

HARM REDUCTION AND ITS ROLE IN IMPROVING HEALTH OUTCOMES IN AN ERA OF FENTANYL

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Executive summary

Reducing harm is a core element of public health and is intertwined with another fundamental tenet of public health—health promotion. Amid record overdose death rates in the United States, reducing the harms associated with drug use is a critically important part of the care continuum for people who use drugs. Harm reduction is both a set of strategies to reduce harms associated with drug use, as well as a philosophical approach centered on the notion of meeting people "where they are" and treating people who use drugs with respect.

The contemporary history of harm reduction was, in part, a response to rising rates of HIV transmission in the 1980s, with the opening of syringe services programs (SSPs) across Europe, and eventually, the United States. Importantly, SSPs are not simply programs to distribute and exchange syringes, they also serve as a client-centered pathway providing services and support to people without stigma or shame.

Harm reduction services offer a critical intervention point for individuals who may have no other access to receive support or services in a non-judgmental, non-stigmatizing environment. The human—and humane—connections fostered through these programs are often less visible than the services themselves, but they are equally important.

Harm reduction, as a philosophical approach where people who use drugs are treated without shame or stigma, can be integrated into treatment and other needed services. Specific harm reduction services may include drug testing kits, syringes to reduce the risk of infectious disease, overdose prevention facilities, and overdose reversal medications for those who may witness an overdose. These programs also provide referrals or direct services that address medical needs and social determinants of health, such as housing, nutrition, legal services, and employment. The services provided at harm reduction facilities adapt to the needs of local communities and continuously evolve.

However, even during an epidemic of overdose deaths, stigma, regulatory barriers, and funding challenges limit access to harm reduction services. Obstacles include funding and operating restrictions, community opposition, and legal prohibitions. Harm reduction services are embedded into the continuum of care, helping to mitigate the negative consequences associated with drug use and improving long-term health outcomes. To deliver these services effectively, policymakers must address racial, ethnic, and other disparities in communities at the greatest risk. Delivering harm reduction at scale requires bridging the gap between service availability and service needs. Leadership must be agile, focusing on providing sustainable, evidencebased, and equitable services amid rapidly changing policy, legal, and drug supply environments.

While investment in rapid research is essential to fill knowledge gaps and develop comprehensive services, grassroots harm reduction programs must also be supported. The debate around harm reduction services is often framed as a choice between public health and community safety. However, harm reduction is essential, particularly when over 40% of fatal overdoses go unreversed even with a bystander present. Perhaps the first step to an idealized vision of harm reduction comprehensive, evidence-based, client-centered, and trauma-informed—is agreeing that there is harm associated with substance use and that each person and community must come together to forge their own unique path forward in reducing those harms.

To achieve these goals, we recommend the following actions:

1. Develop a national strategic plan for harm reduction services: This plan should clearly define and quantify the necessary scale of various harm reduction services. A comprehensive strategy should measure the unmet need for these services based on a strong evidence base, allowing the full scope of need to be estimated and resourced appropriately. Additionally, this plan should include strategies to address those needs and make a strong economic case for harm reduction services.1

- 2. Prioritize translational research: Focus on studies that examine which harm reduction services work under specific circumstances or in different contexts, including when, where, how, and in what combination, to maximize their beneficial impact.2
- 3. Remove legal and societal barriers: Eliminate the obstacles that prevent evidence-based harm reduction programs from being fully implemented at the local, state, and national levels. This includes addressing stigma and legislation that hinder harm reduction efforts.3
- 4. Establish sustainable funding structures: Integrate harm reduction principles into the health care system and support providers at the necessary level.4
- 5. Understand and address social disparities to promote health equity: Gain a better understanding of the social disparities in accessing harm reduction services at the community level. Develop comprehensive, substance use-related programs that prioritize health equity, ensuring that harm reduction services better promote health equity.5

Preamble

We approach the writing of this paper with humility and deep appreciation for those at the forefront of delivering harm reduction services. Individuals working in harm reduction provide care to people who are among the most marginalized and stigmatized individuals in society and are often individuals with lived or living experiences with substance use and/or mental health conditions. Frontline harm reduction workers typically do this work for little or no pay, not only due to the lack of funding but also out of a commitment to treating people who use drugs with respect and dignity.

It is important to acknowledge the considerable risks people in the harm reduction field face, as they may encounter legal consequences while addressing a public health issue that received woefully inadequate attention from most major institutions. For example, as of 2024, over 100 syringe services programs operate across Michigan. However, despite state funding and technical assistance, sterile injection equipment remains classified as drug paraphernalia in some Michigan jurisdictions, putting both staff and clients at risk of arrest.7

In drafting this paper, and throughout our decades of engagement with harm reduction efforts, we have consistently spoken with and listened to those with direct experience in harm reduction. We have sought to honor the principles of harm reduction by incorporating their voices and critical insights into this paper.

Introduction

When most people think of harm reduction, they think exclusively of people who use drugs, overlooking its broader role in public health.8 For example, seat belts, airbags, bicycle helmets, and car seats are all harm reduction tools. These tools recognize that an essential part of public health is reducing the harms linked to everyday life. While seat belts are now standard in vehicles, early efforts to mandate their use faced opposition.9 Harm reduction extends beyond drug use, but it has gained renewed attention in recent years in the context of rising overdose deaths in the United States.

For the 12-month period ending in March 2024, an estimated 103,000 people died from drug overdoses, with nearly 71,000 of those deaths involving "synthetic opioids other than methadone," primarily illicitly manufactured fentanyl. 10 (Throughout this paper, "fentanyl" refers to illicitly manufactured fentanyl, not the prescribed form.) This represents a major public health crisis. To move forward collectively, we need to understand what harm reduction is and position it as

one part of a broader, more comprehensive effort to minimize harms associated with substance use and substance use disorder (SUD).

Harm reduction services, such as syringe services programs (SSPs), began in Europe in the 1980s as a community response to rising rates of HIV.11 Subsequently, these programs were adopted in the United States. However, it has only been in the last decade that harm reduction has gained wider acceptance as part of a public health approach to drug use in the United States. In fact, the National Drug Control Strategy—the country's blueprint for addressing drug use and its consequences—did not include the term "harm reduction" until 2022.12

Three decades of research have shown that SSPs do not increase illegal drug use. In fact, participants in these programs are three times more likely to stop using drugs and five times more likely to engage in SUD treatment compared to those who do not use SSPs. 13 Additionally, SSPs do not lead to increased crime; research indicates they have no impact on crime or can even reduce it.14 Concerns about littered syringes are also unfounded—a 2015 study found that the more sterile syringes distributed by SSPs, the more likely used syringes were to be safely disposed of, protecting both the public and first responders.15

This paper examines harm reduction as a critical component of the public health response to overdose morbidity and mortality. It reviews the research supporting harm reduction, including policies that have facilitated the expansion of these services in the United States, as well as those that further inhibit growth. 16 While harm reduction is both a philosophical approach and a set of tactics and services, this paper will examine harm reduction services and the policies underlying these services.

Harm reduction defined

In her 2021 book "Undoing Drugs," Maia Szalavitz describes one of the earliest meetings of harm reduction activists, which emerged from the ACT UP movement during the AIDS crisis of the 1980s.17 At that meeting, activists agreed on the following definition of harm reduction:

Harm Reduction is a set of strategies and tactics which encourages users to reduce harm done to themselves and their communities by licit and illicit drug use. By allowing users access to the tools to become healthier, we recognize the competency of their efforts to protect themselves, their loved ones and their communities."

More recently, the Substance Abuse and Mental Health Services Administration (SAMHSA) defined harm reduction as:

[A] practical and transformative approach that incorporates community-driven public health strategies—including prevention, risk reduction, and health promotion—to empower PWUD [people who use drugs] and their families with the choice to live healthy, self-directed, and purpose-filled lives. Harm reduction centers the lived and living experience of PWUD, especially those in underserved communities, in these strategies and the practices that flow from them."18

While these two definitions differ, they share a common element: the involvement of people who use drugs in shaping policies and strategies that directly affect them. By reducing the harms associated with drug use, including overdose, harm reduction can provide individuals with the tools to pursue healthier outcomes, including recovery.19

A partial history of harm reduction efforts

While the term "harm reduction" has gained prominence in recent decades, the philosophy of reducing the negative consequences of behavior where eliminating all harm is not possible has a long history. Early efforts include workplace injury prevention, transportation safety initiatives, and disease prevention through vaccination.

A review of that lengthy history might be speculative as to what exactly in the history of public health should and should not be considered "harm reduction"; therefore, we focus instead on the more modern advent of the term which is to be found in the 1980s and early 1990s in efforts to prevent HIV transmission, highlighting key points from SAMHSA's brief history of harm reduction and Don C. Des Jarlais's 2017 critical history.20

In the early 1980s, shortly after the discovery that HIV was the virus that causes AIDS, persons who use drugs (PWUD) and their allies began organizing informal and formal services to distribute sterile injection equipment to limit HIV transmission. However, in 1988, the federal government restricted the use of federal funds to purchase syringes.²¹ Such federal funding barriers made it difficult to implement the European harm reduction model of demonstration projects followed by empirical evaluation and programmatic refinement.²² Despite these barriers, private philanthropic organizations, such as the Comer Family Foundation, funded SSPs and evaluative research in the United States. The favorable empirical and analytic results built a substantial foundation of early evidence of the services' beneficial public health and economic impact.23

Advocates for these important services gathered for a major working group meeting in 1992 that spawned the National Harm Reduction Coalition (NHRC).²⁴ Throughout the 1990s, SSPs rapidly evolved to include more than one-for-one syringe exchange programs to include community-based syringe disposal points and, critically, expanded social services, creating intervention points for referrals to SUD treatment and other necessary medical and social services.²⁵ As these programs grew, they were increasingly seen by communities as a real and viable alternative to more rudimentary, earlier harm reduction approaches, such as the Centers for Disease Control and Prevention's (CDC) recommendations to rinse one's syringe with bleach and then water if sharing injection equipment.26

While much of the evolution of HIV-related harm reduction services for people who inject drugs focused on preventing infectious disease transmission, increasing attention was also given to preventing the negative consequences of substance use. For example, SSPs have become welcoming, supportive pathways to drug treatment and other services. Modeled after efforts from the NHRC, the Comer Foundation, and other forerunners in this space, SAMHSA held its firstever federal Harm Reduction Summit in 2021.27 Experts in SUD care, community members, people with lived experiences, advocates, providers, and funders came together to shape SAMHSA's practical approach and policies on harm reduction as a pillar of the U.S. Department of Health and Human Services' (DHHS) Overdose Prevention Strategy.²⁸ From this summit was born SAMHSA's recent Harm Reduction Framework, which highlights the evolution of Opioid Overdose Reversal Medication distribution in such syringe-related programs as another advance in the harm reduction space. SAMHSA notes that:

From 1996 through June 2014, 136 organizations reported distributing naloxone to 152,283 laypersons. Of the 109 organizations who collect reversal data, 26,463 overdose reversals were reported. Although the number of organizations distributing naloxone has doubled and since 2013 has included organizations other than SSPs, in 2014, SSPs still accounted for 80 percent of the distribution effort to PWUD, as well as 80 percent of overdose reversals.

In 2019, SSPs distributed 702,232 doses of naloxone to 230,506 people in communities across the country. Studies have shown that communities may experience up to a 46 percent reduction in opioid overdose mortality when more than 100 people who are likely to observe or experience an overdose per 100,000 population are enrolled into an Overdose Education and Naloxone Distribution (OEND) program. In addition, SSPs are associated with an estimated 50 percent reduction in HIV and hepatitis C incidence. When combined with medications that treat opioid use disorder (also known as medications for opioid use disorder or MOUD), hepatitis C virus and HIV transmission is reduced by more than two-thirds. The last few decades have solidified the evidence-based practices and individuals have become specialized subject matter experts in the field of harm reduction."29

One historical moment illustrating the constant tension between the strong evidence supporting SSPs and political opposition occurred in 1998.30 Secretary of Health and Human Services Donna Shalala determined that SSPs are effective and do not encourage the use of illegal drugs, but the Clinton administration decided not to support funding these services with federal dollars as a result of an internal political debate.³¹ The purpose of providing this example is not partisan; rather, it is prototypic of an ongoing debate and opposition that characterizes so many efforts to provide harm reduction services to persons who need them at the scale communities require.

The current imperative for harm reduction

The prevalence of overdose morbidity and mortality in the United States has reached such high levels that overdose deaths have contributed to a decline in life expectancy and driven communities apart.32 According to the CDC, provisional data predicting the number of overdose deaths year over year, ending in March 2024, will be approximately 103,000.33 A recently released survey from RAND reported that more than 40% of individuals in the United States knew someone who had died of an overdose.34

While overdose deaths affect every state and nearly every community in the United States, some have been hit harder than others. Societal disruptions driven by COVID-19, historic disparities in access to housing and health care, and increases in illicitly manufactured fentanyl, all combined to increase overdose death rates across the board between 2019 and 2020. However, Black and Indigenous communities experienced a disproportionate share of overdose deaths in that same time period.35 From 2019 to 2020, overdoses in Black populations increased by 44%, and by 39% in American Indian and Alaska Native populations. These increases were driven by systemic racial inequities and long-standing health care access disparities, further exacerbated by the pandemic.36

Providing services across the continuum, including harm reduction services, requires policymakers to address racial inequities in the communities most at risk. This was a point made by Ricky Bluthenthal, professor of preventive medicine and associate dean of social justice at the University of Southern California, at a harm reduction workshop held in January 2024 by the National Academies of Sciences, Engineering, and Medicine (NASEM) and sponsored by the Office of National Drug Control Policy (ONDCP).

There, Bluthenthal noted, "As long as the needs and harms do not drive implementation, racial inequities will persist."37

Given that the United States has been in the "Third Wave" of the overdose epidemic for nearly a decade—marked by an increasingly toxic drug supply containing fentanyl, services that reduce the harms associated with substance use and SUD have taken on new urgency.38 The introduction of fentanyl into the drug supply in the mid-2010s drove unprecedented numbers of overdose deaths. 39 While overdose deaths involving heroin fell by 32% between 2020 and 2021, deaths involving fentanyl soared. 40 Some experts now refer to a "Fourth Wave" of the overdose epidemic, a wave characterized by polysubstance use of opioids concomitant with stimulants, such as cocaine and methamphetamine.41

Harm reduction within the continuum of care

Expanding services across the full continuum of addiction care is essential. This continuum includes prevention, treatment, harm reduction, and recovery services. Harm reduction services provide low-barrier intervention points that can improve health outcomes and often connect individuals to treatment. However, requiring treatment as a condition for accessing harm reduction services runs contrary to the person-centered core principles of harm reduction and general health care principles; therefore, non-compulsory options should be expanded. Historically, treatment and harm reduction have been viewed as separate systems. However, treatment programs have begun to incorporate harm reduction into their approaches. 42 Moreover, harm reduction programs are offering low-barrier treatment options.43 Reforming and reducing barriers to the

receipt of services across the entire continuum of care, including harm reduction services, is paramount, especially given the widespread presence of fentanyl and other synthetic drugs in the street supply.44

At a time when synthetic opioids like fentanyl are the primary drivers of overdose deaths, and people who inject drugs (PWID) remain at high risk of infectious diseases such as HIV and hepatitis C (HCV), it is critical to leverage all strategies across the continuum of care. This includes providing low-barrier access to treatment while offering resources for safer outcomes. Medications for opioid use disorder (MOUD), in addition to promoting long-term recovery and reducing the risk of overdose, are associated with increased adherence to antiretroviral therapy and a reduced risk of HIV and HCV transmission.45 Integrating harm reduction into traditional treatment modalities like MOUD can therefore enhance outcomes for PWID.

Harm reduction interventions can include a wide array of services aimed at reducing the harms associated with drug use. A 2023 survey of U.S. harm reduction facilities revealed that the majority (69.3%) of respondents offer navigation services for health, housing, and other social needs.46 While some interventions—such as housing, nutrition, employment, and child care—may not involve substance use, all of these services remain essential across the continuum of care. 47 Harm reduction settings often provide referrals for these services. Given the number of overdose deaths in the United States driven by fentanyl, requiring individuals to meet certain standards before being provided services is particularly cruel at a time when "rock bottom" too often means death.

Harm reduction services also take on added importance when considering the role that adverse childhood experiences and complex trauma can play in substance use disorder.48 Trauma may include physical, emotional, or

sexual abuse; the loss of a parent; or living with a parent who has SUD or a mental health condition.49 Reducing the risk of trauma by providing services to people who use drugs, therefore, can improve conditions not only for the individual but also for their family and loved ones.

Harm reduction strategies

This section offers an overview of some key harm reduction strategies and services in the United States in an era of fentanyl. It outlines common characteristics and a working categorization of such efforts, before moving to examples of how harm is reduced or negative consequences mitigated in terms of drug sourcing, drug consumption, and drug environments.

COMMON CHARACTERISTICS OF HARM REDUCTION SERVICES

While harm reduction services vary widely in their specific offerings (as detailed below), they generally adhere to the following eight foundational principles articulated by the NHRC:

- 1. Rather than ignore or condemn substance use, the reality of it is recognized and efforts are taken to minimize its negative consequences.
- 2. Recognition that substance use ranges across a broad and complex spectrum, and that some ways of using substances may well be safer than others.
- 3. Rather than holding up absolute abstinence as the criteria for programmatic success, harm reduction services focus on individualand community-level well-being as the goal.
- 4. Harm reduction services are designed to avoid coercion and judgment of and about persons who use drugs.

- 5. Incorporates the voices of people with lived and living experience in designing harm reduction programs.
- 6. Centers persons who use drugs as the primary agents of harm reduction for themselves and other community members who also use drugs.
- 7. Includes services based on the understanding that social determinants of health and social injustices impact substance use and one's opportunity to address drug use.
- 8. While focused on the reduction of harm, such services do not try to downplay or ignore the real and serious negative consequences that may accompany drug use.50

TOWARD A GENERAL CATEGORIZATION OF HARM REDUCTION SERVICES

Harm reduction services addressing substance use have a long history, partly rooted in decades of experience with HIV-related public health challenges. As a result, there are lengthy, complex, and sometimes competing typologies to describe these services.⁵¹ Here, we categorize harm reduction services into three main groups: (a) services to minimize harm in drug sourcing; (b) programs to provide access to safer drug consumption equipment; and (c) strategies to ensure drug use occurs in environments ready to provide emergency services if negative consequences do arise.

Some harm reduction programs integrate all three of these categories, offering interconnected services across this spectrum. Additionally, many harm reduction programs provide pathways to drug treatment for persons interested in and ready to receive treatment services, and some also provide pathways to other health-related services that go well beyond drug treatment (e.g., including the basic provision of—or referral to more complex—chronic and infectious disease care).52

HARM REDUCTION IN DRUG SOURCING

Harm reduction services aimed at reducing the negative consequences arising from sourcing drugs that are not what they appear to be (either through adulteration or other type of deception) take several forms.

Safer supply programs

First, some "safer supply" services have been designed to actually become the source of drugs that are known to be "as advertised" and without adulterants.53 Health Canada describes the purpose of safer supply programs as follows:

Safer supply refers to providing prescribed medications as a safer alternative to the toxic illegal drug supply to people who are at high risk of overdose. Safer supply services build on existing approaches that provide medications to treat substance use disorder. However, they are often more flexible and do not necessarily focus on stopping drug use. Instead, they focus on meeting the existing needs of people who use drugs, reducing the risk of overdose by helping people to be less reliant on the toxic illegal drug supply, and providing connections to health and social services where possible and appropriate."54

Safer supply programs also address comorbidities associated with substance use, such as endocarditis, a heart condition that has increased due to increasingly contaminated drug supplies.55 One cohort study in British Columbia, examining province-level data from early 2016 to early 2022, found that "two years after its launch, the Safer Opioid Supply policy in British Columbia was associated with higher rates of safer supply opioid prescribing but also with a significant increase in opioid-related poisoning hospitalizations."56 (We refer readers to this study for a detailed discussion of why increased hospitalizations may have occurred, and for a description of study limitations.)

Public awareness campaigns

Communication campaigns have been developed to alert individuals, often young people, that even if they think they are purchasing drugs from a perceived reliable source online, that seller may not be who they pretend to be, and the drugs may be counterfeit.57 For instance, an adolescent may unknowingly buy fentanyl from an online vendor, believing they are purchasing some other substance, such as a stimulant or antidepressant.58 In response to these risks, federal and several state governments have implemented awareness campaigns to educate the public on the dangers of illicit drug sourcing. Recent examples include campaigns in Rhode Island and New York.59

Drug checking tests

Drug checking tests can be used to help determine whether a substance has been contaminated with another undesired, potentially dangerous drug. Common examples include fentanyl test strips and, more recently, xylazine test strips.60 Advanced technology, such as mass spectrometry, can detect a wide range of substances in a sample. However, the high cost and specialized training required to operate this equipment generally limit its use to academic institutions and public health departments. For instance, in 2022, Rhode Island initiated the Toxicological and Ethnographic Drug Surveillance Testing RI program, a two-year study that analyzes the local drug supply for adulterants and contaminants, sharing the results with the community.61 This allowed people who use drugs to make more informed decisions about their substance use and adopt appropriate harm reduction strategies.

Individuals may use fentanyl test strips to check if fentanyl is present in drugs they have acquired, such as pressed pills, cocaine, or heroin, before consumption. Similarly, as the newly emergent threat of xylazine, a non-opioid sedative, has arisen as an adulterant of fentanyl and some other drugs, some people may seek

to detect xylazine's presence before drug use. 62 These test strips do not require Food and Drug Administration (FDA) approval when used solely for drug checking purposes. The sensitivity and specificity of such tests are generally high, and their predictive value is most useful when the prevalence of the drug to be detected is neither extremely low nor high (that is, for example, in geographic areas in which the prevalence of xylazine use in humans is neither near non-existent nor close to omnipresent).63

Until the last few years, in most states, drug checking equipment was classified as drug paraphernalia, making the possession or distribution of such tests illegal.⁶⁴ However, many states revised their drug paraphernalia laws and as of December 2023, in 45 states, the District of Columbia, and four U.S. territories, possession or distribution of drug checking equipment (mainly fentanyl test strips) were not subject to criminal penalties.65 Federal government grants allow grantees to use resources from certain federal funding streams to purchase fentanyl and xylazine test strips for drug checking purposes where allowed by state and local law.66

DRUG CONSUMPTION EQUIPMENT

Some type of drug consumption equipment is often required for drug usage. Typically, this would take the form of sterile injection equipment or safer smoking supplies as harm reduction tools.

Syringe services programs

As noted earlier, syringe services programs have a long history, notably being used more than 30 years ago to help persons who inject drugs from acquiring HIV. SSPs not only provide access to sterile needles and syringes but also offer non-judgmental disposal options for used injection equipment.⁶⁷ Further, SSPs provide assisted referral pathways when clients are ready to receive such services, and increasingly have become a provider of basic medical care, such as blood pressure checks, as well as supported

referrals for more complex chronic and infectious disease care.68 SSPs are often staffed, at least in part, by persons with lived experience with substance use and are therefore well attuned to listening for and hearing participants' unmet service delivery needs. According to the CDC, "Nearly thirty years of research shows that comprehensive SSPs are safe, effective, and cost-saving, do not increase illegal drug use or crime, and play an important role in reducing the transmission of viral hepatitis, HIV and other infections."69 Language in the U.S. Department of Health and Human Services Appropriations bill, however, states that federal funds may be used to support SSPs but may not be used to purchase the needles or syringes for such programs.70

One estimate from the Legislative Analysis and Public Policy Association (LAPPA) found that, as of July 2023, there are at least 534 SSPs operating in 45 states, the District of Columbia, and Puerto Rico.⁷¹ According to the same report, 38 states (and Washington, D.C. and Puerto Rico) either by statute or other authority, allow or do not otherwise prohibit SSPs. LAPPA has developed a model state law to provide guidance for states looking to initiate or refine SSPs.72

Safer smoking kits

Safer smoking kits can be used to help minimize the negative consequences of consuming drugs via smoking behavior; further, in some cases, smoking rather than injecting drugs can be considered a form of harm reduction.73 The contents of safer smoking kits vary but may include items such as lip balm, rubber mouthpieces, bandages, and safer smoking literature. Glass stems or pipes might also be included, but federal funds could not be used for their purchase, though federal funds might be used for other elements in the kits.74 A narrative synthesis of the literature on safer smoking practices identified a study that examined the health outcomes of safer smoking materials for crack cocaine users.75 The study found that health issues related to crack smoking (such as sores, coughing blood, and burns) declined with safer smoking kit use.

ENVIRONMENTAL STRATEGIES FOR MINIMIZING NEGATIVE **CONSEQUENCES OF DRUG USE**

At the community or societal level, harm reduction strategies often involve creating or developing systems and environments to maximize the chances that if harm does accrue to a person using drugs, that the harm can be quickly identified and mitigated. For example, naloxone, a highly effective opioid overdose reversal medication, can have a life-saving impact if an opioid overdose occurs. 76 A major challenge of overdose reversal medications like naloxone, however, is ensuring they are widely available, properly distributed, and that individuals are trained in their use when needed.

These "environmental strategies" can encompass efforts to address social, physical, economic, legal, and policy environments. Here, this paper focuses on a few examples to illustrate harm reduction environments but does not cover all types of possible interventions that could be rightly labeled as harm reduction services, such as housing first programs for persons who use drugs.77

Overdose prevention centers

One environmental system strategy is the development of Overdose Prevention Centers (OPCs).78 At these sites, persons come in to use drugs in the presence of trained staff who are highly skilled at identifying and responding to overdoses. Staff may also make referrals to other health or social services for which the clients may have interest and need. The first Overdose Prevention Center opened in Switzerland in 1986.79 The National Institute on Drug Abuse (NIDA), part of the National Institutes of Health, an agency of the U.S. DHHS, states:

Overdose prevention centers have operated for years in countries outside the United States. Evidence from more than 20 years of overdose prevention center operations in other countries indicate that no one has

died of a drug overdose while at an overdose prevention center. However, it is unclear whether such facilities reduce overdose death rates overall. Additional research finds that these facilities are associated with reduced public drug use and lower demand on local healthcare and emergency response services without an increase of crime. Studies also suggest that overdose prevention centers are associated with increased access to substance use disorder treatment."80

New York City was the first U.S. jurisdiction in which OPCs operated.81 Under the guidance of existing SSPs, two OPCs have been operating in the city with private funding.82 These two sites have been reported to have intervened in hundreds of overdose occurrences without a fatality, and they have operated without a concomitant rise in crime in surrounding areas.83 OPCs have not been widely adopted in the United States, largely due to legal uncertainties surrounding their operation.84

In 2021, the Rhode Island state legislature approved the establishment of pilot OPCs, with the first expected to open in 2024.85 Other states, such as Minnesota, and local jurisdictions have approved funding for these sites or conducted feasibility studies, but OPCs are not yet widespread.86 According to NIDA, while the federal government is not currently funding the operation of OPCs, some research evaluating their effectiveness is underway and supported by the agency.87

While Overdose Prevention Centers provide important comprehensive harm reduction services in a controlled environment, certain elements of those services may be delivered on a more community- or system-wide basis. For example, Never Use Alone is a nonprofit organization that runs a crisis hotline for individuals who might otherwise be using drugs alone.88 Massachusetts is also funding SafeSpot, an overdose prevention hotline.89 These services offer telephonic support, which serves as a remote alternative to the in-person supervision provided

at OPCs. Further, this overarching theme of not using drugs alone is commonly found in public health messages designed to support persons engaged in substance use.

Overdose reversal programs

Overdose Reversal Medication distribution and training programs can be the core of community-wide harm reduction efforts, even if they are administered by community members or bystanders rather than Overdose Prevention Center staff.90 Such efforts are seeing rapid acceptance in society as the public and private sectors are increasingly supporting the availability of overdose reversal medications in workplaces, labor organizations, schools, faith communities, housing facilities, and governmental entities (among others).91

The Biden-Harris administration has requested that all federal facilities have overdose reversal medications available in their on-site safety stations.92 It has also urged schools to make these medications available onsite.93 The introduction of over-the-counter naloxone offers the potential for wider access, but some policy and procedural barriers remain, including cost, which could impede its scale-up.94

Community-level overdose reversal programs are critical and should complement the existing role of emergency medical services (EMS) in administering these medications. In 2023, EMS recorded just under 390,000 naloxone administrations, according to a dashboard managed by ONDCP and the National Highway Traffic Safety Administration.95 First responders play a vital role in overdose reversal medication administration but may be approaching a "saturation level" for use.

Going forward, the expansion of community-wide programs may be the key growth area for overdose reversal medication distribution and training.96 The challenge lies in ensuring these programs are widespread enough to cover all who may need an administration, but focused

and timely enough so that they are meaningfully available for persons and communities who need them most. Predicting when and where overdose reversal medications will be needed most is a critical issue, and securing long-term funding is essential as these programs become a standard part of harm reduction and intervention responses.97

Referral services

Intensive, supportive referral services for drug treatment and other health care are key components of OPCs but can also be delivered by other harm reduction and medical providers, including emergency department teams.98 For instance, if a person experiences an overdose which is reversed by a bystander, and an EMS team transports the person who just had the overdose to an emergency department (ED), the ED team might have a component of intensive "wrap around" services to assist the patient in getting drug treatment immediately, if the person desires it.99 This approach is somewhat analogous to the "red carpet" programs developed for individuals newly diagnosed with HIV, so that they could get successfully referred to and engaged in treatment for HIV on the same day as testing.

Several jurisdictions have implemented model wraparound referral programs to connect individuals who have experienced a nonfatal overdose with immediate drug treatment access. Additionally, some law enforcement agencies have adopted a supportive, nonpunitive approach, offering direct and immediate referral to drug treatment for persons in need of these services, rather than arresting them. 100

Support in carceral settings

While harm reduction services may be offered in various environments, carceral settings warrant particular attention. A significant portion of arrests in the United States are related to substance use, and many individuals entering jails and prisons live with SUD.¹⁰¹ However, only a small fraction of these individuals in carceral

settings receive the drug treatment and related services they need. 102 A 2023 survey of U.S. jails found that 71% reported providing any form of SUD treatment, most commonly through self-help or Alcoholics Anonymous-style meetings. Only 43% of jails surveyed reported providing one of the three FDA-approved forms of MOUD, and even then, this treatment is typically limited to those who were already receiving MOUD prior to incarceration.103

Evidence-based treatment in carceral settings is especially important because of the negative sequelae of untreated substance use in jails and prisons, and because rates of fatal drug overdoses are heightened for persons immediately upon release. 104 While policy efforts are underway to expand access to drug treatment in jails and prisons, the existing unmet needs require additional, urgent attention. 105

Harm reduction expansion in the **United States: Barriers and** opportunities

This section charts the expansion of harm reduction in the United States, identifying key barriers and opportunities in the domains of community, legislation, and policymaking.

COMMUNITY BARRIERS

While SAMHSA now includes harm reduction in the continuum of care, for too long, harm reduction was seen as contradictory to prevention, treatment, and recovery. 106 Harm reduction efforts were seen as enabling drug use, which led to fears that it would cause individuals to spiral further into addiction. However, harm reduction is both a set of strategies and an approach

designed to "meet people where they are." Research on harm reduction tactics supports the efficacy of these programs to prevent negative outcomes for people who use drugs, particularly people who inject drugs and who may be at risk for developing blood-borne disease.107

Publicly funded and sanctioned harm reduction services, which may be perceived by some as condoning the use of illegal drugs, have been met with opposition in communities, as well as in the U.S. Congress. 108 This opposition has dire consequences, as the closure of SSPs has been associated with increased rates of infectious disease transmission and overdoses. 109 Stigma and the discrimination that results from it continue to hinder the acceptance of harm reduction programs at the community level. Local opposition to the siting of harm reduction programs, as well as federal and state legislative bans on these services (see next section), frequently block access to vital support and care. 110

To overcome such objections, harm reduction programs may establish mobile services, thus enabling harm reduction services to respond to "hot spots" and provide interventions where they are most needed. 111 Mobile services are an example of harm reduction programs that have developed organically, as communities identify issues and the need for a local response.

Peer distribution of harm reduction equipment, as well as secondary distribution are also ways that harm reduction services reach people in need. For example, the Missouri Network for Opiate Reform and Recovery (MO Network) offers peer recovery support services, including syringe services (in collaboration with the Missouri Safe Project), naloxone distribution, wound care, infectious disease testing, and overdose education, through both a drop-in recovery center and a mobile outreach unit.112 During the COVID-19 pandemic, peer support services became a crucial lifeline for people who use drugs, as many traditional access points to harm reduction services were closed amid lockdown restrictions and concerns about the virus spreading.113

LEGAL BARRIERS

As previously discussed, OPCs are seen as a way to prevent overdose and provide services for individuals who may be experiencing homelessness or need other services. The nonprofit organization Safehouse announced its intent to open an overdose prevention center in Philadelphia, Pennsylvania, in 2019.114 Soon after, the U.S. attorney for the Eastern District of Pennsylvania filed a declaratory judgment asking the federal district court to rule on whether the OPC violated federal law. 115 The section of the U.S. Code in question is commonly referred to as "The Crack House Statute."116 Signed into law in 1986, the statute states that it is unlawful to "knowingly open, lease, rent, use, or maintain any place, whether permanently or temporarily, for the purpose of manufacturing, distributing, or using any controlled substance."117

The U.S. District Court in Pennsylvania ruled in favor of Safehouse, reasoning that the purpose of the facility was "to reduce drug use, not facilitate it." However, this decision was overturned by the Third Circuit Court of Appeals in January 2021. The appellate court ruled that the statute's language was clear and that opening the OPC would violate the law. Subsequent efforts to appeal the case have been unsuccessful, community opposition to the site grew, and Safehouse never opened in Philadelphia.¹¹⁸

In 2022, two sanctioned OPCs began operating in New York City, under the management of OnPoint NYC, 119 and the U.S. attorney in the Southern District of New York has not taken legal action to close it. However, the U.S. attorney stated that New York policymakers must authorize the sites, otherwise they operate in contravention of state, local, and federal laws. 120 As mentioned earlier, an overdose prevention center is slated to open in Rhode Island in 2024 after that state passed legislation authorizing OPCs in 2021.121

Other forms of harm reduction have faced barriers due to long-standing state laws. For instance, naloxone, an opioid overdose antidote, was approved by the FDA in 1971.122 But it was not until 1996, in the face of rising overdoses, that it was more widely distributed. That year, the Chicago Recovery Alliance began distributing naloxone through its SSP,123 marking the start of a grassroots movement to expand access to this life-saving drug. 124

As of December 2022, legislatures in 48 states and the District of Columbia had enacted Good Samaritan laws, which protect individuals seeking emergency assistance for an overdose from legal consequences.125 In the 2024 legislative session, Kansas passed a similar law, leaving Wyoming as the only state without one at the time of writing this paper. 126

OVERCOMING BARRIERS THROUGH POLICY CHANGE

Standing orders: As overdose rates climbed in the first decade of the twenty-first century, state and local governments issued standing orders for naloxone, effectively making it available without a prescription. 127 These orders allowed local authorities to distribute naloxone in areas with high overdose rates. Law enforcement, often the first responders to overdoses in rural areas, also began carrying naloxone. 128 In 2012, the police department of Gloucester, Massachusetts, became one of the first in the country to do so.129

Today, with high rates of opioid overdose in many communities, naloxone distribution programs have the largest impact when they are distributed to people most likely to use drugs or witness an overdose. 130 Community-based naloxone programs have also proven successful at reducing overdose deaths. 131 All 50 states and the District of Columbia now have naloxone and opioid antagonist access laws, and two forms of naloxone have been approved for over-thecounter sales.132

SSP-related policies: A defining moment in recent harm reduction history occurred in the wake of the HIV and HCV outbreak in Scott County, Indiana, in 2015. Given a growing recognition that such a ban increased public health harms and a continued ban would further hamper public health efforts to address the outbreak, state officials reversed the long-standing ban on syringe services programs. 133 The outbreak in Indiana spurred action in rural areas across the country as public health and government officials recognized the risk of similar outbreaks. A 2016 CDC study confirmed these concerns when it identified 220 counties in 26 states at risk of similar HIV and HCV outbreaks due to injection drug use and the lack of services for people who inject drugs. 134 Many of these at-risk counties were in states, such as Kentucky, West Virginia, and Tennessee, which at the time had paraphernalia laws that acted as "bans" on syringe services programs.

In 2015, Kentucky passed legislation authorizing health departments to launch SSPs with the approval of the local Board of Health, county fiscal courts, and city councils. 135 As of 2024, Kentucky operates 84 SSPs across 65 counties—among the highest in the nation.136 Still, the majority of SSPs in Kentucky are only open for limited hours during the week, constituting a barrier to access for participants. 137 Kentucky allows SSPs to require formal registration for participants despite anonymous service access as a best practice for SSPs. 138 A needs-based syringe distribution, allowing for the distribution of sterile syringes based upon participant need rather than exchange, is considered the best practice for SSPs, yet the Kentucky legislation permits a strict one-for-one exchange.139

In the ensuing years, additional states revised their laws on SSPs, and today the majority of states sanction such programs, either explicitly by law or other policy. According to LAPPA, as of August 2023, Kansas, Mississippi, Nebraska, South Dakota, and Wyoming do not have sanctioned SSPs. 140 A directory on the North America Syringe Exchange Network website lists 495 SSPs in the United States. 141 However, SSPs continue to face the threat of closure, often due to local opposition. 142

Historical pace of policy change: While drug use trends evolve, policies seldom adapt as quickly. Bans and other barriers, whether statutory or rooted in long-standing policies, require responsive leadership to navigate significant political challenges. Opposition to harm reduction services often stems from concerns about enabling drug use, leading to restrictive legislation.143

Federal restrictions on funding for syringes and SSPs have shifted over the past few decades. However, the ban on funds for syringe services generally was lifted in 2015 as rural members of Congress, led by Representative Hal Rogers (R-Ky.), recognized the realities of the need for such services in their communities.144 Language was added to congressional appropriations bills to allow federal funds to be spent on the services associated with SSPs, including operations, personnel, and rent.145

In 2021, the U.S. government included "harm reduction" as a policy priority. 146 Further, in 2024, the United Nations' policymaking body for drug control, the Commission on Narcotic Drugs, passed a resolution recognizing the importance of harm reduction, with only China and Russia opposing. 147 However, U.S. policymakers have yet to reach a consensus on the role harm reduction plays in the nation's approach to addiction.

Future of harm reduction in the **United States**

The historical arc of harm reduction efforts in the United States is long, and as we contemplate the future of these services, this paper recognizes that there will be both shorter- and longer-term challenges and opportunities. The immediate priority is overcoming the current policy barriers and social controversies outlined in the previous section. Since these critical challenges have already been discussed, this paper will not repeat them here. Instead, this section focuses on four other key areas that shape the future of harm reduction services and policies: (1) conducting research to address knowledge gaps; (2) scaling up services to meet unmet needs; (3) strengthening the economic case for harm reduction; and (4) applying implementation science models to expand harm reduction programs.

RESEARCH TO ADDRESS KEY REMAINING KNOWLEDGE GAPS

While the evidence base for many harm reduction services is strong, some questions remain about how to deliver these services for optimal impact. In January 2024, the National Academies of Sciences, Engineering, and Medicine, with the sponsorship of ONDCP, held a two-day workshop focused on harm reduction research needs. 148 In his remarks, the workshop chair, former NIDA Director Alan Leshner, observed the workshop's "historic" significance as the first time an administration had sponsored such an event: "For the first time in my [30 years] experience, the government of the United States appears to have a commitment to harm reduction. The pace is too slow, but lives are being saved and hopefully, more will continue to be saved."149

The workshop identified numerous research priorities, with a focus on four main themes:

- 1. The identification of optimally impactful methods for harm reduction service delivery (especially utilizing health services research methods).
- 2. The use of even more expeditious scientific methods (using rapid research methods and meta-analytic, narrative summary, and realist review approaches).
- 3. Improved community bases in the execution of research (employing community-based participatory, ethnographic, and mixed methods research approaches).

4. Better communication of research results to policymakers, program managers, and communities (focused on using the tools of implementation science and translational research).150

In his closing remarks, Nabarun Dasgupta, a senior scientist at the University of North Carolina at Chapel Hill's Injury Prevention Research Center, emphasized three key points: (1) the need to better understand who is not accessing harm reduction services and why, as well as the societal impact of this gap; (2) the costs of not providing harm reduction services in all communities and circumstances in which they are needed; and (3) the consequences of casting harm reduction services in a static public health framework rather than employing more "liberatory practices" to devise flexible services that respond to client and community-level expressed needs.151

SCALING UP TO FULLY ADDRESS UNMET NEEDS

Estimates of how much current total harm reduction services meet the total need are limited, but it is clear that vast unmet needs remain in the United States. 152 One example of this is data from the CDC's State Unintentional Drug Overdose Reporting System (SUDORS), which shows that among persons experiencing a fatal overdose (and recorded in that database), 64.7% had at least one missed opportunity for intervention. Additionally, 43.2% of fatal overdoses occurred with a bystander present, but there was no overdose response. This highlights the need for wider distribution and training in the use of opioid overdose reversal medications. 153

A second example of unmet need is found in the scope of SSPs in the country. 154 A 2022 survey of all known SSPs in the United States revealed that only 5% of rural, 3% of suburban, and 46% of urban setting SSPs met minimum resource benchmarks for even a small-scale SSP operation. 155 These benchmarks included having sustainable funding to continue providing essential services to people at risk of overdose and other health conditions. Thus, even where SSPs exist, they tend to be largely under-resourced.

A third illustration is the need for greater expansion of supportive referral services. 156 Based on data from the National Survey of Drug Use and Health (NSDUH) and the related literature on correction factors for the underreporting of substance use disorders, of the roughly 7.9 million persons with opioid use disorder in the nation, only about 484,000 were receiving treatment at a specialty facility and about 288,00 were receiving MOUD.¹⁵⁷ More generally, the 2023 NSDUH estimated that for all persons living with a substance use disorder of any type (including alcohol use disorder) and needing access to treatment, only 23.6% received any type of drug treatment. 158 Among adults who did not receive treatment for a SUD in the past year, 96.6% did not believe they needed it or did not think they could access it (for various reasons).159 This highlights a significant unmet need for stigma-free referral services that help persons living with SUD receive meaningful, timely, and client-centered access to drug treatment services.

Of great near-term importance would be the compilation of a national strategic plan for harm reduction services that more fully articulates and quantifies the needed scale of various types of harm reduction services. The U.S. Department of Health and Human Services is in a strong position to develop this plan with the aid of several government agencies (such as the CDC, SAMHSA, and NIDA) and in consultation with nonprofit harm reduction organizations. 160 The federal government agencies could marshal their existing evaluative harm reduction data and conduct the quantitative analyses necessary to clearly convey the type and scale of all met and unmet harm reduction needs for the nation, while including qualitative input from communities.

FURTHER MAKING THE ECONOMIC CASE FOR HARM REDUCTION

Implementing harm reduction services at scale requires significant financial investment, which could come from private philanthropic support or, ideally, sustained government funding. To convince funders of the value of these services, including future investment, economic considerations are crucial—especially for securing governmental funding. 161 While demonstrating that a program is cost-saving or cost-effective may not guarantee support, the absence of such data makes gaining support much more challenginq.162

Some harm reduction services, such as SSPs and overdose reversal medication distribution programs, have undergone formal economic evaluations. 163 These studies, often published in peer-reviewed journals, use both empirical and mathematical modeling methods. Two notable examples are SSPs and overdose reversal medication distribution programs, both of which have seen the peer-reviewed publication of economic evaluation studies.164

Investigations of the cost-effectiveness of SSPs date back to the 1990s when the central focus of such programs was their ability to prevent HIV transmission via injection drug use. 165 This line of research has continued to the present day with the vast majority of published analysis showing SSPs to be cost-saving or cost-effective to society. 166 CDC summarizes this published literature by noting that from a national perspective, for every \$1 spent on SSPs, \$7.58 would be saved (largely through averted infectious disease transmission);167 CDC further highlights a New York City SSP that was estimated to have garnered savings to the government of \$1,300 to \$3,000 per client over a one-year time horizon.¹⁶⁸ Substantial cost-savings due to the implementation of syringe services programs also were demonstrated in a more recent study in Baltimore and Philadelphia. 169 This peer-reviewed literature leaves little question that there is a sound economic argument to be made to support the implementation of SSPs (especially in communities where they are needed most).

A 2022 study reviewed the available economic evaluation studies of community distribution of naloxone. 170 Nine studies were found in this systematic review and eight of those estimated that naloxone distribution was cost-effective to society (in terms of cost per quality-adjusted life year saved). Cost-effectiveness was most favorable with strategic prioritization of distribution in communities with higher rates of opioid-related drug overdoses and a greater willingness of bystanders to actually intervene. 171 A more recent analytic study estimated that if 10,000 more naloxone kits were distributed in the state of Rhode Island via programs serving persons who inject drugs (such as SSPs), roughly one-quarter of opioid-related overdoses could be prevented at a cost of approximately \$27,312 per opioid fatality avoided.172

We note that expansion of the economic evaluation literature to more types of harm reduction interventions would be sped along by the establishment of standard parameter values for lifetime cost of care related to substance use, years of life lost due to substance use, and quality of life years lost due to substance use. Once similar parameters were well standardized in the HIV literature, the economic evaluation of a variety of HIV-related services became much more tractable, 173 and we expect the same would be true with more input parameter standardization in the substance use field.

APPLYING IMPLEMENTATION SCIENCE MODELS

In the earliest days of HIV and substance use-related harm reduction, program expansion was the result of rapid (usually privately supported) research and evidence-based advocacy from persons who knew that they were trying to save lives in real-time. SAMHSA's Recovery Community Services Program in 2002 is one example of

a programmatic refocus that helped kickstart the implementation and growth of a network of Recovery Community Organizations (RCOs) and peer recovery supports across the United States.¹⁷⁴ As implementation science as a formal area of inquiry had not yet been established, the frameworks for program expansion needed to be derived quickly and sometimes intuitively. As implementation science has become a more formalized approach to public health service delivery and policymaking, some of its frameworks can now be used in the further expansion of harm reduction services.

One such framework is the Hexagon Model, 175 which posits that decisions regarding the adoption, expansion, or refinement of public health programs should rest on six key pillars:

- 1. Strength of programmatic evidence.
- 2. Usability of the programmatic services for the intended community.
- 3. Support systems (such as adequate staffing, training, information technology, and administrative support systems).
- 4. Identification of the need for the services in and by the focal community.
- 5. Synergistic alignment with existing programs already embraced by the community.
- 6. Capacity to implement services at the scale required to successfully address unmet needs.

While a comprehensive application of the Hexagon Model to all harm reduction services is beyond the scope of this paper, it underscores the importance of using systematic implementation science frameworks when considering the adoption, adjustment, and expansion of harm reduction programs.

Conclusion and policy recommendations

An idealized vision for future harm reduction programs: For the future, we can envision harm reduction programs that provide in one service delivery package synergistic, comprehensive services to address drug sourcing harms, drug use equipment negative consequences, and aversive environmental settings. Ideally, these programs would be evidence-based, client-centered, and trauma-informed, delivered at scale, carefully evaluated and adjusted as necessary, and adaptable to the rapidly changing drug landscape. By anticipating and responding to emerging drug threats proactively, harm reduction services could stay ahead of the curve. These programs would form part of a comprehensive approach to care, one that includes referrals to other needed services, such as treatment, housing, and employment. Further, we can envision these services being offered without stigma and with full public support, including addressing community concerns about public health and public safety.

Perhaps a starting point is to agree that there are harms associated with substance use and that the pathway (and timeline) for eliminating those harms differs across individuals and communities. Because of this, a wide array of supportive services is necessary to meet everyone where they are in their journey toward and along recovery and improved health outcomes. If we can reach widespread agreement on these concepts, then a more widespread acceptance of harm reduction services would seemingly follow.

We also realize that such an idealized situation will require enormous, continued efforts to address decades of substance use stigma and policy opposition. While difficult to achieve, we must pause to envision what idealized harm reduction programs might look like in the future, and what they could accomplish in terms of lives saved, well-being improved, and health equity built.

To that end, this paper proposes the following recommendations:

- 1. Develop a national strategic plan for harm reduction services: This national strategic plan for harm reduction services should be developed to more fully articulate and quantify the needed scale of various types of harm reduction services. This comprehensive strategic plan will measure the unmet need for harm reduction services which already have a strong evidence base so the full scale of need can be estimated, and then resourced appropriately. These measurements should include a discussion of strategies to meet those needs, to include further making the economic case for harm reduction services. 176
- 2. Prioritize translational research: Prioritizing applied studies that examine which harm reduction services work under specific circumstances or in different contexts, including when, where, how, and in what combination, to maximize their beneficial impact.177
- 3. Remove legal and societal barriers:

Eliminating the obstacles that prevent evidence-based harm reduction programs from being fully implemented at the local, state, and national levels. This includes addressing stigma and legislation that hinders harm reduction efforts.¹⁷⁸

4. Establish sustainable funding structures:

Integrating harm reduction programs into the health care system by providing ongoing payment mechanisms that support providers at the necessary levels. 179

5. Understand and address social disparities and promote health equity: Gaining a better understanding of the social disparities in access to harm reduction services at the community level. Develop comprehensive, substance use-related programs that prioritize health equity, ensuring that harm reduction services are available to all who need them, regardless of socioeconomic status, race, and ethnicity. 180

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Acknowledgments

The authors would like to thank Jennifer Martinez, J.D., Ph.D., and University of Connecticut law student Jennifer Logan for their assistance in editing this paper. They would also like to thank Adam Lammon for editing, Rachel Slattery for graphical design and layout, and Diana Paz García for project coordination, as well as extend their gratitude to Jeffrey S. Crowley, MPH; Tom Hill, MSW; Mark Jenkins; and Lauren Kestner for generously sharing their insights on harm reduction.

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