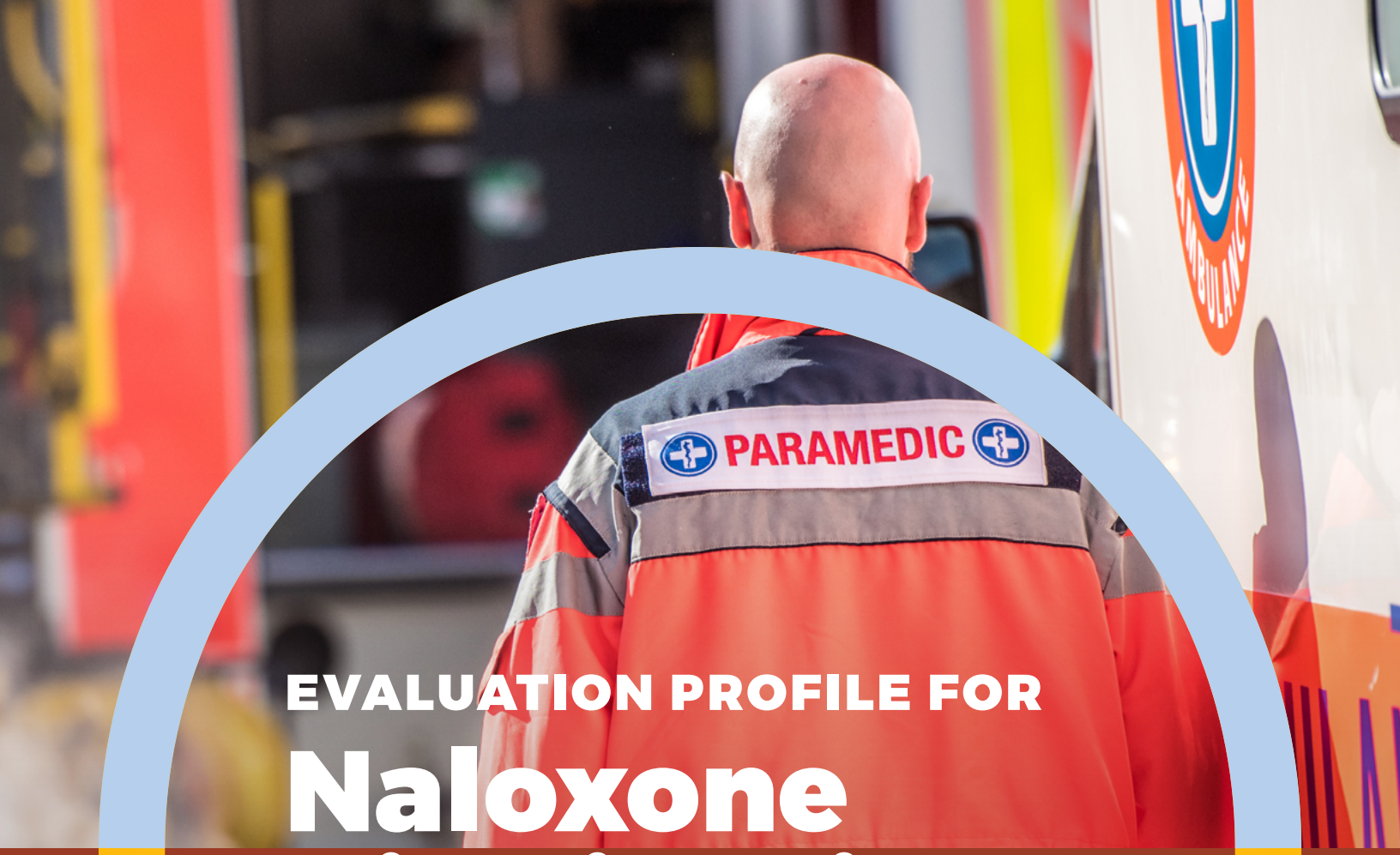

EVALUATION PROFILE FOR

Naloxone Distribution Programs

OVERDOSE DATA2ACTION

Centers for Disease Control and Prevention
National Center for Injury Prevention and Control

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ACKNOWLEDGEMENTS

We acknowledge the following individuals and organizations who contributed to developing, writing, and reviewing this evaluation profile:

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Purpose of the Evaluation Profile

This evaluation profile PROVIDES GUIDANCE in designing evaluations of targeted naloxone distribution.

This resource is meant to demonstrate how to conduct evaluations, in many cases using existing programmatic data, to produce actionable and timely findings. These findings will be used to inform program managers and stakeholders about how well initiatives are being implemented, and how effective they are at bringing about desired outcomes. This profile provides guidance on the types of evaluation questions, indicators, data sources, and data collection methods that can be used to evaluate a given prevention activity.

EVALUATION CONSIDERATIONS

CDC funded entities[1] should tailor their evaluations to stakeholder needs and the stage of development for each activity. Evaluations should serve programmatic needs to ensure high-quality initiatives are developed, reach program goals, and are tested for effectiveness.

The evolving nature of drug overdoses requires that programs strategically pivot to address emerging needs. Evaluators should remain vigilant to changing needs and look for ways to provide practical and actionable information to program implementers and decision makers.[2] Decisions surrounding the level of rigor needed for a given evaluation should be weighed and balanced by the evaluation standards of utility, feasibility, propriety, and accuracy.[3] Examples are provided throughout the profiles to show where less rigorous, but potentially more accessible, data (e.g., discussions with stakeholders, program recipient logs, meeting notes) may be useful in evaluations.

CONTENT ORGANIZATION

The following items are included:

1. **Evaluation Profile**
   The profile is organized by process and outcome evaluation subcategories to demonstrate aspects that stakeholders may want to explore at various stages of an initiative's life cycle. Evaluations often touch upon multiple subcategories; therefore, a glossary is included to provide detailed information on each subcategory.

2. **Description and Logic Model**
   The description highlights core components of each activity, and the logic model shows expected outputs and outcomes. These may help implementers and evaluators see how their own activities or initiatives may be similar or differ from the ones presented.

2 Naloxone Distribution Programs

Targeted naloxone distribution is an EVIDENCE-BASED STRATEGY recommended by CDC.[4] Naloxone is an opioid antagonist that reverses the potentially fatal effects of an opioid overdose if administered in a timely manner.

As the number of opioid overdoses has increased, naloxone use among laypersons has grown substantially in recent years.[5] This expansion requires outreach, education, and distribution outside traditional avenues, including in the lay community, harm reduction organizations, and criminal justice settings, among others. Along with this expanded access, laws and policies have changed in order to accommodate wider distribution and use of naloxone. These laws and policies may include naloxone standing orders, "Good Samaritan" laws, naloxone co-prescribing laws, and third-party payer policies.[6] Overdose education and naloxone distribution (OEND)[7] programs should be developed with components to address stigma, trauma informed care, and norms around naloxone use and possession, as necessary. People who are at high risk of overdose, including people with opioid use disorder (OUD) and their friends or family, should be included in program development, implementation, and evaluation as stakeholders. Implementation will vary depending on the local context and type of activity.

Many targeted naloxone distribution programs have some of the following core components:

1. **Identifying populations at risk and access points for distribution:**
   - → Understand and assess the policies on dispensing and use of naloxone in your jurisdiction
   - → Assess and identify priority populations, including those most at risk[8] for an overdose, or those who may witness an overdose[9]
   - → Identify key individuals, organizations, and locations within the community who serve or come into contact with priority populations[10]
   - → Assess current naloxone distributors to identify gaps in the distribution system, at-risk populations missed, or places stock outs may occur
2. **Establishing and/or maintaining distribution system:**
   - → Identify and recruit additional distribution partners
   - → Train distribution partners on OEND (e.g., OUD, stigma reduction[11], trauma informed care, and harm reduction strategies)
   - → Estimate naloxone need based on OUD prevalence and opioid-related overdose morbidity and mortality among populations at most risk
   - → Prepare and assemble naloxone kits
   - → Secure, maintain, and restock inventory
3. **Establishing an Overdose Education and Naloxone Distribution (OEND) Program:**
   - → Provide training and kits to first responders if they represent gaps in the distribution system
   - → Provide naloxone kits to OEND partners to train and distribute to people who are at risk of overdose, their friends/family, and others in the community likely to witness an overdose (e.g. librarians, homeless shelter staff, social services staff, etc.)[9]
   - → Provide kits to OEND partners to train and distribute to the general public (e.g., training on naloxone, OUD, and stigma reduction)
4. **Tracking and reporting:**
   - → Collect distribution and use data from partners[12]
   - → Disseminate reports on naloxone distribution and use to key stakeholders
   - → Collect information on naloxone administration (often collected when those who carry naloxone return to replace the dose(s) used)
   - → Based on findings, evaluate distribution model and make improvements

LOGIC MODEL

Naloxone[1] Distribution Programs

OVERDOSE DATA2ACTION

INPUTS

Laws, Policies, and Attitudes

Laws and policies increasing access to naloxone (through a standing order) and permitting third party prescribing

Protection for civilians and first responders to administer naloxone ("Good Samaritan laws")

Supportive attitudes among community members and service providers for harm reduction services, including naloxone distribution

Partnerships

Networks among entities procuring naloxone, organizations training/distributing, and those who will be receiving training and distributing naloxone

Resources

Funding to purchase naloxone kits and replacement kits[a]

Needs assessment to identify barriers to overdose education and naloxone distribution (OEND) implementation[b]

OEND curriculum[c] and trainers

Data Management Plan[d]

ACTIVITIES

Identification of Priority Population and Distribution Sites

Assess and identify populations at risk for overdose[e]

Identify access partners and points for distribution of naloxone

Assess current naloxone distributors and identify gaps

Establish/Maintain Distribution System

Recruit and train distribution partners on OEND[f]

Estimate naloxone need based on data

Prepare and assemble naloxone kits

Secure, maintain, and restock inventory

OEND

Outreach and conduct OEND to people at risk of overdose, their friends and family, first responders, and the broader public

Tracking and Reporting

Collect distribution and use data

Evaluate distribution efforts, share findings with stakeholders, and make improvements

OUTPUTS

Identification of Priority Population and Distribution Sites

Populations at risk identified

Distribution partners and avenues identified

Comprehensive map of naloxone distributors created/updated

Establish/Maintain Distribution System

Distribution partners recruited and trained

Naloxone need estimated

Naloxone kits assembled and stock maintained

People at risk, their families/ friends, and community are trained on OEND

Naloxone is distributed to trainees and others via partners

Tracking and Reporting

Naloxone distribution and use data collected and shared with stakeholders

Service gaps and areas for improvement are identified and addressed

SHORT-TERM OUTCOME

Individual-Level

Priority Population

- Increased awareness and knowledge about naloxone
- Increased self-efficacy to recognize and respond to an overdose
- Decreased stigma toward naloxone possession and use and other harm reduction strategies

Distribution Partners

- Improved attitudes towards opioid use disorder (OUD) and harm reduction strategies, including naloxone
- Increased knowledge of OUD, stigma reduction best practices/policies, and naloxone
- Increased self-efficacy to distribute and/or provide OEND in a stigma-free manner

Community and System

Increased collaboration and communication among overdose prevention, response, and treatment partners

Increased distribution points and ability to track naloxone distribution and administration

INTERMEDIATE-TERM OUTCOME

Individual-Level

Increased possession and use of naloxone among priority populations and distribution partners

Increased use of harm reduction strategies

System

Improved community awareness and attitudes toward harm reduction strategies, including naloxone

Increased availability of naloxone and OEND training in jurisdiction

Increased resilience of overdose prevention, response, and treatment systems

LONG-TERM OUTCOME

Morbidity

Decreased rate of opioid misuse, opioid use disorder, and non-fatal overdose

Mortality

Decreased drug overdose death rate, including prescription and illicit opioid-involved overdose death rates

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[a] The purchase of naloxone is prohibited with CDC's OD2A funds.

[b] Barriers can include stigma, access for rural populations, inventory management, etc.

[c] OEND are training programs aimed to reduce harm and risk of life-threatening opioid-related overdose and deaths. The length and content delivered during trainings may vary and can include stigma reduction training, trauma informed care, and education surrounding Good Samaritan laws. Training on naloxone should cover overdose recognition and opioid-related response, particularly the naloxone cascade of care, whereby individuals are aware that naloxone is an effective opioid overdose intervention; have access to naloxone; are trained on how to use naloxone during an overdose event; and address norms on possessing naloxone especially during times of drug use.

[d] CDC requires recipients who collect or generate data with federal funds to develop, submit and comply with a Data Management Plan (DMP) for each collection or generation of public health data undertaken as part of the award and, to the extent appropriate, provide access to and archiving/long-term preservation of collected or generated data. For more information please see CDC DMP policy.

[e] Populations at risk for an overdose can be determined using the jurisdiction's morbidity and mortality data. Friends and families of those at risk should also be included in this group because they may be more likely to witness an overdose.

[f] According to Nyblade, et al, stigma has been shown to serve as a barrier to effective healthcare provision at several levels, including individual, societal, and structural. Health-related stigma describes a socio-cultural process in which social groups are devalued, rejected, and excluded on the basis of a socially discredited health condition, such as substance use disorder. Therefore, reducing stigma can be achieved through interventions focused on people with substance use disorders (self stigma), targeting the general public (social stigma), and healthcare providers and first responders (structural stigma). Stigma reduction training can be conducted with any health facility employee who has client contact, and stigma reduction interventions can address organizational policies and environments. Stigma reduction training helps healthcare providers develop the appropriate skills to work effectively with stigmatized groups.

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3 Process Evaluations

Process evaluations DOCUMENT AND DESCRIBE HOW A PROGRAM IS IMPLEMENTED. They normally occur when programs or initiatives are early in their development and are based on stakeholders' needs.[D]

[D] (Steckler, A & Linnan, L, 2002)

Context

Evaluation Questions

What factors affect access to naloxone?

What factors facilitate and/or inhibit naloxone distribution programs and OEND training in your jurisdiction?

Sample Indicators

Laws, Policies, and Attitudes

- Description of laws and policies relevant to access, dispensing, and administration of naloxone (e.g., standing order, Good Samaritan laws, third-party policies)
- Description of community (including friends/family of people at risk for opioid overdose) and distribution partner's attitudes about and understanding of naloxone and OUD
- Description of the willingness of jurisdictional distribution partners to receive training on stigma reduction and support harm reduction strategies

Partnership and Distribution

- Description of current naloxone distribution networks in your jurisdiction (e.g., assembly process, monitoring and restocking system)[13]
- Description of OEND training activities in your jurisdiction (e.g., format for training, frequency of training offered)
- Number of organizations distributing naloxone, conducting OEND training; number of individuals trained to administer naloxone, including police, fire, emergency medical services (EMS), etc.
- Description of current needs and gaps of overdose prevention services as identified by distribution partners
- Description of existing agreements, memoranda of understanding (MOU), training arrangements, distribution channels, etc., for naloxone

Resources

- Number of naloxone prescriptions dispensed from pharmacies in jurisdiction in a given time frame (e.g., last six months or year)
- Number and percentage of pharmacies dispensing naloxone (e.g., registered with the state to dispense under a standing order)
- Description of current naloxone communication and education campaigns in jurisdiction
- Description of current overdose and drug use trends in jurisdiction

DATA SOURCES

- Jurisdictional laws and policies
- Organizational policies
- Administrative data (e.g. naloxone tracking logs, training evaluation forms, harm reduction intake forms, etc.)
- Stakeholders (e.g., people at risk for overdose, their friends/family, community members, and distribution partners)
- EMS naloxone administration data or dispensing data from PDMP, if naloxone is tracked
- Vital statistics opioid-related overdose morbidity and mortality trend data
- Drug use trend data (e.g., from law enforcement, harm reduction agencies)

DATA COLLECTION METHODS

- Environmental scan
- Document review of administrative data
- Informal or formal interviews with stakeholders
- Community asset mapping of distribution network

- List of organizations or other entities that dispense naloxone outside of pharmacy settings
- Description and amount of funding available for one or multiple sources for one-time or sustainable naloxone distribution efforts

Priority Population[14]

- Description of priority population and organizations serving these populations in your jurisdiction (e.g., number of organizations currently working with individuals at high-risk for opioid overdose by type of organization and percentage of those organizations that are currently distributing naloxone)
- Description of potential implementation barriers and facilitators to OEND implementation[15]
- Description of the service needs of priority population (e.g., wraparound service needs)[16]
- Description of current naloxone distribution and OEND efforts in the priority population
- Descriptions of awareness of and access to naloxone among the priority population and their friends and family

Reach

Evaluation Question

To what extent are naloxone distribution programs and OEND programs reaching the priority population?

Sample Indicators

Establishment/Maintenance of Distribution System

- Number of new naloxone distribution sites added and percentage change in number of distribution sites within the jurisdiction
- Number of new or modified sites that reach jurisdiction's priority population
- Number and percentage of distribution partners who made modifications to their existing distribution or training system to address gaps/needs identified in needs assessment (e.g., number and percentage of sites who included stigma reduction training to their distribution program)
- Number and percentage of partners identified in needs assessment who have undergone training on OUD, stigma reduction, and harm reduction strategies in the previous year

Outreach and Education

- Number of people trained at a train-the-trainer sessions on OEND; stigma reduction, harm reduction strategies, and OUD
- Number of trainings conducted and number of individuals trained, disaggregated by type (e.g., stigma reduction, harm reduction, OEND) and training recipient type (e.g., people at risk of overdose and their friends/family trained, including percentage who are part of priority population)
- Number of naloxone kits distributed and percentage of those that are distributed to priority population

DATA SOURCES

- Administrative data from distribution or training partners
- Stakeholders

DATA COLLECTION METHODS

- Scan of administrative data
- Stakeholder engagement

Dose Delivered or Received

Evaluation Question

To what extent have naloxone kits been received by those who are at-risk for overdose or those who are likely to witness an overdose?

Sample Indicators

Priority Population and Distribution

- Number of naloxone kits distributed and/or refilled by individuals (e.g., one kit used and person returned for another) and percentage distributed per demographic group (e.g., age, gender, race/ethnicity, priority population, etc.)
- Number of trainings conducted by organizations in the jurisdiction by month

Establishment/Maintenance of Distribution

- Number of naloxone kits refilled by partner organizations (disaggregated by sub-group, such as EMS, friend/family of individuals with OUD, harm reduction organizations, etc.)
- Number of naloxone kits reordered by jurisdiction health department

DATA SOURCES

- Stakeholders
- Administrative data from distribution partners

DATA COLLECTION METHODS

- Administrative data
- Stakeholder engagement

Fidelity

There may be circumstances in which strict fidelity to the original plan may actually work against an intended outcome. In this case, adaptation is necessary and expected. Tracking fidelity and purposeful/data-informed deviations are important for understanding implementation; however, strict fidelity should not supersede necessary adaptations that will facilitate outcomes.

Evaluation Questions

To what extent have the naloxone distribution program and OEND programs been implemented as originally planned?

What changes/adaptations were made, if any, and why?

Sample Indicators

Overall

- Description of changes made to the implementation plan
- Description of adaptations made to distribution and OEND to meet the needs of the priority population

DATA SOURCES

- Administrative data (e.g., assessment records, visit logs, etc.)
- Initiative staff and other stakeholders

DATA COLLECTION METHODS

- Scan of administrative data
- Informal or formal interviews with staff and stakeholders

Implementation

Evaluation Questions

How effectively were the naloxone distribution program and OEND programs implemented?

What factors facilitated and/or hindered implementation?

What lessons were learned from implementation that can inform current and future programs?

What system process modifications were informed by an ongoing evaluation?

Sample Indicators

Establishment/Maintenance of Distribution

- → Description of the feasibility of implementing the naloxone distribution program in the jurisdiction, including funding, procurement processes, distribution methods, and inventory management
- → Description of events and practices that facilitated and/or hindered naloxone distribution programs (e.g., what contributed to stock outs, unused or expired naloxone, how different facilities tracked inventory, etc.)
- → Number and percentage of distribution partners who reported no problems with distribution, inventory maintenance, or tracking system

Outreach and Education

- → Description of changes to outreach activities (e.g., those that were/were not successful in reaching the priority population), distribution process, and tracking/reporting
- → Number and percentage of people trained in OEND who would recommend this program to others
- → Number and percentage who reported training was conducted in a non-stigmatizing manner
- → Number and percentage who reported being satisfied with OEND activities
- → Number and percentage who reported OEND training was of high quality[17]

Tracking and Reporting

- → Description of best practices used by partners for compliance in tracking naloxone distribution
- → Number and percentage of distribution partners who provide timely data
- → Description of implementation barriers, facilitators, lessons learned, and improvements made

DATA SOURCES

- Stakeholders
- Administrative data (e.g., issue logs, meeting minutes)
- Program participants', distribution partners', or peer navigators' feedback

DATA COLLECTION METHODS

- Informal discussion or interviews with stakeholders and program staff
- Scan of administrative data
- Survey of clients, providers, or peer navigators

Individual-Level Change Outcomes

Evaluation Question

To what extent did the naloxone distribution and OEND programs result in desired individual-level changes (e.g., awareness, knowledge, attitude, skills, and/or behavior)?

Sample Indicators

Short-Term

- → Priority Population
  - Percentage change of audience(s) awareness of naloxone as an effective opioid overdose intervention
  - Percentage change in audience(s) knowledge about naloxone administration and harm reduction strategies
  - Percentage change in self-efficacy of audience(s) to use naloxone
  - Percentage change of audience's(s') ability to recognize and respond to an overdose
  - Percentage change in attitudes and norms about naloxone distribution and possession of naloxone
- → Distribution Partners
  - Percentage change in attitudes toward naloxone, OUD, and harm reduction strategies among healthcare providers, first responders, and other distribution partners
  - Percentage change in knowledge among distribution partners about OUD
  - Percentage change in attitudes among distribution partners toward people with OUD
  - Percentage change in self-efficacy to distribute and/or provide OEND in a non-stigmatizing manner

DATA SOURCES

- Distribution partners
- Training recipients
- Stakeholders
- PDMP
- ODMAP (Overdose Detection Mapping Application Program) or other mobile apps
- Administrative data (naloxone administration post cards, syringe service partners, training logs/ evaluation forms)

DATA COLLECTION METHODS

- Interviews with distribution partners, program recipients, other stakeholders
- Survey at different points in distribution with distribution partners, training recipients, and naloxone administrators/users[18]

Intermediate-Term

- Percentage change in self-reported use of naloxone for overdose reversal
- Percentage change in number of law enforcement entities, fire departments, EMS, etc., that have undergone naloxone administration training in the last year
- Percentage change in number of law enforcement entities, fire departments, EMS, etc., carrying naloxone and reporting naloxone use
- Percentage change in number of officers or departments who self-reported carrying/possessing naloxone
- Percentage change in self-reported use of harm reduction strategies among priority population

Community and System Change Outcomes

Evaluation Question

To what extent did the program produce or contribute to the intended community and system outcomes?

Sample Indicators

Short-Term

- Percentage change in number of communities in jurisdiction that are served by an OEND provider
- Percentage change in naloxone distributed through partners and/or dispensed in pharmacies in jurisdiction
- Percentage change in number of pharmacies dispensing under a standing order
- Percentage change in number of naloxone kits being dispensed to priority population
- Percentage change in number of naloxone distributors with no more than one stock out in the previous year
- Percentage change in total doses of naloxone dispensed in the jurisdiction (if available in PDMP)
- Description of changes to naloxone inventory management practices (surplus, expired/unused, stockouts, logistics, procurement)
- Change in number of 911 calls for overdose response[19]

Intermediate-Term

- Percentage change in the number of distribution points experiencing one or more stock outs in the previous year
- Percentage change in number of first responders (e.g., police departments, fire departments, EMS, etc.) that include naloxone administration, OUD, and harm reduction strategies in their employee training
- Description of changes in community awareness and attitudes toward harm reduction strategies (including naloxone)
- Percentage change in number of opioids prescriptions co-prescribed with naloxone (if reported to PDMP)
- Percentage change in number of opioid overdoses calls where naloxone was used by first responders (fire, EMS, police, etc.) or other targeted distribution partners
- Percentage change in naloxone access points in distribution area
- Description of changes in availability of naloxone for priority population

DATA SOURCES

- Administrative data
- Distribution partners/ distributors
- Program recipients
- Stakeholders

DATA COLLECTION METHODS

- Scan of administrative data
- Informal discussion or interviews with stakeholders and program staff
- Survey with distribution partners/distributors, recipients, and first responders

Unintended Outcomes

Evaluation Question

What unintended outcomes (positive or negative) occurred as a result of the naloxone distribution programs?

Sample Indicators

Overall

- → Description of unintended outcomes (positive or negative) identified (e.g., positive outcomes, such as increased linkage to care for priority population or negative outcomes, such as increased compassion fatigue or stigma among distribution partners or community)

DATA SOURCES

- Stakeholders
- Distribution partners
- Program recipients

DATA COLLECTION METHODS

- Stakeholder interviews
- Document review

Morbidity and Mortality Outcomes

Evaluation Question

To what extent did naloxone distribution programs affect opioid-related morbidity and mortality?

Long-Term Sample Indicators

Number and percentage changes in morbidity and mortality indicators

Morbidity

- Patients receiving multiple naloxone administrations (MNAs) from emergency medical services (EMS)
- Patients transported to the emergency department (ED) for overdose by EMS where primary impression recorded in NEMSIS is drug overdoses
- Patients refusing transport by EMS where primary impression recorded in NEMSIS is drug overdoses
- EMS calls where naloxone was administered
- All-drug non-fatal overdose emergency department visits
- Emergency department visits involving non-fatal opioid overdose, excluding heroin
- Emergency department visits involving non-fatal heroin overdose with or without other opioids
- All-drug non-fatal overdose hospitalizations
- Hospitalizations involving non-fatal opioid overdose excluding heroin
- Hospitalizations involving non-fatal heroin overdose with or without other opioids

Mortality

All-drug overdose deaths

- Drug overdose deaths involving opioids
- Drug overdose deaths involving prescription opioids
- Drug overdose deaths involving heroin
- Drug overdose deaths involving synthetic opioids other than methadone

DATA SOURCES

- Jurisdictional mortality and morbidity data
- ED/health department morbidity and mortality data
- CDC WONDER
- National Emergency Medical Services Information System (NEMSIS) and/or local EMS data
- PDMP data
- Private data sources (e.g. IQVIA, hospital discharge/billing)
- Local syndromic surveillance systems
- State Unintentional Drug Overdose Reporting System (SUDORS)
- BioSense

DATA COLLECTION METHODS

- Reviews of jurisdictional reports (e.g., annual progress reports)
- Secondary data analysis
- Review of opioid-related morbidity and mortality data dashboards or reports

Glossary

Academic detailing involves interactive educational outreach to physicians to provide unbiased, non-commercial, evidence-based information about medications and other therapeutic decisions with the goal of improving patient care. It is usually provided to clinicians one-on-one in their own offices. The approach is based on the effective communication/behavior change/marketing approach that is used so powerfully by pharmaceutical industry sales reps ("detailers") to increase use of a company's products. However, academic detailing puts this approach solely in the service of providing practitioners with neutral, rigorous information to optimize their clinical decision-making. Definition Source

Good Samaritan laws protect bystanders who help in an emergency situation. Every state has a Good Samaritan statute, but the people eligible for coverage and qualifying circumstances under which care is delivered vary. Generally, Good Samaritan statutes cover the spontaneous, uncompensated rendering of aid; reduce the standard of care that would normally be required of the person supplying aid (e.g., a person administering naloxone if they witness an overdose) to account for the exigent circumstances in which the care is being delivered; and excuse violations of state licensure requirements. Some statutes also have provisions shielding individuals from prosecution for minor drug possession offences. No formal emergency declaration or activation of the volunteer as part of an emergency response force is required for Good Samaritan liability protections to attach. Definition Source

Naloxone is a drug that can reverse the effects of opioid overdose and can be life-saving if administered in time. Naloxone was approved for use in the United States in 1971 to prevent overdose by opioids, such as heroin, morphine, and oxycodone. It blocks opioid receptor sites, reversing the toxic effects of the overdose. Naloxone is administered when a patient shows signs of opioid overdose. The medication can be given by intranasal spray, intramuscular (into the muscle) injection, subcutaneous (under the skin) injection, or intravenous injection. Definition Source

Naloxone standing orders are laws that permit the provision of medicine to a person who meets predetermined criteria.[A] Unintentional drug overdose is a leading cause of preventable death in the United States. Increasing access to naloxone has been a priority for jurisdictions in reducing drug overdose deaths. Naloxone standing orders increase access to naloxone. All jurisdictions now have laws that address access to naloxone for people at-risk of opiate overdose. Thirty-seven jurisdictions provide criminal immunity for prescribers who prescribe, dispense, or distribute naloxone to laypersons. Forty-nine jurisdictions authorize pharmacists to dispense naloxone without a patient-specific prescription. Definition Source

Opioid use disorder (OUD) is a problematic pattern of opioid use that causes significant impairment or distress. A diagnosis is based on specific criteria, such as unsuccessful efforts to cut down or control use, resulting in social problems and a failure to fulfill obligations at work, school, or home, among other criteria.

Outcome evaluations assess progress on the sequence of outcomes (e.g., short-, intermediate-, and long-term) the intervention aims to achieve. Outcome evaluations normally occur when an intervention is established, and it is plausible to expect changes in a given timeframe. They should be planned from the beginning of an intervention, as they often rely on baseline data that need to be collected before the intervention starts.[C] Outcome evaluations may examine the following areas:

- **Individual-Level Outcomes:** The extent to which the intervention has affected changes in a given audience's knowledge, skills, attitudes, intentions, efficacy, and/or behaviors.
- **Community and System Change Outcomes:** The extent to which the intervention has affected changes in a community, organization, or system(s).
- **Unintended Outcomes:** The extent to which the intervention had unplanned or unanticipated effects—either positive or negative.
- **Morbidity/Mortality Outcomes:** The extent to which the intervention has affected changes in target audience's morbidity or mortality.

Overdose education and naloxone distribution (OEND) are training programs aim to reduce harm and risks associated with life-threatening opioid-related overdose and deaths. The length and content delivered during trainings may vary and can include stigma reduction training. Training on naloxone should cover overdose recognition and response, including the naloxone cascade of care whereby individuals are aware that naloxone is an effective opioid overdose intervention, have access to naloxone, and are trained on how to use naloxone during an overdose event. Training should address norms on possessing naloxone, especially during times of drug use. Definition Source

Process evaluations document and describe how a program is implemented. Process evaluations normally occur when programs or initiatives are early in their development, and are based on stakeholders' needs.[D] Process evaluations may examine the following areas:

Context: Aspects of the larger social, political, and economic environment that may influence an activity's implementation.

Reach: The extent to which the intended target audience(s) is exposed to, or participates in an activity. If there are multiple interventions, then *reach* describes the proportion that participates in each intervention or component.

Dose delivered/received: The number (or amount) of intended units of each intervention, or each component that is delivered or provided.

- **Dose delivered** is a function of efforts of the people who deliver the intervention. The extent to which the intervention staff member (e.g., academic detailers, educators, etc) actively engaged with, interacted with, were receptive to, and/or delivered intervention materials and resources to the target audience(s).
- **Dose received** is a characteristic of the target audience(s), and it assesses the extent of engagement of participants with the intervention.

Fidelity: The extent to which the intervention is delivered as planned. It represents the quality and integrity of the intervention as conceived by the developers. (Note: In some circumstances, strict fidelity to the original plan may actually work against an intended outcome. In these cases, adaptation is necessary and expected. Tracking fidelity and purposeful/data-informed deviations is important to understand implementation; however, strict fidelity should not supersede necessary adaptations that will facilitate outcomes.)

Implementation: The extent to which the intervention is feasible to implement and sustain, is acceptable to stakeholders, and is done with quality. Examination of these dimensions may also result in noted lessons learned, barriers, and facilitators that can help others when replicating similar initiatives.

Stigma reduction training includes skill-building activities for healthcare providers to develop the appropriate skills to work directly with a stigmatized group. Stigma reduction training can be conducted with any health facility employee who has client contact, and stigma reduction can also address organizational policies and environments. According to Nyblade, et al, stigma has been shown to serve as a barrier to effective healthcare provision at several levels, including individual, societal, and structural. Health-related stigma describes a socio-cultural process in which social groups are devalued, rejected, and excluded on the basis of a socially discredited health condition, such as substance use disorder. Therefore, reducing stigma can be achieved through interventions focused on people with substance use disorders (self stigma), the general public (social stigma), and healthcare providers and first responders (structural stigma).

[C] (Rossi, PH, Lipsey, MW, & Freeman, HE, 2004)

[D] (Steckler, A & Linnan, L, 2002)

References

[A] Davis, C., & Carr, D. (2017). State legal innovations to encourage naloxone dispensing. Journal of the American Pharmacists Association, 57(2), S180-S184.

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Endnotes

[1] Recipients can be state, district, county, or city health departments, tribal health organizations, or other bona fide agents of the health department.

[2] See Improving the Use of Program Evaluation for Maximum Health Impact: Guidelines and Recommendations for more information on how large programs use evaluation findings to improve their interventions and inform strategic direction. Furthermore, evaluation approaches like developmental evaluation or rapid feedback evaluations may be helpful models for evaluators to use while working on overdose prevention efforts.

[3] CDC Evaluation Standards: https://www.cdc.gov/eval/standards/index.htm

[4] See Evidence-Based Strategies for Preventing Opioid Overdose: What's Working in the United States for more information. The purchase of naloxone is prohibited with CDC's OD2A funds.

[5] Opioid Overdose Prevention Programs Providing Naloxone to Laypersons

[6] Volunteer Protection Acts and Good Samaritan Laws

[7] Overdose Education and Naloxone Distribution (OEND) are training programs aimed to reduce harm and risk of life-threatening opioid related overdose and deaths. The length and content delivered during trainings may vary and can include stigma reduction training, trauma informed care, and education surrounding Good Samaritan laws. Training on naloxone should cover overdose recognition and response, particularly the naloxone cascade of care whereby individuals are aware that naloxone is an effective opioid overdose intervention; have access to naloxone; are trained on how to use naloxone during an overdose event; and address norms on possessing naloxone especially during times of drug use.

[8] Throughout this document, the term "priority population" is used to reference populations at risk for an overdose. Priority populations or populations at-risk for an overdose can be determined using the jurisdiction's morbidity and mortality data. Friends and families of those at-risk should also be included in this priority population because they may witness an overdose.

[9] Groups that may witness an overdose include friends and family members of people with OUD, first responders, law enforcement, service industry employees (e.g., hotel/motel workers, fast food workers), employees at homeless shelters, criminal justice employees, outreach workers, drug-treatment workers, librarians, and others.

[10] For example, medical providers and pharmacists may come in contact with the priority population through co-prescribing of naloxone with opioids; first responders are often first on the scene at an overdose; drug treatment and recovery programs, criminal justice (including probation and parole officers), and detention centers work with populations at high risk of overdose; and syringe services and other harm-reduction programs often have contact with active drug users.

[11] According to Nyblade, et al, stigma has been shown to serve as a barrier to effective health care provision at several levels: individual, societal, and structural. Health-related stigma describes a socio-cultural process in which social groups are devalued, rejected, and excluded based on a socially discredited health condition, such as substance use disorder. Therefore, reducing stigma can be achieved through interventions focused on people with substance use disorders (self stigma), the general public (social stigma), and healthcare providers and first responders (structural stigma). Stigma reduction training can be conducted with any health facility employee who has client contact, and stigma reduction interventions can address organizational policies and environments. Stigma reduction training helps health care providers develop the appropriate skills to work effectively with stigmatized groups.

[12] CDC requires recipients who collect or generate data with federal funds to develop, submit, and comply with a data management plan (DMP) for each collection or generation of public health data undertaken as part of the award and, to the extent appropriate, provide access to and archiving/long-term preservation of collected or generated data. For more information please see the CDC DMP policy.

[13] Naloxone distribution networks and programs may include the following access points and partners: faith communities, health departments, firehouses, community centers, homeless shelters, libraries, social service providers, service industry workers, vending machines, postal service (mail-based programs), etc.

[14] Priority populations could include people at high-risk for overdose including people with opioid use disorder (OUD), justice-involved populations, disproportionately affected populations (e.g., African Americans, Native American/American Indian, pregnant women, seniors, people who lack access to health insurance) or those who experience high rates of opioid prescribing, morbidity, mortality, or naloxone administration.

[15] Possible barriers may include stigma, access in rural areas, inventory management, funding, etc.

[16] Wraparound services may include primary care physician, office-based opioid treatment, addiction specialist, outpatient treatment programs, inpatient treatment programs, mental health services, infectious disease treatment, obstetric services, housing services, vocational or psychosocial rehabilitation, and family resources.

[17] High-quality training has clear learning objectives, maintains audience engagement, incorporates adult learning principles, meets training needs, and improves participants' skills and self-efficacy. Jurisdictions should consider these standards and adapt for the needs of their community.

[18] Surveys can occur with a variety of recipients at different times throughout the naloxone distribution program. For example, people who refill their naloxone could complete a postcard survey when they pick up a new naloxone kit; first responders could submit data to mobile applications like ODMAP about their use of naloxone; OEND training recipients could answer retrospective pre-post surveys indicating changes in their awareness, knowledge, and self-efficacy after a training; people who receive harm reduction services could fill out a post-questionnaire regarding the quality of services provided, etc.

[19] This indicator, like many indicators, should be considered in the specific context of the jurisdiction. An increase in 911 calls could reflect an increase in overdoses or could indicate increased awareness about Good Samaritan laws.