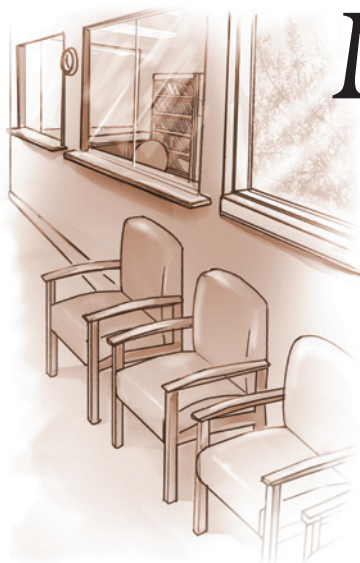


CASE STUDIES IN SOCIAL MEDICINE

Structural Iatrogenesis — A 43-Year-Old Man with “Opioid Misuse”

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Mr. O., a 43-year-old man with severe, destructive rheumatoid arthritis, had been receiving acetaminophen–hydrocodone at low doses from his primary care provider (PCP) for 15 years. He worked in an auto-parts factory in southeastern Michigan, and pain control was essential to maintaining his employment. His pain had been well managed on a stable regimen, and he had not shown evidence of opioid use disorder.

In 2011, his primary care clinic began requiring patient–provider agreements (“pain contracts”) and regular urine drug testing. Mr. O. participated willingly, and his tests were consistently negative for unprescribed substances. In 2014, his insurance company began to require annual prior authorization for all controlled-substance refills. Although there were small delays

in receiving medication once a year when the authorization was due, the patient was able to keep his pain level stable on his usual regimen.

In 2016, Mr. O.’s PCP retired, and his care was transferred to another PCP in the same office, who followed the patient’s existing pain-management plan. The same year, the insurance company began requiring more frequent prior authorizations and then that prescriptions be sent to the pharmacy every 15 days. The new PCP was occasionally late providing these prescriptions and approving prior authorizations because of the required multistep interactions with the insurance company. Mr. O. did not own a car and had difficulty making frequent trips to the pharmacy. He began to have several-day gaps in medi-



cation. During these gaps, he experienced severe pain and mild withdrawal, as a result of which he performed poorly at work and received a citation. He became very concerned about losing his job.

Mr. O. made an appointment with his PCP and requested an increase in his number of pills, wanting to “stockpile pills so that I’ll never run out.” The PCP noted that Mr. O. seemed nervous during the conversation. She noted in the chart that the interaction “made her uncomfortable.” She knew that the previous PCP had reported that Mr. O. had shown no evidence of opioid misuse, but in the current environment of vig-

ilance regarding the risks posed by opiates, she did not feel comfortable increasing the number of pills.

Three months later, the patient submitted a urine sample that tested positive for unprescribed oxycodone. When the PCP discussed the result with Mr. O., she learned that he had obtained oxycodone from a friend during one of his gaps in medication. The following month, oxycodone was once again found in his urine. Already overwhelmed by the frequent need for prior authorizations, and noting that Mr. O. had “violated his contract” by submitting two urine samples containing unpre-

scribed opioids, the PCP referred him to a local pain clinic.

The wait time for an appointment at the clinic was 4 months. The PCP continued to provide prescriptions during that period, planning to stop prescribing as soon as Mr. O. had his first appointment. When he arrived at the pain clinic, Mr. O. learned that it had a policy of not prescribing opioids for the first two visits. Facing a prolonged period without his usual regimen, and having previously failed to obtain any “extra” acetaminophen–hydrocodone from his PCP, Mr. O. began purchasing his full narcotic regimen (in the form of oxycodone) from a friend.

Social Analysis Concept: Structural Iatrogenesis

Through a series of events, Mr. O.'s therapeutic relationship with his PCP deteriorated, and he became compelled to obtain medications outside the medical setting, which in turn increased his risk of overdose, as well as his risk of arrest for possession of unprescribed opioids. This shift was not precipitated by physiological changes in Mr. O.'s disease, need for medication, or personal attributes. Rather, it was caused by structural forces outside his control, ranging from clinic policies (pain agreements, a drug-testing initiative, a moratorium on prescribing) to corporate bureaucracies (insurance companies, factory management) to larger-scale social forces (poverty, lack of availability of transportation, lack of opportunities for work appropriate for someone with a painful condition).

We call this type of harm "structural iatrogenesis" (see box). Drawing on a long history of social science scholarship,¹ the use

of the term "structure" emphasizes that Mr. O.'s poor outcome was determined by social forces and structures outside his control. The term "iatrogenesis" specifically focuses on the harmful role of bureaucratic structures within medicine itself. In Mr. O.'s

Structural iatrogenesis is the causing of clinical harm to patients by bureaucratic systems within medicine, including those intended to benefit them.

case, many of these structures had been instituted to protect patients at risk for opioid use disorder: clinicians acted according to prevailing standards of care in chronic pain management; his prior clinic's pain contract and urine drug screens were meant to prevent deviation from prescribed opioid use that might

place him at risk for overdose or addiction; the pain clinic's protocol of delayed prescribing was meant to prevent patients from "shopping" for opioid prescriptions; prior authorizations required by the insurance company were intended to reduce overprescription of potentially harmful (and costly) medications. But these systems were not beneficial to Mr. O. in the context of his economically and socially precarious life, which was shaped by a lack of transportation and a need to perform painful manual labor for economic survival.

Structural iatrogenesis is a type of "structural violence," defined as the systematic infliction of disproportionate harm on certain people by large-scale social forces such as resource distribution and hierarchies of race, gender, or language.^{2,3} "Iatrogenesis" points to the causation of such harm by bureaucratic systems that are potentially under clinicians' or health systems' control.⁴

Clinical Implications: Stopping Structural Iatrogenesis

Clinicians who identify structural iatrogenesis may alter structures or create action plans to prevent them from causing harm. Generalizing from Mr. O.'s case, we would offer the following approach:

1. *Recognize and alter structures that systematically harm patients.* Clinicians may be the first to identify a structure that is systematically harming patients and can then advocate for or directly effect change. For example, in the 1980s, the Food and Drug Administration and physician organizations recommended that

women undergo pelvic exams before receiving hormonal contraception. Some clinicians noted that these exams were a barrier to contraceptive access and stopped requiring them in their own clinics. By the 1990s, these local changes led to removal of the recommendation from national policy, which increased access to contraception and rates of effective use.⁵

Similarly, if Mr. O.'s PCP noticed that her clinic's opioid-prescribing policy generated frequent gaps in medication coverage for patients in general, she could

have advocated for a new approach. It's important, however, to avoid the pitfall of thinking that structural harm emerges only from "broken" systems. All structures carry a risk of harm, even when they are functioning "properly." The policy in Mr. O.'s PCP's office might have been working well for most patients, but it turned out to be a poor fit for Mr. O.

2. *Bend policies according to context.* Attempts to standardize clinical care in order to ensure high quality often inadvertently lump complex phenomena into sim-

plistic categories. Such oversimplification, in turn, can create structures within clinical care that harm patients more than help them. By questioning how such categories (such as “opioid misuse”) apply to particular patients and types of patients, clinicians can work to reduce the risk of structural iatrogenesis. The label of “opioid misuser,” for example, negatively affected Mr. O.’s care by failing to acknowledge reasons that he might be acquiring medications outside the clinic.

Similarly, clinic policies that penalize patients for arriving late to appointments disproportionately harm people who don’t own a car or control their work schedule. And policies of rewarding clinicians on the basis of quantitative measures of practice quality, such as reductions in glycated

hemoglobin levels, may ignore complex disease interactions and the social factors contributing to diabetes and may create an incentive for clinicians to drop particularly sick patients. Instead, one might identify patients with particular vulnerabilities and adjust policies on the basis of their life context.

3. *Address implicit agendas head-on.* Mr. O.’s care deteriorated when he was labeled an “opioid misuser.” This designation was putatively a clinical diagnosis, but it also marked a tacit category shift from “good patient” to “bad patient,” reflecting the mixing of clinical reasoning with moral judgment. Similarly, the insurance company’s rationale for requiring more frequent prescriptions mixed a harm-reduction agenda (reducing risk for addiction and death) with a profit

motive (reducing payouts for medications). Mr. O.’s poor clinical outcome was due in part to tensions between these implicit agendas. Clinicians often consider such agendas to be outside their purview, but given that they have such a significant impact on clinical outcomes, it may be more effective clinically to identify these agendas, assess their interactions, and decide which ones to prioritize. The staff of Mr. O.’s clinic, for example, could recognize the moral judgment involved in the diagnosis of “opioid misuse” and instead set an explicit goal of identifying behaviors that could increase a patient’s risk of addiction, overdose, or dangerous side effects. They could then assess whether their established protocols were achieving that goal and how to balance it with other goals.

Case Follow-up

At Mr. O.’s next visit, his PCP expressed concern about risks of overdose and legal harm from use of unprescribed oxycodone. She persuaded him to return to the pain clinic, and in the meantime she agreed to continue prescribing his opioids. A medical assistant appealed for an exemption to the insurance company’s 15-day prescription rule, citing

Mr. O.’s lack of transportation, fragile work circumstances, and long-standing treatment. At the time we wrote this article, it remained unclear whether these modifications would stabilize Mr. O.’s

treatment and prevent his use of unprescribed opioids.

The editors of the Case Studies in Social Medicine are Scott D. Stonington, M.D., Ph.D., Seth M. Holmes, Ph.D., M.D., Helena Hansen, M.D., Ph.D., Jeremy A. Greene, M.D., Ph.D., Keith A. Wailoo, Ph.D., Debra Malina, Ph.D., Stephen Morrissey, Ph.D., Paul E. Farmer, M.D., Ph.D., and Michael G. Marmot, M.B., B.S., Ph.D.

The patient’s initial and some identifying characteristics have been changed to protect his privacy.


Disclosure forms provided by the authors are available at NEJM.org.

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