An audio interview with Dr. Derse is available at NEJM.org

process, provision of appropriate palliative care, and fulfillment of the physician's duties to the patient.

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

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Hospital Standards of Care for People with Substance Use Disorder

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More than 100,000 Americans died from drug overdoses in 2021 — a staggering death toll that would have been unthinkable only a few years ago. Approximately 75% of overdoses involved opioids, and most involved multiple drugs, including stimulants and alcohol. Substance use disorder (SUD)–related hospitalizations, readmissions, and health care costs are increasing and are associated with high mortality from drug-related and other causes. In one study of hospitalized adults with opioid use disorder (OUD) in Oregon, 7.8% of patients died within 1 year after discharge — mortality similar to that associated with acute myocardial infarction.[1]

Hospitalization represents a key opportunity for engaging and supporting patients with SUD. One in nine hospitalized adults has SUD, and most are not receiving addiction treatment at admission. A rapidly expanding evidence base describes the benefits of hospital-based addiction care, including improved trust in physicians, increased engagement in postdischarge SUD treatment, and reductions in SUD severity, stigma, and mortality. Furthermore, hospital-based addiction care increases the likelihood that other hospital care will be trauma-informed and meet the comprehensive health needs of people with serious illness and SUD.[2]

Most efforts in hospital-based addiction care to date have been led by motivated clinicians who have made a case that such efforts could improve both financial and quality outcomes.[3] Absent clear funding or financial incentives, however, adoption of best practices varies widely, with most hospitals not offering evidence-based addiction care. Harms of not addressing addiction in hospitals include untreated withdrawal and pain, frequent patient-directed discharges, and moral distress for patients and staff.[2] Moreover, hospitals are the training grounds for most health care professionals. Failing to train the next generation in evidence-based SUD care represents a missed opportunity to improve outcomes and dispel the false notion that SUD is a moral failing rather than a treatable health condition with biologic, social, emotional, and cultural underpinnings.

Evidence-based medications for opioid and alcohol use disorders are effective but widely underused, with only a fraction of patients who are likely to benefit actually receiving them. Decades of evidence shows that treatment with an opioid agonist such as methadone or buprenorphine substantially reduces morbidity and mortality among patients with OUD. Widespread access to medication for OUD (MOUD) is ever more urgent, given the increasingly lethal illicit drug supply; yet most U.S. hospitals do not offer MOUD or effectively connect patients to OUD care after discharge. A nationwide study estimated that only 15% of patients who had OUD when they were admitted to Veterans Health Administration hospitals received any MOUD, and initiation of MOUD treatment plus linkage to post-discharge care was provided in less than 2% of cases.[4] Another study revealed that 46% of New

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Mexico hospitals had no buprenorphine–naloxone in their formulary, and nearly 40% of New Mexico counties had no hospital with buprenorphine–naloxone available.[5] In addition to lacking appropriate inpatient care, many hospitals have no clinicians authorized to prescribe buprenorphine at discharge. These failures are the functional equivalent of nearly half of hospitals lacking both metoprolol (the most commonly prescribed beta-blocker) and clinicians who can prescribe it at discharge.

One factor that is both a cause and a consequence of hospitals' failure to provide appropriate care to people with SUD is the pervasive stigma against people who use drugs, which manifests on both individual and structural levels. People who use drugs report frequent experiences of stigma and mistreatment when attempting to obtain health care, and such experiences lead many of them to avoid necessary care, refrain from disclosing their substance use, underreport pain, and mistrust clinicians. Many clinicians hold negative attitudes toward people who use drugs and may therefore resist delivering evidence-based treatments or blame patients for their illness. This dynamic perpetuates the challenges of an unprepared workforce and limited implementation of effective interventions.[2]

Stigma extends beyond individuals to hospital policies, which commonly endorse punitive approaches to people with addiction. Many hospitals prohibit people who use drugs from leaving their room or having visitors; they may have security guards search patients' bodies, belongings, or visitors; and they may deploy staff or use video surveillance to identify signs of drug use. Patients who do use or possess illicit substances are commonly administratively discharged. Hospitals would never institute a policy of searching the belongings of patients with acute myocardial infarction for cigarettes or discharging patients for not adhering to a heart-healthy diet. Yet similarly punitive and harmful actions remain the stated SUD policy in many hospitals.

Federal law also both reflects and contributes to stigma against the use of MOUD. In the outpatient setting, only clinicians who have obtained a federal "waiver" may prescribe buprenorphine for OUD, and methadone for OUD can be administered only in federally approved opioid-treatment programs. These restrictions can be confusing for many clinicians, who may believe that MOUD is illegal for hospitalized patients (it is not), and can deter other clinicians from offering MOUD because coordinating care after discharge is too difficult or impossible without clear community treatment pathways. Although federal law should be changed to remove unnecessary barriers, hospitals can and should do much more within the existing law.

SUD is costing hospitals, payers, and society. In 2017, addiction and overdose fatalities cost the United States more than $1 trillion, and SUD-related hospitalization costs exceeded $13 billion. Nevertheless, hospitals lack external financial and quality incentives to improve. To date, most reform efforts have relied on highly motivated champions, individual hospital priorities, and local incentives.[5] Even at academic medical centers, which are often rich in resources and located in communities with high SUD-related mortality, funding for addiction consult services typically requires demonstrating financial return on investment from avoiding readmissions and shortening hospitalizations. We believe any imperative that hospital-based SUD care be justified on these grounds is deeply flawed. Cardiology consult services do not exist to save money; instead, myriad policies provide incentives for cardiac care delivery, and sufficient reimbursement further promotes nationwide adoption and sustainability of cardiac best practices.

To reduce stigma and improve outcomes, hospitals can make a concerted, visible commitment to improving SUD care. Changing the standard of care requires reforms well beyond what individual champions or hospitals can accomplish. The path forward will require bold actions across multiple agencies and policy domains, including development and dissemination of national clinical guidance, implementation of financing reforms and new quality metrics, provision of implementation support, and workforce education (see table).

U.S. policymakers could change payment structures to provide incentives for SUD-care provision and fund pilots that can implement and evaluate innovation. Hospitals that do not adopt minimum requirements or that maintain discriminatory institutional policies could be penalized. Hospital payment and public reporting programs could incorporate addiction-related quality measures. For example, the Centers for Medicare and Medicaid Services (CMS) could require hospitals to offer MOUD as a condition of participation and could publicly report hospital rates of naloxone prescribing on its Hospital Com-

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Policy Changes to Support Adoption of Evidence-Based SUD Care in U.S. Hospitals.*

Category	Examples of Policy Change	Examples of Organizations That Could Implement Change
Clinical guidance		
Evidence-based clinical guidelines	Guidelines that promote acute withdrawal and pain management, as well as medication for opioid and alcohol use disorder initiation and treatment linkage	Professional societies, federal and state hospital associations (e.g., AHA)
Hospital policies	Trauma-informed security and behavior policies that reduce discriminatory practices	Federal and state hospital associations, professional societies
Formulary recommendations	Inclusion of all classes of FDA-approved medications for SUD in hospital formularies	ASHP
Financing		
Increased financing within current payment models	Increase in DRG-based payments for SUD	CMS, state Medicaid agencies
Demonstration projects that promote innovation	Funding for interprofessional addiction teams whose comprehensive services are not reimbursed through traditional fee-for-service billing (e.g., addiction social workers, peers, nurses, pharmacists)	CMS, AHRQ
Section 1115 Medicaid demonstration waivers	Incorporation of components of hospital-based SUD care continuum in waiver criteria	CMS
Regulatory standards		
Health and safety standards	Requirement that hospitals adopt basic addiction care standards rooted in evidence (e.g., opioid agonist medications, naloxone)	CMS (conditions of participation)
Hospital preparedness and accreditation	Demonstrated adoption of and adherence to evidence-based clinical guidance, nondiscriminatory hospital policies, and formulary recommendations noted above	Joint Commission, DNV
Publicly reported quality measures	Public reporting on Hospital Compare Star Ratings of hospital performance on disease-specific measures, such as MOUD initiation and engagement or naloxone prescribing	National Quality Forum, CMS (Hospital Compare)
Implementation support		
Practice facilitation	Practice facilitation and technical assistance from existing addiction consult services to sites with emerging services	ONDCP, AHA, professional societies, SAMHSA
Technical assistance	Real-time clinician-to-clinician support (e.g., telephone "warmline" on which addiction medicine experts support generalists to offer medication for opioid and alcohol use disorder, along with other addiction care)	CMS, AHRQ, SAMHSA, state or other sources
Telementoring	Telementoring with ECHO model to support knowledge, skills, and attitudes to improve care for people who use drugs	AHA, SAMHSA
Workforce education		
Physician resident education	Requirement that CMS-funded residency slots offer training in SUD diagnosis and treatment and that funding is contingent on care delivery	CMS, ACGME

* ACGME denotes Accreditation Council for Graduate Medical Education, AHA American Hospital Association, AHRQ Agency for Healthcare Research and Quality, ASHP American Society of Health-System Pharmacists, CMS Centers for Medicare and Medicaid Services, DNV Det Norske Veritas (a quality-assurance and risk-management company), DRG diagnosis-related group, ECHO Extension for Community Healthcare Outcomes, FDA Food and Drug Administration, MOUD medication for opioid use disorder, ONDCP Office of National Drug Control Policy, SAMHSA Substance Abuse and Mental Health Services Administration, and SUD substance use disorder.

pare website. Given long-standing inequalities in OUD outcomes, CMS could also require reporting of MOUD prescribing rates by race, ethnicity, and gender to expose and eliminate disparities. Improving the standard of care also relies on expanded health care professional training and implementation support for hospitals working to deliver better SUD care. These changes are analogous

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to universally adopted clinical practice guidelines that promote cardiac treatment standards, publicly reported cardiology quality indicators, reimbursement structures that sustain cardiac care units and consult services, and universal cardiac care training for all health professionals.

The United States is in the throes of a decades-long exacerbation of drug-related harm. Hospitals are a key domain for implementing person-first, evidence-based interventions for reducing that harm. Yet despite the obvious need, hospitals have been slow to enact reforms to improve the health of people who use drugs. We believe that systemic reform, led by the federal government, is necessary to mitigate the ongoing crisis of drug-related harm.

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

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Improving the Use of FDA Advisory Committees

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When the Food and Drug Administration (FDA) faces a regulatory decision, such as whether to approve a medical product, it sometimes convenes an advisory committee for independent expert recommendations. The FDA has 31 standing independent advisory committees spanning a range of medical disciplines; these committees usually comprise about a dozen subject-matter experts plus patients, consumers, and a (nonvoting) industry representative. The committees exist to offer insight to agency leaders who are facing difficult decisions, such as whether to approve a drug for marketing or whether to permit a drug to remain on the market. Advisory committee proceedings, which are open to the public, also offer an opportunity for participation by patients, advocates, and industry representatives who wish to offer testimony.

When the FDA's ultimate decision aligns with the advisory committee's recommendations, the process can help the agency build public trust. For example, when the FDA authorized the use of the Pfizer–BioNTech Covid-19 vaccine in children 5 to 11 years of age, it emphasized that the advisory committee "overwhelmingly voted in favor of making the vaccine available to children in this age group." But though the FDA usually acts in accordance with its committees' advice,[1] sometimes it doesn't. About once a year since 2010, the agency has approved a new drug after an advisory committee voted that the drug should not receive market authorization.[2] Aducanumab (Aduhelm), for example, received FDA marketing authorization in 2021 for treatment of Alzheimer's disease under the conditional accelerated approval pathway after no member of an advisory committee voted in favor of its full approval.[3] This negative vote was commonly referenced during the ensuing controversy as support for the argument that the FDA erred in approving a drug without clear evidence of efficacy.[4]

For drugs and biologic agents, the FDA has full discretion over not only whether to follow advisory committee recommendations but also whether to convene an advisory committee in the first place. This discretion has allowed the agency to refer far fewer product-approval questions to advisory committees in recent years. In 2010, more than 50% of newly approved drugs had received advisory committee review before approval. By 2021, the proportion had dropped to 6%.[2] Although

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