

THE IMPLEMENTATION AND EVALUATION OF AN EVIDENCE-BASED STATEWIDE PREHOSPITAL PAIN MANAGEMENT PROTOCOL DEVELOPED USING THE NATIONAL PREHOSPITAL EVIDENCE-BASED GUIDELINE MODEL PROCESS FOR EMERGENCY MEDICAL SERVICES

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ABSTRACT

Background. In 2008, the National Highway Traffic Safety Administration funded the development of a model process for the development and implementation of evidence-based guidelines (EBGs) for emergency medical services (EMS). We report on the implementation and evaluation of an evidence-based prehospital pain management protocol developed using this model process. **Methods.** An evidence-based protocol for prehospital management of pain resulting from injuries and burns was reviewed by the Protocol Review

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Committee (PRC) of the Maryland Institute for Emergency Medical Services Systems (MIEMSS). The PRC recommended revisions to the Maryland protocol that reflected recommendations in the EBG: weight-based dosing and repeat dosing of morphine. A training curriculum was developed and implemented using Maryland's online Learning Management System and successfully accessed by 3,941 paramedics and 15,969 BLS providers. Field providers submitted electronic patient care reports to the MIEMSS statewide prehospital database. Inclusion criteria were injured or burned patients transported by Maryland ambulances to Maryland hospitals whose electronic patient care records included data for level of EMS provider training during a 12-month preimplementation period and a 12-month postimplementation period from September 2010 through March 2012. We compared the percentage of patients receiving pain scale assessments and morphine, as well as the dose of morphine administered and the use of naloxone as a rescue medication for opiate use, before and after the protocol change. **Results.** No differences were seen in the percentage of patients who had a pain score documented or the percent of patients receiving morphine before and after the protocol change, but there was a significant increase in the total dose and dose in mg/kg administered per patient. During the postintervention phase, patients received an 18% higher total morphine dose and a 14.9% greater mg/kg dose. **Conclusions.** We demonstrated that the implementation of a revised statewide prehospital pain management protocol based on an EBG developed using the National Prehospital Evidence-based Guideline Model Process was associated with an increase in dosing of narcotic pain medication consistent with that recommended by the EBG. No differences were seen in the percentage of patients receiving opiate analgesia or in the documentation of pain scores.

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BACKGROUND

In the United States, individual states and local emergency medical services (EMS) agencies are responsible for developing, implementing, and evaluating their own prehospital patient care protocols, typically relying on local expertise and consensus-based methodologies. This process has resulted in widely varying protocols and significant differences in patient care for given medical conditions.

Because of concerns regarding the lack of an evidence-based approach to prehospital patient care, both the 2001 National EMS Research Agenda¹ and the 2006 report by the Institute of Medicine (IOM) on the Future of Emergency Care in the United States² called for the development and implementation of evidence-based protocols for prehospital care. In response to these recommendations, the National Highway Traffic Safety Administration funded the development of the National Prehospital Evidence-based Guideline Model Process for Emergency Medical Services, subsequently approved by both the Federal Interagency Committee on EMS and the National EMS Advisory Council.³ The availability of a nationally accepted set of evidence-based model protocols would allow individual emergency medical services agencies access to the best available knowledge about the efficacy of prehospital care, but still allow individual jurisdictional flexibility that takes into account local population needs and available resources.

This study assesses the impact of the adoption of an evidence-based prehospital pain management protocol developed using the National Prehospital EBG Model Process on patient care and outcomes in the Maryland Institute for Emergency Medical Services system.

METHODS

Protocol Development and Adoption

Using the National Prehospital EBG Model Process, an evidence-based guideline and model prehospital protocol were developed for the treatment of pain resulting from injury or burns in the prehospital setting.⁴ The state of Maryland was chosen for implementation because of its use of statewide EMS protocols and due to existing working relationships between the investigators and the MIEMSS state EMS medical director.

Representatives from the MIEMSS Protocol Review Committee were invited to participate on the multidisciplinary panel that was responsible for reviewing the literature and developing the guidelines. All panel members received training in the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) methodology. Representatives from the committee participated in the development of clinical questions, appraisal of scientific evidence, and the development and weighting of recommendations. Following the finalization of the EBG and accompanying model protocol, the protocol was presented to the entire MIEMSS PRC as part of their annual protocol review process in December 2010. The committee discussed potential changes to the existing statewide pain control protocol. The group decided to adopt two major recommendations from the EBG: weight-based dosing of morphine and repeat dosing of morphine.

The committee also discussed but did not adopt other recommendations of the EBG, including elimi-

nating a requirement for medical control prior to dosing with narcotics for pediatric patients and adding intranasal fentanyl as an optional alternative to parenteral morphine. However, in subsequent meetings, the committee recommended eliminating the requirement for medical control for pediatric patients in 2011, and recommended that intranasal fentanyl be added as an option for pain management in 2012. This study evaluated the 2010 changes to weight-based dosing and repeat dosing of morphine and did not examine the last two changes.

Provider Training

Upon completion of the EBG-based modified pain management protocol from the Protocol Review Committee and the approval of the protocol change by the EMS Board, all EMT-basic, EMT-intermediate (cardiac rescue technicians), paramedics, and hospital base station staff were required to complete the annual protocol update before the July 1, 2011 implementation date. MIEMSS developed an electronic learning format using Articulate Studio software, allowing for educational content in Flash format with Sharable Content Object Reference Model (SCORM) packaging, which was housed in the MIEMSS online training center. This educational program was divided into basic life support (EMT-basic), advanced life support (intermediate and paramedic), and base station (hospital nurses and physicians) presentations. The annual educational update for 2011 for paramedic was 58:46 minutes long, of which 8:41 minutes were dedicated to the pain management protocol updates. The annual educational update for 2011 for BLS providers was 39:19 minutes long, of which 5:55 minutes were dedicated to the pain management protocol updates. Upon completion, the results for prehospital care providers were uploaded directly into the providers' state file for continuing education certification. Records for physicians and nurses were collected by the individual hospital and were not recorded at the state level.

The content was also released in DVD format for use in company drills and training academy settings. This allowed for the education of EMS providers who did not have high-speed Internet access. The submitted course rosters were then uploaded into the providers' continuing education record.

Study Population

Our population included prehospital providers with advanced life support (ALS) capabilities working at a Maryland EMS agency, transporting patients with traumatic injury or burn to an emergency department (ED) between July 1, 2010 and June 30, 2012. Since July 1, 2011 was the first day of implementation for the evidence-based protocol, this represented a 12-month preimplementation and a 12-month

postimplementation phase. Unlike many medical studies of a protocol change, we did not include a transition period. The education for the new protocols occurred during the preimplementation phase, but providers were not allowed to change their practice until the official start date of the new protocols, so contamination of the preimplementation phase should not have occurred. This is different from medical practice, in which significant contamination can occur when providers change their practice prematurely.

DATA ELEMENTS

Information regarding the patient demographics, training level of the transporting team (basic life support (BLS) versus advanced life support), pain assessment, and administration of medication were obtained from the MIEMSS electronic patient care record (ePCR) database. This system is designed to allow EMS providers to submit patient encounter data electronically on a near real-time basis. At the time of the study, not all jurisdictions in Maryland reported patient encounter data via this system.

During the study period, there was a change in the EMS database being used, from an internally created system, Electronic Maryland Ambulance Information System (eMAIS), to a vendor-supplied system, Electronic Maryland EMS Data System (eMEDS). This change in database platform during the study period resulted in changes in reporting jurisdictions and variable definitions. The only variable affecting this study was the designation of ALS versus BLS; the newer software does not contain a variable delineating ALS from BLS calls, so the population eligible for morphine (traumatic injury + ALS EMS capability) under the revised protocol could not be determined. This would be expected to bias the results of the study against an effect of the protocol change.

Data Analysis

For each transport we determined the level of training of the transporting team (BLS versus ALS when documented), MIEMSS priority code (1–4), injury versus burn, patient age in years or months (if <1 year), patient weight, patient gender, recorded pain score, total dosage of narcotic pain medication administered, frequency of initial pain score recorded, and naloxone (narcotic antagonist) administration. We compared the percentage of eligible patients who received narcotic pain medications before and after implementation of the statewide EMS pain management protocol. We calculated the total dose of narcotic pain medication in mg/kg for the transports in which the patient weight was documented. We also compared the frequency of documented pain scores and the rate of adverse events, defined naloxone administration by EMS provider af-

ter administration of a narcotic. We performed subgroup analyses comparing the rates of narcotic pain medication administration in male versus female patients, and in pediatric (age < 15 years) versus adult (ages 15–65 years) and geriatric (age > 65 years) patients, during each study time period. Rates of morphine use were compared using the chi-square test. Continuous data (dosing) were compared using Student's *t*-test.

Human Subjects

All data were provided in a de-identified format with no protected health information. This study was certified as exempt under 45 CFR 46.101(4) by the Children's National Medical Center and University of Maryland Institutional Review boards.

RESULTS

Protocol Review and Adoption

After comparing the EBG model protocol with the existing MIEMSS pain management protocol, the PRC recommended revising the state pain management protocol. Specifically, the dosing for narcotic pain medications was changed from a dose range for adults (2–10 mg in 1- to 2-mg increments with a maximum dose of 10 mg) to a calculated bolus dose based on the patient's weight (0.1 mg/kg/dose) with a maximum dose of 20 mg. In addition, the new protocol authorized repeat dosing of pain medication at 0.05 mg/kg following reassessment with an approved pain scale. These recommendations were approved by the Maryland EMS Board and incorporated into the 2011–2012 protocol roll-out and education cycle. The new protocols were implemented on July 1, 2011.

Provider Training

For the EBG-based modified pain management protocol, the following number of EMS providers completed the educational requirements for 2011: total number 19,910, of which 3,941 were ALS providers and 15,969 were BLS providers.

Study Population

Twenty-one of the 24 jurisdictions in Maryland submitted ePCRs using either eMAIS or eMEDS during the two study periods. Transports originating from "other" areas in the state, such as the Aberdeen Proving Ground and the Baltimore Washington Airport, and transports by Maryland ambulances to out-of-state facilities were also included.

There were 1,638 EMS transports of patients with injuries or burns during preimplementation and 1,853

TABLE 1. All trauma/burn EMS transports by study period for reporting jurisdictions in Maryland, July 2010 to June 2012 (N = 3,491)

Data platform/ level of care	July 2010– June 2011	July 2011– June 2012	Total
eMAIS			
ALS + BLS	1,480	853	2,333
ALS	1,336	792	
BLS	144	61	
eMEDS ^a	158	1000	1158
Total	1,638	1,853	3,491

^aUnable to distinguish ALS vs. BLS (see text), transported from July 2010 to June 2012.

during postimplementation for a total of 3,491 transports (see Table 1). Of these runs, 2,333 were in the eMAIS system and were thus included for further analysis. These transports were from 16 jurisdictions and the eMAIS "others" category and represented 23% of Maryland population. Of the 2,333 eMAIS EMS trauma/burn transports, 2,128 (91.2%) were identified as ALS runs and 205 (8.8%) were identified as BLS and therefore not eligible for morphine administration by Maryland State EMS protocols and were excluded from further analysis.

Of the 2,128 eligible ALS transports 1,336 occurred in the preintervention phase and 792 occurred in the postintervention phase. There were no differences in gender or age group distribution by study period (Table 2).

Documentation of Pain Scores

There was no difference in the frequency of documentation of pain scores by providers between the pre- and postintervention periods (Table 2). There was also no

difference in the documented level of pain score (pain score category) between the two study periods. The majority of the patients in both periods reported severe or maximum levels of pain.

Frequency of Morphine Administration

A total of 1,508 (70.9%) eligible transported patients received morphine and 620 (29.1%) did not (Table 3). In the first period (pre-protocol change) there was no significant difference between age groups in rate of morphine administration. However, in the second time period (post-protocol change) significantly more children (<15 years of age) received morphine ($p < 0.01$) compared to older patients.

Females were more likely than males to receive morphine in both study periods ($p < 0.001$). There was no change postintervention in the frequency of morphine administration to female or male patients (Table 3).

There was no statistically significant difference in frequency of morphine administration between age groups in either time period. There was no difference between study periods in the frequency of morphine administration in any of the three age groups (Table 3).

In both time periods, patients with higher pain scores were more likely to receive narcotic pain medication. Patients with no documented pain score were the least likely to receive narcotic pain medication. There was no change in the frequency of narcotic pain medication administration between the two study periods in any of the pain score categories (Table 4).

Dosing of Morphine

The total dose of morphine increased by 18.1%, from an average total dose of 6.0 to 7.1 mg ($p < 0.0001$) (Table 5a). When calculated in mg/kg, the average

TABLE 2. Demographic variables for ALS trauma/burn transports by study period for reporting jurisdictions in Maryland, July 2010 to June 2012 (N = 2,128)

	July 2010– June 2011 n (%) Total = 1,336	July 2011– June 2012 n (%) Total = 792	Total n (%) Total = 2,128	p-value ^a
Gender				
Male	750 (56.1)	432 (54.6)	1,182 (55.6)	NS
Female	586 (43.9)	360 (45.4)	946 (44.4)	
Age groups ^b				
<15	89 (6.7)	45 (5.7)	134 (6.3)	NS
15–65	936 (70.1)	577 (73.0)	1,513 (71.2)	
66+	310 (23.2)	169 (21.3)	479 (22.5)	
Initial pain level	107 (8.0)	68 (8.6)	175 (8.2)	
No or mild pain (0–3)				
Moderate pain (4–6)	165 (12.4)	85 (10.7)	250 (11.8)	NS
Severe pain (7–9)	413 (30.9)	247 (31.2)	660 (31.0)	
Maximum pain (10)	486 (36.4)	284 (35.9)	770 (36.2)	
Pain level unknown (not documented)	165 (12.3)	108 (13.6)	273 (12.8)	

^aChi-square.

^bOne subject was missing age.

TABLE 3. Frequency of morphine administration among ALS trauma/burn EMS transports by study period for reporting jurisdictions in Maryland, July 2010 to June 2012

	July 2010– June 2011 n (%) Total = 1,336	July 2011– June 2012 n (%) Total = 792	Total n (%) Total = 2,128	p-value ^a comparing time periods
Gender				
Female N = 946	455/586 (77.7)	273/360 (75.8)	728/946 (77.0)	NS
Male N = 1,182	501/750 (66.8)	279/432 (64.6)	780/1,182 (66.0)	NS
p-value male vs. female	p < 0.0001	p = 0.0006	p < 0.0001	NS
Age in years ^b				
Less than 15	63/89 (70.8)	38/45 (84.4)	101/134 (75.4)	0.08
15–65	659/936 (70.4)	387/577 (67.1)	1,046/1,513 (69.1)	NS
Over 66	233/310 (75.2)	127/169 (75.2)	360/479 (75.2)	NS
p-value between age groups	NS	p = 0.01	p = 0.02	NS
Total population of morphine given	956/1,336 (71.6)	552/792 (69.7)	1,508/2,128 (70.9)	NS

^aChi-square.^bOne subject was missing age.

total weight-based dose increased from 0.081 mg/kg in the preintervention period to 0.093 mg/kg in the postintervention period, an increase of 14.9% ($p < 0.0001$) (Table 5b).

Frequency of Naloxone Use

Two individuals received naloxone in the preintervention period and no individual received it in the postintervention period. Upon chart review by the state EMS medical director, the use of naloxone in the two individuals who received it was determined not to be related to morphine administration.

DISCUSSION

Our results suggest that incorporation of evidence-based guidelines into a regional prehospital protocol review process can result in improved prehospital care. Specifically, protocol changes with weight-based dosing and optional repeat dosing of morphine resulted in higher total dosing and higher mg/kg dosing without an increase in significant side effects. Unfortunately, we were unable to detect a change in postmorphine

pain scores, which would be an ideal patient-centered outcome measure. While others have shown that a change in a local prehospital protocol for pain management can result in improved outcomes, including pain relief and time to pain medication,^{5,6} we are not aware of any other published report that specifically addresses the implementation of an evidence-based guideline in a state-wide EMS system.

It is important to note that while the Maryland protocol review committee did not adopt all of the recommendations of the EBG during the first year, they did discuss the other recommendations and made changes consistent with these recommendations in subsequent years. We believe that these changes in 2011 and 2012 were influenced by the exposure to the EBG and the development process that occurred in 2010.

We hypothesized that the increased focus on pain management caused by the protocol change and education around that change would increase the proportion of patients receiving narcotics. We did not observe such an increase in the population we studied. One possible reason for this is the fact that the baseline rate of narcotic pain medication administration for this population was already high. Approximately 70%

TABLE 4. Percentage of eligible transports receiving morphine by documented pain score category in the pre- and postintervention period

Documented pain score	Number receiving morphine			p-value ^a comparing study periods
	July 2010– June 2011 n/N (%) Total = 1,336	July 2011– June 2012 n/N (%) Total = 792	Total n/N (%)	
0–3	18/107 (16.8)	7/68 (10.3)	25/175 (14.3)	NS
4–6	99/165 (60.0)	48/85 (56.5)	147/250 (58.8)	NS
7–9	364/413 (88.1)	216/247 (87.5)	580/660 (87.9)	NS
10	465/486 (95.7)	275/284 (96.8)	740/770 (96.1)	NS
Unknown	10/165 (6.1)	6/108 (5.6)	16/273 (5.9)	NS
p-value ^a comparing pain score categories	<0.0001	<0.0001	<0.0001	

^aChi-square.

TABLE 5a. Total dose of morphine (mg/patient transported among ALS trauma/burn transports by study period for reporting jurisdictions in Maryland, July 2010 to June 2012 (N = 1,508)

Period	Mean	Standard deviation	Standard error	Range	95% CI	p-value ^a
July 2010–June 2011 N = 772	6.03	3.67	0.12	0.1 40.0	5.79 6.261	< 0.001
July 2011–June 2012 N = 478	7.12	4.00	0.17	0.4 30.0	6.7848 7.4536	
Difference	-1.09	3.80	0.20	NA	-1.49 -0.693	

^aStudent's *t*-test.

of eligible patients were given morphine in both periods. This is significantly higher than reported in similar populations in other systems.^{7–14} We also did not observe an associated increase in frequency of pain score documentation. However, the baseline rate of documentation was relatively high and there are few reports from other systems to which this rate may be compared.¹⁰ Others have also reported that children, the elderly, and women may be more at risk for lack of analgesia in the prehospital setting.^{8,11,13,14} We did not observe these disparities in our population. In fact, female patients were more likely to receive pain medication than male patients, and children were more likely to receive pain medication than those aged 15–65 years. In addition, although it was not statistically significant, there was a 19.2% increase in the percentage of children receiving morphine in the postimplementation period versus the preimplementation period.

There was an association between pain score documented and narcotic pain medication administration, as has been suggested by previous authors.⁸ It's possible that prehospital providers did not score patients with pain scores of zero, and thus withholding analgesics was appropriate. An alternative explanation for these findings is that some providers may fail to recognize pain and may fail to perform a pain score and treat pain. In this scenario, some patients with significant pain would be undertreated. Further analysis of this group and efforts to increase pain score documentation may help elucidate which of these is occurring. Efforts to further increase the rate of pain score documentation and narcotic pain medication administration should focus on better defining the untreated group and targeting interventions to that group.

Limitations

This study has several limitations. First, because the data were collected primarily for administrative use, the results should be interpreted with caution, as their primary purpose was not for research. For example, the eMAIS data lacked the granularity to provide data such as the frequency of reevaluation of pain level by the prehospital provider. Nevertheless, these data represent the actual prehospital medical records of patients. Second, since all jurisdictions did not report, there is a potential recruitment bias; smaller jurisdictions were more likely to use the eMAIS system. However, smaller jurisdictions tend to be more rural and more likely to have longer transport times, therefore increasing the time potentially available for morphine administration. The influence of transport time on morphine administration could not be determined from the data.

The systemwide implementation of a new and more robust data collection system, eMEDS, limited our ability to compare all reporting jurisdictions before and after the intervention. This was in part due to the lack of a clear operational definition of an ALS ambulance run versus a BLS ambulance run both within the eMEDS system as well as within the National EMS Information System. Within eMAIS, an ALS ambulance transport was indicated in the field by the ALS provider. This was based upon the following: (1) an available ALS provider, (2) an available ALS unit, (3) a patient requiring ALS care, and (4) an ALS evaluation or intervention. While this definition was consistent in both study periods, there may have been individual provider and jurisdiction variability in the application of the definition.

TABLE 5b. Amount of morphine administered (mg/kg) among ALS trauma/burn EMS transports by study period for reporting jurisdiction in Maryland, July 2010 to June 2012 (N = 1,508)

Period	Mean	Standard deviation	Standard error	Range	95% CI	p-value ^a
July 2010–June 2011 N = 772	0.081	0.0514	0.00	0.0014 0.571	0.078 0.0843	< 0.0001
July 2011–June 2012 N = 478	0.093	0.08	0.00202	0.010 0.313	0.089 0.097	
Diff (1–2)	-0.012	0.050	0.00258	NA	+0.007– +0.017	

^aStudent's *t*-test.

CONCLUSIONS

The information obtained from this study on the impact of a protocol change on patient care can be used to further inform future efforts at creating and revising evidence-based guidelines for prehospital care. Our study demonstrates that an evidence-based guideline developed using national expertise and a standardized process can be successfully adopted by a local agency responsible for protocol review and development. This process allowed for the state EMS system to adapt the guidelines to reflect their own priorities and resource availability.

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