Research Protocol for Naloxone Overdose Prevention Laws

Prepared by Legal Science, LLC

August 2016
NALOXONE OVERDOSE PREVENTION LAWS
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Research Protocol


II. Scope: Compile and code state laws that provide civil or criminal immunity to licensed health care providers or lay responders for opioid antagonist administration.

III. Primary Data Collection


B. Data collection methods: Research was conducted by two Researchers, each covering half the states and the District of Columbia.

C. Databases used: Searches were conducted in the state statute and regulation libraries of Westlaw, Westlaw Next and Lexis Nexis.

   i. The full text of the law was pulled from state legislature websites and the session laws from HeinOnline.

D. Search terms: opioid, “opioid antagonist”, naloxone, opiate antagonist

E. Information about initial returns and additional inclusion or exclusion criteria: The Researchers scanned the results for laws related to opioid antagonist administration that were downloaded into folders organized by each state and subfolders organized by the statutory citation. Each Researcher compared their results to publicly available information on state opioid antagonist administration to see if their results were consistent. If a law was found that was not located using the initial search terms, the search terms were reexamined and changed accordingly. This dataset excludes prescriptions to first responders, which was determined to be beyond the scope of the coding scheme, as explained below.

IV. Coding

A. Development of coding scheme: Once the legal research was complete, the Researchers and the Supervisor developed coding


questions which were discussed in group meetings. As necessary, the coding scheme was altered to accommodate newly identified features of the data, and completed states were recoded. Several states have laws regarding first responders administering of naloxone. The Supervisor decided that laws on first responders and naloxone should not be included. This includes excluding peace officers and police officers. The dataset’s scope only focuses on licensed healthcare providers and layperson responders. Due to the changing and expanding nature of these laws, however, this may be an area to further develop and include in this dataset in the future.

For the question, “Are prescriptions of naloxone authorized to third parties?”

The Supervisor determined that “third parties” should mean anyone other than the prescriber and the person actually experiencing the overdose. This would include prescriptions to a family member or friend of someone experiencing, or expected to be experiencing, a drug overdose.

For the child question, “Are prescribers/laypeople required to act with reasonable care?”

The coded answer is “Yes” only if state law explicitly requires persons to act with “reasonable care.”

B. Coding methods: The results are checked against findings from an independent source, (Scott Burris, Temple Beasley Law School Website, (Project on Harm Reduction in the Healthcare System), and divergences are discussed by the entire team and resolved.

V. Updating the Dataset

A. Update: August 2013 – November 2013

i. Data collection methods: Research was conducted by one Researcher (“Researcher #1”). The research sought to identify all laws enacted between August 1, 2012 and November 1, 2013. The work of the Researcher was overseen by a Supervisor. The Supervisor consulted with two Content Experts, Scott Burris, JD and Corey Davis, JD, MSPH, throughout the process. Searches were conducted by Researcher #1 for enacted bills amending the naloxone administration statutes in the Workbench, or new bills

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¹ For example, subsection 4 of N.Y. McKinney’s Pub. Health Law § 3309A states, “A recipient or opioid overdose prevention program under this section, acting reasonably and in good faith in compliance with this section, shall not be subject to criminal, civil or administrative liability solely by reason of such action.” The coded answer to the question “Is acting with reasonable care required as a condition of immunity?” is “No,” because the New York law requires “acting reasonably,” not acting with “reasonable care.”
establishing criminal or civil immunity for naloxone administration. They were conducted in Westlaw Next and Lexis Nexis using the following syntax and search terms: “naloxone,” “opioid,” “opiate,” and “overdose.”

ii. **Coding methods:** Researcher #1 reviewed results for laws related to opioid antagonist administration. The table of contents for any statute identified as relevant was scanned for additional material. Laws referenced in new statutes that impacted coded questions were also added. If a statutory section was found that was not produced using the search terms, they were refined to capture the law.

Maryland’s new law had to be found by searching for the statute number identified in a secondary source on the state’s general assembly website. Oklahoma’s new law was not available in traditional legal databases during our search period, and was added after the Content Expert, Scott Burris, received notification of the new law through a news alert. Each relevant law was downloaded into folders organized by jurisdiction and subfolders organized by the statutory citation. A summary sheet was created for each jurisdiction containing citations to all relevant legal material, the statutory history for each relevant statute in that jurisdiction, and the effective date for each version of the law.

All research results were compared to Content Expert Corey Davis’ Network update article titled “Legal Interventions to Reduce Overdose Morality: Naloxone Access and Overdose Good Samaritan Laws.” If a discrepancy was found, the search strategy was revised.

B. **Update: August 2014**

i. **Data collection methods:** Research was conducted by one Researcher (“Researcher #1”). The research sought to identify all laws enacted between November 1, 2013 and May 31, 2014 and any pending legislation close to passage. The work of Researcher #1 was overseen by a Supervisor. Searches were conducted by Researcher #1 for enacted bills amending the naloxone administration statutes in the Workbench, or new bills establishing criminal or civil immunity for naloxone administration. They were conducted in Westlaw Next and Lexis Nexis using the following syntax and search terms: “naloxone,” “opioid,” “opiate,” “overdose,” and “opioid antagonist.” Secondary sources used: state-specific legislature websites; OpenStates.org.
ii. **Coding Methods:** Researcher #1 reviewed results for laws related to opioid antagonist administration. The table of contents for any statute identified as relevant was scanned for additional material. Laws referenced in new statutes that impacted coded questions were also added. If a statutory section was found that was not produced using the search terms, they were refined to capture the law. Researcher #1 coded any additional questions added to entries already in the Workbench. Then Researcher #1 added new laws and coded them.

Once Researcher #1 completed coding, a second Researcher (“Researcher #2”) redundantly coded a sample of the updated and new records coded by Researcher #1. This means two records were created containing the same law, questions and date. Both Researcher #1 and Researcher #2 coded these records, resulting in two records for the same jurisdiction and date. Records were selected for redundant coding using the random number generator in Microsoft Excel.

iii. **Coding Updated Findings:** Researcher #1 found that new laws were added by Georgia, Maine, Minnesota, Ohio, Tennessee, Utah, and Wisconsin. Changes made to existing laws in Rhode Island and Virginia was also found. Both Tennessee and Virginia passed laws that are not effective until July 1, 2014. Researcher #1 found that two states, Connecticut and New York, have pending legislation that is close to passing.

New York passed a naloxone bill on June 24, 2014. Researcher #1 coded this bill; the entry was then redundantly coded and checked by the Supervisor. Delaware passed a law in August 2014. The law mainly pertains to peace officers, which is outside our scope. However, part of the law is within our scope; therefore, it was coded and redundantly coded. The Supervisor and the Content Experts reviewed the existing coding questions and made revisions to accurately capture changes in the law. Once finalized, the coding questions were entered into the Workbench.

iv. **Quality Control:** The Supervisor reviewed the redundant coding by downloading the data from the Workbench into Microsoft Excel and comparing the records, variable by variable, looking for divergences. The Supervisor also reviewed the coding looking for errors, omissions or caution flags.
When a divergence was identified it was discussed with the researchers. The reason for the divergence was identified and resolved. The divergence rate for the May 2014 update was 12.5%. The rate of divergence for Delaware’s entry was 2%.

C. Update: October 2014

i. **Data collection methods**: Research was conducted by one Researcher (“Researcher #1”). The research sought to identify all laws enacted between August 2014 and November 30, 2014 and any pending legislation close to passage. The work of Researcher #1 was overseen by a Supervisor. Searches were conducted by Researcher #1 for enacted bills amending the naloxone administration statutes in the Workbench, or new bills establishing criminal or civil immunity for naloxone administration. They were conducted in Westlaw Next and Lexis Nexis using the following syntax and search terms: “naloxone,” “opioid,” “opiate,” “overdose,” and “opioid antagonist.”

   a. Secondary sources used to collect the laws: state-specific legislature websites; OpenStates.org.

ii. **Coding Updated Findings**: Researcher #1 found that new laws were passed in: California, Connecticut, Oklahoma, Pennsylvania, Vermont and Wisconsin. California and Wisconsin are effective in the future, so they have been coded and redundantly coded but they are hidden from the front-facing display until they become effective.

iii. **Quality Control**: The supervisor assigned 100% redundant coding for the updated entries. The rate of divergence was 3%. All divergences were discussed in a coding review meeting on October 21, 2014. The final preview link was sent to our Content Expert, Corey Davis, JD, MSPH, for review.

D. Update: December 2014

i. **Data collection methods**: A Researcher (Researcher #1) conducted research to determine if any states had enacted relevant legislation effective through December 31, 2014, and to identify pending legislation that may be close to passage. A Supervisor helped Researcher #1 whenever necessary in this effort. Researcher #1 used WestlawNext using the following syntax and search terms: “naloxone,” “opioid,” “opiate,” “overdose,” and “opioid antagonist.”
a. Secondary sources used to collect the laws: state-specific legislature websites; OpenStates.org.

ii. **Coding Updated Findings:** Researcher #1 found that new laws had been passed in Massachusetts, effective July 1, 2014, and in Michigan, effective October 17, 2014. In New York, an existing regulation was amended, effective November 10, 2014. Relevant laws may be enacted in Ohio and Kentucky soon but have not yet been signed; these laws have been entered into Workbench but will not be coded or displayed until they become effective.

Our Context Expert, Corey Davis, JD, MSPH, consulted with the Supervisor about whether currently coded law in Rhode Island granted civil and criminal immunity to prescribers. After review of the laws, it was determined that the current coding indicating prescribers are granted civil and criminal immunity from charges was incorrect. Rhode Island’s entry was recoded to reflect that its laws do not grant immunity to prescribers.

In all New York coding entries following an amendment to N.Y. McKinney’s Pub. Health Law § 3309 that was effective June 24, 2014, the answer to the question “Is prescription by a standing order authorized?” was changed from “No” to “Yes.” The law permits a health care professional to dispense a “patient-specific or non-patient-specific prescription” for naloxone. As confirmed by Davis, the term “non-patient specific prescription” is equivalent to a standing order.

iii. **Quality Control:** The supervisor assigned 100% redundant coding for the updated entries capturing new laws in Massachusetts and Michigan. The rate of divergence was 41% for the Massachusetts entry and 18% for Michigan. All divergences were discussed by the Supervisor, Researcher #1 and the redundant coder and resolved. The Supervisor communicated with Davis for his approval on the updated entries.

E. **Update: July 2015**

i. **Data collection methods:** A Researcher (Researcher #1) conducted research to determine if any states had enacted relevant legislation effective through July 1, 2015, and to identify pending legislation that may be close to passage. A Supervisor helped Researcher #1 whenever necessary in this effort. Researcher #1 used WestlawNext using the following syntax and search terms: “naloxone,” “opioid,” “opiate,”
“overdose,” “opiate overdose,” “overdose prevention,” and “opioid antagonist.”

Secondary sources used to collect the laws: state-specific legislature websites; OpenStates.org, and Scout.sunlightfoundation.com.

ii. Coding Updated Findings: Researcher #1 found that during this update time interval, 9 new naloxone laws had been passed in Florida, Idaho, Indiana, Mississippi, Nebraska, New Hampshire, South Carolina, West Virginia and Alabama and found that legislators amended 8 naloxone laws in California, Colorado, Kentucky, New Jersey, Tennessee, Vermont, Virginia, and Wisconsin.

iii. Quality Control: Because more than 5 states required an update, the Supervisor assigned redundant coding for 20% of the updated entries with a substantive change. Initially, the Supervisor assigned 4 states to redundantly code. The rate of divergence was at 38% after the first round of redundant coding. All divergences were discussed by the team and resolved. Because of the high divergence rate, the Supervisor assigned 100% redundant coding for the remaining updated states with substantive changes. The divergence rate went down (26.5%). The Supervisor identified the questions at issue and set up a meeting with our content experts, Scott Burris, JD, and Corey Davis, JD, MSPH, to discuss.

iv. Coding: The Supervisor identified that the coders regularly diverged on the question regarding the following questions:

"Is participation in a naloxone administration program required as a condition of immunity?", "Is naloxone program participation required for a third party prescription?", and "Is participation in a naloxone administration program required for prescription by a standing order?"

After the meeting with the content experts, the team decided that the coders will answer “Yes” only when an individual must participate in a “formal” program to receive naloxone. A “formal” program includes laws where the legislators refer to a naloxone administration program. A “formal” program does not include where a person must receive education materials about opioid overdoses or instructions on how to identify an overdose event. The coders will also code “No” where an

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2 For example, N.M. Code R. § 7.32.7. Authorization to Administer Opioid Antagonists includes a provision for the establishment of an “Opioid Antagonist Administration Program.”
individual must complete “training” to receive naloxone. Due to the changing and expanding nature of these laws, however, this may be an area to further develop and include as a separate question in this dataset in the future.

For the question, “Is prescription by a standing order authorized?”

The coders will answer “Yes” where a statute allows healthcare practitioners to prescribe naloxone by “standing order.” This dataset will define a “standing order” as a non-patient-specific prescription order for the provision of naloxone to any individual who meets criteria specified in the order. If the law meets that definition, then the coder will code “Yes.”

F. Update: February 2016

i. Data collection methods: Two Researchers (the Researchers) conducted research to determine if any states had enacted relevant legislation effective through February 1, 2016, and to identify pending legislation that may be close to passage. A Supervisor helped the Researchers whenever necessary in this effort. The Supervisor also evaluated any alerts received during the period since the last update, recording any amended or added laws. These amendments were added to the proper master sheets by the Researchers. The Researchers used WestlawNext and OpenStates to check for new or amended law using the following search terms: “naloxone,” “opioid,” “opiate,” “overdose,” “opiate overdose,” “overdose prevention,” and “opioid antagonist.”

Secondary sources were used to collect the laws, including state-specific legislature websites and OpenStates.org.

ii. Coding Updated Findings: The Researchers found that during this update time interval, 5 new naloxone laws had been passed in Arkansas, Louisiana, Nevada, North Dakota, and Texas. The Researchers also found that legislators amended 12 naloxone laws in California, Colorado, Illinois, Maine, Maryland, New Mexico, New York, North Carolina, Ohio, Rhode Island, Washington, and Wisconsin.

iii. Quality Control: Because more than 5 states required an update, the Supervisor assigned redundant coding for at least 20% of the updated entries with a substantive change. Initially, the Supervisor assigned 5 states to redundantly code. The rate of divergence was at 12.7% after the first round of redundant coding. All divergences were discussed by the team
and resolved. Because the divergence rate was above 5%, the Supervisor assigned 100% redundant coding for two additional updated states with substantive changes. The divergence rate went down to 2.27%. The Supervisor noted the problematic coding questions to discuss with the team and content expert. The team will consider whether the coding questions need to be edited in light of the trends emerging in new and updated laws.

iv. Coding: The Supervisor identified that the Researchers frequently diverged on the naloxone training question. After re-reading the Protocol, the team was able to find the necessary coding rule decided upon from the last update, which drew the line between participation in a naloxone program and providing naloxone information or training. The Researchers were able to use that coding rule to quickly resolve divergences. The Researchers also diverges on the following question:

For the question, “Are prescribers required to act with reasonable care?”

The coders will answer “Yes” where a statute requires a prescriber to act in good faith and in compliance with the standard of care. Although coding “Yes” for this question does require a narrow or explicit reference to “reasonable care,” requiring a prescriber to act in compliance with a professional standard of care sets a higher bar than just a requirement of good faith.³

G. Update: July 2016

i. Data collection methods: Two Researchers (the Researchers) conducted research to determine if any states had enacted relevant legislation effective through July 1, 2016, and to identify pending legislation that may be close to passage. A Supervisor helped the Researchers whenever necessary in this effort. The Supervisor also evaluated any alerts received during the period since the last update, recording any amended or added laws. These amendments were added to the proper master sheets by the Researchers. The Researchers used WestlawNext and OpenStates to check for new or amended law using the following search terms: “naloxone,” “opioid,” “opiate,” “overdose,” “opiate overdose,” “overdose prevention,” and “opioid antagonist.”

³ For example, Ark. Code § 20-13-1604 requires prescribing healthcare professionals to act in good faith and in compliance with the standard of care required for their professions.
Secondary sources were used to collect the laws, including state-specific legislature websites and OpenStates.org.

ii. **Coding Updated Findings:** The Researchers found that during this update time interval, 4 new naloxone laws had been passed in Alaska, Hawaii, Iowa and South Dakota. The Researchers also found that legislators amended naloxone laws in Alabama, Connecticut, Florida, Idaho, Indiana, Louisiana, Maryland, Massachusetts, New Mexico, New York, North Carolina, Oregon, South Carolina, Utah, Virginia, West Virginia, and Wisconsin. The Researchers also fixed legal text errors and updated citations for recently codified laws in Kentucky, Illinois, Nevada, and Washington.

iii. **Quality Control:** Because more than 5 states required an update, the Supervisor assigned redundant coding for at least 20% of the updated entries with a substantive change. Initially, the Supervisor assigned 5 states to redundantly code. The rate of divergence on August 5, 2016 was at 8.10% after the first round of redundant coding. All divergences were discussed by the team and resolved.

a. Because the divergence rate was above 5%, the Supervisor assigned 100% redundant coding for five additional updated states with substantive changes. The divergence rate on August 8 was 11.81%. The team discovered that one of the new laws added a standard of “reasonably” and referred back to the Protocol to ultimately decide that it was not enough to code an explicit reasonable care standard. The Supervisor also noted the problematic coding schemes, especially in New Mexico, to discuss with the team and content expert. The team will consider whether the coding questions need to be edited in light of the trends emerging in new and updated laws.

b. The Supervisor assigned 2 more states to redundantly code. The divergence rate fell to 0% on August 9, 2016.