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Penultimate version, forthcoming in The Hastings Center Report

Opioid Treatment Agreements and Patient Accountability

Abstract:
Opioid treatment agreements are written agreements between physicians and patients enumerating the risks associated with opioid medications along with the requirements that patients must meet to receive these medications on an ongoing basis. The choice to use such agreements goes beyond the standard informed consent process, and has a distinctive symbolic significance. Specifically, it suggests that physicians regard it as important to hold their patients accountable for adhering to various protocols regarding the use of their opioid medications. After laying out a taxonomy of accountability relationships between physicians and patients, I argue that opioid treatment agreements are only justifiable for physicians to use in their provision of care if they improve public health outcomes, which has yet to be demonstrated.

Opioid treatment agreements are an increasingly prevalent part of pain treatment as physician concerns about opioid prescribing have grown.[1] These documents are written agreements between physicians and patients enumerating the risks associated with opioid medications and the requirements that patients must meet to receive these medications on an ongoing basis. The choice to use opioid treatment agreements goes beyond the standard informed consent process, and has a distinctive symbolic significance. Specifically, it suggests that physicians regard it as important to hold their patients accountable for adhering to various protocols regarding the use of their opioid medications.

The American Academy of Pain Medicine recommends the use of these agreements, particularly for patients deemed at high risk of developing opioid use disorder. They provide a template agreement for physicians that explicitly uses the language of accountability: "Because these medications have the potential for abuse or diversion...strict accountability is necessary for both medical safety and legal reasons. Therefore, the following policies are agreed to by you, the patient, to help me keep you safe and to provide you with good care."[2] How should we understand what it means for physicians to hold their patients accountable in this context? After laying out a taxonomy of accountability relationships between physicians and patients, I argue

that opioid treatment agreements are only justifiable for physicians to use in their provision of care if they improve public health outcomes, which has yet to be demonstrated.

Holding Patients Responsible vs. Shallowly Accountable

On one possible view, physicians use opioid treatment agreements to hold their patients *responsible* for taking and otherwise handling opioid medications exactly as prescribed. Holding someone responsible entails several things: First, you regard her as subject to a norm or expectation. Second, in holding her responsible, you are enforcing that norm with her. And finally, you see her as capable of understanding and being motivated by the grounds for that norm. For opioid treatment agreements, this would mean that (a) physicians regard their patients as subject to the expectations expressed in these agreements, (b) physicians are willing to enforce those norms and cut off access to opioid medications if their requirements are not met, and (c) physicians regard their patients as capable of understanding and being motivated by the concern that if they do not satisfy those expectations, they are at risk for developing addiction (among other health concerns).

Rather than holding patients responsible, physicians using opioid treatment agreements might be said to be holding their patients accountable in a shallower sense. Holding someone shallowly accountable, like holding her responsible, involves the enforcement of a previously established norm that you regard the person as capable of understanding. A person can be (and be appropriately held) shallowly accountable whenever a norm applies, and she is able to understand that there is such a norm and act in accordance with it. This does not assume, however, that the person can understand or be motivated by the grounds for that norm. This would mean that physicians regard their patients as subject to the (enforceable) expectations expressed in opioid treatment agreements, but not necessarily because patients are able to

appreciate or be motivated by the grounds for those expectations. Holding someone shallowly accountable is fundamentally a matter of incentivizing desirable behavior and disincentivizing undesirable behavior – in this case, incentivizing adherence and disincentivizing opioid abuse and diversion.

Opioid treatment agreements generally include a description of the risks associated with treating pain using opioids, the sort of information that is important to informed consent to treatment. But these agreements also notably include various stipulations that patients must meet for their physician to continue to prescribe them opioids (see text box for examples of the terms of the American Academy of Pain Medicine template agreement, offered as guidance to institutions seeking to craft their own agreements).[3] These stipulations cannot plausibly be understood as part of a method for holding patients responsible. An implicit assumption of opioid treatment agreements is that patients are unlikely to be adequately motivated to adhere to their physicians' recommendations unless their access to opioids and perhaps even to their physician depends on their doing so. As such, these agreements do not satisfy condition (c) above. Opioid treatment agreements are better understood as a tool for physicians to hold their patients shallowly accountable (as opposed to holding them responsible) for satisfying the expectations described therein.

Holding patients shallowly accountable is not intrinsically objectionable. Relationships, including physician-patient relationships, generally involve incentives to behave in certain ways. Insofar as we care about what others think of us, including our physicians, we will be motivated to live up to their expectations. As citizens, we are subject to legal requirements whether we understand their grounds or not, and in those circumstances, we are being held shallowly accountable for obeying the law. But the practice of holding others shallowly accountable aims

solely at deterring them from committing harmful norm violations. The aims of holding someone shallowly accountable are therefore strictly instrumental. Accordingly, the interventions that are undertaken on these grounds must actually bring about a better outcome than the alternatives. If opioid treatment agreements are tools for physicians to hold their patients shallowly accountable (as I have argued), then the practice of using these treatment agreements is only justified if it is instrumental in improving public health outcomes.

There is not, however, enough evidence that opioid treatment agreements promote patient adherence to justify their use. In a systematic review, Starrels et al. note that few studies have examined whether opioid treatment agreements reduce opioid misuse, and the evidence currently available to support this conclusion is relatively weak.[4] Though absence of evidence is not to be confused with evidence of absence, physicians are not justified in holding patients shallowly accountable using strategies that have not been shown to be instrumentally effective.

Challenges to the Effectiveness of Opioid Treatment Agreements

In some ways, the lack of evidence supporting the effectiveness of opioid treatment agreements for promoting adherence is unsurprising. A survey of 162 opioid treatment agreements from 38 states showed that all of them assumed health literacy skills that surpass the average skills of American adults.[5] If patients do not understand the content of these agreements, then they cannot be held accountable for adhering to them. In addition, if patients are simply given opioid treatment agreements but do not have any further conversations with their physicians about what the agreements say, then patients are unlikely to be aware of what their physicians expect of them and what the consequences will be of their violating their physicians' expectations. Surveying a sample of HIV-infected indigent adults, Penko et al. found that many patients were almost no better than chance at identifying whether their physician had even given

them an opioid treatment agreement.[6] Though these agreements include various requirements that patients must meet to be prescribed opioids, they are not an adequate substitute for an honest conversation between physicians and patients about the risks and benefits of opioid treatment, not least of all because patients may feel pressured to sign these documents to access pain management without really understanding them. Some of these concerns would likely be ameliorated by constructing documents at an appropriate literacy level and discussing them in detail with patients. But given the typical constraints on physicians' time and the fact that the requirements to use opioid treatment agreements often come from above (e.g., from state regulators) rather than from physicians themselves, they are worth noting nonetheless.

In addition, it may be difficult for physicians to assess adherence. There is no single, cost-effective measure that will reliably determine whether a patient is abusing or diverting her opioid medication.[7] Opioid treatment agreements often require patients to agree to random drug testing (most commonly using urine immunoassay), but there are substantial risks of both false positives and false negatives.[8] Further confirmatory methods that improve physicians' ability to correctly interpret urine or blood tests, or using hair analysis instead (which can indicate more about opioid usage over the long term), are significantly more expensive and are less available to physicians.[9] This is not to say that urine drug tests have no clinical value, but to make significant decisions about patient care using tests that are known to be unreliable still raises ethical issues.

Physicians should also be concerned about the symbolic significance of asking patients to sign opioid treatment agreements. Depending on how they are formulated, opioid treatment agreements may seem overly punitive, or express to patients that their physicians do not trust them. In one particularly extreme example, Fishman cites an agreement that asked patients to agree to be monitored by a private investigator if their physician suspects non-adherence.[10] There

is also the matter of how physicians determine when to use opioid treatment agreements, and when to enforce them.[11] Physicians who elect to use or enforce these agreements only with patients they deem to be at high risk of developing addiction must be able to identify such patients without bias, and current evidence suggests that they may not.[12]

Moving Forward

In the current public health climate, there are substantial pressures on physicians and patients alike regarding opioid therapy. Responsible opioid prescribing is often equated with minimizing opioid prescribing as much as possible. While there are other, non-opioid treatments that are effective for many patients seeking pain management, there will likely remain some patients for whom opioids are clinically appropriate. Moreover, there are good reasons deriving from public health ethics to try to monitor these patients closely. One potential benefit of opioid treatment agreements is that they provide guidelines for patients regarding the risks and responsibilities connected to opioid therapy. Another is that they disclose the surveillance that physicians and regulators want to employ with patients on opioids for the sake of public health.[13] Assuming such treatment agreements were written at an appropriate literacy level, and that physicians were also willing to have substantive conversations to ensure their patients understand what is required for adherence, opioid treatment agreements could be protective for patients receiving a therapy likely to cause dependence and potentially addiction. But given the agreement structure, physicians could point to non-adherence as a reason to refuse to continue prescribing, or to dismiss patients from their practice. In such a circumstance, physicians do not seem to regard themselves as accountable to patients to help them manage their pain and receive appropriate care. Opioid treatment agreements are thus not a formal way of expressing the notion

of accountability that is already part of physician-patient relationships, which is fundamentally mutual accountability.

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[1] This is evidenced by the large number of states who have issued laws or regulatory guidance urging the use of opioid treatment agreements in the last five to ten years. See C. Davis, "State-by-State Summary of Opioid Prescribing Regulations and Guidelines," Accessed March 23, 2020, https://www.azdhs.gov/documents/prevention/womens-childrens-health/injury-prevention/opioid- prevention/appendix-b-state-by-state-summary.pdf

[2] "Agreement on Controlled Substances Therapy for Chronic Pain Treatment," American Academy of Pain Medicine, 2013, https://painmed.org/uploads/education/agreement-on-controlled-substances-therapy.pdf

[3] "Agreement on Controlled Substances Therapy for Chronic Pain Treatment," American Academy of Pain Medicine, 2013, https://painmed.org/uploads/education/agreement-on-controlled-substances-therapy.pdf

[4] J.L. Starrels, W.C. Becker, D.P. Alford, A. Kapoor, A.R. Williams, B.J. Turner, "Systematic Review: Treatment Agreements and Urine Drug Testing to Reduce Opioid Misuse in Patients with Chronic Pain. *Annals of Internal Medicine* 152, no. 11 (2010): 712-720.

[5] S.E. Roskos, A. J. Keenum, L.M. Newman, L.S. Wallace, "Literacy Demands and Formatting Characteristics of Opioid Contracts in Chronic Nonmalignant Pain Management," *Journal of Pain* 8, no. 10 (2007): 753-758.

[6] J. Penko, J. Mattson, C. Miaskowski, M. Kushel, "Do Patients Know They Are on Pain Medication Agreements? Results from a Sample of High-risk Patients on Chronic Opioid Therapy," *Pain Medicine* 13, no. 9 (2012): 1174–1180.

[7] S.M. Fishman, B. Wilsey, J. Yang, G.M. Reisfield, T.B. Bandman, D. Borsook, "Adherence Monitoring and Drug Surveillance in Chronic Opioid Therapy," *Journal of Pain and Symptom Management* 20, no. 4 (2000): 293–307.

[8] M. Collen, "Opioid Contracts and Random Drug Testing for People with Chronic Pain — Think Twice," *Journal of Law, Medicine, and Ethics* 37, no. 4 (2009): 841–845.

[9] S.M. Fishman, B. Wilsey, J. Yang, G.M. Reisfield, T.B. Bandman, D. Borsook, "Adherence Monitoring and Drug Surveillance in Chronic Opioid Therapy," *Journal of Pain and Symptom Management* 20, no. 4 (2000): 293–307.

[10] S.M. Fishman, T.B. Bandman, A. Edwards, D. Borsook, "The Opioid Contract in the Management of Chronic Pain," *Journal of Pain and Symptom Management* 18, no. 1 (1999): 27–37.

[11] V. Nikulina, H. Guarino, M.C. Acosta, et al., "Patient vs Provider Reports of Aberrant Medication-taking Behavior among Opioid-treated Patients with Chronic Pain Who Report Misusing Opioid Medication," *Pain* 157, no. 8 (2016): 1791-1798.

[12] L.R.M. Hausmann, S. Gao, E.S. Lee, C.K. Kwoh, "Racial Disparities in the Monitoring of Patients on Chronic Opioid Therapy," *Pain* 154 (2013): 46-52.

[13] J.B. Rager, P.H. Schwartz. "Defending Opioid Treatment Agreements: Disclosure, Not Promises," *Hastings Center Report* 47, no. 3 (2017): 24-33.

Terms of Opioid Treatment Agreements

Category:	Example from AAPM Template:
Risks of improper use	You must discuss the long-term use of controlled substances with your physician. Prolonged opioid use can be associated with serious health risks. You need to understand these risks.
Surveillance and monitoring	You must give the prescribing physician permission to discuss all diagnostic and treatment details with dispensing pharmacists or other professionals who provide your health care for purposes of maintaining accountability and coordinating your care.
Limits on refilling or replacing medication	You must agree that medications will not be replaced if they are lost, flushed down the toilet, destroyed, left on an airplane, etc. If your medication has been stolen and you complete a police report regarding the theft and present that report to the prescribing physician, an exception may be made at the discretion of your treating physician.
Points of termination	You understand and agree that failure to adhere to these policies will be considered noncompliance and may result in cessation of opioid prescribing by your physician and possible dismissal from this clinic.