

REVIVE!

OPIOID OVERDOSE AND NALOXONE EDUCATION FOR VIRGINIA

REVIVE! WHITE PAPER

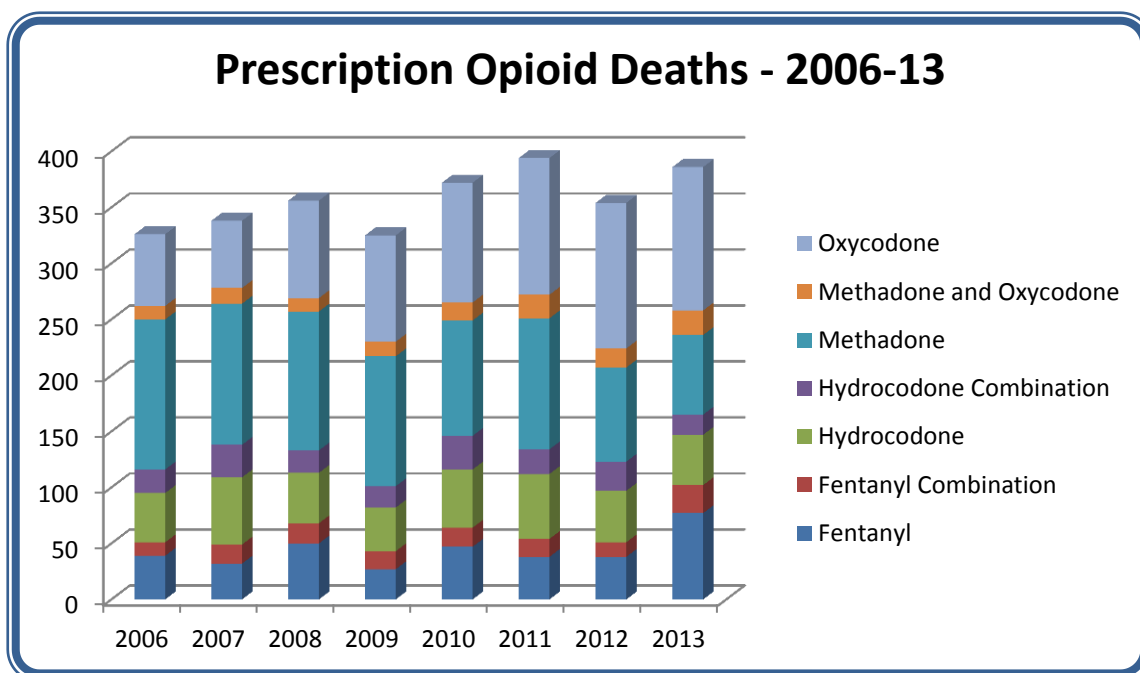
AN OVERVIEW OF VIRGINIA'S OPIOID OVERDOSE AND NALOXONE EDUCATION PROGRAM

I. Purpose

REVIVE! is the Opioid Overdose and Naloxone Education (ONE) program for the Commonwealth of Virginia. REVIVE! provides training to professionals, stakeholders, and others on how to recognize and respond to an opioid overdose emergency with the administration of naloxone (Narcan[®]). REVIVE! is a collaborative effort led by the Virginia Department of Behavioral Health and Developmental Services (DBHDS) working alongside the Virginia Department of Health, the Virginia Department of Health Professions, recovery community organizations such as the McShin Foundation, OneCare of Southwest Virginia, the Substance Abuse and Addiction Recovery Alliance of Virginia (SAARA), and other stakeholders.

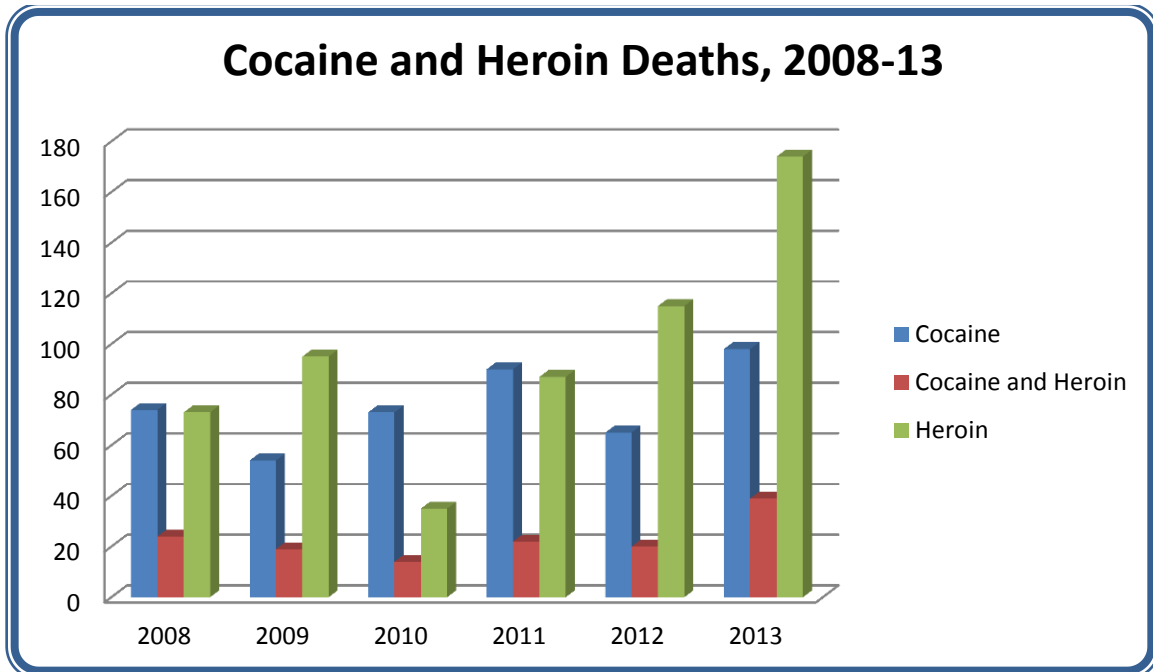
II. Background

Virginia has been severely impacted by opioid abuse, particularly the abuse of prescription drugs. In 1999, the first year for which such data is available, approximately 23 people died from abuse of fentanyl, hydrocodone, methadone, and oxycodone (the leading prescription opioids abused, commonly referred to as FHMO). By 2013, the most recent year for which complete data is available, 386 individuals died from the abuse of FHMO, an increase of 1,578%, with fentanyl being the primary substance fueling this increase. In 2013 alone, there was an increase of more than 100% in deaths attributed to fentanyl use. In 2013, as before in 2011, drug-related deaths happened at a higher per capita level (11.0 deaths per 100,000) than motor vehicle crashes (10.1 per 100,000).¹



¹ <https://www.vdh.virginia.gov/medExam/documents/2013/pdf/Annual%20Report%202011.pdf>

The 2013 data provides evidence of other disturbing trends in Virginia, including a sharp rise in heroin deaths. In 2010, only 49 deaths in Virginia were attributed to heroin use. By 2013, that figure had risen to 213, an increase of 334% in *only four years*, while cocaine deaths remained relatively level. VDH has projected an even further increase in 2016. The first quarter of 2016 had a 29.5% increase in the number of fatal drug overdoses compared to the same time frame (first quarter) of 2015. Heroin, Fentanyl, and prescription opioid related deaths are all on the rise and Carfentanyl has been confirmed in at least one Virginia fatality to date.



The changes in drug-related deaths in Virginia in 2013 are not limited to which substances had the greatest impact. The geography of the opioid epidemic in Virginia is shifting as well. In past years, the Western portion of Virginia typically accounted for approximately one-third of drug-related deaths in any given year. In 2013, for the first time since these records have been maintained, the prevalence of drug-related deaths was spread evenly over the Commonwealth, as the Eastern region of Virginia saw an increase of more than 51% in drug-related deaths in a single year, from 2012 to 2013.

III. Naloxone

Naloxone, a prescription medication, is an opioid antagonist drug that reverses the effects that opioids have in the brain. When a person overdoses on opioids, the opioid overwhelms specific receptors in the brain, slowly decreasing respiration and heart rate before finally stopping it altogether. Naloxone has a very high affinity for these receptors and effectively pushes the opioid off of the brain receptor. This action allows a person's body to resume respiration and respiration. Naloxone has been used for years by emergency medical technicians and emergency room doctors to reverse opioid overdose emergencies. Outside of this singular purpose, naloxone has no effect on the body, and poses no danger to anyone who accidentally administers it to themselves or someone else.

Naloxone is a proven public health response to the epidemic of opioid overdose emergencies. The Centers for Disease Control and Prevention indicate that since 1996, when the first program to distribute naloxone to Lay Rescuers (REVIVE!'s terminology for community members who have been trained on naloxone administration) was implemented, 152,283 persons received training on administering naloxone. Those individuals have saved 26,463 lives by administering naloxone to individuals who were experiencing an opioid overdose emergency.²

When naloxone is administered by a trained emergency medical professional, it is injected into the muscle. However, REVIVE!, and many programs like it around the country utilize use a mucosal atomizer device (MAD) that attaches to the pre-filled syringe containing the medication. This device enables the medication to be administered into the nostrils, which is less likely to lead to acute withdrawal based on anecdotal reports. Intranasal administration also reduces the risk for needle-sticks that could potentially transmit infectious diseases or infection to the victim or keep someone from administering the naloxone due to a fear of needles. Intranasal administration of naloxone has been found to be just as effective as muscular injection in a recent study performed by Lightlake Therapeutics Inc. in conjunction with the National Institute on Drug Abuse.³

In 2014 the Food and Drug Administration recently approved an auto-injector device for the administration of naloxone named Evzio[®]. While utilization of Evzio is low due to its cost, DBHDS includes information about the product in its training documentation.

IV. Legislation

The 2013 Session of the General Assembly, under the sponsorship of Delegate John O'Bannon, enacted House Bill 1672 (<http://1.usa.gov/1mOsgfh>), which authorized the use of naloxone by a Lay Rescuer. The legislation permitted a prescriber to prescribe naloxone to a person for use on a person who may be unknown to the prescriber ("non-patient specific" prescribing), the only medication in the Commonwealth in which a prescriber is allowed to prescribe for someone with whom he does not have a bona fide patient relationship. It also provided immunity against civil liability to individuals who participated in the pilot. The legislation directed DBHDS to be the lead agency for conducting pilot programs on the administration of naloxone to counteract the effects of opioid overdose emergencies. To conduct these pilots, DBHDS chose two regions of the Commonwealth, the Richmond metropolitan region (the city of Richmond and counties of Chesterfield, Henrico, and Charles City) and the far southwestern region (cities of Bristol and Norton and counties of Buchanan, Dickenson, Lee, Russell, Scott, Tazewell, Washington and Wise). These are two regions of the Commonwealth that have experienced significant impact from opioid abuse. The General Assembly appropriated \$10,000 to execute the pilot.

The 2015 Virginia General Assembly passed House Bills 1458 (HB1458, O'Bannon, <http://1.usa.gov/1Le9WvR>) and 1500 (HB1500, Carr, <http://1.usa.gov/1IH6Kse>) and Senate Bill 892 (SB892, Petersen, <http://1.usa.gov/1J1BMhu>). The enactment of these bills into law provides a number of changes for how REVIVE! operates in Virginia.

House Bill 1458 enacts three substantive changes for REVIVE! First and foremost, it removes the pilot designation, making REVIVE! a statewide program. REVIVE! can now to train Trainers and Lay Rescuers throughout Virginia. Second, HB1458 expands civil immunity against liability to anyone who prescribes, dispenses, or administers naloxone throughout the Commonwealth. Starting July 1 every doctor,

² <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6106a1.htm>

³ <http://www.sacbee.com/2013/12/03/5967297/initial-data-from-lightlake-therapeutics.html>

pharmacist, and person in Virginia will be immune from civil liability due to prescribing or dispensing naloxone or a reversal that is unsuccessful or includes adverse consequences. Third, HB1458 allows for a Standing Order for naloxone in Virginia. This means that a prescription will no longer be required to obtain naloxone from a pharmacy. Starting July 1, pharmacies will be able to collaborate with prescribers to be able to dispense naloxone to individuals without a prescription or prior training. HB1458 also explicitly allows law enforcement officials and firefighters who have completed a training program to possess and administer naloxone.

House Bill 1500 and Senate Bill 892 enact a Safe Reporting (also known as a Good Samaritan) law concerning the reporting of overdoses in Virginia. These bills allow a person to assert an affirmative defense against the following charges: unlawful purchase, possession, or consumption of alcohol pursuant to § 4.1-305, possession of a controlled substance pursuant to § 18.2-250, possession of marijuana pursuant to § 18.2-250.1, intoxication in public pursuant to § 18.2-388, or possession of controlled paraphernalia pursuant to § 54.1-3466.

An affirmative defense is a defense that alleges additional facts that defeats or mitigates the legal consequences of otherwise unlawful activity. You can still be charged with these crimes, but you can assert an affirmative defense against them if you are responding to an overdose emergency. To be able to assert an affirmative defense, ALL of the following criteria must be met:

1. You must in good faith seek or obtain medical attention for yourself or someone else experiencing an overdose emergency by reporting the event to a firefighter, emergency medical services personnel, a law enforcement officer, or an emergency 911 system;
2. You must remain at the scene of the overdose or an alternate location which you or the person who suffered the overdose has been transported until a law enforcement official responds to the reported overdose. If no law enforcement officer responds, you must cooperate with law enforcement as indicated and described in the other sections;
3. You must identify yourself to the law enforcement officer who responds;
4. If requested by a law enforcement officer, you must substantially cooperate in any investigation of any criminal offense reasonably related to the controlled substance or alcohol that led to the overdose; and
5. The evidence for the prosecution of an offense was obtained as a result of the individual seeking or obtaining emergency medical attention.

Finally, an affirmative defense may not be asserted if you sought or obtained emergency medical attention during the execution of a search warrant or during a lawful search or arrest. If you are charged with a crime as the result of reporting an overdose emergency, you should consult an attorney about asserting an affirmative defense to any charges that you received as a result of reporting an overdose emergency.

V. Public Health Emergency in Virginia

On November 21st, 2016, State Health Commissioner Dr. Marissa Levine declared the Virginia opioid addiction crisis a Public Health Emergency. This declaration comes in response to the growing number of overdoses attributed to opioid use, and evidence that Carfentanil, a highly dangerous synthetic opioid used to sedate large animals such as elephants, has made its way into Virginia. A Public Health Emergency is an event, either natural or manmade, that creates a health risk to the public. In response to the Public Health Emergency, and in collaboration with Virginia's Board of Pharmacy, Department of Health Professions and Department of Behavioral Health and Developmental Services, Dr. Levine has

issued a **standing order** that allows all Virginians to obtain the Naloxone which can be used to treat opioid overdoses in emergency situations. The standing order serves as a prescription written for the general public, rather than specifically for an individual, removing a barrier to access. - See more at: <https://governor.virginia.gov/newsroom/newsarticle?articleId=18348#sthash.RiawufB.dpuf>

VI. Training

DBHDS and its partners determined that training is a vital part of the successful implementation of the program. Therefore, DBHDS has developed a training curriculum to train Lay Rescuers on how to recognize and respond to an opioid overdose with naloxone. The training covers the following topics:

- Discussing how opioid overdoses and naloxone work
- Discussing methods to differentiate between someone who is high versus someone who is experiencing an opioid overdose emergency
- Identifying causes and risk factors for opioid overdose emergencies
- Clarifying common myths about responding to an opioid overdose emergency
- Providing live, step-by-step training on the administration of naloxone

REVIVE! training has two components. REVIVE! program staff and select trainers who have received specialized training provide Training of Trainers (TOT) events. Participants at these events typically include substance use disorder professionals, healthcare workers, friends and family members of those who have opioid use disorders, and community stakeholders. TOTs train individuals on how to effectively plan for and lead a REVIVE! Lay Rescuer training. TOTs last approximately two and a half hours, and include a thorough review of the Training Guide and a discussion of the logistics of planning and holding a Lay Rescuer Training. Trainers are provided with a prescription for a single box of naloxone that they can use for demonstration of syringe assembly at their Lay Rescuer trainings. The initial training of trainers (TOT) was provided by Joanna Eller, Clinic Director at CRC Health Group. Ms. Eller's experience includes working with Project Lazarus, one of the first naloxone distribution programs in the country. DBHDS has created a training agreement (available on the [REVIVE! website](#)) that must be executed by those who wish to be trainers for REVIVE! The training agreement outlines expectations for trainers, including fidelity to the training curriculum and that training events are to be provided at no cost.

The second component of REVIVE! training is Lay Rescuer trainings. Once individuals have been certified as Trainers, they then lead Lay Rescuer trainings in their community. This allows them to utilize the knowledge and experience they have of their community to assist in the publicity and planning of the training. When individuals complete this training, they will be registered as a Lay Rescuer for REVIVE! DBHDS will maintain a database of these Lay Rescuers. Lay Rescuers receive (at no charge) a kit bag that contains the tools and supplies necessary to respond to an opioid overdose emergency – latex-free gloves, a rescue breathing mask, a mucosal atomization device (MAD), and an instruction card for the administration of naloxone. The Lay Rescuer does still need to go to a pharmacy and obtain naloxone, either via a prescription or from a pharmacy that has worked with a prescriber to establish a standing order.

A database of Trainers and Lay Rescuers is maintained by DBHDS. Trainers and Lay Rescuers are asked to complete a registration form when they attend a training event, but this is a request, not a requirement. Registration is important so that DBHDS has contact information for Trainers and Lay Rescuers in the

event that DBHDS needs to provide them with updated documentation, program announcements, or other information.

There are no eligibility limitations on attending a REVIVE! training event. Everyone, including individuals actively using opioids, is allowed to attend and learn how to save a life with naloxone.

VII. Associated Costs

Trainings and rescue kits are provided at no charge to Lay Rescuers. DBHDS is currently providing the funding to cover these supplies and events, but those funds may be exhausted at some point. Lay Rescuers will need to pay for the medication. DBHDS is exploring options to help defray the cost of medication, and a voucher system to subsidize the cost of naloxone has been implemented in the far Southwest Virginia pilot area thanks to a donation from the Appalachian Substance Abuse Coalition. Kaléo, the manufacturer of EVZIO, the naloxone auto-injector product, has a patient assistance program available to help individuals who qualify obtain their medication. That program can be accessed here - <http://bit.ly/1Gbn9RN>.

VIII. Evaluation and Outcomes

REVIVE! provides a relatively low-cost way for Virginia to address the epidemic of opioid overdose deaths. Studies suggest that the cost of this epidemic around the country measures in the billions of dollars when considering costs related to as criminal justice, healthcare, and lost productivity.⁴

To attempt to measure the impact of REVIVE!, DBHDS included postcards in the first 2,000 kit bags prepared. These postcards were pre-addressed and postage paid and included an index number that allowed DBHDS to determine where in Virginia the kit bag had been distributed. At training events Lay Rescuers were informed about the cards, their purpose, and the importance of submitting the cards once a reversal had taken place. The postcard had the following questions:

- Date and time of the opioid overdose emergency
- Did you call 911?
- Did the person survive the opioid overdose emergency?
- How many doses of naloxone did you administer?
- Did you have any problems using the kit or administering the naloxone?
- Name and address (if a new rescue kit is needed)

As of June 2015, DBHDS has not received any of these post cards from Lay Rescuers. However, DBHDS has received indication through other means that a number of reversals have taken place. In reviewing the protocol, it was determined that the postcard system was not the best way to try and collect this information. As a result, DBHDS has implemented a web-based method for collecting this information. Lay Rescuers can now anonymously and securely submit this information via a web link - <http://svy.mk/1ekciiE>. This reporting method is 100% anonymous; respondents are not required to provide their name or other identifying information, and the link does not capture IP or other identifiable information from the computer or device the respondent is using. This link uses encryption ensuring the respondent's responses are secure. Finally, the link is mobile-friendly, allowing Lay Rescuers to use their tablet or phone to submit this information.

⁴ <http://www.ncbi.nlm.nih.gov/pubmed/21392250>, <http://www.ncbi.nlm.nih.gov/pubmed/23841538>.

IX. Progress

To date, REVIVE! has held more than 50 Training of Trainer events where more than 1500 individuals have been certified as trainers, as well as more than 200 Lay Rescuer trainings where more than 5000 individuals have been certified as Lay Rescuers. To date, DBHDS has received anecdotal evidence of six reversals, but suspects that more have occurred that have not been reported.

X. Frequently Asked Questions

Some concerns have been raised about making naloxone available to Lay Rescuers in the community. Here are some frequently asked questions about naloxone, as well as DBHDS responses to those questions.

Does the availability of naloxone cause drug users to increase how often they use, or how much they use?

There are no scientific data to support the assertion that naloxone availability leads to increased opioid use or engagement in riskier behavior, but there is scientific data that suggests that the availability of naloxone **saves lives**.⁵ For more information on this data, please click this link for a number of naloxone program case studies: <http://bit.ly/1jnspHw>.

Individuals overdose because the strength of the opioid they have taken is greater than that for which the individual has developed tolerance. Over time, the brain becomes accustomed to a certain level of opioid which causes the brain to build up tolerance. This is why prescribers who use opioid pain medication for chronic pain sufferers must increase the dosage of opioid pain medications or change to a medication with a different opioid chemical structure. If the half-life (the length of time the drug stays in the person's system, even after the analgesic effect has worn off) of the new medication is longer than the medication the patient has been using and the pain returns, the patient may inadvertently overdose, unless he or she has been warned by the prescriber.

Individuals who abuse opioids to achieve a high have to increase the amount of the drug they are using to achieve this feeling due to the body building a tolerance for those substances. Long-term users, eventually become physically dependent to opioids, creating a situation where they continue to abuse opioids not to achieve a high, but simply to be able to function on a day-to-day basis. When using heroin, the person may not know the strength of the drug. Furthermore, if the person is an inexperienced user or has not used in a long-time, he or she could accidentally overdose because the strength of the heroin was greater than that for which the individual had physiological tolerance. In addition, heroin suppliers may have mixed several opioids together, mixed opioids with other drugs to amplify the effect of the opioid, or even replaced heroin altogether with another opioid such as fentanyl, which can increase the likelihood of opioid overdose emergency.

Does the availability of naloxone deter drug users from seeking treatment?

There is no scientific data to support this opinion, which assumes that people who abuse drugs do so by choice or as a result of a lack of constitution or moral failing. Addiction is a brain disease that affects an individual's brain chemistry.⁶ Furthermore, naloxone precipitates withdrawal in an individual who has experienced an opioid overdose emergency, which is extremely unpleasant. The availability of naloxone neither deters individuals from seeking treatment nor does it encourage riskier behavior.

⁵ <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3008773/>.

⁶ <http://www.npr.org/templates/story/story.php?storyId=17578955>

Are Lay Rescuers competent to administer naloxone?

Naloxone is a drug that has rare and mild side effects (rashes and hypersensitivity), requires the same dosage for an adult or child, and will have **no impact** if accidentally administered to someone who is not experiencing an opioid overdose emergency or is accidentally self-administered (such as in the case of a child). Studies suggest that laypersons, once trained, can be just as effective as emergency medical technicians in the intranasal administration of naloxone.⁷

Administration of naloxone to someone experiencing an opioid overdose emergency may cause acute withdrawal (which can lead to vomiting and aspiration) or pulmonary edema and cardiac arrhythmias. The half life of naloxone is shorter than some opioids that are abused, and as a result in certain cases a second dose of naloxone may be required.⁸

Lay Rescuers who are participating in REVIVE! will receive comprehensive training on recognizing an opioid overdose emergency, administering naloxone, and encouraging the individual to seek treatment for their drug use. Individuals will be prepared for the possibility of withdrawal symptoms, and will understand the need to stay with the victim until First Responders arrive. Most importantly, Lay Rescuers will understand that calling 911 is a vital and necessary part of responding to an individual who is experiencing an opioid overdose emergency.

If your question has not been answered in this document, please contact the REVIVE! program at REVIVE@dbhds.virginia.gov or (804)786-0464 for more information.

XI. Acknowledgments

REVIVE! would not be possible without the help of many public and private partners, who DBHDS would like to acknowledge for their invaluable assistance.

- Boston Public Health Commission
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- Delegate John O'Bannon, R-73
- Joanna Eller
- Harm Reduction Coalition
- Kaléo
- The McShin Foundation
- Massachusetts Department of Public Health
- Multnomah County (OR) Health Department
- New York City Department of Mental Health and Hygiene
- New York State Division of Criminal Justice Services
- Ed Ohlinger
- One Care of Southwest Virginia
- Project Lazarus
- SAARA Recovery Center of Virginia
- San Francisco Department of Health/DOPE Project
- University of Washington Alcohol and Drug Abuse Institute
- Virginia Department of Criminal Justice Services
- Virginia Department of Health
- Virginia Department of Health Professions

⁷ <http://www.ncbi.nlm.nih.gov/pubmed/24684801>

⁸ <http://www.ncbi.nlm.nih.gov/pubmed/17367258>