

Sound Ethics in Health Care

Informed Consent for Long-Term Opioid Therapy for Pain

Narrator: Welcome to Sound Ethics in Health Care, from the Department of Veterans Affairs National Center for Ethics in Health Care. Today's topic: **Informed Consent for Long-Term Opioid Therapy for Pain.** VHA Directive 1005, **Informed Consent for Long-Term Opioid Therapy for Pain**, defines long-term opioid therapy as "the medically indicated use of opioids on a daily or intermittent basis for 90 or more calendar days to treat non-cancer pain." Dr. Virginia Ashby Sharpe, Chief of Ethics Policy at the National Center for Ethics in Health Care, explains the directive.

Sharpe: VHA issued this directive as part of our commitment to opioid safety. Requiring patient education and signature informed consent before prescribing helps to ensure that patients and their providers have a shared understanding of the patient's goals and the risks, benefits, and alternatives for long-term opioids for pain.

Dr. Rollin Gallagher, National Director of Pain Management for VA, explains the informed consent process.

Gallagher: This includes reviewing the signature informed consent form with the patient, as well as also reviewing the patient education brochure, which describes in great detail the benefits and risks of opioid therapy for chronic pain, the patient's and provider's responsibilities in terms of safe opioid prescribing, and encourages dialog about other treatment options that may be used for chronic pain.

Narrator: Dr. Gallagher discusses the ethical basis of the directive.

Gallagher: Patients being exposed to any treatment have the right to be fully informed about potential risks as well as potential benefits, and have the right to make their own decisions, being fully informed, about whether to proceed with this particular treatment. What we're trying to achieve is a fully informed patient who is making decisions based on a full understanding of the risks and benefits of opioid analgesics. And being able to take that understanding and discuss with their provider and clinical team the pros and cons of starting an opioid therapy trial, and of continuing it for more than 90 days.

Narrator: Dr. Gallagher notes that there are a number of personal health risks associated with long-term opioid therapy.

Gallagher: Burdensome side effects include constipation, nausea, sedation. There are toxic effects, usually at higher doses, which may include respiratory depression, particularly in the high doses and when combined with benzodiazapines. Another toxic effect is worsening of pain due to hyperalgesia, a condition in which long-term exposure to opioids can cause an increase in pain rather than a decrease in pain.

Narrator: Dr. Michael Saenger is a physician at the Atlanta VA Medical Center and the lead physician for pain management in VISN 7. He provides additional information about personal health risks associated with long-term opioid therapy.

Saenger: Some people die, a number of people have complications related to not only worsening sleep but worsening mood, worsening anxiety, worsening problems with memory. There are endocrine dysfunctions. Everybody gets weaker bones. The immune system is affected, as well as a whole host of other things.

Narrator: Long-term opioid therapy has public health risks as well.

Gallagher: They may be misused or abused by persons who borrow, steal, or buy prescription opioids from the street. And this may lead to death from unintentional or intentional overdose, and these deaths are rising rapidly in the general population.

Saenger: It's important for the Veteran to know how to be safe for themselves. It's also important for them to know that if they're not protecting their medications, keeping them in a secure place, and someone steals them, that's a risk to others in society.

Narrator: Dr. Gallagher emphasizes that opioid pain care agreements, or OPCAs, may no longer be used within VHA, for several reasons.

Gallagher: Opioid pain care agreements are not standardized. And when they're poorly constructed, they can intentionally or unintentionally limit patient choices, and in some cases have been found to lead to a sense of coercion and distrust in the patient-provider relationship.

Narrator: OPCAs can also have unintended negative consequences.

Gallagher: The use of variable and erratic consent procedures among providers in the same facility, amongst facilities nationally, heightens the risk of both unsafe opioids and ineffective pain management. And this leads to increasing risks of disability, to toxicity effects, even overdose deaths.

Narrator: Dr. Michael Saenger acknowledges that in a busy clinic, signature informed consent can seem like a barrier to care — but in fact, it can be a tool for reorienting Veterans to care that is safer and more effective.

Saenger: At first, it is scary to Veterans to think that there's going to be change. And if we can spend a little bit of extra time on the front end explaining why we're doing these things with signature consent, that we're going to continue to work with them for more effective therapy and safe therapy, then the Veterans can be won over to this new system and be brought into safer care. We were able to do that in one of the CBOCs here, and over the course of about six months, we were able to have half of the Veterans who were on long term opioids transition to other, more effective, safer therapies, and the remaining half who were still on opioids were in a much safer environment.

Narrator: Dr. Saenger offers tips on introducing signature informed consent for long-term opioid therapy, including strategies for patient education.

Saenger: The whole process of signature informed consent involves a number of steps, but many of those steps can be broken down, assigned to different members of the PAC teamlet. Number one, the education could be done in group training by nurses or clinical pharmacologists. When the nurses are giving the overview of great chronic pain management and of opioid safety in group training, there can also be a time to prompt the Veteran, with their supportive others, to think about, "Well, what is it that I value, and what do I want my health for — what is my functional goal?" Which would be another block to fill in the signature consent. And so all of those steps don't have to happen at the same time. Which means that there's flexibility for busy PAC teamlets to make it work. And to make it work for the safety of the Veterans, and as a tool to encourage a bigger perspective about whole health care and more effective options for the Veteran to thrive for years to come.

Narrator: For links to documents mentioned in this podcast, plus other resources, visit www.ethics.va.gov/soundethics_podcasts.asp. If you have a topic that you would like to see presented in a podcast, send an email to vhaethics@va.gov. Sound Ethics in Health Care is brought to you by the Department of Veterans Affairs National Center for Ethics in Health Care.