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Adherence Monitoring with Chronic Opioid Therapy for Persistent Pain: A Biopsychosocial-spiritual Approach to Mitigate Risk

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Abstract

Opioids represent a mainstay in the pharmacological management of persistent pain. While these drugs are intended to support improved comfort and function, the inherent risk of abuse or addiction must be considered in the delivery of care. The experience of living with persistent pain often includes depression, fear, loss, and anxiety, leading to feelings of hopelessness, helplessness, and spiritual crisis. Collectively, these factors represent an increased risk for all patients, particularly those with a past history of substance abuse or addiction. This companion article to the American Society for Pain Management Nursing (ASPMN) Position Statement on Pain Management in Patients with Substance Use Disorders (2012) focuses on the intersection of persistent pain, SUD, and chronic opioid therapy and the clinical implications of monitoring adherence with safe use of opioids for those with persistent pain. This paper presents an approach to the comprehensive assessment of persons with persistent pain when receiving opioid therapy by presenting an expansion of the biopsychosocial model to now include spiritual factors associated with pain and SUD, thus formulating a biopsychosocial-spiritual approach to mitigate risk. Key principles are provided for adherence monitoring using the biopsychosocial-spiritual assessment model developed by the authors as a means of promoting sensitive and respectful care.

Keywords

adherence monitoring; biopsychosocial-spiritual; opioids; pain; addiction; substance use disorders; addiction disorder; risk stratification; Universal Precautions

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Introduction

The core tenets of nursing include the relief of pain and the provision of comfort while doing no harm. Few areas of clinical practice demonstrate this finely balanced juxtaposition more clearly than the provision of pain management for the patient with a substance use disorder (SUD) and those at risk for such a disorder. Opioids are an essential resource in the management of moderate to severe persistent pain. There is a clear mandate to provide safe, effective care for persistent pain when opioids are used. At the same time, there is also a need to mitigate the risk of improper use of opioids in the context of chronic opioid therapy. When treating persistent pain, clinicians may lack an awareness that the experience of living with this condition often involves depression, fear, loss, and anxiety that can lead to feelings of hopelessness, helplessness, and spiritual crisis. Collectively, these factors represent increased risk for patients with or without a history of SUD.

The use of well-intentioned methods to monitor adherence with chronic opioid therapy may result in patients feeling demoralized and distrustful of the healthcare system and its' providers (St. Marie, 2012). Some may feel they are viewed with suspicion, making it difficult for the healthcare providers to maintain therapeutic relationships. This paper elaborates on the essentials of a comprehensive assessment approach for adherence monitoring for patients with persistent pain using opioid treatment. Included for the clinician is a description of factors which may exacerbate SUDs in the presence of persistent pain. Key issues related to identifying the risk of non adherence to an opioid regimen are described. While the biopsychosocial model is historically recommended to assess and mitigate risks of problematic drug use with persistent pain, this paper endorses the consideration of a spiritual dimension and advocates use of a biopsychosocial-spiritual model (BPSS). The BPSS model promotes a holistic and comprehensive process of adherence monitoring to mitigate the risk of problematic drug use.

A clarification of terms is necessary to minimize misunderstandings and promote a common lexicon. Adherence monitoring refers to the procedures of clinical assessment required to identify problematic drug use from the onset of opioid therapy through the continuum of treatment. The term addiction refers to the brain disease processes involved with craving, dysfunctional behaviors, and an inability to control impulsive substance use despite harmful consequences (American Society of Addiction Medicine, 2012). The term addiction refers to a more severe or persistent clinical expression of SUD. The DSM-5 currently proposes the term SUD to cover a wide array of behaviors including substance misuse, abuse, and addiction (American Psychiatric Association, 2012). Readers are invited to review the glossary of terms included in the Position Paper on the Management of Pain for Patients with Substance Use Disorders (American Society for Pain Management Nursing [ASPMN], 2012). The terms addiction and SUD as used in this document reflect the ASPMN position statement definitions.

Persistent pain requires a comprehensive approach

According to the American Academy of Pain Medicine (2012), at least 100 million Americans suffer from persistent pain, more than the number affected by diabetes, heart disease, and cancer combined. Undertreatment or mismanagement of pain can cause delays in healing as well as changes to the central nervous system (Cheatle & O'Brien, 2011). This problem is exacerbated by a lack of consideration of the complex biologic interplay with psychologic, social and spiritual issues involved with persistent pain (Institute of Medicine, 2011, p.261).

The Institute of Medicine (IOM, 2011) recognized the importance of opioid medicines for treating persistent pain conditions. However, the additional burden of improper prescribing

and incorrect medication use has facilitated the spectrum of prescription drug abuse. Contributing to these problems is the commonly held fear among clinicians and patients of provoking a SUD even when opioids are prescribed or used properly. Fears of addiction are shared by both patients and prescribers, and fears of regulatory scrutiny continue to impact prescribing patterns almost twenty years after they were identified as barriers to optimal pain management (Jacox, Carr, & Payne, 1994; Paice, Toy, & Shott, 1998). All of these problems encumber positive communication between patients and their health care providers. Controversy over prescribing and use of opioids also contributes to further mismanagement of persistent pain.

Addiction is a key concern feared by all stakeholders in pain management, yet it is only one of many serious SUD consequences associated with prescription drug problems. Other important risks include diversion and increased risk of morbidity and mortality when used over time. Also, panels of experts who recommend using opioids unanimously agree that improved function is the anchoring therapeutic goal (Chou, Fanciullo, Fine, Adler, Ballantyne, Davies, et al., 2009). Yet for some persons with persistent pain, opioid use over time results in diminished instead of improved function. Misuse of medications, or a tendency to use medications in a manner other than prescribed, affects a majority of persons with chronic health conditions including those suffering with persistent pain. Fortunately, most recent research and empirical practice have identified an array of factors associated with more or less risk of SUD. These factors can be identified and monitored to inform the rigor of adherence monitoring. These are factors associated with the biological, the psychological, the social, and the spiritual aspects of people's lives. Armed with the knowledge of these factors, clinicians can develop a repertoire of proper assessment strategies to decrease the risk of non adherence when opioids are used for treating persistent pain.

Healthcare clinicians are mandated to provide more sensitive and less stigmatizing care for those receiving opioids in the management of persistent pain. To illustrate the implementation of this mandate, this article is divided into three sections. The first section provides an overview of persistent pain and SUD, offering the rationale for a comprehensive approach for adherence monitoring. The second section presents the expansion of the biopsychosocial model to include the spiritual understanding of patients with pain and their adherence behaviors related to their medication regimen. The third section describes how to implement adherence monitoring using the biopsychosocial-spiritual model developed by the authors as a means of promoting sensitive and respectful care. Key principles in the management of challenging circumstances are highlighted in text boxes.

Overview of Persistent Pain and Substance Use Disorders

SUD and persistent pain

Preliminary research of SUD in persistent pain patients has cited a wide range of prevalence from 0-50%, depending how a SUD is defined (Hojsted & Sjogren, 2007). However, most authorities believe the rate of SUD in persistent pain patients is relatively low if the patient has no significant risk factors for SUD, and if opioid treatment is conducted using adherence monitoring strategies (Cheatle & O'Brien, 2011; Gallagher, & Rosenthal, 2008; Gourlay, Heit, & Almahrezi, 2005). It is important to recognize that upon exposure to chronic opioid therapy, adaptive changes do occur in the nervous system, such as tolerance and physical dependence. These changes of tolerance and dependence, however, do not indicate SUD. Nonetheless, opioids are potentially addictive drugs. With opioid therapy, a risk exists of inciting addictive behavior through the reward circuits located in the mesocorticolimbic dopamine systems and their projections into other areas of the brain (Cheatle & O'Brien, 2011; Hunt & Urch, 2006).

Several authorities have elaborated on the processes involved with persistent pain and SUD. When persistent pain and SUD co-occur, the effect of one is synergistic to the other (Savage, Kirsh & Passik, 2008). Emerging research demonstrates that the adaptive neuronal circuits involved with persistent pain are similar in processes and vulnerabilities to those involved with addiction (Christie, 2008; Kelley, 2004). Addiction is associated with neuroplasticity in the brain circuitry that promotes adaptive behavior (Koob, 2012). Individuals with a vulnerability to addictive drugs may develop a biological adaptation or “learning”, which can lead to compulsive use, craving and continuation despite harm (Cheatle & O'Brien, 2011). Moreover, psychological disorders, most notably depression and anxiety, are common to both persistent pain and addiction, and both have been implicated in opiate abuse (Manchikanti, Giordano, Boswell, Fellows, Manchukonda & Pampati, 2007).

Gourlay and Heit (2008) have described coexisting persistent pain and addiction each as part of a ‘dynamic continuum’ where a person may exhibit symptoms of either disorder over time. The continuum involves both persistent pain and addiction. The continuum model conceptualizes how important it is to assess which aspect of each illness is dominant, as addiction may become dominant over time even after years of recovery (Gourlay & Heit, 2008). “Failure to treat both conditions ...will result in poor outcomes [for both]” (Gourlay & Heit, 2008, p.26). Persons with SUDs are eligible for pain treatment using opioids if the disease of addiction is not active and a plan for relapse is in place and discussed beforehand in a treatment agreement format (Burchman & Pagel, 1995; Chabal, Erjavec, Jacobsen, Mariano, & Chaney, 1997; Compton, 2011; Compton, 2008; Compton, & Athanasos, 2003; and Compton, Darakjian, Miotto, 1998).

Opioids treatment for persistent pain

Many authoritative pain societies and experienced pain clinicians continue to assert that opioids are safely prescribed to treat persistent pain (Cheatle & O'Brien, 2011; Chou, et al., 2009; Gudin, 2012). Despite this, regulatory fears and the association of opioids and addiction have contributed to patient stigmatization. Patients requesting such medicines can be judged by care providers as “drug seeking” without further investigation of their complaints; often feeling stigmatized when opioid medications are used (Vallerand & Nowak, 2009). Patients have related feeling fearful that they will lose their health care providers' care or insurance coverage if they disclose they are on opioids for pain. These factors serve to impede an honest exchange of information in monitoring adherence. Further, health care providers are rarely educated about the most appropriate strategies for interpreting behaviors and discussing sensitive matters associated with persistent pain involving the misuse or abuse of opioids.

Persistent pain creates episodic stressors that may interfere with a strict schedule of adherence to a prescribed regimen, so caution is required for interpreting aberrant behaviors in this population (Savage, et al., 2008; Webster & Dove, 2007). Common stressors include increased physical demands despite pain, financial stress from pain related disability, and difficulty managing normal routines on bad pain days. Although pain flares are similar to other chronic illness exacerbations, treatment of pain flares may involve problematic self-medication above recommended doses. This misuse may be a result of misunderstanding how to take opioids properly and how to manage a pain flare (Savage, et al., 2008; St. Marie & Arnold, 2002). Some patients may misuse their medications because their pain treatment is inadequate, indicating pseudoaddiction (Gourlay & Heit, 2008; Weissman & Haddox, 1989). Pseudoaddiction, a cluster of behaviors indicating addiction that are actually originating from poor pain control, is often clinically confused with addiction. This is because the presenting behaviors of pseudoaddiction overlap with addiction behaviors. Patients who experience pseudoaddiction can be distinguished from those with addiction behaviors when appropriate pain treatment is implemented. Patients with pseudoaddiction

demonstrate improvement with treatment, whereas those with addiction continue with addiction behaviors. Unfortunately, clinicians may miss the opportunity to treat psuedoaddiction effectively, causing additional stigma and marginalization for these patients.

Uncontrolled psychiatric illness may also contribute significantly to the risk of prescription drug abuse. Insurmountable psychological distress can motivate persons to abuse prescription drugs, all too often leading them to use multiple agents to escape their distress. Pain itself is a risk factor for opioid abuse, and if individuals have never learned functional coping skills, they may resort to “chemical coping” or coping by using pain medications (Gourlay & Heit, 2008; Passik & Weinreb, 2000; Webster & Dove, 2007). This “chemical coping” in the presence of existing mood disorders, such as depression and anxiety, may further contribute to medication misuse and overuse (Compton, et al, 1998). When there is a biogenetic vulnerability toward addiction, the opioids may trigger misuse that is characteristic of addiction (Savage, et al., 2008). To illustrate practical clinical suggestions for mitigating risk of addiction, see box 1 entitled: Relapse Prevention and Responses. Lastly, patients may divert prescribed opioids to others, creating a significant public health risk (Savage, et al., 2008).

No single behavior indicates addiction. Observing for patterns of behavior, identifying risk factors, and performing serial assessments of overall function can be useful parameters to verify or rule out problematic use over time. See box 2 entitled, Strategies to Mitigate and Manage the Risk for Abuse of Pain Medications. Patients who have reduced risk may display no problem behaviors, usually keep appointments, take medication as directed, and act on behalf of their own welfare (Webster & Webster, 2005, p. 53). Compton, et al. (1998) further studied problematic medication-taking behaviors among persons with persistent pain and found that medication misuse and abuse behaviors (i.e., self-medicating mood, supplementing medications with alcohol or other psychoactive drugs), considering oneself addicted, and family patterns of enabling drug abuse were all significant risks for SUD. These findings were consistent with Portenoy's empirically based assessment of behaviors believed to be more or less suggestive of addiction (Portenoy, 1994), and can help clinicians remain alert to problematic medication adherence behaviors without over-reacting unnecessarily. Additional examples of aberrant drug-taking behavior depicted in Table 1 for behaviors that are less suggestive of serious abuse, and Table 2 for behaviors that are more suggestive of serious abuse.

A Comprehensive Approach to Persistent Pain and Addiction Disorders

The biopsychosocial approach

The biopsychosocial model has been internationally accepted as the model for pain management (Fillingim, 2009; Jacobson & Mariano, 2001; Melzack & Wall, 1996). There are three overlapping components of the biopsychosocial model that have been well studied, and these are physical pain, psychological pain, and social/cultural pain (Altilio & Otis-Green, 2011; Grinstead, 2007; Keefe, Rumble, Scipio, Giordano, & Perri, 2004; Merskey & Bogduk, 1994; Merskey & Spear, 1967; Turk & Melzack, 2011). Examples of biopsychosocial indices include age, sex, ethnicity, mental health, personality, social relationships, stress reactions, and coping behaviors (Lysne & Wachholtz, 2011).

Psychiatrist George Engel developed the biopsychosocial model based upon his observations while treating patients with chronic illnesses. He noted a lack of regard for the processes that operated over time to allow healing. Dr. Engel proposed that “a medical model must also take into account the patient, the social context in which he lives, and the complimentary system devised by society to deal with the disruptive effects of illness...this

requires a biopsychosocial model” (Engel, 1977, p. 132). This approach evaluated the biological, psychological, and social reactions to distress through astute listening in order to analyze the illness experience and make clinical decisions. Inherent in this process is a therapeutic relationship between the care provider and patient which “powerfully influence[s] the therapeutic outcome for better or for worse” and incorporates the patient's responsibility and involvement in their own health care (Engel, 1977, p. 133). Rapport is naturally built through this therapeutic relationship and promotes mutual trust and honest exchange of information. Nurses are well positioned to evaluate biopsychosocial reactions to persistent pain and enhance communication in the context of the therapeutic relationship (see box 3 entitled, Communicating When Challenges Exist).

The biopsychosocial model for pain

The biopsychosocial model developed for pain recognizes the complexity of the pain experience that is characterized by disability and a lack of a causal mechanism for continued pain over time (Schultz, Cook, Fraser, & Joy; 1998). To an individual suffering with pain, the meaning of pain evolves from their past and current life experiences (Dalton, Keefe, Carlson, & Youngblood, 2004; Matteliano, Chang & Scherer, in press). Along with these experiences, the biological and psychological factors provide the personal milieu for how processes of coping with pain manifest over time. At any point over time, shifts in the manifestation of these complex factors may assume a disproportionate role in presenting symptoms (Matteliano, 2010). Internal (intrinsic) processes interact with external (extrinsic) environmental factors to account for the illness behaviors commonly seen with persistent pain (Matteliano, 2010).

Disability is a common feature when pain is persistent; thus major gains in treating diminished function may not be wholly achievable even with opioids. Psychological and sociocultural factors shape these experiences over time so shifts in the manifestation of these factors evolve during treatment. The biopsychosocial model for pain requires the patient to engage in collaboration with the treatment team to enhance the potential for achieving their personal goals (Schultz, et al. 1998). Taken together, the biopsychosocial model for pain requires a patient centered caregiving approach that recognizes the attendant changes to a person's being, or spirit. These changes can be a result of ongoing suffering from persistent pain. The biopsychosocial model helps the clinician to apprehend the nature of suffering of patients with persistent pain on the spirit.

Suffering is a core human experience of distress and despair, impacting the spiritual in addition to the biopsychosocial aspects of pain. Myles Sheehan has defined spirituality as the human experience of seeking understanding, meaning, strength, and transcendence (Sheehan, 2003). Suffering may change a patient in basic ways. For some, suffering enhances spiritual awareness, but for others suffering is meaningless and results in anger and frustration (Burgardt & Nagai-Jacobson, 2009).

Every person with persistent pain struggles with a core task of surrendering the search for a cure, requiring renewed attention to the task of learning to live with their pain (Risdon, Eccleston, Crombez, & McCracken, 2003). A core human requirement for coping with pain and suffering involves the struggle to find one's own meaning for his or her personal pain experience. Discovering a personal meaning allows some purpose and significance to reveal itself to allow for hope as one continues through life (Frankl, 1992; Lazarus & Folkman, 1984). The search for the meaning of suffering with pain is a personal and spiritual matter because its understanding is derived from one's sense of self and the interaction with the human conditions one experiences.

Biopsychosocial-spiritual model for assessment

In the past decade there has been an expansion in the recognition of spiritual influences and their impact on physical and mental wellbeing. Incorporating spiritual factors into clinical practice offers clinicians an opportunity to deepen understanding of their patients and positively influence health (Giordano & Engebretson, 2006; Levin, Larson & Puchalski, 1997). Because spirituality involves a human search for meaning in life (Tanyi, 2003), listening to patients about how pain has impacted their lives is an entrée into a spiritual relationship. Studies by Bussing, Michalsen, Balzat, Grunther, Osterman, Neugebauer, et al., (2009) and Rippentrop, Altmaier, Chen, Found, and Keffala, (2005), show that incorporating spirituality or religion as part of care is associated with improved coping with pain.

In 2011, the Institute of Medicine (IOM) recognized persistent pain as a separate disease entity, and mandated that assessment and treatment must be transformed to reflect the state of the science and current knowledge bases, including spiritual approaches. Giordano and Engebretson (2006) also describe the beneficial role of spirituality in inducing positive health practices, advocating for the clinicians role to regularly promote spiritual experiences. Levenson, Aldwin and Yancura (2006) evaluated an intervention to improve psychological well-being through spiritual practices. They found there was improvement in depression, spiritual experience, life satisfaction, mastery, forgiveness, and empathy. Therefore, adding the spiritual factors to the biopsychosocial model creates the biopsychosocial-spiritual model, representing a more comprehensive construct with ready clinical application and use. Adding spiritual factors permits a method for ascertaining the meaning of the pain experiences to an individual, allowing for increased connectedness; potentially strengthening a therapeutic relationship.

While the use of spiritual factors to assess people with persistent pain is novel, the treatment of addiction disorders has its roots in spirituality. The traditional 12 step program provides a foundation of therapeutic interventions for addictive disorders by leading people to observe a more spiritual state. Passik and Kirsh (2003) have emphasized that to addiction to pain medicines arises from the complex interplay of genetic, psychiatric, familial, social, as well as spiritual influences. The American Society of Addiction Medicine's public policy statement defines addiction as a dysfunction ...leading to characteristic biological, psychological, social, and spiritual manifestations (American Society of Addiction Medicine., 2012). Extrapolating this definition of the impact of addiction to persons suffering from persistent pain corroborates adding the spiritual dimension into the biopsychosocial model for pain and SUD (Bussing, et al., 2009; Koenig, 2003; Lysne & Wacholtz, 2011; Sumalsy, 2002; Wacholtz, Pearce, & Koenig, 2007).

Figure 1 depicts a biopsychosocial-spiritual model showing extrinsic and intrinsic factors that influence behavioral responses requiring clinical attention. Collectively, the intrinsic and extrinsic factors of the BPSS model provide a more holistic approach to the assessment of patterns, trend, and dynamic reciprocity between pain and problematic drug use. The biopsychosocial-spiritual model directs comprehensive assessment to uncover instabilities in any of these factors impacting the expression of pain and/or addiction disorders. Table 3 displays a list of examples from the clinical experiences of the authors of this article where the intrinsic and extrinsic factors play a role in influencing pain and SUDs.

People with SUDs have a vulnerability to relapse due to the ongoing stress of persistent pain. In addition, opioids used to treat pain impact the same neurochemical pathways as addiction, activating the reward system to create increased vulnerability to relapse. Using the biopsychosocial-spiritual model, this vulnerability can be assessed with a heightened awareness of the existence and interaction of intrinsic and extrinsic factors in a person's life – including the spiritual factors. Placed in this context, the spiritual component in the

biopsychosocial-spiritual model elucidates the connection that pain and addiction have to the ascribed meaning and purpose of an individual's life (Frankl, 1992; Schaub & Dossey, 2009). Identifying the meaning for an individual brings clarity of understanding for the patient and clinician so that treatment goals can be established. When assessing an individual for SUD and pain, the clinician must have an ongoing awareness and appreciation of the interaction of multiple internal and external factors impacting the patient, in order to effectively treat their condition. See box 4 entitled, Adherence Monitoring Questions. Increased understanding of the complexity of these factors identified in the BPSS model leads to the next step of ranking or stratifying the degree of risk for developing an SUD in a given patient. This risk stratification can then be used to guide appropriate responses and treatment planning.

Adherence Monitoring Using the Biopsychosocial-spiritual Model

Incorporating risk stratification into the biopsychosocial-spiritual model

Risk stratification is designed to assess a person's risk for misusing or abusing opioid medications, or for developing or relapsing into addiction. Evaluating risk requires the clinician to assess two main areas including behavior related to pain and opioid use, and mental health.

Behavior related to pain and opioid use—Clinical assessment of behaviors relating to opioid use can be challenging. Risk stratification is an ongoing process that requires observation for a pattern of behaviors over time before surmising whether adherence to a medication regimen is maintained. Gourlay & Heit (2008) described the challenge of providing a balanced approach to pain and addiction, one that manages both when either is out of control. Universal Precautions is a systematic approach designed to help clinicians evaluate and reduce risk all patients placed on chronic opioid therapy for the treatment of persistent pain (Gourlay, Heit & Almahrezi, 2005). See Table 4 for the list of an expansion of the Universal Precautions for Patients with Persistent Pain on Chronic Opioid Therapy using a biopsychosocial-spiritual approach.

Every person for whom opioids are prescribed has the potential to abuse their medication (Webster & Dove, 2007). A person's vulnerability to prescription drug abuse is associated with many variables: the specific drug being prescribed, environmental and genetic factors, other illnesses, use of alcohol and other drugs, and the suffering associated with their persistent pain (Savage, et al., 2008; Webster & Dove, 2007). Because it is impossible to predict who may abuse substances throughout the continuum of care, clinicians are compelled to respectfully assess every person before a prescription is written for an opioid (Heit & Lipman, 2009). A systematic approach using the 10-point assessment of the Universal Precautions has been adapted using the biopsychosocial-spiritual model, and is presented in Table 4. Risk stratification methods include the use of assessment tools to recognize patients at risk for medication adherence problems, and to evaluate problematic behaviors as they impact perceived risk and treatment planning. To assist in risk stratification there are many assessment tools on how to identify those at risk for SUDs, including opioid abuse or addiction (Adams, Gatchel, Robinson, Polatin, Gajraj, Deschner, & Noe, 2004; Belgrade, Schamber, & Lindgren, 2006; Butler, Budman, Fernandez, & Jamison, 2004; Compton, et al., 1998; Ferrari, Cicero, Bertolini, Leone, Pasciullo, & Sternieri, 2005; Friedman, Li, & Mehrotra, 2003; Kirsh, 2007; Li, Katragadda, Mehrotra, Mosuro, & Friedman, 2001; Webster & Webster, 2005). However, in a recent study of 428 health care providers assessing risk factors for opioid abuse, clinicians often misinterpreted initial presentation of aberrant behaviors, failing to appreciate the wide differential diagnosis (Miller, Heit, Gourlay, Peppin, Hampton, & Miller, 2011). If a patient takes more medication than prescribed, is this an indication of abuse, addiction, undertreatment

(pseudoaddiction), anxiety, impulse, or confusion? Behaviors are frequently misunderstood and too often premature assumptions misdirect treatment. There is significant confusion about what it means to be adherent to an opioid regimen, and the screening tools for recognizing the risk of abuse are rarely used although readily available (Miller, et al., 2011; Passik & Kirsh, 2003).

Mental health—Mental health disorders also create an increased risk for substance abuse with prevalence rates of SUDs ranging from 29 to 50% in this population (National Alliance on Mental Illness [NAMI], 2012). Behavioral disorders may be associated with compulsive use of prescription medications to address psychic suffering. Given the overrepresentation of depression and anxiety in persons living with persistent pain, careful assessment of a patient's mental health status is essential. Table 5 shows further examples of risk factors for the abuse of pain medications.

Continual monitoring for adherence using the biopsychosocial-spiritual model allows the clinician to assess patients with persistent pain by watching for behaviors over time that may indicate risk for SUD or misuse of prescribed medications. The clinician can stratify the patient as low risk, moderate risk, or high risk. These layers of risk indicate level of potential harm and the individual may move along the continuum from compliance with the prescribed regimen to misuse or abuse of prescribed medications. This transition towards misuse and abuse may develop discretely over time and can often be confused with tolerance and physical dependence; particularly when clinical decisions are made to increase an opioid dose to treat a patient who complains of high levels of pain (Treisman & Clark, 2011). See box 5 entitled: Setting the Stage for Success. While determining the level of risk, the clinician must employ accurate definitions of addiction, tolerance, and physical dependence found in the ASPMN Position Statement on Pain Management in Patients with Substance Use Disorder (ASPMN, 2012). In the next section, the assessment findings can be methodically applied using the biopsychosocial-spiritual model in the systematic approach explained with the levels of risk.

Strategies to assess risk and treat persons on chronic opioid therapy using the biopsychosocial-spiritual model

By consistently using the biopsychosocial-spiritual model with risk stratification and the Universal Precautions for Patients with Persistent Pain Using Chronic Opioid Therapy, we can more clearly understand our patients and their unique experiences and associated risks over time. However, all patients require regular re-assessment of treatment goals for continuing opioid therapy (Bolen, 2006; Chou, et al., 2009). To be effective in lowering potential harm, risk stratification assessment requires a corresponding clinical response. If mutually agreed upon goals such as improved function despite pain are not achieved with opioids, if benefits do not exceed risk, or if side effects are over-riding considerations, a taper or weaning plan may be indicated.

Characteristics of an individual with low risk for SUD or misuse of prescribed medication include no past history of SUD including alcohol abuse. There would be a stable profile of biopsychosocial-spiritual factors and the 5 A's (analgesia, activity, adverse reactions, aberrant behavior, and affect). If the behavior indicates low risk, the clinician would provide at least annual review of the biopsychosocial-spiritual status, the 5 A's, urine drug testing, pill count/medication review, and screening for SUD and alcohol use. There would also be an annual review of the goals and the expectations established in the Treatment Agreement.

An individual with moderate risk for addiction disorder or misuse of prescribed medication shows an unstable biopsychosocial-spiritual profile, as well as changes in the 5 A's assessment. Additional moderate risk factors include age less than 25 years, a significant

family history of SUD including alcohol abuse, a personal history of a treated SUD including alcohol, as well as a past or concurrent psychiatric disorder. Other behaviors associated with moderate risk include noncompliance with therapeutic recommendations, medication misuse, self report of alcohol use, and inconsistent urine toxicology results when compared with the prescribed treatment. See box 6 entitled, Caution with Urine Toxicology. The individual with moderate risk may have current and stable pharmacotherapy for addiction disorder such as methadone or buprenorphine that requires monitoring. With moderate risk findings, the clinician would provide frequent adherence monitoring that could range from at least monthly to every 6 months. This would include an evaluation of the biopsychosocial-spiritual status, the 5 A's, urine drug testing, pill count/medication review, and screening for SUD and alcohol use. Moreover, specialists are used as needed for pain and addiction support, this would also include psychologist and/or psychiatrist treatment and support groups. The clinician would review the goals and educate the patient on the expectations established in the Treatment Agreement (see box 7 entitled, Suggested Points for Inclusion in a Treatment Agreement).

Persons with high risk for addiction disorder or misuse of prescribed medication demonstrate not only an unstable biopsychosocial profile and changes in the 5 A's assessment, but also have active SUD. They may have major untreated or unstable psychiatric conditions and their urine drug testing is inconsistent with the prescribed treatment. With high risk findings, the clinician would use more frequent adherence monitoring ranging from weekly to monthly. There would be frequent urine drug tests, pill counts, substance abuse/alcohol screens, and evidence of attendance in addiction treatment. If the clinician determines that opioids are necessary for pain management, short refill intervals with weekly office visits are recommended, families or significant others are solicited for assistance in adherence monitoring (with the patient's consent), and referral to or co-management with addiction specialist is required. If opioid interventions are not effective or there is evidence of illegal or dangerous behavior, discontinuation or tapering of opioids is indicated. All high risk patients should receive prompt referral to support groups, counseling on stress reduction or coping strategies, spiritual health interventions, or relapse prevention strategies (Grinstead & Gruber-Grinstead, 2011).

The systematic use of the biopsychosocial-spiritual model integrated into risk stratification and adherence monitoring procedures can guide appropriate therapeutic encounters and treatments. These risk stratification evaluations are most effective when included at regular intervals in routine clinical assessments. The process must be viewed comprehensively as no single feature or characteristic can be used to assign low, medium, or high risk to a patient. Furthermore, the risk categories are not self-contained and may overlap with patients themselves transitioning between risk categories over time, necessitating continual adherence monitoring.

While using opioids to manage pain, the key to risk assessment and treatment planning is establishing an ongoing dialogue with the patient about safety and risk. Through this dialogue, the coping strategies can be identified and education presented regarding the risks of coping with stresses by using pain medications. To further enhance attainment of a positive outcome, identifying the patient's use of their previously successful coping mechanisms allows the clinician to reinforce these strategies with additional suggestions for stress reduction. A review of the opioid agreement, at least annually, provides a mechanism for dialogue and treatment planning. See box 7 entitled, Suggested Points for Inclusion in a Treatment Agreement. If treatment goals are not met or if there are persistent unsafe behaviors, the clinician can respectfully clarify the professional responsibility to end ineffective or unsafe treatment with opioids, while emphasizing other methods to manage

pain that do not include opioids. Patients reveal their risk category through their behaviors over time, so the treatment plan must remain flexible.

In conclusion, the biopsychosocial-spiritual model used for adherence monitoring with chronic opioid provides a holistic approach that systematizes the assessment of complex factors affecting individuals with persistent pain at risk for SUD. This approach allows the clinician to gain knowledge of the influences in patients' lives over time including the spiritual impact of their pain or SUD. Based on this comprehensive assessment, expected results include as follows (1) patient's goals for pain management are determined, (2) treatment options are discussed, (3) mutual expectations are confirmed, (4) inherent risks are revealed, and (5) realistic outcomes are established. These parameters of care are clearly defined using a non-judgmental manner (Heit & Lipman, 2009). The biopsychosocial-spiritual model serves to strengthen the patient's connection to their support systems including the health care providers, minimize risks of misinterpretation or misjudgment, and reduce stigma for those who suffer with persistent pain. The biopsychosocial-spiritual model provides a structured approach to adherence monitoring that facilitates patient centered care, thus reducing mistrust if opioids are used in treating this patient population. Future care for persistent pain using opioids should consider implementing the biopsychosocial-spiritual approach from the onset of care for persistent pain to mitigate risk in this population.

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Box 1**Relapse Prevention and Responses****Principles**

- Persons with SUDs are eligible for pain treatment using opioids if the disease of addiction is not active and a plan for relapse is in place (Compton , 2011)
- SUD/addiction is a chronic, potentially relapsing disease
- Early identification of slip/relapse is necessary to prevent the reoccurring pattern of addiction

GOAL: Promote a supportive recovery environment for those w/ a history of substance use disorders.

Terms

- Recovery: a dynamic process where a patient with addictive disease maintains sobriety
- Relapse: a return to behaviors of addictive disease

PLAN: Decrease risk w/ rigorous adherence monitoring of behaviors & documenting risk level

- Use all adherence monitoring actions as reinforcement of successful adherence as well as setting boundaries
- Discuss and regularly review written treatment agreement
- Distress behaviors and uncontrolled pain trigger a thorough review of function, stressors, mood, any new medications
 - Re-evaluate treatment options based on review

Adherence Monitoring Measures

- Insure documented compliance w/ non-pharmacologic treatment referrals
- Urine toxicology screening
- Pill counts
- Regular review of Prescription Monitoring Programs
- Patient selected family/friend participation in adherence monitoring and medication dispensing

Box 2**Strategies to Mitigate and Manage the Risk for Abuse of Pain Medications**

- Consider how pain interacts with various physical, psychological, social, and spiritual issues over time.
- Establish a therapeutic relationship between patient and provider as the foundation for all interventions and activities.
- Conduct conversations in a respectful and direct manner while avoiding shaming statements.
- Promote an honest exchange of information.
- Provisions of age and education-appropriate educational materials contribute to establishing trust, informed patient consent, and adherence to a therapeutic plan.
- Discuss and obtain an informed written treatment agreement. The treatment agreement provides information for expected behaviors of the prescriber and the patient. It also serves as an educational tool. This agreement should be reviewed periodically to clarify expectations.
- Do not terminate the patient from your practice. Through clear boundaries of care and expectations, the patient may choose to leave your practice if they cannot adhere to your care within the established boundaries. If non-adherence continues despite intervention, weaning off opioids and referral to other forms of pain treatment is indicated. Referral to addiction care may be necessary. Careful documentation to referral sources reduces risk of perpetuating an abuse problem.

Box 3**Communicating When Challenges Exist**

Despite dedicated efforts to maintain a trusting therapeutic relationship, there may be encounters when tensions run high. In the face of challenging patient behavior, the following recommendations can be helpful:

- Focus on the patient and topic. Be sure the topic is clearly stated.
- Facts and expectations must be stated calmly and clearly.
- Remain in control of the discussion by stating the topic in a clear, concise manner.
- When faced with emotionally charged exchanges, maintain an even tone using assertive statements from the treatment agreement.
- Take charge of the time spent on the issue, moving to achievable patient goals to avoid becoming “stuck” on an emotionally charged issue.

Box 4**Adherence Monitoring Questions**

Adherence monitoring procedures should be introduced, defined, and discussed from the beginning of opioid treatment. The goal is to educate, promote, and sustain the safe use of opioids in support of optimal pain management and function.

Adherence monitoring requires focusing on each patient as an individual at each interaction using a biopsychosocial-spiritual (BPSS) approach. Standard assessment includes inquiries directed from the 5 A's (See Table 5 for further explanation), medication use, storage of medications, and with whom the medications have been shared or borrowed. Use caution in relying on one assessment strategy as proof of adherence (Heit & Gourlay, 2004; Heit & Lipman, 2009).

Having a wide range of questions is helpful and can be placed in how they reveal a typical day. Using open-ended questions is usually more effective in gaining information about the patient. A list of questions follow:

- Have you achieved any goals previously set?
- How is your mood or spirits?
- Have you experienced any new medical conditions?
- If there are new medical conditions, how are you coping?
- Do you attend a community of faith, worship, pray, or have spiritual practices?
- Do you have a friend to confide in or receive help or comfort from?
- Are you spending time alone? If so, how much time is spent alone?
- How do you feel about yourself these days?
- Are you having difficulty with your spouse or children or significant other?
- Are there financial problems?
- What feedback do others in the environment give you regarding your overall condition or progress?
- How do you feel about the pain treatment and medication?

The goals of these questions are to gain a holistic perspective regarding changes in pain, mechanisms for coping with pain, level of function/activity, interactions with others in their environment, and any new stressors or coping strategies with ongoing stressors. During the encounter, the healthcare provider observes behaviors looking for eye contact, body positions, and speech patterns. Clinical judgment by the healthcare provider is still required to properly integrate all the individual assessment items and to construct as accurate a picture as possible.

Box 5**Setting the Stage for Success**

- Have a list of available community resources available. These resources would include religious organizations, counseling agencies, volunteer organizations made available for support.
- Know what the patient's health insurance pays for, especially medications. Find out how their insurance will support the pain management plan. Involve Care Coordinators, available through the primary care clinics or the insurance company. The Care Coordinators work directly with the payer systems to ensure the treatment plan is supported financially.
- An inventory of the patient's support system is a valuable method to reduce distress associated with persistent pain or addictive disease. This support system can be available to calm the patient when stress occurs, set up medications or administer medications so that impulsive or compulsive use of opioids and other central nervous system medications is reduced or avoided. This support system includes trusted individuals who are involved in structuring the treatment plan. The support may include Alcoholics Anonymous, Narcotics Anonymous, or other support groups.
- Establish non-pharmacologic techniques for managing pain. The purpose of these techniques is to reduce distress. Examples of these techniques include relaxation breathing, meditation, visual or guided imagery, positive self-statements, (Schaub & Dossey, 2009) and mindfulness training. The goal of teaching self-management of pain symptoms is to help the patient maintain function (St. Marie & Arnold, 2002). Nurses are encouraged to provide intuitive and creative interventions designed for a particular person.

Box 6**Caution with Urine Toxicology**

Urine drug testing (UDT) can be a valuable aid in adherence monitoring but also presents challenges in accurate interpretation by the clinician and in potentially provoking defensiveness in the patient (Gourlay & Heit, 2010). In order to better meet these challenges, clinicians should:

- Consider having another testing method such as saliva testing in case a patient cannot urinate on demand
- Clarify reason for ordering UDT
 - Know specific medications that you're looking for and their metabolites
- Educate patient that purpose of UDT is for safe medication use and preventing harm
 - Discuss with the patient the intent is NOT to punish or degrade them
- Document the last 24 hours of medication used and times of last dose
- Interpret the results accurately and seek consultation with toxicologist as needed, knowing that different testing procedures exist in each facility and quantitative testing is most accurate for adherence monitoring
 - Medications monitored
 - Check time of onset
 - Check peak action
 - Check duration present in urine
 - Expected metabolites
 - Check non-prescribed drugs that may metabolize from parent drugs, for example, hydrocodone metabolizes to hydromorphone or codeine metabolizes to morphine.
 - Check duration present in urine
- Conduct open discussion with patient of results that are expected and unexpected

Use UDT to build trust and decrease stigma whenever possible

Urine toxicology can be used as an educational tool and can be used to reduce stigma (Heit & Lipman, 2009; Manchikanti, et al., 2008).

Box 7**Suggested Points for Inclusion in a Treatment Agreement**

- Honest exchange of information between patient and provider is expected.
- Adherence monitoring is used for all patients receiving opioids to ensure patient and community safety.
- Pill counts and urine toxicology are part of routine care. Explanation of the clinic policy if patient does not follow through with these requests.
- Random pill counts and urine testing can occur at any time.
- It is the patient's responsibility to inform the prescriber of any changes in pain, function, or side effects.
- It is the patient's responsibility to refrain from making independent adjustments in any pharmacotherapy without first discussing with the prescriber.
- It is the patient's responsibility to keep scheduled appointments which allow for regular and systematic assessments.
- It is the patient's responsibility to refrain from obtaining pain medications from any other prescriber without prior notification or discussion.
- Use a single pharmacy for prescriptions that are controlled substances.
- The provider will give instructions for reaching the prescriber during office hours and a preferred plan for obtaining assistance after hours, or in the event of an emergency.
- Discuss a relapse plan. This may include 90 AA or NA meetings in 90 days, smaller supply of opioids and more frequent visits. Discuss the role of the support system in administering the pain medications; use a timed lock box for pain medications. If a taper is recommended then the procedure for the taper is clearly delineated and written.
- Promote a support recovery environment for those with history of substance abuse disorders.
- Discuss an exit strategy for opioid taper and referrals. In the event that either the provider or patient seeks to terminate care, discharge discussions are best implemented by following the exit strategy that the patient agreed to when they started opioids and signed the treatment agreement.

Figure 1. Biopsychosocial-spiritual Model (BPSS)

Table 1
Less Suggestive of Serious Abuse*

Aggressive complaint about need for more or stronger medication
Requesting specific drugs
Requesting refills instead of attending appointments with clinician
Unapproved use of drugs to treat non-painful symptoms
Emergency room visits for pain medicines
Saving unused drugs for later use
Occasional unsanctioned dose escalation
Obtaining similar medication from other sources
Unkempt appearance without other signs of impairment
Unapproved use of the drug to treat another symptom
Reporting psychiatric effects not intended by the prescriber
Occasional impairment

Table 2
More Suggestive of Serious Abuse^{*}

Selling prescription drugs
Prescription forgery
Overdose
Altering mode of administration of drug delivery, i.e. crushing oral meds for IV or rectal use
Obtaining prescriptions from non-medical sources
Concurrent drug/alcohol abuse
Stealing or borrowing drugs from others
Obtaining drugs from other prescribers without informing clinician
Frequently loses prescription
Repeated dose escalations even when warned
Pattern of drug-related deterioration
Repeated resistance to change despite adverse drug effects

^{*} Adapted from Portenoy, R. K. (1994); and Passik, Kirsh, Whitcomb, Dickerson, & Theobald, 2002.

Table 3
Intrinsic and extrinsic factors for pain and addiction using the Biopsychosocial-spiritual model

Intrinsic factors
Spiritual
Personal belief about pain and its meaning
Sense of connection with others
Hope to establish and maintain optimal function and an intact sense of self
Acceptance of the possibility of relapse, and hope for capacity to maintain sobriety/abstinence
Individual
Personal pain tolerance
Variation in pain perception
Genetic differences
Gender differences
Age differences
Coping strategies
Confidence to manage pain
Mental health, i.e. depression, anxiety or post-traumatic stress
Internalized past experiences, i.e. history of substance abuse, sexual abuse, or chaotic lifestyles
Extrinsic factors
Previous pain experience
Social and financial stressors
Positive or negative role modeling from others, i.e. pain behaviors, coping skills, drug abuse
Encouragement or no encouragement from others, i.e. family or health care professionals
Social support system

* adapted from Matteliano, 2010

Table 4
The Ten Principles of Universal Precautions for Patients with Persistent Using Chronic Opioid Therapy *

1	Make a diagnosis with appropriate differential including the biopsychosocial-spiritual status.
2	Psychological assessment including risk of addictive disorders. The assessment of the patient uses the biopsychosocial model with the spiritual factors included.
3	Informed consent (verbal or written/signed). Provide patient education regarding management of pain and side effects.
4	Treatment agreement to establish expectations of both the provider and the patient. Establish a therapeutic relationship promoting trust and honesty. This treatment agreement also includes safe storage of medications in the interest of public safety, i.e. Lock Your Meds®, as well as rationale for potential opioid discontinuation or discharge from medication treatment. See box 7 for Suggested Points for Inclusion in a Treatment Agreement.
5	Pre/post intervention assessment of pain level and function. With the use of the bio-psycho-social-spiritual model, the assessment is included in its entirety.
6	Appropriate trial of opioid therapy and/or adjunctive medications. Promote supportive recovery environment with family and significant other involvement. Integrate non-pharmacologic adjunctive therapies such as biofeedback, relaxation training, physical therapy, cognitive therapy and support groups.
7	Reassessment of pain level and function. With the use of the biopsychosocial-spiritual model, the assessment is included in its entirety. Use of adherence monitoring measures are applied and include urine toxicology, screening tools for alcohol/substance use disorders, pill counts, and overall adherence with treatment plan appointments and medication use.
8	Regularly assess the 5A's which stand for Analgesia, Activity, Adverse Reactions, Aberrant Behavior and Affect **.
9	Periodically review pain diagnosis and comorbid diagnoses, including addictive disorders and mental health.
10	Documentation.

* Adapted from Heit and Lipman, 2009, p. 371

** Adapted from the Four A's of Pain Treatment Outcomes (Passik & Weinreb, 2000). Incorporating the BPSS model, and based on their clinical practice, the authors recognize the need to evaluate affect, mood and psychological well-being. For this reason, we recommend **Five A's** of assessment: Analgesia, Activity, Adverse reactions, Aberrant behavior and Affect.

Table 5
Examples of Risk Factors for Abuse of Pain Medications *

Family and personal history of substance abuse
Cigarette dependency (particularly if smoking occurs first thing in the morning)
History of preadolescent sex or sexual abuse
Psychologic stress
Patterns of impulsive behaviors
Victimization by others in household such as an abusive spouse
History of repeated drug/alcohol rehabilitation
Unwilling to try any other modality for pain relief
Mental health disorder (particularly if unknown to the prescribing clinician)
Young age
Social Patterns of drug use, or polysubstance abuse
Failure to participate in drug or alcohol program for persons with substance use disorder
Poor social support, chaotic lifestyles
Unclear cause of pain, exaggeration of pain
Declining functional status
Large focus on opioids

* Adapted from Webster and Webster, 2005.

Table 6
Listing of the clarification boxes

Box 1 Relapse Prevention and Management
Box 2 Strategies to Mitigate and Manage the Risk for Abuse of Pain Medications
Box 3 Communicating When Challenges Exist
Box 4 Adherence Monitoring Questions
Box 5 Setting the Stage for Success
Box 6 Caution with Urine Toxicology
Box 7 Suggested Points for Inclusion in a Treatment Agreement