

The 2016 FDA Naloxone App Competition Resources for Participants

The Epidemic of Opioid Abuse

What is the opioid epidemic?

- Office of National Drug Control Policy (ONDCP) Fact Sheet: https://www.whitehouse.gov/sites/default/files/ondcp/opioids fact sheet.pdf
- Department of Human Health Services (HHS) About the Epidemic: http://www.hhs.gov/opioids/about-the-epidemic/index.html
- HHS The Opioid Epidemic Fact Sheet:
 http://www.hhs.gov/sites/default/files/Factsheet-opioids-061516.pdf
- Centers for Disease Control and Prevention (CDC) Understanding the Epidemic: http://www.cdc.gov/drugoverdose/epidemic/index.html

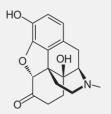


What is the government doing about the opioid epidemic?

- President's National Drug Control Strategy Prescription Drug Abuse (2011): https://www.whitehouse.gov/sites/default/files/ondcp/ndcs2011.pdf
- President's National Drug Control Strategies (2010-2015):
 https://www.whitehouse.gov/ondcp/national-drug-control-strategy
- HHS Opioid Initiative:
 - https://aspe.hhs.gov/sites/default/files/pdf/107956/ib_OpioidInitiative.pdf
- FDA Opioids Action Plan to Address the Prescription Opioid Crisis:
 http://www.fda.gov/downloads/NewsEvents/Newsroom/FactSheets/UCM484743.pdf
- Substance Abuse and Mental Health Services Administration (SAMHSA): http://www.samhsa.gov/atod/opioids
- Veterans Affairs Opioid Safety Initiative Toolkit: http://www.va.gov/PAINMANAGEMENT/Opioid Safety Initiative Toolkit.asp

The Biology of Opioid Abuse

How do opioids work?



- HHS: http://www.hhs.gov/opioids/drug-and-pain-medication-facts/index.html
- SAMHSA: http://www.samhsa.gov/atod/opioids
- NIH-National Institute on Drug Abuse (NIDA):
 https://www.drugabuse.gov/publications/research-reports/prescription-drugs/opioids
- CDC: http://www.cdc.gov/drugoverdose/opioids/index.html

How many types of opioids are there?

- FDA Medication Guides: http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm
- Dailymed via U.S. National Library of Medicine: https://dailymed.nlm.nih.gov/dailymed/index.cfm
- MedlinePlus via U.S. National Library of Medicine: https://medlineplus.gov/

How is opioid abuse treated?

- HHS Treatment and Recovery: http://www.hhs.gov/opioids/treatment-and-recovery/index.html
- HRSA Find a Health Center for Substance Abuse Services: http://bphc.hrsa.gov/index.html
- SAMHSA Medication-Assisted Treatment for Substance Use Disorders: http://dpt2.samhsa.gov/treatment/directory.aspx
- NIDA How do I know if my adult friend or loved one has a substance abuse problem?
 https://www.drugabuse.gov/related-topics/treatment/what-to-do-if-your-adult-friend-or-loved-one-has-problem-drugs

All About Naloxone

What is naloxone?

- Drugs@FDA: http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm
- Dailymed:
 - o Injection: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=76f7eee1-d524-43a4-a868-ffa9f29638a6
 - o Nasal Spray: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=724df050-5332-4d0a-9a5f-17bf08a547e1
- MedlinePlus:
 - o Injection: https://medlineplus.gov/druginfo/meds/a612022.html
 - o Nasal Spray: https://medlineplus.gov/druginfo/meds/a616003.html
- HHS- Naloxone: https://chemm.nlm.nih.gov/countermeasure_naloxone.htm
- FDA Public Workshop (7/1/15-7/2/15): Exploring Naloxone Uptake and Use: http://www.fda.gov/Drugs/NewsEvents/ucm442236.htm
- FDA Public Workshop (4/12/12): Role of Naloxone in Opioid Overdose Fatality Prevention: http://www.fda.gov/Drugs/NewsEvents/ucm277119.htm

How is naloxone used to reverse the effects of an opioid overdose?

- NIDA Naloxone Webpage: https://www.drugabuse.gov/drugs-abuse/opioids/naloxone
- SAMHSA Opioid Overdose Prevention Toolkit: http://store.samhsa.gov/product/Opioid-Overdose-Prevention-Toolkit-Updated-2016/SMA16-4742
- FDA FDA moves quickly to approve easy-to-use nasal spray to treat opioid overdose: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm473505.htm



What kinds of people carry naloxone?

- CDC Morbidity and Mortality Weekly Report Opioid Overdose Prevention Programs Providing Naloxone to Laypersons: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6423a2.htm
- Harm Reduction Coalition First on the Scene: People Who Use Drugs, their Families and their Friends: http://www.fda.gov/downloads/Drugs/NewsEvents/UCM454749.pdf
- CDC Naloxone Use by EMS Providers: http://www.fda.gov/downloads/Drugs/NewsEvents/UCM454805.pdf
- Department of Justice Saving Lives in New Ways: Law Enforcement's Role in Preventing Overdose Deaths: http://www.fda.gov/Drugs/NewsEvents/ucm442236.htm



Whore can	l find data	a on opioid use?	
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National Survey on Drug Use	NSDUH is the primary source of information on the prevalence, patterns, and consequences of alcohol, tobacco,
and Health (NSDUH):	and illegal drug use and abuse and mental disorders in the U.S. civilian, noninstitutionalized population aged 12 or
	older. The survey generates nationally representative estimates at the national, state, and sub-state levels.
	NSDUH includes several data elements relevant to heroin use and prescription pain reliever misuse, including the
	prevalence of use, abuse, or dependence; age at initiation; receipt of treatment; and perceived risk from use.
	http://www.samhsa.gov/data/population-data-nsduh

CMS Medicare Part D Opioid Drug Mapping Tool:

Interactive mapping tool that shows geographic comparisons, at the state, county, and local levels, of deidentified Medicare Part D opioid prescription prescriptions written and submitted to be filled within the United States.

https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/OpioidMap.html

Monitoring the Future (MTF):

MTF is an annual survey funded by the National Institute on Drug Abuse, and designed to assess beliefs, attitudes, and behaviors of young people in the United States. The survey targets 8th, 10th, and 12th graders, college students, and young adults, and includes questions on illicit drug use and prescription opioid abuse. http://www.monitoringthefuture.org/data/data.html

CDC - National Health and Nutrition Examination Survey:

The National Health and Nutrition Examination Survey (NHANES) is a program of studies designed to assess the health and nutritional status of adults and children in the United States. The survey is unique in that it combines interviews and physical examinations.

http://wwwn.cdc.gov/Nchs/Nhanes/Search/Nhanes15_16.aspx

Where can I find data on opioid overdoses and deaths?

CDC - Drug Overdose and Website of Prescription Opioid Overdose statistics.

Prescribing Data:	http://www.cdc.gov/drugoverdose/data/index.html
CDC - Web-based Injury Statistics Query and Reporting System (WISQARS):	CDC's WISQARS™ (Web-based Injury Statistics Query and Reporting System) is an interactive, online database that provides fatal and nonfatal injury, violent death, and cost of injury data from a variety of trusted sources. https://www.cdc.gov/injury/wisqars/

National Vital Statistics System (NVSS):

The National Vital Statistics System is a repository for vital statistics for the United States, obtained from official records of live births, deaths, marriages, divorces, and annulments. A 2016 CDC report analyzing NVSS drug overdose data is available at the Morbidity and Mortality Weekly Report below. http://www.cdc.gov/nchs/nvss/index.htm

http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm

Where can I find healthcare data related to opioid use?

Healthcare Cost and Utilization Project (HCUP) Databases: HCUP is the Nation's most comprehensive source of hospital data, including information on in-patient care, ambulatory care, and emergency department visits. HCUP enables researchers, insurers, policymakers and others to study health care delivery and patient outcomes over time, and at the national, regional, State, and community levels.

http://www.hcup-us.ahrq.gov/databases.jsp

Centers for Medicare and Medicaid Services (CMS) -Data Navigator: The CMS Data Navigator application is an easy-to-use, menu-driven search tool that makes the data and information resources of the Centers for Medicare and Medicaid Services (CMS) more easily available. A Data Navigator enables researchers to find data and information products for specific CMS programs, such as Medicare and Medicaid, or on specific health care topics or settings-of-care.

https://www.cms.gov/research-statistics-data-and-systems/research-statistics-data-and-systems.html

CMS - Basic Stand Alone (BSA) Medicare Claims Public Use Files (PUFs): CMS provides access to its Medicare claims data through the release of de-identified data files available for public use. These files are available to researchers as free downloads in CSV format. They contain non-identifiable claim-specific information and are within the public domain.

https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/BSAPUFS/index.html?redirect=/BSAPUFS

SAMHSA - Emergency Department Data (DAWN): DAWN was established by the Drug Enforcement Administration to track emergency department visits caused by drug abuse in order to identify the drugs being abused, determine patterns in selected metropolitan areas and changing trends across the country, including the detection of new substances of abuse and new combinations. http://www.samhsa.gov/data/emergency-department-data-dawn



Where can I find data related to substance abuse treatment?

The National Survey on Substance Abuse Treatment Services (N-SSATS):

N-SSATS is an annual census designed to collect information from all public and private treatment facilities in the United States that provide substance abuse treatment. Among the data elements included in N-SSATS relevant to opioids are annual national and state single-day counts of the number of clients in substance abuse treatment who received medication-assisted therapy (e.g., methadone, buprenorphine) for prescription opioids misuse. http://www.samhsa.gov/data/substance-abuse-facilities-data-nssats/

SAMHSA - Treatment Episode Data Set (TEDS):

TEDS contains the demographic characteristics and substance abuse problems of persons admitted to treatment facilities in the United States. TEDS includes several data elements relevant to heroin use and prescription pain reliever misuse, including the number of admissions to treatment for opioid use, usual route of opioid administration, and co-occurring mental health issues.

http://www.samhsa.gov/data/client-level-data-teds

Where can I find data on EMS and 911?

National EMS Information System (NEMSIS):

NEMSIS collects data from local and states agencies across the nation to facilitate sharing and analysis of EMS information.

http://www.nemsis.org/