coronary artery bypass grafting: results from the Stent or Surgery (SoS) trial. *Circulation* 2004;**110**:3411–7.
43. Hlatky MA, Bacon C, Boothroyd D, et al. Cognitive function 5 years after randomization to coronary angioplasty or coronary artery bypass graft surgery. *Circulation* 1997;**96**. II-11–14.
44. Avidan MS, Evers AS. The fallacy of persistent postoperative cognitive decline. *Anesthesiology* 2016;**124**:255–8.

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"Pain as the fifth vital sign" and dependence on the "numerical pain scale" is being abandoned in the US: Why?

N. Levy*, J. Sturgess and P. Mills

Department of Anaesthesia and Perioperative Medicine, West Suffolk NHS Foundation Trust, Suffolk, UK

*Corresponding author. E-mail: Nicholas.levy@wsh.nhs.uk.

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In an effort to reduce the burden of under assessment and inadequate treatment of pain, the American Pain Society (APS) in 1996 instituted the "pain as the 5th vital sign" campaign based on quality improvement guidelines published the previous year.[1] The aim of the campaign was to make pain assessment and measurement as important a measure of patient wellbeing as the existing four vital signs. The campaign was initially widely supported by many medical societies, regulatory organisations and pharmaceutical companies,[2–4] and was later adopted in the UK.[5] The APS guidelines suggested that pain should be recorded in a way that makes it highly visible and facilitates regular review by members of the health care team, and recommended use of unidimensional pain scales to record and chart pain intensity. In addition, it was suggested that elevated pain scores should act as a "red flag" to promote action.[1] Examples of recommended scales included the numeric rating scale (NRS), which is also known as the numerical pain scale (NPS); the visual analogue scale (VAS); and the categorical 4 point verbal rating scale (VRS). The NRS is the most commonly used pain scale, and patients are asked to rate their pain on a 0–10 scale. The VAS utilises a similar concept with patients marking a point on a 10 cm line. The categorical 4 point VRS involves asking the patient to state the severity of pain as none; mild; moderate, or severe.[6,7] Over the past 20 years many US healthcare institutions adopted pain as the 5th vital sign, and assessed pain using the self-reported unidimensional NPS.

The United States Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey, used by the Centers for Medicare and Medicaid Services (CMS), is a patient satisfaction survey that facilitates reimbursement for US healthcare providers. The survey includes the question "How often did the hospital or provider do everything in their power to control your pain?" It has been suggested that this question embedded pain as the 5th vital sign in US healthcare, but also had the unintended consequence of encouraging opioid administration in response to patients' self-reported numerical pain scores.[8] As a result, it has been suggested that the "pain as the 5th vital sign" campaign with its reliance on the NPS directly contributed to the prescribed opioid epidemic that America is now experiencing.[2–4] Subsequently, the American Medical Association, the American College of Surgeons, The Joint Commission, The American Academy of Family Physicians, and the Centers for Medicare and Medicaid services have all withdrawn their advocacy of the "pain as the 5th vital sign" campaign.

Prescribed opioid addiction in the US

Opioid misuse is now seen as a major health epidemic in the US, with social, medical and financial consequences.[9,10] In 2016, it was estimated that the combined economic effect of the opioid epidemic (health care, labour, and criminal justice costs) was $92 billion.[9] Not surprisingly, there is now a presidential commission to combat the opioid drug addiction crisis. For many years it was believed that the risk of addiction to opioids prescribed for pain was rare.[2,11] There are currently an estimated 2 million US residents aged 12 and older who are addicted to prescription opioids.[9] That the risk of developing addiction to opioids prescribed for acute pain management was rare was not only erroneous but in part propagated by pharmaceutical companies.[2,12] In 2007, three drug company executives pleaded guilty to federal criminal charges that they misled regulators, doctors, and patients about the risk of addiction associated with prescribed opioids.[12] There have been at least 600,000 deaths in the US from prescribed opioids, and another 180,000 more are predicted by 2020.[9,10]

Numerical pain scale used alone is misleading

Unidimensional self-reported pain scores have been implicated in contributing to the prescribed opioid epidemic and is associated with over-sedation. One US hospital reported that following introduction of treating pain according to a

numerical pain treatment algorithm the incidence of opioid over-sedation adverse drug reactions per 100,000 inpatient hospital days increased from 11.0 to 24.5.[13] Many researchers have not been able to demonstrate improved pain treatment or better pain outcome by measuring pain as the 5th vital sign using numerical pain scores.[14,15] As a result there is a movement within the US to abolish pain scores as a surrogate outcome measure of good care, and to stop the exclusive use of unidimensional pain assessment tools, as well as ending the direct relationship between provider reimbursement and patient self-reports of pain control[3,4,8,9,16–18]

The Joint Commission, which acts as the regulatory body for many US healthcare institutions, now recognises there is a direct link between healthcare policies, the numerical pain scale, pain expectations and opioid addiction.[17] In an effort to mitigate against the harm from prescribed opioid addition The Joint Commission has developed 19 different "elements of performance" (EPs) that accredited hospitals will need to comply with by January 2018. To support this transformation of services they have published a detailed R[3] (Requirement, Rationale, Reference) manual to support each EP.[18]

Element of Performance 7 states that "*using numerical pain scales (NPS) alone to monitor patients' pain is inadequate*" and "*stresses the importance of assessing how pain affects function and the ability to make progress towards treatment goals*." They give the example of major abdominal surgery, and suggest that "*immediately after surgery the goal of pain control may be the patient's ability to take a breath without excessive pain. Over the next few days, the goal of pain control may be the ability to sit up in bed or walk to the bathroom without limitation due to pain*".[18]

Other pain assessment tools

In 2016, the American Pain Society published authoritative guidelines on the management of postoperative pain and whilst they strongly recommend the use of validated scoring systems such as NRS, VRS, VAS and the faces rating scales, they acknowledge that the evidence surrounding their use is weak.[7] In addition to the validated scoring system, they propose that there should be 7 further elements to pain assessment, in effect promoting a pain conversation based around the following questions:

1. Onset and pattern (When did the pain start? How often does it occur? Has its intensity changed?)
2. Location (Where is the pain? Is it local to the incisional site, referred, or elsewhere?)
3. Quality of pain (What does the pain feel like?)
4. Aggravating and relieving factors; What makes the pain better or worse?
5. Previous treatment (What types of treatment have been effective or ineffective in the past to relieve the pain?)
6. Effect (How does the pain affect physical function, emotional distress, and sleep?)
7. Whether there are barriers to pain assessment (eg cultural or language barriers, cognitive barriers, misconceptions about interventions).[7]

Clinicians dealing with patients in chronic pain clinics have sufficient time to use multi-dimensional pain scores that integrate functional activity and pain that allow the analgesia to be titrated to pain and function.[6] However, none of these tools have been validated in assessing acute postoperative pain in busy time-pressured surgical wards, and may be too unwieldy for the members of the ward healthcare staff to reliably use.

The functional activity scale (FAS) is a novel development that builds on the rationale of the dynamic pain score.[6,19] The functional activity scale is a simple three level ranked categorical score applied at the point of care. It is used to assess whether the patient's pain is sufficiently controlled to enable them to undertake appropriate activity for their surgery and premorbid state. The FAS is recorded as:

A. No limitation: the patient is able to undertake the activity without limitation due to pain;
B. Mild limitation: the patient is able to undertake the activity, but experiences moderate to severe pain;
C. Significant limitation: the patient is unable to complete the activity due to pain, or pain treatment-related adverse effects.

Pain interventions are instituted to facilitate function, rather than empirical treatment of a self-reported pain score. The FAS score has not been independently validated but it is sufficiently brief to allow its adoption into routine clinical practice and has the potential to help rationalise the inappropriate use of analgesic interventions by promoting goal-directed pain control.[6,19]

Dreaming

Dreaming is the concept of providing optimal perioperative pain management that promotes drinking, eating and mobilisation(i.e. function), and is considered a prerequisite to enhancing recovery after surgery.[20] A recently published editorial by Joshi and colleagues highlights that despite the well documented benefits, postoperative pain continues to be inadequately treated.[21] Furthermore, rather than simply using opioids as the backbone of multimodal analgesia, Joshi and colleagues argue that procedure-specific postoperative pain management (PROSPECT) utilising local anaesthetic techniques should be utilised when and where possible, based on the following benefits:

1. reduces the burden of untreated pain
2. promotes drinking, eating and mobilisation (function)
3. reduces perioperative use of opioids (and consequently associated opioid side-effects including delirium, hallucinations, sedation, dizziness, nausea, vomiting, reduced gastric emptying, constipation, tolerance, respiratory depression, hyperalgesia and dependence).

Deprescribing and safe opioid disposal

The risk of prescribed opioid addiction following surgery in the US in previously opioid-naive surgical patients may be as high as 1 in 16.[22] Deprescribing is the concept of weaning/tapering of medicines once there is no clinical benefit. Anaesthetists should provide education to all patients on how to taper/deprescribe their analgesics after hospital admission.[7,23]

It is acknowledged that opioid diversion is major cause of opioid dependency.[10] Opioid diversion occurs when people use prescribed opioids that were initially intended for someone else; justifiably The Joint Commission now demands processes for safe disposal of unwanted and expired medication.[18]

Implications for the UK

Prescriptions in the UK for opioids have increased by 400% in the past decade.[24] In 2012, the UK was the largest consumer of

opioids within Europe, with over ten million people prescribed an opioid. France was the next biggest user with 4 million people prescribed opioids. In 2015, it was estimated that almost 1 million people in the UK were dependant on codeine-containing analgesics.[25] This dramatic escalation in opioid use may be due to the increase in chronic pain states. However, like in the US, where 1 in 16 opioid naïve surgical patients subsequently become dependent on prescribed opioids, it is possible (and probable) that opioids commenced in the post-operative period were not discontinued.

It is now time for the anaesthetic community within the UK to re-evaluate our reliance on self-reported unidimensional pain intensity scores in our management of postoperative pain, and to be judicious in both prescribing and deprescribing of opioids.[26] We too must implement processes to ensure safe disposal of unwanted and expired opioids in the community to avoid opioid diversion. In addition, authoritative UK literature that states prescribed opioid dependency is rare must now be reconsidered, for example the British National Formulary (BNF) still espouses the concept that opioid dependency is "rarely a problem with therapeutic use."[27] Clinical anaesthesia needs to focus on the development and the adoption of effective procedure-specific analgesic strategies that promote drinking, eating and mobilisation (function) while reducing the risk of opioid dependence, as well as the validation of postoperative pain assessment tools that promote function without predisposing to opioid dependency.

Author's contributions

NL, JS and PM worked together to draft, produced and approved the manuscript.

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References

1. American Pain Society Quality of Care Committee. Quality improvement guidelines for the treatment of acute pain and cancer pain. *JAMA* 1995;**274**:1874–80.
2. Becker WC, Fiellin DA. Limited evidence, faulty reasoning, and potential for a global opioid crisis. *BMJ* 2017;**358**:j3115.
3. CNN. Opioid history: from 'wonder drug' to abuse epidemic. Published October 2016. Available from: http://edition.cnn.com/2016/05/12/health/opioid-addiction-history/ (Accessed 23 October 2017)
4. Mandell BF. The fifth vital sign: a complex story of politics and patient care. *Cleveland Clinic Journal of Medicine* 2016;**83**:400.
5. Faculty of Pain Medicine of the Royal College of Anaesthetists. Core Standards for Pain Management Services in the UK (CSPMS UK). Published October 2015. Available from: https://www.rcoa.ac.uk/system/files/CSPMS-UK-2015-v2-white.pdf (Accessed 23 October 2017)
6. Schug SA, Palmer GM, Scott DA, Hallivell R, Trinca J. Acute Pain Management: Scientific Evidence.4th ed. Melbourne: ANZCA and FPM; 2015. Working Group of the Australian and New Zealand College of Anaesthetists and Faculty of Pain Medicine. Available from: http://fpm.anzca.edu.au/documents/apmse4_2015_final (Accessed 23 October 2017)
7. Roger CD, Gordon D, Oscar A, et al. Guidelines on the Management of Postoperative Pain: A Clinical Practice Guideline From the American Pain Society, the American Society of Regional Anesthesia and Pain Medicine, and the American Society of Anesthesiologists' Committee on regional Anesthesia, Executive Committee, and Administrative Council. *The Journal of Pain* 2016;**17**:131–57.
8. Adams J, Bledsoe GH, Armstrong JH. Are pain management questions in patient satisfaction surveys driving the opioid epidemic? *Am J Public Health* 2016;**106**:985–6.
9. Gostin LO, Hodge JG, Noe SA. Reframing the opioid epidemic as a national emergency. *JAMA* August 23, 2017. http://dx.doi.org/10.1001/jama.2017.13358. Published online.
10. Kharasch ED, Brunt LM. Perioperative opioids and public health. *Anesthesiology* 2016;**124**:960–5.
11. Leung PT, Macdonald EM, Stanbrook MB, Dhalla IA, Juurlink DN. A 1980 letter on the risk of opioid addiction. *New England Journal of Medicine* 2017;**376**:2194–5.
12. Griffin OH, Miller BL. OxyContin and a regulation deficiency of the pharmaceutical industry: rethinking state-corporate crime. *Critical Criminology* 2011;**19**:213–26.
13. Vila Jr H, Smith RA, Augustyniak MJ, et al. The efficacy and safety of pain management before and after implementation of hospital-wide pain management standards: is patient safety compromised by treatment based solely on numerical pain ratings? *Anesth Analg* 2005;**101**:474–80.
14. Mularski RA, White-Chu F, Overbay D. Measuring pain as the 5th vital sign does not improve quality of pain management. *Journal of General Internal Medicine* 2006;**21**:607–12.
15. Zaslansky R, Rothaug J, Chapman CR, et al. PAIN OUT: the making of an international acute pain registry. *European Journal of Pain* 2015;**19**:490–502.
16. Centers for Medicare and Medicaid services. CMS finalizes hospital outpatient prospective payment system changes to better support hospitals and physicians and improve patient care. Published November 2016. Available from: https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2016-Press-releases-items/2016-11-01.html (Accessed 23 October 2017)
17. The Joint commission's pain standards: origins and evolution. Published May 2017. Available from: https://www.jointcommission.org/assets/1/6/Pain_Std_History_Web_Version_05122017.pdf (Accessed 23 October 2017)
18. The Joint Commission. *R3 Report Issue 11: pain assessment and management standards for hospitals*. August 2017. Available from: https://www.jointcommission.org/r3_issue_11/ (Accessed 23 October 2017)
19. Scott DA, McDonald WM. Assessment, measurement and history. In: Macintyre PE, Rowbotham D, Walker S, editors. *Clinical Pain Management: Acute Pain*. 2nd ed. London: Hodder Arnold; 2008.
20. Levy N, Mills P, Mythen M. Is the pursuit of DREAMing (drinking, eating and mobilising) the ultimate goal of anaesthesia? *Anaesthesia* 2016;**71**:1008–12.
21. Joshi GP, Kehlet H, Beloeil H, et al. Guidelines for perioperative pain management: need for re-evaluation. *British Journal of Anaesthesia* 2017;**119**:703–6.

22. Brummett CM, Waljee JF, Goesling J, et al. New Persistent Opioid Use After Minor and Major Surgical Procedures in US Adults. *JAMA Surgery* 2017, e170504.
23. Hermanowski J, Levy N, Mills P, Penfold N. Deprescribing: implications for the anaesthetist. *Anaesthesia* 2017;**72**:565–9.
24. Shapiro H, Daly M. Highways and buyways: a snapshot of UK drug scenes 2016. Published 2017. Available from: http://www.drugwise.org.uk/wp-content/uploads/Highwaysandbyways.pdf (Accessed 23 October 2017)
25. Shapiro H. *Opioid painkiller dependency(OPD). A report written for the All-Party Parliamentary Group on Prescribed Medicine Dependency*. 2015. Available from: http://www.drugwise.org.uk/wp-content/uploads/opioid_painkiller_dependency_final_report_sept_201.pdf (Accessed 23 October 2017)
26. Martinez V, Beloeil H, Marret E, Fletcher D, Ravaud P, Trinquart L. Non-opioid analgesics in adults after major surgery: systematic review with network meta-analysis of randomized trials. *Br J Anaesth* 2017;**118**:22–31.
27. Pain. Joint Formulary Committee. In: *British National Formulary*. 74 ed. London: BMJ Group and Pharmaceutical Press; 2017. p. 421.

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How to prevent medication errors in the operating room? Take away the human factor

R. S. Litman[1,2]

[1]Institute for Safe Medication Practices, Horsham, PA, USA and [2]Department of Anaesthesiology and Critical Care, The Children's Hospital of Philadelphia, Philadelphia, PA, USA

E-mail: litmanr@email.chop.edu.

In this modern era of unprecedented safety in anaesthesia, it is difficult to believe that accidental administration of the wrong medication can occur and seriously injure or even kill a patient. Just ask Dale and Gary Micalizzi (The Letter that Took Me Ten Years to Write… http://justinhope.tumblr.com/post/10380571733/the-letter-that-took-me-ten-years-to-write), whose healthy 11-yr-old son Justin underwent drainage of an ankle abscess under general anaesthesia. In a child such as Justin, the chance of a serious adverse event caused by a mistake in anaesthetic management is infinitesimally low. 'It's safer than driving to the hospital' is an often-heard phrase in the preoperative waiting room. Indeed, this may be true. However, Justin was the unheard-of statistic. Instead of administering ondansetron, Justin's anaesthesiologist accidently administered concentrated phenylephrine. The 1-ml vials look very similar and were located near each other in the anaesthesia drug tray. Ondansetron does not need to be diluted out of the vial, but phenylephrine requires a 100-fold dilution before administration. When Justin's anaesthesiologist accidently selected the wrong vial, he unknowingly administered a 100-fold overdose of phenylephrine. Justin developed severe hypertension, which led to a fatal heart arrhythmia.

We would all like to believe that these accidental mix-ups are rare, but in this issue of *British Journal of Anaesthesia*, Gariel and colleagues[1] present evidence of a higher incidence (2.6%) of perioperative medication errors than previously reported in paediatric anaesthesia. Perhaps it was because the study targeted paediatric patients, where weight-based calculations may predispose to dosing mistakes,[2,3] which represented their largest category of errors. However, we cannot ignore the fact that the operating room is one of the only areas of medicine where the provider prescribes, prepares, and administers each medication, often without the assistance of a second provider, without electronic clinical decision support, and sometimes under stressful or chaotic conditions. These factors combine to result in a variety of different mechanisms for drug error, and the potential for more dangerous outcomes.[4,5]

In the operating room, there are two mechanistic opportunities for error during the drug administration process. The first opportunity presents itself during preparation of the medication syringe from the drug's vial or ampule. During this process, it is possible to accidently choose the wrong vial (i.e. phenylephrine is chosen instead of ondansetron) or the unintended concentration of the correct medication (i.e. lidocaine 2% instead of lidocaine 1%). These errors are more likely when drug containers look similar or are situated near each other in the anaesthesia drug tray. The second opportunity for error is when the anaesthesia provider accidently chooses the wrong syringe (i.e. succinylcholine is given instead of neostigmine), a process referred to as 'syringe swap'. If operating theatres have not been equipped with the means to avoid these errors, patients have no choice but to rely solely on the anaesthesiologist's mental focus and vigilance to get it right, each and every time.[6] Of course, that is impossible because human errors are inevitable and arguably normal. Therefore, medication errors that result from human error are also normal. To quote safety expert Sydney Dekker, adverse medication events are 'baked into the very fabric of delivering assorted compositions of volumes, and weights, and rates of substances through various means'.[7] Therefore, systems must be engineered to bypass human factors to prevent the error from ever occurring.