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What can be done to improve management of perioperative pain?

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Approximately 232 million patients undergo major surgery worldwide, each year⁽¹⁾ and up to 80% of these patients will report pain of an intensity that is moderate to severe⁽²⁾. Specifically, approximately 185 million will people endure pain that will persist for days to weeks and months after surgery. Severe post-operative pain is not innocuous, it has documented harmful effects on short and long term recovery, affecting patients and sometimes also their families. As an example, after Caesarean Delivery, women with severe pain have a 2.5 to 3 fold increased risk of developing postpartum depression and persistent pain 8 weeks after surgery⁽³⁾. This in turn, may have a negative effect on the cognitive development of infants born to these mothers⁽⁴⁾. Pain degrades patient and family quality of life, increases health care utilization, and so drives up associated costs⁽⁵⁾. Severe pain is one of the most consistent risk factors for developing chronic post-surgical pain, occurring in 10% up to 50% of patients after surgery⁽⁶⁾. Of the known risk factors, pain is possibly one of the few factors that can be modified by healthcare providers. The literature describes large variability in patient care⁽⁷⁾, an indicator of poor practice⁽⁸⁾. These findings are well documented for patients in high resource countries, such as the United States⁽²⁾ and in Europe^(7,9). Garcia et al⁽¹⁰⁾ have written a comprehensive review about findings in Latin America, indicating that problems are similar to those found in other countries.

Healthcare providers, researchers and policy makers have made considerable efforts over the last 50 years to improve management of perioperative pain at local, national and international levels. Efforts include, among others, advocacy and policy making, creating tools for education, carrying out basic and clinical research leading to development of clinical practice guidelines and establishing structures within hospitals of specialized teams, such as Acute Pain Services. Yet, surveys conducted since the 1960s and until today show that post-operative pain remains under treated⁽⁹⁾. One of the multiple reasons for lack of change, could be that the field lacks methods to generate, evaluate and disseminate evidence about the management provided in the clinical routine and the associated outcomes. Furthermore, the field lacks consent on criteria as to what is defined as good quality care. Without clear and measurable targets, it is difficult for the multi-disciplinary teams caring for surgical patients to provide quality care. Barriers such as these served as incentives so that an international team of clinicians and researchers sought new approaches for improving

quality of care. These included creating a registry and using methods of Quality Improvement (QI).

The PAIN OUT perioperative pain registry (www.pain-out.eu) was established in 2009, with funding from the European Commission. The registry currently holds > 70,000 patient datasets, contributed by collaborators in 112 hospitals in 25 countries, in Europe, the Americas, Southeast Asia and Africa.

A patient registry is an organized system that uses observational study methods to collect uniform data to evaluate specified outcomes for a population defined by a particular disease, condition or exposure⁽¹¹⁾. In contrast to findings from Randomized Clinical Trials, registry information reflects management and outcomes from the clinical routine because it does not exclude difficult patients, those who are elderly or burdened with co-morbidities. Data from registries can be used for multiple purposes. This includes QI, advocacy and policy making. Registry data also provide opportunities for carrying out observational and clinical studies. It can serve as a platform for evaluating costs of services. Advances in computer technology and the internet in recent decades make it possible to share information between hospitals nationally and internationally. Healthcare organizations in the United States, Australia, Canada and European countries are increasingly using QI methods to work in a structured way to improve quality of care⁽¹²⁾. These methods, adapted from industry, aim to avert predictable human error, to eliminate unnecessary and harmful variations in practice, and to improve the production of goods and services. A basic premise of QI, is that 'if you do not measure it, you cannot improve it'⁽⁸⁾. The Structure-Process-Outcome model, first developed by Donabedian and later adopted by many investigators is a useful framework for measuring care. Structure is defined as the physical and organizational properties of the setting in which care is provided, e.g. availability of institutionalized policies and procedures or staff trained in pain management. Process refers to what is done for patients, e.g. whether pain was assessed or whether patients received non-steroidal anti-inflammatory medications. Outcomes relate to what is accomplished for patients, e.g. pain severity or pain interference; short and long-term side effects or complications. These dimensions can be measured from different perspectives, such as, healthcare providers and patients⁽¹³⁾.

In contrast to many QI initiatives which generally focus on evaluating structures and processes, the PAIN OUT platform evaluates all three dimensions of quality, with a focus on measuring patient reported outcomes (PROs). PROs are evaluated using the validated International Pain Outcomes questionnaire (IPO-Q), which patients fill in on the first day of surgery⁽¹⁴⁾. The IPO-Q has been translated into 20 languages,

allowing patients, in different countries, to use a standardized and common platform for evaluating their experience of pain after surgery. Patients evaluate their pain across four domains, its intensity, the extent it interferes with activity and with affect and evaluation of the care they received. Process data is collected by addressing the type of surgery the patient underwent, the form of anesthesia provided and which medications for pain were given perioperatively, up until the first day after surgery. Information about structure addresses issues such as the hospital type and its size. Once the data is collected, it is entered into a web-based mask and participants can receive information about the PROs using another QI tool, feedback and benchmarking. In PAIN OUT, feedback involves administering participants with summarized information about PROs from their patients. Benchmarking, compares findings from one's own patients with similar patients in other institutions. Recognizing that performance is not optimal can stimulate corrective action to reduce the discrepancy⁽¹⁵⁾.

In addition to evaluating care through feedback and benchmarking, the PAIN OUT registry offers participants opportunities to conduct epidemiological and clinical research at the single and multiple-center level. Landmark studies carried out to date, include the following. Schwenkglens et al⁽¹⁶⁾ found that three PROs explained over a third of the variance related to patient's satisfaction with pain treatment. These PROs were extent of pain relief, higher participation in decisions about pain treatment and no wish for further pain treatment. Gerbershagen et al⁽¹⁷⁾ evaluated postoperative pain scores in 50,523 patients and across 179 surgical groups, finding that pain scores were high in a large proportion of patients and generally worst in «minor» procedures, including appendectomy, cholecystectomy, hemorrhoidectomy, and tonsillectomy, possibly due to under-treatment with analgesics. Fletcher et al⁽¹⁸⁾ found that risk factors for developing chronic post-surgical pain included chronic pain before surgery, undergoing orthopedic surgery and the percentage of time in severe pain on the first day of surgery.

In recent years PAIN OUT has been working with hospitals to extend the QI tools used. We have added a pre- post-study design in which multidisciplinary teams of anesthesiologists, surgeons and nurses from several hospitals within the same country, work together in a structured way as a group, forming a 'network'. Staff collect data to establish a baseline from one to two wards in their hospital. This is followed by introducing an intervention for improving practice and then, once again, collecting data to evaluate the effect of the intervention on treatment processes and PROs. This cycle can be performed once or iteratively. To date, collaborators in PAIN OUT have completed such a cycle in two projects⁽¹⁹⁾, the second of which

took place in Mexico, funded by an unrestricted educational grant from the 'Global Independent Grant for Learning and Change' from Pfizer. Projects following a similar structure are currently under way in eight European countries, in China and several others will begin later in 2019.

In Mexico, the first project with PAIN OUT was carried out between July 2016 and December 2018. Locally, the project was led and coordinated by Dra. Ana Lilia Garduño López, Coordinator of the Acute Pain Service and Dr. Victor Manuel Acosta Nava, Director of the Department of Anesthesiology, at the Instituto Nacional de Ciencias Médicas y Nutrición «Salvador Zubirán» (INCMNSZ). An additional nine hospitals took part in this project.[‡] In total, 2,939 patients were recruited, including 1,643 patients from 18 wards, at baseline, and 1,296 patients, from 15 wards after the intervention. Both PROs and processes improved during the course of the project, principally, a significantly higher proportion of patients reported that they received information about their pain treatment options. This could be associated with teaching about pain and pain management practices forming a major component of the interventions across all centers, often including physicians, anesthesiologists and surgeons, and nurses. In some hospitals, collaborators developed and implemented clinical practice guidelines. Principal investigators reported that carrying out the surveys had been very useful, as it increased staff awareness about the importance of evaluating pain from the patient's perspective. Investigators noted, that initially, surgeons were not necessarily interested in taking part, but after receiving concrete information about their own patients, interest and involvement increased. Investigators learned to appreciate the key role of teaching about pain management and that setting up multi-disciplinary teams of anesthesiologists, surgeons, and nurses working together, is a prerequisite for this type of improvement work. Patients also provided feedback, reporting that they appreciated the attention and care they received.

An additional outcome of the work carried out by the Mexican PAIN OUT coordinators and network participants is creating a rich teaching and training resource about pain

management, directed at Mexican anesthesiologists. The current volume of *Revista Mexicana de Anestesiología* introduces guidelines and a new website to readers of this journal. The guidelines, derived from contemporary, international literature²⁰⁻²² have been translated into Spanish and aim to promote evidence-based, safe and effective perioperative pain management in Mexico. The guidelines include recommendations for assessing postoperative pain, monitoring patient's response to treatment and how to address an acute pain crisis in the postoperative setting. Additionally, they include patient- and condition- specific recommendations, for example how to manage pain in patients who are elderly, oncological, pregnant, with kidney disease. The website created by the Mexican PAIN OUT network (www.painoutmexico.com) includes links to diagrams for decision making in surgery-specific procedures, videos detailing treatment approaches such as the Patient-Controlled Analgesia and regional ultrasound guided blocks. We envisage that this information will help guide design of futures studies in Mexico related to perioperative pain management.

A follow up Global Independent Grant for Learning and Change from Pfizer, assures that PAIN OUT will continue with another phase of the project in Mexico, starting in mid 2019, and capably led, once again, by Dr. Ana Lilia Garduño López and Dr. Victor Manuel Acosta Nava. Some features of the study design will resemble the first round, with some hospitals continuing and new ones joining. Other features will be new, and will include patients assessing pain at time points in addition to the first post operative day, evaluation for better understanding of the processes that contribute to improved PROs, and discussion how to create sustainable improvement in perioperative care across hospitals in Mexico.

The work carried out so far in Mexico, demonstrates impressively that improvement in perioperative pain management is possible. The initiative should result in meaningful improvement in care for patients in Mexico. It also serves as a template of how to change and improve practices and care, internationally, thereby, propagating the efforts to reduce the burden of perioperative pain and improve outcomes for patients and their families.

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