Hospital and Emergency Department-Based Naloxone Distribution

Opioid Overdose Prevention Seminar
12/17/2020

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https://bit.ly/39L9AlN

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Disclosures

- **Grant funding: AHRQ R01HS027426, NIDA UG1DA015831**
- **Annual stipend: JAMA Network Open**

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Why Distribute Naloxone?

To Save Lives

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Why Distribute Naloxone?

It is a Token that Increases Therapeutic Alliance

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Why Distribute Naloxone?

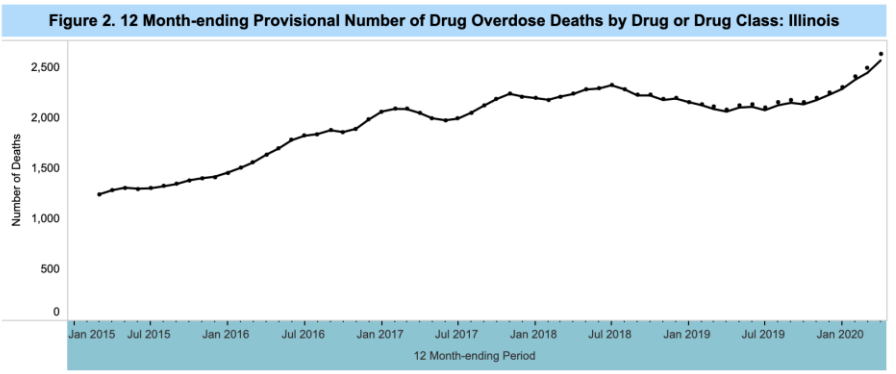
Opens to Door for a Conversation on MOUD

Objectives

- **Describe recent trends in Illinois opioid overdoses**
- Define various models of naloxone distribution
- Discuss common barriers to implementation of naloxone distribution programs
- Describe key logistical details relating to building and sustaining a naloxone distribution program

IL Opioid Overdose Trends

Overdose Deaths



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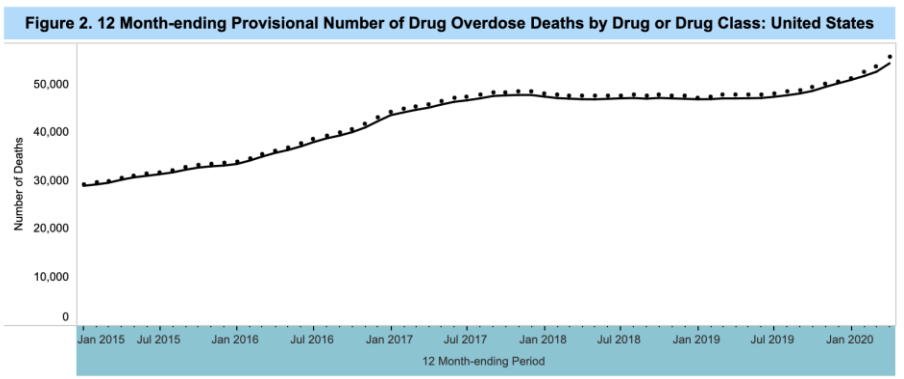
US Opioid Overdose Trends

Overdose Deaths



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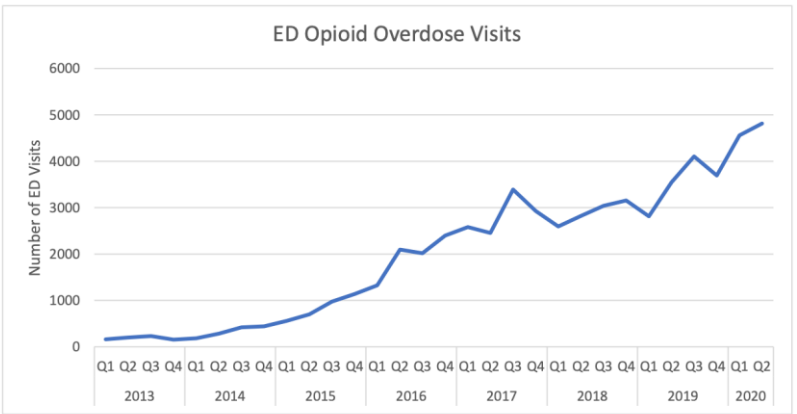
IL Opioid Overdose Trends

ED Visits



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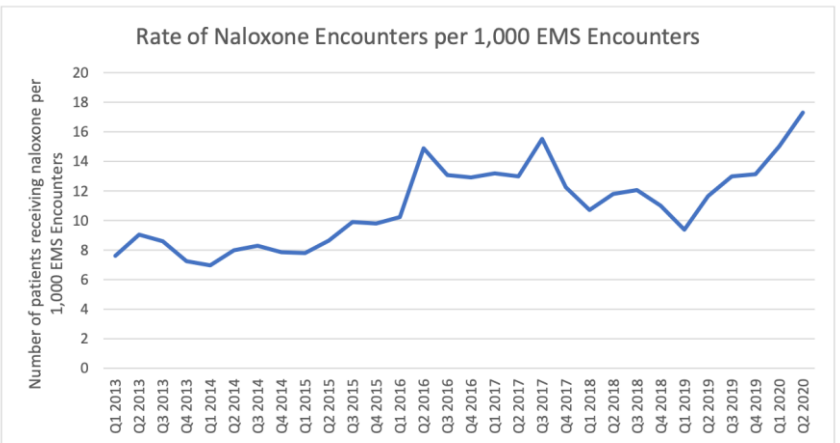
IL Opioid Overdose Trends

EMS Encounters



IDPH

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IL Opioid Overdose Trends

Opioids Involved in Overdose

Opioid-related overdose death characteristics, Chicago January - June 2020

	January -June 2019			January - June 2020			2019-2020
	n	%	Rate[ii]	n	%	Rate[ii]	% Change in rate
Chicago	**370**	**100.0%**	**13.6**	**573**	**100.0%**	**20.9**	**53.7%**
Drug Type[i]							
Heroin-involved	211	57.0%	7.8	264	46.1%	9.7	24.4%
Fentanyl-involved	297	80.3%	11.0	471	82.2%	17.2	56.4%
Fentanyl – only opioid involved	118	31.9%	4.3	213	37.2%	7.7	79.1%
Opioid pain reliever-involved[iii]	26	7.0%	0.9	36	6.3%	1.2	33.3%
Methadone-involved	25	6.8%	0.9	62	10.8%	2.3	155.6%

CDPH Chicago Department of Public Health

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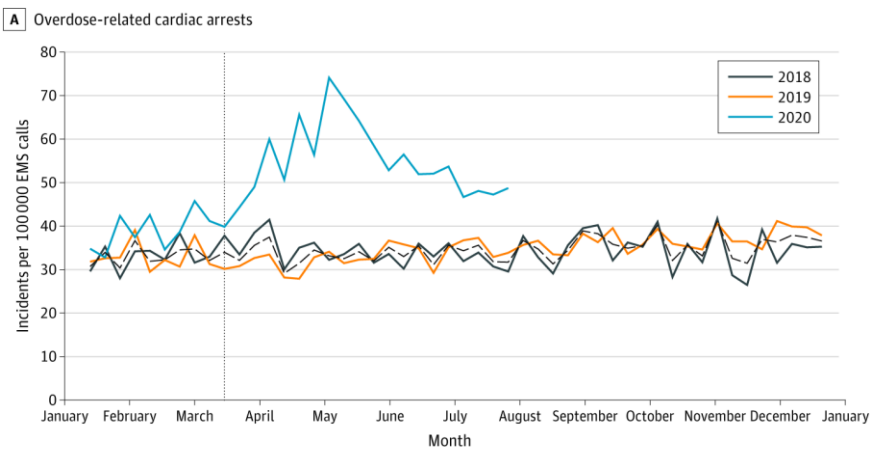
Opioid Overdose Trends

During COVID?



JAMA Psychiatry. 2020 Dec 3. doi: 10.1001/jamapsychiatry.2020.4218. Online ahead of print.

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Naloxone Distribution

Prescribing vs Dispensing Definitions

PRESCRIBING: Traditional process of writing a prescription, filling it at a pharmacy

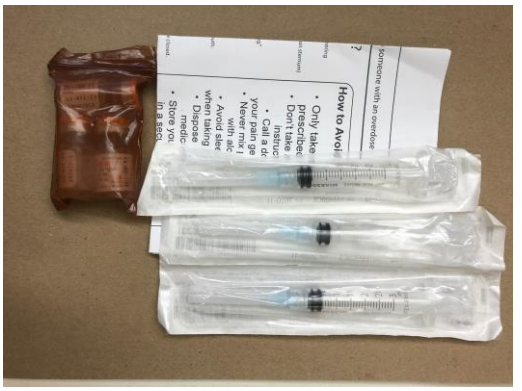
- **Cook County: Less than 1 in 5 ED naloxone prescriptions filled**
- **Multiple barriers to prescription filling:**
  - Limited stock (1/3 of pharmacies reported not in stock)
  - Limited knowledge of standing orders (2/3 reported required an Rx)
  - High Cost ($145)
  - Limited open hours
  - Lack of transportation
  - Stigma

Am J Emerg Med. 2019 Jan;37(1):164-165. doi: 10.1016/j.ajem.2018.05.044.
JAMA Netw Open. 2019 Jun 5;2(6):e195388.

Naloxone Distribution

Prescribing vs Dispensing Definitions

DISPENSING: Hand the medication to the patient as they walk out the door (ie, "take-home naloxone")



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Naloxone Distribution

Prescribing vs Dispensing Definitions

FACILITATED OUTPATIENT FILLING: Hybrid of prescribing and dispensing models used primarily for hospitalized patients

- Care team assists in fulfilling all steps of obtaining a prescription medication on behalf of the patient

Disadvantages:

- Substantial time investment
- Requires processing of patient insurance or payment

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Naloxone Distribution

Delivery Models

- **Prescribing:** indirect
  - Traditional Rx from physician
  - Naloxone standing order
- **Dispensing:** direct
  - Take-home naloxone
- **Facilitated outpatient filling:** hybrid

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Naloxone Distribution

Formulations

Intramuscular:

- **"Vials and supplies" kit**
- **Evzio® Auto-Injector**

Intranasal

- **Narcan® Nasal Spray**
- **Multi-Step Atomizer Kit**

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Naloxone Distribution

"Vials and Supplies"

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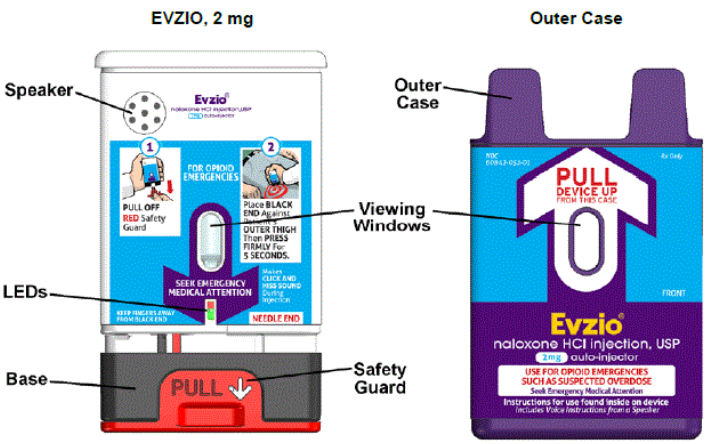
Naloxone Distribution

Evzio®



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Naloxone Distribution

Narcan®

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Naloxone Distribution

Multi-step Atomizer

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Naloxone Distribution

Formulations

Intramuscular:

- "Vials and supplies" kit
- Evzio® Auto-Injector

Intranasal

- Narcan® Nasal Spray
- Multi-Step Atomizer Kit

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Naloxone Distribution

Settings

- Community-based
- Jail-based
- Hospital/ED-based

No matter the setting, naloxone distribution works!

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Take-Home Naloxone Works!

Community Distribution

MA communities trained by OEND programs

- 2912 bystanders trained, 327 rescues reported (**11.2%)**
- Reduction in overdose death for communities that had high enrollment in OEND: **aRR 0.54** (95% CI 0.57-0.91)

NM Outpatient Opioid Treatment Program

- 395 trained, 114 community reversals reported (**18%)**

BMJ. 2013 Jan 30;346:f174.
JAMA Netw Open. 2020 Feb 5;3(2):e200117.

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Take-Home Naloxone Works!

Jail-Based Distribution

San Francisco County Jail

- 453 trained, 63 community reversals reported (**13.9%)**

Cermak Health Services at Cook County Jail

- 60 trained, 23 community overdoses reported (**38.3%)**

J Correct Health Care. 2019 Oct;25(4):394-404.
J Correct Health Care. 2020 Sep 15;1078345820954586.

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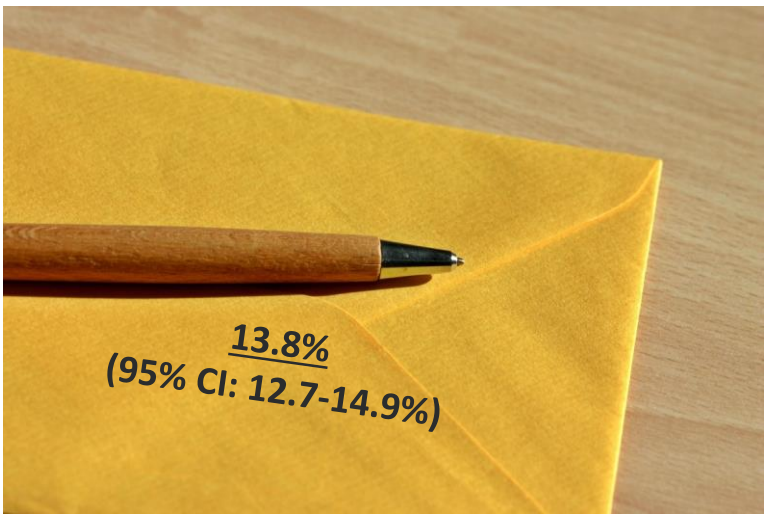
Take-Home Naloxone Works!

Pooled Utilization Rate



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Objectives

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- Describe key logistical details relating to building and sustaining a naloxone distribution program

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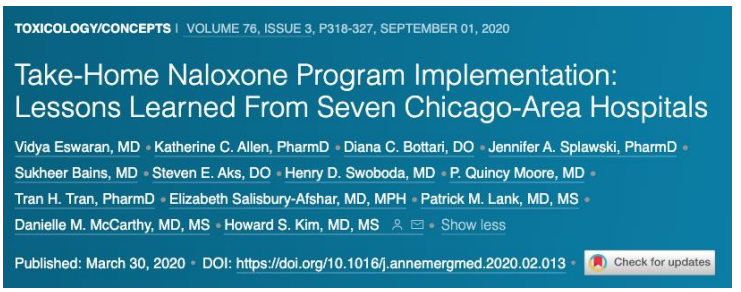
Building a Naloxone Program

Barriers and Facilitators

- **Lessons learned from conversations with hospitals**
- **Every hospital/health system is different**



TOXICOLOGY/CONCEPTS | VOLUME 76, ISSUE 3, P318-327, SEPTEMBER 01, 2020

Take-Home Naloxone Program Implementation: Lessons Learned From Seven Chicago-Area Hospitals

Vidya Eswaran, MD • Katherine C. Allen, PharmD • Diana C. Bottari, DO • Jennifer A. Splawski, PharmD • Sukheer Bains, MD • Steven E. Aks, DO • Henry D. Swoboda, MD • P. Quincy Moore, MD • Tran H. Tran, PharmD • Elizabeth Salisbury-Afshar, MD, MPH • Patrick M. Lank, MD, MS • Danielle M. McCarthy, MD, MS • Howard S. Kim, MD, MD • Show less

Published: March 30, 2020 • DOI: https://doi.org/10.1016/j.annemergmed.2020.02.013 • Check for updates

Ann Emerg Med. 2020 Sep;76(3):318-327.

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Building a Naloxone Program

Barriers

- **Most Frequent Barriers:**
  1. **Uncertainty re: legitimacy/legality**
  2. **Finding a naloxone supply**
  3. **Staff resistance**
  4. **Administrative bureaucracy**

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Building a Naloxone Program

Barrier 1: Uncertainty re: Legitimacy/Legality

Generally:

"Are you sure this is legitimate?"

Specifically:

1. Do we have the authority to dispense a medication?

2. What is our liability exposure (criminal, civil, licensing)?

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Building a Naloxone Program

Barrier 1: Uncertainty re: Legitimacy/Legality

Generally:

"Are you sure this is legitimate?"

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Building a Naloxone Program

Barrier 1: Uncertainty re: Legitimacy/Legality

Specifically:

1. Do we have the authority to dispense a medication?

- IL Pharmacy Practice Act (225 ILCS 85)
- IDPH/IDFPR/DHS "Illinois Naloxone Standardized Procedure"
- Analogy to post-exposure prophylaxis for sexual assault

2. What is our liability exposure (criminal, civil, licensing)?

- Drug Overdose Prevention Program Law (IL 096-0361)
- Good Samaritan Act (IL 097-0678)
- Heroin Crisis Act (IL 099-0480)

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Building a Naloxone Program

Barrier 1: Uncertainty re: Legitimacy/Legality

Statute	Date Enacted	Action	Effect
Drug Overdose Prevention Program Law (IL Public Act 096-0361)	Jan 1, 2010	Amended the Alcoholism and Other Drug Abuse and Dependency Act (20 ILCS 301/5-23 new)	Authorized Drug Overdose Prevention Programs for dispensing or distributing naloxone to individuals not personally at risk of opioid overdose Health care professionals who prescribe and dispense naloxone in good faith, and provide appropriate training on use, are not subject to disciplinary or other adverse action under any professional licensing statute. Any person who has received proper training can legally administer naloxone and is immune from criminal prosecution for the unauthorized practice of medicine or the possession of an opioid antidote.
Emergency Medical Services Access Law, aka Good Samaritan Act (IL Public Act 097-0678)	Jun 1, 2012	Amended the IL Controlled Substances Act (720 ILCS 570/414 new)	Established limited criminal immunity for drug possession charges (previously a class 4 felony) for any individual seeking emergency medical assistance for either themselves or another individual experiencing overdose.
Illinois Pharmacy Practice Act (225 ILCS 85)	Apr 20, 1975 Apr 23, 2015	Established definitions and procedures for pharmacy practice Amended section 1330.530: Onsite Institutional Pharmacy Services	A medication may be immediately dispensed by the institutional pharmacy to a discharged ED patient, provided it meets proper record-keeping and labeling requirements (sections b.1–3 and c.3, respectively). In the absence of an institutional pharmacist, a medication may be dispensed from the ED by a practitioner licensed to prescribe and dispense and only during hours in which outpatient institutional pharmacy services are not available, provided the dispensed medication meets proper labeling requirements and the hospital has a written policy for ED dispensing (section e.4).
Heroin Crisis Act, aka Lali's Law (IL Public Act 099-0480)	Sep 9, 2015	Amended the Illinois Pharmacy Practice Act (225 ILCS 85/19.1 new) Amended the Alcoholism and Other Drug Abuse and Dependency Act (20 ILC 301/5-23 new) Amended the Illinois Insurance Code (215 ILCS 5/356z.23 new) Amended the Good Samaritan Act (745 ILCS 49/36 new)	Authorized a standing order for retail pharmacists to dispense naloxone to patients without a prescription, provided a standardized protocol is in place and the pharmacist has completed a training program Clarified language on Drug Overdose Prevention Programs to indicate that naloxone may be dispensed or distributed to persons who may be in a position to assist other individuals during drug overdose Health care professionals who prescribe or dispense naloxone in good faith, and provide appropriate training on use, are not subject to criminal liability (in addition to existing protections from disciplinary action under professional licensing statutes). Any person who has received proper training can legally administer naloxone and is immune from civil liability (in addition to existing criminal liability). Any individual or group health insurance policy with prescription drug benefits must provide coverage for at least 1 form of naloxone. Insurance that provides prescription coverage must cover at least 1 opioid antagonist. Pharmacists who dispense naloxone in good faith and in compliance with the Pharmacy Practice Act are immune from civil liability.

IL, Illinois; ILCS, Illinois Compiled Statutes.

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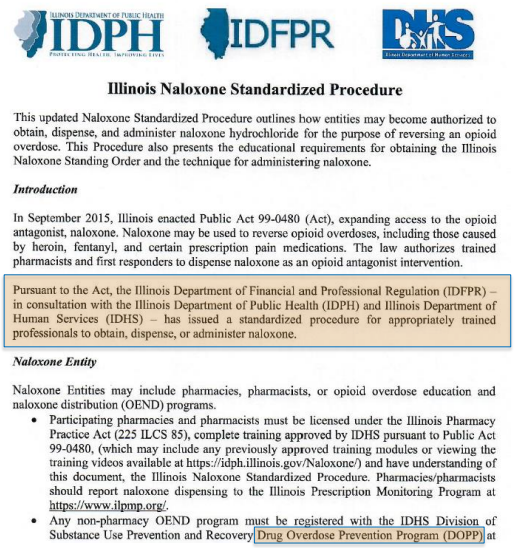
Building a Naloxone Program

Barrier 1: Uncertainty re: Legitimacy/Legality



Illinois Naloxone Standardized Procedure

This updated Naloxone Standardized Procedure outlines how entities may become authorized to obtain, dispense, and administer naloxone hydrochloride for the purpose of reversing an opioid overdose. This Procedure also presents the educational requirements for obtaining the Illinois Naloxone Standing Order and the technique for administering naloxone.

Introduction

In September 2015, Illinois enacted Public Act 99-0480 (Act), expanding access to the opioid antagonist, naloxone. Naloxone may be used to reverse opioid overdoses, including those caused by heroin, fentanyl, and certain prescription pain medications. The law authorizes trained pharmacists and first responders to dispense naloxone as an opioid antagonist intervention.

Pursuant to the Act, the Illinois Department of Financial and Professional Regulation (IDFPR) – in consultation with the Illinois Department of Public Health (IDPH) and Illinois Department of Human Services (IDHS) – has issued a standardized procedure for appropriately trained professionals to obtain, dispense, or administer naloxone.

Naloxone Entity

Naloxone Entities may include pharmacies, pharmacists, or opioid overdose education and naloxone distribution (OEND) programs.

- Participating pharmacies and pharmacists must be licensed under the Illinois Pharmacy Practice Act (225 ILCS 85), complete training approved by IDHS pursuant to Public Act 99-0480, (which may include any previously approved training modules or viewing the training videos available at https://idph.illinois.gov/Naloxone/) and have understanding of this document, the Illinois Naloxone Standardized Procedure. Pharmacies/pharmacists should report naloxone dispensing to the Illinois Prescription Monitoring Program at https://www.ilpmp.org/.
- Any non-pharmacy OEND program must be registered with the IDHS Division of Substance Use Prevention and Recovery Drug Overdose Prevention Program (DOPP) at

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Building a Naloxone Program

Barrier 1: Uncertainty re: Legitimacy/Legality

No known cases of medical negligence for distributing naloxone

Duty / Breach / Causation / Damage

Duty to exercise a degree of care expected of a reasonably competent practitioner in the same class to which the practitioner belongs, acting under similar circumstances.

What is the standard of care?

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Building a Naloxone Program

Barrier 2: Finding a Naloxone Supply

Multiple EDs have tried to solve the billing/reimbursement puzzle and have failed

- Numerous logistical challenges

The defining feature of any take-home naloxone program is that the medication comes at no cost to the patient.

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Building a Naloxone Program

Barrier 2: Finding a Naloxone Supply

Where do I even begin the process of procuring naloxone?

Pathways:

1. **Donation from an existing naloxone distribution program**
2. **Purchase using hospital pharmacy procurement process**

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Building a Naloxone Program

Barrier 2: Finding a Naloxone Supply

1. Donation from an existing naloxone distribution program

IDHS/SUPR Funded OEND Programs:

Provider	Program Contact	Email	Program Contact Phone
Champaign-Urbana Public Health District**	Candi Crause	ccrause@c-uphd.org	217-531-5372
Chestnut Health Systems*	Donna Nahlik Naloxone Hotline	dnahlik@chestnut.org sr-narcan@chestnut.org	618-205-8133 618-512-1781
Chicago Recovery Alliance*	Greg Scott	greg_scott@me.com	312-953-3797
DuPage County Health Department*	Mila P. Tsagalis	mtsagali@dupagehealth.org	630-221-7572
Egyptian Public and Mental Health Department**	Katie Unthank	kunthank@egyptian.org	618-273-3326 ext. 2133
Human Service Center of Peoria**	Chrissy Smith	CHSmith@hscpeoria.org	309-282-1084
Kane County Health Department**	Uche S. Onwuta	onwutauche@co.kane.il.us	630-444-3077
Kankakee County Health Department**	Lindsay Wilson	lwilson@kankakeehealth.org	815-802-9396
Lake County Health Department*	Martin Clancy	Mclancy@lakecountyil.gov	847-377-8199
Sangamon County Health Department**	Joan Stevens Thome	joans@co.sangamon.il.us	217-535-3100 ext. 3709
Will County Executive Office*	Kathleen Burke	kathleenburke@willcountyillinois.com	708-205-5782
Winnebago County Health Department**	Cheryl Floyd	CFloyd@wchd.org	815-720-4315

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Building a Naloxone Program

Barrier 2: Finding a Naloxone Supply

2. Purchase using hospital pharmacy procurement process

<u>Possible funding sources:</u>

- **340b discount program**
- **Hospital charity funds**
- **Implementation grants**

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Building a Naloxone Program

Barrier 3: Staff Resistance

Resistance from staff about:

1. **Isn't this just encouraging risky behavior (moral hazard)?**
2. **Serving as the prescriber of record**

Responses:

1. A patient presenting to your hospital/ED with opioid overdose is already engaging in the riskiest behavior possible

2. You can use the Illinois Standing Order for Naloxone

3. Publicize "wins" among your department

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Building a Naloxone Program

Barrier 4: Administrative Bureaucracy

Implementation is frequently obstructed by endless red tape, which stymies all enthusiasm/momentum

Strategies:

1. **Do your homework beforehand, come prepared**
2. **Find a C-suite champion**
3. **Engage with hospital/ED pharmacy early**

The biggest obstacle is uncertainty!

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Objectives

- Describe recent trends in Illinois opioid overdoses
- Define various models of naloxone distribution
- Discuss common barriers to implementation of naloxone distribution programs
- **Describe key logistical details relating to building and sustaining a naloxone distribution program**

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Naloxone Program Logistics

Supply Estimation

How much naloxone do you need?

<u>Options:</u>

- **Experience of Chicago EDs: 4-12 kits/month**
- **Run your own ICD-10 query to estimate opioid visits**

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Naloxone Program Logistics

Choosing a Formulation

Which formulation should you use?

- **"Vials and Supplies" (IM)**
- **Narcan® nasal spray (IN)**
- **Multi-step atomizer (AT)**

Naloxone Program Logistics

Choosing a Formulation

Comparing usability of IM vs IN vs AT among laypersons:

Table 3. Outcomes

Device type	Successful naloxone administration	Median time to successful naloxone administration	Usability of device, median score[a]
Nasal spray (n=69)	66.7%[b]	16 sec[d] (n=47)	10[c]
Intramuscular (n=68)	51.5%[b]	58 sec (n=35)	8[b]
Improvised nasal atomizer (n=70)	2.9%	113 sec (n=2)	4

- **IN slightly more usable than IM**
- **AT device very hard to utilize**

Pharmacotherapy. 2020 Jan;40(1):84-88.

Naloxone Program Logistics

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Comparing usability of IM vs IN vs AT among laypersons:

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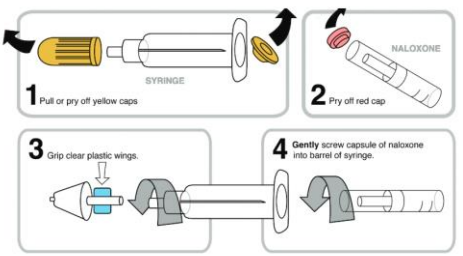

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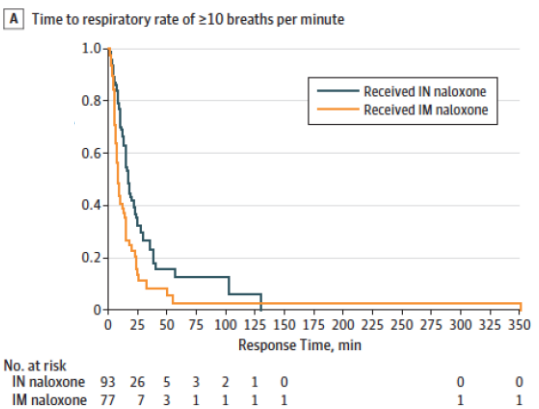
Naloxone Program Logistics

Choosing a Formulation

Comparing clinical effects of IM vs IN among professionals:



JAMA Netw Open. 2019 Nov 1;2(11):e1914977.

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Naloxone Program Logistics

Choosing a Formulation

Comparing costs:

- **"Vials and Supplies" (IM): $13-$15/kit**
- **Narcan® nasal spray (IN): $115-$150/kit**
- **Multi-step atomizer (AT): $66/kit**
- **Evzio auto-injector: $178/kit**

All things considered, "vials and supplies" likely best option

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Naloxone Program Logistics

Recordkeeping, Labeling, Education

Meeting Dispensing Requirements:

- **Recordkeeping:** Create a custom EHR order for easy tracking
- **Proper Labeling:** Link custom order to printed label (central pharmacy) with name, prescriber, dosing info. Or utilize blank sticker labels that can be filled in
- **Patient Education:** Utilize a non-physician educator

  IDHS has education/training materials: https://bit.ly/39K4YfT

The entire process should be easily triggered, efficient and automated!

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Naloxone Program Logistics

Recordkeeping, Labeling, Education

Utilize a non-physician educator!

Table 2. Key features of take-home naloxone programs at 7 Chicago-area hospitals.

Hospital	Clinical Setting	Annual ED Visits	Program Conception	Program Launch	Funding Source	Delivery Model	No. of Monthly Kits Dispensed	Naloxone Formulation	Primary Educator	Prescriber
1	ED	110,000	May 2018	Oct 2018	Donation	Take-home naloxone	7.5	Intramuscular (3 vials/syringes)	ED nurse/video	Standing order
	IP		Dec 2018	Dec 2018	Patient insurance*	Filled Rx to bedside	4.4	Intranasal (2 prefilled syringe/atomizer)	IP nurse/video	Standing order
2	IP	66,000	Nov 2015	Nov 2016	Patient insurance†	Filled Rx to bedside	10.4	Narcan nasal spray (2)†	IP nurse	Treating provider
3	ED	43,000	Jan 2018	Aug 2019	Charity	Take-home naloxone	4.0	Narcan nasal spray (2)	ED pharmacist	Treating provider
4	ED+IP	120,000	Jan 2010‡	May 2011	Patient insurance	Patient given Rx	N/A§	Intramuscular (3 vials/syringes)	OP pharmacist	Treating provider
5	ED	72,000	Mar 2019	May 2019	Charity	Take-home naloxone	8.0	Intramuscular (2 vials/syringes)	ED nurse	Treating provider
	OP		Jun 2018	Jul 2018	Donation	Take-home naloxone	15.0	Intramuscular (2 vials/syringes)	OP nurse	Treating provider
	IP		Jan 2018	Apr 2018	Patient insurance*	Filled Rx to bedside	20.0	Narcan nasal spray (2)	IP pharmacist‖	Treating provider
6	ED	91,000	Jan 2018	Oct 2018	Donation, charity	Take-home naloxone	9.4	Intramuscular (3 vials/syringes)	ED pharmacist	Treating provider
7	ED	76,000	Jan 2018	Apr 2019	Grant	Take-home naloxone	12.5	Intramuscular (2 vials/syringes)	ED nurse/video	Treating provider

Ann Emerg Med. 2020 Sep;76(3):318-327.

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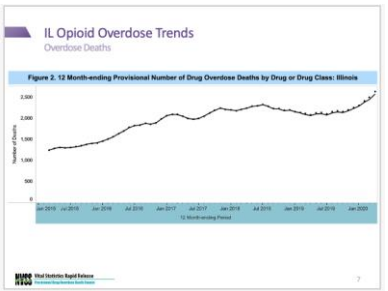
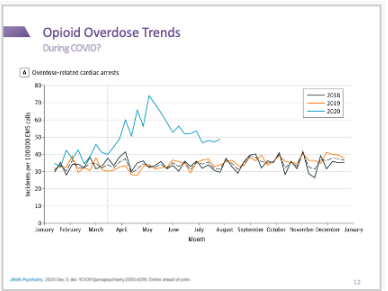
Summary

1. Describe recent trends in opioid overdoses





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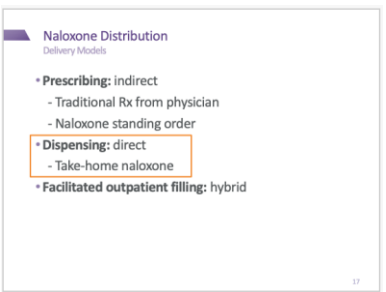
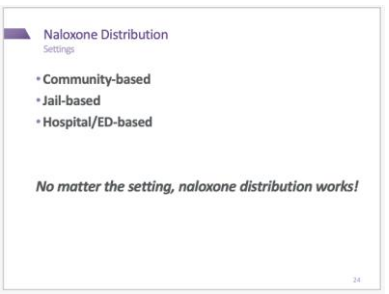
Summary

2. Define various models of naloxone distribution





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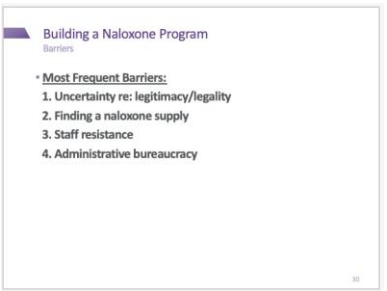
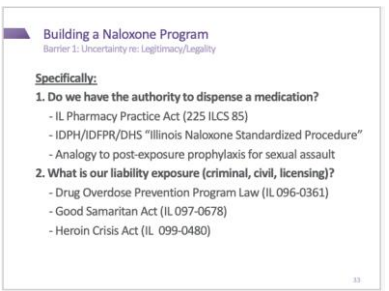
Summary

3. Discuss common barriers to implementation of naloxone distribution programs





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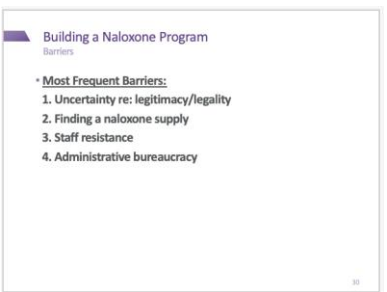
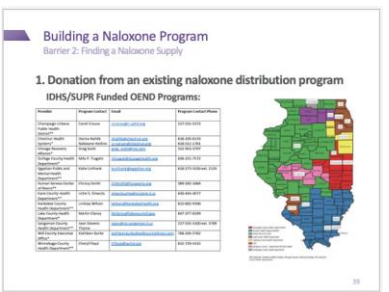
Summary

3. Discuss common barriers to implementation of naloxone distribution programs





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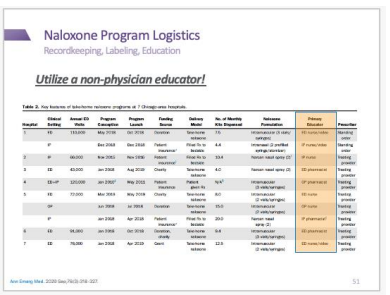
Summary

4. Describe key logistical details relating to building and sustaining a naloxone distribution program



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Questions?

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