Project protocol – general		
Title	PAIN OUT: an international quality improvement and research network for optimizing management of post-operative pain	
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Clinicaltrials.gov-identifier	NCT02083835	
Trial Design	Prospective, non-interventional / observational, cohort (= patients after surgery) study, multi-center.	
Background	A large body of evidence indicates that post-operative pain management is not optimal and that this is true worldwide. There is ample evidence from the literature that poorly managed pain impedes recovery, diminishes quality of life, causes needless suffering and can extend time of discharge from hospital [1]. Measuring quality of clinical decisions through audit and feedback (A&F) (assessing one's own performance over time) and benchmarking (comparing one's results with those of others) is widely used in medicine to change provider conduct and improve quality of care. A&F is based on the premise that professionals will modify their performance when they receive feedback that their practice is not in line with a desired target [2]. Tools facilitating standardized A&F in multiple institutions, internationally, might pave the way to improve outcomes related to management of pain after surgery. PAIN OUT is a web-based international registry providing clinicians with standardized and validated tools to carry out audit and to receive feedback of pain related outcomes in patients after surgery [3,4]. Clinicians receive immediate online feedback about summarized PROs. The project is modelled after Quality Improvement in Post-Operative Pain Management project (QUIPS). QUIPS has been operating in Germany under the auspices of the German Society of Anaesthesiology and Intensive Care Medicine (DGAI) since 2005. QUIPS currently registers data from 550,000 patients, recruited from 190 medical centres in Germany and Austria. QUIPS's success in providing clinicians with information about their practices and about PROs within Germany, led in 2009 to development of PAIN OUT (www.pain-out.eu), a project with a similar philosophy but carried out internationally and funded by the European Commission's FP7 framework program. PAIN OUT is carried out in Europe, USA, some sites in South East Asia and some countries in Africa.	
Objectives and significance of the study	(1) To assist clinicians improve management of perioperative pain of their patients by providing them with feedback (=information about their own patients and benchmarking (=comparison with similar patients in other hospitals) of pain-related patient reported outcomes and processes obtained during the perioperative period. (2) To carry out clinical studies using ones own data and / or data in the international database. The findings will be used to increase knowledge about post-surgical pain and its management. The study is significant as management of post-operative pain is not optimal, worldwide. PAIN OUT is unique in being an international quality improvement and research network of clinicians and researchers collaborating to provide patients with better care of pain related to surgery.	
Assessment Schedule	(1) Recruitment: before surgery OR on the first post-operative day (POD1). (2) Assessment of patient reported outcomes (patient) and clinical variables (abstracted from the patient's medical file): POD1	

Timetable/Trial Duration	For quality assessment: continuous collection of a minimum of approximately 60 datasets per ward per quarter is recommended.
Population	Adult patients (in most countries ≥ 18 years old) undergoing surgery.
Inclusion criteria	(1)Patient is on the first post-operative day AND back on the ward from surgery ≥ 6 hrs (2) Patient is of consenting age (3) Patient has given consent for participation in the survey. Consent can be oral or written, depending on requirements of the local ethics board.
Exclusion criteria	Patient does not give consent for reasons such as being : too ill OR too tired OR it is not possible to communicate with the patient for reasons such as deafness / cognitive impairment / a patient outcomes questionnaire is not available in a language that the patient knows.
Outcomes assessed	(i) Patient Reported Outcomes (PRO) are assessed in a questionnaire consisting of 13 questions, with additional sub-questions, relating to severity of pain; its interference with activities in and out of bed and on affect (anxiety and helplessness), adverse effects, whether the patient received information about management of pain, use or receipt of non-pharmacological treatment, existence of chronic pain before surgery and its severity [4]. • The questionnaire is written in the patient's native language. • Takes the patient 5 - 10 minutes to fill in. • Patients may receive help from the surveyor in filling in the questionnaire, if they request this. (ii) Demographics & clinical data include the patient's gender, age (in decades), language in which the questionnaire is fill in; country where the assessment takes place; type of surgery using ICD9 codes, type of anesthesia, analgesics given for pre-medication, intra-operatively, in recovery, on the ward. Blank fields can be used to collect data items which are specifically interesting to the local site. (iii) This information is abstracted by the surveyor from the medical record. PROs (i) are obligatory as they allow for screening the quality of pain management on the ward being assessed; items (ii) are optional, in the event that there is a shortage of staff for data collection. However, without this data it is difficult to evaluate which processes to change in the event that outcomes on the ward are not optimal
Collection of data	Surveyor(s) who are nurses, students (e.g. medical, nursing, or social sciences) or residents will collect the data. As much as is possible, the surveyor(s) should not have clinical duties on the ward being surveyed. This is aimed so that patients do not feel obliged to please the surveyor in the answers they provide when filling the patient reported outcomes questionnaire. Training for data collection consists of reviewing the PAIN OUT standard operating procedures, followed by a quiz. This requires approximately 3-4 hours. Once the quiz is successfully completed, surveyors are given access to the project's website and materials. They collect and input 10 datasets into the web-based mask, which are reviewed for completeness and accuracy by the project coordinators. After approval, surveyors can begin collecting data. Each PAIN OUT dataset (demographic and clinical variables and patient reported outcomes) takes approximately 20 minutes to collect and 5 minutes to enter the data into the web-based The demographic and clinical data can be inputted directly into the web-based mask using a tablet PC. This requires having WiFi on the ward where the data is collected.
Safety	This is an observational study; patients are not exposed to any risks.
Discontinuation Criteria	Patients may stop filling in the questionnaire at any point.
Sample Size, Estimation and Statistical Analysis	Collaborators are advised to collect a minimum of approximately 60 datasets per ward per quarter. A smaller number of datasets yields information that is not helpful for assessing management on a particular ward. Clinical users can access data from the repository either on- or off-line. Online analysis provides access to the patient reported outcomes, demographic variables and surgical procedure. This analysis is descriptive and is provided in a format of figures and tables, showing data from ones own site (identified) against the context of other wards in the same discipline (anonymized). This is chiefly intended for quality assurance. Offline analysis

	providers access to all the variables in the repository and is intended for research and in-depth analysis of the findings for quality assurance. Clinical users are able to download and carry out analysis of raw data collected in their site. They can submit requests to other collaborators to pool data from several centres and investigate a research question or topic related to quality assurance across centres.
Health Risks and Risk-Benefit-Analysis	This is an observational study - not relevant. Risk: Patients participating in the survey are not exposed to any risks. They spend a short time (5-10 minutes) being briefed about the survey and filling in the 13 questions in the patient outcomes questionnaire. Patients who are in too much pain or tired or feel otherwise unable to fill in the questionnaire independently can still participate, the surveyor may interview them and fill in the questionnaire Benefit: While patients themselves will probably not benefit directly from participating in the survey, the information they provide should help improve pain management of future patients admitted to wards participating in the survey.
Simultaneous enrolment in other trials:	Patients participating in this survey are not restricted from participating in other studies.

Flow Chart		
	Assessment before surgery or First post-operative day	**When relevant to the study Ambulatory surgery**
	At site	At site / at home
Subject Information.	X	X
Oral or written informed consent (determined by the local ethics committee).	X	X
Inclusion & exclusion criteria	X	X
Randomization (when necessary, see the project's Standardized Operating Procedures).	X	X
Assessment of pain related patient reported outcomes, demographics, type of surgery and peri-operative pain management.	X	X

References

(1) Brennan F, Carr DB, Cousins M. (2007). Pain management: a fundamental human right. Anesth Analg. 105, 205-21.
(2) Hysong SJ. Meta-analysis: audit and feedback features impact effectiveness on care quality. Med Care 2009; 47(3):356-63.
(3) Zaslansky R, Rothaug J, Chapman CR, Bäckström R, Brill S, Fletcher D, Fodor L, Gordon DB, Komann M, Konrad C, Leykin Y, Pogatski-Zahn E, Puig MM, Rawal N, Ullrich K, Volk T, Meissner W. PAIN OUT: the making of an international acute pain registry. Eur J Pain. 2015 Apr;19(4):490-502.
(4) Rothaug J, Zaslansky R, Schwenkglenks M, Komann M, Allvin R, Backström R, Brill S, Buchholz I, Engel C, Fletcher D, Fodor L, Funk P, Gerbershagen HJ, Gordon DB, Konrad C, Kopf A, Leykin Y, Pogatzki-Zahn E, Puig M, Rawal N, Taylor RS, Ullrich K, Volk T, Yahiaoui-Doktor M, Meissner W. Patients' perception of postoperative pain management: validation of the International Pain Outcomes (IPO) questionnaire. J Pain. 2013 Nov;14(11):1361-70.