REPORT OF THE

JOINT COMMISSION ON HEALTH CARE

NALOXONE PUBLIC ACCESS AND STORAGE

TO THE GOVERNOR AND

THE GENERAL ASSEMBLY OF VIRGINIA

REPORT DOCUMENT NO. 414

COMMONWEALTH OF VIRGINIA
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Code of Virginia § 30-168.

The Joint Commission on Health Care (the Commission) is established in the legislative branch of state government. The purpose of the Commission is to study, report and make recommendations on all areas of health care provision, regulation, insurance, liability, licensing, and delivery of services. In so doing, the Commission shall endeavor to ensure that the Commonwealth as provider, financier, and regulator adopts the most cost-effective and efficacious means of delivery of health care services so that the greatest number of Virginians receive quality health care. Further, the Commission shall encourage the development of uniform policies and services to ensure the availability of quality, affordable and accessible health services and provide a forum for continuing the review and study of programs and services.

The Commission may make recommendations and coordinate the proposals and recommendations of all commissions and agencies as to legislation affecting the provision and delivery of health care.

For the purposes of this chapter, "health care" shall include behavioral health care.

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Preface

House Joint Resolution 653 (Delegate Gooditis) would have required a study of the barriers and solutions to co-locating naloxone in Automatic External Defibrillators (AEDs) as well as implementing an education program. The resolution was tabled in House Rules Committee with the understanding that the Joint Commission on Health Care (JCHC) would consider researching the topic in 2019. The study was approved by Commission members during the work plan meeting.

The study focused on naloxone training and education, its accessibility in public places, and factors affecting the supply of and demand for naloxone. Based on recommendations made for each area of focus, five policy options were presented for consideration by Commission members and they approved four options.

Joint Commission members and staff would like to acknowledge and thank those who assisted in this study, including representatives from the Virginia Department of Behavioral Health and Developmental Services, the Virginia Department of Health, the Virginia Association of Counties and the Virginia Municipal League.

The study and this report was assigned to and completed by Andrew Mitchell, Senior Health Policy Analyst at the Joint Commission on Health Care.

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Executive Summary

House Joint Resolution 653 (Delegate Gooditis) requested that the Virginia Department of Health (VDH) study barriers and solutions to co-locating naloxone in Automatic External Defibrillators (AEDs) as well as propose and implement an education program. The resolution was tabled in House Rules Committee with the understanding that the Joint Commission on Health Care (JCHC) would include a study of the issue in its 2019 workplan for member consideration. A subsequent letter from Delegate Gooditis requested that JCHC focus on: whether removing barriers to administering naloxone in public places is likely to save lives without causing significant damage to public health; and whether/how naloxone can be placed in publicly accessible places, such as alongside AEDs.

A combination of federal actions/funding and state-level policies have increased accessibility to naloxone – generally regarded as a safe antidote to an opioid overdose – to the general public. Although evidence suggests that naloxone can be successfully administered by lay rescuers without specialized training, opioid overdose-related training and education may be important in ensuring that the most effective response is taken. A limited number of localities and one state across the U.S. have experience with positioning naloxone in public places, and data from Virginia suggest that approximately 50% of fatal opioid overdoses occurring outside of the home take place in close proximity to a variety of public places where naloxone could be positioned.

Recommendations were made relating to naloxone training and education, positioning naloxone in public places, and addressing supply-/demand-side barriers to community-based naloxone availability. These included: authorizing public places to maintain naloxone on their premises with trained staff authorized to administer naloxone; exploring opportunities to expand the capacities or reach of other sources of opioid-related information (e.g., 911 call centers, regional Poison Control Centers); requesting that the Board of Pharmacy re-emphasize in its communications to regulated professions that Virginia law permits dispensing of naloxone without a patient-specific prescription; and broadening criminal and civil liability protections for possession and administration of naloxone regardless of the channel through which naloxone was obtained.

Five policy options were presented for consideration by Joint Commission on Health Care members and they voted against the option to take no action and approved all of the other options.

NALOXONE PUBLIC ACCESS AND STORAGE

Study Mandate

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

Background

Naloxone hydrochloride is a short-acting opioid antagonist that is a "safe antidote to a suspected overdose" (Office of the Surgeon General 2018). Although naloxone is a Schedule VI Controlled Substance in Virginia, it is not scheduled federally by the Drug Enforcement Agency, is not psychoactive, has no effect in the absence of opioids, and has no abuse potential (Mueller et al. 2015). Initially approved by the Federal Drug Agency (FDA) in 1971 for opioid overdose reversal in clinical settings by intravenous (IV), intramuscular, or subcutaneous administration, naloxone has been FDA-approved for use in community settings since 2014. Three products are currently FDA-approved in non-clinical settings: intranasal (IN) nasal spray (Narcan and a generic version) and intramuscular auto-injector (EVZIO). FDA approvals were based on evidence of equivalent effectiveness as previously approved injectable formulations and usability without prior training (Lewis et al. 2017). Intranasal-administered naloxone has a high rate of success in reversing effects of opioid overdoses in both clinical and non-clinical settings: opioid overdose reversal rates of intranasally-administered naloxone by both medical professionals and laypersons exceeds 75 percent (Lewis et al. 2017; Lynn & Galinkin 2018).

As highlighted in Figure 1, studies have found that most reported adverse events to naloxone administered in formulations approved for community use are minor and relate to reactions due to precipitated opioid withdrawal (Wermeling 2015), although naloxone may play a role in the rare side effect of non-cardiogenic pulmonary edema during an ultrapotent opioid overdose (Ng et al. 2019). The dosage and route of administration are significant factors in both the occurrence and intensity of adverse reactions: naloxone administered in a non-intravenous (IV) route may be better tolerated by individuals than when administered by an IV route due to a slower onset of revival. Opioid withdrawal is generally not life-threatening – withdrawal symptoms tend to dissipate within 30 to 60 minutes – although naloxone's short-half-life compared to opioids' longer persistence in the blood stream can necessitate repeat naloxone dosing (Wermeling 2015).

Figure 1. Adverse Events to Naloxone Administered Intramuscularly or Intranasally

Adverse events after naloxone 2 mg by intramuscular (IM) or intranasal (IN) routes:

2005 study

Event term	IM (n = 71) n (%)	IN (n = 84) 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%)

2009 study

Event term	IM (n = 89) n (%)	IN (n = 83) 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)

Recent legislation and regulatory changes in Virginia have taken steps to increase public accessibility to naloxone. In the context of over 1,200 opioid overdose fatalities occurring annually in Virginia – more than double the level in 2012[1] (Virginia Department of Health 2019a)(Virginia Department of Health 2019c), steps to increase naloxone availability in community settings include:

- Elimination of a Controlled Substance Registration (CSR) requirement for naloxone dispensing by organizations providing substance abuse services/naloxone training (2019 legislative session)
- Establishment (2016 legislative session) and expansion (2017 legislative session onwards) of a list of professionals authorized to possess, administer and dispense naloxone
- Requirement that naloxone be co-prescribed with opioids for high-risk patients (Administrative Code changes to 18VAC85-21-40, effective 2018)

In particular, pursuant to VDH's statewide Standing Order – or any other Standing Order issued by a practicing physician – Virginia Code §54.1-3408(X) authorizes specific categories of professionals – such as first responders, professionals working in school settings providing health services, and correctional facility employees – as well as representatives of organizations that provide services and/or training in naloxone to individuals at risk for opioid overdose to possess, administer and dispense naloxone to laypersons. As of 2019, Board of Pharmacy protocols require authorized dispensers to provide some form of naloxone-related instruction, and/or the Department of Behavioral Health and Developmental Services (DBHDS') naloxone training REVIVE! brochure, to lay individuals at the time of dispensing. Topics to be covered in naloxone instruction include: opioid overdose prevention, recognition, and response; and naloxone dosing, effectiveness, adverse effects, storage conditions/expiration date, shelf-life and safety (Board of Pharmacy 2019).

[1] In 2018, # opioid overdose fatalities decreased from previous year for the first time since 2011

Several agency initiatives have also focused on increasing public accessibility to naloxone. These include initiatives by:

- VDH: Between 2016 and the time of writing of this report, VDH had procured almost 31,000 Narcan kits through around $1.75M in funding, distributing almost 23,000 kits to local health departments, and over 7,000 kits to Community Services Boards, law enforcement/fire protection agencies, and Emergency Medical Services personnel (Virginia Department of Health 2019b).
- DBHDS: To date, 35,000 lay individuals trained in REVIVE! training on opioid overdose (the program currently has around 4,000 trainers).
- Virginia Department of Education (VDOE): Superintendent's Memo # 198-19 (2019) requires local school boards to develop and implement policies and procedures for school-based naloxone administration and school personnel training. At the time of this report, four school districts were currently stocking naloxone on school premises (Hampton, Virginia Beach, Roanoke County, Roanoke City), and VDOE was in the process of developing a guidance document for local school divisions.

Naloxone Training and Education

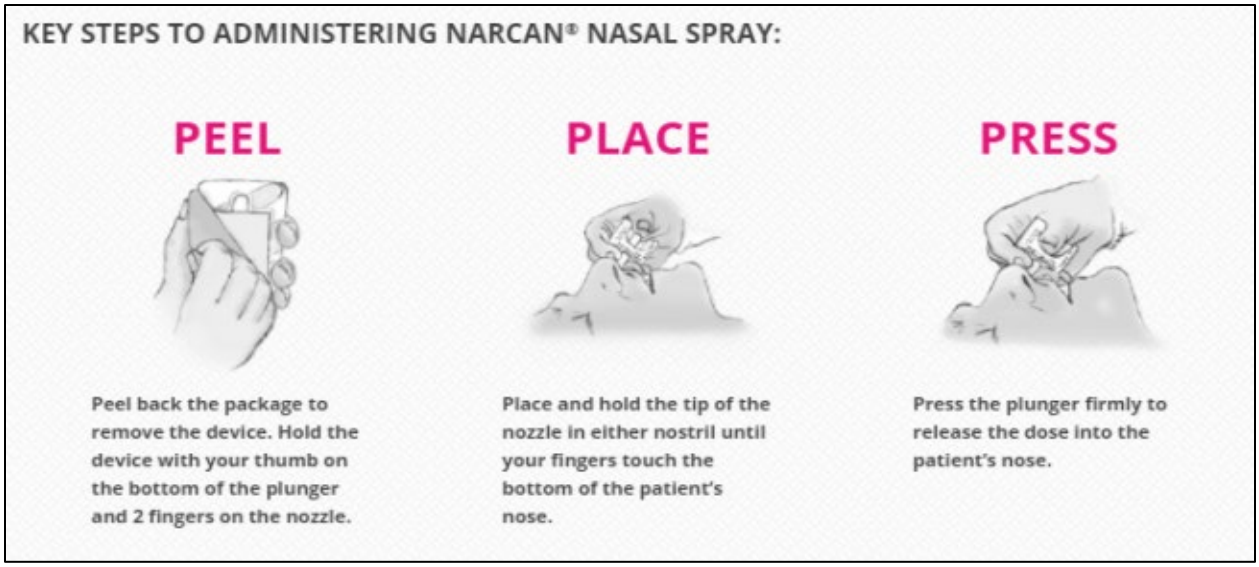
Numerous studies on opioid overdose education and naloxone distribution (OEND) programs point to the effectiveness of both in mitigating the impact of opioid overdoses. Reviews of OEND programs have found that they improve participants' abilities to recognize overdoses and appropriate need for naloxone administration, as well as to administer naloxone safely and effectively in overdose situations (Mueller et al. 2015; Green et al. 2008). Although the evidence base on which these conclusions are drawn is limited (e.g., lack of Randomized Control Trials, pilot studies with limited follow up time), a recent meta-analysis of available evidence indicated that participants in OEND programs scored higher on tests of naloxone administration, overdose recognition, and overdose response. Further, administration of naloxone by trained bystanders is associated with increased odds of recovery from opioid overdoses (Clark et al. 2014; Giglio et al. 2015).

Training in naloxone administration and handling

Little to no training in administration of naloxone is required to successfully administer FDA-approved formulations of naloxone for community use. As illustrated in Figure 2, administration of naloxone requires a limited number of steps that can be followed through simple visual aids (the EVZIO product additionally includes voice guidance). Multiple simulation studies have found that more than 90% of untrained participants were able to successfully administer either version (Ryan & Dunne 2018; Tippey et al. 2019; Goldberg et al. 2018). However, administration of naloxone with user-assembled atomizer kits using off-label formulations of naloxone has been found to be less successful. For example, one study found that fewer than 60% of participants successfully administered a dose of injectable naloxone using an atomizer kit even after receiving training (Ryan & Dunne 2018).

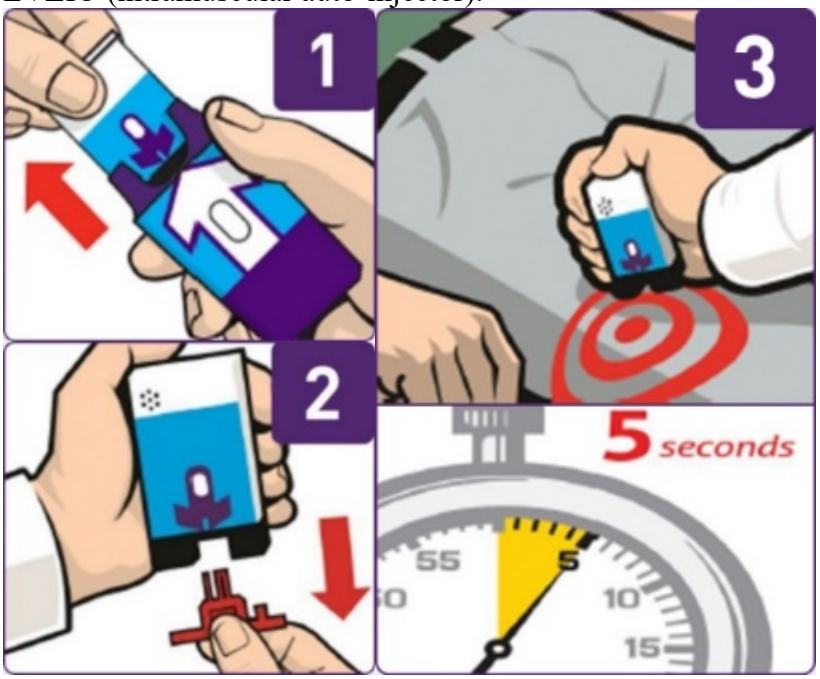
Figure 2. Naloxone Administration Instructions

Narcan (nasal spray):



Source: (Adapt Pharma 2017)

EVZIO (intramuscular auto-injector):



Source: (kaleo 2016)

Additionally, appropriately storing naloxone does not require specialized knowledge. With a shelf life of 18 to 24 months, manufacturer guidelines indicated that naloxone can be stored between 59°F and 77°F, with limited "excursions" permitted between 39°F to 104°F. A small body of research suggests that naloxone remains chemically stable under conditions outside of those temperature ranges: one study found no change in naloxone's drug concentration after 28

days of continuous heat-/freeze-thaw cycles, while another found that naloxone remained chemically stable 10 months after its expiration date (Lai et al. 2019; Thomas 2018).

Training in opioid overdose recognition and response

By contrast with training in naloxone administration and handling, education on opioid overdose recognition and response – which usually accompanies training in naloxone administration – can be important to enable a lay rescuer to respond as effectively as possible to an opioid overdose event. Training in naloxone administration is typically accompanied by education in a broader set of topics of importance in any given scenario. Key steps for lay rescuers to take indicated in DBHDS' current REVIVE! training module include: how to identify an opioid overdose; checking for responsiveness; calling 911; administering naloxone; performing rescue breathing; and providing aftercare[2] (Department of Behavioral Health and Developmental Services 2019). As highlighted in Table 1, not being aware of and/or following key steps could compromise both patient outcomes and lay rescuer's safety.

Table 1. Risks of Naloxone Administration by Untrained Lay Rescuers

• 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

Training and education on opioid overdose/naloxone in Virginia

DBHDS' REVIVE! training is the primary channel that the public can access in-depth information on naloxone/opioid overdoses. With a variety of modules developed for different audiences (lay rescuers, law enforcement, first responders), its current module for the general public takes one to 1.5 hours to complete. REVIVE! training is evolving as public awareness of opioid overdoses and naloxone increases and training needs change. As a result, DBHDS has recently developed an abbreviated (7-10 minute) "Rapid REVIVE" in-person training model that targets high-volume events, high-risk groups, and treatment centers, and is currently investigating use of federal funds to produce a 10 to 15 minute online version for lay rescuers. DBHDS anticipates that its formal classroom-based trainings – appropriate for organizations with recurrent needs (e.g., Recovery Community Organizations, churches) – will continue to be offered.

[2] The components of REVIVE! training cover: naloxone-related laws; understanding addiction; opioid definition; opioid overdose definition, risk factors/signs, and "don'ts" (what not to do); how naloxone works; how to administer naloxone; responding to a suspected overdose; and hands-on training. These topics are similar to those covered by authorized dispensers listed in Virginia Code §54.1-3408(X) when providing naloxone to lay individuals (see section).

In addition to information provided to the public through REVIVE! trainings, Public Safety Answering Points (PSAPs, or 911 call centers) and regional Poison Control Centers (PCCs) are two additional sources of guidance and/or information for the public on opioid overdose and naloxone. In acute situations, 911 call centers with Emergency Medical Dispatch (EMD) can assist callers in addressing opioid events. While some call centers in Virginia are in the process of integrating protocols for dispatchers on opioid overdoses and naloxone administration, not all call centers currently have such protocols. Additionally, survey data of 911 call centers collected by VDH in 2018 indicated that around one-third of Virginia localities – usually smaller and/or rural – do not have a 911 call center that provides EMD services at all (Virginia Department of Health 2018). In the context of either acute or non-acute situations, regional PCCs –confidential call-in resources staffed 24/7 hours per day by medical professionals – have expertise in opioid overdose response and naloxone. However, PCCs are not widely known to the public as a source of information.

Opportunities may exist to both build EMD capacities and leverage existing PCC capacities. 911 call centers lacking EMD services, for example, could explore enhancements through VDH Public Rescue Squad fund. VDH and regional PCCs could explore a regional PCC role in opioid overdose data collection. Along these lines, in 2019, Connecticut established a State-Wide Opioid Reporting Directive (SWORD) initiative involving the state's PCC to collect data on opioid overdoses and be able to better respond to future events. Under this initiative, first responder/EMS personnel at the scene of an overdose are required to call the PCC to provide data on the overdose (e.g., patient demographics, type of opioid, whether patient transported to hospital) (Gutierrez 2019).

Recommendations on Naloxone Training and Education

- If JCHC members consider legislation on positioning naloxone in public places, retain training requirement for lay administrators.
- JCHC members may wish to request stakeholders to investigate opportunities to strengthen emergency communications capacities in opioid overdose/naloxone administration and leverage existing capacities of regional Poison Control Centers in non-acute and/or acute situations.

Naloxone Accessibility in Public Places

For the 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; and regularly staffed. This definition is consistent with how the Code of Virginia defines "public place" as:

- "Any place, building, or conveyance to which the public has, or is permitted to have, access" (§4.1-100)
- "Any area that is used or held out for use by the public, whether owned or operated by public or private interests" (§10.1-1414)

- "Any enclosed, indoor area used by the general public" (§15.2-2820)

It is also consistent with a definition of public places found in model "universal naloxone access" legislation that provides examples such as bars/restaurants, fitness centers, government office buildings, hotels, and theaters (National Alliance for Model State Drug Laws 2019).

A limited number of other States and localities have experience with positioning naloxone in public places to provide opportunities to lay rescuers to respond to opioid overdose emergencies. Under Rhode Island "NaloxBox" program, organizations establish Memoranda Of Understanding (MOUs) with the State's Disaster Medical Assistance Team/Medical Reserve Corps (RIDMAT/MRC) to position publicly accessible kits of naloxone on their premises. The program originated with an initiative by the state's Department of Public Health to provide mini-grants ($5,000 or less) to organizations to procure NaloxBoxes (naloxone must be procured separately). Taking over administration in 2017, MOUs between RIDMAT/MRC and participating organizations – which can be publicly or privately owned – establishes the MRC as the participating organization's Medical Director, and delineates a variety of requirements related to naloxone storage/quality assurance, personnel training and reporting. NaloxBox units currently retail for $245 (RIDMAT 2019).

Other local-level governments have experience positioning naloxone in public places. In Grand Forks, North Dakota, naloxone has been co-located with AED units in 15 to 20 locations since 2018 (Grand Forks Public Health 2019). Since 2018, Delaware County, Pennsylvania has co-located naloxone with approximately 130 County-owned AED units, and around 50 units in County YMCA's, colleges, and universities (Delaware County Intercommunity Health Coordination 2019). The city of Boston, Massachusetts is currently rolling out deployment of naloxone in all of its city buildings (Boston Public Health Commission 2019). To date, across both the NaloxBox program and other examples cited, no instances of naloxone administration have been reported through these initiatives.

Co-locating Naloxone With AED Units

Data limitations make it difficult to evaluate the appropriateness of co-locating naloxone with AEDs where AED units are currently located. There are a highly limited number of locations in which Virginia Code or administrative regulations require or recommend that AEDs be placed: jails/lockups (6VAC15-40-405), shipyards (16VAC25-100-1915) and Emergency Medical Services vehicles (12VAC5-31-860). Data on locations of AEDs have not been collected by the Commonwealth since 2003; prior to that year, organizations were required to register AEDs and receive related training. In 2003, House Bill 1860 (Delegate O'Bannon) eliminated AED unit registration/training requirements based on research indicating that untrained individuals can use AEDs safely and effectively. Since that time, neither VDH nor any other state agency has overseen AED units. While non-state-affiliated data sources do exist (e.g., Pulsepoint), data made available for this study were found to be far from comprehensive.[3]

[3] A dataset of all AED locations registered with Pulsepoint included 327 AED units across 22 localities across Virginia.

There are nonetheless potential advantages of co-locating naloxone with AED units. First, AED units are widely recognized – if the public knew that naloxone was co-located inside, familiarity with AED units might facilitate a rapid response. Second, the possibility of an overdose-related sudden cardiac arrest could necessitate the need for defibrillation along with naloxone administration. However, studies have found that sudden cardiac arrest from an overdose is significantly less likely to be able to be restarted by an AED shock compared to cardiac arrest from cardiac causes, so the value of co-locating in AED units may be diminished (Elmer et al. 2015; Smith et al. 2019). Finally, AED-related software/apps that link AED locations to first responders could possibly be leveraged to provide information about co-located naloxone.

Conversely, there are several reasons that a program to co-locate naloxone with AED units may not be an optimal approach. First, it may not be cost-effective to do so. On the one hand, a small body of research suggests that co-locating naloxone with existing AEDs is not likely to have a large impact on preventing overdose fatalities (Salerno et al. 2018). On the other hand, a program to saturate localities with co-located naloxone/AEDs could be costly. For Richmond City, for example, it is estimated that 7,750 AED units would be required to ensure bystander accessibility within 2 minutes for a total cost of around $12M (Ornato 2019). Second, there may be a higher potential for theft of naloxone kits compared to AEDs. Finally, there may be liability concerns with positioning naloxone – a Schedule VI Controlled Substance in Virginia – in publicly accessible AED units.

Positioning Naloxone in Public Places

Positioning naloxone in public places could increase opportunities under some circumstances for lay rescuers to respond to opioid overdose emergencies. On the one hand, naloxone positioned in public places is not likely to be the most effective strategy for the majority of opioid overdose fatalities that occur inside the home, which constitute the majority of such fatalities in Virginia (between 2016 and 2018, over 60% of opioid fatalities in Virginia occurred at home)[4] (Office of the Chief Medical Examiner (VDH) 2019). In these cases, alternative approaches to publicly positioned naloxone – such as immediately calling 911 – may be more effective strategies. Additionally, urban areas that generally have the highest concentration of public places are also likely to have other sources of rapid access to naloxone, such as EMD personnel dispatched by 911 call operators. Richmond City, for example, has a six-minute average response time for ambulance arrival for 911 calls, and VCU researchers are currently exploring drone-delivered naloxone/AED units to reach overdose events within 1 minute of contact with 911 dispatch[5] (Ornato 2019; Richmond Ambulance Authority 2019). On the other hand, positioning naloxone in public places could be an effective strategy when bystanders are hesitant to call emergency

[4] Approximately 70% of fatalities taking place within the victim's home involved prescription opioids – while only 56% not involving prescription opioids occurred in home – suggesting that positioning naloxone in public places is more likely to address fatalities from illicit opioids compared to prescribed opioids.

[5] VCU (Department of Emergency Medicine) is currently submitting grant applications to pilot drone-delivered naloxone in Richmond City/Roanoke. Five drones are estimated to be able to cover 90% of Richmond City with median delivery of less than one minute (total drone cost: $50,000) (Ornato 2019).

services (e.g., when illicit drugs are present) or when opioid overdoses are consistently clustered in certain areas (e.g., hotels).

Geographical location data were collected on "public places" and opioid overdose fatality events occurring between 2016 and 2018 in three metropolitan areas – Hampton Roads, Richmond City and Roanoke – to analyze the degree to which fatalities took place in close proximity to public places. A variety of public places were considered in the analysis and included: 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; and shopping malls.[6]

Data collected on locations of public places and opioid fatalities indicate that approximately 50% of opioid overdose fatalities that happened outside of the victim's home between 2016 and 2018 occurred within 1/10th mile of a public place. Percentages of fatalities occurring most frequently in proximity to different types of public places is indicated in Table 2, below. Additional analyses indicated that in the metro Richmond area, approximately 38% of suspected non-fatal overdoses occurred in proximity to public places.

Table 2. Opioid overdose fatalities occurring outside of home 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%

Availability of Naloxone in Community Pharmacies

Although the Virginia Statewide Standing Order for Naloxone is intended to facilitate access by the public to naloxone – including through retail pharmacies – media reports and previous research indicate variability in the public's ability to obtain naloxone through the pharmacy channel (Albiges 2019; Guadamuz et al. 2019). Primary data were collected from respondents in community retail pharmacies in Virginia to gauge the degree to which information provided by pharmacies on naloxone availability aligned with VDH's standing order. Specifically, 300 pharmacies were randomly selected from all community retail pharmacies in Virginia to obtain a

[6] Establishments for which street addresses could not be confirmed and it was not clear whether the public was invited or permitted to enter were excluded from analysis. Establishments that had no website and/or the street address could not be confirmed through Google maps were excluded from analysis.

statewide representative sample (hospital/medical center outpatient pharmacies; DBHDS-licensed pharmacies; and specialty pharmacies were excluded).

Calls were made to sampled pharmacies to collect data on availability of naloxone without a patient-specific prescription, as well as other characteristics of its availability. Using the methodology described in Evoy et al. (2018), the caller, posing as a person who wanted to obtain naloxone for a family member, followed a standard interview protocol asking a series of questions with each one determined by the pharmacy employee's previous responses. The two primary data points collected were: whether the pharmacy was willing to make naloxone available to the caller without a patient-specific prescription; and, if so, whether any naloxone was in stock at the time of contact.

According to data collected for this survey, 77% of the overall sample of pharmacies accurately indicated that a patient-specific prescription was not required to purchase naloxone. However, only around 49% of *independent* pharmacies provided accurate information on obtaining naloxone without a patient-specific prescription (compared to 87% of chain pharmacies). Between pharmacies indicating that naloxone was not available without a patient-specific prescription and those indicating that it could be obtained without a patient-specific prescription but did not have it in stock at the time of the call, around 65% of pharmacies overall had naloxone available without a patient-specific prescription at the time of contact.

Recommendations on Naloxone Accessibility in Public Places

- If JCHC members consider legislation on positioning naloxone in public locations, focusing on co-location with AED units may not be the most effective strategy.
- JCHC members may wish to consider legislation adding to the list of individuals explicitly authorized to possess and administer intranasal/intramuscular formulations of naloxone persons acting on behalf of public places who have completed a training program.
- JCHC members may wish to request that the Board of Pharmacy re-emphasize in communications that Virginia law permits dispensing of naloxone without a patient-specific prescription.

Supply-/Demand-Side Considerations

A variety of no-pay and discounted options exist to purchase naloxone. While typical cash prices for naloxone range from around $120/kit (Narcan) to over $4,000/kit (EVZIO), the public can obtain VDH-procured naloxone at no cost – through completion of selected REVIVE! trainings, or directly from Local Health Departments/Community Services Boards – and/or through most health insurers for a co-pay. At the time of writing of this report, the manufacturer of EVZIO (kaleo, Inc.) is currently seeking FDA approval for an authorized generic anticipated to retail for $178 for a kit (i.e., two units). Additionally, Narcan/EVZIO manufacturers currently have community/public pricing programs for qualifying organizations. Narcan, for instance, can be purchased for $75/kit by non-profit organizations, and certain schools, YMCAs and libraries are eligible to obtain two kits at no cost directly from the manufacturer. According to data from Emergent Biosolutions (Narcan's manufacturer), 75 scholastic institutions and one library had

received free kits at the time of the writing of this report. EVZIO can be purchased for $178/kit by government agencies, first responders, and "other qualifying groups".[7]

However, survey data collected for this study suggest hesitancy by locality-managed public places to stock naloxone. In a survey of 58 locality/county administrators[8], 25% reported previous discussions on maintaining stock of naloxone, and only 30% indicated that their local government would be somewhat or very likely to consider stocking naloxone if authorized by Virginia Code. As highlighted in Figure 3, major concerns expressed related to liability, employee training, costs and naloxone security/theft.

Figure 3. Concerns expressed by localities with maintaining naloxone in local government buildings

Source: Staff survey

Additionally, current Virginia law related to naloxone possession and administration may be a deterrent to willingness to use naloxone in certain circumstances. Although Virginia Code provides Good Samaritan (civil) liability protections for naloxone administration by individuals who are dispensed naloxone under authorized channels, individuals may come to possess and administer naloxone in other ways. Possession through unauthorized channels is a Class 4 misdemeanor – up to $250 fine – and administration would not be covered by Good Samaritan liability protections. The limited applicability of liability protections could deter willingness of naloxone administration by individuals (e.g., in opioid overdose events involving illicit substances) and public places/organizations (e.g., to develop on-premise naloxone policies due to liability concerns stemming from individual-level liabilities). Broadening civil/criminal liability protection could diminish those deterrents.

Recommendations on Naloxone Accessibility in Public Places

- JCHC members 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).
  - Illustrative language: A person who is: 1) not otherwise authorized to administer naloxone or other opioid antagonist used for overdose reversal and 2) acting in good

[7] Representatives of kaleo, Inc. indicated interest in expanding the scope of organizations that would qualify as an "other qualifying group".
[8] Response rate for all counties/localities was around 30%.

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. A person who administers an opioid antagonist pursuant to this article is personally immune from civil or criminal liability for any act or omission resulting in damage or injury.

Policy Options and Public Comment

Comments were received from the following organizations:

- Dean Lynch, Executive Director, **Virginia Association of Counties** (VACo)
- Janet Areson, Director of Policy Development, **Virginia Municipal League** (VML)

Policy Option	Support	Oppose
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	• VML	
Option 3: Introduce legislation broadening criminal and civil liability protections for naloxone administration	• VACo • VML	
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		
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		

Subsequent Actions by the Joint Commission on Health Care

During the JCHC's November 14, 2019 Decision Matrix meeting, policy options two through five were approved by the Commission Members.

Legislation Enacted

HB 908 (Hayes), SB 836 (Suetterlein) , and SB 566 (Edwards). Acts of Assembly - Chapters 92, 302 and 1095, respectively.

The purpose of these bills is to provide greater access to naloxone, or other opioid antagonists, to reduce the number of deaths due to opioid overdose. House Bill 908 is the most extensive, allowing trained employees of a public place to *possess and administer* (except in needle or syringe form) and any bystander to *administer* the drug with liability protection for civil damages, unless the personal injury was the result of gross negligence or willful and wanton misconduct.

House Bill 908:

> § 54.1-3408. Professional use by practitioners.
> X. …*Notwithstanding any other law or regulation to the contrary, an employee or other person acting on behalf of a public place may possess and administer naloxone or other opioid antagonist, other than naloxone in an injectable formulation with a hypodermic needle or syringe, to a person who is believed to be experiencing or about to experience a life-threatening opioid overdose if he has completed a training program on the administration of such naloxone and administers naloxone in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health.*
> *For the purposes of this subsection, "public place" means any enclosed area that is used or held out for use by the public, whether owned or operated by a public or private interest.*
> *Z. A person who is not otherwise authorized to administer naloxone or other opioid antagonist used for overdose reversal may administer naloxone or other opioid antagonist used for overdose reversal to a person who is believed to be experiencing or about to experience a life-threatening opioid overdose.*
>
> § 8.01-225. Persons rendering emergency care, obstetrical services exempt from liability.
> A. Any person who:
> *21. In good faith administers naloxone or other opioid antagonist used for overdose reversal to a person who is believed to be experiencing or about to experience a life-threatening opioid overdose in accordance with the provisions of subsection Z of § 54.1-3408 shall not be liable for any civil damages for any personal injury that results from any act or omission in the administration of naloxone or other opioid antagonist used for overdose reversal, unless such act or omission was the result of gross negligence or willful and wanton misconduct.*

Senate Bill 836 allows trained employees of a public place to *possess and administer* (except in needle or syringe form).

Senate Bill 566 allows any person to *administer* the drug with liability protection for civil damages, unless the personal injury was the result of gross negligence or willful and wanton misconduct.

JCHC Staff for this Report

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Senior Health Policy Analyst

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Naloxone Public Access and Storage (HJ 653)

Joint Commission on Health Care
October 3, 2019 Meeting

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

Study Mandate

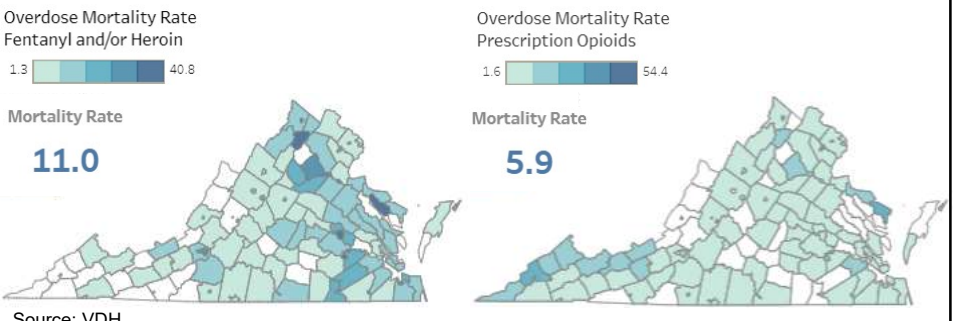
- HJ 653 (Delegate Gooditis) requested the Virginia Department of Health (VDH) study barriers/solutions to co-locating naloxone in Automatic External Defibrillators (AEDs) and propose/implement an education program
  - HJ 653 was tabled in House Rules Committee with understanding that JCHC would consider 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

2

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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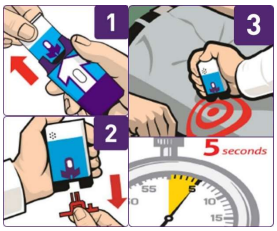
Administering & Maintaining Narcan / EVZIO requires little prior training

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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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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