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Preventing Unintentional Prescription Drug Poisoning, 2010 Report

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Summary of Project Activities, 2010

This narrative addresses the three broad categories of project objectives for 2010:

- (1) The development of an Unintentional Prescription Drug Poisoning Coalition to address the problem by reviewing relevant data and making recommendations to Public Health Dayton-Montgomery County and the Ohio Department of Health.
- (2) The development of a Poison Death Review process.
- (3) The facilitation and conduct of targeted Information, Training, and Educational Opportunities to help address and prevent the problem.

Drug Poisoning Coalition: Community stakeholders identified in the RFP were invited to join the coalition. In addition, other community members who could provide specific expertise were recruited. The coalition consists of representatives from public health, drug treatment, hospitals, pharmacies, law enforcement, fire department emergency services, a medical school, coroner's office, a pain clinic, the community-at-large, the alcohol, drug and mental health board, and Family and Children First Council (see attached Membership List). There were four meetings of the Drug Poisoning Coalition. Notes from these meetings are available on the project web site: <http://www.med.wright.edu/citar/prescriptiondrugs.html>. Coalition members prioritized activities, focusing on identifying the nature and extent of the unintentional drug poisoning problem in the county. They reviewed data on overdose deaths, prescriber and first responder views of the problem, and available research findings on the problem. The Coalition also reviewed information provided at Ohio Prescription Drug Abuse Action Group meetings, attended by the Injury Prevention Coordinator. In addition, the Coalition considered and approved recommendations, including the naloxone education and distribution program recommendation required by ODH.

Poison Death Review: To develop the Montgomery County Poison Death Review process, the project examined Ohio's Child Fatality Review process; reviewed other states' death review mechanisms; evaluated the ODH pilot data entry form; and assessed local capacity for gathering, disseminating, and analyzing poisoning death data. The process met with the approval of the Unintentional Prescription Drug Poisoning Coalition.

The process for review of drug poisoning deaths consists of:

- (1) Montgomery County Coroner's Office identification of individuals whose death has been determined to be the result of an unintentional drug poisoning.
- (2) Coroner's Office provision of the following data:

- a. General information report, including case synopsis by coroner's office investigator
 - b. ODH Supplemental Medical Certification
 - c. ODH Certificate of Death
 - d. Report of postmortem examination
 - e. Toxicology laboratory report
 - f. Toxicology inventory of prescription drugs found at the scene of death.
- (3) Review of the data by the Unintentional Prescription Drug Poisoning project team (Principal Investigator, Co-Investigators, and Injury Prevention Coordinator).
 - (4) Entry of the data into the database developed by the team's data specialist.
 - (5) Data analysis.
 - (6) Review of data by members of the Coalition.

A Narrative Summary of 2010 data and a Data Summary Report are included as items 2 and 3 in this report.

Information, Training, and Educational Opportunities: The Coalition's principal activities related to this objective were to assess the need for training. The Coalition also attempted to gauge our ability to effectively conduct this assessment within the resources available. Finally, the Coalition publicized and made available a training opportunity for emergency department physicians and conducted a community-oriented, on-line symposium.

This effort began with a survey of coalition members' views of the unintentional poisoning death problem. The Coalition membership survey was followed by an on-line survey of prescribers who were identified through the Montgomery County Medical Society, the Dayton Dental Society, and area hospitals. These prescribers were notified by mail and asked to complete an on-line survey. Approximately 10% of the prescribers completed the survey. This assessment strategy was modified for a survey of first responders. The first responders were notified electronically through the membership list of the Greater Miami Valley Emergency Medical Services Council. The response rate to this survey was similar to that of the prescriber survey. The results of both surveys are posted on the Coalition web site under "Reports." These surveys helped inform the development of a community-oriented, on-line symposium, conducted December 9, 2010. Publicity for the symposium was jointly carried out by the Wright State University School of Medicine and Public Health Dayton-Montgomery County. Coalition

members comprised the expert panel and moderators for the symposium. Participation was estimated by unique logins to the symposium web site and was approximately 150 individuals.

A Training Plan for 2011 will incorporate lessons learned from 2010 assessment activities. Projected activities for 2011 include expansion of on-line surveys to include pharmacists, substance abuse treatment providers, and the community-at-large. The Coalition also identified opportunities to provide OARRS training and further training with medical students, emergency department physicians, and first responders. An outline of the potential training activities for 2011 is included as item 5 in this report.

Attached: Membership List

**Montgomery County Unintentional Drug Poisoning Death Coalition
Membership List**

Gary LeRoy, M.D.

Chair, Unintentional Drug Poisoning Coalition
Associate Dean
WSU Boonshoft School of Medicine

James Gross, M.P.H.

Vice-Chair, Unintentional Drug Poisoning
Coalition
Health Commissioner
Public Health - Dayton & Montgomery County

Gideon S. A. Adegbile, M.D.

Medical Director
Project C.U.R.E.

James E. Brown, M.D., EMT-P

Chair and Residency Program Director
Department of Emergency Medicine
WSU Boonshoft School of Medicine

Rick Buenaventura, M.D.

Pain Relief of Dayton

Robert Carlson, Ph.D.*

Co-PI, Unintentional Drug Poisoning Project
CITAR, WSU Boonshoft School of Medicine

Gail Chmielewski, M.S.

Outpatient Program Coordinator
Center for Alcoholism and Drug Addiction
Services

Raminta Daniulaityte, Ph.D.*

Co-I, Unintentional Drug Poisoning Project
CITAR, WSU Boonshoft School of Medicine

Russel Falck, M.A.*

PI, Unintentional Drug Poisoning Project
CITAR, WSU Boonshoft School of Medicine

Andrea Herman, M.P.A.

Director, Division of Program & Outcome
Evaluations
Public Health - Dayton & Montgomery County

Mark Hess

Assistant Chief
Dayton Police Department

Andrea Hoff

Program Coordinator
Montgomery County Office of Family and
Children First

William Holly, M.P.A.

Executive Director
Project C.U.R.E.

Karen Kirkham, M.D.

Asst Professor, Department of Internal Medicine
WSU Boonshoft School of Medicine

D. Timothy Lane, M.Ed.*

Injury Prevention Coordinator
Unintentional Drug Poisoning Project
CITAR, WSU Boonshoft School of Medicine

Lee D. Lehman, Ph.D., M.D.

Chief Deputy Coroner
Montgomery County Coroner's Office

Lauren Marinetti, Ph.D., D-ABFT

Chief Toxicologist
Montgomery County Coroner's Office &
Miami Valley Regional Crime Laboratory

Bradford Nickels

Division of Emergency Services
Dayton Fire Department

Jeffrey Payne

Assistant Chief
Division of Emergency Services
Dayton Fire Department

Brenda Roman, M.D.

Professor of Psychiatry
WSU Boonshoft School of Medicine

Willie Scales

Community Representative

Chris Stieritz, R.Ph.

Chief Pharmacist, Southview
Kettering Health Network

Monica Sutter, R.N., B.S.N.

Chemical Dependency Resource Nurse
Good Samaritan Hospital

Doug Teller, M.D.

Internal Medicine/Addiction Medicine
Kettering Health Network

Cathy Trame, R.N., M.S.

Coordinator, Pain Clinic
Miami Valley Hospital

* Center for Interventions, Treatment & Addictions Research (CITAR) Unintentional Drug Poisoning Project Staff

Narrative Summary of Poisoning Death Review Data, 2010

The Montgomery County Poisoning Death Review process is informed by:

- (1) examination of Ohio's Child Fatality Review process;
- (2) review of other states' death review mechanisms;
- (3) evaluation of the ODH pilot data entry form; and
- (4) assessment of local capacity for gathering and disseminating poisoning death data.

The process for review of drug poisoning deaths consists of:

- (4) Montgomery County Coroner's Office identification of individuals whose death has been determined to be the result of an unintentional drug poisoning.
- (5) Coroner's Office provision of the following data:
 - a. General information report, including case synopsis by coroner's office investigator
 - b. ODH Supplemental Medical Certification
 - c. ODH Certificate of Death
 - d. Report of postmortem examination
 - e. Toxicology laboratory report
 - f. Toxicology inventory of prescription drugs found at the scene of death.
- (6) Review of the data by the Unintentional Prescription Drug Poisoning project team (Principal Investigator, Co-Investigators, and Injury Prevention Coordinator).
- (7) Entry of the data into the database developed by the team.
- (8) Review of data by members of the Coalition.

Cases of Unintentional Drug Poisoning Fatalities reviewed in 2010: 81

Date of Death for Most Recent Case Reviewed: September 12, 2010

Estimated Completion Date for all 2010 Cases: March 15, 2010

Unintentional Drug Poisoning Fatalities, 2008: 132

Unintentional Drug Poisoning Fatalities, 2009: 126

Projected Unintentional Drug Poisoning Fatalities, 2010: 130

Demographic Characteristics of Population:

Male: 53%

White: 89%

Average Age: 40

High School Graduate: 73%

Single: 42% Married: 30% Divorced: 23%

66% of the deaths occurred in the decedent's home; 15% in the home of a friend; and 9% in a medical facility.

Most overdose deaths (81%) occurred among individuals with a mental or physical disability. 67% of the decedents suffered from heart disease of varying severity.

The population consisted primarily of poly-drug users, with high rates of prescription opioid use (81%) and frequent exposure to sedatives, including benzodiazepines (73%).

Coroner's Office toxicology report data show that prescription opioids consisted primarily of methadone (36%), hydrocodone (30%), and oxycodone (23%).

Alprazolam was the most prevalent benzodiazepine (56%), followed by clonazepam (25%) and diazepam (14%).

There was only one death in which heroin was the only drug noted in the coroner's toxicology report. There were three additional cases in which heroin was listed as the *sole cause of death*, even though other drugs were in the decedent's system at the time of death.

In only 36% of the cases was there a verifiable valid prescription for controlled drugs listed on the toxicology report. However, since no Ohio Automated Prescription Drug Reporting System (OARRS) data was available that could be matched to individual cases, these data reflect only prescription drugs found in their containers at the scene of death or in the home of the decedent.

The demographic characteristics of the group of 66 opioid users were nearly identical to those of the other 15 individuals in the population.

There was a relatively low incidence of overdoses (15%) that might have been prevented by the use of opioid antagonists by family members or fellow users.

POISONING DEATH REVIEW SUMMARY REPORT, 2010

POISONING DEATH REVIEW SUMMARY REPORT, 2010				
Total Cases				81
DEMOGRAPHICS				
Characteristic	Data Source	Category	Percent	Frequency
Age	Death Certificate	<15 years	0%	0
		15-24 years	15%	12
		25-34 years	20%	16
		35-44 years	28%	23
		45-54 years	19%	15
		55-64 years	15%	12
		65-74 years	4%	3
		75+ years	0%	0
Gender	Death Certificate	Male	53%	43
		Female	47%	38
Race	Death Certificate	White	89%	72
		Black	11%	9
		Other	0%	0
Hispanic	Death Certificate	Hispanic/Latino	0%	0
Education	Death Certificate	<High School	23%	19
		HS graduate	73%	59
		College graduate	1%	1
		Post-graduate	1%	1
Marital Status	Death Certificate	Single	42%	34
		Married	30%	24
		Divorced	23%	19
		Separated	2%	2
		Widowed	2%	2
Military	Death Certificate	Ever in US Armed Forces	11%	9

HEALTH				
Characteristic	Data Source			
			Percent	Frequency
Physical Disability/Illness	Case Synopsis and Postmortem Report		81%	66
Heart Disease			67%	54
Mental Disability/Illness			33%	27
HISTORY OF SUBSTANCE ABUSE				
		2010	Total Cases	81
Substance Abuse	Data Source		Percent	Frequency
Any history			67%	54
Alcohol			11%	9
Cocaine			16%	13
Marijuana			6%	5
Methamphetamine			0%	0
Heroin			21%	17
Prescription opioids			26%	21
Benzodiazepines			17%	14
Other Prescription Medications			1%	1
Over-the-Counter Medications			0%	0
Other Medications			1%	1

DEATH INVESTIGATION				
Characteristic	Data Source	Category	Percent	Frequency
Location of death	Case Synopsis	Decedent's home	66%	53
		Relative's home	1%	1
		Friend's home	15%	12
		Place of work	0%	0
		School	0%	0
		Hospital	9%	7
		Drug tx facility	0%	0
		Jail/detention area	0%	0
		Public area	3%	2
		Other	6%	5
911 called	Case Synopsis	Yes	94%	75
Person reporting death	Case Synopsis	Coroner	1%	1
		Hospital physician	19%	15
		Other physician	0%	0
		Mortician	0%	0
		EMS/Police	80%	64
Possible prevention by use of opioid antagonist?	Case Synopsis Postmortem Report Toxicology Report		15%	12

TOXICOLOGY REPORT				
		2010	Total Cases	81
Characteristic	Data Source	Category	Percent	Frequency
Alcohol	Toxicology Report	Alcohol	23%	19
Illicit Drugs		Marijuana	31%	25
		Cocaine	31%	25
		Methamphetamine	1%	1
		Hallucinogen	0%	0
		Heroin	28%	23
Prescription Opioids		Any	81%	66
		Oxycodone	23%	19
		Hydrocodone	30%	24
		Methadone	36%	29
		Fentanyl	6%	5
		Tramadol	7%	6
		Hydromorphone	1%	1
		Morphine	7%	6
		Propoxyphene	2%	2
		Meperidine	0%	0
		Buprenorphine	0%	0
		Other	2%	2
Anti-Depressants		Any	44%	36
Sedatives (Including Benzodiazepines)		Any	77%	62
Benzodiazepine		Any	73%	59
Any Prescription Opioid + Any Anti-Depressant			37%	30
Any Prescription Opioid + Any Benzodiazepine			64%	52
Any Prescription Opioid + Any Benzodiazepine, BUT WITHOUT Heroin or Anti-Depressants			27%	22

Any Prescription Opioid, Without Heroin or any Sedative--disregarding presence or absence any other drug	Toxicology Report		11%	9
Heroin+ Any Prescription Opioid AND/OR Any Sedative			21%	17
Heroin WITHOUT Alcohol, Prescription Opioids, Sedatives or Anti-Depressants			1%	1
Other Prescription		Any	49%	40
Over-the-counter		Any	20%	16
Verifiable Valid Prescription for Controlled Drugs in Tox Report	Case Synopsis and Postmortem Report		36%	

PRESCRIPTION OPIOIDS			2010 Cases with Prescription Opioids		All 2010 Cases
Decedents with Postmortem Prescription Opioids:			66	81%	81
Age	Death Certificate	<15 years	0	0%	0%
		15-24 years	9	14%	11%
		25-34 years	13	20%	19%
		35-44 years	17	26%	32%
		45-54 years	15	23%	19%
		55-64 years	11	17%	15%
		65-74 years	1	2%	4%
		75+ years	0	0%	0%
Gender	Death Certificate	Male	33	50%	55%
		Female	33	50%	45%
Race	Death Certificate	White	60	91%	89%
		Black	6	9%	11%
Hispanic	Death Certificate	Hispanic/Latino	0		0%

Education	Death Certificate	<High School	16	24%	26%
		HS graduate	49	73%	66%
		College graduate	1	1%	0%
		Post-graduate	1	1%	0%
Marital Status	Death Certificate	Single	27	41%	38%
		Married	23	35%	28%
		Divorced	13	20%	26%
		Separated	1	2%	0%
		Widowed	2	3%	2%
Military	Death Certificate	Ever in US Armed Forces	7	11%	9%
Verifiable Physical Illness	Case Synopsis and Report	Any	56	85%	85%
Heart Disease	Case Synopsis and Report		44	67%	73%
Verifiable Valid Prescription				36%	39%

Summary of Unintentional Prescription Drug Poisoning Literature from Peer Reviewed, Public, and Media Sources

12 Recent Articles on Unintentional Prescription Drug Poisoning, from Peer Reviewed and Government Sources:

Beletsky L, Burris S, and Kral A. Closing death's door: action steps to facilitate emergency opioid drug overdose reversal in the United States: A Conference Report from The Center for Health Law, Politics and Policy Temple University Beasley School of Law. Electronic copy available at: <http://ssrn.com/abstract=1437163>

A comprehensive conference report with recommendations

CDC. CDC's issue brief: unintentional drug poisoning in the United States. March 19, 2010/59(10);300. Available at:

<http://www.cdc.gov/homeandrecreationalsafety/poisoning/brief.htm>

What the CDC is doing, and links to some State responses to the epidemic

Cicero, Theodore J.; Lynskey, Michael; Todorov, Alexandre; Inciardi, James A.; Surratt, Hilary L. Co-morbid pain and psychopathology in males and females admitted to treatment for opioid analgesic abuse. Pain Vol 139(1)2008 p.127-135 Elsevier Science, Netherlands

A description of a population of 1408 individuals admitted for opioid abuse treatment in the US

Dormitzer C. Summary of drug abuse "rates" in the United States. Available at:

<http://www.fda.gov/ohrms/dockets/ac/08/slides/2008-4356s1-04-fda-corepresentations.ppt> (Starts on slide 13 of link provided)

Gaston RL, Best D, Manning V, Day1 E. Can we prevent drug related deaths by training opioid users to recognise and manage overdoses? Harm Reduct J. 2009; 6: 26.

The need for a naloxone implementation model

Hall AJ, Logan JE, Toblin RL, et al. Patterns of abuse among unintentional pharmaceutical overdose fatalities. JAMA 2008;300:2613-20.

An examination of all West Virginia pharmaceutical overdose deaths in 2006

Kim D, Irwin K, and Khoshnood K. Expanded Access to Naloxone: Options for Critical Response to the Epidemic of Opioid Overdose Mortality. American Journal of Public Health March 2009, Vol 99, No. 3. Electronic copy available at:

<http://www.ajph.org/cgi/doi/10.2105/AJPH.2008.136937>

Paulozzi, Leonard J.; Annest, Joseph L. US data show sharply rising drug-induced death rates. Injury Prevention. Vol 13(2), Apr 2007, 130-132.

Substance Abuse and Mental Health Services Administration. Drug Abuse Warning Network, 2007: area profiles of drug-related mortality. Rockville, MD: Substance Abuse and Mental Health Services Administration; 2009. HHS publication no. SMA 09-4407. Available at:

<http://dawninfo.samhsa.gov/pubs/mepubs>

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Substance Abuse and Mental Health Services Administration. Results from the 2008 National Survey on Drug Use and Health: national findings. Rockville, MD: Substance Abuse and Mental Health Services Administration; 2009. HHS publication no. SMA 09-4434. Available at: <http://www.oas.samhsa.gov/nsduh/2k8nsduh/2k8results.cfm>

Warner M, Chen LJ, Makuc DM. Increase in fatal poisonings involving opioid analgesics in the United States, 1999--2006. NCHS data brief, no 22. Hyattsville, MD: National Center for Health Statistics; 2009.

UNINTENTIONAL PRESCRIPTION DRUG POISONING LITERATURE

Description of Problem and Population

Adams, Edgar H.; Breiner, Scott; Cicero, Theodore J.; Geller, Anne; Inciardi, James A.; Schnoll, Sidney H.; Senay, Edward C.; Woody, George E. A Comparison of the Abuse Liability of Tramadol, NSAIDs, and Hydrocodone in Patients with Chronic Pain. *Journal of Pain and Symptom Management* Vol 31(5)2006 p.465-476 Elsevier Science, Netherlands.

<http://www.ncbi.nlm.nih.gov/pubmed?term=16716877>

Arkes, J. and Iguchi, M.Y., (Fall 2008) How Predictors of Prescription Drug Abuse Vary by Age. *Journal of Drug Issues*, 0022-0426/08/04 Vol. 38 (4) p. 1027-1044.

<http://www.ncjrs.gov/App/Publications/abstract.aspx?ID=248641>

Birnbaum HG, White AG, Reynolds JL, Greenburg PE, Zhang M, Vallow S, et al. Estimated costs of prescription opioid analgesic abuse in the U.S. in 2001; *Clin J Pain* 2006;22:667-76.

<http://www.ncbi.nlm.nih.gov/pubmed?term=16988561>

Carise D, Dugosh KL, McLellan AT, Camilleri A, Woody GE, Lynch KG. Prescription OxyContin Abuse Among Patients Entering Addiction Treatment. *Am J Psychiatry*. 2007 November; 164(11): 1750-1756.

<http://www.ncbi.nlm.nih.gov/pubmed?term=17974941>

Cicero, Theodore J.; Inciardi, James A. Diversion and Abuse of Methadone Prescribed for Pain Management. *JAMA: Journal of the American Medical Association* Vol 293(3)2005 p.297-298 American Medical Assn, US.

<http://www.ncbi.nlm.nih.gov/pubmed?term=15657321>

Cicero, Theodore J.; Lynskey, Michael; Todorov, Alexandre; Inciardi, James A.; Surratt, Hilary L. Co-morbid pain and psychopathology in males and females admitted to treatment for opioid analgesic abuse. *Pain* Vol 139(1)2008 p.127-135 Elsevier Science, Netherlands

<http://www.ncbi.nlm.nih.gov/pubmed?term=18455314>

Cicero TJ, Surratt H, Inciardi JA, Munoz A. Relationship between therapeutic use and abuse of opioid analgesics in rural, suburban, and urban locations in the United States. *Pharmacoepidemiol Drug Saf* 2007; 16: 827–840.

<http://www.ncbi.nlm.nih.gov/pubmed?term=17636553>

Coffin PO, Galea S, Ahern J, Leon AC, Vlahov D, Tardiff K. Opiates, cocaine and alcohol combinations in accidental drug overdose deaths in New York City, 1990–98. *Addiction* 2003; 98:739–747.

<http://www.ncbi.nlm.nih.gov/pubmed?term=12780362>

Cone E. J., Fant R. V., Rohay J. M., Caplan Y. H., Ballina M., Reder R. F. et al. Oxycodone involvement in drug abuse deaths. II. Evidence for toxic multiple drug–drug interactions. *J Anal Toxicol* 2004 Oct; 28(7):616-24.

<http://www.ncbi.nlm.nih.gov/pubmed?term=15516322>

Darke, Shane and Zador, Deborah, "Fatal Heroin 'Overdose': A Review." *Addiction*. 1996; 91(12): pp. 1765-1772.

<http://www.ncbi.nlm.nih.gov/pubmed?term=8997759>

Dasgupta N, Mandl ND, Brownstein JS. Breaking the News or Fueling the Epidemic? Temporal Association between News Media Report Volume and Opioid-Related Mortality. *PLoS One*. 2009; 4(11): e7758.

<http://www.ncbi.nlm.nih.gov/pubmed?term=19924221>

Dasgupta N, Kramer ED, Zalman M, et al. Association between non-medical and prescriptive usage of opioids. *Drug Alcohol Depend* 2006; 82: 135–142.

<http://www.ncbi.nlm.nih.gov/pubmed?term=16236466>

Donaldson AE, Larsen GY, Fullerton-Gleason L, Olson LM. Classifying undetermined poisoning deaths. *Inj Prev* 2006; 12: 338–343.

<http://www.ncbi.nlm.nih.gov/pubmed?term=17018678>

Fischer B, Brissette S, Brochu S, Bruneau J, el-Guebaly N, Noël L, Rehm J, Tyndall M, Wild C, Mun P, Haydon E, Baliunas, D. Determinants of overdose incidents among illicit opioid users in 5 Canadian cities. *CMAJ*. 2004 August 3; 171(3): 235–239.

<http://www.ncbi.nlm.nih.gov/pubmed?term=15289420>

Forman RF. Availability of opioids on the Internet. *JAMA* 2003;290:889

<http://www.ncbi.nlm.nih.gov/pubmed?term=12928464>

Graham N. A., Merlo L. J., Goldberger B. A., Gold M. S. Methadone- and heroin-related deaths in Florida. *Am J Drug Alcohol Abuse* 2008; 34: 347–53.

<http://www.ncbi.nlm.nih.gov/pubmed?term=18428077>

Green CR, Ndao-Brumblay SK, West B. Differences in prescription opioid analgesic availability: comparing minority and white pharmacies across Michigan. *J Pain* 2005; 6: 689–699.

<http://www.ncbi.nlm.nih.gov/pubmed?term=16202962>

Grella CE, Karno MP, Warda US, Niv N, Moore AA. Gender and comorbidity among individuals with opioid use disorders in the NESARC study. *Addict Behav* 2009; 34(6-7): 498–504.

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Hall A. J., Logan J. E., Toblin R. L., Kaplan J.A., Kramer J. C., Bixler D. et al. Patterns of abuse among unintentional pharmaceutical overdose fatalities. *JAMA* 2008; 300: 2613–20.

<http://www.ncbi.nlm.nih.gov/pubmed?term=19066381>

Hu, Guoqing¹; Baker, Susan P. Trends in Unintentional Injury Deaths, U.S., 1999–2005: Age, Gender, and Racial/Ethnic Differences. *American Journal of Preventive Medicine*, Volume 37, issue 3 (September, 2009), p. 188-194.

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Inciardi, James A.; Cicero, Theodore J.; Muoz, Alvaro; Adams, Edgar H.; Geller, Anne; Senay, Edward C.; Woody, George E. The Diversion of Ultram, Ultracet, and Generic Tramadol HCL. *Journal of Addictive Diseases* Vol 25(2)2006 p.53-58 Haworth Press, US

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Inciardi, James A.; Surratt, Hilary L.; Cicero, Theodore J.; Beard, Ronald A. Prescription opioid abuse and diversion in an urban community: The results of an ultrarapid assessment. *Pain Medicine* Vol 10(3)2009 p.537-548 Wiley-Blackwell Publishing Ltd., United Kingdom

<http://www.ncbi.nlm.nih.gov/pubmed?term=19416440>

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<http://www.ncbi.nlm.nih.gov/pubmed?term=17305688>

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Narrative Summary Naloxone Literature Reviews

Background:

Drug overdoses have overtaken such high-profile causes of death as AIDS and homicide as a leading cause of accidental injury death in the U.S. (Sporer et al., 2007). In Ohio, unintentional poisoning has already surpassed motor vehicle accidents as the leading cause of accidental death (Ohio Department of Health, 2009). Opioid drugs are driving this surge, contributing to the deaths of over 16,000 Americans each year. “With better availability of opioid pharmaceuticals to treat serious pain, prescription drugs have become a substantially bigger source of overdose risk, though research on the key risk factors for pharmaceutical opioid overdose, its circumstances, and successful intervention strategies remains too sparse. Although more research is needed, it is abundantly clear that timely, coordinated, and well-balanced action is necessary to assure that society can get the benefits of adequate pain care while minimizing overdose risk” (Beletsky, 2008).

Naloxone’s potential for preventing opioid overdose deaths:

Naloxone is an effective opioid antagonist. If it is injected soon after an opioid overdose, naloxone prevents and reverses the effects of opioids on the brain and restores respiration. When given intramuscularly, the onset of action is about two minutes. One benefit of naloxone in preventing overdoses, is that it exhibits essentially no pharmacological activity in the absence of the agonist effects of opioids. It is an inexpensive, non-scheduled drug available by prescription only through medical professionals (Green et al., 2008; Tobin et al., 2005).

Description of efforts to employ naloxone in opioid overdose prevention:

The Food and Drug Administration approved naloxone in 1971 for complete or partial reversal of narcotic depression. Naloxone has been used by emergency medical personnel for more than three decades. However, peers or family members are often in the best position to respond to overdose symptoms. Data from pilot programs suggest that lay persons can be consistently successful in administering naloxone to reverse opioid overdose (Kim, 2009).

Many states and localities are attempting to expand access to naloxone to intravenous drug users and their peers as a public health intervention for reducing overdose deaths. To do so, several states (California, Connecticut, Illinois, Maryland, Massachusetts, Oregon, Pennsylvania, New Mexico, New York, North Carolina, and others) have pilot programs or established programs for naloxone distribution among drug users. Many of these programs claim impressive declines in their overdose mortality numbers, 17–20% in some cases (Green et al., 2008).

Results from programs that employ naloxone in opioid overdose prevention:

Although naloxone distribution to drug users has been ongoing in several U.S. jurisdictions, few formal, empiric evaluations have been conducted and published in the peer-reviewed literature (Baca and Grant, 2005). Syringe exchange and methadone maintenance programs in San

San Francisco, Baltimore, and New Mexico have distributed naloxone to injection drug users (IDUs) and their peers (Seal et al., 2005), but these programs have not been rigorously evaluated. Evidence from a program in Chicago suggests that there was a 30% decrease in overdose deaths concurrent with the implementation of a citywide naloxone distribution program (Maxwell et al., 2006). Two U.S.-based formal evaluations of naloxone distribution programs, involving small numbers of individuals (24 IDUs in San Francisco (Seal et al., 2005) and 25 IDUs in NYC (Galea et al., 2006)) were conducted in the last 10 years. The pilot project evaluations suggested that distribution of naloxone to drug users was feasible and that it might be associated with reduction in overdose mortality (Piper et al., 2008).

Descriptions of Some Current Naloxone Distribution Programs:

Project Lazarus, Wilkes County, NC

Goals for participants:

- Recognize the signs of overdose
- Understand the importance of calling 911
- Perform rescue breathing
- Administer intranasal naloxone
- Obtain treatment for substance abuse and misuse

Participants: Injection drug users and others at risk of opioid overdose, receiving prescribed naloxone

Research Results: None available.

Overdose Prevention Project, Prevention Point Pittsburgh

Goals:

- Teach people who use drugs how to prevent and respond to overdose
- Reduce obstacles to calling 911
- Make naloxone directly accessible to individuals who use drugs and are most often present when overdoses occur

Participants: 336 individuals likely to be at risk of opioid overdose or likely to be present, receiving prescribed naloxone

Research Results: Survey of 173 program participants who used naloxone:

- 172 reported successful use of naloxone
- One death reported – suspected suicide
- 90 reported performing rescue breathing in addition to naloxone administration (61%).
- Evaluation of program found no increase in drug use among program participants as a result of having naloxone
- Out of 153 cases where 911 was not called, 95 (72%) gave the reason for not calling 911 as “fear of police involvement” (Prevention Point Pittsburgh, 2007).

Staying Alive, Baltimore, MD

Goals: Teach participants how to:

- Prevent overdose
- Recognize overdose symptoms
- Perform rescue breathing
- Call 911
- Administer naloxone

Participants: 85 injection drug users receiving Staying Alive training

Research Results:

- 43 participants reported having witnessed an overdose
- Post-training, naloxone was administered by 19 with no reported adverse effects
- Post-training, a greater proportion of participants reported using resuscitation skills taught in the SA program along with increased knowledge specifically about naloxone
- “Results from this study provide additional evidence to support the effectiveness of overdose prevention training programs that include skills building for drug users to administer naloxone” (Tobin et al., 2009)

Skills and Knowledge on Overdose Prevention (SKOOP), New York, NY

Goals:

- Reduce overdose-related deaths through the distribution of naloxone hydrochloride to injection drug users in NYC
- Build evidence for the effectiveness of take-home naloxone in harm reduction settings
- Create wider support for the inclusion of naloxone in harm reduction, methadone, and other public health programs

Participants: 1004 injection drug users, 122 participating in the research arm of the program. All were given a prescription for naloxone by a physician. Participants in SKOOP were over the age of 18 and current or former drug users.

Research Results:

- 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 (Piper et al., 2008)

England, United Kingdom

Goal: Train participants in overdose management and naloxone administration

Participants: 239 opiate users, recruited from across 20 drug services in England. Eighty (34%) were attending in-patient services, 149 (62%) attending out-patient services and 10 (4%) attending criminal justice intervention programs in the South East, South West, Midlands and North of England.

Research Results:

- Training in management of overdose can be given successfully to drug users in treatment, resulting in substantially improved knowledge and competence
- The training is followed by implementation in subsequent overdose situations, detectable even within a 3-month follow-up period
- No unexpected adverse reactions were identified
- Beyond the high numbers of drug users trained within the clinical services, this knowledge was spread further to family and peers
- There is considerable evidence of benefit to others—drug-users other than the patient to whom the naloxone was given (Strang et al., 2008)

Factors influencing implementation of naloxone distribution programs:

Training:

“Receipt of training and higher perceived competency in recognizing signs of an opioid overdose were associated independently with higher overdose recognition scores. Trained respondents were as skilled as medical experts in recognizing opioid overdose situations (weighted kappa = 0.85) and when naloxone was indicated (kappa = 1.0). Results suggest that naloxone training programs in the United States improve participants’ ability to recognize and respond to opioid overdoses in the community. Drug users with overdose training and confidence in their abilities to respond may effectively prevent overdose mortality”. (Green et al., 2008).

Attitudes of Providers and First Responders

“Overall attitudes [of first responders] toward training drug users to administer naloxone were negative with 56% responding that this training would not be effective in reducing overdose deaths” (Beletsky, 2008).

Provider concerns included drug users’ inability to properly administer the drug, program condoning and promoting drug use, and unsafe disposal of used needles. Incorporating information about substance abuse and harm reduction approaches in continuing education classes may improve the attitudes of provider toward naloxone training programs (Tobin et al., 2009).

“Less than one in four of the respondents in our sample [physicians] reported having heard of naloxone prescription as an intervention to prevent opiate overdose, and the majority reported that they would never consider prescribing the agent and explaining its application to a patient. Factors predicting a favorable attitude towards prescribing naloxone included fewer negative perceptions of IDUs, assigning less importance to peer and community pressure not to treat IDUs, and increased confidence in ability to provide meaningful treatment to IDUs. Our data suggest that steps to promote naloxone distribution programs should include physician education about evidence-based harm minimization schemes, broader support for such initiatives by professional organizations, and policy reform to alleviate medico-legal concerns associated with naloxone prescription. FDA re-classification of naloxone for over-the-counter sales and promotion of nasal-delivery mechanism for this agent should be explored” (Ruthhauser et al., 2007).

Privacy and Legal Liability Concerns:

“Research in the domain of heroin use suggests that witnesses to overdose involving illegal drugs are reluctant to call 911 out of fear of police involvement and mistrust of health care providers” (Beletsky, 2008).

“A number of states have initiated ‘good Samaritan’ laws to protect from legal recourse citizens who carry and administer naloxone and medical professionals who prescribe it (e.g. Connecticut, Illinois, New York)” (Green et al., 2008).

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Summary of Discussions with Naloxone Distribution Program Representatives

Maya Doe-Simkins, MPH; Boston Medical Center

Program operated by Boston Public Health Commission

- Authorized in 2006, by Boston Public Health Commission (BPHC) regulation
- Intranasal naloxone education and distribution of the spray to potential bystanders
- Participants taught by trained nonmedical needle exchange staff
- After 15 months, the program provided training and intranasal naloxone to 385 participants who reported 74 successful overdose reversals
- Results published in *Am J Public Health*. 2009;99:788-791. doi:10.2105/AJPH.2008.146647.

Key Findings:

Needle-exchange participants experienced and witnessed high rates of overdoses.

Needle-exchange participants successfully recognized overdose and used intranasal naloxone to reverse potentially fatal opioid overdoses.

Overdose prevention programs can provide training and distribute intranasal naloxone without a direct clinical health care provider-patient encounter.

Overdose prevention programs that include the distribution of intranasal naloxone by nonmedical personnel are feasible for city public health departments.

Issues to Consider Relative to Montgomery County:

- BPHC distribution program population is more African-American, male, heroin injecting
- IN is standard
- Program going state wide

Nabarun Dasgupta, Department of Epidemiology, University of North Carolina

Program: Project Lazarus Wilkes County, North Wilkesboro, North Carolina

<http://www.harmreduction.org/downloads/North%20Carolina%20Naloxone%2007.pdf>

- Funded by the Northwest Community Care Network (NCCN, the regional Medicaid authority), Drug Policy Alliance, Wilkes County Health Department, doctor's offices and the pharmaceutical industry

- Started in 2008
- No published peer reviewed evaluation

Key Initial Finding:

Project Lazarus estimates that if a single hospital encounter were prevented, a savings of \$20,468 to \$31,083 would be realized, including prevention of productivity loss.

Issues to Consider Relative to Montgomery County:

- Similar population demographics and drug use patterns
- Much more rural
- Program engages doctors and other prescribers
- Requires watching 20 minute video prior to receiving naloxone
- Requires designating family member or other to receive education
- Education conducted at physician's office or point of sale (retail pharmacy)

Naloxone Fact Sheet

Published by: Harm Reduction Coalition

Available at: <http://www.harmreduction.org/article.php?id=529>

Naloxone (also known as Narcan®) is a medication used to counter the effects of opioid overdose, for example morphine and heroin overdose. Specifically, naloxone is used in opioid overdoses to counteract life-threatening depression of the central nervous system and respiratory system, allowing an overdosing victim to breathe normally. Naloxone is a nonscheduled (i.e., non-addictive), inexpensive (less than \$2 per dose) prescription medication with the same level of regulation as prescription ibuprofen. Naloxone only works if a person has opioids in their system; the medication has no effect if opioids are absent.

Although traditionally administered by emergency response personnel, naloxone can be administered by minimally trained laypeople, which makes it ideal for treating overdose in people who have been prescribed opioid pain medication and in people who use heroin and other illicit opioids.

The federal Centers for Disease Control and Prevention reports that drug overdose is a growing problem and that the rate of deadly drug overdoses has increased nearly 70% since 1999. Overdose is second only to motor vehicle crashes as the leading cause of unintentional injury death in the United States. It is the leading cause of death among people who inject drugs, and increasingly common among individuals taking prescription narcotics.

Naloxone Distribution Programs

In most jurisdictions naloxone is only available to people experiencing overdose when emergency medical services are summoned. However, recognizing that many fatal opioid overdoses are preventable, a number of jurisdictions in California and throughout the United States are providing overdose prevention, recognition, and response training. These include training in calling 911, performing rescue breathing, and take-home prescriptions of naloxone to drug users and their community.

Studies indicate that many victims of opioid overdoses never receive proper medical attention because their peers and other witnesses (who are often drug users themselves) do not call 911, for fear of police involvement. While not all opioid overdoses are fatal, the provision of naloxone to those who would otherwise not receive it could save hundreds of lives each year. Additionally, timely provision of naloxone may help reduce some of the morbidities associated with non-fatal overdose. Witnesses who are able to provide rescue breathing and naloxone to an overdose victim experiencing respiratory depression will likely prevent brain damage in the victim (brain damage begins within 3-5 minutes after someone stops breathing).

In Cook County Illinois, the first naloxone distribution program in the United States, operated by the Chicago Recovery Alliance, helped to bring down the number of overdose deaths from

466 in 2000 to 324 in 2003. Dan Bigg, director of the program, said that since 1997 they have reported at least 745 episodes of reversed opiate overdoses—most or all of which would have been fatal.

Since November 2003 the Harm Reduction Coalition's Drug Overdose Prevention & Education Project has collaborated with the San Francisco Department of Public Health to provide overdose prevention, recognition, and response training as well as naloxone prescriptions to over 1,100 drug users and has heard back from over 270 of them that they have used naloxone to reverse an overdose.

Policy Reform to Support Effective Opioid Overdose Response

Although naloxone has no effect on someone not on opioids and has almost no side effects when administered to someone on opioids, other than the effects of withdrawal in opioid-dependent individuals, some clinicians are concerned about providing take-home naloxone for use by lay people. Clinicians voice concerns that patients may use naloxone on a third party experiencing and overdose and, in the event of an adverse reaction, the clinician could be held liable.

In New York, New Mexico, and Connecticut legislation was enacted to address the issue of health care provider and third party liability. This legislation provides specific immunities to health care providers and third persons who are involved in the distribution and/or administration of naloxone. For example, it is well documented that many drug users fear calling 911 to summon emergency medical response for fear of police involvement. New Mexico's Good Samaritan legislation provides limited immunity from prosecution for a person who seeks or obtains medical assistance for a drug-related overdose. In New York State, the naloxone liability legislation passed unanimously and the Governor signed the bill into law without opposition from constituent groups.

California Senate Bill (SB) 767, the Overdose Treatment Liability Act, was signed by Governor Schwarzenegger and went into effect on January 1, 2008. Senator Ridley Thomas' bill, cosponsored by the Harm Reduction Coalition (HRC), the County of Los Angeles, and the Los Angeles Overdose Taskforce creates a 3 year pilot project in seven counties: Alameda, Fresno, Humboldt, Los Angeles, Mendocino, San Francisco, and Santa Cruz, to authorize overdose prevention programs and protect providers who prescribe take-home naloxone to people who use opiates and may be at risk of an overdose. While the legislation does not protect a third party who administers naloxone in an overdose event, the legislation will encourage more medical providers to prescribe and dispense this life-saving drug in California.

To support effective overdose response among communities of illicit drug users, policy reforms are essential. Amnesty from arrest and/or prosecution for those who witness an overdose and summon emergency medical services is required. Funding is needed to sustain or expand current naloxone distribution programs and create new programs in areas where none exist. Best practices and training guidelines that encourage and support overdose prevention in a variety of harm reduction and primary care settings should be culled and distributed by both

federal and local health jurisdictions. Finally, national, state, and local surveillance of drug-related overdoses is necessary in providing the most immediate and effective overdose prevention strategies to licit and illicit opioid users.

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Overview of Naloxone Effectiveness, Costs, and Barriers to Use

1. Effectiveness and Cost Effectiveness of Naloxone Distribution

Reversal Rates from Various Naloxone Distribution Programs

New York City Department of Health and Mental Hygiene:

3% (25 overdose reversals among 754 trainees provided with kits) during the first six months of program implementation

7% (104/1,485) after 12 months.

9% (162/1,800) after 18 months

Drug Overdose Prevention and Education (DOPE) Project, San Francisco: 24% (170/700)

Staying Alive, Baltimore, MD: 14% (131/951)

Chicago Recovery Alliance: 7% (446/6,000)

Heller, D.I. & Stancliff, S. (2007). Providing naloxone to substance users for secondary administration to reduce overdose mortality in New York City, *Public Health Reports*, 122 (3), 393-397.

Cost Effectiveness, Project Lazarus, Wilkes County, North Carolina

Mean cost of inpatient hospitalization for accidental prescription opioid poisoning in North Carolina: \$12,379 (Agency for Healthcare Research and Quality, 2007).

Loss of productivity due to poisoning in US: \$18,704 (Corso, Finkelstein et al. 2006).

Project Lazarus estimates that if a single hospital encounter were prevented, a savings of \$20,468 to \$31,083 would be realized, including prevention of productivity loss.

<http://www.harmreduction.org/downloads/North%20Carolina%20Naloxone%2007.pdf>

2. Cost Estimates for Naloxone Distribution in Ohio

a. Injectable Naloxone; \$1-2 per dose (usually two doses provided)

b. Intra-nasal Naloxone Kit: \$25-30

3. Prescription Status of Naloxone

Beletsky, L., Burris, S., & Kral A. (2008). *Closing death's door: Action steps to facilitate emergency opioid drug overdose reversal in the United States*. A Conference Report from the Center for Health Law, Politics and Policy Temple University Beasley School of Law.

Although it is an opioid derivative, naloxone is not classified as a controlled substance in Ohio. This reduces the level of regulatory control over its possession and use, but the drug is still classified by the FDA as requiring a prescription.

The prescription requirement creates several hurdles for naloxone distribution programs. First, it means programs must have medical personnel authorized to issue prescriptions, which can raise costs and add logistical complexity. Because health professionals have to be involved, these programs must deal with practitioner concerns about malpractice liability. Second, before the drug can properly be provided to an overdose prevention program participant, a licensed healthcare professional authorized to issue prescriptions must complete an exam or another interaction with a patient (as required by state law) and give the patient information about the indications for the drug, its proper use, and its risks and benefits. While some of these functions can be delegated to allied health providers working under standing orders or other appropriate practice guidelines, the medical model is cumbersome and limits the discretion of programs to follow other procedures that may be appropriate and supported by evidence. In some states medical boards have agreed to an abbreviated medical encounter for naloxone prescribing, similar to the reduced requirements underlying community-based seasonal influenza vaccination. Many states make it a crime to possess a prescription drug without a prescription, so participants in naloxone distribution programs are potentially in jeopardy if they do not have, or fail to carry, a prescription.

Finally, the prescription requirement limits who takes part in overdose prevention programs. In strict legal terms, a prescription is only appropriate if it is issued to a patient for the patient's own medical need. A lay person who is not a drug user but is trained to help others at risk of overdose, strictly speaking, has no personal medical need for the drug. Moreover, providing naloxone under those terms would amount to deputizing the lay person as a medical practitioner, which contravenes the basic idea of licensure and criminal laws that prohibit the unlicensed practice of medicine.

Though unlikely to give rise to real legal problems in fact, concerns about issues related to naloxone's prescription status present obstacles for the planning and implementation of overdose education and prevention initiatives. The limitation on prescribing to lay persons has been a particular problem, holding up the start of programs for months or years in some places.

4. Good Samaritan Laws

<http://www.ohioabar.org/Pages/LawYouCanUseDetail.aspx?itemID=477>

Ohio's Law

a. **Q.: What is the "Good Samaritan" law?**

A.: The "Good Samaritan" law provides certain protection from lawsuits to people who give first aid or other emergency care or treatment to someone suffering an injury or sudden illness. This statute is listed in the Ohio Revised Code, Section 2305.23.

b. **Q.: Under what circumstances does the Good Samaritan law apply?**

A.: The care or treatment must be given at the scene of an emergency outside of a hospital, doctor's office, or other medical facility. The law protects volunteers who help when someone becomes ill or is injured in places such as on the street or highway, in parks, restaurants, businesses, even private residences. If someone is already at a hospital or other medical facility, the law does not apply.

c. **Q.: Are there any limits to the protection of the Good Samaritan law?**

A.: The law does not protect against lawsuits or criminal charges for "willful or wanton" (intentional or malicious) misconduct. Examples of willful or wanton misconduct would include stealing from an accident victim or inappropriate sexual touching.

Also, if the person providing the emergency care or treatment is paid or expects to get paid for giving the care or treatment, whether by the victim or someone on behalf of the victim (such as an insurance company), the Good Samaritan law does not provide protection. This is because a person who is paid generally is not considered a volunteer, and the Good Samaritan law is intended to protect those who volunteer in emergencies. The statute provides one exception to this not-being-paid rule: An on-duty police officer or fire fighter who gives emergency care or treatment may be covered by the Good Samaritan law. The reasoning is that, even though the police officer or firefighter is being paid by the department for working a shift (or responding to a call-out in the case of volunteer firefighters), payment is not being provided specifically for giving care to a particular individual in an emergency.

d. **Q.: Does the Good Samaritan law protect doctors, nurses, and other health care professionals?**

A.: Yes, if the health care professional volunteers her/his services at the scene of an emergency that is outside a hospital, doctor's office or other medical facility. However, a professional who seeks payment for this volunteer emergency care or treatment loses the protection under the Good Samaritan law.

Ohio does not have a Good Samaritan Law specifically designed to protect people who report an overdose.

New Mexico was the first state with a Good Samaritan Law to protect people who report an overdose, passed in 2007. Washington passed such a law in 2010. According to the National Conference of State Legislatures, Hawaii, Massachusetts, Minnesota, and Rhode Island are considering similar measures.

Under Washington's law, if someone seeks assistance for an individual who has overdosed, neither party can be prosecuted for drug possession. Good Samaritans could, however, be charged with manufacturing or selling drugs. The bill also allows people to use naloxone, if it is used to help prevent an overdose.

5. Legal and Regulatory Barriers to Implementing an Overdose Prevention Program With *Intranasal* Naloxone Distribution by Nonmedical Personnel

Seal, K. H., Thawley, R., Gee, L., Bamberger, J., Kral, A. H., Ciccarone, D., Downing, M., & Edlin, B. R. (2005). Naloxone distribution and cardiopulmonary resuscitation training for injection drug users to prevent heroin overdose death: A pilot intervention study. *Journal of Urban Health, 82* (2), 303-11.

Barrier:

Nonmedical personnel are not authorized to distribute prescription medication and are not authorized to administer a prescription medication to a person who has not been prescribed the medication.

Response:

The standard of care for the use of naloxone has for decades included use by pre-hospital personnel in nonclinical settings operating under standing orders from physicians who are neither on-site nor directly supervising.

Other life saving prescription medications, such as epinephrine injectors for anaphylactic shock, and other devices, such as automated external defibrillators, are used by bystanders and nonmedical personnel.

Other states, such as New Mexico, New York and Connecticut, have addressed this by passing laws that limit the liability of medical and nonmedical personnel who administer and distribute potentially lifesaving medication.

A study of 6 programs that train bystanders to recognize and respond to opioid overdose by using naloxone has demonstrated that trained potential bystanders are similarly skilled as medical experts in recognizing opioid overdose situations and when naloxone is indicated.

A local public health regulation was passed by BPHC, the City of Boston's board of health, identifying the overdose-prevention naloxone distribution program as an official public health program and assuming liability for the work of medical and non-medical personnel involved in the program. Under the medical license of the Medical Director of Boston Emergency Medical Services, potential bystanders received a standard curriculum about overdose prevention with instructions and demonstration of how to properly use the medication. Receipt of this curriculum was documented by BPHC staff.

Barrier:

Intranasal delivery of naloxone is an off-label method.

Response:

Prescriptions drugs may be and are routinely given for any indication not explicitly prohibited by law.

While no large scale randomized clinical trials have been conducted, intranasal naloxone has been evaluated in several research studies, with little evidence of adverse events. A small randomized trial comparing intranasal with intramuscular delivery of naloxone used by emergency personnel demonstrated that intranasal delivery had a longer time to clinical response (8 minutes vs 6 minutes), but less agitation or irritation (2% vs 13%).

Intranasal naloxone is a first-line treatment for opioid overdose among emergency medical personnel in the local Boston community.

Potential Training Activities, 2011

The Coalition engaged in a variety of training activities in 2010—coalition member, prescriber, and first responder needs assessments, small group training, and a community on-line symposium. Based on a review of those activities, we anticipate conducting the following activities in 2011:

1. Needs Assessment:
 - a. Increase understanding of local issues bearing on drug overdoses and inform training activities by using on-line surveys of:
 - i. Pharmacists
 - ii. Substance abuse treatment providers
 - iii. Community-at-large
 - b. Evaluate Dayton Area Drug Survey data to inform involvement of health care providers in curriculum development for Miami Valley area high school students.
 - c. Evaluate symposium responses to determine effectiveness of the on-line symposium and determine next steps relative to on-line efforts.
 - i. On-line training for OARRS
 - ii. On-line training of medical students, emergency department personnel, first responders (especially concerning issues bearing on naloxone distribution), dentists
 - iii. Consider CEUs and BRCHs for providers
2. Using November brief OARRS training as a model, implement OARRS training:
 - a. WSU medical students
 - b. Emergency department physicians
 - c. Grand Rounds and other venues
3. Conduct four unintentional prescription drug overdose-related training sessions:
 - a. WSU medical students
 - b. Grand Rounds at area hospitals
 - c. First responder training through the Emergency Medical Services Council
4. Publicize Coalition web site as resource for community, with video links.

General Recommendations

The Montgomery County Unintentional Poisoning Death Coalition makes the following recommendations:

1. Needs Assessment & Training
 - a. Increase understanding of local issues bearing on drug overdoses by using on-line surveys and training modules:
 - i. Physicians
 - ii. Dentists
 - iii. First Responders
 - iv. Pharmacists
 - v. Substance abuse treatment providers
 - vi. Community-at-large.
 - b. Using November brief OARRS training as a model, implement OARRS training with medical students, physicians, dentists, podiatrists.
 - c. Evaluate responses to symposium to determine effectiveness of on-line symposium and determine next steps relative to on-line efforts.
 - d. The Dayton Area Drug Survey identifies increases in use of tranquilizers and prescription opiates by Miami Valley area high school students. This suggests an opportunity for developing curricula for area schools.
2. Poison Death Review
 - e. Pursue possible electronic data transfer from Montgomery County Coroner's Office to WSU.
 - f. Continue currently established PDR process.
 - g. Continue routine summary of data for Coalition.
3. Other
 - h. Analyze Greater Dayton Area Hospital Association data on overdoses.
 - i. Conduct ethnographic interviews with survivors of prescription opioid overdoses, *if feasible*.

Recommendation on Naloxone Education and Distribution

The Montgomery County Unintentional Prescription Drug Poisoning Coalition recommends deferring on a recommendation on the establishment of a naloxone education and distribution program in Montgomery County until additional study can be completed. The Coalition recognizes that naloxone education and distribution may be an effective method of preventing opioid overdose deaths among non-medical pain pill users; however, a number of issues regarding the establishment of such a program are unresolved, precluding a recommendation at this time. The following issues were of primary importance in the decision to continue to examine the issue:

1. The suitability of naloxone education and distribution for the population of Montgomery County residents who are in danger of experiencing fatal overdoses is as of yet uncertain because:

- a. Poly-drug users with high rates of prescription opioid use, frequent exposure to sedatives (including frequent exposure to benzodiazepines along with opioids), and few instances of uncomplicated heroin overdose, may not benefit from naloxone programs as currently operated.

Our Poison Death Reviews of selected 2008 and 2009 cases, the coalition's examination of the 2010 deaths from January 1 - September 15, and a preliminary overview of hospital visits for overdoses, reveal drug use patterns that are significantly different from the heroin injection use which has been successfully addressed by naloxone distribution programs in several locales.

- b. There is a relatively low incidence of overdose that might have been prevented by family members or fellow users having access to naloxone.

Of the 81 Montgomery County drug-related OD death cases reviewed so far in 2010, approximately 85% were judged unlikely to have been prevented by the use of an opioid antagonist. In these instances, the Poison Death Review indicated that: (1) the decedent was alone at the time of the overdose; or (2) bystanders or family members were not in the position to notice the symptoms of overdose during the period when opioid antagonists could have been effective.

- c. Based on our survey of first responders, it appears that the majority of professionals who directly respond to overdoses in Montgomery County, and who, therefore, are in a position to understand the possible impact of naloxone use by the public, have a very negative view of the propriety or potential effectiveness of naloxone distribution.

First responders thought that overdose was a significant problem, but they were very pessimistic about the suitability or effectiveness of a naloxone distribution program.

2. Additional information and data may help clarify the appropriateness of naloxone distribution for Montgomery County. This will include:
 - a. Examination of additional coroner cases to see if a higher percentage of cases where naloxone might help emerges;
 - b. Reviewing peer-reviewed results of current naloxone programs in Boston and North Carolina, which may be available in the coming year;
 - c. Further measures to bring clarity to the issue might include:
 - i. Ethnographic interviews with OD survivors
 - ii. Further on-line surveys (community- at- large, pharmacists, others)
 - iii. Community symposium to discuss naloxone
 - iv. First responder/prescriber/pharmacist education and focus groups.
3. If further examination of the county's unintentional poisoning data, results from interviews and surveys, and positive published results from other naloxone programs indicates that naloxone distribution might be an appropriate way to reduce unintentional OD fatalities, other significant issues to establishing a naloxone distribution program in Montgomery County need to be addressed. Some of these are:
 - a. Garnering support from the health care community
 - b. Garnering widespread community support. This might include:
 - i. Surveying community attitudes and support for naloxone distribution
 - ii. Education to increase community familiarity with purposes and mechanisms of a naloxone distribution program
 - iii. Identifying or building an infrastructure to support a naloxone distribution program. Unlike Boston, which has a needle exchange programs, or Wilkes County, NC, where there is direct recruitment through a small number of prescribers, there is no ready-made infrastructure for such a program in Montgomery County.
 - c. Financial support is necessary. Funds are in short supply at this time.

Potential Alternative Approach

One alternative to traditional naloxone distribution programs that was discussed by the coalition and merits further consideration is predicated on naloxone education delivered by, or through, prescribers and/or pharmacists, and a naloxone prescription that is paid for by a drug user (or his/her family). Thus, the cost (intra-nasal naloxone is approximately \$30 for the customary 2 dose kit; injectable naloxone is typically supplied in two syringes, at a cost of around \$2 per dose) would be borne by those use the service. Epinephrine injections for bee stings is an instructive model here.

A recommendation on naloxone education and distribution will be made by the end of Year 2 of the project.