Naloxone Public Access and Storage (HJ 653)

Joint Commission on Health Care
October 3, 2019 Meeting

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* I would like to thank Anita Kumar, JCHC Graduate Student Intern, for her work on this study

Study Mandate

- HJ 653 (Delegate Gooditis) requested the Virginia Department of Health (VDH) study barriers/solutions to co-locating naloxone in Automatic External Defibrillators (AEDs) and propose/implement an education program
  - HJ 653 was tabled in House Rules Committee with understanding that JCHC would consider study in its 2019 workplan
- Subsequent letter from Delegate Gooditis requested that JCHC focus on:
  - Whether removing barriers to administering naloxone is likely to save lives without causing significant damage to public health
  - Whether/how naloxone can be placed in publicly accessible places, such as alongside AEDs

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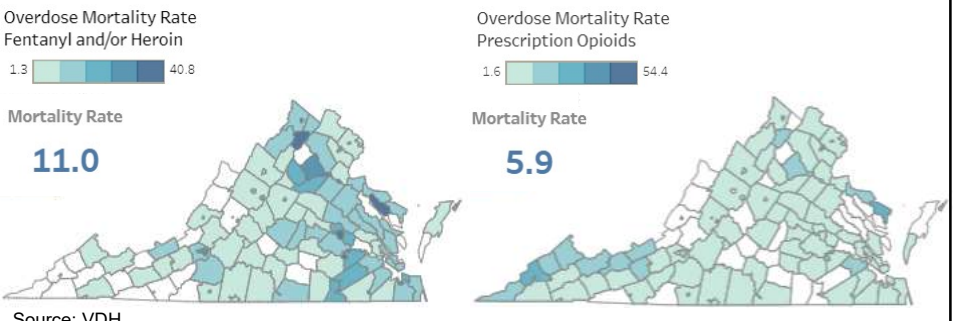
Background

Opioid Overdose in Virginia

- Over 1,200 opioid overdose fatalities each year in Virginia – more than double level in 2012
  - In 2018, # opioid overdose fatalities decreased from previous year for 1st time since 2011



Source: VDH

- Naloxone is highly successful in reversing opioid overdose
  - > 75% overdose reversal rate in out-of-hospital settings

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Naloxone-Focused Response in Virginia

- Recent legislation has reduced barriers to public's access to naloxone
  - Elimination of Controlled Substance Registration requirement for naloxone dispensing by organizations providing substance abuse services/naloxone training
  - Expansion of list of professionals authorized to possess, administer and dispense naloxone
  - Required co-prescription of naloxone with opioids for high-risk patients
- Agency programs focus on increasing opioid overdose awareness and preparedness
  - VDH: Since March, 2017, >23,000 naloxone kits purchased through federal/State funds (~$1.75M) distributed at no cost to Local Health Districts, Community Services Boards, law enforcement, Emergency Medical Services
  - DBHDS: to date, 35,000 lay individuals trained in REVIVE! training on opioid overdose (program currently has ~4,000 trainers)
  - VDOE: Recent Superintendent's Memo requires development of local school division naloxone policies*

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* See slide 32 in Appendix for additional detail

VA Code has expanded ability to dispense naloxone with education to lay administrators

- Naloxone is Schedule VI drug in VA (not scheduled federally)
- Under Standing Order, VA Code (§54.1-3408) authorizes naloxone dispensing by:
  - Pharmacists, emergency medical services personnel
  - 10 categories of professionals (e.g., 1st responders, school nurses, regional jail employees) who have completed a training program
  - Representatives of organizations providing services/training in naloxone to individuals at risk for opioid overdose
- Board of Pharmacy protocols require dispensers to provide some form of naloxone instruction to lay individuals*
  - "Instruction" topics: opioid overdose prevention, recognition, response; naloxone administration and characteristics
  - If recipient refuses instruction, dispenser can provide recipient with DBHDS REVIVE! brochure to satisfy training requirement

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* See slide 33 in Appendix for additional detail

Key Concerns With Reducing Current Safeguards for Lay Administration of Naloxone

- Will effectiveness/appropriateness of naloxone administration be compromised if naloxone is administered by individuals without training?
- Would increased accessibility in public places and/or co-located with AEDs be an effective use of resources?
- What are supply-/demand-side considerations of positioning naloxone in public places?

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Naloxone Training and Education

Naloxone generally regarded as safe

- Naloxone hydrochloride is short-acting opioid antagonist for respiratory/central nervous system depression from opioid overdose
- Surgeon General: “Naloxone is a safe antidote to a suspected overdose”
  - Naloxone not psychoactive, has no effect in the absence of opioids, and has no abuse potential
- FDA-approved formulations for community use are designed for lay rescuer administration*
  - FDA approval of Narcan nasal spray/EVZIO auto-injector for naloxone use in community settings based on evidence of equivalent effectiveness as injectable form, usability without prior training
  - FDA has encouraged manufacturers to submit applications for Over-The-Counter formulation
- Most reported adverse events relate to reactions due to precipitated opioid withdrawal*

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* See slides 34 and 35 in Appendix for additional detail

Naloxone effective when administered by trained lay individuals

- Training associated with higher knowledge of naloxone administration, opioid overdose recognition, overdose response
- Opioid Education and Naloxone Distribution (OEND) programs focused on high-risk individuals (users) associated with lower overdose mortality
  - ~33% higher rate of recovery after lay administration
  - 0% mortality after lay administration compared to 11% when not administered

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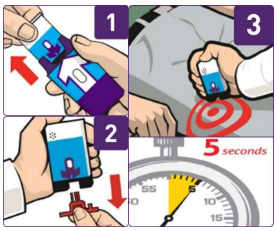
Administering & Maintaining Narcan / EVZIO requires little prior training

EVZIO:



- Studies have found successful administration by untrained lay rescuers in >90% cases
  - However, rates of successful/equivalently rapid administration of off-label atomizer kit found to be substantially lower (~60%)
- Naloxone does not require special storage/handling conditions*
  - Stored at room temperature; cold/hot weather "excursions" permitted
  - Small body of research suggests naloxone is chemically stable under varying environmental conditions
  - Shelf life: 18-24 months

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* See slide 36 in Appendix for additional detail

Prior training may be important for improving outcomes of naloxone administration

Key steps in naloxone administration*:

- Identify opioid overdose
- Check for responsiveness
- Call 911
- Administer naloxone
- Perform rescue breathing
- Provide aftercare

Possible consequences if not trained in key steps:

• Incorrectly identifying overdose cause (e.g., alcohol) • Incorrectly positioning patient after naloxone administration	→	Vomit-induced aspiration after naloxone administration
• Not calling 911 • Not preparing for overdose relapse	→	Risks to patient health from delayed / foregone 2nd naloxone dose or medical care
• Not preparing for patient agitation from opioid withdrawal	→	Physical harm to patient and/or lay administrator

Recommendation: If JCHC considers legislation on positioning naloxone in public places, retain training requirement for lay administrators

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* See slide 33 in Appendix for additional detail

Opioid Overdose & Naloxone-Related Training in Virginia

- DBHDS REVIVE! training is primary source of opioid overdose/naloxone-related information for lay audiences
  - Modules developed for law enforcement, 1st responders, lay rescuers
  - Lay rescuer training takes 1-1.5 hours to complete
- REVIVE! training is evolving as public awareness increases and audience needs change
  - Recently developed abbreviated (7-10 minute) "Rapid REVIVE" in-person training targets high-volume events, high-risk groups, treatment centers
  - DBHDS currently investigating use of federal funds to produce 10-15 minute online version for lay rescuers
  - Formal classroom-based trainings – appropriate for organizations with recurrent needs (e.g., Recovery Community Organizations, churches) – will continue to be offered
- REVIVE! brochures provided by authorized dispensers provide additional source of training/education

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Additional Channels of Opioid Overdose Information for Public

- In acute situations, 911 call centers with Emergency Medical Dispatch (EMD) services are potential source of guidance/information on opioid overdose and/or naloxone administration
  - Some 911 call centers currently integrating opioid overdose and/or naloxone administration protocols into EMD services
  - Around 1/3 call centers – usually smaller, rural – don't provide EMD services
- In acute or non-acute situations, regional Poison Control Centers (PCCs) are additional source of guidance/information
  - 24/7 confidential call-in resource staffed by medical professionals with expertise in opioid overdose signs/symptoms
  - Not widely known to public as source of information
- Opportunities may exist to build EMD capacities and leverage existing PCC capacities
  - Examples: 911 call centers lacking EMD services could explore enhancements through VDH Public Rescue Squad fund; VDH/PCCs could explore regional PCC role in OD data collection

JCHC may wish to request stakeholders to investigate opportunities to strengthen emergency communications capacities in opioid overdose/naloxone and leverage existing capacities of regional Poison Control Centers in non-acute and/or acute situations

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Naloxone Accessibility in Public Places

Working Definition of "public place"

- "Public place" in VA Code is broadly defined:
  - "Any place, building, or conveyance to which the public has, or is permitted to have, access"
  - "Any enclosed, indoor area used by the general public"
  - "Any area that is used or held out for use by the public, whether owned or operated by public or private interests"
- Examples of public places in model "universal naloxone access" legislation include: bars/restaurants, fitness centers, government office buildings, hotels, theaters
- For purposes of this study, "public place" is defined as any enclosed location that is:
  - Used or held out for use by the public, whether owned or operated by public or private interests
  - Regularly staffed

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Limited number of other States/localities position naloxone in public places

- Rhode Island
  - Under "NaloxBox" program (established in 2017), MOU between organizations/RI Medical Reserve Corps (MRC) establishes: MRC as organization's Medical Director; storage, training and reporting requirements*
- Grand Forks, ND
  - Naloxone co-located with AED units in 15-20 locations (since 2018)
- Delaware County, PA
  - Naloxone co-located with ~130 County-owned AED units, ~50 units in County YMCA's, colleges, universities (since 2018)
- Boston, MA
  - Currently rolling out deployment of naloxone in all city buildings
- To date, no instances of naloxone administration have been reported through these programs

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* See slide 38 in Appendix for additional detail

Considerations on positioning naloxone with AED units

- Locations of AED units in Virginia largely unknown*
  - VA Code requires/recommends AEDs in highly limited number of locations
  - Since 2003, VDH has not had role in oversight of AEDs
  - Data from other sources provide incomplete picture of current AED locations
- Pros of co-location
  - Public familiarity with AED units
  - Possibility of overdose-related sudden cardiac arrest
  - Existence of AED apps linking events to 1st responders (e.g., Pulsepoint)
- Cons of co-location
  - May not be the most cost-effective approach
    - Small body of research suggests co-locating naloxone with existing AEDs not likely to have large impact on preventing overdose fatalities
    - Effectively saturating localities with AED-naloxone units could be costly
  - Theft potential for naloxone in unsecured AED locations
  - Liability concerns of naloxone administration as controlled substance in VA

If JCHC considers legislation on positioning naloxone in public locations, focusing on co-location with AED units may not be most effective strategy

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* See slide 37 in Appendix for additional detail

Considerations on positioning naloxone in public places in Virginia

- Positioning naloxone in public places not likely to address majority of opioid overdose fatalities
  - Between 2016-2018, majority (62%) of fatalities occurred at home
    - 70% of fatalities involving prescription opioids (56% not involving prescription opioids) occurred in home
  - Alternatives to accessing naloxone positioned in public places may be more effective for these events (e.g., immediately calling 911)
- Geographic areas with highest concentration of public places likely to have alternative sources of rapid access to naloxone
  - In Richmond City:
    - 6-minute average response time for ambulance arrival for 911 calls
    - VCU researchers currently exploring drone-delivered naloxone/AED units to reach overdose events within 1 minute of contact with 911 dispatch*
- Naloxone positioned in public places could be more effective strategy than alternatives in other circumstances
  - Examples: events with illicit drugs involved → hesitation to call 911; areas with consistent clustering of opioid overdoses
- Naloxone positioned in public places could increase incidence of nearby opioid use

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* See slide 39 in Appendix for additional detail

Data on public places and opioid overdoses in Virginia (2016-2018)

- In 3 urban areas, ~50% of confirmed opioid overdose fatalities outside of home occurred in proximity to (within 1/10th mile of) public places*
  - Metro Richmond: 51%; Hampton Roads/Roanoke: 47-48%

% overdose fatalities outside of home occurring within 1/10th mile of:

Location Type**	Richmond (n=260)	Hampton Roads (n=278)	Roanoke (n=55)
Eating establishment	15%	16%	16%
Gas station/convenience store	15%	13%	9%
Hotel	10%	20%	16%
Religious establishment	14%	13%	15%
Municipal/government building	9%	1%	0%
Pharmacy	7%	5%	5%

- In metro Richmond, ~38% of suspected non-fatal overdoses occurred in proximity to public places

JCHC may wish to consider legislation adding persons acting on behalf of public places who have completed a training program to list of individuals explicitly authorized to possess and administer intranasal/intramuscular formulations of naloxone

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* See slide 40 in Appendix for additional detail; ** Not all location types listed

Considerations on naloxone accessibility in community pharmacies

- Media reports/previous research indicates variability in ability for public to obtain naloxone through pharmacy channel
- Statewide representative sample of ~300 community/retail pharmacies contacted to ascertain availability of naloxone
  - Could it be obtained without patient-specific prescription?
  - Was it in stock at time of contact?
- Discrepancy in accuracy of information about naloxone availability without a prescription
  - Overall, 77% indicated patient-specific prescription not required
  - ~49% independent pharmacies (87% chain pharmacies) indicated patient-specific prescription not required
- Naloxone immediately available without a prescription in ~65% of pharmacies

JCHC may wish to request Board of Pharmacy to re-emphasize in communications that Virginia law permits dispensing of naloxone without patient-specific prescription

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* See slide 41 in Appendix for additional detail

Supply-/Demand-Side Considerations

Naloxone supply: options for public to obtain naloxone

- Typical cash prices for naloxone range widely
  - Narcan: ~$120/kit (2 units)*; EVZIO: >$4,000/kit (2 units) (authorized generic for $178/2 units currently in FDA approval process)
  - Prefilled syringe with mucosal atomizer (off label): $29/kit
- Channels exist for individuals to obtain discounted naloxone
  - "No cost" naloxone: completion of selected REVIVE! trainings; directly from Local Health Departments, CSBs
  - Copay for insurance-based purchase
- There may be opportunities to build on manufacturers on existing manufacturer community/public pricing programs
  - Narcan: $75/kit for not-for-profit organizations; 2 free kits available to libraries, YMCAs, schools through direct distribution
    - To date: 75 scholastic institutions/1 library have received free kits
  - EVZIO: Kits for $178/2 units available to government agencies, 1st responders, "other qualifying groups"
    - Kaleo has expressed interest in expanding scope of other qualifying groups

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* Based on community pharmacy survey results; interquartile range: $100-$143

Demand for positioning naloxone in public places: perspectives of Virginia localities

- Survey of 58 locality/county administrators suggests concerns with maintaining naloxone on premises
  - ~25%: local government had discussed maintaining stock of naloxone
  - ~30%: local government would be somewhat / very likely to consider stocking naloxone if VA Code allowed it
  - Major concerns related to liability, employee training, costs and naloxone security/theft

Concerns with maintain naloxone in local government buildings

Source: Staff survey

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Civil/criminal liabilities for naloxone possession/administration are possible

- VA Code provides Good Samaritan (civil) liability protections to individuals dispensed naloxone under authorized channels
- Individuals could possess and/or administer naloxone through unauthorized channels
  - Example: Naloxone dispensed to individual A who gives Individual B naloxone to administer on Individual C who is experiencing overdose
- If possessed through unauthorized channels, criminal penalties could be incurred
  - Possession of Schedule VI drug is Class 4 misdemeanor with fine up to $250
- If administered though unauthorized channels, Good Samaritan Law protections (§8.01-225) would not apply

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Civil/criminal liabilities for naloxone possession/administration are possible

- Possibility of naloxone possession/administration charges could be barrier to:
  - Naloxone administration by individuals in opioid overdose events involving illicit substances
  - Willingness of public places/organizations to developing on-premise naloxone policies due to liability concerns stemming from individual-level liabilities
- Illustrative legislation broadening naloxone liability protections:
  - A person who is: 1) not otherwise authorized to administer naloxone or other opioid antagonist used for overdose reversal and 2) acting in good faith, and in the absence of gross negligence or willful and wanton misconduct, may administer an opioid antagonist to another person who appears to be experiencing an opioid related drug overdose. The person administering naloxone or other opioid antagonist used for overdose reversal shall not be considered to be engaged in the unauthorized practice of medicine or the unlawful possession of an opioid antagonist.

JCHC may wish to consider legislation broadening criminal and civil liability protections for possession and administration of naloxone (e.g., regardless of channel naloxone was obtained)

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Policy Options

Policy Options

Policy Option(s)	Pros	Cons
Option 1: Take No Action		
Option 2: Introduce legislation authorizing persons acting on behalf of public places who have completed a training program to possess and administer intranasal / intramuscular formulations in case of suspected overdose	• Could promote further availability of naloxone in public places and # individuals/organizations trained in responding to opioid overdoses	• Could have limited adoption by entities considered to be "public places"
Option 3: Introduce legislation broadening criminal and civil liability protections for naloxone administration	• Could reduce perceived concerns with naloxone administration by public • Could encourage public places to consider maintaining naloxone on premises	• Unknown degree to which liability protection concerns discourage naloxone administration by public

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Policy Options

Policy Option(s)	Pros	Cons
Option 4: By letter of the JCHC Chair, request that the Board of Pharmacy include information about Virginia laws making naloxone available without a patient-specific prescription in the next pharmacy profession license renewal communication	• Would ensure all pharmacy-related professions have current information on VDH Standing Order	• Would not compel pharmacies to convey accurate information to public on obtaining naloxone without patient-specific prescription
Option 5: By letter of the JCHC Chair, request that the HHR Secretary convene a task force to study current roles of Public Safety Answering Points (911 call centers) and regional Poison Control Centers in providing information/assistance to the public on opioid overdoses and naloxone in both acute and non-acute situations. A written report – submitted to the JCHC by October 31, 2020 – should provide recommendations on any necessary enabling legislation or funding that may be required to enhance their respective roles.	• Aligns with activities of current structures in place addressing opioid addiction (Governor's Advisory Commission and Executive Leadership Team on Opioids)	• Does not directly facilitate public accessibility to naloxone

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Public Comment

Written public comments on the proposed options may be submitted to JCHC by close of business on October 25, 2019.

Comments may be submitted via:

- ❖E-mail: jchcpubliccomments@jchc.virginia.gov
- ❖Fax: 804-786-5538
- ❖Mail: Joint Commission on Health Care
  P.O. Box 1322
  Richmond, Virginia 23218

Comments will be provided to Commission members and summarized before they vote on the policy options during the JCHC's November 14th decision matrix meeting.

(All public comments are subject to FOIA release of records)

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Appendix

VDOE Naloxone Requirements

- Recently issued VDOE Superintendent's Memo (# 198-19) requires local-level naloxone policies
  - School boards required to develop/implement policies and procedures for school-based naloxone administration, school personnel training
- Four school districts currently stock naloxone in their schools (Hampton, VA beach, Roanoke County, Roanoke City)
- VDOE currently developing guidance document for local school divisions

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Components of REVIVE! Training and Authorized Dispenser Naloxone Instruction

REVIVE! Training

- Naloxone-related laws
- Understanding addiction
- Opioid definition
- Opioid Overdose:
  - Definition
  - Risk factors/signs
  - Don'ts (what not to do)
- How naloxone works
- How to administer naloxone
- Responding to suspected OD
- Hands-on Training

Authorized Dispenser Instruction

- Opioid overdose:
  - Prevention
  - Recognition
  - Response
- Naloxone administration:
  - Dosing
  - Effectiveness
  - Adverse effects
  - Storage conditions
  - Shelf-life
  - Safety
- Provide REVIVE! brochure to patient

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FDA Approval of Naloxone

- Naloxone initially FDA-approved in 1971 for opioid overdose reversal in clinical settings
  - Naloxone hydrochloride is short-acting opioid antagonist for respiratory/central nervous system depression from opioid overdose
  - Approved for intravenous, intramuscular, or subcutaneous use
- Since 2014, FDA has approved naloxone for use in community setting
  - Approvals based on evidence of equivalent effectiveness as injectable and usable without prior training
  - 3 products currently FDA-approved: nasal spray (Narcan, generic); auto-injector (EVZIO)
- Off-label use in community setting includes nasal atomizer kit using injectable naloxone

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Naloxone Adverse Reactions

- Adverse events from intramuscular/intranasal naloxone:

Table 7. Adverse events after naloxone 2 mg by intramuscular (IM) or intranasal (IN) routes [Kelly *et al.* 2005].

Event term	IM (n = 71)	IN (n = 84)
	n (%)	n (%)
Agitation and/or irritation	10 (14%)	2 (2.4%)
Nausea and/ orvomiting	4 (5.6%)	6 (7.1%)
Headache	2 (2.8%)	0 (0%)
Tremor	1 (1.4%)	1 (1.2%)
Sweating	0 (0%)	1 (1.2%)

Table 8. Adverse events after naloxone 2 mg by intramuscular (IM) or intranasal (IN) route [Kerr *et al.* 2009].

Event term	IM (n = 89)	IN (n = 83)
	n (%)	n (%)
'Minor events'	17 (19.1%)	16 (19.3%)
Agitation and/or irritation	7 (7.9%)	5 (6.0%)
Nausea and/or vomiting	7 (7.9%)	7 (8.4%)
Headache	3 (3.3%)	4 (4.8%)
'Major event'		
Convulsion	1 (1.1%)	0 (0%)

Source: Wermeling (2015)

  - Naloxone may play role in rare side effect of noncardiogenic pulmonary edema
- Dose/route of administration are significant factors in occurrence/intensity of adverse reactions
  - Slower revival onset from non-IV administered naloxone may be better tolerated by recovering patients
- Opioid withdrawal is generally not life-threatening
  - Withdrawal symptoms tend to dissipate in 30–60 minutes
  - Naloxone short-half life compared to opioids longer persistence in blood stream can necessitate repeat naloxone doses

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Naloxone storage/handling

- Narcan/Evzio manufacturer guidelines
  - Storage temperature: 59°F to 77°F (limited “excursions” permitted between 39°F to 104°F)
  - Shelf life: 18-24 months
- Small body of research suggests naloxone is chemically stable under varying conditions
  - No change in drug concentration after 28 days of continuous heat-/freeze-thaw cycles
  - Naloxone may remain chemically stable 10 months after expiration date

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State involvement in AED oversight

- VA Code requires or recommends AED installation in limited number of places
  - Jails/lockups, shipyards, select dentist offices
- No State agency has tracked AED locations since 2003
  - Prior to 2003, organizations required to register AEDs with/receive training from VDH
  - In 2003, HB 1860 (O'Bannon) eliminated registration/training requirements based on research indicating that untrained public can use AEDs safely and effectively
  - VDH does not currently have role in oversight of AEDs

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Rhode Island NaloxBox Program

- Program origins: Rhode Island's Department of Public Health provided mini-grants ($5,000 or less) to stock NaloxBoxes
  - Naloxone must be procured separately
- Since Rhode Island Disaster Medical Assistance Team (RIDMAT) took over program, ~225 NaloxBoxes have been purchased in 4 States (CA, IA, OH, RI)
  - Units retail for $245
- Organizations participating in RI program establish MOUs with RI Medical Reserve Corps (MRC)
  - Allows MRC to serves as organization's Medical Director
  - MOUs include storage, training and reporting requirements

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Drone-Delivered AED/Naloxone Initiative

- Background: In context of cardiac arrest from cardiac causes, rapid response time to out-of-hospital cardiac attacks (OHCA) is major determinant of survival probability
  - Every additional 1 minute in response time → 10% survival reduction
- Non-targeted approaches to equipping bystanders with means to respond to OHCAs may be inefficient or ineffective
  - Toronto study of CPR-trained bystanders notified by app of suspected OHCAs: bystanders 1st on scene 1% time (out of <1,200 OHCAs)
  - Saturating localities with co-located naloxone/AEDs could be costly
    - Example: 7,750 AED units would be required in Richmond City to ensure bystander accessibility within 2 minutes (total cost: ~$12M)
- VCU (Department of Emergency Medicine) currently submitting grant applications to pilot drone-delivered naloxone in Richmond City/Roanoke
  - 5 drones estimated to be able to cover 90% of Richmond City with median delivery of <1 minute (total drone cost: $50,000)

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Analysis of opioid overdose event proximity to public places

- Public places considered in analysis
  - Banks
  - Eating establishments (e.g., fast food, coffee shops, restaurants)
  - Fitness centers
  - Gas stations/convenience stores
  - Grocery/home goods stores
  - Hotels
  - Entertainment venues (e.g., bowling alleys, movie theaters, skating rinks)
  - Municipal/government building locations (e.g., community centers, pools, fire/police stations, other government administrative buildings)
  - Religious establishments
  - Shopping malls
- Opioid overdose data sources
  - VDH Office of the Chief Medical Examiner opioid overdose fatalities (2016-2018)
  - HIDTA ODMAP suspected opioid overdose fatalities and non-fatalities (2018-2019)
- Public place data sources
  - Various organizations' websites
  - Google Maps

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Community Pharmacy Survey

- Following methodology described in Evoy et al. (2018), data collected from 300 randomly selected community pharmacies
  - Sample excluded: hospital/medical center outpatient pharmacies; DBHDS-licensed pharmacies; specialty pharmacies
- Sample pharmacy characteristics similar to those for all community pharmacies in Virginia
  - % pharmacies in given zip code compared to all sampled pharmacies within 1% point of % pharmacies in VA in given zip code relative to all community pharmacies in VA

Metropolitan Area	Sample		All Pharmacies	
	%	N	%	N
Hampton Roads	13%	41	11%	170
Richmond City	12%	37	8%	124
Roanoke	2%	7	1%	19

Ownership	Sample		All Pharmacies	
	%	N	%	N
Chain (store-based)	28%	86	28%	448
Chain (stand-alone)	43%	136	41%	645
Independent	29%	91	31%	483

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Considerations on Naloxone and Compensatory Behaviors

- Little evidence that increased naloxone accessibility associated with riskier behaviors (moral hazard effect)
  - Most – but not all – studies do not find increased opioid use
- Little evidence of compensatory behaviors in other areas of public health
  - Mandated seat belts not associated with increased reckless driving
  - Initiation to HIV treatment not associated with increased sexual risk behaviors

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References

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Slides 5 (Naloxone-Focused Response in Virginia), 31 (VDOE Naloxone Requirements)

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Slides 9 (Naloxone generally regarded as safe), 33 (FDA Approval of Naloxone), 34 (Naloxone Adverse Reactions)

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Slide 10 (Naloxone effective when administered by trained lay individuals)

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HJ 653

WHEREAS, the United States is experiencing a growing opioid epidemic, resulting in an alarming rise of opioid-related deaths; and

WHEREAS, naloxone is an antidote to opioid overdose, and timely administration of the drug can reverse opioid-induced respiratory depression; and

WHEREAS, naloxone is available in multiple dosage forms, including by nasal spray and injection; now, therefore, be it

RESOLVED by the House of Delegates, the Senate concurring, That the Virginia Department of Health be requested to study the feasibility of expanding naloxone access through the placement of naloxone in automated external defibrillator (AED) cabinets across the Commonwealth.

In conducting its study, the Virginia Department of Health shall (i) determine any current barriers to expanding naloxone availability through its placement in AED cabinets; (ii) propose potential solutions, as practicable, to current barriers to expanding naloxone availability through its placement in AED cabinets; and (iii) develop and implement a program to educate schools, hospitals, public institutions, and the general public regarding current requirements for storage of and access to naloxone.

All agencies of the Commonwealth shall provide assistance to the Virginia Department of Health for this study, upon request.

The Virginia Department of Health shall complete its meetings by November 30, 2019, and shall submit to the Governor and the General Assembly an executive summary and a report of its findings and recommendations for publication as a House or Senate document. The executive summary and report shall be submitted as provided in the procedures of the Division of Legislative Automated Systems for the processing of legislative documents and reports no later than the first day of the 2020 Regular Session of the General Assembly and shall be posted on the General Assembly's website.

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Delegate Gooditis Letter to JCHC Re: HJ 653

Dear Dr. Chesser,

I write to request a study from the Joint Commission on Health Care in 2019 concerning public access to naloxone, a life-saving drug that reverses the effects of opioid overdoses.

In the 2019 legislative session I introduced HJ 653, which requested the Virginia Department of Health study the placement of naloxone alongside Automatic Electronic Defibrillators (AED's). On January 29th, 2019, House Rules Subcommittee #1 heard HJ 653 and accepted an amendment broadening the scope of the study to include all methods of increasing public access to naloxone.

The subcommittee then voted 7-0 to lay HJ 653 on the table upon the verbal agreement that the Chair of the House Committee on Health, Welfare, and Institutions would send a letter to the Joint Commission on Health Care requesting the study. The Executive Director of the Joint Commission on Health Care also agreed verbally to place the study on the Commission's 2019 work plan.

To best serve the needs of the public, I would request this study examine:

a) whether removing barriers to administering Naloxone, such as the requirement to obtain training before using the drug, is likely to save lives without causing significant damage to public health, and

b) if so, which barriers to administration we should remove, and

c) whether and how we could place naloxone in publicly accessible places, such as alongside Automatic Electronic Defibrillators (AEDs)

Sincerely,

Delegate Wendy Gooditis

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