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An Examination of Statewide Protocols for Emergency Medical Services Administration of Naloxone

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Introduction: Death due to opioid overdoses are on the rise in the United States. Naloxone is a potentially life-saving treatment that has been proven to be safe and effective in treating an opioid overdose. Emergency Medical Services (EMS) are often the first on the scene for medical emergencies and may play a key role in early interventions to reverse opioid overdose. We examined publicly available EMS protocols for opioid overdose for all 50 states in the U.S. to determine EMS scope of practice regarding naloxone administration and available routes of administration.

Methods: Publicly available statewide EMS protocols and supplemental documents such as training documents, updated directives, or dosing charts were identified from state official websites. These protocols and supplementary documents were reviewed independently by two abstractors who collected data regarding the routes of administration and scope of practice by provider level. Any inconsistencies between abstractors were remediated by the research team.

Results: Comprehensive naloxone-specific EMS protocols were available for 35 out of 50 (70%) states with an additional 5 (10%) states only having documents pertinent to the route of administration by provider level. Among them, 28 states (70%) permitted Emergency Medical Responders (EMRs) to administer naloxone whereas 9 (22.5%) states only allowed Emergency Medical Technician (EMT) administration, and 3 (7.5%) states allowed Paramedic administration respectively. The Intranasal (IN) route of administration was available in all 40 (100%) states, Intravenous (IV) route available in 37 (92.5%), and Intramuscular (IM) route available in 32 (80%) states. Less common routes of administration including auto-injection was available for 23 (57.5%) states while subcutaneous route was only used by 8 (20%) of states.

Conclusion: Our analysis of publicly available EMS protocols in the United States showed that most states allowed EMRs to administer naloxone for presumed opioid overdoses aligned with the current National EMS Scope of Practice Model recommendations. However, the minimum level of training required for administration varied between states with several states still requiring EMT-level training. Our findings suggest the need for greater consistency between EMS naloxone protocols between states to reduce mortality associated with the opioid epidemic.

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Introduction

Over the past two decades, nearly 500,000 people have died from an overdose of an illicit or prescription opioid in the United States.[1]Further, the opioid epidemic has been worsening in recent years. In the United States, 81,230 drug overdose deaths occurred over 12 months ending in May 2020, which was an 18% increase from the previous 12 months.[2] This acceleration was largely driven by the use of synthetic opioids, such as fentanyl.[3] Naloxone is a safe and effective treatment to reverse life-threatening respiratory distress from opioid overdose and is proven to save lives. To address the nation's opioid crisis, current public

health strategies include expanding naloxone access and use by bystanders and healthcare providers.[4]

Emergency medical services (EMS) play a vital role in providing early naloxone administration to suspected opioid overdose patients. EMS is often first on the scene to provide advanced care for difficult overdose reversals and other acute complications.[5] However, utilization of naloxone by EMS depends on several factors, including the individual patient, EMS provider's certification level and training, and availability and other resources within the EMS system. Naloxone must be administered in sufficient quantities for adequate reversal response but also in a judicious manner to avoid side effects and the possibility of subsequent patient agitation.[6]

Limited data exists on the efficacy and bioavailability of naloxone administered via different routes. In a limited open-label crossover study, Dowling et al found that intramuscular and intravenous naloxone provided high systemic concentrations both immediately and four hours after administration while intranasal route of administration demonstrated poor bioavailability.[7] Other novel routes of administration such as buccal and sublingual are currently not FDA approved and are under clinical investigation.[8]

Recent evidence-based guidelines recommend the provision of naloxone in the scope of practice for all EMS provider levels.[9] However, in the United States, until recently, only advanced life support provider levels (i.e., Advanced Emergency Medical Technician (AEMT) and Paramedic) were recommended to administer naloxone.[10] This may have contributed to the findings of Grover et al in their recent study of a large urban EMS system that found that 43% of patients with presumed or known opioid use were not administered naloxone.[11]

In 2019, National EMS Scope of Practice Model included the use of auto-injector and intranasal naloxone in the Emergency Medical Responder (EMR) and Emergency Medical Technician (EMT) scopes of practice.[12] While there are multiple common routes of administration, each comes with its own set of strengths and weaknesses, and EMS system may elect to maintain more than one option to optimize patient care.

In the United States, EMS is regulated at the state level, which is believed to contribute to regional and system-level variations in prehospital emergency care.[13] To better understand the provision of naloxone across the United States, we examined statewide EMS protocols for suspected opioid overdose patients and naloxone administration. Specifically, our study aimed to describe scopes of practice by EMS provider level and routes of administration with the goal of exploring opportunities to expand access to naloxone among basic life support providers. Further, we sought to compare common routes of administration including intramuscular, intranasal, subcutaneous, and intravenous including relative benefits and harms. Our work builds on the current literature of Smart et al., who examined EMS naloxone protocols via a legal lens, by providing a clinical perspective with a different methodology.[14]

Methods

This structured examination of statewide EMS protocols for naloxone administration followed previously published methods.[15,16] Only states with a publicly available statewide protocol or other relevant documentation such as training documents, updated directives, or dosing charts were included. States with no statewide naloxone protocol or directive were excluded; jurisdictions smaller than the state level were not examined in this study. Suspected opioid overdose patient care protocols were collected from the EMSprotocols.org website or the state's EMS or public health agency websites between September 2018 and June 2020. If multiple versions of a protocol existed, the most updated version was used. Secondary sources of naloxone-specific information included factsheets, medication lists,

scope of practice documents, standing orders from medical directors, legal documents on updated policies, and official statements from governors on naloxone policies. Links to these online resources are provided in Supplementary Table 1.

Protocols and related documentation were abstracted for 1) EMS provider levels permitted to administer naloxone, 2) routes of administration (i.e., auto-injection (AI), intranasal (IN), intramuscular (IM), subcutaneous (SQ), and intravenous (IV)), and 3) provider levels for each route of administration. EMS provider levels included from lowest to highest: Emergency Medical Responder (EMR), Emergency Medical Technician (EMT), Advanced EMT (AEMT), and Paramedic.

To ensure accurate information, protocols were abstracted independently by two authors (HF, IK). Each abstractor was blinded to data collected by the other. Discrepancies were then reviewed and adjudicated by the lead and senior authors (RBS, MDP).

RESULTS

Of the 50 states in the United States, we identified 35 (70%) statewide EMS protocols for naloxone administration and an additional 5 (10%) states with relevant documentation on routes of administration by provider level. Full results are provided in Supplementary Table 2.

Among these 40 states, 28 (70.0%) permitted EMRs to administer naloxone whereas the minimum provider was EMT in 9 (22.5%) and Paramedic in 3 (7.5%) (Figure 1). All states examined allowed more than one route of administration. The IN route was available in all 40 states (100%). In addition, the majority of states used the IV and IM routes (37 (92.5%) and 32 (80.0%), respectively). Administration with AI was less common (23 states (57.5%), and only 8 states (20.0%) used the SQ route.

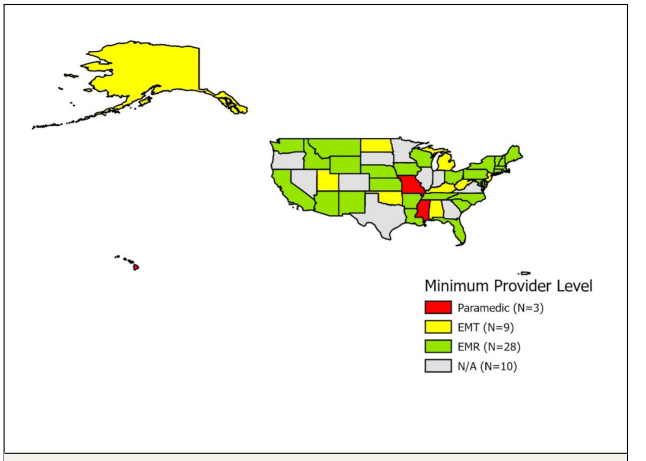

Figure 1. Minimum EMS Provider Level for Naloxone Administration in Statewide Protocols

Table 1 presents the minimum EMS provider level permitted to administer naloxone by specific routes. While in most states EMRs were permitted to use AI and IN, 30% still required at least EMT level. Moreover, 3 states (8%) required a Paramedic level for IN administration. The greatest variation in minimum provider level across states appeared to be for the IM route. A minimum AEMT level was required for most states (78%) providing IV naloxone although 1 state allowed EMTs to administer by the IV route. Supplementary Table 1 provides additional details and a breakdown of minimum EMS provider level required for specific routes of administration for naloxone by state.

Discussion

Our nationwide examination of EMS protocols for suspected opioid overdose found the majority of states allow all levels of EMS providers to administer naloxone, consistent with the current National EMS Scope of Practice Model. However, we identified several states that still require at least an EMT certification level even when the national model recommends otherwise[12], and auto-injectors are being provided to the public for bystander use.[17,18] Our findings suggest states lagging behind in updating their EMS protocols to reflect national recommendations and the

Table 1. Minimum EMS Provider Level by Route of Naloxone Administration in Statewide Protocols

Minimum EMS Provider Level	Route of Administration				
	Auto-injection (N=23)	Intranasal (N=40)	Intramuscular (N=32)	Subcutaneous (N=8)	Intravenous (N=37)
EMR	16 (70%)	25 (63%)	5 (16%)	1 (13%)	0 (0%)
EMT	7 (30%)	12 (30%)	6 (19%)	1 (13%)	1 (3%)
AEMT	0 (0%)	0 (0%)	17 (53%)	5 (63%)	29 (78%)
Paramedic	0 (0%)	3 (8%)	4 (13%)	1 (13%)	7 (19%)

Abbreviations: EMR=Emergency Medical Responder, EMT=Emergency Medical Technician, AEMT=Advanced Emergency Medical Technician

generally increased popular support for wider availability of naloxone.

This delay stands in contrast to findings by Nugent et al that suggest that patients have similar outcomes but receive naloxone sooner when treated by EMRs such as Basic Life Support (BLS) certified providers versus waiting for Advanced Life Support (ALS) providers.[19] Updating EMS protocols has the potential to increase use of naloxone by prehospital providers for reversal of opioid overdose.

The delay in updating EMS protocols to reflect national recommendation is likely multifactorial. State specific EMS protocols are written and updated at various times and may have used outdated material at the time of their development. Furthermore, expanding EMS scope of naloxone administration would require further funding and training which may be limited. Finally, expanding scope may also require changes to laws and statutes at the regulatory level which may be burdensome, time-consuming and expensive.

There is limited scientific evidence on the relative benefits and harms of the various routes of administration for naloxone. Intranasal administration is known for ease of use, low cost, and for eliminating risk of needle-stick injuries.[9,20] While the IN route was identified in all states examined in our study, several states still require an EMT certification level or higher even though IN falls within the scope of practice of all provider levels. Intravenous administration is considered the ideal method for patient care because of the ability to titrate to responsiveness and prevent side effects from larger doses than needed.[9] Although the large majority of states included the IV route, a few lacked the option in addition to other routes. Intramuscular administration of naloxone has significant benefits including the ease of use of an auto-injector, improved pharmacokinetics compared to intranasal, and the ability to deliver a consistent dose with rare adverse effects.[21,22] However, IM administrations may be associated with concerns of practitioner safety and worries of needlestick injuries and agitation leading to refusal of transportation.[9]

Evidence-based guidelines recommend multiple routes of naloxone administration made available by EMS systems.[9] In our study, all statewide protocols examined included more than one route of administration.

Our analysis adds to the recent body of work by Smart et al who assessed EMS protocols and routes of administration albeit with different results.[14] Whereas Smart et al conducted a "legal review" by a single "legal researcher", our systematic examination of protocols was through a clinical lens with two independent reviewers and input from subject matter experts. Furthermore, they found 39 states allowing naloxone administration by EMRs whereas our work found 28. This may reflect a difference in sources used to access available EMS protocols or differences in data collection and reconciliation processes.

Limitations

Our study has some important limitations. First, a lack of publicly available statewide protocol does not necessarily indicate a lack of any guidance for naloxone administration within the state. Rather, for many states, internal statewide protocol documents might be present, or the guidelines might be deployed at the local, municipal, or county levels. Related to this, our findings may not be representative of the entire U.S. since many large cities that have their own protocols were not included in this review. Second, we only identified and abstracted naloxone-specific protocols though relevant information may be documented in different sections, such as formularies. Information from other documentation could alter the overall conclusions of our assessment regarding dosing, scope, and routes of administration. For example, states may allow IO administration for any medication allowed to be given intravenously, which may not be stated in a naloxone protocol. Nevertheless, the high degree of variation between states for naloxone administration would most likely still be present. Third, due to the manual nature of our review, errors in data collection and interpretation are possible; however, we utilized two independent reviewers to minimize this limitation as much as possible and to ensure accurate data collection. Lastly, state protocols are updated periodically at different intervals; hence, although the information presented is up to date at the time of publication, it might not necessarily be up to date when read beyond the date of publication.

Conclusion

Our examination of statewide EMS protocols across the United States identified most states allow EMRs to administer naloxone to reverse opioid overdose following the current National EMS Scope of Practice Model. However, several states (22.5%) still require at least an EMT provider level. Our findings suggest a need to update EMS protocols for naloxone administration. Future directions of research regarding EMS naloxone administration may include comparing EMS scope of naloxone administration with opioid overdose outcomes in each state to assess for trends and possible correlations. Further, implementation studies may involve revamped training for EMS naloxone administration and subsequently investigating changes in opioid overdose related death rates in particular states.

Appendix

See Supplementary Table 1 above.
View Supplementary Table 2 by clicking on additional document under the manuscript link on CJIM website.

ARTICLE INFORMATION

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Supplementary Table 1. Scope of practice for emergency medical personnel for naloxone administration

States	Auto-Injector	IN	IM	IV	IO	SQ	ET	Titrate
1.Alabama	B, A, P	B, A, P	A, P	A, P				Yes
2.Alaska	B, A, P	B, A, P	A, P	A, P				No
3.Arizona	B, A, P	R, B, A, P	R, B, A, P	A, P	A, P		A, P	No
4.Arkansas	R, B, A, P	R, B, A, P	P	P			P	Yes
5.California	R, B, A, P	B, A, P	B, A, P	A, P				No
6.Colorado								
7.Connecticut	R, B, A, P	R, B, A, P	P	P	P			Yes
8.Delaware	B, A, P	R, B, A, P	B, A, P	P	P			No
9.Florida	R, B, A, P	R, B, A, P	P	P	P			Yes
10.Georgia								
11.Hawaii		P		P	P			Yes
12.Idaho		R, B, A, P	A, P	A, P				No
13.Illinois								
14.Indiana								
15.Iowa	R, B, A, P	R, B, A, P	A, P	A, P		A, P		No
16.Kansas	R, B, A, P	R, B, A, P	R, B, A, P	A, P	A, P			No
17.Kentucky		B, A, P	A, P	A, P	A, P	A, P		No
18.Louisiana	R, B, A, P	R, B, A, P	R, B, A, P	A, P				No
19.Maine	R, B, A, P	R, B, A, P	A, P	A, P	A, P			Yes
20.Maryland		R, B, A, P	A, P	A, P	A, P		A, P	Yes
21.Massachusetts		R, B, A, P	A, P	A, P	A, P			No
22.Michigan	B, A, P	B, A, P	A, P	A, P				Yes
23.Minnesota								
24.Mississippi		P		P				No
25.Missouri		P	P	P	P	P	P	Yes
26.Montana		R, B, A, P	B, A, P	B, A, P	B, A, P		A, P	No
27.Nebraska	R, B, A, P	R, B, A, P	A, P	A, P	A, P			No
28.Nevada								
29.New Hampshire		R, B, A, P	A, P	A, P				Yes
30.New Jersey	B, A, P	B, A, P						No
31.New Mexico		R, B, A, P	R, B, A, P	A, P	A, P	R, B, A, P	A, P	Yes
32.New York	R, B, A, P	R, B, A, P	A, P	A, P				Yes
33.North Carolina	R, B, A, P	R, B, A, P	R, B, A, P	A, P	A, P		A, P	Yes
34.North Dakota	B, A, P	B, A, P		A, P	P	B, A, P		No
35.Ohio	R, B, A, P	R, B, A, P	A, P	A, P	A, P	A, P	A, P	No
36.Oklahoma		B, A, P		A, P	A, P			No
37.Oregon								
38.Pennsylvania	R, B, A, P	R, B, A, P	A, P	A, P	A, P			Yes
39.Rhode Island		R, B, A, P	A, P	A, P				No
40.South Carolina	R, B, A, P	B, A, P						No
41.South Dakota								
42.Tennessee	R, B, A, P	B, A, P	B, A, P	A, P	A, P			Yes
43.Texas								
44.Utah		B, A, P	B, A, P	A, P	A, P			No
45.Vermont		R, B, A, P	A, P	A, P	A, P	A, P		Yes
46.Virginia								
47.Washington		R, B, A, P	B, A, P	A, P				No
48.West Virginia		B, A, P		A, P				Yes
49.Wisconsin		R, B, A, P	A, P	A, P		A, P		No
50.Wyoming	R, B, A, P	R, B, A, P						No

R = EMR/First responder, B = EMT-Basic, A = Advanced EMT, P = Paramedic

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