

Treatment: Naloxone

Evaluation of a Naloxone Distribution and Administration Program in New York City

TINKA MARKHAM PIPER,¹ SHARON STANCLIFF,²
SASHA RUDENSTINE,¹ SUSAN SHERMAN,³ VIJAY NANDI,¹
ALLAN CLEAR,² AND SANDRO GALEA^{1,4,5}

¹Center for Urban Epidemiologic Studies, New York Academy of Medicine, New York, New York, USA

²Harm Reduction Coalition, New York, New York, USA

³Department of Epidemiology, Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland, USA

⁴Department of Epidemiology, University of Michigan School of Public Health, Ann Arbor, Michigan, USA

⁵Department of Epidemiology, Columbia University Mailman School of Public Health, New York City, New York, USA

Naloxone, an opiate antagonist that can avert opiate overdose mortality, has only recently been prescribed to drug users in a few jurisdictions (Chicago, Baltimore, New Mexico, New York City, and San Francisco) in the United States. This report summarizes the first systematic evaluation of large-scale naloxone distribution among injection drug users (IDUs) in the United States. In 2005, we conducted an evaluation of a comprehensive overdose prevention and naloxone administration training program in New York City. One hundred twenty-two IDUs at syringe exchange programs (SEPs) were trained in Skills and Knowledge on Overdose Prevention (SKOOP), and all were given a prescription for naloxone by a physician. Participants in SKOOP were over the age of 18, current participants of SEPs, and current or former drug users. Participants completed a questionnaire that assessed overdose experience and naloxone use. Naloxone was administered 82 times; 68 (83.0%) persons who had naloxone administered to them lived, and the outcome of 14 (17.1%) overdoses was unknown. Ninety-seven of 118 participants (82.2%) said they felt comfortable to very comfortable using naloxone if indicated; 94 of 109 (86.2%) said they would want naloxone administered if overdosing. Naloxone administration by IDUs is feasible as part of a comprehensive overdose prevention strategy and may be a practicable way to reduce overdose deaths on a larger scale.

Keywords substance use; injection drug users; naloxone; overdose prevention; syringe exchange programs

Address correspondence to Sandro Galea, Department of Epidemiology, School of Public Health, The University of Michigan, 1214 S. University, Room 243, Ann Arbor, MI 48104-2548. E-mail: sgalea@umich.edu

Introduction

Drug-induced and drug-use-related deaths have been increasing for the past decade throughout the United States (Centers for Disease Control and Prevention, 2000a; Centers for Disease Control and Prevention, 2000b; Centers for Disease Control and Prevention, 2004). Half of all heroin drug users report at least one nonfatal overdose during their lifetime (Ochoa et al., 2001; Seal et al., 2001; Davidson, Ochoa, Hahn, Evans, and Moss, 2002). In New York City (NYC), approximately 900 persons die from drug overdoses yearly, more than in any other U.S. city (New York City Department of Health and Mental Hygiene, 2003). It is estimated that 51% percent of all overdoses in the United States (Sporer, 1999) and 70% of all overdoses in NYC, are associated with opiate use (Galea et al., 2003).

Naloxone, an opiate antagonist, has long been administered by doctors and paramedics during emergency resuscitation after an opiate overdose. Programs in Europe (Jersey, England, and Berlin, Germany) and in several jurisdictions in the United States affiliated with harm reduction programs and/or city public health departments have been established to distribute naloxone to drug users themselves for immediate reversals of opiate overdoses (Dettmer, Saunders, and Strang, 2001; Bigg and Maxwell, 2002; Drug Overdose and Prevention Project, 2006). These preliminary reports have documented that peer-administration of naloxone is feasible; that there are few adverse effects during peer-administration of naloxone, increased overdose awareness and preparedness among opiate users; and that peer-administration of naloxone is associated with reversal of opiate overdose (Strang et al., 1999; Lenton and Hargreaves, 2000; Dettmer, Saunders, and Strang, 2001; Seal et al., 2005). Results from these programs suggest that distribution of naloxone to opiate drug users may be a practicable and potentially life-saving practice (Seal et al., 2005; Galea et al., 2006).

Although naloxone distribution to drug users has been ongoing in several U.S. jurisdictions, few formal, empiric evaluations have yet to be conducted and published in the peer-reviewed literature (Baca and Grant, 2005). The best available evidence from an extensive program in Chicago suggests that there was a 30% decrease in overdose deaths concurrent with the implementation of a citywide naloxone distribution program (Chicago Recovery Alliance, 2006; Maxwell et al., 2006). Syringe exchange and methadone maintenance programs in San Francisco, Baltimore, and parts of New Mexico have also distributed naloxone to injection drug users (IDUs) and their peers (Seal et al., 2005; Chicago Recovery Alliance, 2006; Drug Overdose and Prevention Project, 2006); although again, these programs have yet to be evaluated. We are aware of two U.S.-based formal evaluations of naloxone distribution programs. Both of these were pilot projects—one involved 24 IDUs in San Francisco (Seal et al., 2005) and the other, 25 IDUs in NYC (Galea et al., 2006). These small pilots suggested that distribution of naloxone to drug users is feasible and that it may be associated with reduction in overdose mortality.

To measure overdose response and naloxone use among IDUs, we implemented and evaluated naloxone distribution programs in New York City. This study presents data from the first systematic evaluation of large-scale naloxone distribution among IDUs in the United States.

Methods

Study Design

This evaluation was part of a comprehensive training course for IDUs in overdose prevention and proper naloxone administration developed as collaboration between NYC Syringe

Exchange Programs (SEPs) and the Harm Reduction Coalition. The training program was called SKOOP (Skills and Knowledge on Overdose Prevention). The overdose training program and evaluation instrument were modeled after existing naloxone distribution programs in Chicago and San Francisco (Chicago Recovery Alliance, 2006; Drug Overdose and Prevention Project, 2006) and are available from the authors. Opiate users were trained individually, in pairs, or in small groups (5–15 people) by SEP staff and volunteers. Each training lasted between 10 and 30 minutes. The SKOOP curriculum focused on overdose prevention education and naloxone administration (intramuscular injection practices, the use of naloxone only with opiate-related overdose and the potential need for a second dose of naloxone). SEP trainers also discussed rescue breathing practices, methods of cooperating with police and medical staff post-naloxone administration, and the importance of talking to drug using partners about naloxone and overdose response. Participants received a public transportation voucher (\$4 value) for completing the training. No follow-up training was provided unless requested by participants. Table 1 summarizes the key elements of SKOOP.

Data Collection

Participants received training in overdose prevention and naloxone administration from SEP staff. After a brief, targeted medical history, a physician dispensed a kit containing 2 doses of naloxone in prefilled syringes (1 mg/ml) and a prescription as proof of the legitimacy of the medication. Between March 2005 and December 2005, participants who returned for a naloxone refill were administered a 33-item questionnaire that was informed both by prior research and by our experience with drug use and overdose. The instrument documented demographic characteristics and recent drug use experience and asked about overdoses experienced or witnessed since the last assessment; if multiple overdoses were witnessed, detailed information about the most recent overdose witnessed was collected. Measures of comfort with naloxone administration such as discussing overdose risk and naloxone use with other people, ease of intervening in an overdose scenario, and experiences with law enforcement were also collected. After completing the questionnaire, participants received an additional naloxone kit from a physician.

Trained SEP staff and external interviewers administered the questionnaire in English and Spanish. Participants were current drug users and their partners and over the age of 18. Outreach efforts to recruit participants into the program included flyers, word of mouth, enlistment during syringe exchange sessions and other educational and medical programs and word of mouth. Respondents were asked questions using a structured questionnaire. Verbal consent was obtained before questionnaire administration. Participant names or any identifying information were not recorded on the survey. All trainings, naloxone prescription dispensing, and survey administration were conducted on site at NYC SEPs. The Institutional Review Board at the New York Academy of Medicine approved this study.

Statistical Analyses

Cross-sectional data analysis was conducted to characterize the refill participant population. The objectives of the analysis are to describe the overdose experience of participants who used naloxone posttraining as well as to convey the comfort level with naloxone. Overdose is defined in this study as “someone who collapses, has blue skin color, convulsions, difficulty breathing, loses consciousness, cannot be woken up, or has a heart attack or dies while using drugs.” Frequency distributions of overdose experience and naloxone use were assessed. We present sub-sample analysis of overdose-related questions for participants who administered naloxone. With this subsample, we display frequency distributions for questions including

Table 1
Overview of SKOOP Training Program

Component	Description
Training methodology	Participants trained either individually, in pairs, or in small groups (5–15 people) by SEP and HRC staff
Duration of training	10–30 minutes
Overdose prevention curriculum	(a) The causes of opiate overdose (i.e., loss of tolerance, mixing drugs, physical health and variation in strength of ‘street drugs’) (b) How to avoid an opiate overdose (i.e., know your tolerance and supply, control your high, injection techniques, aware of risks of mixing drugs, and minimize using alone) (c) Signs of an opiate overdose
Naloxone curriculum	(a) Information on naloxone (b) Education about appropriate responses to opiate overdose (i.e., calling 911 and performing rescue breathing) (c) Instructions on naloxone administration (intramuscular injection practices, the use of naloxone only with opiate-related overdose and the potential need for a second dose of naloxone) (d) Methods of cooperating with police and medical staff post-naloxone administration and the importance of talking to drug using partners about naloxone and overdose response
Physician involvement	Posttraining, participants in the program met with an on-site physician for a brief (1–2 minutes), targeted medical history who then gave each participant a “naloxone kit”
Naloxone kit	A carrying case with the following contents: two doses of naloxone in pre-filled syringes (1 mg/ml), a rescue breathing mask, and written information summarizing overdose revival steps. A prescription was also give as proof of the legitimacy of the medication.

relationship of person that overdosed, drugs used at time of overdose, and responses to overdose. With the full refill participant sample we examined questions associated with comfort level using naloxone as reported by the participants. Frequency distributions for these questions include comfort with naloxone, location of naloxone, police harassment for carrying/using naloxone, and participants wanting naloxone administered to them if

experiencing an overdose. Statistical analysis was conducted using the SAS version 8.0 statistical software.

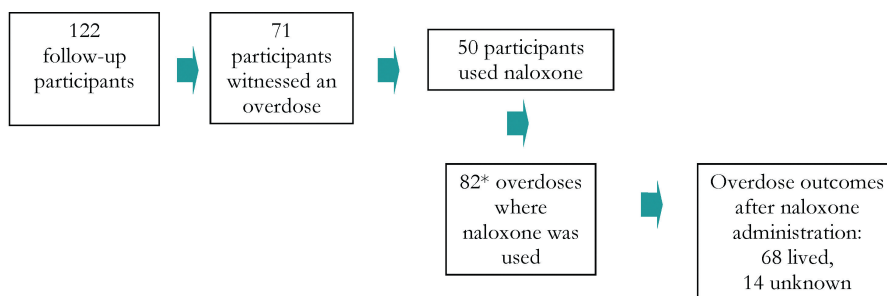
RESULTS

One hundred twenty-two participants were enrolled in this evaluation between March 2005 and December 2005. Ninety-five participants (87.2%) were male, 13 (11.9%) were female, and 1 (0.9%) was transgendered. Forty-nine (45.8%) participants were White, 38 (35.5%) were Hispanic/Latino, and 15 (14%) were Black. More than half of the sample (65 participants, 53.7%) had been homeless during the past 6 months. During the 6 months prior to their assessment, 71 (58.7%) participants had injected heroin, 44 (36.1%) had injected cocaine or crack, 89 (73.0%) had been in a methadone maintenance program, and 28 (23.0%) had used street-bought methadone. One hundred thirteen (92.6%) were opiate users. The most common drug use setting was a personal apartment, room, or house, followed by someone else's apartment, room, or house.

Figure 1 shows the distribution and use of naloxone at overdose witnessed among study participants. Among the 122 participants, 71 (58.2%) participants reported witnessing an overdose since their training. Among these 71 participants, 50 (70.4%) participants used naloxone during an overdose event they witnessed. Naloxone was administered 82 times (i.e., some participants had used naloxone more than once); 68 (83.0%) persons who had naloxone administered to them lived, and the outcome of 14 (17.1%) overdoses was unknown.

In Table 2, we show details about the 50 participants who used naloxone in the most recent overdose event they witnessed. The most common relationship of the person who overdosed to the participant was friend (26, 53.1%), followed by acquaintance (22, 44.9%). Heroin was used by 44 (88%) of the persons who overdosed, followed by benzodiazepines and alcohol, both 13 (26%). In addition to administering the naloxone, responses to overdose included trying to cause pain, administering a shower or bath, and/or applying ice (41, 82%) and calling an ambulance (37, 74%).

Table 3 shows comfort level with overdose prevention and naloxone among refill study participants. Ninety-seven (82.2%) said they felt comfortable or very comfortable using naloxone if indicated; 94 (86.2%) said they would want naloxone administered if they were overdosing. Thirty-one (27.0%) reported having kept the naloxone with them at all times or in their house where they usually used drugs; 15 (12.7%) participants reported police harassment over their possession of naloxone. Twenty-eight (24.1%) reported that their



* Participants may have witnessed more than one overdose

Figure 1. Distribution and use of naloxone at overdose witnessed since training/refill.

Table 2
Overdose experience of participants who used naloxone posttraining (n = 50)^a

	N	%
Relationship of person that overdosed (n = 49)		
Friend	26	53
Acquaintance	22	45
Spouse	1	2
Boyfriend/girlfriend	0	—
Drugs used at the time of overdose		
Heroin alone	21	42
Heroin plus substance(s) ^b	23	46
Alcohol	13	26
Benzodiazepines	13	26
Methadone or other prescription opiates	7	14
Cocaine or crack	6	12
Other drugs	1	2
Responses to overdose		
Called their name to try to wake them up	43	86
Tried to wake person by causing pain or shower/bath/ice	41	82
Called ambulance	37	74
Placed in the rescue position (on their side)	36	72
Took to hospital	30	60
Mouth to mouth/heart massage, CPR	27	54
Did something else (e.g., carry, move, walk around, or injected with cocaine, water, or salt)	4	8
Did nothing	2	4

^aDenominators may vary throughout the table because not all participants answered each question.

^bSubstances include: alcohol, benzodiazepines, methadone/other Rx opiates, cocaine/crack, other drugs.

naloxone had been stolen. Thirty-six (41%) participants had their naloxone refilled more than once since their training.

Study's Limitations

There are several considerations relevant to the interpretation of results in this study. First, persons volunteered for the study, meaning participants could be particularly motivated to use naloxone and may thus be different from other drug users. Second, the questionnaire relied on self-report so we have no external validation of the overdoses reported by participants or their consequences. Third, this was not a longitudinal study so we were unable to capture data overtime of participants. Fourth, the same researchers who implemented the program were also involved in its evaluation which may increase the potential for bias, but given the innovative nature of the project and the unusual collaborative and evaluative processes, we feel that there is valuable insight to be gained from the team's experiences with naloxone distribution in NYC over the past 2 years.

Table 3
 Comfort with naloxone and overdose prevention among participants in a formal evaluation of naloxone distribution (n = 122)^a

	N	%
Comfort level intervening in an OD situation (n = 118)		
Very uncomfortable	10	8
Uncomfortable	11	9
Comfortable	36	31
Very comfortable	61	52
Location of naloxone (n = 116)		
With you at all times	31	27
In your house	30	26
Lost/stolen	28	24
Given to someone else	25	22
Confiscated by police	5	4
Somewhere else	3	3
Used it at overdose	1	1
Police harassment for carrying/using naloxone (n = 118)	15	13
When you're out on the streets, do you worry that police will harass you for carrying naloxone (n = 117)	28	24
Want naloxone administered to you if you OD'd (n = 109)	94	86
Number of times naloxone refilled since training (n = 87)		
0	24	28
1	27	31
2	14	16
3	15	17
4	7	8

^a Denominators may vary throughout the table because not all participants answered each question.

Notwithstanding these limitations, the evaluation demonstrates project feasibility and the benefit and safety of naloxone distribution in drug-use settings.

Discussion

This evaluation suggests that it is feasible that naloxone administration by IDUs may be used as part of a comprehensive overdose prevention strategy and may be a practicable means for reducing overdose deaths on a larger scale. Participants in this evaluation reported high levels of comfort with naloxone administration and no adverse consequences following administration.

The majority of naloxone use during this assessment appeared to be appropriate and associated with near-immediate reversal of the opiate overdose. Although other studies have cited concerns about IDUs using naloxone for non-opiate-related drugs, such as cocaine or methamphetamine, and being intoxicated while attempting naloxone administration on an overdosing peer (Lenton and Hargreaves, 2000; Sporer, 2006), as best as we know, the use of naloxone by participants occurred with opiate overdoses, specifically with heroin used 88% of the time by IDUs at the time of overdose. Of the remaining 12%, one person overdosed with methadone and alcohol; the others did not record information on the drugs used in the overdose. These data are reassuring as it suggests that IDUs recognize that

naloxone is appropriate only for opiate-related overdose; however, we cannot account for missing data that may yield other information.

Participants reported calling an ambulance in 37 of 50 overdose events (74%) after using naloxone, a practice emphasized during the overdose prevention training. This is substantially higher than the proportion of drug users in NYC who have, in previous studies, reported calling an ambulance during witnessed overdose events (Tracy et al., 2005) suggesting, as expected, ancillary benefits of the comprehensive naloxone distribution program that included a substantial component of participant education.

A recent pilot naloxone distribution project in San Francisco trained 24 study participants in heroin overdose prevention and management, including cardiopulmonary resuscitation and naloxone administration. During a 6-month follow-up, participants reported successful resuscitations during 20 heroin overdose events and naloxone was used in 15 events (Seal et al., 2006). The study found no evidence of increases in drug use or heroin overdose in study participants and based on the results, the San Francisco Department of Public Health is now training IDUs and distributing naloxone. A NYC pilot overdose prevention and reversal program trained 25 participants in overdose prevention; after 3 months, 22 participants reported 26 overdoses and 10 successful uses of naloxone (Galea et al., 2006). Two preliminary reports in Berlin, Germany; and Jersey, United Kingdom, were the first to describe lifesaving events through peer administration of naloxone without adverse effects (Strang et al., 1999; Lenton and Hargreaves, 2000; Dettmer, Saunders, and Strang, 2001). Consistent with these data, this systematic evaluation highlights the lifesaving potential of naloxone distribution in conjunction with overdose prevention education programs aimed at improving drug-user responses to a witnessed overdose.

These data add to a growing body of literature that shows that naloxone distribution to drug users is feasible and may save drug-users' lives. Since instituting overdose prevention in San Francisco, the overdose rate has dropped to the lowest level in a decade while overdose rates have risen 42% in the rest of the state (*Los Angeles Times*, 2006; San Francisco Department of Public Health, 2006). In Baltimore, naloxone distribution began in April 2004; as of March 2006, 951 individuals have been trained in naloxone administration and a reported 131 overdoses have been reversed with the use of naloxone (Sherman et al., manuscript under review). Soon after initiating overdose prevention programs, the Baltimore Health Commissioner acknowledged the role of naloxone administration in a 12% decrease in overdose deaths (Baltimore Sun, 2005). New data suggest that drug-related deaths in Baltimore are now at a 10-year low, owing to increased availability drug treatment programs, as well as the distribution of naloxone to drug users (Sherman, Cheng, and Kral, manuscript under review, 2006). Currently in New York City, since April 2005, 1,485 people have been trained and received naloxone prescriptions with approximately 104 reported overdose reversals (Stancliff, 2006). Other feasibility studies recommend prescription and distribution of naloxone to drug users to prevent fatal heroin overdose.

The prevalence of overdose mortality and the role of naloxone in overdose prevention are gaining increased public health-related attention. Beginning in April 2006, a New York State law authorizes the state health commissioner to establish standards for overdose prevention programs to promote the use of naloxone by nonmedical staff in the case of an overdose, at least nine programs are now registered (New York State Department of Health, 2006). Under the Ryan White Care ACT Title 1, the largest federally funded AIDS services legislation, NYC has recently allocated \$11 million for "Harm Reduction, Recovery Readiness and Relapse Prevention" and requires grantees to include training of opiate users in naloxone administration (Medical and Health Research Association of New York City, 2006). Additional community-based organizations interested in minimizing the adverse consequences of drugs in cities in the United States, including Boston, Los Angeles,

Providence, and Pittsburgh, are in the process of planning and developing naloxone administration programs for drug users.

This evaluation of naloxone administration suggests that drug users can be trained to respond to heroin overdose by giving naloxone and that naloxone administration by drug users can save lives. Future research may fruitfully consider (a) the effectiveness of peer interventions to prevent fatal heroin overdose using longitudinal follow-up designs, (b) cost-effectiveness evaluations of peer-based naloxone interventions, and (c) formal testing of different peer-training programs. Challenges to the widespread implementation of naloxone remain, including the frequently inhospitable political climate to programs that may help substance users, extant prescription drug lows, and low public support (Markham Piper et al., 2007). Further evidence about the safety and effectiveness of naloxone administration may contribute toward improving political and public attitudes toward naloxone administration.

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RÉSUMÉ

Évaluation d'un programme de distribution et administration du Naloxone à New York City

Naloxone, un antagoniste opiacé qui peut éviter la mortalité d'overdose opiacée, a seulement récemment été prescrit aux consommateurs de drogues dans quelques juridictions (Chicago, Baltimore, Nouveau Mexique, New York, et San Francisco) aux États Unis. Cette étude résume la première évaluation systématique de la distribution à grande échelle de Naloxone parmi les consommateurs de drogues d'injection (IDUs) aux États Unis. En 2005, nous avons accompli une évaluation d'une programme complète de prévention d'overdose et de l'entraînement de l'administration de Naloxone à New York. 122 IDUs des programmes de l'échange de seringues (SEPs) ont été entraînés en SKOOP (habilités et connaissance sur la prévention de l'overdose). Tous ont reçu une ordonnance pour Naloxone par un médecin. Les participants de SKOOP avaient plus de 18 ans, et ils étaient participants actuels de SEPs, et consommateurs de drogues actuels ou anciens. Les participants ont rempli un questionnaire au sujet de leur expérience d'overdose et de l'utilisation de Naloxone. Naloxone était administré 82 fois; 68 personnes (83%) à qui l'on a administré le Naloxone ont survécu, et le résultat de 14 overdoses (17.1%) est inconnu. 97 des 118 participants (82.2%) ont dit qu'ils se sont sentis confortables ou très confortables à utiliser le Naloxone si indiqué; 94 de 109 (86.2%) ont dit qu'ils voudraient qu'on leur administrerait le Naloxone s'ils surdosaient. L'administration de Naloxone par IDUs serait réalisable si elle faisait partie d'une stratégie de prévention d'overdose complète et peut être une façon praticable pour réduire les morts d'overdose sur une plus grande échelle. Les restrictions de l'étude sont notées.

RESUMEN

Evaluación de un programa de distribución y administración de la naloxona en Nueva York

La naloxona, un eficaz antagonista de los opiáceos capaz de reducir la mortalidad por sobredosis, ha comenzado a ser recetado recientemente a consumidores de drogas en

algunas regiones de los Estados Unidos (Chicago, Baltimore, Nuevo México, la Ciudad de Nueva York y San Francisco). Este estudio resume la primera evaluación sistemática de los resultados de la distribución de naloxona en gran escala a consumidores de drogas inyectables (CDIs) en los Estados Unidos. En 2005, evaluamos un programa de prevención de sobredosis y administración de la naloxona en Nueva York. Ciento veintidós CDIs participantes de programas de intercambio de jeringas fueron entrenados en SKOOP (“Skills and Knowledge on Overdose Prevention”: Capacidades y Conocimiento para la Prevención de Sobredosis). Todos los participantes recibieron una receta médica para obtener naloxona. Los participantes de SKOOP eran mayores de 18 años, participaban en un programa de intercambio de jeringas y consumían o habían consumido drogas anteriormente. Esos individuos completaron un cuestionario que evaluaba la experiencia en sobredosis y el uso de naloxona. Naloxona fue administrada 82 veces: 68 (83%) de la personas que recibieron naloxona sobrevivieron; en 14 casos (17.1%), el resultado de la sobredosis es desconocido. Noventa y siete de los 118 participantes (82.2%) dijeron que se sentían “cómodos o muy cómodos” usando naloxona cuando estaba indicada; 94 de 109 (86.2%) dijeron que querían recibir naloxona si sufrían una sobredosis. La administración de naloxona por consumidores de drogas intravenosas es factible como parte de una estrategia global de prevención de la sobredosis, y puede constituir una forma práctica de reducir la mortalidad por sobredosis a gran escala. Las limitaciones del estudio son señaladas.

THE AUTHORS



Tinka Markham Piper, M.PH, C.S.W., is a Senior Project Director at the Center for Urban Epidemiologic Studies at the New York Academy of Medicine. She has experience in studies of fatal injury, including drug overdose, homicide, and suicide.

Sharon Stancliff, M.D., is the Medical Director of the Harm Reduction Coalition where she oversees overdose and buprenorphine projects. She is a Family Practitioner with additional certification in Addiction Medicine.

Sasha Rudenstine, B.A., is currently a Project Director at the University of Michigan, School of Public Health. Her interests are in human vulnerability and resiliency, and she has experience in studies of mental health in the postdisaster context.



Susan Sherman, Ph.D., M.P.H., is a social scientist at Johns Hopkins Bloomberg School of Public Health whose work focuses on the social determinant of HIV and other morbidities among drug users. She has experience in studies of randomized behavioral intervention trials, correlates of injection initiation, and epidemiology of drug use.



Vijay Nandi, M.P.H., is a Senior Research Analyst at the Center for Urban Epidemiologic Studies at the New York Academy of Medicine. She has experience in studies of substance abuse, immigrant populations and cardiovascular disease.



Allan Clear is the Executive Director of the Harm Reduction Coalition. He serves on many committees and advisory boards, including the Advisory Board of the North American Syringe Exchange Network, and the New York City Commission on AIDS.



Sandro Galea, M.D., Dr. PH, is an Associate Professor in the Department of Epidemiology, School of Public Health at the University of Michigan. His primary areas of research concern the epidemiology of mental health and substance use in urban areas.

Glossary

Naloxone: A drug that antagonizes morphine and other opiates. Naloxone is a pure opiate antagonist and prevents or reverses the effects of opioids including respiratory depression, sedation, and hypotension.

Injection Drug Users (IDUs): A person who uses a drug (e.g., heroin, cocaine) that is administered with a needle and syringe.

Substance Abuse: A destructive pattern of substance use leading to clinically significant (social, occupational, medical) impairment or distress. Symptoms include: suffering from withdrawal symptoms within several hours to a few days after a reduction in the amount of the substance taken over a prolonged period of time, taking substances to relieve withdrawal symptoms, inability to cut down or quite use of substance(s), and excessive time spent in trying to obtain substance(s).

Syringe Exchange Programs (SEPs): Centers and clinics that conduct health promotion and disease prevention programs for IDUs. SEPs provide sterile syringes in exchange for used syringes to reduce the transmission of human immunodeficiency virus (HIV) and other bloodborne infections associated with the reuse of potentially blood-contaminated syringes among IDUs. SEPs also offer counseling and case management services, as well as referrals to drug treatment, medical care, and peer education programs.

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