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Intraspinal Drug Delivery Reservoir Refill Procedure by Non-Physician Clinicians: A Nation-Wide Survey of Training, Pocket Fill Experience, and Life-Long Learning Behaviors

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ABSTRACT

INTRASPINAL DRUG DELIVERY RESERVOIR REFILL PROCEDURE BY NON-PHYSICIAN CLINICIANS: A NATION-WIDE SURVEY OF TRAINING, POCKET FILL EXPERIENCE, AND LIFE-LONG LEARNING BEHAVIORS

Intraspinal drug delivery (IDD) is a safe and efficacious method used to deliver medications for the treatment of chronic neurologic disease that requires periodic reservoir refills that can place patients at risk for a rare, accidental but potentially life-threatening, pocket fill. In the United States (US), non-physician clinicians perform this procedure. This study reports the results of a nationwide survey completed by 65 non-physician clinicians, obtained through social media, who performed the reservoir refill procedure. The results of the survey showed no standardized training was used, lack of attention to existing clinical practice guidelines in the training given, lack of supervision and mentoring for inexperienced clinicians, an unexpected number of pocket fills, and limited participation in professional meetings where intraspinal therapy is discussed. Suggestions for improvement are given.

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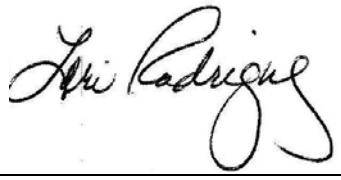

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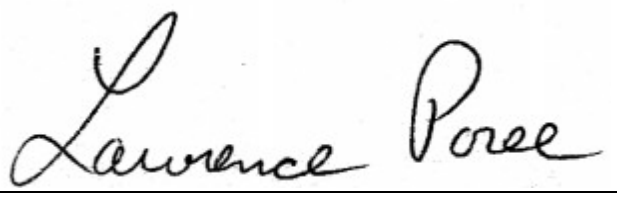

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CHAPTER 1: INTRODUCTION

While intraspinal drug delivery (IDD) is largely a safe alternate route for the administration of medications used for the treatment of chronic pain and spasticity, the system's reservoir refill procedure is not without risks, which include infection and pocket fill, the unintentional injection of the concentrated infusate into the subcutaneous cavity that contains the pump (Dario et al., 2005; Staats, 2008). A pocket fill may result in respiratory depression, altered mental status, hemodynamic instability, and death from the rapid, subcutaneous absorption of the drug intended for the reservoir (Prager et al., 2014).

Background

Intraspinal drug delivery is a safe and efficacious alternate route for medication administration used to treat chronic pain and spasticity approved by the Federal Drug Administration (FDA) for patients who suffer dose-limiting side effects to systemic analgesics or baclofen (Bethoux et al., 2013; Deer et al., 2012b; Hayek & Haynes, 2014; Myers, 2010). Long-term IDD was initially used in the 1980s for administration of medications for the treatment of patients with severe, uncontrolled cancer pain during the final stages of the disease (Krames, 2012). The drug delivery system is an implanted medical device that consists of a subcutaneous pump located in the patient's abdomen that is connected to an intraspinal catheter for the continuous administration of morphine, ziconotide, or baclofen directly to targets in the spinal cord (Medtronic, 2011). The drug reservoir is contained within the pump and requires periodic refills, a sterile procedure that demands accurate localization of the reservoir access port where a non-coring needle is inserted through the port and into the drug reservoir for refill (Medtronic, 2014). The reservoir refill procedure is performed by physicians and non-physician clinicians (NPC), including nurses, advanced practice nurses, and physician assistants.

A pocket fill is an unintended procedural event that occurs during a reservoir refill when the infusate intended for the reservoir is erroneously injected into the subcutaneous pocket around the pump, the etiology of which has not been well studied. A pocket fill is a medication error defined by the FDA's National Coordinating Council for Medication Error Reporting and Prevention (n.d.) as a "preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional…." Pocket fills are speculated to be the result of improper needle placement during the refill procedure, pump manufacturing design changes, and inadequate clinician training (Johnson, Visser & Goucke, 2011; Perruchoud et al., 2012). Pocket fills are thought to be rare; however, the true incidence is unknown and likely under-recognized and under-reported (Johnson, Visser, & Goucke, 2011; Medtronic, 2011). Pocket fills have been reported in the ambulatory, acute, and home care settings (Coyne et al., 2004; Frye & Vance, 2000; Johnson, Visser, & Goucke, 2011; Peccora, Ross, & Hanna, 2013; Perruchoud et al., 2012; Salva & Kuhn, 1987; Sauter et al., 1994; Shirley et al., 2006; Wu & Patt, 1992; Yilmaz, Sogut, & Sogut, 2003). The risk for pocket fills, a serious adverse event associated with the pump reservoir refill procedure performed by NPCs, may be minimized through standardized training and adherence to clinical practice guidelines (CPG).

Problem Statement

Currently, no standardized training program for the pump reservoir refill procedure for NPCs exists, which can be a source of clinical practice variability, a known factor that contributes to suboptimal patient outcomes (Fernandez-de-Maya & Richart-Martinez, 2013; Karnon, Partington, Horsfall, & Chew, 2015; Timmermans & Mauck, 2015). Clinical practice guidelines with recommendations for clinician training, performing the reservoir refill procedure,

and pocket fill prevention and management have been published and provide the best evidence available to improve patient outcomes (Deer et al., 2012a; Deer et al., 2012b; Prager et al., 2014). Little is known about how NPCs are trained, their utilization of CPGs, and attendance at meetings where intraspinal therapy is discussed. More information is needed about the NPCs who perform the reservoir refill procedure and the behavioral and environmental features that have an impact on the safety of the reservoir refill procedure before the risk for pocket fills can be reduced and the safety of IDD improved.

Purpose of the Project

Gaps in knowledge regarding medication errors have been identified and incidence rates, costs, and the effectiveness of prevention methods are not fully understood (Institute of Medicine [IOM], 2007). Creating a safety culture in health care organizations has been advanced as a method to reduce medical error (Edwards, 2016). The concept of a safety culture is defined as the interaction of multiple factors, processes, and human behaviors that foster workers to naturally resist or ignore procedural harms (Reason, 1998). Pocket fills are not random medication errors, but may share what Reason (1998) identified as elements of an accident; universal hazards associated with the reservoir refill procedure combined with local traps or human error and drivers, environmental or behavioral motivations which result in patient injury. A proposed model of the safety culture concept posited that factors that affect safety can be measured for quantification and intervention, which provided the framework for this study (Cooper, 2002).

The purpose of this study was to begin to build the knowledge base of some of the human factors that affect the safety of IDD by collecting data on the NPCs who perform the reservoir refill procedure. The aims of the study sought to: (a) describe the training and experience of the

NPCs who perform the reservoir refill procedure including pocket fills, (b) determine their utilization of CPG for the refill procedure, and (c), compare those who attend meetings where intrathecal therapy is discussed with those who do not for implementation of clinical practice guidelines (Deer et al., 2012a; Prager et al., 2014).

CHAPTER 2: LITERATURE REVIEW

A large scale, industry sponsored investigation of 557 physician-reported deaths of patients receiving intraspinal opioids revealed 88 deaths that occurred within 3 days of a pump-related procedure, a third of which were associated with a reservoir refill and opioid overdose was determined to be the cause of death (Coffey et al., 2009). Medtronic (2011), the manufacturer of the Synchromed®II pump, notified health care professionals of 351 pocket fills reported from 1996-2010 that resulted in 8 patient deaths as well as an FDA Class I recall of the refill procedure (US Department of Health and Human Services, 2011).

The etiology of a pocket fill is speculative but reports of patient injury and death temporal to and case reports of pocket fills suggested inaccurate needle placement (Coyne et al., 2004; Frye & Vance, 2000; Johnson, Visser, & Goucke, 2011; Peccora, Ross, & Hanna, 2013; Perruchoud et al., 2012; Wu & Patt, 1992). A small European study used an observational design to compare the accuracy of the SynchroMed®II pump manufacturer's template with fluoroscopy for locating the reservoir access port (Maino, Koetsier, & Perez, 2014). Investigators marked the site of the access port using the template first followed by fluoroscopy and found that the template, which is provided and recommended for the refill procedure by the manufacturer, was significantly inaccurate when controlled with fluoroscopy (Maino, Koetsier, & Perez, 2014).

Case reports described the use of ultrasound for improved accuracy of reservoir access port localization and pocket fill aspiration; however, the use of ultrasound for pump refills is off-label according to a spokesperson for the manufacturer of the pump and the cost of equipment and training are barriers to its use (Greher, Eichenberger, & Gustorff, 2005; Peccora, Ross & Hanna, 2013; Shankar, 2009; M. Ujhelyi, personal communication, April 24, 2015). Although

the evidence to support the use of ultrasound specific to the reservoir refill procedure is lacking, CPGs suggest it may be beneficial (Deer et al., 2012a).

It has been observed that NPCs' practice patterns and use of CPGs for the refill procedure depend on the practice patterns of the physician who trained them. No standardized training program for the NPC exists and the use of CPGs by physicians is variable and dependent on patient and physician characteristics (McKinlay et al., 2007). Barriers to CPGs adherence include physician disagreement and unfamiliarity with CPG, routine practice patterns, and non-adherence to CPG is a deterrence to evidence-based practice (Timmermans & Mauck, 2015).

Conference or national meeting attendance provides a source of the most current practice information, including CPGs, for clinicians and is known to promote professional development through networking with thought leaders and colleagues (Nebrig & Munafo, 2015). To demonstrate the value of conference attendance, Nebrig and Munafo (2015) created a model based on adult learning principles, which included session pre-planning, use of facilitators, and clear expectations to guide employees' conference experience. Post-conference evaluation revealed attendees experienced enhanced learning and increased interest in participating in clinical research studies (Nebrig & Munafo, 2015).

A study by Owens, Palmieri, and Greenhalgh (2014) used a cross-sectional design to describe the multiple clinical roles and level of involvement of an international group of Mid-level providers (MLP) in a national burn care specialty organization. They reported that out of 97 successfully delivered surveys, 48 (49%) were returned and over 80% of the respondents were members of the organization (Owens, Palmieri, & Greehalgh, 2014). The sample size was small given the quantity of potential subjects that were recruited by using contact information obtained through the specialty organization, which most likely explains the high percentage of

membership in the sample (Owens, Palmieri, & Greenhalgh, 2014). The use of CPGs and attendance and membership in national meetings and organization membership has not previously been described for NPC who perform the refill procedure.

CHAPTER 3: METHODS

This study used a cross-sectional, descriptive research design to describe a national group of NPCs who perform the reservoir refill procedure. Primary and secondary study outcomes were: (a) to describe the training and experience of the non-physician clinician who performs the reservoir refill procedure including pocket fills, (b) to determine their utilization of clinical practice guidelines for the refill procedure, and (c) to compare those who attend national meetings where intrathecal therapy is discussed with those who do not for implementation of clinical practice guidelines (Deer et al., 2012a; Prager et al., 2014).

A 23-item questionnaire was developed based on the current CPGs and pilot tested on a group of non-clinicians for question clarity (Deer et al., 2012b; Prager et al., 2014). The questionnaire addressed NPC demographics, training, years of experience performing the reservoir refill procedure, their experience with pocket fills and ultrasound, and life-long learning behaviors. The questionnaire also included two attitudinal questions regarding the appropriateness of ultrasound use by the NPC and the need for a standardized reservoir refill course. No standardized or validated instruments were available to measure the study outcomes.

Approval for the study and use of the survey was obtained from the Institutional Review Board (IRB), Office of Research and Sponsored Programs, California State University, Fresno. The survey questionnaire was posted online using SurveyMonkey,® a confidential web based survey platform and was available from September 15, 2015 through December 30, 2015. Participants were recruited for the survey by announcing it on social media with the survey link and reminder/recruitment emails were sent out to physicians and clinicians on a weekly basis through mid-November. Participants accessed the survey via the web link, passcode, and title of

the specific questionnaire, “Improving the Safety of Intraspinal Drug Delivery Therapy: What is the Non-physician Clinician’s Training and Experience?”

After entering a passcode and reading the letter of introduction, which explained the purpose, risks, and benefits of the study, participants completed and anonymously submitted their responses by hitting a “submit” button at the end of the survey. Completion of the survey constituted implied consent and there were no safety risks. Participation in the study was voluntary and anonymous, and subjects received no compensation. One hundred participants were anticipated, however, survey activity ceased on November 10, 2015 for unknown reasons. Completed questionnaires were downloaded from the survey website by the study team, examined for eligibility then data cleaning and coding was performed for statistical analysis and reporting using SPSS software, IBM.®

CHAPTER 4: RESULTS

Sixty-seven NPCs from across the US who perform the pump reservoir refill procedure submitted the questionnaire. Two respondents were excluded because he/she had not refilled a reservoir within the last year or not at all.

The young, male gender, and racial and ethnic NPCs were underrepresented in this sample. Participants (n = 65) were predominantly white, middle-aged female registered nurses with a bachelor's or master's degree with greater than 5 years' experience in performing the reservoir refill procedure (see Table 1). Other NPC titles were physician assistant, clinical nurse specialist, and nurse practitioner with a wide range of educational levels from Associates to Doctoral degrees.

Table 1

Subject Demographics

Subject Demographics	n (%)
Title	
PA	6 (9.2)
RN	36 (55.4)
CNS	5 (7.7)
NP	14 (21.5)
Missing	4 (6.2)
Total	65 (100)
Degree	
AA	13 (20.0)
BSN	21 (32.3)
MS	22 (33.8)
DNP	1 (1.5)
BA	2 (3.1)
Missing	6 (9.2)
Total	65 (100.0)
Age	
25-35	6 (9.2)
36-45	17 (26.2)
46-55	24 (36.9)
56-65	16 (24.6)
Missing	2 (3.1)

Total	65 (100)
Race/Ethnicity	
Asian	1 (1.5)
White	57 (87.7)
Hispanic	3 (4.6)
Missing	4 (6.2)
Total	65 (100)
Gender	
Male	6 (9.2)
Female	57 (87.7)
Missing	2 (3.1)
Total	65 (100)

Training

Training varied widely for the NPC. Nearly half reported that training was provided by a peer or physician and 25% were trained by a combination of the pump manufacturer's representative, peer, and physician or more than one trainer (See Figure 1).

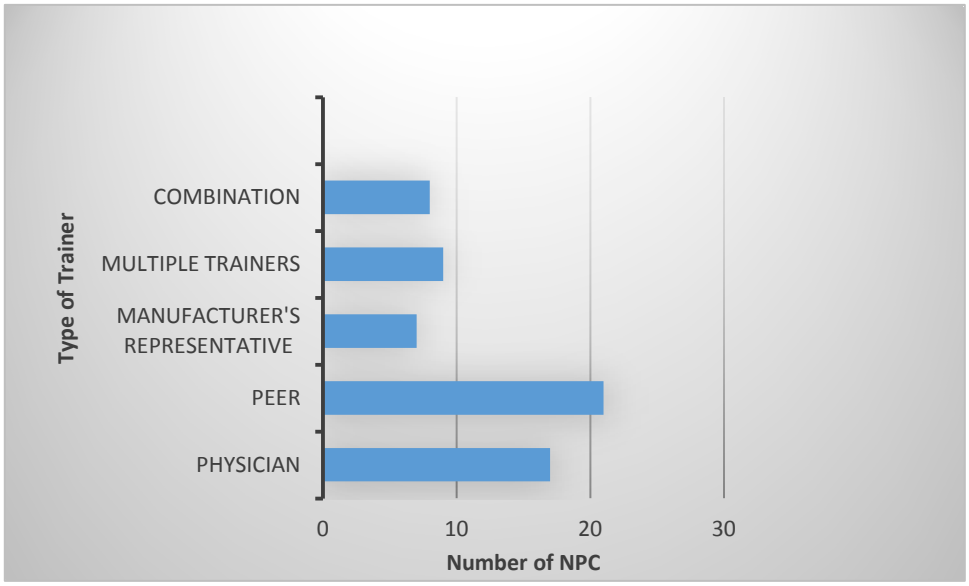

Figure 1. Number of NPCs and types of trainers

Competency measures and length of training were inconsistent. Performance of 10 to 30 reservoir refills was required to achieve competency for half the sample with a range from no limit to over 50 (see Figure 2) with other reported parameters of less than 10, no certain number

or when the NPC was comfortable refilling independently, and no requirement but had physician support when needed. In fact, 14% of the sample was not observed during training.

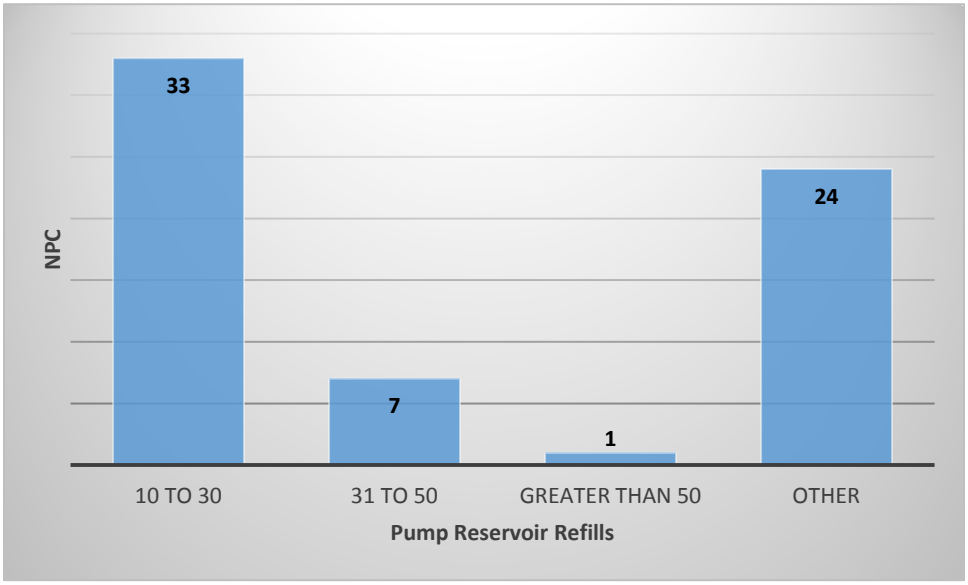

Figure 2. Refills required to achieve competency

The length of time for training ranged from no time limit to more than two months with the most frequently reported training duration of two months (see Figure 3).

Figure 3. Percent NPCs and duration of training

The use of CPG during training was significantly different from use of guidelines in practice. Procedural resources used during training were predominantly the pump manufacturer's refill procedure guide (58%) and refill kit (77%), but only 25% of the sample used published CPGs such as the Polyanalgesia Concensus Conference Guidelines of 2012 (PACC, 2012) and Best Practices for IDD for Pain (Deer et al., 2012b; Prager et al., 2014) (see Table 2).

Table 2

Procedural Resources Used During Training

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Manufacturer's refill procedure manual	38	58.1	58.1	58.5
	Poly-Analgesia Consensus Conference Guidelines (PACC)	3	4.6	4.6	63.1
	None of the above	11	16.9	16.9	80.0
	All of the above	13	20.0	20.0	100.0
	Total	65	100.0	100.0	

Even though CPGs are used minimally during training, the proportion of those who used CPGs in their practice increased significantly compared to the proportion of those who used clinical practice guidelines during training (see Figure 4).

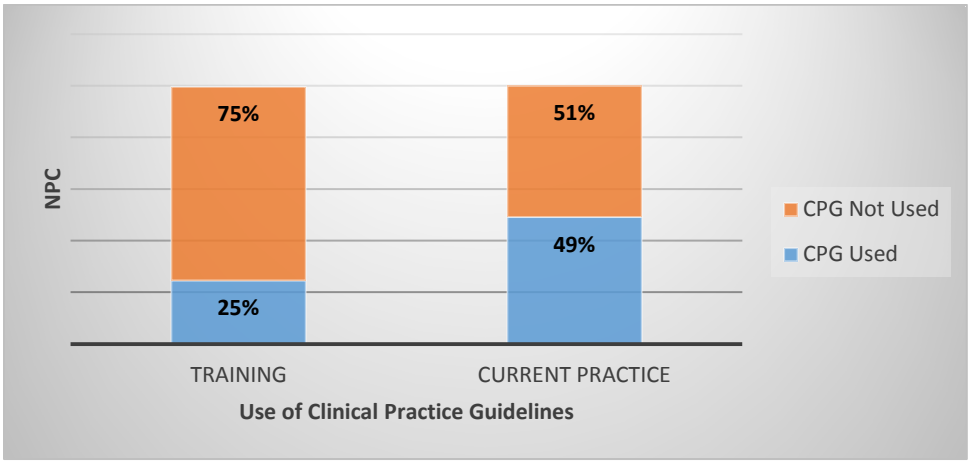

Figure 4. Comparison of use of CPGs during training with current practice

Note. McNemar's χ^2 (1)(12.8) = 29.782, $p < .0003$)

Experience

Most respondents were experienced NPCs who independently performed the reservoir refill procedure less than 10 times per week in a clinic. Of the participants, 70% had greater than five years of experience in refilling pump reservoirs (see Figure 5) where over 50% refilled 10 or fewer pump reservoirs per week on average (see Figure 6), primarily in the ambulatory setting, 25% in the home, and rarely in the acute care setting (see Figure 7), and as recently as the previous week (83%).

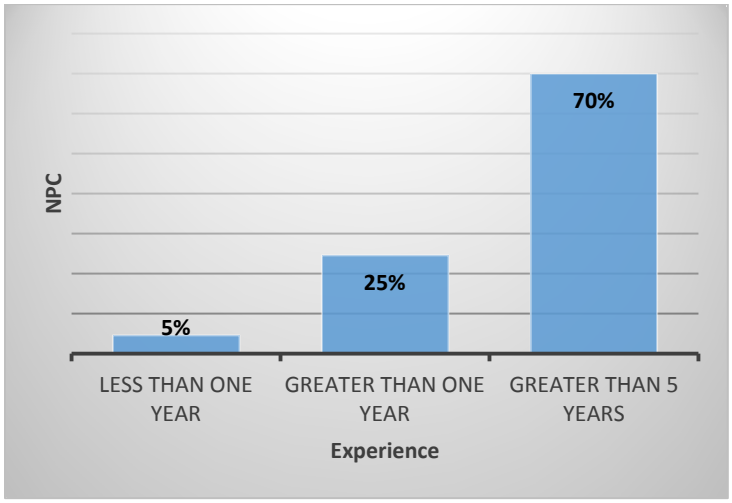

Figure 5. Number of years independently refilling pumps

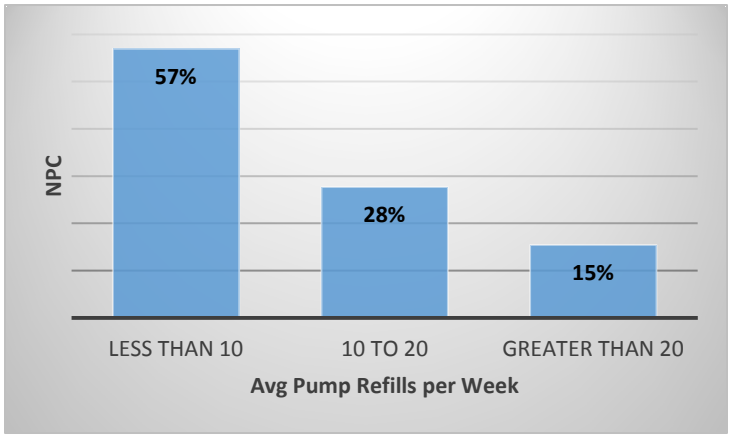

Figure 6. Weekly average number of pump refills

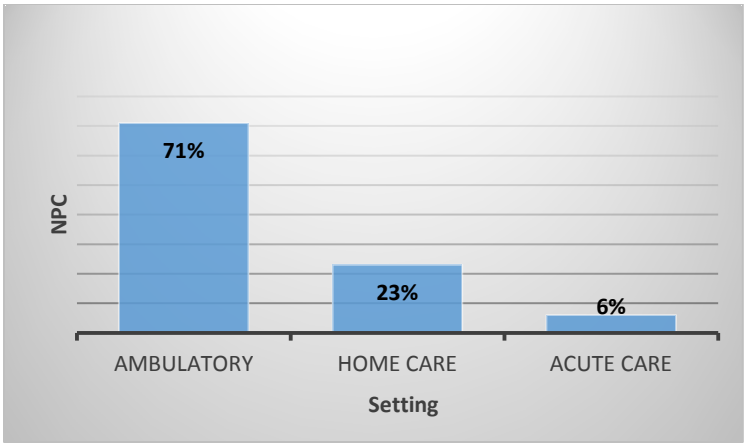

Figure 7. Primary setting of pump refill procedure

Out of the 65 participants, 12 (18%) experienced pocket fills after a pump reservoir refill procedure they performed. No pocket fills were reported by the under one year of experience group, two NPCs reported one pocket fill each after the first year of experience, but for those with over 5 years of experience, the number of NPCs who experienced a pocket fill(s) escalated. Six NPCs reported one each, two reported 2 each, one reported 3 pocket fills, and one reported greater than three pocket fills (see Figure 8).

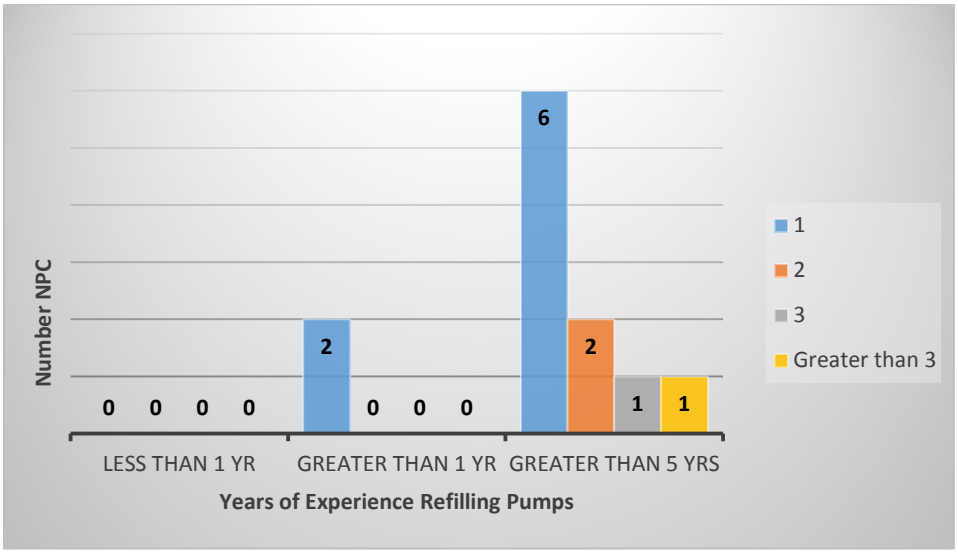

Figure 8. Number NPCs who reported pocket fills, years of experience, and number of pocket fills

Those with the most experience with the pump reservoir refill procedure reported the greatest number of pocket fills. Most pocket fills occurred in the clinic, two were reported to have occurred in the acute care setting, and one in the home (see Figure 9).

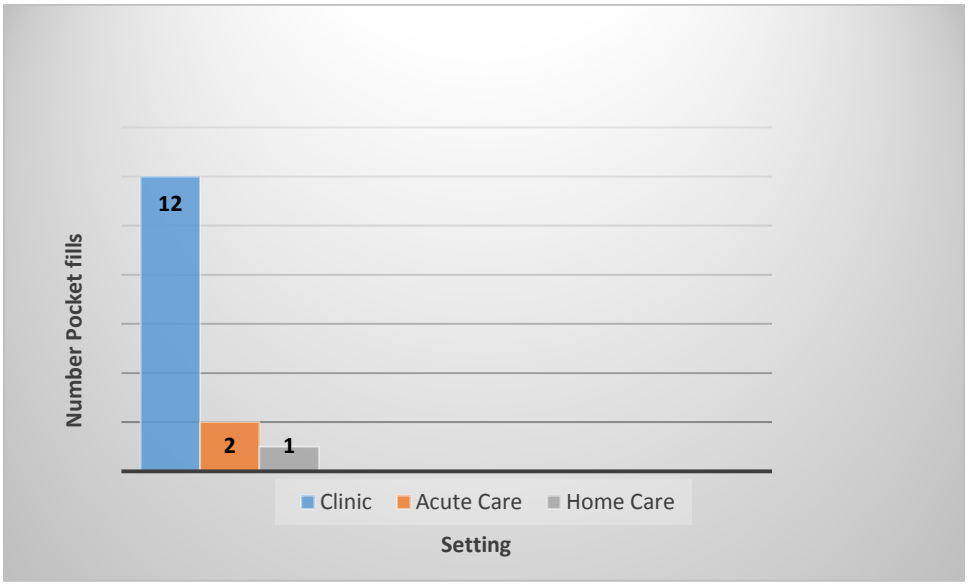

Figure 9. Setting where pocket fill occurred

The most frequently reported sign of a pocket fill was altered mental status in the patient following the refill procedure. Other observations and findings reported were the inability to aspirate fluid from the pump reservoir while refilling, bent needle after de-accessing the reservoir access port, or the needle felt too shallow upon de-accessing. Less frequent observations included pin-point pupils, clear fluid leakage from puncture site, obvious welts on skin surrounding access site, and the patient's complaint of a burning feeling at the injection site (see Table 3).

Table 3

Signs/Symptoms of Pocket Fill

Signs/Symptoms	*n* (%)
Altered Mental Status	12 (18.5%)
Unable to Aspirate	1 (1.5%)
Bent Needle	1 (1.5%)
Other:	1 (1.5%)
Burning at site	
Pin-point pupils	
Welts at access site	
Clear fluid at puncture site	2 (3.0)
Aspirate 2 cc less than expected	1 (1.5)
Leakage on needle de-access	1 (1.5)
Reaccessed, aspirate less than expected	1 (1.5)
Method Used to Confirm Pocket Fill	
Reaccessed, found aspirate less than expected compared to volume injected during refill procedure	13 (20.0)
Pocket aspirated	1 (1.5)

Pocket fill confirmation was performed most often by re-accessing the reservoir port, aspirating the contents and comparing the aspirate with the injected volume (expected). Over 80% of the sample felt adequately trained in the risks, recognition, and initiation of an emergency protocol should a pocket fill occur.

Use of ultrasound for needle guidance during reservoir port access, although not widely used, was accepted by the NPCs (see Figure 10). Of the NPCs that reported, 60% stated that ultrasound for needle access guidance is not used in their practice setting while 25% of the sample reported that ultrasound was used with every pump reservoir refill. Most agreed that ultrasound is appropriate for the NPC to use during the reservoir refill procedure.

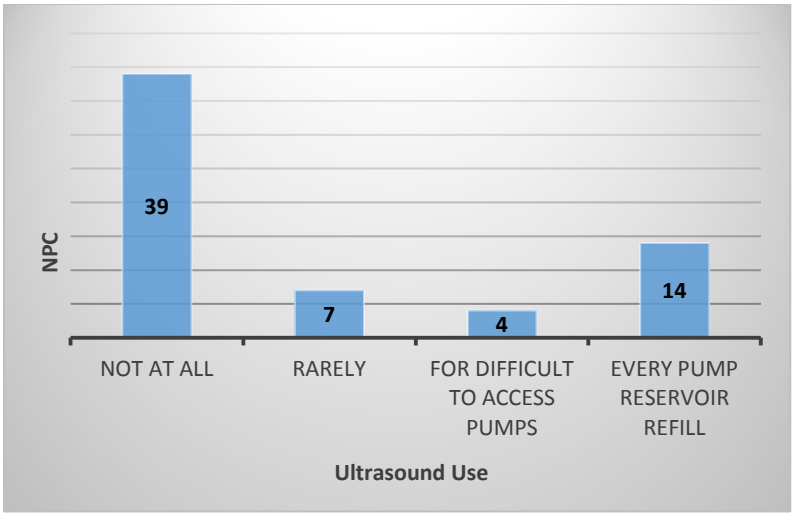

Figure 10. Use of ultrasound for the reservoir refill procedure

Attendance at neuromodulation educational meetings or membership in organizations within the specialty of neuromodulation, where intraspinal therapy is discussed, was very low for this group. Eighty-five percent of this sample did not belong to NANS, the professional specialty organization for neuromodulation, and 70% did not attend NANS meetings or other meetings where intraspinal therapy is discussed (see Figure 11).

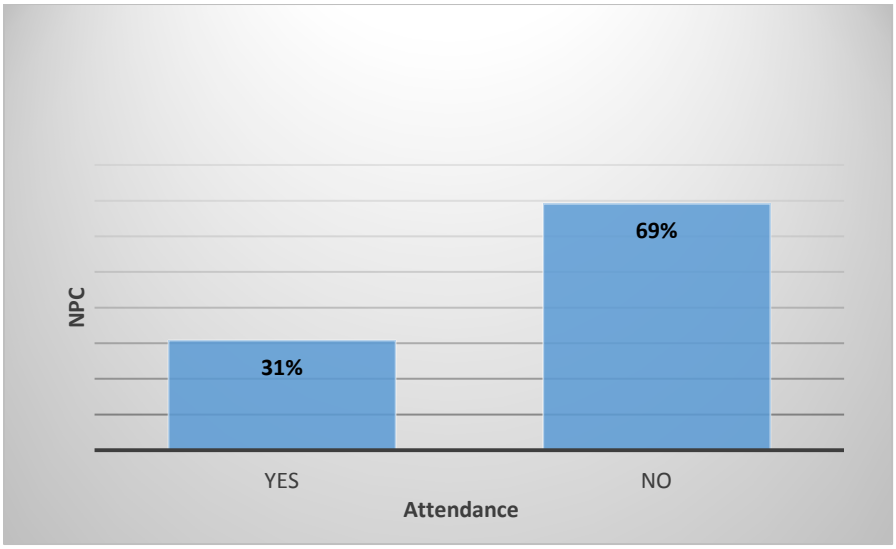

Figure 11. Attendance at NANS and other meetings where intraspinal therapy is discussed

Less than 5% of this group of clinicians attended other meetings, which included the California Society of Interventional Pain Physicians (CASIPP) (NANS 2013) and the Napa Pain Conference. The use of CPGs in clinical practice was not significantly different for the proportion of those who attended the North American Neuromodulation Society (NANS) meetings compared to the proportion who did not (see Figure 12).

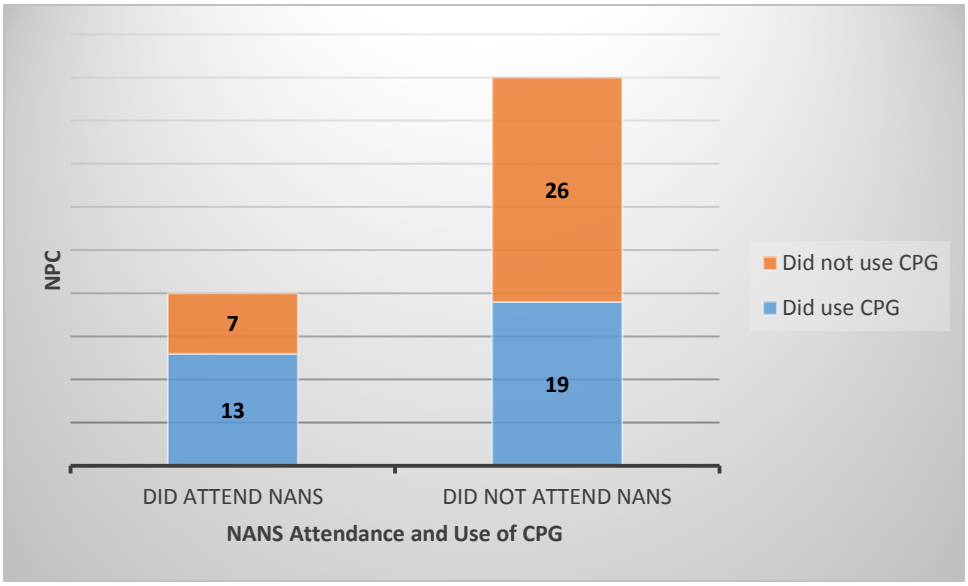

Figure 12. Comparison of NANS attendance and use of CPGs

Note. (χ^2 (1) = 2.874, p = .090)

CHAPTER 5: DISCUSSION

The IOM has put forth multiple national initiatives that address healthcare quality and access, health disparities and cultural diversity, and the transformation of the nursing workforce (IOM, 2001; IOM, 2002; IOM, 2004; IOM, 2011). The National Patient Safety Foundation (NPSF), an independent not-for-profit organization, published eight recommendations to improve patient safety, two of which endorse a culture of safety within the healthcare workplace and full patient engagement (NPSF, 2015). Both entities champion safer health care with an emphasis on increasing cultural competence in health care delivery (IOM, 2002; IOM, 2004) and creating a culture of safety to reduce medical errors (NPSF, 2015).

Minorities comprise 37% of the US population and less than one fifth of the nursing workforce (Xue & Brewer, 2014), and of that, less than 10% are men (MacWilliams, Schmidt, & Bleich, 2013). Our study sample demographics were consistent with what is known about the health-care workforce in general, and specifically in nursing—that it does not reflect the diversity of our society (Xue & Brewer, 2014). More research is needed to understand the cultural competence and diversity of this specialized NPC group and its impact on the safety of IDD.

The safety of IDD demands clinicians who are knowledgeable, proficient in the performance of the reservoir refill procedure, and exercise sound clinical reasoning and judgment. Currently, no standardized training course for the reservoir refill procedure for the NPC exists. Deer et al. (2012a) cited that clinical practice guidelines that specifically provide recommendations to minimize patient morbidity and mortality recommend that requisite physician and staff training for IDD include "…hands-on training, didactic teaching, mentoring, and proctoring" (p.469) and caution that improper training can directly affect all patient safety

outcomes. Study results demonstrate that NPC training for the reservoir refill procedure varied widely in duration, performance criteria, and supervision, and was arbitrary for more than 15% of the sample who were trained without procedural resources including the manufacturer's refill procedure manual or clinical practice guidelines. Fourteen percent of the participants reported they were not proctored during their training, 41.5% reported a combination of or multiple trainers provided "hands-on" training which is not optimal for mentoring, and only one third attended meetings such as the NANS or ASIPP where intraspinal therapy is discussed and are credible sources for didactic teaching. Deer et al. cited that the morbidity and mortality mitigation CPGs also recommend that at a minimum, trainees should demonstrate "adequacy and competency" (p.478) instead of a pre-determined number of successful reservoir refills, a common yet controversial measurement of competency during training which we found ranged widely from no limit to over 50. Even though the CPGs opposed the performance of a specific number of proctored refills the value of quantified procedures operationalizes "hands-on training" (p.469) and is analogous to practicing the skill set to satisfy behavioral expectations in the absence of high-fidelity simulation technologies, and should continue to be a key component of training. Learning how to perform the reservoir refill procedure unproctored is inappropriate and unsafe, given the known risks of the procedure; yet 14% of this sample were not supervised during their training. Currently, no performance-based outcome standards have been established. Interprofessional collaboration with neuromodulation physician and NPC experts and educators is needed to define concepts and language, establish performance-based outcomes for NPC training, and arrive at a consensus about content and behavioral standards to develop an evidence-based reservoir refill course. All study participants agreed that a standardized training course would improve the safety of the reservoir refill procedure.

One of the critical patient management safety issues directly related to the reservoir refill procedure is the prevention and management of the unintended injection of the reservoir infusate into the subcutaneous tissues surrounding the pump or pocket fill (Deer et al., 2012a; Prager et al., 2014; Staats, 2008). Twelve experienced clinicians (18%) reported a pocket fill during the performance of a reservoir refill procedure and those with the most experience reported the greatest number of pocket fills. This was an unexpected finding that suggests pocket fills occur more frequently than the estimated incidence of 0.0101 % previously reported by the device manufacturer and warrants further investigation (Medtronic, 2011).

Most pocket fills occurred in the ambulatory setting and ultrasound was not routinely used. The most frequently reported sign of a pocket fill was altered mental status in the patient immediately following a refill procedure. It is not known if the results reflected inappropriate training, practice variance, or an environment with multiple distractions, which can contribute to medication errors (IOM, 2007). More research is needed to better understand the NPC work environment, patient load, and experience with pocket fills.

Life-long learning behaviors of this sample, defined as membership in organizations, and attendance at meetings where intraspinal therapy is discussed, and the use of CPGs was less than expected. Equally disturbing was the finding that 75% of the sample did not use CPGs during their training, a clinical support tool designed to decrease practice variability and improve patient outcomes (Fox, Patkar, Chronakis, & Begent, 2009). A large Spanish study that explored factors associated with practice variability in vascular access device management, a long-term, implanted medical device that requires accessing via a port with a non-coring needle, a procedure that is similar to the reservoir refill procedure, found that geographic location and practice site size were factors that influenced practice variability. The study found that large

chemotherapy units were more likely to observe clinical practice recommendations (Fernández-de-Maya & Richart-Martinez, 2015). Our results were consistent with the Fernández-de-Maya and Richart-Martinez (2015) findings in that most participants performed less than 10 procedures per week, which may represent small pump practice sites and only half of the total sample used CPG in practice. However, use of CPGs increased significantly in practice compared to training ($p < .0003$). Additionally, the use of CPGs was higher in the proportion of NPCs who attended meetings where intraspinal therapy was discussed compared to the proportion of those who did not, a result that may have clinical significance even though the difference between the two groups did not reach statistical significance ($p = .090$).

These two findings suggest that when NPCs engage in life-long learning, use of CPGs increases when they are in practice and neuromodulation meeting attendance may exert a positive influence on the use of CPGs. Currently, there is no professional neuromodulation organization that specifically represents the NPC, a heterogeneous group of clinicians that includes nurses, physician assistants, clinical nurse specialists, nurse practitioners, pharmacists, and medical assistants. Low attendance and participation in neuromodulation specialty societies is not well understood and more research is needed to determine the life-long learning needs of the NPC, provide opportunities to meet those needs, and engage with neuromodulation experts.

This is the first study that describes the training and experience of a national sample of NPCs who perform the reservoir refill procedure and quantifies the number of pocket fills that occurred within this sample. It is also the first study to explore the use of ultrasound and CPGs, life-long learning behaviors, and gain consensus among the NPC regarding the need for a standardized reservoir refill training course. A total of 67 participants from across the U.S. responded to the survey, a modest but impressive number given that this is a specialty group that

was challenging to access compared to the 48 participants that were recruited from a burn care association special interest group membership list (Owens, Palmieri, & Greenhalgh, 2014). The use of social media for recruitment and SurveyMonkey® for administration of the questionnaire helped to contain the cost of the study, which had no financial support. Anonymity provided a safe mechanism for study participants to disclose and provide information regarding their experience with pocket fills, which may be under-reported due to psychological factors including shame and fear of being judged incompetent or lose their job.

The modest sample size, however, does affect the generalizability of the results to the total population of NPCs who perform the reservoir refill procedure. Use of social media for recruitment and participation in the study may have introduced bias in favor of those who use social media to the exclusion of participants who do not. The survey tool was not a validated tool and was biased by the creator's values, judgment, and perspective. Questionnaire content and format limited the statistical analyses. Studies using larger samples and a comprehensive, validated evaluation tool are needed to further our understanding of the life-long learning needs of the NPC, establish performance-based training outcomes and behavioral standards, and determine the human, job, and organizational factors that affect the safety of the reservoir refill that place patients at risk for harm.

Conclusion

Our findings show that in a national sample of NPCs who perform the reservoir refill procedure training was highly variable, CPGs were not used during the training received, and supervision and mentoring was lacking for the inexperienced clinician. The highest number of pocket fills was reported by the most experienced NPCs and warrants further investigation. NPCs are consumers of CPG and attendance at national meetings where intraspinal therapy is

discussed may influence practice behaviors in this group including the use of CPG. Standardized training with performance-based outcomes, behavioral and competency standards, and evidence-based course content for NPCs is needed and their life-long learning needs should continue to be explored. The safety culture model may provide the best fit to methodically identify the modifiable factors that result in a pocket fill to assure the highest quality of care for the patient with an IDD system during the reservoir refill procedure (Cooper, 2002).

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