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Point

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Counterpoint

Point/Counterpoint:

Opioid Abuse in the United States

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Moderator

The opioid epidemic is of utmost concern to many, including clinicians, patients, administrators, regulators, and members of the public. The following discussion focuses on regulation of opioid prescriptions to manage the opioid epidemic in comparison to improved education for healthcare professionals and patients.

For this discussion, we were honored to hold this timely conversation with two renowned individuals who understand the opioid epidemic well.

Dr. Jane C. Ballantyne is a professor of anesthesiology and pain medicine at the UNIVERSITY OF WASHINGTON in Seattle and advocates for the appropriate use of opioids and education for physicians and patients. **Ms. Meghna Patel** is director of the Prescription Drug Monitoring Program (PDMP) Office in the PENNSYLVANIA DEPARTMENT OF HEALTH in Harrisburg. She has implemented key regulations in the state of Pennsylvania to try and curb the opioid epidemic, starting with providing the prescription monitoring system to all the providers prescribing and pharmacists dispensing opioid or controlled substance medications.

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Dr. Antonia Chen: How do we fix the opioid epidemic?

Dr. Jane Ballantyne: We now have a situation where we have thousands, maybe millions, of patients already on opiates. We cannot just take those patients off their opiates because it is inhumane. We created this problem; we need to treat it as well.

However, if taken off the medication, it is highly likely that these patients will seek out illicit sources and are at risk of getting into real problems with opiate overuse and overdose. Many of these patients will be the ones that end up as death statistics, unfortunately. Thus, we cannot just cut those patients off.

To fix the opioid epidemic, we need two main courses of action. One is to change the culture in terms of the role of opiates in the treatment of chronic pain; the other is to accept that we produced the iatrogenic disaster.

For the first point, chronic pain is not treated well with opiates. There are a lot of common pain conditions, particularly back pain, and all the central pain syndromes—including fibromyalgia, irritable bowel syndrome, pelvic pain syndromes, and headaches—all of which do badly when treated with opiates. What we need is a complete change in thinking about the role of opiates in chronic pain. We should be coming from the perspective that opiates are usually not helpful for chronic pain, with some rare exceptions (treatment of pain at the end of life, treatment after surgery, treatment after trauma), instead of from the opposite perspective, which is that we should be using opiates for chronic pain. It does not mean that we should never use them, but we should use them rarely. There are some disease states where nothing else really helps, but there are also a lot of common conditions where opiates are a disaster.

For the second point, since we produced the disaster, we need many more people to recognize what opiate dependence is, and we need more people who know how to use Suboxone®, a prescription medicine that contains the active ingredients buprenorphine and naloxone. It is used to treat adults who are dependent on, or addicted to, opioids, either prescription or illegal.

We also need to do much more research into the difference between dependence and addiction, because in my view, there is no bright line between dependence and addiction. We grossly underestimate the number of patients who are in trouble with opiates by being dogmatic about what the term addiction means.

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Ms. Meghna Patel: The CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC) just released its 2015 data, where every day, 91 Americans die from opiate overdoses. This includes not only heroin, but also prescription opioids, and nearly half of the patients died due to opioid overdoses. I believe that physician involvement is significant in battling this opioid epidemic, and the regulations to support this would be very ideal.

In many instances, because prescription opioids have been the primary driver, reducing the overprescribing patterns can be the main focus by which we can reverse these overdose trends. We have seen the implementation of regulations in many states, such as Kentucky, New York, and Florida, where, along with regulations, providing many tools and resources to the physicians, and in some situations, dispensers, significantly helps in cutting down overprescribing patterns, which then cuts down on opioid overdoses.

Dr. Chen: What is the role of regulation for physicians in the light of the current opioid epidemic?

Ms. Patel: In Pennsylvania, the PDMP system was available to prescribers and dispensers starting August 2016. Prior to that date, it was solely used by the OFFICE OF THE ATTORNEY GENERAL (OAG) and law enforcement in Pennsylvania. The data that the OAG collected were only obtained every month, so month-old data were always received as a batch.

With the regulation ABC-MAP Act that was passed in 2014, there was no budget to start a PDMP office in the DEPARTMENT OF HEALTH. However, as soon as the budget was provided, the program in Pennsylvania was built up. To build a program, there were mass communications and constant outreaches to all the pharmacies in Pennsylvania to submit all controlled substances prescription dispensation data within 72 hours. Once we had a good handle of the data reporting, we identified a date where we could implement this system and have the program available to all prescribers and dispensers in Pennsylvania.

Source: <https://www.cdc.gov/drugoverdose/epidemic/>

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Pennsylvania is the 49th state that is opening this program up for prescribers and dispensers, so we learned a lot of lessons from other states on what they have improved. Launching the system per the regulations combined with communication and education has been helpful. We have received many phone calls, e-mails, and communication from patients after the launch of this system. If a physician sees that a patient is doctor-shopping by looking at the PDMP system, most physicians would say, “I am not going to prescribe you [the patient] opioids anymore, because clearly the state is tracking these data, and I do not want to prescribe it anymore.”

When we launched the PDMP program in August, we gave physicians all the resources of how to register, how to identify red flags, how to search for patients in the system, where to refer patients to treatment programs, and other clinical resources. We also understand that a physician’s clinical time is very tight, so physicians do not need to always go and check the PDMP system. They can allow a delegate from their office to check the PDMP system on their behalf, so the physician can be the one who talks to the patient about diagnosis, treatment, and others things. Delegates can handle patient searching, so the administrative burden can be slightly reduced.

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Dr. Ballantyne: I work in the state of Washington, which is the only state in the country that introduced laws, as opposed to regulations, that make it illegal for physicians to prescribe over a certain dose. So, what Washington State did is make restrictions on a dose level, and that dose was 120 mg of morphine equivalent daily.

This law has been heavily criticized and has created quite a lot of difficulty both for physicians who must apply the law and for patients. For physicians, it has created a lot of extra work in prescribing opioids, and it has made physicians afraid to prescribe opiates at all. There are now practices in Washington State that will not prescribe opiates at all for any indication in primary care, and there are even some emergency rooms that will not prescribe any opiates at all.

For patients, this means two things. One is that patients sometimes have difficulty getting ahold of opiates, even for appropriate indications. Second, if they are already on opioids, they can be cut off. And, as I mentioned before, for opioid-dependent patients, this can result in consequences of seeking illicit supplies of opiates to treat their own dependence. This is the negative aspect of having a law.

The good aspect of having the law is that it seems to have reduced prescription opioid deaths. Unfortunately, there has also been an increase in heroin-related deaths in Washington State, so it is not quite clear whether that is because patients who have been prescribed opiates have resorted to using heroin, especially when their doctors stopped prescribing opioids for them, or whether it was completely unrelated to the attempts to control the dosing of prescription opioids.

This rise in heroin-related deaths makes me think that laws are not necessarily the answer to the opioid epidemic. However, laws are not strictly regulations. I envision regulations in the form of what the FOOD AND DRUG ADMINISTRATION (FDA) does in terms of regulating supplies and indications for chronic opioids. The FDA can publish safety guidance and make educational processes required, which is called Risk Evaluation and Mitigation Strategies (REMS). In fact, now, those risk mitigation strategies are not mandatory but voluntary, but that will change in the near future.

Dr. Chen: What is the best way to educate patients and doctors?

Dr. Ballantyne: An important educational message to both patients and physicians is that opiates should not be used for the treatment of most chronic pain. Additionally, in having created this disaster, which is evident by the number of patients who are already on opiates, especially in high doses, we have to provide people with the tools and education on how to deal with this opioid epidemic.

That is why I would favor education instead of regulation that provides the correct education, which includes the correct indications for prescribing opiates, and how they can be used safely, not the sort of regulation that just shuts down prescribing opioids completely.

The DRUG ENFORCEMENT AGENCY (DEA) can do a lot more in terms of the education it requires from prescribers. Prescribers could receive education such as that required to prescribe buprenorphine or Suboxone for the treatment of addiction. This sort of model could be very helpful in terms of combining regulation and education as part of the drive to promote safer prescribing.

Ms. Patel: Education about regulation is key because as parts of the regulations are set out, one of the most effective measures that we will see is from pain management education for prescribers. We have seen that the CDC released chronic pain prescribing guidelines, but then some states have their own prescribing guidelines that are effective educational tools for prescribers.

Patients, on the other hand, also need to know everything about opioids in the sense that when a physician is prescribing opioids, they should inform patients about the short-term benefits and long-term risks. Patients should also be cognizant of the side effects of opioid prescriptions, as well as other options of

From the CDC: What can be done about the opioid epidemic?

- Improve opioid prescribing to reduce exposure to opioids, prevent abuse, and stop addiction.
- Expand access to evidence-based substance abuse treatment, such as Medication-Assisted Treatment, for people already struggling with opioid addiction.
- Expand access and use of naloxone—a safe antidote to reverse opioid overdose.
- Promote the use of state Prescription Drug Monitoring Programs, which give healthcare providers information to improve patient safety and prevent abuse.
- Implement and strengthen state strategies that help prevent high-risk prescribing and opioid overdose.
- Improve detection of the trends of illegal opioid use by working with state and local public-health agencies, medical examiners and coroners, and law enforcement.

Source: <https://www.cdc.gov/drugoverdose/epidemic/index.html>

opioid prescriptions. In other situations, we have seen that if a patient is in chronic pain or has always been getting opioids of >250 mg morphine equivalent, physicians are just cutting them off from opioids and/or care. You cannot just take that patient off opioid medication. Physicians need to taper down opioid usage slowly, and the effect of tapering down must be discussed with the patients.

Something unique that most states have enacted nationwide, including Pennsylvania, is Act 126, which discusses opioid education and a patient directive, which allows patients to then execute a voluntary non-opioid directive form. Patients can deny or refuse the administration or prescription of controlled substances containing an opioid. However, these educational pieces must be tied together with regulation.

During the launch of the PDMP, a communication was sent around describing what resources were available. For example, if a clinician finds out that a patient is doctor-shopping, what should the provider do? Thus, providers were given resources and information to contact a SINGLE COUNTY AUTHORITY (SCA). SCAs can help physicians help the patient, or can serve as a bridge between that physician and a patient to help them get placed into a treatment program or treatment center.

Of the 67 counties in Pennsylvania, all 67 have SCAs where some of the SCAs overlap in multiple counties because of resource shortages. These SCAs are the people who receive calls either directly from a patient or from a prescriber's office or dispenser's office. If a physician sees that a patient is clearly addicted, wants medication immediately, does not want to talk about alternative treatments, was caught doctor-shopping, and/or agrees that the patient needs any help, then a provider or physician can contact the local SCA. There is a local number available for SCAs and a main number available as well where they can be referred to the correct source.

These educational pieces have helped a lot, because the lesson learned from the other 49 states was that if this program is launched and if proper communication, education, or resources for your prescribers and dispensers are not available, then there is going to be a rise in illegal drug use and an overdose epidemic.

Dr. Chen: How do we counsel patients who are worried about being undertreated for their pain?

Dr. Ballantyne: To be frank, I don't know what undertreatment of pain means. There is a lot of concern, and the media picks up on it, in terms of opioid-treated patients who are afraid that their lives are going to be terrible if they cannot get ahold of their opiates. But this is often because they are dependent, and when you are dependent and you cannot get opiates, your pain will get worse. Without opioids, patients enter the process of withdrawal, which can take months. This is a painful process, not just in terms of the immediate classic symptoms of withdrawal, but certainly the effect on mood and pain that can take months to normalize.

It is easy for patients who are already treated with opiates to believe that there is no alternative to opiates, and that withdrawal of opiates is a cruel and unusual punishment. But the more we look at this, the more we realize that people who tend to succeed in getting off opiates altogether often feel a lot better, and patients who never go down the opiate pathway usually have much better outcomes in terms of their function and even pain.

Thus, the idea of undertreatment of pain has more to do with not offering the best approach to the management of pain, and it is also due to the unrealistic expectation that pain can be relieved significantly. Most treatments for chronic pain, including opiates, only reduce the pain slightly. Thus, if you are talking in terms of pain on a scale from 0 to 10, the most you will ever get as a reduction is three points, and that is often an outlier. Usually, we do not see much more than the reduction of one point. Often pain treatment is not dramatic, as it does not completely take pain away.

The concentration of pain treatment should be successfully teaching people how to live well with pain and how to minimize it using various strategies, not just medication, but also engagement in the process of healing and life-style changes of the patients themselves, because medical treatment is not as powerful as what patients can do for themselves.

Ms. Patel: I think that the total avoidance of prescription opioids is not an ethical option. If a patient is in chronic pain, then the patient may need a prescription opioid and whatever the physician thinks is best for the patient.

If the patient has always been on opioids, there is a developed physician-patient relationship that can effectively be used to communicate to patients about the

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tapering down of opioid usage. By enacting a change in prescription patterns, you can bring change in a patient's life-style.

From the program side of it, we have to do a much better job in constantly educating prescribers and dispensers, and patients as well, so that they do not feel undertreated for pain and make this education a continuous process for everybody.

Dr. Chen: How should physicians respond to the opioid epidemic?

Dr. Ballantyne: When you introduce laws and regulations, you can produce a situation where physicians are less inclined to prescribe, or are even frightened of prescribing, because when it becomes a law, it is an issue of their medical license and therefore their livelihood. That can be quite a potent factor in discouraging people from prescribing. This is not the appropriate way for physicians to respond.

Ms. Patel: I understand how physicians and patients feel when a program is launched, because when regulations and laws are enacted, it creates this whole perception that the program is going to dictate what you do or how you receive treatment. The media also hypes it up. This just means that at the program level, we have to do a better job in educating and talking about that these regulations, and programs at the state level, are there to help professionals and patients. The goal of these programs or regulations is not to stop the use of opioids, but primarily and importantly just to cut down on the misuse and abuse that has led to this opioid epidemic.

Dr. Chen: Who should be prescribing opioids? Should opioid prescriptions be limited to pain specialists?

Dr. Ballantyne: You cannot have only pain specialists treating pain. Pain is ubiquitous. Pain is about 70% of the complaints brought to primary-care practice, so you have to have internists and particularly primary-care physicians who are knowledgeable about treating pain.

The role for the specialist, I believe, is for the treatment of complex chronic pain, because complex chronic pain, apart from everything else, is best managed in a multidisciplinary or interdisciplinary setting. This involves psychologists and physical therapists approaching complex chronic pain as a team effort, because no single person can help the patient with complex chronic pain. As an example, primary care is becoming very good at developing these interdisciplinary teams for the management of chronic illness in general, and a lot of those principles can be applied to chronic pain, not just to other chronic illnesses.

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Ms. Patel: We have seen that at least one in four people receive prescription opioids as a long-term medication in a primary-care setting. Thus, it should not be just a primary-care specialist's position to prescribe opioids. Clearly, patients should not be cut out from already prescribed opioids—that is not how this epidemic can be stopped—but it definitely can be tapered down, followed by alternative pain management treatment options from the pain specialist providers.

Dr. Chen: What is the role of other alternative medications to use considering the opioid epidemic?

Dr. Ballantyne: We are in the very early days of really understanding the role of marijuana in the treatment of chronic pain, or where it stands, because the regulations themselves are all over the place, and different states have different rules.

In Washington State, it is legal to use marijuana for both medical and recreational purposes, so it is becoming an important feature in pain management. Patients want to know if it is okay for them to take marijuana; if we approve and if we will prescribe opiates while they are taking marijuana, or whether we will prescribe it ourselves. We are still seeking more scientific support for the use of marijuana in the treatment of pain, although clearly a lot of people benefit and will report that they get a lot of comfort from using marijuana. Additionally, it is much safer than using opioids.

Beyond cannabis, there are lots of other medications that we use for chronic pain, including antidepressant drugs, anticonvulsant drugs, and nonsteroidal anti-inflammatory drugs. Each of those classes of drugs has its own limitations, and each of them does not provide the same immediacy or even level of analgesia as opioids. However, since we know that the use of opioids over time results in tolerance and dependence, opioids become less effective. Thus, opioids themselves are not really a good solution for long-term pain management. The best solutions for most chronic pain are actually physical and behavioral interventions.

Ms. Patel: Recently, in Pennsylvania, medical marijuana was legalized. We have not talked much about using marijuana to decrease opioid use, and we have not brainstormed about the role of marijuana, since both of the programs are new for Pennsylvania. Post-implementation of a medical marijuana program, we can look into PDMP data in a few months or even at the end of the year to see if and how opioid prescribing patterns have changed.

Washington State legalized:

- Marijuana for medical purposes
- Marijuana for recreational purposes

Pennsylvania legalized:

- Marijuana for medical purposes

Dr. Chen: What do you foresee being done in the future to help curb the opioid epidemic?

Dr. Ballantyne: One of the problems about the regulation route, particularly the legal route, is that physicians just don't know what to do with the opioid epidemic, and they throw their hands up in horror and stop prescribing opioids.

We have a lot of initiatives in Washington State, two of which we have had to institute to cope with the huge numbers of patients on very high doses of opioids. Thus, we implemented hotlines for physicians that are suddenly faced with a patient who they did not start on opiates but someone else has placed on very high doses. This happens quite often in Washington State because they come in from other states, and Washington State has a law against these high doses, so the physicians must do something.

Thus, we implemented a hotline, which is answered by pharmacists who are truly incredible. They play a very useful role in response to the epidemic, because they will give advice about how to taper or when it is appropriate to taper. These pharmacists will also help with the taper regime, and they also advise when to administer Suboxone. They can help make the diagnosis of addiction and advise when a patient should go to an addiction program and not be prescribed any further opioids by primary care.

Additionally, we utilize telemedicine. Thus, physicians who really struggle in their communities who have many patients with opioid dependence or addiction may reach out to other providers. These individuals may be the sole provider with no help from psychologists or addiction programs, and they can call into our telemedicine line to bring cases to a panel of experts. The hotline and the telemedicine portal are linked, so that cases that pharmacists cannot solve by themselves get referred to telemedicine. It is a very helpful form of education or people who are struggling with these issues.

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Conclusion from Dr. Chen

You both make excellent points.

Dr. Ballantyne, your points throughout the conversation emphasizing that regulation and education are not mutually exclusive are very well taken. There is no doubt, with regard to the opioid abuse epidemic, that physicians, pharmacists, pain specialists, and patients must educate themselves to prevent further abuse of these prescribed medications. That, and there must be a cultural change when approaching this epidemic, especially when it comes to changing the way we think about pain and the treatment of pain. Thank you for making these important points, recognizing that thousands of opioid-dependent patients are suffering due to outdated practices and practice norms. You point out that opioid-addicted patients need special treatment and that their providers must also have special training and education to avoid more problems and additional abuse in the future. Thank you for making these extremely important arguments.

Ms. Patel, as Director of the PDMP Office, your evidence-based approach is crucial to better understanding what policies and regulations must be instated to create positive change effectively with regards to this epidemic. Your comments underscoring the importance of data and evidence-based research not only drive the conversation as far as the need for updated state regulations, but emphasizes the importance of implementation of regulation based on education and, most importantly, that this education must be part of the curriculum. You also make the excellent point that healthcare providers must be reminded from time to time that their greater purpose in their profession is to consider consistently the care of their patients—not only in relieving their pain, but finding better ways to treat their pain that does not include prescription opioids. Your emphasis on effective communication between doctors and patients is of utmost importance. Thank you for your very important contributions.

Thank you both for taking the time to be part of this important conversation. We truly appreciate your time and commitment to addressing this crisis. ■■■