

# The Need for Compassionate Assessment of the Chronic Intractable Pain Patient and Balance in the War on Drugs



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## Introduction

In visiting historic American homes, I learned of a now antiquated practice of family bathing. It was considered as an expedient method at the time; addressing the limited resource of hot water. Each member of the entire family would share a single tub on bath day, one by one, starting with the eldest and continuing to the youngest. Because the baby was last to be bathed prior to emptying the tub, the baby could potentially be discarded along with the bath water. The idiom don't throw out the baby with the bath water, has come to represent the risk of discarding something of value when purging that which is no longer needed or desired. In prioritizing the risk of opioid abuse as the signal issue of the opioid crisis, the patient in pain has been placed at significant risk of neglect and abuse.

Pain is a legitimate symptom of varying degree but cannot objectively be measured at this time. Therefore, Healthcare Providers (HCP) must rely upon the subjective, self-reporting of pain by the patient. Validation of the patient's complaint requires a specific skill set that can be learned, but often is not taught. Simple tools, such as the Visual Analogue Scale (VAS), or some other form of this rating tool, is used to gauge pain severity, most commonly on the Numeric Pain Rating Scale (NPRS) from 0-10 [1]. In this way pain can be rated from none to most severe. Although it is a subjective scale, it remains in use as the most common method to correlate with the intensity of pain experienced by an individual. This information provides the basis upon which subsequent decisions on pain management are made. Unfortunately, although pain is universally acknowledged as the most frequent reason for people seeking medical attention, evaluation and treatment strategies of the person in pain are not well covered in medical school or most residency programs. There often is a sense that the patient in pain represents an endless series of complaints for which the potential treatment options create problems in

management. Thus, there is an inherent difficulty in evaluating the veracity of pain complaints reflecting difficulty in validating the degree of pain and then there also is a stigma associated with the most appropriate choices for providing relief. This conundrum is further compounded in a legal climate under pressure to resolve the opioid crisis. To some HCP, the patient complaining of pain may appear to be drug seeking. There is an ongoing emphasis on the dangers of substance abuse and addiction [2]. This is because of the real potential for that to occur with some of the medications used to provide pain relief. However, this concern is also influenced by the dangers associated with drugs obtained through illegal means, and the tainting of illicit drugs, like heroin, with more potent, and thereby more risky, synthetic opioids like fentanyl [3]. The dilemma at this time is that the best option for providing adequate pain relief may be use of a medication for which the potential for addiction exists. However, this does not mean that such medication should not be used for the relief of acute or chronic pain. The notion that all patients treated with an opioid for providing pain relief automatically become addicted to their medication is false. But that does not diminish the need for awareness and evaluation of the potential for addiction to develop.

There is a dichotomy between people who are subject to becoming addicted to pain medication [4], which usually reflects characteristics of the individual, and alleging that people who are in severe pain, who receive relief through the judicious use of opioid analgesics, will inevitably become addicted to their medication. Although the possibility of addiction must always be kept in mind, since death can be caused by issues associated with opioid addiction [5], inadequate treatment of chronic pain, in particular, may also lead to death, often by suicide [6]. While the crisis of opioid abuse must be addressed, it should not be done penalizing those who are legitimate pain patients.

Opioid medications should not be considered only for or confined to those patients who have or have had cancer. Chronic pain from other causes, such as Complex Regional Pain Syndrome (CRPS), various post-operative conditions, including Failed Back Syndrome (FBS) and arachnoiditis, severe arthritis, sickle cell disease and a multitude of other diagnoses are also real conditions. The pain from these conditions may be just as harsh as the most severe pain experienced in cancer and is compounded by the issues inherent in each of those conditions. The demonstrable basis of pain in cancer patients, due to evident tissue invasion, should not be the basis for denying the legitimacy of pain severity in non-malignant diseases, where objective tissue damage may be more difficult to document. The pain is no less legitimate and may in fact be more incapacitating. I believe the focus on cancer pain is a reflection of an unintended dual bias. The first bias is that cancer pain may be a manifestation of a terminal condition. Therefore, the issue of addressing addiction becomes less significant than providing palliative relief of pain. However, this presumes that chronic pain of other origins, is less significant or life threatening, regardless of its severity, because the underlying condition is not considered terminal. This is false. Chronic intractable pain can also lead to death. The second bias is derived from an artifact associated with a practice of the pharmaceutical industry in which analgesic efficacy is initially evaluated by seeking pain relief in clinical studies performed on cancer patients. This practice reflects the effort to expedite FDA approval of a new drug for pain relief. However, success in relieving cancer pain should not a priori preclude equianalgesic effectiveness in relieving chronic pain originating from other causes. This issue deserves further consideration by the appropriate regulatory bodies.

Effective treatment of chronic pain requires careful assessment of the individual and the reason(s) for their need for pain relief, an open and honest discussions addressing the addictive potential of opioids, and close monitoring of their medication usage [7]. Family members and/or significant others should be included early on in the evaluation. Sometimes a patient is reticent to disclose other addictive behaviors, such as alcohol abuse or gambling. The need for time to assess this level of interaction must be recognized and properly reimbursed by third party payers. Third party payers also typically require prior authorization for doses and quantities of opioid analgesics for use in chronic pain conditions that are outside of CDC guidelines [8]. While this is, in general, is a good oversight practice, this screening is heavily focused on opioid use in cancer rather than equally addressing chronic pain of non-malignant causes, and there is a serious risk in suddenly stopping opioid therapy.

Additionally, there often is a Medical Director who can be contacted in an appeal, but this causes more delays. A major shortcoming is that the Director is NOT familiar with the patient and their needs. Even if practicing within the same sub-specialty of medicine as the HCP, the Medical Director may not be familiar with the more subtle details of the condition under treatment.

An unsupportive decision will inevitably cause further delay of treatment, since the only course that remains is to appeal the decision of the Medical Director. This final decision inevitably is made by individuals who are even further removed from the patient or their condition. The process of prior authorization often takes a great deal of time, taking the HCP away from the care of patients. The time invested in obtaining a prior authorization is not reimbursed, so it de facto also presents a financial burden to the HCP. The time lost further impinges on the close monitoring of treatment efficacy of the pain patient, including additional input from specialty practitioners. Worse still, the delay or denial of authorization by an insurance company of payment for a pain medication already utilized for years may have dire consequences, including influencing a patient to turn to available alternatives, including "street drugs." This prospect demands close attention.

Additional concerns in the use of opioid therapy include that of tolerance, defined as greater doses being required to achieve the same therapeutic effect [9]. This has been considered by some to be the hallmark of the addict's drug-seeking behavior, and it has also been used as a strong argument against the long-term use of opioids. However, tolerance is not an inevitable consequence of proper drug administration. In fact, maintenance of a stable dose of opioid is a cornerstone of many drug addiction-treatment programs [10], alternatively switching to another opioid molecule (opioid rotation) may provide better relief [11]. The mechanism of tolerance has been demonstrated to be a function of the interaction between the medication and its receptor. The opioid receptor is a genetically defined molecule, of which multiple varieties exist [12]. Naturally occurring analgesic molecules, endorphins and enkephalins exist in the brain. These endogenous molecules bind to these receptors [13], as do opioids. The runner's high, elicited by vigorous exercise or running, has been attributed to these endorphins. Antagonist molecules, which block the binding of these molecules to their receptors, can effectively block the action of opioids at these receptors and reverse their effects. This is the basis of the use of naloxone [14] as a rescue treatment of an opioid overdose.

The relationship between medication and receptor is also essential in treating chronic pain. Proper pain treatment with opioids requires adjusting the choice of the particular drug, the dose and the frequency of administration of the medication to reduce the pain to a tolerable level. It is unrealistic to expect opioids, or any other class of medication, to completely eliminate all pain manifestations. In fact, if an individual lacks the appropriate opioid receptor for the selected opioid administered, that opioid will NOT be effective in providing pain relief. These are also important points of discussion between the HCP and the patient. If a patient indicates inadequate pain relief with the medication provided, an opioid to which the individual lacks the appropriate receptor or an inadequate dose may have been provided, and an alternative opioid must be selected.

Pseudo-addiction refers to the need for additional opioid medication to achieve a therapeutic effect [15]. Although the term has become incorporated into discussions in pain management, it is imperative to understand the underlying physiologic basis of this phenomenon. Pseudoaddiction is most often seen during the initiation of opioid therapy and may reflect a poor match to the individual's opioid receptor profile or an ineffective dose to provide sufficient receptor saturation to afford adequate pain relief. This is best determined by observing the response to gradual incremental escalation of the present opioid or alternating course and switching to another opioid (a form of opioid rotation). However, an important rule of thumb must be emphasized. Always begin therapy with the lowest dose and gradually escalate to achieve the most effective therapeutic response with the fewest side effects.

A depressed mood and/or stress can also worsen pain perception. For this reason, utilizing self rating clinical tools such as the Zung or Beck depression rating scales can be useful in assessing the status of a pain patient [16]. It is also important to acknowledge that there are different contributing sources of pain. These are identified as pain generators. Therefore, relieving pain may sometimes require an approach much akin to finding the correct key for a particular lock or pain generator. The reality of pain management is that some of the locks may require a key of a different configuration or more than one key. This translates into alternative medication, a higher dose of a particular medication, or the simultaneous use of multiple medications, which is referred to as polypharmacy. When carefully planned and documented, the use of multiple medications in this fashion is referred to as rational polypharmacy. The correct combination of medication and dose are specific and unique to each individual patient. A fixed regimen cannot always be applied across the board, although most clinicians will find there is a particular therapeutic range that is most effective when treating a specific condition. The World Health Organization devised an escalating scale of drug potency, or ladder, which provides a useful guideline in both selecting an appropriate analgesic medication and dose regimen for any given patient [17].

It is also important to discuss that opioid receptors are widespread throughout the body [18]. This accounts for the commonly experienced, dose-dependent side effects of opioids, which can include drowsiness, respiratory depression and constipation, amongst others [19]. Careful monitoring of the specific opioid, its dose, dosage form (immediate vs extended release) and frequency of administration are imperative.

In this context of receptors, it is helpful to review several additional concepts. These include physical dependence, withdrawal and rebound. Physical dependence refers to the manifestations that occur upon withdrawal of the medication. This reflects physiological changes of state in the individual, and are unique to the individual, although more common with certain

classes of medications, such as opioids [20]. It is not addiction. Rebound refers to the return of pain that is the same or worse than it had been while taking the medication, with the consequence of seeking medication for pain reduction [21]. This is a receptor-mediated function, and is similar to opioid-induced hyperalgesia [22], in which, in rare instances, opioid medication can contribute to the pain state. Further research is being conducted on these physiological phenomena, which certainly will provide greater insight on pain management. However, it is my personal opinion that these events should not be reason to eliminate the potential use of opioid therapy in the treatment of non-malignant chronic intractable pain conditions.

When there are clearly evident objective findings, such as a fracture or laceration, the source of the pain, and hence, the requirement for pain medication is readily identified and considered reasonable. However, when the source of the pain is not recognized or identified, such as an acute migraine or CRPS, the patient may be labeled as "drug seeking." New additions to address the presently identified specific mediators of migraine have become available in recent years, and further developments are in progress. However, headache is a symptom, not a singular diagnosis. Therefore, there may be more than one source of the headache pain, and each may require a unique treatment approach.

Although a multi-modal approach is utilized in treating CRPS once it is diagnosed, it often evolves into a chronic intractable pain condition. Although CRPS is a form of neuropathic pain, the intractable aspect may not be identified until the pain has persisted and is acknowledged as a chronic condition. Once again, qualitative pain symptoms, such as burning, aching or shooting, etc., will require individualized attention with specific medications designed to address these symptoms in order to maximize the therapeutic effect.

Regardless of its source, chronic intractable pain conditions may require indefinite long-term opioid therapy to provide sufficient pain relief to allow more normal function in Activities of Daily Living (ADL), as well as more demanding activities, such as driving and working, in order to maintain a degree of Quality of Life (QOL). This requires achieving a balance between pain relief measures and the inevitable side effects of the treatment modalities employed.

It is always the responsibility of the HCP to discuss and evaluate potential side effects of opioid medications at each interaction. It is important to identify whether anyone else within the home utilizes related medications for pain control, and imperative that there are rules and responsibilities associated with receiving pain medications at each encounter. These medications must be locked away, rather than kept in a medicine cabinet to which there is access by other family members and guests to the home. It is imperative that the schedule of use of the medication be reviewed and that the medication be taken as prescribed. With

chronic intractable pain, a regular schedule of dosing is important to stay ahead of the pain. This helps to determine the elements which require additional attention for pain symptom control and the need for medication for breakthrough pain. Finally, patients should be encouraged to bring a significant other or family member, especially when they do not agree with the patient's need for opioids. Sometimes these individuals question the need for pain medicine, and their learning more of the nature of the problem and how they can be of help may be very useful in achieving more successful pain management.

Patient confidentiality must also be protected at the pharmacy. Announcement of a prescription opioid alone or along with a patient name is not only a HIPPA breach, but also leaves the named patient as a potential target of vandals regarding the type of medication they received. Furthermore, it is also unacceptable for some pharmacists to treat a patient receiving an opioid as though they were drug seeking. Communication between the prescribing physician and the pharmacists is to be encouraged whenever any questionable activities may arise.

In summary, when pain is chronic and intractable, its treatment does require measures that may initially seem extreme. Such an approach is nevertheless essential in order to provide sufficient relief to allow the patient to tolerate and interact well with others and to get needed sleep. Sleep deprivation will aggravate the perception of pain and mood. In the effort to control the Opioid Epidemic, there has been an emphasis to increase the public's perception of the addictive potential of these drugs [23]. In this process, the potential therapeutic value of careful administration of various opioids has NOT adequately been addressed. There is a need for greater balance in this discussion. People in need of opioid treatment should not be left to feel like victims of the War on Drugs, and reluctant to utilize these medications under appropriately carefully monitored conditions when the utilization of these medications are warranted.

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