

Optimizing Institutional Care of Implantable Intrathecal Drug Delivery Systems

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Abstract: Intrathecal drug delivery systems (IDDS) have been a valuable therapeutic modality in the treatment of intractable chronic pain, typically reserved for cases where conservative pain management has failed. Given the high risk of this treatment and infrequent encounters with IDDS, it is essential to develop an institutional process to ensure the safe and effective management of patients. Our multidisciplinary team utilized healthcare failure mode and effects analysis (HFMEA™) to identify risks and redundancies in our current processes, subsequently implementing changes to prevent them. Risks identified included: handwritten orders, no standard order set, manual drug calculations, poor identification of IDDS upon hospital admission, and scarce nursing documentation of intrathecal medication. Following this step, our team incorporated tools and technologies to manage the more complex IDDS patients: standard order sets, computerized physician order entry (CPOE) systems, and computerized clinical decision support (CCDS) systems. Also, an excel calculator was introduced—seemingly the first of its kind in clinical practice—thus making the process more unique, thorough, and safe. There is a large body of evidence supporting the use of computerized physician order entry systems (CPOE) to reduce medication errors, and providing access to a computerized clinical decision support system (CDDS) at the time of prescribing to improve outcomes in patient care. Incorporating these tools into the management of IDDS patients is a significant opportunity to reduce risks and improve patient outcomes.

Keywords: Intrathecal, Pain Management, Quality Improvement, HFMEA

1. Introduction

Long-term management of chronic pain remains a significant challenge as the efficacy of oral analgesics (the typical treatment option) diminishes over time and patients build up a tolerance. Strategies to overcome this phenomenon include higher doses of oral medication, opioid rotation, and opioid holidays. Despite these strategies, 10%-30% of patients taking oral analgesics fail to obtain adequate analgesia levels [1]. Pain management has advanced dramatically, with the advent of new medications and new technologies all focused on improving the balance of pain control while preventing medication-related toxicity. As

such, intrathecal drug delivery systems (IDDS) have been a valuable therapeutic modality in treating intractable chronic pain.

IDDS is often reserved for cases in which conservative pain management has failed [2]. While IDDS is not considered the first line of therapy in treating refractory pain conditions, it is quite effective at relieving pain and restoring quality of life. In fact, IDDS usage continues to grow with the evidence regarding criteria for patient selection, trialing methods, and initial starting doses of applied drugs. However, there is limited guidance around the operational issues required to perform successful IDDS treatments, such as solution preparation, pump implantation, and resolving pump malfunctions.

As implantable IDDS continues to evolve in clinical practice, it is important to establish standards to ensure the safe and effective management of patients who require these systems. In addition, at large hospitals and academic centers—where patients are often seen by multiple specialties—it is essential to standardize the ways in which patients gain access to these systems. Specifically, it is vital to understand pump function and to safely manage intrathecal infusions as mismanagement of pumps can expose patients to significant complications and even death. Patient safety depends on establishing a standard and collaborative process across medical centers.

This paper outlines institutional best practices in implementing intrathecal drug delivery systems, specifically the use of healthcare failure mode effect analysis (HFMEA™) to improve the process of ordering, preparing, communicating, and managing IDDS in inpatient hospital settings. Its design represents a unique process of intrathecal drug delivery dose automatic calculation and complete integration with electronic medical record.

2. Methods

This project received a formal determination of quality improvement status according to the University of Chicago Medicine institutional policy. The project was deemed non-human subject research and therefore not evaluated by the Institutional Review Board. The revised Standards for Quality Improvement Reporting Excellence (SQUIRE 2.0) provided a framework for reporting and development of this manuscript [3].

HFMEA is a prospective assessment that identifies and improves steps in a process, thereby reasonably ensuring a safe and clinically desirable outcome [4]. It is a systematic approach to identifying and preventing product and process problems before they occur. HFMEA points out system and/or process vulnerabilities within a five step process: define the topic, assemble the team, describe the method (graphically), conduct hazard analyses, and identify/measure potential actions and outcomes.

In our case, HFMEA focused on identifying causes of undesirable patient outcomes and gaps in practices that could prevent negative effects in patients with IDDS. The HFMEA team consisted of pain physicians from anesthesia departments, pharmacists, and nurses. The team used flow charts to describe the current process for each clinical scenario, including: intrathecal medication trials, IDDS

implantations, IDDS refills, and identification of IDDS patients at the point of hospital admittance. This step was followed by a hazard analysis to identify failure modes, determine their severity and probability, and ascertain their causes. Next the team decided whether to accept, eliminate, or control the causes for failure and created an action plan for each failure mode, identifying ways to control or eliminate each failure. After completing the HFMEA process and analysis, the team employed the Institute for Healthcare Improvement's plan-do-study-act (PDSA) methodology to develop a standard process for managing patients with intrathecal pumps at hospital admittance.

3. Results

The team identified several areas of vulnerabilities within the IDDS process and developed risk-mitigation standards for these areas. The results are organized into six categories: 1) intrathecal medication trialing, 2) IDDS order development, 3) IDDS calculation process development, 4) IDDS order set development, 5) IDDS identified upon admission, and 6) IDDS nursing documentation.

3.1. Intrathecal Medication Trialing

Intrathecal medication trialing is often performed on patients for whom IDDS has been identified as a potential treatment option by a board-certified pain physician. Once eligibility criteria are met, an intrathecal catheter is placed in the patient under fluoroscopic guidance in the pain clinic. Medication trials occur on hospital wards with all patients admitted for 24-48 hours either directly to Acute Pain Service (APS) or to a variety of primary services with APS on consult to manage the catheter infusion titration.

The HFMEA process identified two areas of failure: 1.) admission notification when patient was not admitted to APS service, and 2.) APS documentation in electronic medical records. There was no established process for patient coordination between APS and primary service in regards to managing the intrathecal catheter, including expectations, side effects and monitoring. The second area of failure was delay in APS documentation as the pain service was not promptly notified when it was *not* the admitting service. The solution: The team developed a standard workflow for patients admitted for intrathecal medication trialing that requires notifying APS regardless of the admitting service (table 1).

Table 1. Workflow for starting inpatient intrathecal medication trial with 2 possible scenarios: (1) acute pain service (APS) is the admitting service and (2) APS is not the admitting service.

Intrathecal medication trialing admission	
Primary service is admitting service	APS is admitting service
1. APS notified via text page when patient arrives on floor	1. APS notified after the catheter is placed
2. APS manages intrathecal medication trial process	2. APS manages intrathecal medication trial
3. APS notifies pharmacy of intrathecal medication trial order	3. APS notifies pharmacy intrathecal medication trial order
4. APS documents initiation, change, and stop of intrathecal medication	4. APS documents initiation, change, and stop of intrathecal medication

3.2. IDDS Order Development

The next step was to create a process for ordering the pain solution to be administered intrathecally either through the external pump (trial) or the implanted reservoir. The HFMEA team identified a few failure mode causes within the current process, including risk of transcription error due to handwritten orders, non-standard medication records, and a confusing process for order modifications.

3.2.1. Handwritten Orders

Historically, upon patient admission, APS submits IDDS orders to the pharmacy on a handwritten order form for processing and preparation; the pharmacy creates, then, a custom medication record in the electronic health record. The handwritten order varied based on provider preference and this lack in consistency presented a risk for error. To eliminate risks in the process, the team developed a standard

template for handwritten orders, the team developed standard medication records and created a standard template was created for handwritten orders which included: drug concentration or dose per day, standardization of units (mg/ml, etc.), total volume, and initial rate. In addition, the team mandated the removal of trailing zeros (1.0 vs 1) and the incorporation of leading zeros (.1 vs 0.1).

3.2.2. Nonstandard Medication Records

The team first identified the medication combinations to be utilized in the IDDS solutions, and then built six standard medication records based on the opioid component (fentanyl, hydromorphone, morphine) for both trialing and pump fill orders during device implantation. These records allowed for additional medication components, such as local anesthetic (bupivacaine) and/or clonidine (Figure 1).

Order: **HYDRomorphine intrathecal pump with additives [179463732]**

Ordered Dose: **50.85 mg** Route: **Intrathecal** Frequency: **CONTINUOUS @ 0.0819 mL/hr**

Dose Calculation Information:
 50.85 mg × 1 mL/10 mg
 = 5.09 mL × 10 mg/mL (rounded to the nearest 0.01 mL from 5.085 mL)
 = 50.9 mg
 = 50.85 mg for display (within 5% of actual 50.9 mg dose)

Scheduled Start Date/Time: 03/20/19 1200 End Date/Time: 03/20/19 1756

Admin Instructions:
 High Alert Medication: Nursing double check required. **All preservative free for intrathecal administration**
 Medication(s) Dose per Day:
 HYDRomorphine: 2.5 mg/day
 CloNIDine: 105 mcg/day
 Bupivacaine: 5 mg/day
 Final Medication Concentrations:
 HYDRomorphine: 1.3 mg/mL
 CloNIDine: 53.4 mcg/mL
 Bupivacaine: 2.5 mg/mL
 Total volume = 40 mL
 Rate = 1.97 mL/day

Component	Order Dose	Admin Dose
HYDRomorphine 10 mg/mL Soln	50.85 mg	50.85 mg
clonidine 1,000 mcg/10 mL (100 mcg/mL) Soln	2,135.59 mcg	2,135.59 mcg
bupivacaine preservative free (0.75%) Soln	13.56 mL	101.7 mg

Order part of Order Set: **XYZ: IP INTRATHECAL PAIN PUMP ORDER SET**

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Figure 1. UChicago IDDS Intrathecal Medications-continuous infusion-pump fill order.

Order: **HYDRomorphine intrathecal pump with additives (Trial) [155657435]**

Ordered Dose: **2 mg** Route: **Intrathecal** Frequency: **CONTINUOUS @ 0.7 mL/hr**

Dose Calculation Information:
 2 mg
 = 0.017 mg/kg × 117.5 kg (Dosing weight as of Tue Jan 16, 2018 1008)

Scheduled Start Date/Time: 01/16/18 1500 End Date/Time: 01/17/18 0852

Admin Instructions:
 High Alert Medication: Nursing double check required. Bag change required in 72 hours.
 All preservative free for intrathecal administration
 Medication(s) Dose per day (Initial Order Parameters):
 HYDRomorphine: 0.24 mg/day
 Final Medication Concentrations:
 HYDRomorphine: 0.02 mg/mL
 Total volume = 100 mL

Component	Order Dose	Admin Dose
sodium chloride 0.9 % Soln	100 mL	100 mL
HYDRomorphine 10 mg/mL Soln	2 mg	2 mg

Original order: HYDRomorphine intrathecal pump with additives (Trial) [155592821]

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Figure 2. UChicago IDDS medication-continuous infusion- trialing order; order modification can occur by pressing on the “original order”.

3.2.3 Order Modifications

During the trialing period, orders are often modified to achieve the response desired for pain management while limiting side effects and adverse events. However, medication records in the electronic health record did not allow order modifications for rate changes. So rather than modify an order, the order had to be deleted and reordered. This resulted in confusion for medical services, pharmacy, and nursing. Today, the provider can modify standard medication records for rate changes while maintaining the order within the electronic medical record. (Figure 2).

3.3. IDDS Drug Calculation Process Development

During the order development process, the HFMEA team identified several failure-mode causes, including lack of standardized drug concentrations and the utilization of manual calculations by APS and the pharmacy department. Although both APS and pharmacy performed a second check during the ordering process, verification, compounding, and the final product check; the manual process still left room for error. The following solutions were introduced:

3.3.1. Standardized Drug Concentrations

The HFMEA team identified drugs to be utilized for IDDS compounding solution and verified drug concentration availability with pharmacy purchasing. The standardized drug concentrations for compounding IDDS solution (all preservative free) are as follows: morphine 25mg/ml, hydromorphone 10mg/ml, bupivacaine 7.5mg/ml, fentanyl 50mcg/ml, clonidine 0.1mg/ml, and baclofen 50mcg/ml.

3.3.2. Standardized Calculations

Because manual calculations present a risk for human error, the team standardized calculations in the following three phases:

(i) Phase I

Employed calculation worksheets within the pharmacy department to standardize the manual calculation process. The team developed two standard calculation worksheets, one for the trial and the other for pump fill orders. The worksheets incorporate first and second checks of calculations by two pharmacists to eliminate calculation errors. In addition, calculation worksheets include a day-supply for pump fill orders; this is important as some institutions have compounding restrictions. In cases where high concentrations of medication are expected, an external compounding facility is used. The calculation worksheet, with its day-supply column, allows physicians and pharmacists to plan appropriately when ordering medications.

(ii) Phase II

Developed an excel calculator from the standardized calculations. To accommodate different drug solutions, the team developed three separate calculators: initial trial, two drug pump fill (i.e., hydromorphone, bupivacaine) and three drug pump fill (i.e., hydromorphone, bupivacaine, and clonidine). All calculators incorporate standard preservative-free drug concentrations and are based on dose per day. It was determined that per-day doses should be the standard for all orders. This process was necessary to eliminate a manual calculation step by APS (not identified initially) and to ensure consistency of all order processes.

A	B	C	D	E	F	G	H	J
Medtronic Pump Fill (Non-TRIAL) 2 DRUG Calculation Worksheet								
1								
2	Solution	Stock Concentration	Ordere Dose (dose/day)		PTM Dose			
3	Hydromorphone PF (mg/mL)	10	enter in milligrams/day		enter in milligrams			
4	Fentanyl PF (mcg/mL)	50	enter in micrograms/day		enter in micrograms			
5	Morphine PF (mg/mL)	25	enter in milligrams/day		enter in milligrams			
6	Bupivacaine PF (7.5 mg/mL)	7.5	enter in milligrams/day					
7	Clonidine PF (mcg/mL)	100	enter in micrograms/day					
8	Baclofen PF (mcg/mL)	50	enter in micrograms/day					
9								
10	PTM Doses per Day (Lockout)							
11	Total Volume (mL) - Range: 20-40mL							
12	Overflow Volume (mL)	0						
13								
28	Step #3: Total volume of drug drawn from stock solution		Total Dose Required = Drug volume from stock solution (mL) x Stock Concentration (Enter into Epic)					
29	Hydromorphone Volume Required (mL)	#DIV/0!	Stock solution concentrations used (see above)	Hydromorphone Total Dose Required (mg)	#DIV/0!			
30	Fentanyl Volume Required (mL)	#DIV/0!		Fentanyl Total Dose Required (mcg)	#DIV/0!			
31	Morphine Volume Required (mL)	#DIV/0!		Morphine Total Dose Required (mg)	#DIV/0!			
32	Bupivacaine Volume Required (mL)	0.00		Bupivacaine Total Dose Required (mg)	0.00			
33	Clonidine Volume Required (mL)	0.00		Clonidine Total Dose Required (mcg)	0.00			
34	Baclofen Volume Required (mL)	0.00		Baclofen Total Dose Required (mcg)	0.00			
35								
36	Step #4: Day Supply (days) - Continuous Infusion ONLY	#DIV/0!	GOAL: Mimimum of 14 days					
37	Step #4: Day Supply (days) - Continuous Infusion + PTM	#DIV/0!	GOAL: Mimimum of 14 days					
38								
39	Step #5: Final Drug Concentrations							
40	Hydromorphone (mg/mL)	#DIV/0!						
41	Fentanyl (mcg/mL)	#DIV/0!						
42	Morphine (mg/mL)	#DIV/0!						
43	Bupivacaine (mg/mL)	#DIV/0!						
44	Clonidine (mcg/mL)	#DIV/0!						
45	Baclofen (mcg/mL)	#DIV/0!						
46								
47	Step #5: Infusion Rate (mL/day)	0.00	Min Rate: 0.048 mL/day; Max Rate: 24 mL/day					
48								
49	Step #6: Infusion Rate (mL/hr)	0.0000	mL/hr					
50								

Figure 3. UChicago automatic IDDS 2 drug Calculator-Blank.

	A	B	C	D	E	F	G	H	J
1	Medtronic Pump Fill (Non-TRIAL) 2 DRUG Calculation Worksheet								
2	Solution	Stock Concentration	Ordere Dose (dose/day)		PTM Dose				
3	Hydromorphone PF (mg/mL)	10		enter in milligrams/day		enter in milligrams			
4	Fentanyl PF (mcg/mL)	50		enter in micrograms/day		enter in micrograms			
5	Morphine PF (mg/mL)	25	3.8	enter in milligrams/day		enter in milligrams			
6	Bupivacaine PF (7.5 mg/mL)	7.5		enter in milligrams/day					
7	Clonidine PF (mcg/mL)	100	100	enter in micrograms/day					
8	Baclofen PF (mcg/mL)	50		enter in micrograms/day					
9									
10	PTM Doses per Day (Lockout)	0							
11	Total Volume (mL) - Range: 20-40ml	40							
12	Overfill Volume (mL)	0							
13									
28	Step #3: Total volume of drug drawn from stock solution		Total Dose Required = Drug volume from stock solution (mL) x Stock Concentration (Enter into Epic)						
29	Hydromorphone Volume Required (mL)	0.00		Hydromorphone Total Dose Required (mg)	0.00				
30	Fentanyl Volume Required (mL)	0.00		Fentanyl Total Dose Required (mcg)	0.00				
31	Morphine Volume Required (mL)	5.28	Stock solution concentrations used (see above)	Morphine Total Dose Required (mg)	131.94				
32	Bupivacaine Volume Required (mL)	0.00		Bupivacaine Total Dose Required (mg)	0.00				
33	Clonidine Volume Required (mL)	34.72		Clonidine Total Dose Required (mcg)	3472.22				
34	Baclofen Volume Required (mL)	0.00		Baclofen Total Dose Required (mcg)	0.00				
35									
36	Step #4: Day Supply (days) - Continuous Infusion ONLY	34.72	GOAL: Mimimum of 14 days						
37	Step #4: Day Supply (days) - Continuous Infusion + PTM	34.72	GOAL: Mimimum of 14 days						
38									
39	Step #5: Final Drug Concentrations								
40	Hydromorphone (mg/mL)	0.0							
41	Fentanyl (mcg/mL)	0.0							
42	Morphine (mg/mL)	3.3							
43	Bupivacaine (mg/mL)	0.0							
44	Clonidine (mcg/mL)	86.8							
45	Baclofen (mcg/mL)	0.0							
46									
47	Step #5: Infusion Rate (mL/day)	1.15	Min Rate: 0.048 mL/day; Max Rate: 24 mL/day						
48									
49	Step #6: Infusion Rate (mL/hr)	0.0480	mL/hr						
50									

Figure 4. UChicago automatic IDDS 2 drug Calculator-Using 2 Drugs.

(iii) Phase III

Incorporated patient therapy manager (PTM) doses to the excel calculator for pump-fill orders. This process was necessary for a more accurate day supply to determine internal vs. external compounding facilities as institutional compounding is limited by drug concentration restrictions. The calculator incorporated device agreed upon institution specific parameters: trial orders ≤ 3ml/hr, pump fill concentration rounded to 1 decimal point, pump rate rounded to 4 decimal points, range 0.5ml-1ml/day ≤1ml/day, and a minimum lowest programmable rate 0.048ml/day (Figures 3 and 4, not pictured IDDS trialing and 3 drug calculators).

3.4. IDDS Order Set Development

After standardizing medication records, the HFMEA team focused on developing IDDS order sets to allow for computer physician order entry (CPOE). The order set incorporated the six medication records based on primary opioid use of hydromorphone, morphine, or fentanyl (3-drug-trial and 3-drug-pump fill orders) and a link to the excel calculator. Physicians use the excel calculator to perform calculations prior to submission of orders to verify dosing, day supply, and ability to compound at our center. Prior to going live with CPOE, the pharmacy trained APS providers on order entry and ways to incorporate the excel calculator into their IDDS process. The training included a tip sheet and hands-on guidance of trials and fill orders. A pharmacy point person was on hand to assist in order entry during the transition

3.5. IDDS Identified Upon Patient Admission

The team identified several failure-mode causes for patients with IDDS admitted to the hospital for various

medical conditions. Failures included: no standard process for identifying patients with an IDDS, no documentation of IDDS, and no chartable medical record for IDDS. The team took the following steps to help mitigate these risks.

3.5.1. Developed a Standard Process to Identify IDDS Patients

To ensure identification upon admission, the team developed screening questions to incorporate into the initial patient assessment process. When a patient is identified to have an IDDS, the nurse performing the initial patient assessment informs the primary service physician that the patient has an implantable device. The primary service physician consults APS for further management of the IDDS patient.

3.5.2. Developed a Standard Process for Documenting IDDS

The APS consult service interrogates the pump within 24 hours of admission and documents information recorded from the IDDS in the standard APS progress note template (table 2).

Table 2. APS template progress note requirements.

Standard APS Progress Note
1. Initial pump volume
2. Medication (s) concentration: i.e., hydromorphone mg/ml, bupivacaine mg/ml, clonidine mcg/ml
3. Medication (s) dosing: i.e., hydromorphone mg/day, bupivacaine mg/day, clonidine mcg/day
4. PTM dosing and frequency
5. Low alarm volume
6. Refill date
7. Any dose changes made to pump
8. Provider interrogating pump

variation in prescribing, workflow, etc. The Institute for Safe Medical Practices (ISMP) provides guidelines for standard order sets to help ensure that the elements of safe-order communications have been followed when designing paper or electronic order sets [21]. Overall, the goal is to reduce complexity, standardize the format, and eliminate error-prone processes such as use of leading zeros, trailing zeros, and drug abbreviations. Lastly, the role of a medication place-holder order is to communicate ongoing treatment to the medical team. For example, a medication place-holder order may be utilized for antibiotics administered intermittently post hemodialysis or to identify a patient with a continuous insulin pump, baclofen pump, or intrathecal pain pump. The IDDS order set incorporates the guidelines provided by ISMP standard order sets, including medication place-holder orders to identify patients admitted with ongoing IDDS.

At the time of implementation, our IDDS process lacked structure and had a high risk for error: handwritten orders, manual calculations, no standard medical records, and limited staff awareness of the process. In addition, there was no set process to identify IDDS patients admitted to our institution for initiating or continuation of IDDS, and there was minimal literature to assist with the implementation of the process beyond patient/drug selection. Several forums discussed the need for a set process or inquired about other institutions practices for IDDS patients. For these reasons, we set forth to develop a standardize process for the initiation of IDDS and identification of patients admitted with existing IDDS at our institution.

The process limitations are notable in admissions, screening, and continued staff education. Since these procedures are elective, admissions providers would prefer to enter orders prior to a patient's admission. However, currently there is a gap between outpatient and inpatient order entry systems that prevents preadmission order entry. Additionally, because screening for IDDS upon admission is not a standard practice, patients are admitted without APS notification, pump interrogation, or medical record documentation. Lastly, interdisciplinary staff education on IDDS needs to be continuous as the process requires a lot of hands-on attention due to its infrequency and high-risk nature.

5. Conclusion

The complexity and acuity of IDDS has triggered institutional risk. As described in this paper, the risk is largely due to the general medical staff's unfamiliarity with IDDS and the high-risk nature of the medication processes, which can lead to injury related to the pump or the medications within the pump. Therefore, timely identification of patients receiving IDDS can prevent such injuries. Interdisciplinary quality improvement processes can be employed to identify and standardize practices for medication preparation and IDDS patient care. There is a large body of evidence supporting the use of computerized physician order entry systems (CPOE) to reduce medication

errors, and providing access to a computerized clinical decision support system (CDDS) at the time of prescribing to improve outcomes in patient care. Incorporating these tools into the management of IDDS patients is a significant opportunity to reduce risks and improve patient outcomes.

Glossary of Terms

IDDS-Intrathecal drug delivery systems
 IT-Intrathecal
 HFMEA™-Healthcare failure mode and effects analysis
 CPOE-Computerized physician order entry systems
 CDDS-Computerized clinical decision support system
 IOM-Institute of Medicine
 e-MAR-electronic medication administration record
 APS-Acute pain service
 PDSA-Plan-do-study-act
 Squire 2.0-Standards for Quality Improvement Reporting Excellence

Authors' Contributions

AMK – literature review, manuscript drafting and revisions
 RWK – manuscript drafting and revisions
 MA – manuscript drafting and revisions

Disclosure Statement

The authors of this article have nothing to disclose.

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