



# Improving perioperative pain management: a preintervention and postintervention study in 7 developing countries

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## Abstract

**Introduction:** The burden of untreated postoperative pain is high.

**Objective:** This study assessed feasibility of using quality improvement (QI) tools to improve management of perioperative pain in hospitals in multiple developing countries.

**Methods:** The International Pain Registry and Developing Countries working groups, from the International Association for the Study of Pain (IASP), sponsored the project and PAIN OUT, a QI and research network, coordinated it, and provided the research tools. The IASP published a call about the project on its website. Principal investigators (PIs) were responsible for implementing a preintervention and postintervention study in 1 to 2 surgical wards in their hospitals, and they were free to choose the QI intervention. Trained surveyors used standardized and validated web-based tools for collecting findings about perioperative pain management and patient reported outcomes (PROs). Four processes and PROs, independent of surgery type, assessed effectiveness of the interventions.

**Results:** Forty-three providers responded to the call; 13 applications were selected; and PIs from 8 hospitals, in 14 wards, in 7 countries, completed the study. Interventions focused on teaching providers about pain management. Processes improved in 35% and PROs in 37.5% of wards.

**Conclusions:** The project proved useful on multiple levels. It offered PIs a framework and tools to perform QI work and findings to present to colleagues and administration. Management practices and PROs improved on some wards. Interpretation of change proved complex, site-dependent, and related to multiple factors. PAIN OUT gained experience coordinating a multicentre, international QI project. The IASP promoted research, education, and QI work.

**Keywords:** Pain, Surgery, Quality improvement, Perioperative pain management

## 1. Introduction

Perioperative pain management is an important public health concern because, annually, approximately 240 million patients undergo major surgery worldwide,<sup>45</sup> and management of these patients' pain is often not optimal.<sup>2,13</sup> Specifically, a high proportion of patients report moderate to severe pain,<sup>14</sup> few report they obtained adequate relief,<sup>5</sup> the pain interferes with function, and variability in care is considerable.<sup>25,26</sup> Negative effects of postoperative pain include suffering,<sup>4</sup> diminished quality of life,<sup>41</sup> increased risk of complications developing in the immediate postoperative period, and of chronic pain in the months after surgery.<sup>23</sup> These findings are well documented for patients in developed countries.<sup>5,11,32</sup> The situation in developing countries is less well studied, but evidence indicates that the problems described in developed countries are mirrored and often compounded in developing countries because of the low priority given to management of pain and a general lack of resources such as personnel, medications, and equipment.<sup>8,43,48</sup>

Strategies used over the last 50 years to improve management of perioperative pain include the following: compiling evidence-

based clinical practice guidelines; establishing professional societies in pain; performing basic and clinical research; and training specialized teams to care for patients in pain such as Acute Pain Services.<sup>31,47</sup> However, these efforts have failed to yield widespread improvement for reasons common to other fields, namely that evidence and teaching do not, in themselves, change practice.<sup>12</sup> Additional hindrances to improvement are lack of consensus as to what constitutes quality perioperative care, making it challenging to determine objectives for change.

Resistance to change in perioperative pain practices motivated members of the International Association for the Study of Pain (IASP), specifically from the International Pain Registry (IPR) and Developing Countries Working Groups (WG), to seek a new approach for improving quality of care in patients after surgery. One mission of the IPR WG is to improve quality of perioperative pain management by creating a registry and using methods of Quality Improvement (QI) such as auditing, feedbacking, and benchmarking.

The objective of this study was to perform a pre-post intervention study in 1 to 2 surgical wards in up to ten hospitals

in developing countries, over a period of 12 months. We predicted that the intervention would improve one or more measurable outcomes of perioperative pain management and/or patient-reported outcomes (PROs). The project assessed the following aspects: (1) technical, whether such a project could be performed; and (2) clinical, whether treatment processes and/or PROs would change. This article describes findings from the project.

## 2. Methods

### 2.1. Participants

In 2013, the IASP posted a call on its website inviting providers from developing countries to apply for a project addressing quality of perioperative pain management. Principal investigators (PIs) could be anaesthesiologists, surgeons, or nurses caring for patients undergoing surgery. PAIN OUT took responsibility for overseeing the project, supporting PIs in implementing the project within their institution, and providing methodology for the project. PAIN OUT is an international, QI, and research network with a large registry focusing on perioperative pain management in the clinical routine.<sup>50</sup> The PAIN OUT methodology is registered with the U.S. National Library of Medicine (ClinicalTrials.gov), reference number NCT02083835. The IASP WG members supported PIs with advice about devising their interventions. All PIs obtained approval for collecting non-identified patient data from their local ethics committees. [(1) Prizen Regional Hospital: permission 7/23, Kosovo Ministry of Health. (2) Military Hospital, Serbia: permission MMA/11.12.2013. (3) Rahima Moosa Mother and Child Hospital:

protocol number M140153, University of Witwatersrand. (4) University College Hospital Ibadan: permission NHREC/05/01/2008a. (5) Hospital Kuala Lumpur: clearance number: 18852. Malaysian Research and Ethic Committee. (6) Cullion Sanitarium and General Hospital Philippines: permission CSGH 2015001. (7) Sir Run Run Shaw Hospital: Ethics Committee of Tongde Hospital of Zhejiang Province, Zhejiang Tongde permission [2018]006. (8) Zhujiang Hospital, Southern Medical University: permission number ZJYY-2014-HLB-001].

### 2.2. Study design

Each PI was responsible for implementing an uncontrolled pre-post study design in 1 or 2 wards in his/her hospital. Principal investigators were free to select the surgical discipline(s) where they would perform the project and the nature of the intervention. We expected that all the interventions would be based on evidence-based recommendations, used routinely for managing perioperative pain and tailored to local conditions.

The stages in the study would include the following:

- (1) Collecting baseline data consisting of PROs and process records (120 data sets/ward) over a 4-month period. We chose 120 data sets to assure sufficient statistical power for contrasts that we or the PIs would wish to make, based on the variability in data from previous studies in the PAIN OUT network;
- (2) Analysing the data and using findings as the basis for planning an intervention related to management of perioperative pain and implementing the intervention over a 2-month period;
- (3) Continuing to implement the intervention and collecting postintervention data, similar to baseline, over a 4-month period; and
- (4) Comparing the preintervention and postintervention findings and writing a report summarizing the project, over a 2-month period.

The IASP allocated funds, so that ten hospitals could participate in the project.

### 2.3. Measures for studying processes and outcomes of the interventions

Inclusion criteria required that the patient (1) was of consenting age, 18 years or older; (2) was on the first postoperative day (POD1) and back on the ward from the postanesthesia care unit for at least 6 hours; and (3) agreed to participate in the survey. Consent could be oral or written, depending on requirements of the local ethics committees.

Data collection for each patient involved the following:

- (1) Questionnaire assessing demographic and perioperative clinical data comprising variables such as patient sex, age (year of birth), analgesics administered perioperatively, type of surgery (using the International Classification of Disease procedure codes [ICD9]), method of anaesthesia, and whether there was a record of evaluating pain intensity in the patient's chart at least once since surgery. A study surveyor obtained this information from the medical record.
- (2) International Pain outcomes Questionnaire (IPO-Q)<sup>35</sup> consisting of 13 items evaluating 4 domains: (1) intensity of pain; (2) interference of pain with activities in and out of bed and with negative affect; (3) severity of 4 adverse effects associated with the anaesthesia and treatment with opioids; and (4) perception of care, which includes wish for more treatment for pain and receipt of information about pain treatment options. Patients assess most items using an 11-point numerical rating scale (NRS, 0 = no sensation, 10 = worst possible) and 3

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questions require dichotomous yes/no replies. Patients are asked to relate the outcomes questions with the time since their surgery. The IPO-Q is validated in English and has been translated into 19 languages.

#### 2.4. Data collection, management, and storage

Surveyors in each hospital undergo training for collecting data and approaching patients. This includes reading a manual, filling in a quiz, and submitting test data sets, which are audited for completeness and accuracy of data entry. Surveyors enter the data into a web-based, password secure portal. The Institute for Medical Informatics, Statistics, and Epidemiology at the University of Leipzig, Germany, hosts and maintains the PAIN OUT database.

#### 2.5. Approach chosen to assess impact of the intervention

We assessed the feasibility of using QI methods to change practices and PROs by addressing the following features:

##### 2.5.1. Technical

- (1) Number of providers applying to the IASP call for the research project;
- (2) Number of PIs that completed the administrative phase of joining PAIN OUT;
  - a. Ethics committees in some countries did not readily approve of projects whose sponsors were in a different country.
- (3) Number of hospitals that completed the program and within the designated timeframe; and
- (4) Missing data collected at baseline and postintervention for key variables.
  - a. Rate of missing variables is a marker for feasibility of data collection and less than 5% data loss is regarded as inconsequential for data analysis and concerns about bias.<sup>16</sup>

##### 2.5.2. Clinical

We wished to use a common framework for the evaluations, which would allow for the assessment of change in care across the different surgical specialties selected by the PIs, in the different wards.

For change in processes, we evaluated interventions that are recommended for most patients undergoing surgery as part of a multimodal analgesic regimen,<sup>5,36,37</sup> and thus, we regarded them as being largely independent of type of surgery. We assessed the proportion that care providers performed the following during the baseline-intervention vs postintervention phases: (1) assessment of pain; (2) providing information about pain treatment options [PAIN OUT lacks a process measure that records whether patients are provided with information about their pain treatment options. In this project, we used a surrogate measure in the form of a PRO, which asks patients whether they received information about their pain treatment options]; (3) infiltrating the surgical wound at the end of surgery; and (4) administering a nonopioid on the ward.

Change in PROs due to the multidimensional characteristic of pain, the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) group on the research design for clinical trials in acute pain recommend that studies should evaluate several outcome domains.<sup>6</sup> We thus, selected 1 PRO from each of the 4 domains in the IPO-Q and used a threshold above which clinical intervention is generally

recommended.<sup>27</sup> The domain-specific PRO and thresholds were (1) pain intensity: worst pain since surgery  $\geq 6/10$ ; (2) interference of pain with activities in bed (eg, sitting up or turning)  $\geq 4/10$ ; (3) adverse effect: nausea  $\geq 4/10$ ; and (4) perception of care: wish more treatment for pain = YES. We chose "worst pain" as this is the most commonly used item in studies of perioperative pain. Function is an important feature in recovery from surgery,<sup>22</sup> and so we wished to evaluate the degree that pain interfered with activity. Nausea is the most commonly reported adverse effect of the ones evaluated in PAIN OUT. "Wish for more pain treatment" is one measure of the extent patients feel that care is appropriate.<sup>38</sup> We determined the proportion of patients in each ward whose evaluations were above the thresholds in the baseline and postintervention phases.

##### 2.5.2.1. Qualitative assessment of the project once it was completed at each site

Principal Investigators filled in a questionnaire evaluating the usefulness of the project to the staff, both clinical and administrative, and patients, as well as barriers and challenges related to performing the project and whether they would wish to continue and upscale the project.

##### 2.5.2.2. Statistical analysis

Principal Investigators provided hospital-level information addressing hospital characteristics: type of hospital, teaching status, number of beds in the hospital, and nature of services for treating acute pain. This is a standard questionnaire that collaborators taking part in PAIN OUT complete.

We used Fisher's exact test (exact  $2 \times 2^{10}$ ), to compare the differences in the relative frequencies of each process and outcome variable between baseline and after the intervention. We assessed effect size using Cramer's  $V/\phi$  coefficient (Psych R-package<sup>33</sup>) with  $\phi$  coefficient = 0.5/0.3/0.1 and representing a large/medium/small effect, respectively. Effect size criteria are guides rather than absolutes, and interpreting the response requires personal judgment regarding the practical or clinical importance of the effect. As this is an exploratory study, we identified variables that demonstrated a small or larger size as indicating change between baseline and after the intervention. We considered  $P \leq 5\%$  as statistically significant with 2-tailed contrasts but relied on effect size for inference. For the analysis, we used R<sup>30</sup> and SPSS (Version 22, IBM). We relied on the SQUIRE 2.0 guidelines for writing this report.<sup>29</sup>

## 3. Results

### 3.1. Technical aspects of implementing the project

Forty-three providers responded to the call. Thirteen applications were selected by the IASP working groups. Three applicants were unable to complete the administrative process of joining the project. The Ministry of Health in one country and local ethics committee in another did not grant these applicants permission to participate in an international study. Two sites completed the necessary administrative steps to join the project but were unable to start collecting data, and they were replaced by another applicant.

Eight PIs completed the project between November 2013 and December 2015. They held senior positions in their hospitals and included 6 anaesthesiologists, 1 surgeon and 1 nurse from China (2 hospitals), Malaysia, Philippines, Serbia, Kosovo, South Africa, and Nigeria. Three of the 8 PIs completed the project within the planned schedule of 1 year. **Table 1** describes characteristics of

**Table 1****Characteristics of the hospitals, facilities for treating acute pain, and the principal investigators.**

Hospital	Hospital characteristics				Acute pain service				Principal investigator (PI)	
	Type	Teaching status	No. of beds	Dedicated nurse	% Position	Dedicated physician	% Position	Created local guidelines	Role of PI in the hospital	Discipline
1	Publicly funded	Non-university	<199	No		No		No	Chair of department	Anaesthesiology
2		University	≥1000	Yes	Full time	Yes	Full time	Yes	Director of APS	Anaesthesiology
3		University	800–999	No		No		No	Senior lecturer	Surgery
4		Non-university but teaches medical students	≥1000	Yes	Full time	No		Yes	Director of APS	Anaesthesiology
5		Non-university but teaches medical students	400–599	No		No		No	Chair of department	Anaesthesiology
6		University	>200–399	No		Yes	Full time	Yes	Head of clinical unit	Anaesthesiology
7		University	≥1000	No		No		No	Faculty member	Anaesthesiology
8		University	≥1000	No		Yes	Part time	Yes	Director of nursing	Nursing

participating hospitals, services for treating acute pain, and of the principal investigators.

Of the staff in 15 wards that collected data at baseline, staff in 14 wards were able to collect data after the intervention. At baseline, staff from 8 wards collected the required data sets, and after the intervention, it was from 5 wards. Staff on 2 wards collected a number of data sets far exceeding the recommended number. **Table 2** shows the number of data sets collected in the participating wards during the course of the project, and **Table 3** lists the variables and wards with missing records. Missing records for the individual wards can be found as supplementary material (available at <http://links.lww.com/PR9/A38>).

### 3.2. Clinical features of implementing the project

The types of interventions devised and implemented in each of the hospitals are outlined in **Table 4**. Teaching formed a major component of the intervention in all the hospitals but one. Most often, the teaching included both physicians and nurses; in 2 hospitals, the teaching involved nurses only. Four hospitals developed local protocols; one was able to establish an Acute Pain Service and another to receive additional resources for an existing Acute Pain Service. Principal Investigators used a variety of sources in developing their interventions, including consultants from high resource countries with which they had been collaborating for some years, the IASP working groups, PAIN OUT, and resources from their own hospital.

### 3.3. Process indicators

Across the 14 wards and 4 interventions, there were 56 potential episodes for change. Pain assessment and administration of nonopioids on the ward reached maximal performance at baseline in 8 wards. One of these wards obtained maximal performance for both indicators. In PAIN OUT, both these measures have limited sensitivity to detect change because they are dichotomous, and so the activity registers as having been performed even if it was performed only once rather than regularly, as is the intention of the recommendation.

Of the potential remaining 48 instances for improvement, there were 17 (35%) episodes of improvement, 22 (46%) of no change and

9 (19%) where the intervention was performed less frequently compared with baseline. The interventions that improved most often, in 5 wards, were receipt of information and wound infiltration, whereas pain assessment improved in 3 wards. Administration of nonopioids improved in 2 wards but was performed less frequently, compared with baseline, in 4 wards (**Table 5**).

### 3.4. Patient reported outcome indicators

Of the 56 potential episodes for change in a PRO, there were 21 (37.5%) episodes of improvement and 30 (53.6%) episodes in which the PROs did not change and 5 (9%) where a PRO worsened compared with baseline (**Table 5**). Wish for more treatment improved most often, in 7 wards, ie, fewer patients would have wished for more treatment for pain after the intervention compared with baseline. The proportion of patients reporting severe pain was smaller in 6 wards, and the extent that pain interfered with activities in bed and nausea improved in 4 wards. All 4 PROs improved in 2 wards in the same hospital, and 3 PROs improved in 1 ward and 2 in another ward in the same hospital.

### 3.5. Qualitative assessment of the project's effects

One PI reported that availability of quantitative findings from patients in his institution and presenting them to colleagues and the hospital administration served as a “wake up call,” an “eye opener,” allowing him to mobilize and engage colleagues from within his institution. The findings were also used to convince the hospital’s administration to provide resources for setting up an Acute Pain Service. The PI in another center also presented findings to his hospital administration and received funding to develop an electronic database for the Acute Pain Service and to recruit additional personnel. He plans to work at the provincial and national levels to create standards for treatment. Most PIs would choose to upscale the project to other wards in their hospital.

Two PIs described team-level factors in their hospitals.

#### 3.5.1. Hospital A

The PI, a clinician at the management level, reported being able to enlist collaboration from multidisciplinary providers, surgeons,



**Table 2**  
**Number of data sets collected in participating hospitals and wards during the 2 project phases.**

	Baseline, n = 15 wards	Postintervention, n = 14 wards
Hospital 1—ward 1	21	41
Hospital 1—ward 2	37	47
Hospital 2—ward 1	61	32
Hospital 2—ward 2	61	32
Hospital 3—ward 1	46	29
Hospital 4—ward 1	48	41
Hospital 4—ward 2	82	52
Hospital 5—ward 1	249	70
Hospital 5—ward 2	141	71
Hospital 6—ward 1	379	351
Hospital 6—ward 2	1337	1154
Hospital 7—ward 1	100	96
Hospital 7—ward 2	94	122
Hospital 8—ward 1	92	0
Hospital 8—ward 2	78	181
Total	2826	2319

anaesthesiologists, and nurses to implement change. It was the first time they were involved in a project of this format and so were eager to succeed and gain new skills. Baseline conditions were low. Structural changes were extensive, including teaching staff and patients, changing forms to allow for recording pain management routinely, changing treatment routines, and setting aside an area for recovery after surgery. This is one of the hospitals that completed the study within the designated 12 months. Two processes improved in each of the 2 participating wards, 1 worsened, 3 PROs improved in 1 ward, and 2 in another.

### 3.5.2. Hospital B

The PI was keen and enterprising but relatively junior who had a clear action plan in the form of creating a standardized order sheet for administering treatment after surgery. However, the PI

was unable to enlist collaboration from physician colleagues who were more senior and from nurses, who lacked sufficient support from management. Staff on the ward and at the managerial level expressed lack of interest in the project. Departmental heads delayed providing evaluations of the proposed intervention. Surgeons regarded filling in the standardized order as redundant and a waste of their time, saying that their focus was on managing the patients' surgical features of care and less on pain. Nurses did not cooperate with performing the recommendations written on the standardized order sheet. They considered the work as burdensome, adding to their existing workload and not being within their job description. Changes in small effect sizes took place. Surgeons on 1 of the 2 wards changed their practice to the extent that the proportion of patients receiving wound infiltration increased. Administration of nonopioids, in the second ward, increased, but report of receipt of information decreased. A PRO in each ward improved. Baseline performance for some treatment practices on these wards was good; they achieved maximal scores for assessment of pain at baseline; and nonopioids were given to a high proportion of patients.

### 3.6. Benefits of the project to individual researchers

Principal investigators presented findings for the work in their hospitals at scientific meetings. A nursing student submitted a master's thesis based on the work performed in her centre and published the findings in a peer-reviewed journal.<sup>7</sup> Work in another hospital served as the basis for a PI's Doctoral thesis.

## 4. Discussion

Our findings demonstrate that multidisciplinary providers, working in hospitals in developing countries, were able to perform work to improve care of perioperative pain in their institutions. The large number of applicants responding to the call for participation in the project suggests that providers in developing countries are interested in undertaking QI work. The project proved achievable but challenging. Although we had funding for ten hospitals, 8 completed the program. At baseline, staff from the 8 hospitals collected data from 15 wards, and after intervention, data collection continued in 14 of these wards. Interestingly, although local teams worked independently of one another, teaching staff about management of perioperative pain formed the major component of the intervention in all but one hospital.

The overall low rate of missing data records indicates that surveyors and patients in the different institutions were able to collect data and fill in the project questionnaires for the variables we analysed. This is consistent with findings in an earlier study where we examined missing scores for all variables in the process and IPO questionnaires.<sup>50</sup> Wound infiltration records were missing in 2 hospitals, for both treatment phases, indicating that recording this variable was challenging. Surgeons perform wound infiltration and document this in the surgical record. However, surveyors report that this information is not consistently available, even if the infiltration is performed. Missing records for age and surgical code indicate that surveyors in those wards may have required further training.

The field of perioperative pain management lacks consensus about quality indicators for assessing pain management, which treatment targets to aim for and how to analyse them.<sup>15,26</sup> Without such information, it is difficult to determine what the goals of an intervention should be and whether they have been achieved. We consequently selected 4 process and 4 PROs from the project questionnaires and cutoff levels for the PROs. As

**Table 3**  
**Wards with missing records for key variables.**

Variable	No. of wards with missing records	
	Baseline	Postintervention
Demographic/surgical code		
Gender	0	0
Age*	3	1
ICD-9 code	3	1
Processes		
Pain assessment†	3	3
Wound infiltration‡	4	3
Ward nonopioids	1	0
Patient-reported outcomes		
Worst pain	0	0
Interference in bed	1	0
Side-effect nausea	0	0
Wish more treatment	1	0
Received information	0	1

\* One of the wards has missings at baseline vs postintervention.

† Different wards.

‡ Three wards are the same.

**Table 4****Description of the intervention(s) performed in each of the participating hospitals.**

Hospital	Surgical discipline	Formal teaching		Creating and introducing local management protocols	Acute pain service
		Physicians	Nurses		
1	General Surgery & Obstetrics		+		
					& survey assessing knowledge & attitudes
2	Orthopedics & General Surgery	+	+	+	+
					Services expanded
3	Orthopedics	+	+		
4	General Surgery & Orthopedics	+	+	+	
					Standardized postoperative order sheet
5	General Surgery & Obstetrics	+	+	+	
6	Obstetrics & Gynaecology				+
					Introduced a physician-based 24-hour service available for consultation about complex patients
7	Orthopedics & Urology	+	+	+	
8	Orthopaedics (& General Surgery at baseline)		+	+	
					& survey assessing knowledge and attitudes

staff in each hospital worked independently, developing local change management programs, we endeavoured to provide each team with feedback for the interventions they performed. The format we used to present the findings was intended to be a simple, visual display of the changes in the process and PRO indicators. We aimed that this would facilitate identifying areas of practice strengths and weaknesses as well as benchmarks to provide direction for future practice change and improvement.<sup>46</sup> In future, we will perform work to validate whether these indicators or others are suited to follow-up practice change.

Interestingly, when PROs improved, they tended to cluster in the same ward and same hospital. Wound infiltration at the end of surgery was 1 of the 2 processes that changed the most. A PI attributed this change initially to teaching, and later, it was reinforced by the surgeons experiencing, first hand, that the intervention was effective in alleviating pain. By contrast, the frequency of administration of nonopioids on the ward decreased in 4 wards, and these were all wards where the proportion of wound infiltration increased. The PI attributed this to the wound infiltration being so effective, at least during the first hours after surgery, that surgeons may have regarded writing an order for nonopioids as unnecessary. Alternatively, nurses on the ward, finding the patients comfortable, may have decided that it was unnecessary to administer the nonopioids. However, as ratings of worst pain changed in only 2 of these 5 wards, it seems that the surgeons and/or nurses' observations did not align with the patients' reports.

After the intervention, the proportion of patients reporting they received information about their pain treatment options increased in 6 wards. It is possible that members of staff were more informed as a result of the teaching they received, and consequently, patients benefited from this. As shown by other studies,<sup>5,37</sup> staff education is an important component in improving patient outcomes. Findings from a large study including 138 hospitals and over 21,000 patients in Germany showed that informing patients about postoperative

management options demonstrated a consistent and positive effect on PROs.<sup>26</sup> Providing information about pain treatment options and involvement of patients in decisions about treatment were key predictors of patient satisfaction with postoperative pain therapy.<sup>38</sup> By contrast, it is not clear why the proportion of patients who reported receiving information was reduced in 4 wards in the second part of the study. Two indicators, assessment of pain and administration of nonopioids, demonstrated a ceiling effect in 7 wards. At present, we do not know whether this suggests good management, leaving little room for further improvement for these indicators on these wards or a limitation of the dichotomous method used in PAIN OUT for registering these variables. Our work<sup>50</sup> and other studies<sup>15,25,28</sup> suggest that there is little relationship between pain assessment and documentation as performed in the clinical routine and PROs, making this a weak quality indicator. However, it is possible that pain assessment in the clinical routine is not implemented as recommended by guidelines, eg, it is not followed up by treatment and/or reassessment. Further inspection of the data demonstrated that patients were not administered full doses of nonopioids, thereby, indicating that there is room to improve how this treatment process is performed.

#### 4.1. Impact of the project on people and systems

At the current stage of developing this change management program, we are unable to formally suggest which factors and conditions contributed to change, or lack of change, in the processes or PROs in the different hospitals or wards. A Cochrane review<sup>19</sup> found that QI projects using auditing and feedback (A&F) yielded a median 4.3% increase in provider compliance with practice recommendations (interquartile range: 0.5%–16%), indicating that the effect of A&F on professional behavior and on patient outcomes ranged from little or no effect to a substantial effect. Conditions in which A&F may be most

**Table 5**  
**Changes in the patient reported outcome and process indicators as a result of the project.**

	Hospital & wards	Patient reported outcome indicators					Processes indicators				
		Worst pain $\geq 6$ NRS	Interference in bed $\geq 4$ NRS	Nausea $\geq 4$ NRS	Wish more treatment	Number improvements /ward	Pain assessment	Treatment information	Wound infiltration	Non-opioids on ward	No. of improvements /ward
Hospital and ward level information	1—ward 1	Large	Medium	Medium	Large	4/4	Medium	Small	0	max	1/4
	1—ward 2	Small	Medium	Small	Large	4/4	Medium	0	0	max	1/4
	2—ward 1	Medium	0	0	Medium	2/4	max	Large	Medium	Small	2/4
	2—ward 2	0	Small	0	0		max	Large	0	max	
	3—ward 1	Small	0	Small	Small	1/4	0	Small	0	0	1/4
	4—ward 1	0	0	0	Small	1/4	max	0	Small	0	1/4
	4—ward 2	0	0	Small	0	1/4	max	Small	0	Small	1/4
	5—ward 1	Small	Small	0	Small	3/4	0	Medium	Large	0	2/4
	5—ward 2	Medium	0	0	Medium	2/4	0	Large	Large	Small	2/4
	6—ward 1	0	0	0	0		0	0	0	Small	
	6—ward 2	0	0	0	0		0	0	0	0	
	7—ward 1	0	0	0	Small		Small	Medium	Medium	Small	2/4
	7—ward 2	0	0	0	0		Large	Small	Large	Small	3/4
8—ward 1	Medium	Small	Small	Large	3/4	max	Large	0	0	1/4	
Summaries across the wards					Sum changes					Sum changes	
	Max at baseline					5	0	0	3	8	
	Improved	6	4	4	7	21/56	3	6	6	2	17/48
	No change	7	9	9	5	30/56	5	4	8	5	22/48
	Worsened	1	1	1	2	5/56	1	4	0	4	9/48

In the top part of the table, each row represents findings for 1 ward for the 4 outcome and process indicators and whether they changed from baseline to after implementation of the intervention. The background colour of the cell denotes the pattern of change, and the effect size of the change is listed for each variable.

A cell with a blue background denotes that the indicator changed in the expected direction, ie, improved from baseline to postintervention measurement.

"0" denotes no change in the indicator, and the background is coded in white.

A red background denotes that the performance of the indicator worsened during the 2 observations periods.

The shade of the background of the cell is light if the effect size is small and darker if the effect size is medium or large.

"max" denotes that the indicator was at maximal performance during both assessment periods.

The bottom part of the table summarizes the number of changes that occurred for the indicators across the wards.

effective include low baseline performance, when the person responsible for performing the A&F is a supervisor or colleague, if it is provided more than once, when it is given both verbally and in writing, and if it includes clear targets and an action plan. Whether A&F is more effective when combined with other interventions, such as teaching and reminders, is still uncertain.<sup>20</sup> Although A&F is a widely used QI approach in health care, there is still need to identify the key ingredients for successful A&F interventions and to understand the mechanisms of action of which lead to effective A&F interventions.<sup>9,24</sup>

Positive "organizational culture" is increasingly understood as fundamental to achieving high performance in health care settings,<sup>3</sup> although both culture and performance are challenging concepts to define, operationalize, and measure.<sup>39</sup> According to Vaughn et al.,<sup>42</sup> characteristics of high performing organizations include a positive organizational culture, in the form of norms, values, and basic assumptions of an organization, which embraces change. This flexibility may accelerate adoption of initiatives that improve care. In addition, in high performing organizations, change is led by committed individuals who support and respect employees. On the other hand, poor organizational culture is one factor leading to lack of change within health care organizations. PAIN OUT has not addressed organizational culture to date. It is possible that features of organizational culture facilitated the changes in some hospitals and wards and prevented them in others. Future projects within PAIN OUT may consider adopting methodology that would address this issue formally.

## 4.2. Comparison of results with findings from other publications

Medical faculty from high resource countries are increasingly involved in programs for teaching local physicians, residents, and allied personnel in developing countries and coupling this with QI projects.<sup>34,44</sup> PAIN OUT methodology has been used to perform single A&F projects in Kenya, Rwanda, and Gaza.<sup>49</sup> Our findings indicated the feasibility of data collection, but they also revealed some challenges. Staff whose pay is low were not keen to take on additional work without remuneration. Furthermore, costs of paper and ink on which to print questionnaire was covered, at times, out of pocket. Both factors restricted the scope of these audits and of implementing longer term QI projects. Funding for QI projects from either academic sources or from pharmaceutical companies is not readily available. The educational grant from the IASP, as a professional society, facilitated the current project.

## 4.3. Strengths of the project

Pain management and its outcomes are not typically assessed in the clinical routine.<sup>1,40</sup> Availability of the PAIN OUT platform for standardized collection of data made this possible. A review of interventions used to assess change in clinical practice found that 89% of trials used process outcomes, whereas less than a third measured whether the trial altered or did not alter patients' health status.<sup>21</sup> The current project measured processes but also PROs as indicators for change. Patient-reported outcomes are particularly important when evaluating pain because pain is a highly

individualized, subjective experience and processes are not necessarily reflected in a change in PROs.<sup>15,26</sup>

Commitment of the PIs was notable given that the project was performed on a low budget, and that PIs and their collaborators were required to volunteer their time in addition to their regular clinical duties. An additional challenge was that communication between staff in each hospital, and the sponsors was predominantly through email.

#### 4.4. Limitations, and efforts made to minimize and adjust the limitations

In this study, we used one of the most commonly used pre–post study designs, an uncontrolled before and after study or a quasiexperimental design.<sup>17</sup> This study design is often used where there are practical and ethical barriers to conducting randomized controlled trials.<sup>18</sup> This is a relatively simple study design to conduct and is superior to observational studies. However, it is a weak evaluative design, in that secular trends or sudden changes make it difficult to attribute the observed changes to the intervention. Furthermore, the intervention can be affected by confounders such as the Hawthorne effect (the nonspecific beneficial effect on performance of taking part in research), which, in turn, can lead to an overestimate of the effectiveness of an intervention. This was the first multicenter QI project coordinated by PAIN OUT. The experience gained indicates that we may need to improve the study design, and that we should continue to learn from other fields where improvement science is maturing as a field.<sup>20,24</sup>

Principal investigators and their teams resided in 7 countries, the geographical distance and differences in work culture meant that they were working independently and could not support each other. The study phases in most hospitals took longer than the planned 12 months. Both geographical distance and providing support are currently being addressed by designing projects where groups of up to ten hospitals from the same geographical region or country work together. The timeframe for the project has been increased, providing leeway to accommodate for unforeseen difficulties. In the course of the project, collaborators collected extensive data about perioperative treatments and patients' experiences of pain in the different hospitals, offering a unique opportunity to learn about a wide range of practice patterns and patient evaluations. We used only a fraction of the data collected in this current study, leaving further work for subsequent studies.

Sustainability of this project can be viewed on 3 levels. Some PIs expressed interest to continue with the project in other surgical wards at the hospital or regional level. For PAIN OUT, the project has led to establishing networks of hospitals, worldwide. The IASP was able to promote research, education, and QI.

#### Disclosures

The authors have no conflict of interest to declare.

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## Appendix A. Supplemental digital content

Supplemental digital content associated with this article can be found online at <http://links.lww.com/PR9/A38>.

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