

Opioid moderatism and the imperative of rapprochement in pain medicine

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A brief history of the “prescription opioid crisis”

Few would deny that the first decade of this millennium was marked by a “prescription opioid crisis” in the United States, characterized by overprescription and frank opiphilia. Although many have attempted to blame this crisis on a single cause, more thoughtful analysis has yielded numerous contributors to the onset and maintenance of the abuse crisis.¹ Schatman,^{2,3} among others, has posited that health insurance carriers’ decision to discontinue coverage of interdisciplinary pain management programs left physicians without the most effective means of treating chronic pain, resulting in the consequence of turning to increased opioid prescribing. Dasgupta et al¹ recently suggested that the pharmaceutical industry responded to this void by propagating not only long-acting opioids but forms that were ultra-rapid-acting, including dissolving strips and nasal sprays. They also noted that safety issues associated with non-opioid pain medications such as non-steroidal anti-inflammatory drugs and acetaminophen may have further fueled opioid prescribing. Perhaps the aggressive and fraudulent marketing of OxyContin as “nonaddictive” has been considered the primary culprit in the prescription opioid crisis,⁴ although other questionable industry behaviors such as kickback schemes,⁵ lucrative compensation for speaking as an incentive to prescribe,⁶ and promotion of off-label use⁷ have also been implicated as contributing to the prescription opioid conflict. In the late 1990s patient advocates began to encourage the assessment of pain as the “fifth vital sign”, and those most vehemently against opioids have gone so far as to suggest that pharmaceutical industry lobbying was responsible for the Joint Commission on Accreditation of Healthcare Organizations’ (JCAHO) advocacy for the institution of such.⁸ JCAHO’s proclamation has been indicted as creating a culture resulting in a marked increase in opioid prescription.⁹ Other causes to which the prescription opioid crisis has been attributed include unscrupulous physicians operating “pill mills”,¹⁰ unrealistic expectations of patients regarding complete relief of pain,¹¹ state medical boards curtailing restrictions on prescribing opioids for noncancer pain,¹² the Affordable Care Act’s provision requiring hospitals’ provision of patient satisfaction surveys that included satisfaction regarding pain relief,¹³ increased availability of prescription opioids without a prescription over the internet,¹⁴ and providers’ failures to adequately identify and monitor misuse and overuse.¹⁵ This list is far from exhaustive, with a recent assessment¹⁶ reporting that “The root causes of the modern opioid crisis are complex and traceable to at least 30 or more factors” (p. 943).

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However, despite a lack of consensus, a recent analysis¹⁷ concluded that the prescription opioid crisis is over, replaced by an even more deadly epidemic of overdose deaths from heroin and illicit fentanyl and its analogs. This is consistent with the United States Food and Drug Administration's data, which demonstrate a decrease in total opioid sales (as measured by morphine milligram equivalents [MME]) every year since 2010.¹⁸ Similar to the lack of consensus regarding the root cause(s) of the prescription opioid epidemic is that regarding the cause(s) of the precipitous decline in overall opioid prescribing over the past 8 years.

Efforts to curb the “prescription opioid crisis”

Some have opined that America's “war on opioids” began a century and a half ago in response to injured Civil War veterans becoming dependent on morphine, with this dependence referred to as the “soldier's disease”.¹⁹ When Congress passed the Harrison Act in 1914, its purpose was to prohibit recreational use of opioids, which had become rampant. However, in fact, a result of this legislation was what approximated prohibition of medical use of opioids, as physicians were often charged with violating the Harrison Act.²⁰ Perhaps the modern day “war on opioids” began with the passage of the Controlled Substances Act (CSA) in 1970, accompanied by President Nixon's declaration of a “War on Drugs”²¹ the following year. Although this was seen primarily as a war on illicit drugs, it has been noted that the following years were marked by progressively increasing opiophobia,²² although much of this opiophobia was likely due to the power that the CSA afforded the Drug Enforcement Administration.²³ This opiophobia is thought by some to have resulted in an “epidemic of pain undertreatment” in the 1990s,²⁴ resulting in the pendulum swinging awry toward the opiophilia that characterized the most recent prescription opioid crisis. By 2002, epidemiologic data suggested that 4.7% of US residents over the age of 12 had abused a prescription opioid during that year.²⁵

Although it is difficult to definitively identify the initial effort to curb overprescription of opioids in this millennium, it may have been the College on Problems of Drug Dependence's commission of its Taskforce on Prescription Opioid Abuse in 2001 that marked the first concerted effort to address the nonmedical use and abuse of prescription opioids.²⁶ They emphasized that “... the need to control and reduce abuse, diversion, and trafficking of opioid analgesics must be balanced against the need for physicians and patients to have access to licit opioids for the treatment of

pain” (p. 216). However, as the decade progressed, the published literature became progressively less balanced, and the pendulum began to swing more strongly toward opiophobia. Prescribing guidelines of questionable quality were released by interventional pain societies,^{27,28} as they recognized an opportunity to increase their own market share of chronic pain patients by demonizing opioid analgesia.

Washington State's Medical Director of workers compensation began his war on opioids in 2005, publishing a retrospective study in which he and his colleagues found a positive correlation between high-dosage opioids and overdose death in workers compensation patients.²⁹ In 2007, a group that he led developed an “educational” opioid prescribing guideline,³⁰ followed by a “recommended” guideline in 2010³¹ and an updated guideline in 2015.³² Each iteration was more restrictive regarding its recommended arbitrary opioid limits or “triggers” than the previous one, and was based on “consensus” rather than “evidence”. Although these guidelines were promoted as “voluntary”, their “chilling effect” resulted in widespread fear among Washington physicians, thereby reducing prescribing.³³

As soon as the 2015 Washington State guideline was published, many of its authors began working with the United States Centers for Disease Control and Prevention (CDC) on its 2016 guideline,³⁴ which was also touted as “voluntary”. However, even before it was released, concerns were expressed that its intention was to become de facto law: “In fact, the CDC imprimatur makes it more likely that these guidelines become de facto requirements through adoption by state health departments, professional licensing bodies or insurers.”³⁵ Tragically, this is what appears to have happened, in state legislatures, state medical boards, and among both private and public insurers. State legislatures have already passed draconian legislation mandatorily limiting opioid dosing for acute pain, with no evidence of societal benefit. For example, Florida recently enacted a law that generally limits duration of opioid prescription for acute pain to 3 days,³⁶ without regard for elderly, impoverished patients who may not have transportation to get new prescriptions as well as not being able to afford additional copays. Similar legislation was already in place in Kentucky.³⁷ The law in Florida becomes potentially even more destructive, in that it requires that all prescribers take a 2-hour continuing education course on the law at each license renewal in order to maintain their controlled substance licenses. This type of overreaching legislation may discourage some physicians from prescribing controlled substances altogether. Although no state has yet passed legislation that limits MME below

levels recommended by the CDC guideline, states are writing guidelines and laws that require prescribers to consult with a “pain specialist” in order to prescribe MME well below those recommended by the CDC guideline. Given the shortage of board-certified pain specialists and that primary care physicians are generally ill-equipped and poorly supported,³⁸ this may pose a problem, particularly in rural and other underserved areas.³⁹ Perhaps one of the best known of such laws is that of Indiana, stipulating that after 3 months of a mere 15 MME, a “trigger” necessitating that prescribers alter their standard prescribing practices goes into effect.⁴⁰ Although there appears to be considerable “internet chatter” regarding individual state legislatures passing de jure laws creating “hard ceilings” for opioid MMEs, any such laws, at this point, are de facto rather than de jure. Unfortunately, anecdotally, patients in numerous states are being told by their physicians that they have to cut back their opioid dosages due to state laws requiring them to do so, which is inaccurate and disingenuous.

Another way in which state laws now potentially limit access to opioid analgesia is a subtler one, pertaining to Prescription Drug Monitoring Programs (PDMPs). Recently, the Kentucky PDMP began to identify any past illicit drug convictions within the past 5 years.⁴¹ Accordingly, if a legitimate pain patient had been convicted of a marijuana possession offense 5 years ago, his/her PDMP results would indicate such, and potentially reduce the likelihood of that patient receiving opioid analgesia, perhaps based more on stigma than on actual current risk.

Health insurers, on the other hand, are indeed mandating hard limits on MMEs for chronic pain, and this is causing considerable distress. One group of insurers that has been particularly short-sighted in its recent policies is state-managed Medicaid programs, which are operated under federal guidelines. However, as they are managed by individual states, their policies, including those pertaining to opioids, vary dramatically from state to state. Although initially, some states’ Medicaid programs focused on limiting short-acting opioid units,⁴² the recently proposed law in Oregon essentially eliminating Medicaid coverage for any chronic opioid therapy for chronic noncancer pain is particularly oppressive. Specifically, the Oregon Health Authority’s Chronic Pain Task Force has proposed a 90-day limit on prescription opioids for certain chronic pain conditions for Medicaid recipients, and that those patients who have been receiving opioids for more than a year to be tapered off of them completely.⁴³ The “consolation”, however, is that Oregon Medicaid would cover 30 sessions of “evidence-based” treatments in lieu of opioids.

These treatments include complementary and alternative medicine approaches, the evidence-bases for most of which for a number of chronic pain conditions that will no longer be treated with opioids through Oregon Medicaid are hardly impressive.^{44,45}

Another health insurer/health care system that has mandated harsh decreases in opioid use over the past year is Veterans Affairs (VA) Medical Centers. Between 2012 and 2017, 99% of all VA facilities reduced their percentage of patients to whom opioids were prescribed with a decrease of 41% in the ratio of patients prescribed an opioid to those patients prescribed any medication.⁴⁶ This can be compared to a 22% reduction in the number of opioid prescriptions in the general population between 2013 and 2017.⁴⁷ While the VA has attempted to counteract the impact of this substantial reduction by developing interdisciplinary chronic pain management programs, limited funding has allowed for the development of only a small number of them, resulting in numerous veterans receiving inadequate analgesia with no adequate substitute treatment available. Although the efforts of for-profit, private insurers to reduce opioid prescribing have been less transparent, for the most part, a 2018 formulary change by Cigna has demonstrated that private insurers are now in the “business” of reducing opioid prescribing. Cigna switched its “preferred” brand of abuse-deterrent extended-release opioid to a newer drug, with a deal with the new manufacturer to encourage physicians to prescribe lower dosages of the medication that became a preferred drug on the formulary.⁴⁸ Although health insurers’ policies on opioids have been questioned as merely tools for increased cost-containment and profitability,³² the impact of these changes on levels of oligoanalgesia has yet to be determined.

The result of the “war on prescription opioids” – “collateral damage”

A primary result of what has been both an evolution and a devolution in America’s opioid policy has been increased suffering for many for whom there are no other accessible options for their chronic pain other than opioid analgesia. For many years, the plight of these patients was ignored, with an emphasis on the far “sexier” “opioid epidemic”.⁴⁹ However, well-respected academicians have been exposing the impact of the “opioid pendulum” on pain patient well-being over the past several years, with progressively more papers on the “new opioid crisis” of opiophobia being published. For example, in 2013, Schatman and Darnall revived the Ethics Forum in Pain Medicine, with the initial article titled, “A pendulum swings awry: seeking the middle ground on

opioid prescribing for chronic non-cancer pain".⁵⁰ Shortly after its publication, Atkinson et al⁵¹ wrote an article on the "pendulum swinging too far", noting the damage that was being done to patients. Subsequently, numerous articles on the topic have been written not only by pain specialists⁵²⁻⁵⁶ but by other health care professionals,^{57,58} including addiction medicine specialists⁵⁹⁻⁶¹ and bioethicists.^{62,63} Mainstream media has finally begun to recognize the plight of patients with pain, with the number of articles written on the gravity of the situation progressively increasing.⁶⁴⁻⁷⁰ However, opioid-phobia – as practiced in academic and community medical centers – continues to increase in scope and severity, thus promoting the passage of even more draconian legislation and the insurance industry's further limitation of access to opioid analgesia to patients for whom there is no other adequate and accessible option. As a result, the plight of patients with chronic pain is at a modern-era height of severity, with no sign of the end of the "war on opioids" in which patients are the "collateral damage".

Solving the dilemma

To this point, this analysis has focused on the history of the United States' prescription opioid crisis, (at times misguided) efforts to end it, and the suffering that patients with pain have experienced as a result of these efforts. The remainder of this essay will focus on several strategies that will be imperative if the plight of the patient with chronic pain is to be eased. Doing so will require a widespread acceptance of "opioid moderatism", which seems to be a stance that few in the pain world (patients, physicians, insurers, and legislators) are willing to consider. However, we are concerned that the "opioid wars" will continue to harm patients, physicians, and society broadly until a moderatist stance is shared by all the parties involved.

Provider responsibilities

Few would deny that only several years ago, opioids were severely overprescribed in the United States. Reckless overprescription is clearly inconsistent with aggressive risk mitigation, and is perhaps its antithesis. Although no single risk mitigation strategy is a panacea for opioid overuse, abuse, and diversion, practices such as medication agreements,^{71,72} consistent use of PDMPs,⁷³⁻⁷⁵ and urine drug toxicology (UDT)⁷⁶⁻⁷⁸ all have at least moderate evidence-bases for increasing prescription safety. However, the lack of use of these tools in many clinical settings in which pain is treated is disturbing. For example, despite the use of medication agreements being recommended in treatment guidelines for

patients with chronic pain taking opioids,³³ a recent study of such patients⁷⁹ determined that only 46% were on an agreement. Currently, PDMP use is mandatory for prescribers in only 34 states,⁸⁰ with rates of failure to consult with the PDMP before prescribing varying between these states. In the 16 states in which PDMP use is voluntary, rates of use also vary. A recent study of PDMP use in Florida⁸¹ (a state known in the past for "pill mills" and considered one of the most "problematic" states for opioid abuse and diversion⁸²) indicated that only 31% of prescribers in the state were even registered to use the PDMP, and that pharmacists were actually querying the PDMP more frequently than physicians. UDT use has also been woefully low. For many years, it appeared to be linked closely to high levels of remuneration for physicians,⁸³ with profiteering and kickback schemes involving both physicians and UDT labs rampant.⁸⁴ Despite considerable disagreement between legislators, medical associations, and state medical boards regarding the optimal approach to UDT,⁸⁵ it is apparent that it is underutilized in opioid management. Among the most troubling data on underutilization of UDT are from a 2012 study⁸⁶ that determined that only 7% of patients prescribed opioids on multiple occasions at an HIV clinic underwent UDT. Similarly discouraging are results of a 2011 study of over 1,600 patients on chronic opioid therapy in which only 8% underwent UDT.⁸⁷ Perhaps these two studies represent an extreme. Recent investigations of the prevalence of UDT use in patients receiving chronic opioid therapy suggest that although rates may be higher (eg, 32.8%,⁸⁸ 33%⁸⁹) the determined prevalences do not approach the 2016 CDC guideline's recommendation for universal use of UDT in treating chronic pain with opioids.³³ It should be noted that opioid risk reduction initiatives can make a difference in the rate of UDT utilization, with a recent study finding that providers participating in such initiatives increased their UDT compliance from <15% to 50%, while those in control clinics increased only to 20%.⁹⁰

The Boston PainCare model of opioid risk mitigation: a glimmer of hope?

We are concerned that a failure of clinicians to adequately mitigate risk (as demonstrated by the data presented above) has resulted in prescription opioids having essentially been "litigated away" – resulting in widespread opioid-phobia and oligoanalgesia. Few argue for a return to patterns of reckless prescribing that was one of the root causes of the prescription opioid crisis. However, a more moderatist approach needs to be considered if the opioid pendulum is to ever find a safe yet humane resting place.

Boston PainCare is a community-based, tertiary chronic pain care facility that was founded by a group of anesthesiologists in 2007. Despite pain management's reputation as operating primarily for financial incentives,^{91–96} Boston PainCare's philosophy of integrated chronic pain care transcends what is being seen as the "new normal" in American pain medicine.⁹⁷ One way in which this is being done is through extremely comprehensive yet patient-centered opioid risk mitigation. First, Boston PainCare is neither "pro-opioid" nor "anti-opioid", but rather "pro-patient". Boston PainCare's mission is to restore the function and improve the quality of life of those suffering from chronic pain while reducing the overall financial and social cost associated with chronic pain treatment. The facility embraces a patient-centered interdisciplinary model of care that involves collaboration between providers. The center employs functional and behavioral interventions as the core treatments to achieve its mission. Ancillary treatments (such as medication management) are used to facilitate core treatment engagement while post-treatment compliance is promoted through patient education and self-advocacy. Integration of care is key to the success of Boston PainCare's treatment model and is supported through the use of customized electronic health record (EHR) technologies. Data analysis (both individual and aggregate) is employed to monitor individual progress toward goals, monitor and improve the efficacy of the center's treatment algorithms, and determine the best practice approaches through examination of population-based data. EHR customization allows for the early identification and expedient analysis of medication aberrancy data used by clinicians to develop treatment plans (eg, opioid reduction/elimination), identify interventions needed to end the aberrancy (eg, behavioral modification), initiate appropriate referrals (eg, addiction intervention, psychiatric treatment), and when necessary, engage local, state, and federal law enforcement.

Given the chilling effect of media reports, increased regulatory and/or legal sanctions, and the CDC's continued exaggeration of prescription opioid mortality,¹⁷ patients with intractable chronic pain for whom there are no other effective and accessible options can no longer necessarily find health care practitioners who will provide them with ongoing opioid therapy. As a result, Boston PainCare is referred many "inherited" or "legacy" patients, with the patient expectation of receiving opioid analgesia. The frequency and challenges of these scenarios have been documented in the literature.^{98–100} However, as Boston PainCare considers chronic opioid therapy an ancillary treatment to facilitate functional and behavioral interventions and engagement, these new patients

are not necessarily considered appropriate candidates for chronic opioid therapy – based on medical, functional, and behavioral evaluations and risk assessments. From the initiation of treatment, patients are informed that chronic opioid therapy, if otherwise appropriate, is contingent upon making functional gains and/or maintaining their functional capacities. The goal of opioid treatment is an individualized one, that is, tapering dosages to levels that maximize both safety and function in each individual patient. This stance is consistent with the recent literature that questions whether analgesia in and by itself should be considered an appropriate "ends" of pain medicine.^{101,102} All patients at Boston PainCare sign treatment consents, and those who are enrolled in the facility's medication management program sign opioid agreements on an annual basis. Not only is the Massachusetts PDMP checked on a regular basis, but the PDMPs from the other New England states and New York are consulted as well. UDT is performed at every appointment for each patient prescribed opioids at the facility using a semiquantitative immunoassay machine that produces results that make the necessity of expensive confirmatory testing rare. The testing is performed in-house during the patient's appointment, and the clinician has the results before seeing the patient. Although some have contended that certain physicians engage in urine drug overtesting based on profit motivation,⁷⁸ the facility charges for only what is considered medically necessary by the insurance carrier. This is done in the purest spirit of opioid risk mitigation, the purpose of which is to protect individual patients as well as society, generally.

Patients are considered for the center's Medication Management Program based on thorough medical, functional, and behavioral evaluations and risk assessments. For patients who are accepted into the program, Boston PainCare has created five distinct tiered medication care plans that provide varying levels of services, monitoring, and support based on the risks and needs of the individual patient. Patients on chronic opioid therapy at Boston PainCare fall into four levels of monitoring. Certain patients are on a PRN opioid regimen, with enrollment in this program requiring an absence of aberrant behaviors in conjunction with the need for less than daily use of opioid medication. Those receiving chronic opioid therapy deemed to be at the lowest level of risk based on history, psychosocial risk factors, and a lack of aberrancy are seen monthly through the Medication Management Program. Patients at a higher level of risk are seen every other week in the program, in which behavioral services are highly recommended. The majority of the patients in this program receive behavioral services on a regular basis. Finally, those

patients determined to be at “significant risk” for either medication misuse or whose behaviors are suggestive of a possible undiagnosed substance abuse disorder are enrolled in the Medsafe program. Medsafe is an 8-week care plan in which the goal is to either end the pattern of aberrant behavior through medical and behavioral treatments or to identify the presence of a disorder (ie, substance use disorder, significant psychiatric condition, and so on) that may require treatment external to Boston PainCare. These patients are seen weekly for their prescribing visits and are also engaged in frequent, mandatory behavioral treatments. Failure to “graduate” from the Medsafe program will result in referral to an addiction medicine program, as the facility’s philosophy is that while there may be a potential benefit to opioid therapy, continuing with such would be inappropriate when the risks of harm outweigh its potential benefit.

Although some may see Boston PainCare’s comprehensive, integrated approach as being overly paternalistic, the facility’s philosophy is that for some patients, ongoing opioid therapy is the only viable and accessible treatment – and needs to remain so. However, the patient’s “right” to be treated with opioids is contingent upon adherence. Furthermore, efforts are made to taper all patients down to safer dosages, with a motivational interviewing approach in conjunction with psychoeducational intervention resulting in great success in terms of helping patients understand that “less may be more”. Perhaps the greatest attestation to the facility’s approach may be that for 11 years, thousands of patients have been treated with chronic (often high-dosage) opioid therapy – without Boston PainCare’s knowledge of a single overdose death while in the program.

Rapprochement

As has been discussed above, the “opioid wars” between those who are “anti-opioid” and those who are equally “pro-opioid” have resulted in patients with intractable chronic pain becoming the collateral damage in the conflict,^{103–107} with the extent of the damage seemingly devolving from patient suffering to the tragedy of overdose deaths due to patients involuntarily tapered from prescription opioids seeking stronger, illicit opioids. A review of social media, particularly Twitter, indicates a progressively harsher level of discourse between patients with pain along with pain patient advocates and those that they perceive to be the cause of their suffering. Yet, many health care providers who consider themselves opioid moderatists are beginning to reach out to those considered to be anti-opioid ... with the olive branch generally being accepted, and the level of discourse improving. As moderatists believe

that those seen as anti-opioid share their goal of improving the quality of pain care in the United States, collaborations are being proposed. Key opinion leaders can be found on both sides of the “opioid argument”, and seeking a middle-ground together will likely to be essential in creating a national opioid policy that focuses on opioids not as a first-line treatment of chronic pain, yet as a tool that society cannot afford to eradicate from providers’ pain management armamentaria. Excellent examples of such are recent studies and articles on improving the safety and efficacy of compassionate and (ideally) voluntary opioid tapers.^{58,108–111} Furthermore, the authors of this article have been involved firsthand in efforts to create collaborations between all sides of the opioid argument, recognizing that only a complex solution to a very complicated problem will ever result in the commonly held goal of improved pain care and safety. We are particularly encouraged by a recent paper spearheaded by Dr Beth Darnall on the need for action against forced opioid tapering,⁵⁶ as the signatories included over 100 key opinion leaders in pain and addiction medicine, patient advocacy, and bioethics whose positions have recently ranged from radically pro-opioid to radically anti-opioid – with a surprising number embracing a moderatist position.

Summary and conclusion

The history of the prescription opioid crisis in the United States is a complex and discouraging one. However, on a positive note, we opine that the “crisis” of overprescription of the previous decade is now over, although has been replaced by a crisis consisting of opiophobia, oligoanalgesia, and progressive increases in the use of far more deadly illicit opioids by patients left without an adequate plan for pain relief and improvement of quality of life. As is far too common in American society, efforts to identify the primary culprit for the crisis of the past have focused on individual players and policies rather than recognizing that it was due to an unfortunate confluence of factors. Almost as old as the prescription opioid crisis itself has been efforts to quell it – some of which have benefited society, others of which have resulted in the “double effect” of reducing prescription opioid availability and deaths while perhaps contributing to the substantial increase in overall opioid mortality though its contribution to the exponentially increasing illicit opioid crisis – which indeed now constitutes an epidemic.

As the perhaps unintended consequence of the 2016 CDC guideline, opioid analgesia runs the risk of essentially being legislated away. While this process may indeed be beneficial in terms of reducing prescription opioid mortality, it has been

accompanied by considerable suffering among chronic pain patients being denied opioid analgesia, even in cases in which opioids have helped them to become more functional. Furthermore, the process has contributed to the illicit opioid crisis that is resulting in considerably more mortality than was ever due to prescription opioids.¹¹² Accordingly, we posit that draconian laws and policies of legislative and regulatory agencies need to be replaced by increased prescriber responsibility, such as that practiced at Boston PainCare for more than the past decade. Finally, the numerous stakeholders in the opioid wars need to continue to work toward rapprochement, recognizing that many of the leading players in the opioid wars are key opinion leaders – all of whom have much to contribute to finding a solution to this unprecedented social problem. Without such cooperation, individual and societal suffering will only continue to increase, which is certainly not the goal of any of the players involved.

Disclosure

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