

Estimated Number of Patients with Daily Chronic Pain

Francesco S*

Department of Emergency and Organ Transplantation, Assistant Professor of Veterinary Anaesthesia, University of Bari, Italy

Abstract

Careful consideration of how outliers will be defined is needed to avoid patient harm. Patient care should be based primarily on the clinical context and the patient-clinician interaction. Opioid stewardship programs can provide a holistic, efficient, comprehensive, multidisciplinary approach to address safer opioid prescribing within a health system, thus empowering cross-disciplinary collaboration and inclusion with the development of measures to guide implementation and successful efforts.

Keywords: Clinical context; Quality measures; Patient care; Regulatory changes; Therapeutic alternatives; Patient safety

Introduction

Quality measures should include function, QOL, and ADL. CMS is currently implementing sections of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act. The SUPPORT Act requires CMS to convene a technical expert panel; make recommendations regarding quality measures for opioids; identify outlier prescribers and furnish technical support regarding proper prescribing practices; and implement minimum standards for states' Drug Utilization Review programs regarding opioid prescribing, including safety edits on refills and daily dosage policies. It is essential to ensure that careful consideration of clinical context is always considered. Shortages of pharmacologic and biological products, including opioid and non-opioid analgesics, can have severe and immediate consequences for patient care. Appropriate treatment can be delayed or denied because of unavailability and, in other cases, result in the use of second-line, less effective alternatives [1]. Several underlying factors have contributed to national shortages, including manufacturing problems that affect the drug supply chain and quality control, as well as regulatory changes in response to the opioid overdose public health crisis. Tracking data from the FDA show that drug shortages peaked in 2011, with more than 250 new drug shortages, and although the number has steadily declined, 2017 saw 39 new shortages and a failure to adequately address existing shortages. Health care systems and providers, with clinical pharmacists, are responding to the drug shortages by identifying therapeutic alternatives and prioritizing supplies. Patient safety events namely, medication errors are more likely to occur during times of shortages because of the increased prescribing of less familiar pharmacologic agents. Use of compounded products or alternative preparations is a common underlying cause of errors. An investigation by the Institute for Safe Medication Practices into shortage-related patient safety events cited that use of an alternative drug or alternative dosage form/strength of a substitute drug accounted for up to 27% of reported harmful outcomes. Advance notice of shortages, communication and education, consultation with clinical pharmacists, and standardized management algorithms help mitigate the effects of drug shortages. For instance, a retrospective chart review of patients admitted to the pediatric intensive care unit during a 2011-2012 peak shortage of injectable benzodiazepines and fentanyl reported no significant increase in rates of prescribing error and adverse patient outcomes because of well-established guidelines for prioritized and alternative analgesic and sedative management protocols [2]. Current widespread shortages of several key parenteral opioids used for fast and reliable analgesic effects, including morphine, hydromorphone, and fentanyl, are affecting hospitals and

cancer centres nationwide, leading to compromised acute pain management in the critical care and postoperative settings. Morphine, hydro-morphone, and fentanyl are the most commonly used opioid injectables because of their fast and reliable analgesic effects and because they offer a viable option for patients unable to tolerate oral administration. Other potential analgesic shortages include the NSAIDs ketoprofen and ketorolac tromethamine, methocarbamol, methadone, promethazine, and remifentanyl [3]. In July 2018, the FDA established the Agency Drug Shortages Task Force, charged with identifying the causes of medication shortages and proposing solutions. The results will be summarized in a report to Congress, informed by input from the pharmaceutical and health care industries, patient representatives, the FDA's federal partners, and Congress. Patients with complex and persistent pain often experience barriers to care related to non-existent or insufficient insurance coverage and reimbursement for evidence-based medical, behavioural, and complementary pain management services [4]. Although the HHS National Pain Strategy calls for greater coverage for pain management services, there is a lack of uniformity in insurance coverage and lack of coverage alignment with current practice guidelines for pain management. This is particularly true for nonpharmacologic280 and behavioural health interventions. The process for determining insurance coverage for pain management services is lengthy and complex, often requiring product testing, assessment against evidence-based protocols, determination of medical necessity, evidence-based coverage determination processes, and review by physician networks and stakeholders. Moreover, there is substantial variability in the availability and structure of guidance regarding the data needed to qualify for coverage provided to developers working on innovative non-pharmacologic treatments [5]. For example, CMS uses national coverage determinations (NCDs) to determine whether to cover a particular item or service. In the absence of a national coverage policy, an item or service may be covered at the discretion of the Medicare contractors based on a local coverage determination. Such practice leads to variation in coverage of items and

***Corresponding author:** Francesco S, Department of Emergency and Organ Transplantation, Assistant Professor of Veterinary Anaesthesia, University of Bari, Italy, Tel: 039063900, E-mail: franstafferi@tin.it

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services that can affect medical care. In addition, CMS requires testing of products in the Medicare-aged population for NCDs. Guidance to medication and product developers working on alternatives to opioids and opioid-sparing technologies; procedures concerning data needed to qualify for CMS coverage determinations; and innovation payments under CMS programs, especially for Medicare-eligible Americans in pain, are limited to basic statutory language [6]. In contrast, the FDA provides extensive guidance on data needed to qualify for labelling for products like abuse deterrent medicines. The inconsistencies in insurance policies, the variability in guidance regarding coverage determinations, and the variability in utilization management tools that coverage providers use can cause delays in service delivery, provision of inadequate treatment, and added financial and psychosocial burden for patients with pain. Requiring patients and health care professionals to navigate burdensome and variable coverage policies may contribute to slow development, adoption, and implementation of timely and effective pain treatments and may force providers to treat patients in a less-than-optimal fashion. Consistently forcing providers to try a series of non-first-line treatments prior to authorizing treatment plans can be problematic, hindering appropriate patient care, creating tremendous inefficiency, and resulting in a loss of time and resources [7]. This situation is problematic when patients change insurance coverage, requiring a new set of preauthorization rules to be followed and potentially leading to delays in critical, on-going treatment. Reimburse complex opioid and non-opioid management consistent with the time and resources required for patient education; safe evaluation; risk assessment; re-evaluation; and integration of alternative, non-opioid modalities. CMS and private payers should investigate and implement innovative payment models that recognize and reimburse holistic, integrated, multimodal pain management, including behavioural health. Many pain-related payer guidelines are outdated with respect to current clinical practice guidelines [8]. CMS and private payers should align their reimbursement guidelines for acute and chronic multidisciplinary pain management with current CPGs. Pain management specialists possess expertise and are specially trained in the evaluation, diagnosis, and treatment of acute and chronic pain.468 Because of an inadequate number of specialized pain physicians, PCPs are tasked with managing the majority of patients with painful conditions, often without adequate time and resources.469 This indicates the need for an increase in the pain specialist workforce to support PCPs while also ensuring that specialists and PCPs have adequate time, incentives, and resources to manage patients with painful conditions. Likewise, access to behavioural pain management is limited because financial incentives are lacking for psychologists and other providers to specialize in pain. Many insurance programs do not reimburse for behavioural pain treatments, or they reimburse at a much lower rate than for pharmacologic or interventional treatments. Because of the lack of incentives, not enough providers are trained in behavioural pain management. Taken together, the severe shortage of pain medicine specialists and under-resourced and insufficiently trained PCPs treating pain along with insufficient access to behavioural therapists, pharmacists, and other members of the pain management team has hindered the development of efficient, cost-effective health care delivery models to treat chronic pain. Research is fundamental to advancing both the understanding and treatment of acute and chronic pain [9]. The NIH Help to End Addiction Long-term (HEAL) initiative is a trans-NIH effort to improve prevention and treatment strategies for opioid misuse and addiction and to enhance pain management. Resources include governance and guidance as well as research and funding opportunities. NIH launched the Acute to Chronic Pain

Signatures program to investigate the biological characteristics underlying the transition from acute to chronic pain and to look at mechanisms that make some people susceptible and others resilient to the development of chronic pain. New knowledge development is needed in various areas of pain research, with emphasis placed on molecular and cellular mechanisms of pain, the genetics of pain, bio-behavioural pain, and preclinical models of pain. Supporting research initiatives throughout these fields across the basic science, translational, and clinical research arenas will aid in addressing current research gaps. This will lead to understanding the mechanisms of pain and SUD, translating promising advancements into effective therapies, and identifying best practices to implement in the management of acute and chronic pain [10]. As novel and proven treatment options emerge to improve acute pain and specific chronic pain conditions, they should be rapidly incorporated. Incentives for innovations in the treatment of chronic and acute pain are necessary for the advancement of treatment.

Conclusion

Support public-private partnerships for improved funding to support and accelerate basic science, translational, and clinical research of pain and implementation research in health care systems. Allocate funding to develop innovative therapies and build research capabilities for better clinical outcomes tracking and evidence gathering. There is a lack of understanding of contributing factors that predispose certain patients to SUD and addiction. There is a lack of research on and funding of potentially innovative modes of health care delivery and treatment.

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Conflict of Interest

None.

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