

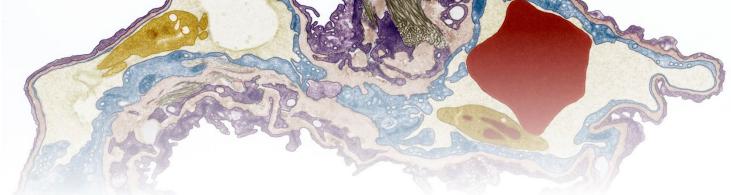
# Harm Reduction and Opioid Use Disorder

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# AMA Journal of Ethics<sup>®</sup>

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# **FROM THE EDITOR**

# Why Harm Reduction and Equity Are Ethical Imperatives in Opioid Use Disorder Care

Jeremy Weleff, DO

Evidence-based harm reduction practices for opioid use disorder (OUD)-such as syringe services programs,<sup>1</sup> among others-hold promise to help advance approaches to thinking of comprehensive OUD care as a human right, but successful implementation of harm reduction interventions in the United States has been hampered by increasingly heated politicization of addiction care and a long history of a patchwork of federal and state laws that create gaps for many.<sup>2,3,4</sup> From the middle of the 20th century and into America's seemingly endless so-called War on Drugs, the addition of more regulations have increased the difficulty of accessing treatment and care for those who use opioids and other drugs. From the relegation of methadone treatment to opioid treatment programs in the 1970s<sup>5</sup> (unlike other countries such as Canada, Australia, and the United Kingdom that allow for general prescribing or dispensing<sup>6</sup>) to the federal "crack house statute" of 1986,7 the vestiges of these laws continue to contribute to a rigid and slow response to effective implementation of best practices to reduce mortality and morbidity from opioid use. This uniquely American model of OUD care that now exists and has produced a record number of deaths as of June 20238 is the result of discriminatory laws against those who use drugs that began at the turn of the century during America's earlier opioid epidemics.9

Given this legislative history, tertiary prevention strategies for OUD, which include naloxone distribution, syringe services programs, drug testing and checking, safe consumption sites, and safe/safer supply programs, have faced public and executive branch resistance in the United States.<sup>10,11</sup> These harm reduction strategies, which are fundamentally situated in a perspective that upholds respect for bodily autonomy, freedom of choice, and person-centered care, continue to be included in international practice guidelines for OUD.<sup>12</sup> These strategies have never been more needed, as recent waves of the opioid epidemic have been characterized by a rapidly changing and dangerous drug supply made up of illicitly manufactured, high-potency opioids and by supply-side drivers that contribute to an unpredictable drug supply.<sup>13</sup>

It wasn't until the COVID-19 pandemic that the United States made some of its largest steps in decades toward more equitable and evidence-based OUD care. During the pandemic, methadone prescribing laws were loosened to allow for more take-home doses,<sup>14</sup> laws that limited the prescribing of buprenorphine were removed,<sup>15</sup> and the first safe consumption site opened in New York City.<sup>16,17</sup> These steps, which should be

celebrated and more closely align the United States with international and evidencebased practices, are hopefully the first of many toward advancing equity in OUD care. This issue of the AMA Journal of Ethics examines many of these advances, as well as barriers to OUD care that produce systemic inequities. In so doing, it contributes to the critical conversation on addressing the opioid epidemic earnestly and fully to ensure access to the full spectrum of evidence-based interventions for all individuals, regardless of race, ethnicity, gender, or socioeconomic status.

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## CASE AND COMMENTARY: PEER-REVIEWED ARTICLE

# How Should Risks and Benefits of Short-Acting Opioids Be Evaluated in the Care of Inpatients With OUD?

Kathryn A. Dong, MD, MSc and Katherine M. Duthie, PhD, HEC-C

#### Abstract

Severe opioid withdrawal, risk of patient-initiated discharge, and some inpatients' use of unregulated substances prompt clinical and ethical questions considered in this commentary on a case. Short-acting opioids can be used to manage inpatients' pain and opioid use disorder (OUD) withdrawal symptoms. Including evidence-based interventions—such as naloxone kits, substance use equipment, and supervised consumption in some inpatients' care plans may make those patients safer and reduce their risk of death. These and other strategies align with clinicians' ethical duties to minimize harms and maximize benefits for inpatients with OUD.

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#### Case

KC is admitted for infective endocarditis secondary to microbes entering their bloodstream during repeated injection drug use. KC has a long history of opioid use disorder (OUD) and has intermittently been treated for it. KC's history of using opioids started when KC exhausted a supply of oxycodone, prescribed with limited refills for postoperative pain management, which led KC to start using heroin and then fentanyl.

Members of KC's clinical team have not come to consensus about how to manage KC's pain or OUD. They are aware that KC has their own supply of drugs and wants to leave the hospital as soon as possible and against medical advice, if necessary. Team members consider administering short-acting opioids to keep KC comfortable and in hospital for intravenous antibiotics and evaluation for cardiac surgery, but one clinician opposes any care plan that "feeds" KC's OUD.

#### Commentary

People who initiate their own discharge from hospital have a well-documented increased risk of death,<sup>1,2</sup> and people who use substances are at greater risk of premature discharge than other groups.<sup>3</sup> Every effort must therefore be made to engage people in care that offers concomitant management of their primary medical condition and any

substance-related diagnosis. For people with OUD, such care includes immediate access to all forms of opioid agonist treatment (OAT)<sup>4,5</sup> and effective management of pain and withdrawal. OAT options include buprenorphine formulations, methadone, slow-release oral morphine, and injectable treatments such as hydromorphone and diacetylmorphine.<sup>4</sup> Of note, slow-release oral morphine and injectable treatments are not currently available in the United States for people with OUD.

Even if they offer these interventions, hospitals must accept that not all individuals will stop using regulated or unregulated substances. To reduce morbidity and mortality risk from ongoing substance use while in hospital, access during hospitalization to other interventions such as naloxone kits, clean substance use equipment (eg, syringes, cookers, sterile water), and supervised consumption services should be considered.

#### **Prioritizing Harms for Reduction**

Although the standard of care for the treatment of infectious endocarditis is several weeks of intravenous antibiotic therapy, a scoping review found that published guidelines on the management of endocarditis in people who inject drugs rarely recommend addiction medicine consultation or opioid agonist treatment, and none discuss withdrawal management.<sup>6</sup> These guidelines suggest that OUD is considered unique or separate from other medical needs during a hospital admission, supporting the perspective that treatments and referrals that respond to a patient's substance use are optional or exceptional. In many cases, this belief is an error. The method for assessing which harms should be prioritized for a patient with OUD should be similar to, if not the same as, the method used for a patient with multiple comorbidities that do not include OUD.

Clinical judgments about the potential likelihood and severity of harms are the first important step in determining which clinical needs should be given priority. KC has 2 urgent medical concerns: infectious endocarditis and OUD. Discussions with KC should include how treatment of one clinical need might be necessary to facilitate treatment of the other; in this case, offering OAT<sup>7</sup> and short-acting opioids for withdrawal management is a means of enabling access to a complete course of antibiotics for endocarditis.

KC's goals, values, and beliefs should inform which clinical needs take priority. KC might not wish to initiate long-term treatment for their OUD during this admission, but they might be interested in other interventions that could reduce their risk of negative health outcomes related to substance use and help them achieve other important goals. As with any patient, KC ought to be given choices regarding treatment options (including the option not to treat), and those choices should be respected, even if they do not align with what the care team sees as optimal or most appropriate.

#### **Risks and Benefits of Short-Acting Opioids**

People with OUD who regularly use illegally manufactured synthetic opioids (eg, fentanyl, carfentanil) are likely to have developed a high tolerance to opioids.<sup>8</sup> As such, opioid withdrawal should be anticipated. While non-opioid medications such as acetaminophen, ibuprofen, clonidine, and others can help with the symptomatic management of some opioid withdrawal symptoms, they will not meet the baseline opioid requirements or severe acute pain and withdrawal management needs of individuals who regularly use highly potent synthetic opioids.<sup>9</sup> Short-acting opioids can be titrated to effectively manage acute pain and withdrawal in patients who are started

on OAT, such as buprenorphine-naloxone or methadone or slow-release oral morphine titrated over days to weeks; one meta-analysis found that the rate of all-cause mortality during OAT is more than half the rate during time out of OAT.<sup>10</sup> Short-acting opioids can also be used to manage acute pain and withdrawal in hospitalized patients who decline OAT initiation.<sup>9,11</sup>

Undertreated withdrawal and pain are two of the main drivers of patient-initiated discharge in hospitalized patients with OUD.<sup>12</sup> The risks of patient-initiated discharge for patients like KC include complications related to untreated infective endocarditis such as heart valve dysfunction, septic emboli, worsening systemic infection, and death.<sup>13</sup> They also include the risks of untreated active, severe OUD, such as drug poisoning death, traumatic injury, suicide, and complications related to injection drug use (eg, blood-borne infections like HIV or hepatitis C).<sup>14</sup> In addition to reducing these risks, hospitalization can offer other benefits, such as screening and treatment for sexually transmitted and blood-borne infections; vaccinations; assistance with housing and income support applications; and referral to community-based primary care, addiction treatment, and other services.

Are there risks to KC, or to society in general, if short-acting opioids are used in a hospital setting? KC is already physically dependent on high-potency synthetic opioids and likely meets the fifth edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-5) criteria for severe OUD.<sup>15</sup> It is unlikely that the short-term use of less potent, regulated opioids in a hospital setting will worsen the severity of their OUD. People with severe OUD, by definition, will continue to use opioids despite ongoing negative health and social consequences. While concern exists over the diversion of prescription opioids into the community at large, this concern can be largely mitigated in hospitals by ensuring that short-acting opioids are prescribed in formulations that are harder to divert (eg, liquid) and that ingestion is witnessed by a regulated health professional. While the risks to KC or society in general are likely small in the hospital setting, unique legislative restrictions on the prescribing and dispensing of opioid medications in the United States (Administering or Dispensing of Narcotic Drugs<sup>16</sup>) and Alberta, Canada (the Mental Health Services Protection Act<sup>17</sup> and Mental Health Services Protection Regulation<sup>18</sup>) can contribute to confusion about where, when, and for how long medications like short-acting opioids can be used, which in turn potentially contributes to inaction and undertreatment of pain and withdrawal.

As part of the informed consent process, the duration for which short-acting opioids will be prescribed should be discussed in advance with the patient. There is considerable variation across North America in the use of short-acting opioids for people with OUD in community-based settings.<sup>19,20</sup> Whether these medications will be tapered prior to or after discharge or continued with the transfer of care to another prescriber in the community should be discussed prior to their initiation in hospital.

#### Managing Risks of Nonprescribed Substance Use

Even with expertly managed pain and withdrawal and access to the full continuum of treatment options for OUD (both of which should be part of the standard of care in hospital settings), some people might continue to use their own substances while admitted.<sup>21</sup>

The ongoing use of nonprescribed substances in hospitals might present risks to the patient (eg, unattended drug poisoning event, recurrent infections from lack of access to

clean supplies) and to staff (eg, contact with used injection equipment). Abstinenceoriented hospital policies might also place staff and patients in conflict when sanctions for ongoing substance use are implemented (eg, hospital-initiated discharge, constant patient surveillance, revocation of off-unit privileges).<sup>22</sup> Both hospital- and patientinitiated premature discharge can preclude patients from accessing high-quality medical care.<sup>23</sup>

These risks can be mitigated by taking a more pragmatic, harm reduction-oriented approach to care,<sup>22,24</sup> which can include the integration of interventions that have been well studied in community settings into hospital-based care. Naloxone kit distribution, safer substance use education for patients and staff, access to new consumption equipment and sharps disposal containers, and ensuring patients have access to secure storage might all help reduce the risks associated with substance use in hospitals. Access to supervised consumption services that provide sites where hospital patients can consume their own substances under medical supervision is another example of how hospitals have tried to reduce the risks to patients of taking a nonprescribed substance.<sup>25,26</sup> Formalized supervised consumption services offer several advantages over other ad hoc measures, such as protection from illegal drug possession charges for staff and patients while following the approved policies and procedures of the service, safe disposal of used equipment, and the availability of an immediate medical response to any adverse reactions.

#### Language Use When Caring for People With OUD

Patients who use substances often experience being stigmatized and mistreated by health care professionals during hospital admissions.<sup>27</sup> The language used to describe patients with OUD affects how health care professionals (and others) judge and value these patients, perceive the cause of the problem, and view whether the patient is deserving of treatment.<sup>28</sup> Stigmatizing language (eg, *substance abuser, addict*) should be strenuously avoided in favor of more neutral language that recognizes patient dignity and emphasizes a medical approach to OUD.

In cases like KC's, questions have been raised about whether there is value in using terms like *life-threatening* to describe risks associated with failing to offer resources to address patients' OUD. In general, any terminology that is used should be accurate and, when possible, supported by evidence. If a course of action or lack of action is life-threatening, then it should be described as such. OUD would certainly be considered a life-threatening or life-limiting diagnosis, with the average life expectancy of people who have been prescribed OAT being approximately 15 years shorter than that of the general population.<sup>29</sup>

That said, it is not clear that using terms like *life-threatening* will motivate health care practitioners who hold stigmatized views of OUD to take steps to address a patient's OUD. If OUD is perceived as a character flaw or a concatenation of "bad" individual decisions (which might be the perception of KC's clinician, who is concerned about "feeding" their OUD), then describing OUD as life-threatening might not result in someone seeing a greater need to act. Death might simply be seen by some clinicians as the unfortunate result of an individual's poor choices—with no burden of responsibility for medical professionals or the health care system, politicians, or society to bear.

This view that no one bears responsibility for the preventable (though perhaps regrettable) death of a patient with OUD because it is the result of that patient's choices stands in stark contrast to general societal expectations of the role of physicians and hospitals. We expect-and demand-that hospitals provide care for the most urgent medical, surgical, and psychiatric issues 24 hours a day, 365 days per year. There is an expectation that all efforts will be made to provide life-preserving care, whether or not the life-threatening circumstances experienced by patients were the result of their own actions or choices. Hospitals offer the most advanced and intensive treatment options for (almost) all medical conditions, yet, in most hospitals in North America, access to physicians with addiction medicine expertise is rare,<sup>30,31</sup> and access to specialized treatment options (such as injectable OAT like diacetylmorphine or hydromorphone<sup>32</sup>) is virtually nonexistent. This lack of access to OUD care in hospitals is not only inconsistent with the broader expectations of health care, but also discriminatory and in violation of the Americans with Disabilities Act.<sup>33</sup> When faced with emerging threats, such as COVID-19, the health system was able to respond quickly to deliver new expertise, testing, medications, and vaccinations. Yet interventions proven to reduce deaths in people with OUD have not been spread and scaled in a commensurate way.

#### Conclusion

People with OUD in hospital settings urgently require access to a full continuum of evidence-based OUD care that is provided without stigma or judgment. Such care is consistent with clinicians' ethical duties to minimize harms and maximize benefits for their patients and to set the conditions whereby patients might optimally benefit from treatment of their acute medical illness. Access to all forms of OAT (buprenorphine, methadone, slow-release oral morphine, and injectable formulations), naloxone kits, clean substance use equipment, safe disposal of used equipment, and supervised consumption services in combination have the potential to dramatically decrease the risks that patients with OUD currently experience in hospital settings. Providing patients evidence-based care for both their OUD and their other conditions, without negative bias, is the standard generally expected for treating any condition.

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### Editor's Note

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The people and events in this case are fictional. Resemblance to real events or to names of people, living or dead, is entirely coincidental. The viewpoints expressed in this article are those of the author(s) and do not necessarily reflect the views and policies of the AMA.

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## CASE AND COMMENTARY: PEER-REVIEWED ARTICLE

When Medication Treatment for Opioid Use Disorder Gets Disrupted by Extra-Clinical Variables, How Should Clinicians Respond?

Taleed El-Sabawi, JD, PhD and Kelly Gillespie, JD, PhD, RN

#### Abstract

Structural and systemic discrimination against people with substance use disorder is pervasive. Clinicians caring for patients receiving medications for opioid use disorders (MOUDs) should plan for possible disruptions of treatment caused by arrests and pretrial confinement in jails. This case commentary suggests that harms caused by such treatment disruption can be mitigated by clinicians who take some of the practical approaches outlined in this commentary to better preserve continuity of care for people receiving MOUD.

#### Case

MJ has been in a methadone treatment program for 20 years. Moderately high doses of methadone are needed to treat MJ's opioid cravings and are prescribed and managed by Dr D.

MJ does not use other drugs, works full-time, and spends free time with family members. After driving over the speed limit to get to a hospital where their daughter was giving birth, MJ was pulled over and arrested after violating the suspension of their driver's license for past traffic violations. While jailed for nearly 2 days, MJ did not have access to their prescribed methadone; MJ experienced severe withdrawal symptoms and cravings, none of which were treated while they were incarcerated.

MJ's release from jail did not incorporate follow-up appointments for MJ's usual treatment program, and a couple of days after their release, MJ still had not returned to the clinic. Dr D worries that MJ has returned to drug use and wonders what to do.

#### Commentary

Because of structural discrimination wrought by more than a century of racism, ableism, and classism in prohibitionist drug policy,<sup>1</sup> persons who use opioids have higher rates of criminal legal system involvement than those who do not report opioid use.<sup>2</sup> As in MJ's case, this involvement may include incarceration in jails (locally operated settings where people are confined before adjudication or sentencing or for sentences of less than a year).<sup>3</sup> Although it is difficult to get an estimate of the number of persons with opioid use disorder (OUD) in jails, it was estimated that, between 2007 and 2009 (the most recent period for which these statistics are available), 63% of persons serving sentences in jails

had a substance use disorder (SUD) compared with only 5% of the general adult population.<sup>4</sup> When left untreated (or when medications are discontinued, as was the case with MJ), persons who are released from jail are more likely to experience overdose deaths on release, with increased risk of drug overdose death being associated with repeat jail bookings.<sup>5</sup> Conversely, provision of medications for opioid use disorder (MOUD) in jail is associated with an 80% reduction in overdose mortality in the first month post release.<sup>6</sup>

Even short-term incarceration seriously disrupts access to treatment. Many jails and prisons do not provide evidence-based treatment for SUD (such as MOUD) or for alcohol or opioid withdrawal, despite the Supreme Court's interpretations of both the Eighth and the Fourteenth Amendments of the Constitution as obligating states to provide necessary health care to people who are incarcerated and the protections offered such persons under Title II of the Americans with Disabilities Act (ADA).<sup>7</sup> Persons covered by Medicaid often have their coverage suspended or even terminated upon entry to a carceral setting, leading to further barriers to accessing care upon release.<sup>8</sup> The futility and cruelty of the continuing War on Drugs produce structures and systems wherein people like MJ and, by association, Dr D, are discounted, disempowered, and silenced.9 These consequences are a matter of profound epistemic injustice-both testimonial injustice (when the listener's prejudice against the speaker leads them to discount the speaker's credibility) and hermeneutical injustice (when someone is unable to understand or share their social experience due to a lack of interpretive resources caused by the marginalization of a social group to which the individual belongs).<sup>10</sup> For those who provide SUD treatment like Dr D, oppressive and harm-inducing legal regimes and attendant practices also create moral distress and ethical dilemmas because ethically appropriate care is hampered by the inability (or perceived inability) to execute it-either out of fear of violating the law or due to feeling helpless to intervene when patients are arrested and detained in jails. There are, however, some affirmative steps clinicians can take to mitigate some of the structural harm to their patients who may be experiencing, or newly released from, incarceration.

#### Withdrawal in Carceral Settings and Legal Protections

People who are incarcerated have constitutional and civil rights to receive medical treatment in many circumstances. The Supreme Court has interpreted the Fourteenth Amendment as guaranteeing substantive due process protections<sup>11</sup> to persons awaiting trial and sentencing, and the Eighth Amendment prohibits cruel and unusual punishment<sup>12</sup> for persons convicted of a crime. In Estelle v Gamble, the Supreme Court held that "deliberate indifference" to serious medical illness constitutes "cruel and unusual punishment," requiring that persons in custody receive adequate medical care to prevent "the unnecessary and wanton infliction of pain."13 Additionally, Title II of the ADA prohibits discrimination based on a disability (including SUD) and applies to state and local entities,<sup>14</sup> including jails. People like MJ, who have SUD and are currently receiving MOUD, are protected by the ADA, and jails that fail to arrange for continued treatment are likely in violation of the law. Courts across the country have required jails to continue providing MOUD to persons who become incarcerated.15,16,17,18 The Department of Justice, responsible for enforcing Title II and federal constitutional rights vis-à-vis civil rights laws, has explicitly stated that it is an ADA violation for a jail not to allow MOUD continuation.19

Nonetheless, patients receiving MOUD treatment, like MJ, are too often forced into withdrawal by noncompliant jails that refuse to provide continued MOUD treatment upon

incarceration. While courts increasingly find that the ADA and the US Constitution require that jails and prisons offer MOUD, uptake in jails and prisons remains slow.<sup>20</sup> The US Department of Justice Bureau of Justice Statistics estimates that only 54% of jurisdictions with jails provided at least one form of MOUD at mid-year 2019.<sup>21</sup> A 2022 study of a representative sample of US jails found that only 20% provided MOUD to all persons with OUD (as opposed to restricting access to certain categories of persons such as pregnant persons with OUD), and many of the jails did not provide access to all 3 US Food and Drug Administration-approved MOUDs (methadone, buprenorphine, and naltrexone).<sup>22</sup>

Even in carceral facilities that provide MOUD, treatment delays may occur while the correctional staff contacts the community MOUD provider to verify prescriptions. These delays can lead to forced withdrawal, which poses health risks, increased risk of suicide, and even death.<sup>23</sup>

Since pre-trial detention is short-term incarceration, with many individuals being released once they have been arraigned, clinicians who provide MOUD should create contingencies to allow for continued MOUD treatment while their patients are in custody, especially when the patient is being administered methadone by that prescriber. In fact, the duty to create these contingencies arises, in part, out of the structural inequalities created by the regulation of methadone.

#### Structural Inequity and Contingency Planning

For people with OUD, one structural driver of continued barriers to appropriate care is the long-standing legal segregation of treatment of opioid use disorder from the rest of health care—which serves the expressive function of further stigmatizing people with OUD and communicates that their treatment is inherently different, dangerous, and warrants exacting legal control.<sup>24</sup> Such excessive regulation is discordant with evidence of the safety and broad efficacy of MOUD.<sup>25</sup> While restrictions have been relaxed in recent years, especially regarding buprenorphine prescribing, methadone remains highly regulated when used to treat OUD.<sup>24</sup> Unlike buprenorphine, which can be prescribed in an outpatient setting,<sup>24</sup> methadone is generally provided by registered opioid treatment programs (OTPs).<sup>26</sup>

Most patients must report daily to the OTP in person to take their methadone dose in the presence of OTP staff.<sup>26,27</sup> Due to the shortage of OTPs, some patients have to travel long distances to receive their daily doses.<sup>27</sup> As a result, some patients must navigate transportation, childcare, and work schedules to receive their methadone dose at the OTP–making it difficult for patients to attend school, maintain stable employment, and otherwise manage their lives.<sup>28</sup> While "take-home doses" are now increasingly allowed due to changes in regulations,<sup>24,26</sup> OTPs have significant latitude in determining when to allow take-home doses. Recent studies suggest that even when patients receive take-home doses, they are often for only 1 to 2 days.<sup>24,26,27</sup>

Since MJ appears to be a "stable patient" (as defined by federal law<sup>29</sup>), Dr D could ensure that MJ has the maximum allowable take-home doses in their jurisdiction. Although having take-home doses on hand is no guarantee that the jail will agree to administer them, it decreases some administrative hurdles. Take-home doses provide evidence of MJ's enrollment in a methadone program and prescribed dosage and even allow for the medication to be brought immediately on-site. Furthermore, upon release, MJ will have their take-home doses to continue treatment.

#### Planning for Disruption, Incarceration, and Transition

Dr D's patients are part of a highly stigmatized group by virtue of both their diagnosis and the medication used to treat OUD.<sup>30</sup> They may have multiple additional marginalized identities (eg, disability other than SUD, race, prior criminal system involvement), which increases the risk of enhanced police surveillance and future criminal legal system involvement and incarceration (often for matters that would not lead to incarceration for those with more privilege). These social and structural determinants of health lead to health inequities and injustice, and physicians have an ethical obligation to address them.<sup>31</sup> In addition to providing the maximum allowable take-home doses, therefore, Dr D can take several steps to plan for periods of treatment disruption caused by incarceration.

First, Dr D should consider advance care planning for the possibility of treatment interruption, including interruptions caused by criminal legal involvement, with patients like MJ. Such a plan would allow both Dr D and the patient to prepare for and minimize treatment disruptions. For example, Dr D could provide patients with a signed letter to keep on hand if they are incarcerated. The letter could include a brief treatment summary, up-to-date medication and dosage information, and emergency contact information for Dr D so that the institution can reach out for additional relevant medical information for the purposes of treatment. Federal privacy law allows the sharing of information with correctional institutions for treatment purposes with consent and without consent by court order to prevent "substantial risk of death or serious bodily harm" under the Health Insurance Portability and Accountability Act (HIPPA).<sup>32</sup> Of note, , special care must be taken to avoid secondary disclosure of information of any recent use of illegal drugs (by, for example, notating it in patient histories).

Second, Dr D and the medical team can build a relationship with the local jail and the jail's correctional health care practitioner to understand and possibly improve the jail's process for care continuation. More specifically, Dr D could find out what information a patient would need to provide the jail, how Dr D could quickly deliver the verifications the jail requires, and ways in which Dr D could facilitate dose administration if a patient becomes incarcerated. If needed, the jail's physician could be reminded that federal regulations allow any physician with a Drug Enforcement Administration license to prescribe controlled substances to dispense methadone for up to 3 days to prevent persons with OUD from experiencing withdrawal during treatment transitions.<sup>33</sup>

Third, in MJ's case, Dr D can report the jail to the Department of Justice, Civil Rights Division, for violating MJ's civil rights by failing to properly screen MJ for OUD and failing to provide MJ with necessary medical care.<sup>34</sup> The reports often form the basis of investigations of ADA violations, leading to practice changes or even enforcement actions.<sup>35</sup>

Additionally, Dr D can join national advocacy efforts to improve laws and policies that continue to harm people with SUD, especially those who are members of already marginalized groups. Many health professional organizations, for example, provide advocacy tools and training for their members. For patients like MJ, Dr D should advocate for policies that make MOUD more accessible to incarcerated populations, including through the reform of Medicaid exclusions that would allow persons who are incarcerated to remain on Medicaid if eligible, requiring jails to provide access to all 3 forms of MOUD, encouraging clinician education about the ADA and robust enforcement of existing civil rights laws, and supporting legal changes that expand access to MOUD—

such as the changes to methadone regulation  $^{24}$  and continued federal permissions that allow for telehealth access to buprenorphine.  $^{36}$ 

In sum, the unfortunate reality is that Dr D—and others who provide MOUD—should expect and plan for treatment disruptions, such as the one experienced by MJ, and strive to incorporate in their treatment plan strategies to help reduce the harm caused by systematic and policy failures, such as the ones experienced by MJ.

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The people and events in this case are fictional. Resemblance to real events or to names of people, living or dead, is entirely coincidental. The viewpoints expressed in this article are those of the author(s) and do not necessarily reflect the views and policies of the AMA.

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## CASE AND COMMENTARY: PEER-REVIEWED ARTICLE When Are "Paraphernalia" Critical Medical Supplies?

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#### Abstract

Evidence of harm reduction interventions' morbidity and mortality benefits is abundant and of high quality, so there are good reasons for regional and national groups to advocate for more widespread distribution of legally regulated "drug paraphernalia," including needles, syringes, and fentanyl test strips. But lack of consistency among states' laws means that patients' interstate travel can subject them to being charged with possession of illegal items. This commentary on a case offers guidance to clinicians looking to help patients understand legal risks of interstate travel with supplies that are prescribed or recommended to reduce harms of their drug use and explores the ethical responsibilities of physicians in jurisdictions that legally prohibit these harm reduction interventions.

#### Case

GG has opioid use disorder (OUD) with a history of multiple incidental overdoses. Part of GG's OUD treatment plan, managed by a local clinic team, requires GG's use of clean syringes and fentanyl test strips, a supply of which GG brings when visiting family. GG is pulled over by a state trooper just after crossing an interstate border. A search of the vehicle finds no illegal drugs, but GG's syringes and test strips are confiscated. GG tries to explain, "Those are medical supplies I get from my clinic. I need those," but GG is arrested and jailed for drug paraphernalia possession.

#### Commentary

We considered this case as physicians in Texas, which has an opioid crisis and laws that hinder distribution of harm reduction supplies, identified in state and federal law as "drug paraphernalia."<sup>1,2</sup> Texas state law and federal law define drug paraphernalia as "any equipment, product or material . . . primarily intended or designed for . . . processing, preparing, injecting, ingesting, inhaling . . . into the human body a controlled substance,"<sup>1,2</sup> and Texas law also includes in its definition "testing equipment used or intended for use in identifying or in analyzing the strength, effectiveness, or purity of a controlled substance."<sup>1</sup> In the last decade, Texas has experienced a steady increase in opioid-related deaths,<sup>3</sup> with a sharp increase beginning in 2019, similar to national trends.<sup>4</sup> Because in Texas and other states with similar laws patients' interstate travel

can subject them to being charged with possession of illegal items, this commentary offers guidance to clinicians looking to help patients understand legal risks of interstate travel with supplies that are prescribed or recommended to reduce harms of drug use and explores the ethical responsibilities of physicians in jurisdictions that legally prohibit these harm reduction interventions.

#### Paraphernalia and Harm Reduction

Harm reduction strategies are important in limiting the morbidity and mortality associated with opioid and other substance use disorders (SUDs). Cities with syringe service programs (SSPs; previously described as needle exchange programs), where people who inject drugs obtain sterile needles and syringes for injection use, are associated with a decrease in HIV seroprevalence compared to an increase in HIV seroprevalences in cities without these programs.<sup>5</sup> Meta-analyses confirm that SSPs are associated with decreases in HIV transmission.<sup>6,7</sup> Similarly, fentanyl test strips, which allow for identification of drugs containing fentanyl, are a form of paraphernalia that serve as a preventive medical supply, given the association of fentanyl with overdose deaths.<sup>4</sup> People who inject drugs identify fentanyl testing as protective against overdose and will alter their use behavior if a sample contains fentanyl.<sup>8,9,10</sup> Indeed, fentanyl test strips are in high demand among people who inject opioids.<sup>11</sup> Expert consensus supports broad availability of fentanyl test strips as a component of comprehensive harm reduction.<sup>12,13,14</sup> Thus, this evidence suggests that fentanyl test strips and sterile needles and syringes serve as medical supplies that decrease mortality and morbidity associated with injection drug use despite their regulation as drug paraphernalia in certain jurisdictions.

#### Legality of Service Programs

SSPs operate legally in 38 states, the District of Columbia, and Puerto Rico; they are present in an additional 6 states through unregulated or unauthorized programs.<sup>15</sup> The Centers for Disease Control and Prevention recommends that SSPs "ensure lowthreshold access to services."16 The White House Office of National Drug Control Policy in 2021 helped to create a model SSP state policy to enhance consistency in program regulations across state lines.<sup>17</sup> This model act outlines components of a high-quality SSP, including access to SUD treatment, testing and treatment for HIV and hepatitis, access to general and mental health care, data collection and reporting requirements, immunity from criminal charges and prosecution for SSP operators and patients, education and training materials for the community, and funding.<sup>17</sup> Drafters of the model act took into account existing state laws that pose barriers to implementation of SSPs in attempting to draft model legislation that would reduce barriers to both program implementation and access to high-quality services and related referrals by not requiring "a potentially burdensome application process."<sup>17</sup> Nevertheless, states' adoption of the model act has been slow, and laws imposing tight restrictions and limitations on care remain common.<sup>15,18</sup> For example, states can require registration of participants and employees of the programs or methods of identification for the needles and syringes supplied by the SSPs or implement a one-to-one exchange model in which participants receive one clean hypodermic needle and syringe for every used one returned.<sup>15</sup> These requirements likely limit engagment with SSPs, but, in Texas, SSPs and fentanyl test strip distribution to patients remain legally prohibited.<sup>15,19</sup> The Texas Medical Association has unsuccessfully advocated for legal reform in these areas.<sup>20,21,22</sup> The American Medical Association (AMA) also has policy supporting access to fentanyl testing strips and SSPs, including modification of paraphernalia laws to protect SSP patients and employees.23

Harmonization of laws across state lines is critical, as differences between the states can delay care. For example, requirements in some states for identifiable needles and syringes and one-to-one exchange could lead to legal consequences for SSP patients crossing state lines who are not familiar with the laws in their new state or have not yet registered in an SSP.

#### **Steps for Clinicians**

Adopt the medical perspective. The ethics of SSPs is straightforward from a narrow utilitarian perspective in that the primary harm of opioid use is death; this harm provides a low bar for ethical analyses that frame the issues in terms of benefits counterbalancing the potential harm of death.<sup>24,25</sup> However, in the public sphere, attitudes toward and perspectives on harm reduction strategies are more complicated. Arguments against harm reduction typically take the form of opposition to "enabling" and using tax or health care dollars to support illicit drug use.<sup>26</sup> This polarization around harm reduction can be understood through differences between medical and religious/legal/criminal justice understandings of illicit drug use. Physicians identify SUD as an illness resulting from multicausal, multilevel biopsychosocial vectors that requires evidence-based treatment, including harm reduction. For physicians, allowing individuals to die due to their behaviors violates fundamental nonmaleficence and beneficence principles. The legal and criminal justice systems understand drug use as wrongful but responsible, freely chosen behavior by individuals subject to punishment under the US retributive justice model, which is underpinned by the metaphysical assumption that punishment and allowing death by overdose are just deserts of illicit use and that harm reduction interventions serve to delay these just-desert consequences. Further analyses of this culture clash can be found in several recent publications.<sup>25,27,28</sup> Clinicians should adopt the medical viewpoint, as this standpoint is lifesaving, more humane, and beneficent, and they are called to advocate for this approach under principle III of the AMA Principles of Medical Ethics: "A physician shall respect the law and also recognize a responsibility to seek changes in those requirements which are contrary to the best interests of the patient."29

*Provide disclosure and consent for patients traveling across jurisdictions.* Conscientious care involves anticipating and preventing harms that patients might encounter and counseling them about legal risks posed by items such as syringes and test strips. Counseling should include informing patients that travel with their treatment materials might place them at risk of arrest when traveling to jurisdictions that either do not recognize or explicitly prohibit these harm reduction strategies.

*Provide adequate support materials for traveling outside the home jurisdiction.* Emerging guidance about traveling recommends that patients carry their materials in their suitcase using the original containers, including prescription information on the original container and a letter on official letterhead from the treating physician or treatment program that indicates that they are treatment materials<sup>30,31,32</sup> and not paraphernalia. Syringes and needles are common suitcase objects for a variety of medical conditions and do not commonly elicit TSA queries in airport security screening.<sup>32</sup> Nevertheless, patients should be counseled on being aware of differing laws across jurisdictions and carefully considering the risks and benefits of out-of-state travel with harm reduction supplies. The potential persists for criminal consequences of possession of these materials in jurisdictions that do not recognize them as legitimate medical equipment. Be aware of personal risk in providing harm reduction materials to patients in unfriendly *jurisdictions*. The situation in which a conscientious physician in a forbidding jurisdiction seeks to provide harm reduction materials is the most ethically fraught situation under consideration. Our review of available information did not identify legal or professional regulatory consequences for conscientious, evidence-based practice in unfriendly jurisdictions. Physicians can mitigate legal or regulatory risk by seeking information assistance from state medical societies, as well as by using online state Department of Health or Department of Health and Human Services legal databases, such as those for Texas.<sup>33,34</sup>

A professional obligation to care for one's patient in the face of some degree of risk to oneself is a personal decision for the doctor and patient. Two relevant principles from the AMA Principles of Medical Ethics illustrate this dilemma. Principle III states: "A physician shall respect the law and also recognize a responsibility to seek changes in those requirements which are contrary to the best interests of the patient."<sup>29</sup> Principle IX states: "A physician shall support access to medical care for all people."<sup>29</sup> The case dilemma here involves a situation in which respecting the law involves denying access to medical care for a group of people. Advocating for change in this lamentable situation is recommended and might be considered an ethical obligation.

#### Conclusion

From a clinical perspective, harm reduction equipment being called "drug paraphernalia" is misleading and can compromise the care and safety of patients and place patients and physicians at legal risk. Sorting out the nomenclature of medical harm reduction strategies and equipment is a task to be addressed at the level of state regulation, assisted by organized medicine's advocacy. At present, important differences among states persist despite advocacy and policy guidance for standardization across state lines. These inconsistencies increase both health and legal risks experienced by people who inject drugs.

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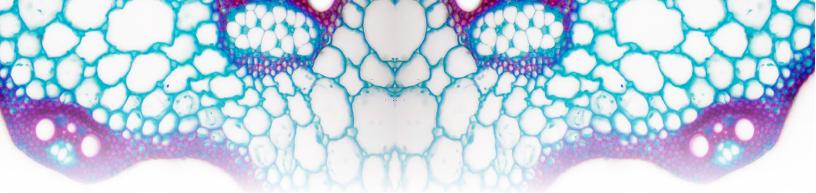
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The people and events in this case are fictional. Resemblance to real events or to names of people, living or dead, is entirely coincidental. The viewpoints expressed in this article are those of the author(s) and do not necessarily reflect the views and policies of the AMA.

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### IN THE LITERATURE: PEER-REVIEWED ARTICLE

# How Should Harm Reduction Strategies Differ for Adolescents and Adults?

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#### Abstract

Overall rates of opioid use are low in adolescents; however, recent increases in mortality from overdose in adolescents have outpaced increases in the general population. This article highlights the importance of expanding evidence-based treatment for adolescent opioid use, especially medication, while also addressing key ethical considerations of harm reduction practices and how application of such practices with adolescents may differ from adults. Concepts related to adolescent populations are discussed, including autonomy, confidentiality, and brain development. Application of harm reduction practices should be age appropriate, express respect for patients' autonomy, include social support, and be accompanied by broader aims to minimize adolescent initiation, escalation, and overall harm caused by opioid use.

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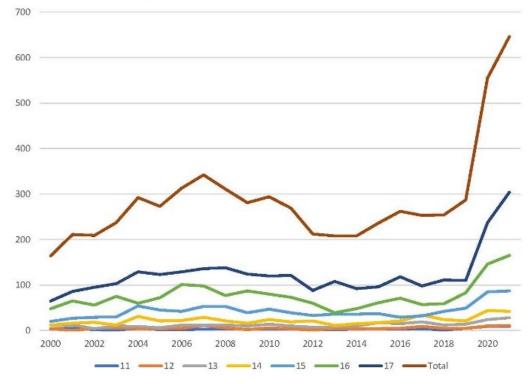
#### **Opioid Crisis and Adolescents**

The opioid crisis has had a profound influence on individuals, families, and communities throughout the United States. Increasing rates of overdose deaths—fueled largely by fentanyl and by the simultaneous use of other substances, including stimulants—are alarming.<sup>1,2</sup> Yet overdose deaths represent only a fraction of the all-cause mortality and devastation caused by opioid use disorder (OUD).<sup>3,4,5</sup> Harm reduction represents a promising approach to limiting the morbidity and mortality associated with OUD, a disorder recognized as a disease and condition in need of treatment.<sup>6,7</sup> Harm Reduction International defines harm reduction as "policies, programmes and practices that aim primarily to reduce the adverse health, social and economic consequences" of substance use,<sup>8</sup> and, as others have noted, it focuses on "the prevention of harm, rather than on the prevention of drug use itself."<sup>9</sup> The Substance Abuse and Mental Health Services Administration (SAMHSA) includes "prevention, risk reduction, and health promotion" as key aspects of harm reduction and further specifies that, within a harm reduction framework, "abstinence is neither required nor discouraged."<sup>10</sup>

Questions remain on how harm reduction efforts for people who use drugs (PWUD) should be applied to adolescents (here defined as those under the age of 18). Abstinence has long been the preferred approach, with public health efforts promoting "just say no" to practices other than prevention. There is a complete prohibition of sales of alcohol, tobacco, and cannabis (where legalized) to individuals under the age of 21 in the United States.<sup>11,12,13</sup> Despite these and other efforts to promote abstinence and prevention, many youth access and use substances, with the annual 12th-grade prevalence of alcohol use at 51.9%, vaping at 32.1%, and illicit substance use at 32.6% (8% when cannabis is excluded) in 2022 in the United States.<sup>14</sup>

By contrast, rates of opioid use are low in US adolescents, with 1.9%, 0.9%, and 0.7% of 12th, 10th, and 8th graders, respectively, reporting oxycodone misuse and 0.3%, 0.2%, and 0.3% of 12th, 10th, and 8th graders, respectively, reporting heroin use in 2022.<sup>14</sup> However, national trends in adolescent overdose fatalities have shown a rapid increase in recent years (see Figure), with a disproportionate increase in overdose fatalities between 2020 and 2021 among adolescents aged 14 to 18 relative to the general US population (20% vs 11.5%).<sup>1</sup> Seventy-seven percent of the overdose fatalities in US adolescents in 2021 involved fentanyl,<sup>1</sup> which is higher than the estimated 66% of all overdose deaths for synthetic opioids (primarily fentanyl) for all ages.<sup>15</sup> Of concern, many of these overdose fatalities are due to unintentional exposure to fentanyl by adolescents intending to misuse other substances.<sup>1</sup>

Figure. Total Number of Drug-Related Overdose Deaths of US Youths by Age, 2000 to 2021



Data source: Centers for Disease Control and Prevention WONDER (Wide-Ranging Online Data for Epidemiologic Research) database.

These data indicate a need for a thoughtful and comprehensive approach to adolescent opioid use beyond just prevention or abstinence. While we will limit our discussion to harm reduction as it applies specifically to opioid use and OUD within this population, we recognize that opioid use represents a small percentage of overall substance use in this age group and that some of the principles discussed are applicable to other substances, as discussed in recent papers.<sup>16,17</sup>

Prevention, Health Promotion, and Potential Benefits and Risks of Harm Reduction Multipronged approach needed. Adolescence is a period of high neuroplasticity and rapid neurodevelopment through synaptogenesis, dendritic and synaptic pruning, progressive and differential myelination, and neurotransmitter-specific changes that are influenced by the complex interplay of genetics, epigenetics, and environmental factors.<sup>18,19</sup> These changes contribute to developmentally appropriate (and necessary) strengths, as well as vulnerabilities, including risk-taking, novelty seeking, higher salience of emotions and sensations, impulsivity, and greater peer influence.<sup>18,20</sup> These changes also make adolescents particularly vulnerable to experimentation and the associated euphoria of substance use while having decreased ability to consider negative outcomes. The developing adolescent brain is also uniquely susceptible to the building and reinforcing of unhealthy neural circuitry.<sup>18,21</sup> Earlier substance use is correlated, among many other negative outcomes, with a higher likelihood and severity of later substance use disorders.<sup>22</sup> Due to these particular vulnerabilities, ethically, as health care professionals, we should acknowledge that the best developmental outcomes occur with abstinence from all substances, that limited use is better than regular use, and that treatment is preferable to harm reduction alone. Thus, one ethical imperative in addressing adolescent substance use is an even greater emphasis on prevention of and reduction in use than on reduction in harm.

*Harm reduction*. Given the relatively small number of adolescents who have used opioids,<sup>14</sup> there is little data on the efficacy of harm reduction strategies specific to this age group. The potential benefits of many of the most common harm reduction approaches are universal, and evidence supporting their use can be generalized to youth (eg, regardless of age, naloxone is effective for opioid overdose reversal, and sterile syringes have decreased risk of infection). In tandem with these efforts, youth should be encouraged to participate in evidence-based treatment (ie, medication for opioid use disorder [MOUD], including buprenorphine and naltrexone), although treatment should not be a requirement for accessing harm reduction services. Additionally, widespread implementation of harm reduction interventions for adolescents has significant potential to diminish disparities in access to MOUD based on minoritized group, socioeconomic, and demographic statuses. Street-involved youth represent a particularly vulnerable group that benefits from expanded harm reduction efforts.<sup>23,24,25,26</sup>

While employing harm reduction practices for the protection and benefit of members of the highest-risk population—adolescents who use opioids—it is imperative to avoid harming or increasing risk for others. Specifically, while providing harm reduction to adolescents in need, it is important to consider if such efforts might encourage or escalate use in both those seeking services and their peers. Harm reduction practices might be perceived by youth as condoning use and consequently lead to greater experimentation or continued use. Specific supplies, such as sterile syringes, might lead youth to perceive substance use as less risky and thereby increase it. These theoretical

risks are worthy of rigorous study; however, just as in adults, so in adolescents, inaction is leading to actual harm through the spread of infections and death.

Some may worry that one mechanism by which harm reduction can lead to escalation of adolescent substance use is via the diminished perception of risk. Several large data sets and individual studies have demonstrated an inversely proportional relationship between perceived risk and experimentation with or regular use of substances among adolescents.<sup>17,27</sup> However, there are limited data on the direct impact of harm reduction practices on adolescent perception of risk. One study showed that a higher proportion of youth (ages 14 to 16) reported seeing PWUD at a needle exchange program as a deterrent rather than an incitement to use (46% vs 11.1%, with 42.4% saying it had no effect).<sup>28</sup> In an older study among youth (ages 13 to 23) who inject drugs, most reported that they did not believe that needle exchange programs led to earlier intravenous (IV) use, increased frequency of IV use, or decreased treatment-seeking behaviors.<sup>29</sup> Of note, it is not known how harm reduction practices tailored to adolescents would affect their perception of risk or actual use of substances. Ongoing research is needed to evaluate the impact of the availability of harm reduction services on youth substance use, especially when these harm reduction strategies are accompanied by robust treatment options and evidence-based prevention strategies.

#### Adults and Adolescents, Consent and Confidentiality

The use of harm reduction strategies with adolescents is significantly different than with adults concerning the principle of autonomy. Autonomy has been defined as "the obligation to respect the actions of persons and valuing informed voluntary consent, confidentiality and privacy."<sup>30</sup> Inherent in this definition is the expectation that an individual has the capacity—ethically, developmentally, and legally—for informed consent. In our current health care and legal systems, capacity to make one's own decisions is an age-based construct barring any gross deficits or court-ruled limitations. Neuroscience and developmental theory teach that capacity for decision-making evolves through childhood and into adulthood. While some "as young as 14 can understand medical information" to the point of making an informed decision,<sup>31</sup> each individual's developmental trajectory is subject to biological and environmental influences, thus confounding the idea that a single age confers decision-making readiness. Should we then restrict autonomy to choose treatment or harm reduction for someone of a certain age who has already exercised that autonomy to choose substance use?

It is beyond the scope of this article to provide a complete overview of the complexities of adolescent consent and confidentiality laws, which vary widely by state. Most states allow for adolescent consent for some specified medical, mental health, or substance use treatment,<sup>32</sup> even while 48 states recognize 18 as the age of majority.<sup>32</sup> These statutes are meant to encourage youth to access needed care, increase engagement, allow the confidence and trust necessary for full disclosure, and create a more meaningful therapeutic relationship.<sup>33,34</sup> State laws permitting minors to consent to substance use treatment vary based on age (12 to 16 or unspecified), the allowable location of treatment (inpatient or outpatient), and the types of treatment provided (medical or nonmedical).<sup>35</sup> Some states require parents to consent to inpatient or outpatient substance use treatment for their children.<sup>35</sup> State medical societies, other organizations (eg, the Center for Adolescent Health and the Law), and published articles can provide additional information on state-specific policies.<sup>32,35</sup> Practitioners should be aware of state-specific laws governing substance use treatment and harm reduction

strategies for adolescents. They should also be aware of confidentiality laws and best practices related to adolescent substance use treatment (see Table 1).

45 CFR §164.50236	42 CFR §2.14 <sup>37</sup>	Proposed best practice
• A minor who consents to medical treatment, including substance use treatment, according to state law, controls the medical record of that treatment.	<ul> <li>If adolescents have state-based legal ability to consent to treatment, written consent is required to disclose to parents.</li> <li>Confidentiality can be breached:         <ul> <li>If there is concern that there is "substantial threat to the life or physical well-being of the minor applicant or any other individual" and</li> <li>The threat "may be reduced by communicating relevant facts to the minor's parent, guardian" and</li> <li>The minor is deemed to lack capacity based on "extreme youth or mental or physical condition to make a rational decision"</li> </ul> </li> </ul>	<ul> <li>Using age-appropriate language, discuss confidentiality upon initiation of treatment.</li> <li>Identify limits of confidentiality based on federal and state law.</li> <li>Discuss exceptions to confidentiality, including concerns for safety and how disclosures would be made.</li> <li>Possible language: "If I am concerned about your safety, I will talk with you about involving other people, like your caregiver, who can help provide you with support. We would decide together how to do this."</li> </ul>
		<ul> <li>Because there are no definitive guidelines on what constitutes a "substantial threat," practitioners should include their clinical rationale in their documentation.</li> </ul>

 Table 1. Adolescent Confidentiality Protections and Proposed Best Practices

Abbreviation: CFR, Code of Federal Regulations.

With legal and clinical efforts often focused on the autonomy and confidentiality of adolescents, parents, guardians, and other caregivers (hereafter referred to as parents) can be left with a sense of powerlessness in helping promote abstinence and safety for their teens. Although parents have a legal and moral responsibility to provide for the health and well-being of their children, they often are unable to prevent or control their children's substance use. Nevertheless, adolescents' perception of parental monitoring is associated with lower rates of substance use,<sup>38</sup> and family-based treatment has a strong evidence base.<sup>39,40</sup> Efforts should be made by clinicians to work with adolescents to engage supports, including parents. Once parents are part of treatment, tension may arise regarding types of treatment, location of treatment, and primary treatment goals. Depending on the state, parental consent may be needed to provide harm reduction measures or treatment for OUD. Clinicians need to be aware that because adolescents may primarily seek harm reduction and parents may only be interested in abstinence, additional work may be needed to help patients and families align their goals.

# What Are Key Opportunities to Expand Harm Reduction Strategies for Adolescents With OUD?

While not specifically harm reduction, MOUD represents one of the best treatment tools to reduce risks of substance use in adolescents with OUD.<sup>16,41,42</sup> There is substantial evidence of the effectiveness of MOUD in adults and growing evidence of its effectiveness in adolescents; buprenorphine is approved by the US Food and Drug Administration (FDA) for those 16 years and older, and naltrexone is FDA approved for adults 18 years and older.<sup>43</sup> It is essential to expand access to MOUD for adolescents with moderate or severe OUD by increasing the comfort and willingness of clinicians to prescribe to adolescents of any race or ethnicity.<sup>44</sup> Despite increasing rates of opioid

overdose deaths among adolescents (see Figure), recent data have shown that buprenorphine prescribing to youth decreased from 2015 to 2020.<sup>45</sup> Clinicians interested in prescribing MOUD can access resources on education and on peer supervision and mentorship at the Providers Clinical Support System, a program funded by SAMHSA.<sup>46</sup>

Naloxone is a lifesaving medication to which adolescents who use substances, including opioids, and those who care about them should have easy access. Given adolescents' high risk for unintentional and intentional exposure to fentanyl,<sup>1</sup> all clinicians who work with adolescents who use substances should prescribe, provide, or educate on how to obtain naloxone.<sup>47</sup> In March 2023, the FDA approved over-the-counter naloxone nasal spray,<sup>48</sup> which has increased access throughout the country for patients and families. Accordingly, patients, families, and friends should be educated on symptoms of overdose and administration of naloxone, as is done in Massachusetts.<sup>49</sup> Recently, the American Medical Association adopted a resolution to back making naloxone available to teachers, staff, and students and to remove barriers for youth to carry naloxone.<sup>50</sup> Education on the important role naloxone plays in decreasing the risk of fatal overdose not only saves lives but also provides an opportunity to emphasize the risk associated with using substances alone and provides additional resources to mitigate that risk, such as never-use-alone hotlines.

Youth should also be educated on the risks associated with specific use patterns and be provided with guidance and tools to mitigate that risk. Discussion of safety should cover risks associated with current use patterns and potential escalation of use (eg, IV use), as well as methods (and their availability) to mitigate risk. Clinicians should be clear that the safest approach is abstinence, while also providing additional information that aligns with patients' goals and priorities and facilitating open communication. In providing this education, it is important for clinicians to be aware of local laws that may limit access to specific harm reduction strategies or require parental consent and thereby limit confidentiality. In addition to providing education and information on obtaining supplies, within the local legal limits, clinicians should consider providing clinically indicated harm reduction materials to adolescents (eg, fentanyl test strips, xylazine test strips, naloxone nasal spray, safe injection supplies).

Table 2 summarizes harm reduction practices relevant to adolescents with OUD.

Harm reduction and treatment practices	Considerations when working with adolescents
Overdose education	<ul> <li>Since polysubstance use is common, provide education on risks associated with combining sedating substances and risks of counterfeit pills.</li> </ul>
Naloxone distribution	<ul> <li>Because many adolescent drug overdoses occur in the home,<sup>51</sup> distribute naloxone to the adolescent and other caregivers or peers who live with the adolescent.</li> </ul>
Medication for OUD	<ul> <li>Despite being the standard of care for treatment, MOUD is often not accessible to adolescents because it is not offered by pediatric clinicians or in adolescent treatment programs.<sup>45,52</sup> The American Academy of Pediatrics and the American Academy of Child and Adolescent Psychiatry advocate that adolescents should be offered medication to treat OUD.<sup>53,54</sup></li> </ul>

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Parent/guardian involvement	• Family-based treatments have substantial evidence supporting their use in treatment of adolescent substance use. <sup>39,40</sup> Although parents and guardians can help mitigate risk, if an adolescent does not consent to caregiver involvement in treatment, caregivers can still share information with clinicians.
Infection-related practices	<ul> <li>Because adolescents lack access to needle and syringe exchange programs and cannot buy syringes at pharmacies, provide education on risks of IV use and discuss risk-mitigation techniques, including limiting IV use, access to sterile supplies, and sterile techniques. Provide counseling on other methods of reducing infection (eg, PrEP, vaccinations). PrEP is FDA approved for use by adolescents who weigh at least 77 pounds.<sup>55</sup></li> </ul>
Drug testing	<ul> <li>Adolescents should be educated on unsafe drug supplies, adulterants, and pressed pills. Additionally, fentanyl test strips and other adulterant testing can reduce unintentional overdose. Clinicians should be aware of state-based restrictions since some states consider test strips drug paraphernalia.<sup>56</sup></li> </ul>
Never-use-alone hotlines	<ul> <li>Adolescents should be provided with information on safer consumption, including not using alone and contacting available hotlines.</li> </ul>

Abbreviations: FDA, Food and Drug Administration; IV, intravenous; MOUD, medication for opioid use disorder; OUD, opioid use disorder; PrEP, pre-exposure prophylaxis.

Clinicians and organizations should approach adolescents with respect for their autonomy and with a clear understanding of the benefits and potential harms associated with treatment and harm reduction. Optimal clinical care should be nonjudgmental and seek to include and expand natural supports. A successful encounter may have less to do with sobriety and more to do with engagement and patient-centered care. Additionally, clinicians are uniquely positioned to discuss confidentiality with adolescents and to find ways to encourage engagement of families in harm reduction and treatment. Family-based approaches represent some of the strongest evidence-based treatments for adolescents.

#### Conclusion

Harm reduction represents, in part, a pivot from blame and punishment to the principles of autonomy, beneficence, nonmaleficence, and justice in addressing substance use (see Table 3).<sup>57</sup> Adolescents who use opioids or have OUD can equally benefit from harm reduction approaches. From an ethical standpoint, a teen should have equal, if not expanded, opportunities to choose treatment over use and harm reduction over no treatment. However, legal limits may impair adolescents' autonomy and ability to access this care.

**Table 3.** Application of Ethical Principles to Harm Reduction for Adolescents Who Use

 Opioids

Ethical principle	Applications of principle
Beneficence	<ul> <li>Increase access to lifesaving interventions such as naloxone.</li> </ul>
	<ul> <li>Expand availability of standard of care treatment for OUD, such as buprenorphine, to all age groups.</li> </ul>
	<ul> <li>Provide robust education about the risks of opioid use to adolescents and families.</li> </ul>
	<ul> <li>Address known, high risks for one population (eg, risk of overdose, risk of infection) rather than prioritizing hypothetical, low risks for another population (eg, possible decreased risk perception).<sup>58</sup></li> </ul>

Nonmaleficence	• Ensure that harm reduction messaging doesn't convey a permissive approach that might lead some adolescents to experimentation or use.
	• Ensure that tertiary prevention efforts are accompanied by primary and secondary prevention efforts.
	<ul> <li>Continue to monitor and address needs of any subgroup, even if small, which is in any way at higher risk because of harm reduction measures.</li> </ul>
Justice	Apply harm reduction principles and standard of care across all care settings.
	<ul> <li>Identify and correct disparities existing in harm reduction availability and awareness among minoritized populations.<sup>26</sup></li> </ul>
Autonomy	Know local laws and guidelines concerning confidentiality and consent.
	<ul> <li>Utilize a collaborative care approach when inviting an adolescent to consider family-based interventions and caregiver participation in treatment.</li> </ul>
	<ul> <li>Prioritize allowing individual choice in treatment planning.</li> </ul>

Abbreviation: OUD, opioid use disorder.

While clinicians and organizations seek to expand harm reduction to minimize risk in the most vulnerable adolescent population, it is vital that reducing harm not be the only message that adolescents receive. It should be clear that brain development is best supported by abstinence from all substances. Furthermore, limited use is better than regular use; certain patterns and methods of use are less dangerous than others. While regular use is strongly discouraged for adolescents, harm reduction can help prevent significant negative outcomes, including death and severe infections. Expanding resources only to prevent the worst outcomes without equal or expanded efforts to promote and provide primary and secondary prevention (eg, early screening, detection, and intervention) may inadvertently convey the wrong message to adolescents and, at a minimum, may fail to prevent experimentation and escalation of use.

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## HEALTH LAW: PEER-REVIEWED ARTICLE

# What Should the US Learn From New York's and Portugal's Approaches to the Opioid Crisis?

Maura McGinnity

#### Abstract

Between 1999 and 2020, more than 564 000 people in the United States died from opioid overdose. Domestically, the opioid epidemic tends to be approached not as a public health problem but as a law enforcement or judicial problem. Some US localities, however, are trying interventions modeled after international approaches that decriminalize opioid dependence. This article describes Portuguese approaches to persons with opioid use disorder.

#### Background of the US Opioid Crisis

Prior to the 1980s, the prescription of opioids in the United States was the exception for treating pain management. Health care professionals would only prescribe minimal opioids "unless death seemed imminent."<sup>1</sup> This practice drastically changed in the 1990s, when the US Food and Drug Administration approved oxycodone to be used for chronic pain management.<sup>1,2</sup> Pharmaceutical companies began pouring millions of dollars into marketing opioids to physicians and the public at large.<sup>1</sup> The opioid crisis in the United States has unfolded in 3 waves. The first wave began in the 1990s with the increased prescription of opioids for chronic pain.<sup>2</sup> The second wave began in the early 2010s with an increase in deaths associated with an expanding heroin market.<sup>2</sup> The third wave came in 2013 with an increase in deaths related to illegal synthetic opioids, such as fentanyl.<sup>2</sup> Between 1999 and 2020, more than 564 000 people died from an overdose involving any type of opioid.<sup>2</sup>

The opioid epidemic has not affected communities equally across the United States. Rural, typically working-class communities have traditionally been seen as the hardest hit. Specifically, the Appalachian region has higher opioid overdose death rates than the rest of the country.<sup>1</sup> An investigation conducted by the House Energy and Commerce Committee in West Virginia found that, from 2008 to 2018, 20.8 million hydrocodone and oxycodone pills were delivered to Williamson, West Virginia, a town with less than 3200 residents.<sup>1</sup> However, more recent research has shown the severe impact of the opioid crisis on African Americans and those living in urban communities as well.<sup>3</sup> The types of communities and individuals that have been affected likely contributed to the response, or lack thereof, for many years. The US government and all 50 states "criminalize possession of illicit drugs for personal use."<sup>4</sup> The number of individuals who suffer from opioid use disorder (OUD) and are involved with the criminal justice system has been increasing; such individuals are less likely to become repeat offenders if they participate in drug courts.<sup>5</sup> In the United States, the criminal justice system maintains a punitive approach to addiction and punishes individuals instead of viewing OUD as a disease that requires treatment.<sup>6</sup> To decrease overdose deaths, the United States must take steps to reduce bias and stigma against individuals with OUD. Increasing access to medication-assisted treatment (MAT) and learning from countries that have successfully managed their own opioid crisis is necessary for the United States to solve this ongoing crisis and decrease the burden on the strained criminal justice system.

#### **Domestic Solutions**

States like New York have begun to make efforts to combat the opioid crisis. In 2017, Buffalo, New York implemented the first court to specifically address OUD by greatly reducing the time between arrest and treatment for nonviolent users.<sup>7</sup> Although general drug courts have been implemented throughout the country, opioid intervention courts are focused on short-term interventions to prevent overdoses and assess the individual's needs. In Buffalo, if the arrested individual agrees to participate, they are brought in front of a judge within hours of arrest and are ideally evaluated by a doctor and nurse within the first 24 hours.<sup>7</sup> Buffalo's opioid intervention court provides evidence-based treatments, including MAT, and daily court appearances for 90 days for individuals to have conversations with judges.<sup>7</sup>

Another benefit of opioid intervention courts is that they can focus time and resources on rehabilitating individuals with OUD. When an individual is in an opioid intervention court program, their criminal charges are suspended during treatment, lessening the burden on the justice system and allowing the individual to focus on recovery. Individuals who receive MAT while incarcerated are more likely to enter treatment after release and less likely to test positive for illicit opioids 1 month after their release,<sup>5</sup> thereby breaking the cycle of relapse following release from incarceration perpetuated by an already-strained legal system. However, many prisons, jails, and courts do not offer MAT.<sup>5</sup> The opioid crisis largely affected poor and minority communities that lacked resources to begin with.<sup>8</sup> By implementing opioid intervention courts, resources can be effectively distributed to individuals who would not otherwise have access to them.

#### Portugal's Solutions

In the 1990s, Lisbon was arguably the heroin capital of Europe. It was even estimated that 1% of Portugal's population was addicted to heroin.<sup>9</sup> However, in 2001 Portugal moved to decriminalize all individual drug use.<sup>6</sup> Instead of being sent to jail or prison, individuals caught with drugs are sent to a local panel called the Commission for the Dissuasion of Drug Addiction.<sup>10</sup> These 3-person panels are typically made up of legal, health care, and social work professionals.<sup>10</sup> The commission then assesses whether the individual is addicted and determines what type of treatment, if any, is appropriate.<sup>10</sup> With this system in place, individuals who use drugs are more open to treatment and are no longer afraid of going to prison if they get caught. This model focuses on humanism—the understanding that these individuals have an illness and that health interventions are needed, not punitive judicial intervention.

This model has had a drastic impact on the country, as Portugal in 2017 had the lowest drug-related death rate in Western Europe.<sup>10</sup> The number of people who use heroin dropped from a staggering 100 000 before the 2001 law to about 25 000 in 2017.<sup>10</sup> The decriminalization of drugs in Portugal has had many other positive outcomes aside

from decreasing the number of users. During the same period, the number of HIV infections resulting from drug injections dropped by more than 90%.<sup>10</sup>

Portugal acknowledges that there are people who do not want to cease using drugs by focusing on harm reduction strategies. These programs provide those who use drugs with support, clean needles, condoms, and safe injection sites.<sup>10</sup> Safe injection sites aim to reduce the transmission of diseases, prevent drug-related overdose deaths, and connect people who use drugs to resources, addiction treatment, and social services.<sup>11</sup> Safe injection sites provide sterile equipment and access to health care professionals in the event of an overdose and to social services for counseling.<sup>11</sup> Decriminalization, accompanied by harm reduction, has allowed Portugal to recover from its opioid crisis in a way that focused on individuals' needs and recovery. In recent years, however, the number of Portuguese adults using illicit drugs has increased, along with overdose rates, due to disinvestment in rehabilitation programs.<sup>12</sup>

#### Decriminalization

While New York State is making efforts to combat the opioid crisis, there is still much work to be done across the country. Other states and cities struggling with the opioid crisis might benefit from adopting programs like opioid intervention courts. The United States might also look to Portugal's method of decriminalization and safe injection sites to decrease the stigma associated with OUD.

Following New York's lead, implementing opioid intervention courts in states or counties with high rates of opioid use and overdose deaths attributed to opioid use would ensure that people who use drugs get necessary treatment instead of cycling through the criminal justice system repeatedly. Based on the Buffalo court, 10 essential elements have been identified for implementing a successful opioid intervention court: (1) "broad legal eligibility criteria," (2) "immediate screening and assessment for overdose risk," (3) "informed consent after consultation with defense counsel," (4) "suspension of prosecution or expedited plea during stabilization," (5) "rapid clinical assessment and treatment engagement," (6) "recovery support services," (7) "frequent judicial supervision and compliance monitoring," (8) "intensive case management," (9) "program completion and continuing care," and (10) "performance evaluation and program improvement."<sup>7</sup> Implementing opioid intervention courts throughout the United States not only would help more individuals obtain treatment and support but also could be seen as a move toward general decriminalization, as an individual's charges are suspended throughout this process.

More broadly, following Portugal's approach by decriminalizing drug use would likely benefit the United States, although it might not be a realistic option at the federal level, given Oregon's recent recriminalization of possession of certain drugs.<sup>13</sup> To attain success similar to Portugal, the United States would need to stop viewing people who use drugs as criminals and begin seeing drug addiction as an illness that can and should be treated. For example, states that legalized medical marijuana between 1999 and 2010 had on average a 25% lower annual opioid overdose death rate than states that did not.<sup>14</sup> These laws show that even a small shift in attitudes toward drugs can lead to overall improvements, such as decreased mortality, and that decriminalization might be better implemented at the state level as opposed to federally.

In addition to reducing rates of overdose deaths, the implementation of safe injection facilities in larger cities and areas with high rates of drug use would help prevent

transmission of disease through unsanitary needles and provide safe spaces for people who use drugs to seek treatment and counseling. Current precedent set by the US Court of Appeals for the Third Circuit has held that safe injection facilities violate the so-called "crack house" statute,<sup>15</sup> which prohibits the operation of houses and buildings where crack and other drugs are made or used.<sup>16</sup> However, New York City has implemented safe injection facilities regardless of a lack of federal support.<sup>15</sup> In addition to safe injection facilities, more harm reduction programs can be put in place to curb the spread of HIV and sexually transmitted infections among people who use drugs.

While there is evidence of progress in New York State and Portugal, the United States has a long way to go in destigmatizing and treating OUD. One of the biggest challenges will be changing attitudes toward those who use drugs. Decriminalization helps change public perception of drug use by acknowledging that addiction is a public health problem and not something that should be criminalized.

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# **POLICY FORUM: PEER-REVIEWED ARTICLE**

# How Should the Use of Opioids Be Regulated to Motivate Better Clinical Practice?

Ellen L. Edens, MD, MPE, MA, Gabriela Garcia Vassallo, MD, and Robert Heimer, PhD

#### Abstract

This article describes historical and political reasons for—and devastating consequences of—US opioid prescribing policy since the 1990s, which has restricted opioid prescribing for pain less than for treating opioid use disorder (OUD) treatment. This article considers merits and drawbacks of a new diagnostic category and proposes a regulatory and clinical framework for prescribing long-term opioid therapy for pain and for prescribing opioids to treat OUD.

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#### Approved Uses of Opioids

There are 2 US Food and Drug Administration (FDA)-approved uses for opioid medications: the treatment of moderate to severe pain and opioid use disorder (OUD). Current best practices call for limiting opioid prescribing for pain to acute situations, terminal illness, and certain chronic conditions wherein other medications or treatments are ineffective.<sup>1,2</sup> Conversely, clinical guidelines for treating OUD call for expanding access to long-term medications, with opioid agonists or partial agonists—limited in the United States to methadone and buprenorphine—being first-line treatment.<sup>3</sup> Contrary to available evidence, current US regulatory policies restrict access to opioids for OUD treatment more than for to opioids prescribed for pain.

Treatment guidelines for the management of chronic pain with opioids and for OUD have fluctuated over time due to changing drug policies and historical developments that impact medical practice and disproportionately affect minoritized communities through treatment disparities and stigma.<sup>4,5,6,7,8</sup> While the use of opioids to control pain has long been recognized,<sup>9</sup> their use in treating OUD remains controversial, highlighted by the misnomer "medication-assisted treatment."<sup>10</sup> Opioid-agonist medications for OUD are not assisting treatment; they *are* the first-line treatment. In this paper, we explore the impact of treatment guideline fluctuations on patients and clinicians and provide an

ethical analysis for maximizing benefits and minimizing risks arising from long-term opioid prescribing for pain and for OUD.

#### Not New

To gain insight into our current situation and identify potential treatment improvements for the future, it is crucial to possess a basic understanding of the historical context of opioid use in the United States. Modern opioid use emerged in the 19th century with the isolation of morphine. Its use for the treatment of acute trauma was advanced by the invention of the hypodermic syringe, leading to its widespread battlefield use during the Crimean War and US Civil War.<sup>11</sup> An unregulated patent medicine market and physician prescribing, mostly to women, throughout the second half of the 19th century increased opioid dependence within the general US population.<sup>11</sup> Concurrently, while people with narcotic dependence, mostly White, were considered medically ill and in need of treatment and were treated in psychiatric facilities, individuals with cocaine dependence, who were putatively disproportionately Black, were vilified; they were described as murderers, perverts, and drug fiends and were incarcerated—or worse.<sup>12</sup>

Initial efforts to reduce opioid misuse arose through public concern about morphine. Arguably, the early 20th-century US progressive and temperance movements did more to reduce opiate importation and consumption than did enactment of state laws designed to limit access.<sup>13</sup> Government efforts to control and regulate the influx and distribution of products containing opium and cocaine included the Pure Food and Drug Act of 1906 and the Harrison Narcotics Tax Act of 1914.14,15 The former, the first law at the federal level to regulate dangerous goods, required product labeling and allowed the federal government to set purity standards covering 10 addictive ingredients. Misrepresentation of the latter statute as a prohibitive act by law enforcement had dire consequences, including increased stigma directed against people using the regulated drugs and the assumption that addiction was a moral failing.<sup>16</sup> Two Supreme Court rulings in 1919 upheld that opioids could not be used to treat OUD.<sup>17,18,19</sup> Within 4 years, and against the backdrop of a wave of prosecutions against prescribing physicians, "maintenance clinics" providing morphine were shuttered nationally and life expectancies of patients with OUD plummeted.<sup>13,20,21</sup> Between 1935 and 1974, 2 large federal facilities devoted to treating people with addiction were operated jointly by the US Public Health Service and the Federal Bureau of Prisons (so-called "narcotic farms").<sup>22</sup> Treatment was provided to both those who were voluntarily seeking treatment and those serving drug-related sentences, highlighting the long-standing tug-of-war between conceptualizing addiction as a medical condition deserving of treatment or as a moral failing deserving of punishment. In 1962, a Supreme Court ruling held that addiction was a disease and not an act deserving of punishment.<sup>23</sup>

In the 1960s, the United States saw an increase in illegally trafficked opioids, and heroin addiction became widespread among young American men.<sup>11</sup> Heroin use further increased with easy access to the drug among soldiers serving in the Vietnam War.<sup>11,13</sup> In response, small trials using medications for OUD (MOUD) treatment were conducted and demonstrated the potential effectiveness of methadone, a long-acting full agonist.<sup>24,25</sup> Treatment centers, largely operating under investigational new drug regulations, scaled up methadone treatment from a handful of patients in 1968 to 73 000 by 1973.<sup>26</sup> Fears of inappropriate use, diversion, and profiteering, however, led to the creation of the current closed system under the Narcotic Addict Treatment Act of 1974, in which only clinics registered with the Substance Abuse and Mental Health Services Administration can dispense methadone and patients, especially early in treatment, are required to visit almost daily to obtain their medication.<sup>27</sup> In the 50 years since the passage of this act, the burdensome regulations have limited access to and acceptability of methadone and stigmatized it—even as it has become all but universally recognized as safe and effective.<sup>28,29,30,31,32,33</sup> These regulations were relaxed only at the start of the COVID-19 pandemic.<sup>34</sup>

During the period when methadone was being underutilized to treat OUD, there was one positive development. In 1966, the long-acting, partial agonist buprenorphine was discovered, along with its analgesic properties,<sup>35</sup> and, as early as 1978, its potential use for treating narcotic addiction was reported.<sup>36</sup> Buprenorphine ultimately proved to be an excellent candidate for MOUD,<sup>37</sup> given its safety profile, lower abuse potential, and effectiveness. However, even with these advantages and its Schedule III drug classification, the Drug Addiction Treatment Act of 2000 mandated that prescribers undergo extensive training and limited the number of patients they could treat.<sup>38</sup> These restrictions were substantially more onerous than those required to prescribe opioids for pain. Moreover, widespread stigma directed toward both patients using buprenorphine and prescribers remains a barrier to expanded prescribing, with people of color disproportionately denied access to MOUD.<sup>39</sup>

Meanwhile, the use of opioids to treat pain increased. Until the 1980s, opioid use focused primarily on acute pain and palliation of terminal diseases like cancer.<sup>40</sup> Beginning at that time, however, there was growing recognition that patients experiencing pain healed more slowly when their pain went untreated.<sup>41,42</sup> To promote more liberal prescribing of opioids for pain, interested physicians and physician administrators had to overcome decades of fear of prosecution and lack of training in medical schools. Nonetheless, pain became a "fifth vital sign" in assessing patient health.<sup>43,44</sup> As it provided effective pain relief in certain circumstances, long-term opioid therapy (LTOT) increased, including for conditions with little evidence of benefit. This range of conditions for which opioids were prescribed-combined with the development of synthetic opioids, time release formulations, and aggressive marketing strategies from the pharmaceutical industry<sup>45</sup>-led to a fivefold increase in morphine milligram equivalents prescribed between 1999 and 2010.46 Opioid overdose deaths rose in parallel, increasing nearly fourfold during the same period.<sup>47,48</sup> The exponential rise in opioid overdose deaths prompted efforts-reminiscent of a century prior-to reduce access to opioids. Guidelines recommending a limit to opioid prescribing were promulgated as early as 2009, while other supply-side efforts to reduce opioid use relied on law enforcement, civil litigation, and reformulation of high concentration opiates to be more tamper resistant.<sup>49</sup> After peaking in 2012, high-dosage opioid prescribing fell almost 50% by 2017.50

Nevertheless, total opioid overdose deaths continued to rise. Although the consequence of a supply-side only approach should have been anticipated, little was done initially to provide demand-side increases in the availability—or to promote the acceptability—of either form of MOUD.<sup>51</sup> Between 2010 and 2015, deaths involving heroin tripled, and from 2014 to 2015, deaths from fentanyl and its congeners increased 72%.<sup>52</sup> As recently as 2016, the Centers for Disease Control and Prevention (CDC) prescribing guideline seemed to prioritize tapering or discontinuation of prescribing, with referral to treatment for OUD being the last of 12 recommendations.<sup>6</sup> Moreover, the guideline offered no indication of which forms of treatment should be promoted or discouraged.<sup>6</sup> Individuals dependent on opioids increasingly turned to illegal drug markets, and outbreaks of HIV and hepatitis increased.<sup>53</sup> Between the release of the CDC guideline in 2016 and 2021, annual opioid overdose deaths roughly doubled to over 80 000.<sup>54</sup>

#### Influences on Patients and Clinicians

Interwoven throughout the history of opioids outlined above is the intersection of law and health care. Negative consequences arise when medical treatment is stipulated by an impersonal legal system and the sociocultural powers that drive it. These regulations have struggled to keep pace with current evidence, instead being informed by a misplaced belief that a chronic condition like OUD can be cured through short-term abstinence. A proper understanding of drug control and prohibition legislation, which is beyond the scope of this short report, places the spotlight on political strategies, such as propaganda and mass incarceration, that were utilized to demonize people who use drugs and make draconian legislation palatable to the majority.55,56 These laws set the stage for reliance on a criminal justice approach, which disproportionately affects the most vulnerable and takes precedence over a public health perspective. This approach has also allowed medical professionals, even those acting in good faith, to become targets of the criminal justice arm of drug control efforts, just as they had in the 1920s following Supreme Court interpretations of the Harrison Narcotics Tax Act. 57,58,59 To say that this approach has failed—with over 80 000 opioid-related deaths in 2021<sup>54</sup>—feels like an understatement.

#### **Guidelines for Better Practice**

In 2022, responding to the tidal wave of opioid deaths, the CDC revised its 2016 guidelines on the use of opioids for chronic pain to emphasize patient-centered care, slow tapering of opioids with consideration of a switch to buprenorphine, and assessment for OUD with initiation of or referral to treatment.<sup>2</sup> Correspondingly, and prompted by the COVID-19 pandemic, MOUD regulations saw the first major relaxation in mandated methadone treatment practices since 1975, including termination of the moratorium on mobile methadone units in 2021, and a substantial easing of the Drug Addiction Treatment Act's restrictions on buprenorphine prescribing.<sup>60,61</sup> In parallel, the US Department of Health and Human Services' Overdose Prevention Strategy has incorporated harm reduction principles and best practices as 1 of its 4 pillars. The expanded distribution of naloxone kits and fentanyl test strips to prevent overdose—along with the establishment of safe injection sites, sterile syringe programs, and funding for research on innovative harm reduction approaches—represents a significant and encouraging policy advance aimed at addressing the current opioid crisis.

Nonetheless, while opioids are less likely to be initiated for treating pain than in the past,<sup>62</sup> the range of FDA-approved opioid formulations available for treating chronic pain remains wide, which is not the case for OUD treatment. OUD treatment is limited in the United States to just 2 opioid-agonist formulations (and one opioid antagonist), and there is little discussion of (or research dollars going toward) expanding options for those who do not tolerate or accept the current FDA-approved choices. The FDA, mandated to prioritize safety, seems to assume that approved medications for OUD will be misused or diverted.

Consistent with this assumption, the FDA has put in place onerous risk evaluation and mitigation strategies (REMS) requirements that limit access to lifesaving medications. For instance, the stringent requirements imposed on 6-month subcutaneous buprenorphine implants in 2016, including a skills assessment for clinicians, arguably reflected contemporary bias against people treated with MOUD and their prescribers.

Despite a buprenorphine implant being a simple outpatient procedure similar to an etonogestrel implant (an implantable birth control medication), no such clinician assessment was required for contraceptive implants. The buprenorphine implants were withdrawn in 2020 due to low uptake, not safety concerns.<sup>63</sup> The FDA's approach to long-acting injectable buprenorphine products also involves restricting distribution and access through REMS certification for specialty pharmacy distributors and clinics. This approach lacks flexibility and risk tolerance compared to opioids for pain and potentially overlooks the high prevalence of substance use disorders in the general population receiving controlled substances for non-SUD indications. The consequences of stringent regulations for public health, clinician training, and public health literacy are not adequately considered.<sup>28</sup>

Outside the United States, however, there are a greater number of options for treating OUD. In Canada, for example, as early as 2018, slow-release oral morphine (SROM), a 24-hour formulation, became a guideline-recommended second- or third-line treatment for OUD, based upon moderate-quality evidence.<sup>64</sup> And, in 2019, recognizing that the emergence of fentanyl might require further alternative treatments, a Canadian guideline review committee published guidance on the use of injectable opioid agonist treatments for OUD.<sup>65</sup> The committee recommended that individuals with severe OUD who inject opioids and who have not adequately benefited from oral opioid agonist treatments be considered for injectable diacetylmorphine or hydromorphone treatment,<sup>65</sup> and the government approved both treatment options.<sup>66</sup> Similarly, several countries in the European Union offer alternatives to methadone and buprenorphine, including SROM and diacetylmorphine.<sup>67</sup>

Recent moves in the United States to bring guidance, legislation, funding, practice, and treatment access more in line with the evidence base for both chronic pain and OUD are indeed promising and have helped moderate the ethical quandaries we have described. Yet they remain insufficient. More flexible, patient-centered access to MOUD should be made available. Additionally, a clear path forward to expanding the number of MOUD options should be outlined. As early as 2019, the National Academies of Sciences, Engineering, and Medicine proposed exactly this solution—but noted that many of these options would require changes to the Harrison Narcotics Tax Act of 1914.<sup>28</sup> As of this writing, these changes have not been made.

#### **Ethics and Evidence**

There is now an ethical imperative to rethink our approach to the management of opioid prescribing. Conceptualizing chronic pain treated with LTOT as different than OUD, from both clinical and regulatory perspectives, is problematic and has led to a 2-tiered system that confuses clinicians, patients, and regulators.

Both OUD and long-standing debilitating pain are chronic conditions with strong evidence bases for appropriate treatment. Opioids have evidence of benefit for relief of acute pain and treatment of OUD.<sup>37,68</sup> In contrast, accumulating evidence supports alternatives to LTOT for most chronic pain conditions.<sup>2</sup> For those currently prescribed such treatment, however, tapering opioids to discontinuation is often difficult, risks substantial harm, and forces clinicians to fit patients' experiences into regulatory—rather than clinical—boxes. Illustratively, researchers are now proposing a new diagnostic category instead of using the robustly validated OUD diagnostic criteria in the fifth edition of the *Diagnostic and Statistical Manual of Mental Disorders* (*DSM-5*) for patients on LTOT who demonstrate an inability to taper prescription opioids despite

awareness of the high risk of harm and low functional benefit<sup>69</sup> because the stigma of OUD attached to patients and prescribers is substantial and reflected in regulations.<sup>70</sup> Proponents of the new diagnosis recommend excluding not only *DSM*-5 criteria of tolerance and withdrawal, which are currently excluded in the case of long-term opioid prescribing for pain, but also the criterion of "persistent desire or unsuccessful efforts to reduce use" because difficulty tapering is also "normal, expected" in the context of LTOT. Exclusion of this latter criterion "better aligns with patients' experience on LTOT" and helps patients avoid a "stigmatizing and confusing experience of being incorrectly diagnosed with OUD."<sup>69</sup> Generally, meeting 3 of the well-validated SUD criteria is sufficient to diagnose mild OUD. Yet, rather than working to change discrepant regulations between prescribing opioids for pain and prescribing opioids for OUD, those in favor of creating LTOT as a new diagnosis tend to discount the continuum of severity already embedded in *DSM*-5 diagnostic criteria.

We propose that approaching both chronic pain and OUD as the chronic conditions they are provides an ethical and practical framework for addressing these diagnostic inconsistencies. This framework would include complete evaluation and diagnostic workup; patient-centered consent, with discussion of risks and benefits of various treatment options; monitoring for safety; and reevaluation of the clinical plan at regular intervals. It would also require regulatory bodies and research funding agencies to consider other opioid formulations for OUD and less restrictive REMS and distribution requirements. It would also require expanding the number and kind of settings in which MOUD treatment can be prescribed and dispensed. Chronic conditions require consideration of pathophysiology and related evidence-base treatments, relative harm, an integrated and collaborative health care system, and a treatment team that leverages patient characteristics and preferences to maximize patient self-management. Conceptualizing and managing both OUD and chronic pain requiring LTOT as chronic medical conditions could help address diagnostic inconsistencies, clinical confusion, and stigma experienced by patients.

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### **MEDICINE AND SOCIETY: PEER-REVIEWED ARTICLE**

# How Should Harm Reduction Be Included in Care Continua for Patients With Opioid Use Disorder?

Elizabeth Salisbury-Afshar, MD, MPH, Catherine J. Livingston, MD, MPH, and Ricky N. Bluthenthal, PhD

#### Abstract

Practices and interventions that aim to slow progression or reduce negative consequences of substance use are harm reduction strategies. Often described as a form of tertiary prevention, harm reduction is key to caring well for people who use drugs. Evidence-based harm reduction interventions include naloxone and syringe service programs. Improving equitable outcomes for those with opioid use disorder (OUD) requires access to the continuum of evidence-based OUD care, including harm reduction interventions, as well as dismantling policies that undermine mental health and substance use disorder treatment continuity, housing stability, and education and employment opportunities.

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#### Background

Harm reduction, often described as a form of tertiary prevention, represents a set of practices that aim to reduce the negative consequences of substance use by adopting patient-centered approaches that are nonpunitive, nonjudgmental, and practical.<sup>1,2</sup> Its origins in the United States date back to the HIV epidemic of the 1980s, when transmission rates were high among people who injected drugs, which led activists, people who use drugs, and their allies to implement syringe exchange programs beginning in the late 1980s.<sup>3,4</sup> This approach was politically controversial and illegal in many states at the time and would not be federally supported for decades.<sup>4,5</sup> Currently, some harm reduction approaches, such as naloxone distribution (now available in all 50 states)<sup>6</sup> and syringe service programs, are becoming more accepted in the United States as a result of HIV outbreaks in rural settings such as Scott County, Indiana<sup>7</sup>; the national hepatitis C virus epidemic<sup>8</sup>; and the ongoing opioid overdose crisis.<sup>9,10</sup> However, harm reduction efforts still face major barriers due to a combination of stigma, preferences for punitive approaches to substance use, and policy and legal-moral objections.<sup>11</sup> Political opposition to harm reduction interventions also impacts willingness to adopt harm

reduction-inspired, evidence-based interventions for addressing opioid use disorder (OUD).

A professional duty to offer comprehensive evidence-based health care to all those who use drugs within the context of the ongoing opioid overdose crisis, inequitable opioid-associated outcomes in low-income and minoritized communities, and underlying contributors to multiple health challenges require physicians caring for people who use drugs and policy makers to (1) include harm reduction in the continuum of services for people who use substances; (2) embrace evidence-based policies and practices, including harm reduction approaches in health care systems and public health; (3) develop strategies to address underlying social determinants of health (SDoH); and (4) address health inequities in outcomes related to OUD treatment and opioid overdoses.

#### Harm Reduction Services

From an ethical standpoint, an important component of the success of harm reduction programs has been their focus on the autonomy and consent of people who use drugs. What in the medical field might be considered person-centered care has been key to the behavior changes and health benefits associated with harm reduction strategies. People who use drugs vary in their interest in engaging in treatment services, so providing a continuum of options (ranging from residential treatment to outpatient, low-barrier buprenorphine and syringe services programs or overdose prevention sites) is essential for improving health outcomes for all people who use drugs. Without a full range of interventions for OUD, individuals may be dissuaded from participating in health care, with avoidable adverse health outcomes. For instance, patient-directed discharge is more common among people who have substance use disorders (SUDs) than other populations,<sup>12</sup> yet harm reduction practices could reduce patient-directed discharge among people with OUD, given the discrimination experienced by people who use drugs in hospital settings,<sup>13</sup> by actively managing opioid withdrawal symptoms,<sup>14</sup> consistently prescribing evidence-based medications for opioid use disorder (MOUD),<sup>15</sup> providing naloxone upon discharge from inpatient settings, and improving systems for care continuity as patients transition through health care and community settings.<sup>16</sup>

During the COVID-19 pandemic, the regulations for MOUD were loosened. The changes included permitting telehealth prescribing of controlled substances, wider buprenorphine prescribing authority based on a telehealth evaluation, and more flexibility in methadone dosing and take-home protocols.<sup>17,18</sup> These types of person-centered care approaches that are informed by harm reduction practices could be critical to expanding the availability of highly effective medications to the many patients who need them. Implementation of better payment schemes for MOUD is also helpful in making it more widely available.<sup>19</sup> Codifying approaches that safely maximize access to MOUD (including low-barrier access), naloxone, and other harm reduction approaches are likely to have significant impacts on patient outcomes and population health.<sup>20</sup>

#### Adopt Evidence-Based Policies and Programs

From a tertiary prevention standpoint, evidence demonstrating reduced morbidity and mortality outcomes from harm reduction interventions<sup>21</sup> is compelling enough to support expansion of evidence-based policy interventions across the country. The Substance Abuse and Mental Health Services Administration (SAMHSA), the Centers for Disease Control and Prevention (CDC), and the Office of National Drug Control Policy convened stakeholders to develop a harm reduction framework to help guide policies, programs, and practices at SAMHSA. The Harm Reduction Framework<sup>22</sup> acknowledges that

structural inequities and SDoH contribute to substance use and SUDs. While SAMHSA's identified core practice areas focus on specific services related to reducing harms at the individual level,<sup>22</sup> it is critical that national harm reduction efforts have a broader focus and address the underlying structural factors and policies that actively cause harm to people who use drugs.

Policies and programs need to be based on evidence of reduced morbidity and mortality; and when reliable evidence of benefit of innovative practices exists, integrating, scaling, and spreading these practices to achieve improved health outcomes is necessary. Examples include community-based naloxone programs, which are associated with decreased opioid mortality,<sup>23,24</sup> and syringe service programs, which are associated with reduced transmission of HIV and hepatitis C, as well as reduced soft tissue skin infections.<sup>25,26</sup> While adoption of interventions that have been shown to reduce morbidity and mortality seems a straightforward policy choice, even when harm reduction approaches have strong supporting evidence, uptake has taken decades.<sup>27</sup> New harm reduction practices and policies are emerging quickly, such as drug-checking programs,<sup>28</sup> overdose prevention sites,<sup>29</sup> and decriminalization of personal substance possession.<sup>30</sup> Research evaluating these measures will be critical to understanding their impacts on morbidity and mortality, as well as their impact on community health. Conversely, when research identifies existing practices or policies that are causing harm, steps must be taken to modify or eliminate those practices or policies. Examples of policies associated with harm include prohibiting MOUD in jails and prisons, criminalizing possession of drug use equipment (which has long been known to increase infectious pathogen transmission, including of HIV and hepatitis C virus),<sup>25</sup> and closing syringe services programs.<sup>31</sup>

#### Structural Determinants of Health

Naloxone distribution and syringe service programs are critically important and effective interventions, but they are also downstream approaches that do not directly address the risk factors associated with the development of OUD. A prevention framework additionally encourages a focus on primary prevention interventions that address risk factors associated with a health condition and thereby aim to prevent the development of that condition. SDoH, by contrast, address factors such as access to food, education, housing, affordable health care, job security, and social inclusion that provide a foundation for achieving well-being<sup>32</sup> by moving even more upstream to what is known as primordial prevention.<sup>1</sup> Addressing upstream factors such as these could reduce the development of OUD, therefore also reducing its associated morbidity and mortality.<sup>1,2</sup> SDoH that are associated with the development of OUD include adverse childhood experiences (ACEs).<sup>33</sup> limited access to educational and job opportunities, lack of affordable housing, lack of available mental health services, racism, and lack of health insurance. For example, broad exposure to ACEs is associated with a 4- to 12-fold increase in the risk of substance use, depression, or suicide attempt in adulthood.33 Preventing ACEs is one strategy that could reduce opioid morbidity and mortality; known evidence-based interventions include community-level strategies, such as strengthening economic supports for families (eg, universal basic income<sup>34</sup>) and supporting positive parenting and resiliency to protect against adversity.<sup>2,35</sup>

In addition to impacting the risk of opioid use and development of OUD, SDoH also affect an individual's ability to recover from OUD. SAMHSA describes the 4 major dimensions of recovery as health, home, purpose, and community.<sup>36</sup> Ensuring access to health care and housing is a necessary step in supporting individuals with OUD. An

excellent example is the Housing First approach, which provides permanent supportive housing to those experiencing homelessness and SUD without a requirement of abstinence, unlike the standard treatment-first approach that requires people to first engage in treatment and to be substance use free before they are eligible for housing. Compared to treatment-first models, Housing First programs reduced homelessness by 88% and, in patients living with HIV, decreased emergency department visits by 41%, hospitalizations by 36%, and mortality by 37% within 2 years or less in most studies.<sup>37</sup> Moreover, among individuals who were chronically homeless with severe alcohol problems, housing first was associated with a decrease in total costs (including costs associated with jail bookings, days incarcerated, and substance use and health care services) at 6 months relative to wait-list controls.<sup>38</sup> Housing First programs, however, have faced political barriers, including stigma and perceived high costs associated with program implementation. Typically, strategies are funded by a specific sector (eg, housing, health care, or carceral settings), neglecting the interconnected nature of OUD impacts that transcend these silos. This oversight can lead to insufficient investment in innovative cross-sector strategies.

#### Strategies to Reduce Inequity

Implementing strategies to reduce inequity is imperative. Although community naloxone distribution and MOUD have gained national acceptance and increased funding, inequities in access exist. For example, a recent study found that among Medicare beneficiaries who experienced an opioid-related emergency department visit or hospitalization, White patients were more likely to receive buprenorphine treatment and naloxone than Black or Hispanic patients.<sup>39</sup> Another study found that, among Medicaid participants diagnosed with OUD, Black enrollees were less likely than White enrollees to start MOUD, and incarceration in county jail was associated with lower likelihood of initiating MOUD within 180 days of an OUD diagnosis.<sup>40</sup> Community-based studies similarly show inequitable uptake of naloxone, including in receipt of naloxone training and possession of naloxone among Black and Latinx compared to White people who use illicit opioids.<sup>41</sup> These examples demonstrate the failure of current strategies to adequately address inequity in receipt of evidence-based services.

In addition to disparities in access to evidence-based services, there are also significant disparities in how the War on Drugs has been implemented, with disproportionate impact on Black and Latino communities.<sup>42</sup> The Controlled Substances Act of 1970,<sup>43</sup> which established the current drug scheduling system, was motivated by the Nixon Administration's desire to target countercultural movements and racial minorities.<sup>44</sup> This punitive approach to drug policy, focused on criminalization and tough-on-crime policies, has been disproportionately enforced in Black and Latino communities-thereby perpetuating stigma-and failed to effectively address public health concerns. Despite similar rates of substance use compared to White people, Black people are more likely to face arrest, prosecution, conviction, and incarceration for drug-related offenses and, once convicted, face harsher criminal penalties.<sup>45</sup> Harsh criminal penalties and fearbased education campaigns have had little impact on reducing drug supply or demand. while incarcerating individuals with SUD is traumatizing and actively increases harm to these individuals.<sup>46</sup> Additionally, drug-related felony charges limit individuals' future housing, educational, and employment opportunities,47 making their path to recovery even more challenging.

The combined forces of the War on Drugs, stigma against people who use illicit substances, and structural inequalities have created the conditions for multiple health

crises and epidemics among people who use drugs. Stigma affects risk behaviors, help seeking, remaining in care, availability of services, and willingness to invest in nonpunitive approaches to substance use-related health problems.<sup>48,49,50</sup> Prohibition and stigma interact with existing structural inequalities to increase health harms and impede efforts to improve health outcomes among people who use drugs. Poverty, structural violence, and structural racism all contribute to health risk in this population.<sup>51</sup>

#### Conclusion

Harm reduction should be embraced as a core component of the continuum of services required for an effective response to the opioid overdose epidemic. Harm reduction interventions, such as syringe services, naloxone distribution, Housing First models, and low-barrier MOUD, are evidence based and should be funded and expanded nationally, with an eye toward reducing inequities. Programs and policies that are not effective or that contradict best practice standards should be dismantled.

To be effective at reducing harms, efforts should focus on not only the late-stage sequelae of OUD but also the structural factors that predispose people to developing OUD in the first place. Factors such as access to physical and behavioral health care, educational and job opportunities, and housing are all critical, as is a greater focus on reducing ACEs and other forms of community trauma.

Physicians have significant influence in advancing harm reduction services for individuals who use substances and in advocating for policies and programs that tackle SDoH. Within clinical practice, it is crucial for physicians to integrate harm reduction measures, thereby ensuring patients' access to a nonstigmatizing continuum of OUD care. This care includes prescribing naloxone and low-barrier MOUD as a routine part of outpatient and inpatient medical care, as well as establishing referral pathways to connect patients with community-based resources like syringe services and drug-checking programs. Additionally, physicians must be trained in treating SUDs, as such training has been found to increase physicians' perceived preparedness for and comfort in treating SUDs.<sup>52,53</sup> At the policy level, by voicing concerns and advocating for structural interventions, physicians can contribute to broader initiatives that address societal contributors to the ongoing opioid overdose mortality crisis and associated inequities.

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# **MEDICINE AND SOCIETY: PEER-REVIEWED ARTICLE** What Would Equitable Harm Reduction Look Like?

Oluwole Jegede, MD, MPH, Julio C. Nunes, MD, Terence Tumenta, MD, MPH, Carmen Black, MD, and Joao P. De Aquino, MD

#### Abstract

Structural determinants of health frameworks must express antiracism to be effective, but racial and ethnic inequities are widely documented, even in harm reduction programs that focus on person-centered interventions. Harm reduction strategies should express social justice and health equity, resist stigma and discrimination, and mitigate marginalization experiences among people who use drugs (PWUD). To do so, government and organizational policies that promote harm reduction must acknowledge historical and ongoing patterns of racializing drug use. This article gives examples of such racialization and offers recommendations about how harm reduction programming can most easily and effectively motivate equitable, antiracist care for PWUD.

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#### Background

The escalating drug overdose crisis in the United States and the stark racialized inequity it has revealed—notably during the COVID-19 pandemic—underscore the urgent need to reconsider traditional health care approaches by placing greater emphasis on harm reduction and on social and structural determinants of health (SDoH)—specifically, systemic racism. The pandemic years witnessed drug-related mortality rates in the United States exceeding 100 000 annually,<sup>1</sup> with the rate of deaths among Black individuals surpassing that of White individuals for the first time in 2020—a shift not seen since 1999 during the first wave of opioid overdose deaths.<sup>2</sup> In particular, the drug overdose death rate for Black individuals increased from 24.7 per 100 000 in 2019 to 36.8 per 100 000 in 2020, which was 16.3% higher than the rate for White individuals (31.6 per 100 000) in 2020.<sup>2</sup> Moreover, Black individuals have experienced higher annual percentage increases in overdose death rates than their White counterparts since 2012, much earlier than previously recognized.<sup>2</sup>

Conventional health care systems, medical education, and clinical practice have predominantly leaned on biological disease models while often sidelining the role of social causation. This oversight may contribute to the racialized disparities observed in

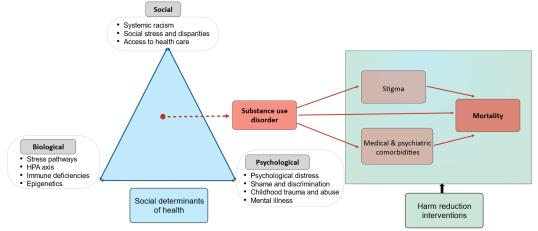
drug-related mortality, particularly among structurally vulnerable, racially minoritized individuals with substance use disorders (SUDs). In contrast to treatment informed by biological disease models, harm reduction focuses on the impact of negativeconsequences of drug use rather than drug use itself as the target of intervention.<sup>3</sup> There is a pressing need to explore alternative models, frameworks, and care systems in addressing SUDs and, in particular, to center racialized inequity and SDoH within a harm reduction framework.

In this article, we explore the interrelatedness of harm reduction and SDoH (including systemic racism) within a framework for the treatment of SUDs. We explore their potential to address health inequities faced by racially minoritized people—specifically, people who use drugs (PWUD)—and make the case that harm reduction programming must pay attention to social context in order to achieve the goal of health equity.

#### Inequality vs Inequity

Health inequalities describe any observed disparities in health outcomes regardless of underlying causes, while health inequities are disparities stemming from systemic, avoidable, unjust, and frequently racialized social and economic policies and practices.<sup>4</sup> Even though these terms are often used interchangeably, their nuanced differences in meaning hold significant implications for clinical practice, health care policy, and research. For example, while the removal of the mandatory training requirement for prescribers of buprenorphine—a major step in bridging the access gap for patients with opioid us disorder (OUD)—addresses *inequality*, further steps may be needed to ensure true *equity*, including, among others, addressing the lack of availability of buprenorphine prescribers within historically marginalized neighborhoods and communities that continue to be left behind in terms of access to medications for OUD.<sup>5,6</sup> This distinction between inequality and inequity is essential to truly grasp the intricate relationship between harm reduction and SDoH (including racism)—especially in enhancing health outcomes for racially marginalized groups (see Figure).

**Figure.** The Interrelation of Structural Determinants of Health and Harm Reduction Interventions



On the left, the Figure depicts the etiological and contributing factors underlying substance use disorder, which leads to stigma and to medical and psychiatric comorbidities, both of which, along with SUD itself, contribute to mortality. Harm reduction strategies intervene to mitigate drug-related harm and stigma. Abbreviation: HPA, hypothalamic-pituitary-adrenal.

#### Structural Determinants of Substance Use

Structural determinants of SUD refer to the conditions in which PWUD are born, live, learn, work, play, worship, and age. These factors affect the health, functioning, health risks, and quality of life of PWUD in many ways through a complex set of interrelated, mutually reinforcing pathways. Notably, structural determinants interact with biological aspects in pain perception, possibly increasing activation of stress-related neural pathways,<sup>7</sup> which could perpetuate the addiction cycle. Social influences may not only contribute to adverse health outcomes<sup>7</sup> but also serve as primary risk factors.<sup>8</sup>

Structural determinants function synergistically, not in isolation, as shown in the Figure. For example, SDoH may limit access to evidence-based, lifesaving interventions for OUD, such as buprenorphine, particularly for members of historically racially minoritized groups. To fully understand why, it is essential to consider both downstream and upstream structural determinants.<sup>8</sup> Downstream factors include health-related knowledge, attitudes, and beliefs,<sup>8</sup> as well as behaviors such as frequently returning to nonmedical substance use or medication nonadherence, which are often present but unrecognized in clinical settings. These downstream factors arise from and are shaped by more remote upstream determinants that include unstable housing, racial profiling by law enforcement, overreaching policies that produce high incarceration rates, and income inequality.<sup>9</sup> The health effects of income inequality are evident in the unequal distribution of buprenorphine that often favors more affluent, White areas whose residents have access to private insurance.<sup>10,11</sup> Highlighting the impact of income on drug overdose deaths, one study showed that, in 2020, "overdose death rates increased with increasing county-level income inequality ratios."12 Among Black persons, overdose death rates were highest in counties with the highest income inequality (46.5 per 100 000 population) and lowest in those with the lowest inequality (19.3 per 100 000 population).<sup>12</sup> Curiously, among the American Indian and Alaska Native populations. overdose death rates were still very high even in counties with the lowest inequality levels (35.2 per 100 000 population),<sup>12</sup> suggesting that structural factors other than income inequality may significantly influence overdose rates among minoritized populations.

#### Equity and Inclusion in Harm Reduction

Harm reduction is a practical and transformative approach that incorporates communitydriven public health strategies to empower PWUD (and their families) with the choice to live healthy, self-directed, and purpose-filled lives.<sup>13</sup> Central to harm reduction are health promotion and substance use risk mitigation. Harm reduction is based on grassroots, patient-centric approaches championed by people who use drugs themselves rather than on conventional top-down health care models. Its commitment to equity is evident in several key aspects: (1) reducing the stigma of substance use by providing an alternative to the moral failure and disease model approaches to substance use treatment<sup>14</sup>; (2) respecting the human rights and personhood of PWUD; (3) elevating and affirming the autonomy of PWUD and their right to be included in their own treatment by providing a choice for safer use, managed use, or abstinence; and (4) adopting a community-oriented approach by ensuring the overall safety of the community.<sup>13</sup>

Harm reduction principles were embraced and adapted by civil rights groups fighting anti-Black racism in the United States. For example, some of the early practitioners and proponents of harm reduction were the Black Panthers, who provided free breakfasts for children, and the Young Lords, who provided acupuncture for PWUD in the South Bronx.<sup>15</sup> When harm reduction was championed by people with a deep understanding of systemic racial minoritization, practices were holistically attuned to combating racialized and ethnic disparities by ensuring resources for and attention to individuals who otherwise would be excluded.

While minoritized communities have adapted harm reduction models to better serve their unique needs, there are indications that some contemporary harm reduction programs may inadvertently perpetuate racial disparities.<sup>16</sup> A thematic analysis of harm reduction practices in Toronto revealed the prevalence of structural and institutional racism in harm reduction services, highlighting "colour-blind policies and practices that fail to address the intersectional nature of the drug policy crisis."16 Other studies have echoed this concerning trend. For example, the adoption of Good Samaritan laws, which ostensibly confer criminal immunity to individuals who offer assistance during an overdose, may inadvertently exacerbate preexisting racialized inequities because public education campaigns have failed to offer minoritized individuals with SUD the same level of awareness of these laws as privileged populations, thereby fostering misinformation about the protections these laws offer and lack of willingness among minoritized individuals to offer assistance.<sup>17</sup> Similarly, emerging evidence has also shown deficiencies in naloxone training and distribution among minoritized PWUD.<sup>18,19</sup> For example, drawing on Medicare claims data from 2016 to 2019, Barnett and colleagues observed that within 180 days of an index event, only 14.4% of Black/African Americans with OUD were prescribed naloxone compared to 22.9% of their White peers.19

Taken as a whole, harm reduction practices cannot offer social justice without explicitly naming and intentionally targeting racialized injustice within current drug policies and practices. This sentiment is echoed by Lopez et al, who concluded that the assessment of social and structural dynamics is needed to ensure harm reduction protections for racially minoritized Black and Brown people.<sup>20</sup>

#### **Measuring Structural Determinants**

To address SDoH in treatment of SUDs, interventions must operate on multiple levels. Single-level strategies, while valuable, offer a limited perspective. Comprehensive interventions intersect various socioecological levels, including individual, interpersonal, organizational, community, and policy levels.<sup>21</sup> But for such interventions to yield tangible change, clinicians must avoid reductionist leanings and embed SDoH indices in their routine practice without oversimplifying complex socioecological elements. Without accurate measurement of social determinant indices, we lack insight into their influence on harm reduction and broader health interventions. Several tools have emerged to assess facets of social and economic stability that range from individual characteristics to overarching societal contexts.<sup>22</sup>

Some of the tools with potential utility in clinical settings include (1) the Protocol for Responding to and Assessing Patients' Assets, Risks, and Experiences (PRAPARE); (2) the Social Needs Screening Tool; (3) the Health-Related Social Needs Screening Tool; and (4) the Structural Vulnerability Assessment Tool. PRAPARE is an evidence-based and standardized patient risk assessment protocol designed to assess SDoH. It has 4 core domains: personal characteristics, family and home, money and resources, and social and emotional health.<sup>23</sup> The Social Needs Screening Tool, designed by the American Academy of Family Physicians, is used for screening across 5 core health-related domains, including housing, food, transportation, utilities, and personal safety.<sup>24</sup> The

Health-Related Social Needs Screening Tool, created by the Center for Medicare and Medicaid Innovation, uses the Accountable Health Communities Model; it screens across 5 core domains including housing instability, food insecurity, transportation problems, and utility help needs. Results from this tool are often used to inform treatment plans and make referrals to community services.<sup>25</sup> Finally, the Structural Vulnerability Assessment Tool is a 43-item questionnaire that assesses needs across the 6 domains of economic stability, education, social and community context, health and clinical care, neighborhood and physical environment, and food security.<sup>9,26</sup> In essence, grasping SDoH is crucial for addressing SUDs, but so is having precise instruments to measure and address them. When assessments are adeptly applied, they can foster more insightful and holistic health care solutions, ensuring a complete understanding of an individual's socioecological environment.

#### Conclusion

The devastating grip of drug overdose mortality in minoritized communities underscores the urgent need to center SDoH in harm reduction frameworks. While the impact of SDoH continues to be characterized and described in the medical literature, challenges remain in establishing the most culturally appropriate SDoH metrics. Integrating harm reduction into health care systems and practices is critical but insufficient without a thorough understanding of social context. Although the core principles and strategies of harm reduction were promoted within the context of the civil rights and antiracist movements,<sup>8</sup> harm reduction strategies can only realize their transformative power by remaining unwaveringly committed to equity, autonomy, and justice. To save the lives of historically marginalized people amidst the relentless drug overdose crisis, our health care systems must integrate harm reduction strategies that center SDoH.

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# **HISTORY OF MEDICINE: PEER-REVIEWED ARTICLE**

# Drawing on Black and Queer Communities' Harm Reduction Histories to Improve Overdose Prevention Strategies and Policies

Sterling Johnson, JD, MA and Kimberly L. Sue, MD, PhD

### Abstract

Harm reduction emerged as a set of strategies developed by and for people who use opioids and other substances and strive to do so in ways that are as safe as possible. This article reviews histories of Black and queer community-based harm reduction practices and suggests how these histories can inform harm reduction policy and guide development and implementation of anti-overdose interventions.

### **Overview of Harm Reduction**

Harm reduction can be considered as a set of both practical strategies and tools to prevent the harms of substance use, sex work, or other potentially problematic behaviors, but-perhaps most importantly-it is also a philosophy and practice born of people's lived experience of structural violence arising from the HIV/AIDS epidemic in the late 1980s.<sup>1</sup> Harm reduction is not simply access to sterile syringes, naloxone, or condoms but a lifesaving movement of mutual aid by and for people who had been relegated to harm or death by society more broadly.<sup>2</sup> Harm reduction must be seen as an evolving and emergent set of strategies that can be utilized and adapted by people who use drugs or engage in sex work; to prevent harms associated with these practices, public health officers and medical professionals must work in tandem with local communities to implement harm reduction interventions and promote harm reduction policies. We consider harm reduction to be a crucial part of the spectrum of interventions for responding to the current overdose death crisis facing the United States, with its unrelenting upward mortality trend-more than 110 000 overdose deaths in the previous 12-month period ending August 2023-largely due to the rise of illicitly manufactured fentanyl in the unregulated drug supply.<sup>3</sup>

### **Pioneers in Harm Reduction**

Harm reduction began as a movement by regular people who performed extraordinary lifesaving acts that were often illegal at the time and now can be fully understood as essential to public health and safety. In the United States, this multiracial movement was led by Black, Latinx, Muslim, and queer communities that started HIV/AIDS groups for structurally vulnerable people at risk for HIV and harms of substance use. Imani Woods, Dan Bigg, John Paul Hammond, Keith Cylar, Charles King, Kiyoshi Kuromiya, Michael Hinson, Dr Rashidah Abdul-Khabeer, Waheedah Shabazz-El, Jose Demarco,

Paul Yabor, Charlene Arcila, Jaci Adams, John Bell, and Tyrone Smith are an incomplete list of minoritized harm reduction pioneers in the United States. Dr Abdul-Khabheer, for example, is a Black registered nurse who founded a group called Bebashi (Blacks Educating Blacks About Sexual Health Issues) in 1985 and played an essential role in the Philadelphia HIV prevention scene for Black women.<sup>4</sup> Jose de Marco, a Black and Puerto Rican queer man, was foundational to the AIDS Coalition to Unleash Power Philadelphia, which was organized by the queer community and protested for decades for access to HIV medications and harm reduction efforts across the country.<sup>5</sup> Imani Woods, another leading voice of the harm reduction movement, offers a critical role model in harm reduction advocacy as a Black woman who operated within a history of structural marginalization in all her work. She writes about how she converted from being a staunch opponent of harm reduction-even calling harm reduction a genocidal operation-to grasping the power of providing practical tools to ensure health and protect the Black community against the harms of HIV and substance use.<sup>6</sup> Her transformation occurred in 1989, when she witnessed a man displaying sterile syringes on a table out in the open and how individuals came up to him and exchanged their used syringes and took educational materials.6

Harm reduction was also a global movement. Harm reductionists around the world have advocated for decriminalization of drug use, paraphernalia, and sex work; access to sterile supplies, naloxone, and drug consumption sites; and low-barrier access to methadone and buprenorphine. The earliest harm reduction efforts originated in the Netherlands in the 1980s, when the Junky Union distributed sterile syringes in solidarity with community health care workers to prevent HIV and hepatitis B transmission.<sup>7</sup> In the United States, early needle exchanges emerged in Tacoma, Washington, and in New Haven, Connecticut.<sup>8,9</sup>

Nurses and doctors were essential in providing solidarity and material support for people who used drugs during the 1990s to early 2000s. For example, in 2002, nurses at the Dr Peter Centre in Vancouver started supervising injections with the support of the Registered Nursing Association of British Columbia, which stated that it was part of their ethical obligations and duties as nurses to supervise drug consumption and ensure the safety of patients under their care.<sup>10</sup> In an act of civil disobedience, a nurse was arrested as one of the so-called "Needle Eight" who was tried in New York City in 1991 for handing out clean needles to protest the illegality of syringe service provision under Mayor Dinkins.<sup>11</sup> Doctors like Sarz Maxwell and Shawn DeLater participated in harm reduction services that distributed naloxone in Chicago in the late 1990s before the establishment of legal frameworks (E. Wheeler, personal communication, February 1, 2024). Unlike other professionals, health care clinicians risked their licenses and livelihoods to provide solidarity and care for people who used drugs.

### Formal Harm Reduction Frameworks

The Biden administration has declared that harm reduction is 1 of 4 pillars (prevention, harm reduction, evidence-based treatment, and recovery support services) in the US Health and Human Services federal overdose prevention strategy.<sup>12</sup> To guide these harm reduction efforts, the Substance Abuse and Mental Health Services Administration (SAMHSA) recently convened community harm reduction leaders to draft a harm reduction framework.<sup>13</sup> The framework builds on the expansion of syringe access programs, naloxone access legislation, and harm reduction technical assistance, as well as decades of advocacy by communities and advocates doing this work.<sup>14</sup> The framework outlines several core values, such as respecting autonomy and practicing

acceptance of people who use drugs. Critically, it acknowledges that people with lived and living experience of substance use have and should inform all initiatives. However, it does not capture the nuanced gendered and racialized experiences of diverse marginalized communities with particular local histories.

To learn from diverse community leaders, those seeking to apply the framework can turn to harm reduction organizations that specialize in prioritizing assistance to people experiencing homelessness (eg, VOCAL-NY's homeless union), street-based sex workers (eg, Project SAFE), women and non-binary people (eg, Metzineres), Black or other racialized peoples (eg, HIPS), or trans people (eg, Ark of Safety). These organizations have arisen out of the lived experiences of people who have been discriminated against and oppressed in mainstream spaces and are maximally effective, as they have the trust of—and experience working within—disenfranchised and stigmatized groups of people at risk of violence or harm from law enforcement. For example, groups like HIPS work with communities where minoritized groups are subject to everyday police harassment and violence and where even carrying naloxone as a Black person or a person doing sex work could put that person at risk of arrest or harassment.<sup>15</sup>

The harm reduction principles adopted by the SAMHSA framework have not arisen in an ahistorical vacuum, and they risk losing their original radical meaning and nature upon becoming mainstream and being adopted by public health more broadly. If interpreted within a narrow clinical scope, these principles can lose their community-oriented origins and focus myopically on individual behavioral interventions without recognizing political and economic structures of violence and harm. Thus, funding for minoritized groups and their community development and resilience must be specifically earmarked in harm reduction proposals.

### **Contested Histories**

As historian David Musto has argued, US drug policy swings between periods of relative liberalization and relative conservatism, as well as between a medical or public health approach and criminalization.<sup>16</sup> Currently, carceral approaches are favored, given the proliferation of fentanyl in the street drug supply, with politicians calling for increased criminalization of people who sell and use drugs,<sup>17</sup> medicalization of and involuntary conservatorships for people who use drugs or experience homelessness or mental health exacerbations,<sup>18</sup> and a more expansive border surveillance apparatus to stop drugs from entering the country.<sup>19</sup>

Current criminal-legal approaches to drug use lean heavily on "carrots and sticks," with drug court or diversion programs, for example, offering incentives (treatment) backed by threats of punishment (judicial accountability).<sup>20</sup> Unfortunately, these programs continue the legacy of putting punishment before treatment and care. In some recent instances, state judicial systems such as Pennsylvania's have been sued by the federal government for judges prohibiting those who are participating in drug court programs from using medication for opioid use disorder and violating the Americans with Disabilities Act.<sup>21</sup> These carceral responses are not rooted in harm reduction history.

Rather than relying on carrots and sticks, approaches to drug use should be informed by experiences of people who use drugs, with some recent texts advocating community-based solutions.<sup>2,6,22</sup> Imani Woods' legacy of community building among minoritized groups by funding and empowering them provides some steps forward. Woods focused primarily on the Black community, analyzing the struggle for harm reduction in the

context of Black employment, health, and general opportunities. Woods understood that harm reduction and public health programs led by White people would be viewed with suspicion by the Black community due to its members' history of slavery and experience of violence.<sup>6</sup> Faced with increased overdose rates among minoritized populations,<sup>23,24</sup> clinicians and communities alike must take these histories into account for interventions to be relevant or effective.<sup>25</sup> Woods framed the overdose crisis as requiring an understanding of self-determination of individuals and their communities. She argued for the need to reckon with racialized drug policy harms and leverage the resilience of Black people.<sup>6</sup> Supporting this kind of community leadership, informed by harm reduction history, is essential to present efforts.

### Look Back to Envision Forward

As harm reduction hits milestones in gaining political and funding footholds in the United States, it is imperative to trace its history in grassroots organizations built out of hardship and necessity within local communities of people helping others with grave needs. There was a power forged by giving or receiving a new syringe or condom to another person who looked like you. These structures and the leadership of people who use drugs must be cultivated and nourished with material support, space, and solidarity. Community-based harm reduction organizations with class-conscious and gender- and race-based approaches are often sidelined and forced underground. Although many organizations in the United States continue to distribute naloxone, sterile syringes, pipes, and testing supplies, in some states, such as Texas, syringe exchanges are still illegal.<sup>26</sup>

Harm reduction must be accompanied by decriminalization efforts, such as Oregon's<sup>27</sup> (partially reversed in 2024<sup>28</sup>). Globally, there have been efforts to reverse so-called Waron-Drugs responses, such as Uruguay's and Colombia's decriminalization of drug possession.<sup>29,30</sup> Yet, unfortunately, there is no panacea for the unacceptably high rates of overdose deaths in the United States, including harm reduction or other strategies such as decriminalization. However, harm reduction is and always will be an evolving care strategy developed by and for people who use drugs to keep each other alive and safe.

There are clear policy goals to advance harm reduction in communities facing racialized disparities in overdose deaths. Clinicians must work with local harm reduction groups at the clinic and statehouse level to provide them with expansive support, including in states like Texas. Clinicians must not be gatekeepers or moralizers but rather must partner with communities to create accessible, affordable, and low-barrier access to all services people need to obtain health and well-being. As community activists and clinicians, we must work in concert to ensure as much safety and compassion as possible for our patients and their communities, recognizing the complex history of harm reduction. Involving people with trusted histories in their communities, such as Imani Woods, to participate in all levels of decision-making and fairly compensating them is vital. Funding must be specifically allocated to community groups led by people of color, as well as to organizational development and fostering of young leaders. Finally, policy and research efforts should be intersectional by design and co-created by people with lived and living experience of substance use.

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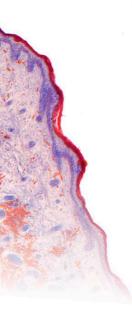
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# VIEWPOINT

# **Opioid Epidemic Grief and Characterological Harm Reduction** Christy A. Rentmeester, PhD

### Abstract

This article considers what it might mean to do the moral work of grieving during an opioid epidemic. Becoming callous, bitter, or resentful are harms we can suffer to our characters when grieving losses, especially at epidemic scale. This article suggests how appreciating beauty can play roles in grieving that could help mitigate these harms.

### **Shared Vulnerability**

Not much new can be said about the tragedy of ongoing opioid crises. Much, however, can and should be said about experiences of individual persons whose pain responds or responded to opioids. For some of us, opioids are key to short-term relief from pain and recovery from accidental or surgical injury. For those of us whose pain is hard to manage, opioids' capacity to assuage suffering can also render us susceptible to the physiological grip of chemical dependency and withdrawal, which, even if we manage to survive, will likely command how we orient ourselves to pain for the rest of our lives.

Many artists' uses of opioids have been widely documented in popular culture and provide one source of evidence for the universality of our vulnerability to pain . . . and its treatment. Frédéric Chopin was one composer and pianist who used opium to manage respiratory pain,<sup>1</sup> which he suffered throughout many of his 39 years of life, and which was wrought by what is widely thought to have been tuberculosis. Like Chopin, we are all subject to our bodies' unpredictable responses to accidents and pathogens, and any one of us might manage similar symptoms just as he did.

If relief from pain comes from opioids, as it did for Chopin, depending on how carefully those opioids or synthetic opioids are prescribed and managed, we can be at risk of experiencing, as our colleague in bioethics Travis Rieder<sup>2</sup> has, how temporary pain relief via opioids can be followed by withdrawal symptoms that also incur pain and loss, if not appropriately clinically managed. Socially, we've long known that one prominent source of opioid use disorder (OUD) is iatrogenic<sup>3,4</sup> and that a clever combination of overprescribing and marketing poised pharmaceutical industrialists to scale OUD epidemic profiteering to ruthless proportions.<sup>5</sup> Historically, we collect artifacts<sup>6</sup> that attest to opioids' or synthetic opioids' capacity for cultural disruption, and we've coined

monikers that refer to persons whose agency has been coopted by these substances' physiological effects (eg, opium eaters, junkies, people who use drugs). These monikers range in meaning from overtly stigmatizing to barely describing a problem, but the key ethics upshot from Reider, and perhaps from Chopin, is to draw our attention to the universality of our shared vulnerability to opioid dependency: people who use drugs who develop OUD could be any of us, under the right alignment of stars and constellation of circumstances.

### When the Dead Have Been Tragically Slain

Suffering pain is its own moral work; orienting ourselves to threats of pain, navigating life with pain, or coming to terms with knowledge that we will need to learn to live with pain all require us to draw on our emotional and characterological stamina. We must bear and grieve losses of our abilities and of time invested in securing futures that might not come to pass. Many of us, like Chopin, must try to practice our life's work despite limitations our illnesses impose.

When we suffer pain *wrought by treatment of illn*esses, however, and when morbidity (eg, OUD) and mortality (eg, death by overdose) persist as epidemic in volume and scale, part of the moral work of grieving among survivors requires orientation to survivorship itself, as those of us who survive do so relative to those *tragically slain*. These italicized words help bring the moral work required of opioid epidemic grieving into focus: *tragedy* connotes preventability—we are not grieving accidental losses only—and *slain* connotes killing in great numbers—we are not grieving only single deaths of those personally close to us. For even those killed accidentally or unintentionally, carelessness exacerbated and exacerbates the epidemic of morbidity and mortality caused by opioid dependence, and carelessness is salt in the wounds of tragedy. For these reasons, I suggest that grieving the epidemic dead requires morally relevantly different work by survivors than our grieving a single death of someone whom we know personally. *What might it mean morally to do the work of bereaved survivorship well during an opioid epidemic*?

### Beauty and Characterological Harm Reduction

One thing being good at being a bereaved survivor might mean is seeking and appreciating art of enduring beauty. Chopin, for example, created many beautiful works, mostly for piano, and one of them is the *Nocturne in B major Op. 62 No. 1*. In this work, a trill carries the melody in one particularly engaging passage, which is one reason a work composed between 1845 and 1846 is still beautiful today. When we gather synchronously or asynchronously to listen, live or via recording, to an experienced and skillful player interpret what Chopin wrote, we celebrate our capacity to draw on art and artists, living or dead, to guide members of contemporary humanity through grief with beauty in our midst.

Few among us will create something now that is still beautiful 2 centuries hence, so it's lucky that humanity needs art appreciation as much as it needs art creation. Art and artists guide our habits of discerning what beauty is and where beauty might be. Not every work is beautiful or equally beautiful to everyone, but consensus is not required; what is required to seek and appreciate beauty is close looking or listening. Artworks and artists are beauty innovators in that each forges new ways by which beauty can possibly be revealed, perceived, understood, engaged, and inspire awe. Artists create works that give us opportunities to practice our skills of perception. To listen and to look closely are to maintain and grow habits of perception<sup>7</sup> that are generous rather than meager, capacious rather than narrow.

Listening or looking with these moral purposes can be one part of grieving that engages our capacities to experience beauty. Like nourishing our capacities for perception, bereavement can be a moral accomplishment that expresses how we draw, individually and collectively, upon our characterological and aesthetic resources to respond, even to losses that are epidemic in volume and scale. Maintaining discernment open to beauty is one approach to survivorship that might help us avoid becoming callous, bitter, or resentful, which are a few of the most familiar harms<sup>8</sup> losses can incur to our characters. Chopin's lived experience and creative work invite us to share beauty in common, just as Reider calls us to regard our vulnerabilities to opioid dependence as shared. Both guide us in doing moral work of grieving that is not only personal, but communal.

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