

## **A Better Way to Deliver Oral PRN Pain Medications – The MOD<sup>®</sup> Oral PCA Device Offers a More Frequent Dosing Interval Alternative versus Traditional Administration**

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The electronic MOD (Medication on Demand) device uses bedside technology for better pain management and patient-centered care. The device allows patient access to a single dose of oral pain medication following each prescribed minimal time interval between doses. The radiofrequency identification (RFID) wristband, programmed for the patient's exclusive device, provides secure access to each dose of medication. To obtain medication, the patient must record the level of pain from 0 to 10 to activate the device recognition of the unique RFID wristband. The device then responds by presenting a single dose of medication. The device memory stores the date, time, and pain score for each administered dose of medication. Data can be obtained regardless of the hospital's level of technology integration, and ultimately, as the technology evolves, the data can be directly forwarded to the patient's electronic medical record.

Effective pain management is a crucial factor in the recovery of patients who experience pain during the hospital stay. Poor pain control interferes with sleep, appetite, morale, physical therapy, and motivation for recovery (1,2). Pain control after discharge and the induction of chronic pain is influenced by how well pain is managed during the acute injury phase in surgical patients (3,4,5). In spite of this realization, as recently as 2009, patients reported that their pain was well controlled only 68% of the time when using traditional pain control procedures during their hospital stay. CMS-mandated data, called HCAHPS, is online and listed for individual hospital by ZIP code and includes pain control statistics for a given facility. It provides transparent data for consumers and identifies areas for improved quality care that impacts patient outcomes; see [www.hospitalcompare.hhs.gov](http://www.hospitalcompare.hhs.gov) (6).

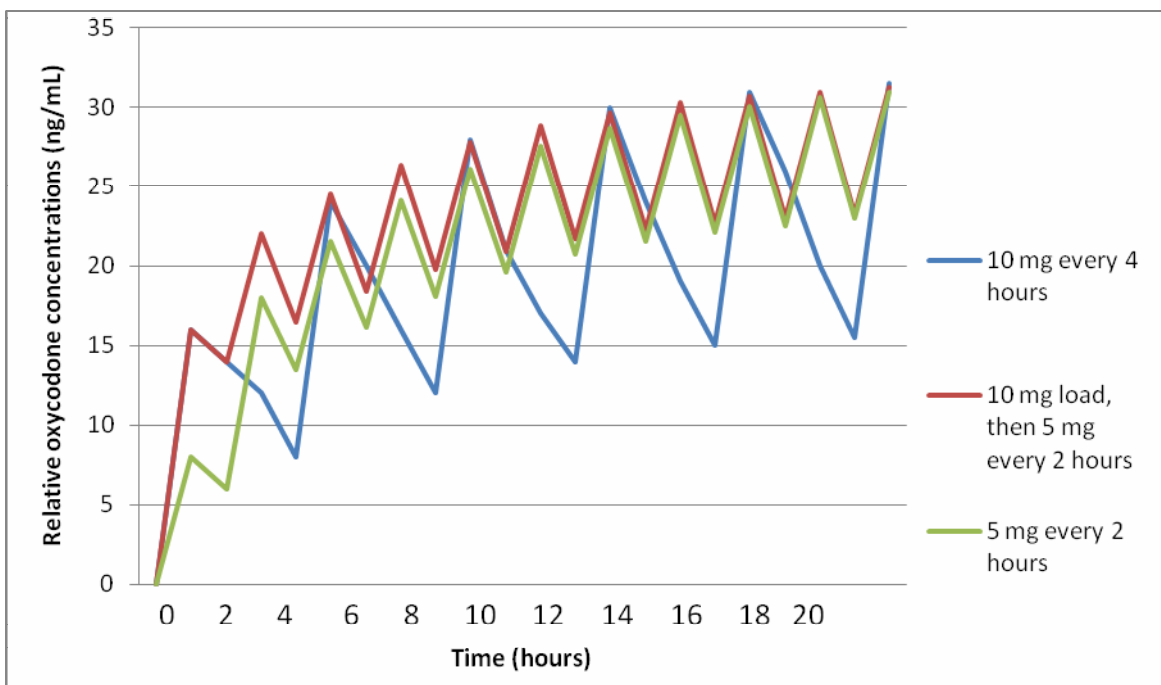
Minimally invasive surgical procedures using robotics and laparoscopy have shortened the hospital stay for many patients (7). Targeted nerve blocks in orthopedic surgery have reduced the need and duration of intravenous opioids post-operatively with a more rapid transition to oral pain management (8,9). Several surgical specialties are reporting earlier oral medications and nutrition replacing the traditional approach of waiting for bowel resuscitation, thereby producing shorter hospital stays (10,11,12).

Since prn oral pain medications are starting earlier in the hospital stay for many patients, increasing their overall use, the burden upon nursing staff to administer these medications encumbers a significant portion of nurse shift time. The nurse is also required to obtain a pain score for each delivered dose and return for a pain reassessment within a specified time interval following medication administration. Although the intent of these tasks is to improve patient pain management, these added duties repeated multiple times during each shift are an inefficient use of nursing time that could be used for more direct, thoughtful patient care. For instance, if a nurse is responsible for six post-operative orthopedic patients during a 12-hour shift and these patients have a pain medication ordered every 3-4 hours as needed for pain, the nurse could spend two hours or more during the shift on oral pain medications alone (13). A study in 2008 by the American Academy of Nursing Workforce Commission on inefficiencies of nursing care concluded that only the adoption of new technology by highly trained nurses will enable better patient care (14). The MOD is an example of new technology to create a more efficient use of nursing time while improving pain management and patient satisfaction.

The manual delivery of prn oral pain medications can only realistically be accomplished on an every 3-4 hour basis with traditional nursing workflows. A four hour time interval between doses creates an initial high plasma drug peak for analgesia followed by a steep trough at the four-hour mark. A patient whose plasma drug concentration falls below steady state often asks for pain medication sooner than the ordered time between doses. When the required time interval has been reached and patients request their medication, the delivery is often further delayed by busy nursing staff or unanswered pages to physicians for an earlier dose. This not only compromises pain management; it also compounds the frustration and anxiety patients experience while waiting for on-demand delivery of oral immediate-release pain medication.

Patients in two Florida hospitals were enrolled in an IRB-approved nurse-blinded pilot study to measure the wait time experienced after requesting prn oral pain medications (15). Following informed consent, they were given a card to record the time of request and the level of pain at medication request on a scale of 1-10. Once the nurse delivered the pain medication and left the room, patients recorded the time of delivery, pain score at the time of delivery, and if the nurse scored their pain. The mean wait time for all patients (n=28) was 18.6 minutes according to patient data and 19.2 minutes according to nursing chart data. (range: 4 minutes-109 minutes) Five patients (19%) recorded wait times of 30 minutes or longer. Of those five patients, four recorded a higher pain scale at the time of medication delivery as compared to the score at the time of the request. Forty-one percent of the time, the nurse did not obtain a pain scale at the time of the medication delivery.

A more efficient method for the delivery of oral pain medications in hospitals would improve patient pain management and patient satisfaction and save nursing time. An advantage of the use of the MOD electronic device is the ability to allow more frequent patient dosing as compared to a traditional 3-4 hour interval used for the manual delivery of medications. A comparison of these two approaches for maintaining peak plasma analgesic levels would be the use of oral oxycodone given in the traditional every 4-hour route prn as compared to a 2-hour prn dosing interval using the MOD.



**Figure 1 – Depiction of plasma levels of oral oxycodone immediate release**

Oral oxycodone is used as an example for dose rate comparisons as it is the most commonly prescribed prn pain medication in cancer patients (16) and a frequent choice for oral pain medication following inpatient surgical procedures (8,17). A recent study reported the plasma half-life of oxycodone after oral administration from 3 to 6 hours with an average of  $4.8 \pm .03$  hours, depending upon the age of the individual from ages 20 to 90 years (18). The time to peak analgesic effect is 30 to 60 minutes with a one-compartment or first-order kinetic linear rate of elimination from the plasma (19,20,21). A linear assumption model in Figure 1 shows the relative relationship between various dosing regimens given at specific intervals using published data to demonstrate the expected approximate plasma concentrations of total plasma oxycodone in ng/ml (18).

Figure 1 reveals the sharp peaks and troughs when oxycodone 10 mg is administered every 4 hours prn. Clinically, this results in good initial analgesia with a rapid fall off to subtherapeutic levels by the end of 4 hours. However with an oral loading dose of 10 mg followed by an allowed 5 mg every two hours, plasma levels rise rapidly and appear to remain in the therapeutic range a larger percentage of time due to the increased frequency of dosing. This approach more closely mimics an intravenous administration and a closer approximation to the steady state without the deep peaks and troughs seen with less frequent dosing. A 2-hour dosing interval would be impossible with the manual delivery of medication by nursing staff, but the use of the MOD device at the bedside enables the patient to obtain the medication on time more frequently. The total amount of medication used would likely be the same since, at the end of each 4-hour period, the patient is allowed to take a total of 10 mg of oxycodone. This principle would apply to any oral pain medication dosing regimen comparing the traditional time interval between doses to the 2-hour time interval with the MOD device.

The use of the MOD device also removes the need for “range orders” since a single dose of pain medication is allowed more frequently. This eliminates the need for nursing to decide whether to allow one or two doses of medication pursuant to the patient report which is not always well communicated. Data comparing patient satisfaction with the MOD approach as compared to the usual procedure for the delivery of oral pain medication appears to verify these assumptions (22,23). An ongoing study in progress will provide additional sufficient data to validate this assumption with statistical significance.

## References

1. McMain L. Pain management in recovery. *J. Perioper Pract.* 20: 59-65, 2010.
2. Samarae A, Rhind G, Saleh U, Bhattacharya V. Factors contributing to poor post-operative abdominal pain management in adults patients: a review. *Surgeon.* 8:151-158, 2010.
3. Peters ML, Sommer M, Kleef MV, Marcus MA. Predictors of physical and emotional recovery 6 and 12 months after surgery. *Br J. Surg.* August 24, 2010. (Epub ahead of print)
4. Zaslansky R, Chapman R, Rothaug J, Meissner W. PAIN-OUT: An international acute pain registry. *International Association for the Study of Pain Newsletter*, June/July 2010, pp. 7-9. See [www.pain-out.eu](http://www.pain-out.eu).
5. Reuben SS. Chronic pain after surgery: What can we do to prevent it. *Curr Pain Headache Rep.* 11: 5-13, 2007.
6. Giordano LA, Elliott MN, Goldstein E, Lehrman WG, Sencer PA.. Development, implementation, and public reporting of the HCAHPS survey. *Med Care Res Rev.* 67:27-37, 2010.
7. Amodeo A, Linares Quevedo A, Joseph JV, Belgrano E, Patel HR. Robotic laparoscopic surgery: cost and training. *Minerva Urol Nefrol* 61: 121-128, 2009.
8. Krych AJ, Horlocker TT, Hebl JR, Pagnano MW. Contemporary pain management strategies for minimally invasive total knee arthroplasty. *Instr Course Lect.* 59: 99-109, 2010.

9. Hogan MV, Grant RE, Lee L. Analgesia for total hip and knee arthroplasty: a review of lumbar plexus, femoral and sciatic nerve blocks. *Am J Orthop.* 38: E129-133, 2009.
10. Andersen HK, Lewis SJ, Thomas S. Early enteral nutrition within 24h of colorectal surgery versus later commencement of feeding for postoperative complications. *Cochrane Database Syst Rev.* 4: CD004080, 2006.
11. Davis KM, Esposito MA, Meyer BA. Oral analgesia compared with intravenous patient-controlled analgesia for pain after cesarean delivery: a randomized controlled trial, *Am J Obstet Gynecol* 184: 967-971, 2006.
12. Pearl ML, McCauley DL, Thompson J, Mahler L, Valea FA, Chalas E. A randomized controlled trial of early oral analgesia in gynecologic oncology patients undergoing intrabdominal surgery, *Obstet. Gynecol.* 99: 704-708, 2002.
13. Unpublished data from Phase I Clinical Trial MOD-04. Determining the time it takes for a single nurse to manually deliver one dose of oral pain medication, document the delivery, do a pain reassessment, and document the results on an orthopedic post-operative unit at the U. of Pittsburgh Medical Center. Time is 10.9 minutes, minimum time 2.77 minutes and maximum time 33.0 minutes in preparation for publication.
14. Bolton LB, Gassert CA, Cipriano PF. Smart Technology, Enduring Solutions, Technology Solutions Can Make Nursing Safer and More Efficient. *J Healthcare Information Management,* 22: 24-30, 2008.
15. Clinical Trial Protocol: MOD-02. Evaluation of time requirements and pain scale variation for conventional PRN Oral Pain Medication Delivery by Blinded Nursing Staff in Florida Hospitals. Unpublished data. Study Sponsor: Avancen MOD Corporation, 2006-2007. Data available upon request.
16. Rosati J, Thomas C, Buffington N, Conley S. The most frequently used oral breakthrough pain medication in oncology. *J. Supportive Oncology,* 4:443,2006.
17. Hohwu L, Akre O, Bergenwald L, Tornblom M, Gustafsson O. Oral oxycodone hydrochloride versus epidural anesthesia for pain control after radical retropubic prostatectomy. *Scan J Urol Nephrol.* 40: 192-197, 2006.
18. Liukas A, Kuusniemi K, Aantaa R, Virolainen P, Neuvonen M, Neuvonen PJ, Olkkola KT. Plasma concentrations of oral oxycodone are greatly increased in the elderly, *Nature* 84:462-466, 2008.
19. Staahl C, Upton R, Foster DJ, Christrup LL, Kristensen K, Hansen SH, Arendt-Nielsen L, Drewes AM. Pharmacokinetic-pharmacodynamic modeling of morphine and oxycodone concentrations and analgesis effect in a multimodal experimental pain model. *J Clin Pharmacol.* 48: 619-631, 2008.
20. Trescot AM, Sukdeb D, Lee M, Hansen H. Opioid pharmacology. *Pain Physician* 11: S133-S153, 2008.
21. Brunton L, Lazo J, Parker K. Goodman & Gilman's *The Pharmacological Basis of Therapeutics*, Chapter 1, Pharmacokinetics and Pharmacodynamics; the dynamics of drug absorption, distribution, action and elimination p 1-40, McGraw Hill, NYC, NY. 11th Edition, 2006.
22. Rosati J, Gallagher M, Shook B, Luwisch E, Favis G, Deveras R, Sorathia A, Conley S. Evaluation of an oral patient-controlled analgesia device for pain management In oncology inpatients. *Supportive Oncology,* 5:443-448, 2007.
23. Ongoing clinical trials in individual hospitals using a 2-hour lockout with the MOD device.