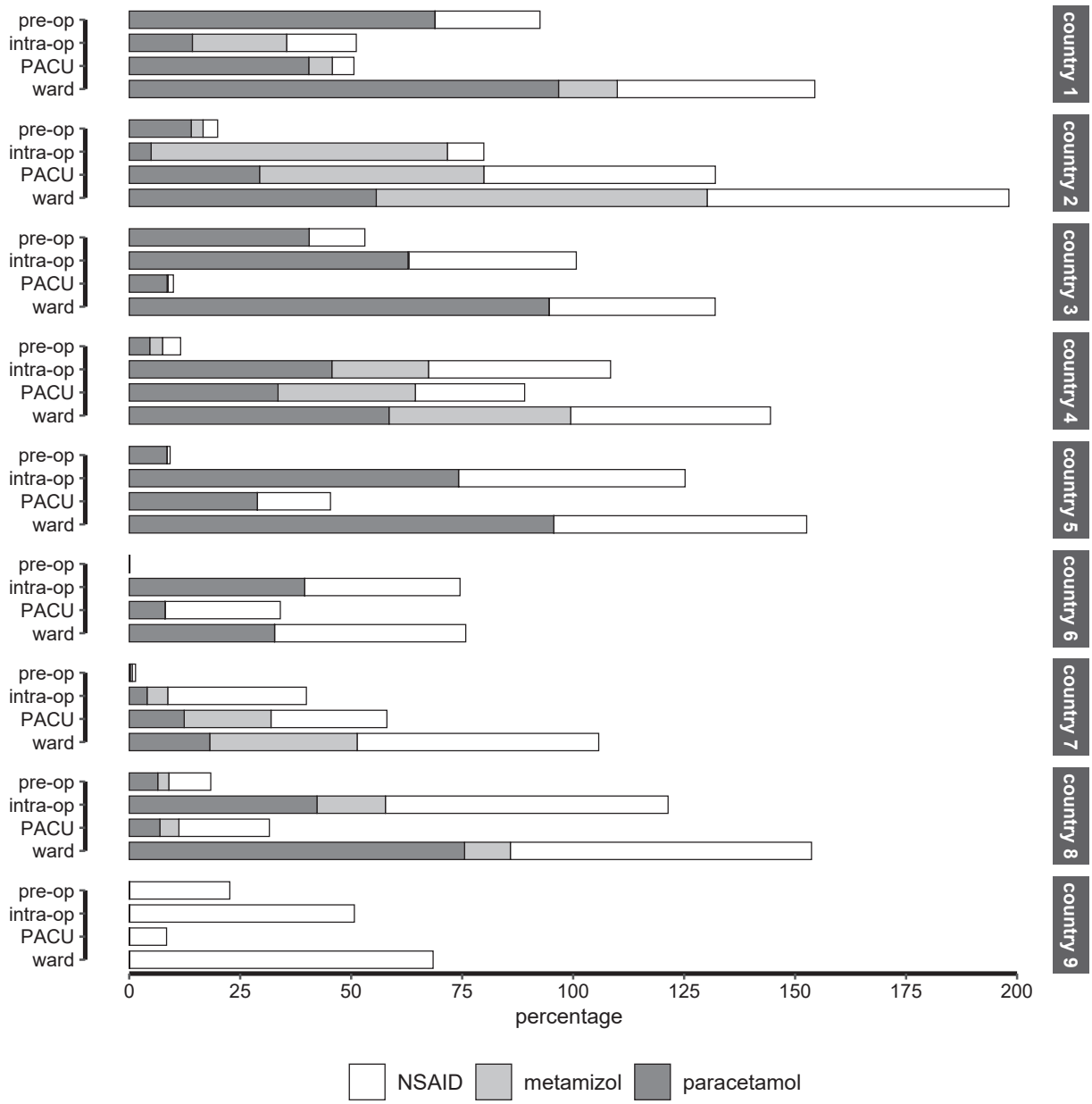

FIGURE 3 The overall percentages of patients receiving NSAIDs, metamizole and paracetamol are stratified by country and perioperative phases: Pre-medication (pre-op), intra-operatively (intra-op), PACU and ward. The percentage scale exceeds 100, as some patients received more than one class of non-opioid.

unlikely that the opioid epidemic is an outcome of administering opioids in the immediate or sub-acute postoperative phase, and thus, there is little justification of denying patients opioids on the first day after surgery, when clinically warranted (Kharasch & Clark, 2021) and to patients who wish to receive them (van Dijk et al., 2015).

The large number of countries and wards included allowed us to seek out the underlying sources of variability in PROs and treatments. For PROs, a median of 88.2% of the variance remained unexplained. Variables routinely used for assessing their contribution to pain intensity, such as sex, age, pre-existing chronic pain (Ip et al., 2009), explained a negligible proportion of the variance. This might underline the limited predictive value of these variables in explaining pain or consumption of analgesics after surgery. It is possible that some of the variance in pain responses is associated with psychological, social, cultural and health literacy factors (Sobol-Kwapinska et al., 2016) indicating the need for an even broader assessment approach than was used here. Country explained a negligible proportion (2.6%) of the variance. The difficulty in teasing out differences in PROs reported by patients from different countries might be attributed to 'country' serving as a poor surrogate for differentiating between people

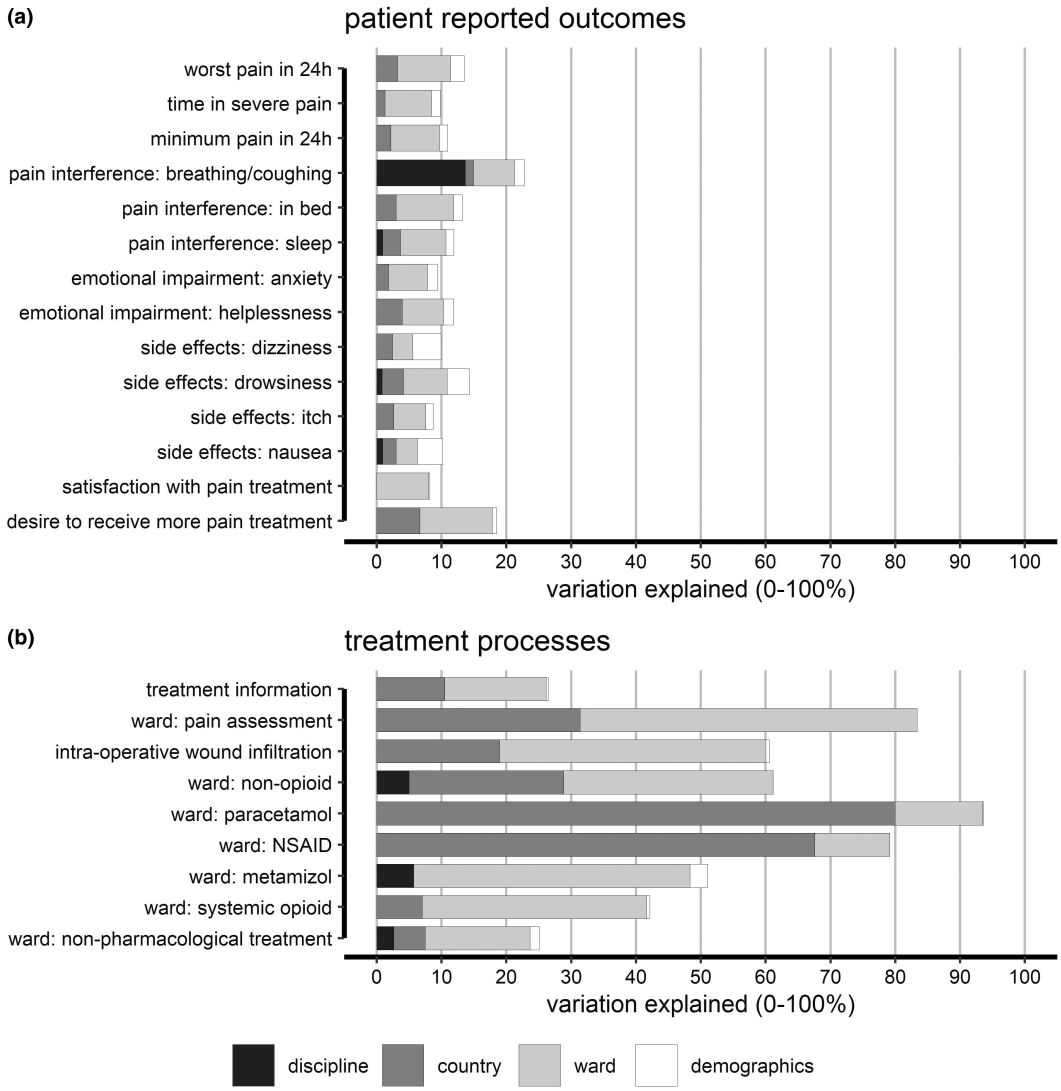

FIGURE 4 Explained variation in (a) patient reported outcomes and (b) and treatment processes. The proportions are shown for discipline (general surgery, orthopaedics and traumatology, obstetrics and gynaecology and urology), country ($n = 9$), participating wards ($n = 105$) and demographic variables (age, sex and pre-existing chronic pain).

from different cultures/ethnicities (Sharma et al., 2020). Consensus regarding the methodology for defining this variable is limited (Brady et al., 2016). For treatment processes, ward-specific effects accounted for the majority of the variance in most variables. This finding is useful for QI endeavours as care at the ward level is a factor that providers can change (Usichenko et al., 2013).

Thresholds have been recommended for evaluating care in individual patients, in clinical studies and as quality indicators (Serlin et al., 1995). Yet, they have generally been applied to one variable only, 'worst pain'. Using a data-driven technique, we extended the approach and determined specific thresholds for all the continuous PROs in the International Pain Outcomes questionnaire. Interestingly, results for the PROs were largely similar across the surgical disciplines, suggesting that pain intensity and interference measures were driven less by the surgical discipline and more by the management provided (Gerbershagen et al., 2013).

Strengths and limitations associated with this study

PAIN OUT is one of two active multi-centre perioperative pain registries known to us. QUIPS facilitates data collection within Germany (Meissner et al., 2008), whereas, PAIN OUT is international. A registry has a more or less fixed set of measures, allowing for standardized data collection in different settings. For evaluating quality of care, assessments carried out once for each patient are probably sufficient (Liu et al., 2006). Longitudinal evaluation, over days or months, aims to improve understanding of pain mechanisms. However, this complicates the study design and execution as patient identification is necessary, a practice that ethics committees are often reluctant to grant. Also, attrition of staff and patients can be considerable, leading to missing

data and reduced data quality (Houle et al., 2017). Thus, the current design facilitated obtaining findings from a large, international sample, who, otherwise, would not have participated in such an endeavour. We cannot exclude selection bias, as most collaborators came from teaching hospitals and were interested in QI. Thus, the findings might be indicative of practices where they are at their best. Sample sizes contributed by the different wards and countries varied. Yet, as the analysis was carried out at the ward-level, and findings relied on percentage of patients above thresholds for the PROs and for the dichotomized processes, the results are less affected by the sample size. Our cohort included middle and high-income countries. We did not evaluate whether this feature had bearing on findings, however, as 'country' explained a very small proportion of the variance, we assume that a country's economic level had little effect on outcomes. Evaluating effects of regional anaesthesia on outcomes is of interest; however, as this tends to be procedure-specific, it was not the focus of the current study, and will be addressed in future.

5 | CONCLUSION

We carried out a comprehensive study of 10,415 patients, from 10 countries, on the first post-operative day. A large proportion of patients reported severe pain and pain-related interference. PROs and care varied considerably between wards, with much of the contributing factors un-elucidated for the former and largely related to practices on the ward, for the latter. The findings obtained were used by teams for devising and implementing QI programmes in their hospitals. Future analysis of these findings will offer new insights as to which interventions proved useful. The current database serves as a reminder that quality of perioperative pain care, at the global level, is still lacking, urging stakeholders to continue striving to improve it.

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2. Pfizer Global Medical Grants provided two unrestricted educational grants to carry out pre- post- Quality Improvement (QI) studies in 10 hospitals in México (grant received February 2016) and in 10 hospitals in China (grant received December, 2017). Funding covered: [i] the cost of the annual subscription to PAIN OUT for hospitals over a 2-year period, [ii] travel so that the Principal Investigator and one research surveyor from each participating hospital could join two half day face-to-face meetings to review the findings and [iii] partial remuneration to hospitals for datasets collected. The manuscript here describes the first phase of these projects. The trial protocol, analysis plan, analysis itself or any drafts of the manuscript were not requested or sent prior to submission for publication to Pfizer Global Medical Grants.
3. Grünenthal GmbH, within the CHANGE PAIN® acute initiative, provided EFIC (European Pain Federation) funding to cover costs of QI projects in seven European countries, which included the: [i] annual subscription to PAIN OUT for hospitals over a 2-year period; [ii] two half day face-to-face meetings so that the Principal Investigator and one research surveyor from each hospital could review the findings and [iii] partial remuneration to hospitals for datasets collected. PAIN OUT received the funding in two instalments, August 2017 and June, 2018. The manuscript here describes the first phase of these projects. The analysis or any drafts of this manuscript were not requested or sent prior to submission for publication to Grünenthal GmbH.
4. EFIC provided funding from its own resources to cover costs of the project in Serbia. Funding included: [i] annual subscription to PAIN OUT for hospitals over a 2-year period; [ii] two half day face-to-face meetings so that the Principal Investigator and one research surveyor from each hospital could review the findings and [iii] partial remuneration to hospitals for datasets collected. The funds were transferred to the Serbian Pain Association, who then contacted each of the participating hospitals.

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CONFLICTS OF INTERESTS

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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