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Impact of emergency medicine clinical pharmacist practitioner-driven sepsis antibiotic interventions

Aubrie Hammond, PharmD *,[1], Regan Porter, PharmD, Kevin E. Lynch, PharmD, Taylor H. Cason, PharmD, Patrick Passaretti, PharmD

CaroMont Regional Medical Center, 2525 Court Dr, Gastonia, NC 28054, United States of America

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ABSTRACT

Background: The 2021 Surviving Sepsis Campaign Guidelines recommend administration of antimicrobials within the first hour of recognition of sepsis. Over the last decade, several studies have demonstrated improved time-to-antibiotic administration and antibiotic appropriateness when a pharmacist was involved in the care of patients with sepsis. To our knowledge, no studies evaluating the appropriate use of antibiotics in sepsis driven entirely by an Emergency Medicine (EM) Clinical Pharmacist Practitioner (CPP) have been published. The purpose of this study is to evaluate the impact of an EM CPP-driven protocol on antimicrobial interventions in patients with sepsis in the emergency department (ED).

Methods: This was a retrospective comparison of patients with sepsis for whom antimicrobials were ordered in the ED without pharmacist intervention to patients whose antimicrobials were ordered by an EM CPP via a sepsis consult to pharmacy. An EM CPP reviewed individual patient profiles for pertinent historical admissions, culture data, and allergy profiles to guide antimicrobial selection for the suspected source of infection and entered orders under their scope of practice with formal documentation in the electronic medical record (EMR). The primary objective of this study was to compare the rates of appropriate empiric antibiotic utilization in septic patients admitted from the ED pre- and post-protocol implementation. Secondary endpoints included the following, broadening of ED-initiated empiric antibiotics on hospital admission, time-to-antibiotic administration, in-hospital mortality, Rapid Emergency Medicine Score (REMS) association with in-hospital mortality, and hospital length of stay.

Results: A total of 144 patients were included: 80 patients prescribed antibiotics without pharmacist intervention and 64 prescribed antibiotics by an EM CPP. Appropriate empiric antibiotic selection in the ED improved from 57.5% (46/80) to 86% (55/64) with EM CPP intervention (difference 28.5%; $p < 0.01$). Time-to-first antibiotic administration decreased by 64 min ($p < 0.01$). Administration of antibiotics within 60 min, broadening of antibiotics on admission, hospital length of stay, and in-hospital mortality did not significantly differ across groups.

Conclusions: In this small, single-center study, an EM Clinical Pharmacist Practitioner-driven protocol for patients with sepsis in the emergency department improved the rate of appropriate empiric antimicrobial selection and time-to-antibiotic administration.

1. Introduction

Sepsis is life-threatening organ dysfunction caused by a dysregulated host response to infection [1]. In a typical year, >1.7 million American adults develop sepsis and of those, approximately 270,000 die as a result [2]. The 2021 Surviving Sepsis Campaign (SSC) Guidelines recommend administering antimicrobials immediately or within the first hour of recognition of sepsis in patients with a high likelihood for sepsis or septic shock [1]. A multicenter, retrospective study found that with each additional hour between Emergency Department (ED) presentation and antibiotic administration, there was a 9% increased risk of mortality [3]. A similar study found that mortality increased by

Abbreviations: ED, Emergency Department; EMR, Electronic Medical Record; CMS, Centers for Medicare & Medicaid Services; EM, Emergency Medicine; CPP, Clinical Pharmacist Practitioner; ICD, International Classification of Diseases; IDSA, Infectious Diseases Society of America; REMS, Rapid Emergency Medicine Score; SSC, Surviving Sepsis Campaign.

* Corresponding author.
E-mail address: aubrie.hammond@caromonthealth.org (A. Hammond).
[1] Postal address: 2525 Court Dr., Gastonia, NC 28054 Attn: Pharmacy Department, United States of America.

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7.6% for every hour of delay in the administration of antimicrobial therapy [4]. The Centers for Medicare & Medicaid Services (CMS) Early Management Bundle, Severe Sepsis/Septic Shock Measures (SEP-1) is more lenient in that they require "broad-spectrum or other antibiotics" to be administered within three hours for institutional reimbursement [5].

Prior to July 1, 2021, SEP-1 required empiric antibiotic(s) to be selected from the pre-defined list of SEP-1 antibiotics (see supplement 1) [5]. Although intended to reduce morbidity, mortality, and hospital length of stay (LOS), the prespecified list of broad-spectrum antibiotics was frequently misaligned with good antimicrobial stewardship values. These requirements often disregarded targeted treatment of suspected sources and patient-specific factors in the interest of broadly covering the majority of patients with sepsis [6]. The predefined nature of these expectations set by CMS SEP-1 and other core measures led to frequent misuse and overuse of broad-spectrum antimicrobials in the ED. [7] With the removal of SEP-1 required antibiotics, Emergency Medicine (EM) clinical pharmacists are uniquely positioned to impact antimicrobial use in sepsis. EM clinical pharmacists can thoroughly review patient-specific and facility-specific factors based on the suspected source of infection and provide guideline-directed recommendations in the selection of empiric antibiotics [8].

The first study evaluating the role of EM clinical pharmacists in sepsis was published in 2012 [9]. This study reported that EM clinical pharmacists make an average of 4.5 interventions per patient with sepsis including dosing recommendations, optimizing antibiotics, drug preparation, and satisfying other drug information requests [9]. Since then, several studies have been published highlighting the pharmacist's role in optimizing time-to-antibiotic administration and appropriate antibiotic selection in the ED. At this study's facility, the ED is staffed twenty-four hours a day, seven days a week with full-time, Clinical Pharmacist Practitioner (CPP) credentialed, EM clinical pharmacists. CPP credentialing entitles a licensed pharmacist in the state of North Carolina to prescribe drug therapy management under the supervision of a licensed physician per institutional protocols [10]. To our knowledge, no studies exist evaluating appropriate antibiotic use in sepsis driven entirely by an EM CPP or the appropriate use of initial antibiotics in sepsis following the removal of the pre-specified antibiotics per the SEP-1 CMS requirements. Therefore, the purpose of this study is to evaluate the impact of an EM CPP protocol on guideline recommended, appropriate empiric antibiotic therapy for sepsis in the ED.

2. Methods

2.1. Study setting and design

This was a single center, retrospective study conducted at a 435-bed community hospital with an average of 80,000 ED visits per year. This study received approval from the hospital's institutional review board. Outcomes of patients with sepsis who were prescribed antibiotics by EM physicians without EM clinical pharmacist intervention between October 1, 2021 – February 28, 2022 were compared to patients who were prescribed antibiotics by a consulted EM CPP between October 1, 2022 – February 28, 2023. Patients in the EM CPP consulted group had antibiotic therapy ordered under the scope of the ED CPP protocol based on Infectious Diseases Society of America (IDSA) guideline-recommended empiric therapy for the suspected source of infection. EM CPPs took into consideration individual allergy profiles, historical culture data, institutional antibiograms, and guideline-validated risk factors when selecting empiric antibiotics. Institutional antibiotic decision trees for each suspected source of infection were developed by EM CPPs based on these principles of antimicrobial stewardship and IDSA guidelines and were utilized to objectively grade appropriateness of antibiotic selection for this study (see supplements 2–12). For the purposes of this study, only antibiotic use was evaluated with the exception of central nervous system (CNS) infections where antivirals were ordered when clinically appropriate.

2.2. Patient selection

Patients at least 18 years of age admitted to the hospital from the ED with a diagnosis of sepsis were included in the study. Patients could be included in the study more than once if they had more than one admission for sepsis within the study timeline. For the purposes of this study, two SIRS criteria with a suspected source of infection defined sepsis. In alignment with the Surviving Sepsis Campaign Guidelines, those with an unconfirmed source of infection were excluded as goals for antibiotic administration differ from those with a definitive source of infection. Additionally, those with multiple suspected sources of infection, vulnerable populations including those pregnant or incarcerated, patients admitted from or transferred to an outside facility, patients with advanced directives of comfort measures only, and those who expired prior to hospital admission were excluded.

Patients who were prescribed antibiotics without an EM clinical pharmacist intervention were identified by a report generated within the electronic medical record (EMR) utilizing International Classification of Diseases (ICD) codes, excluding those who had the consult order "Sepsis Antibiotic Alert to Pharmacy". Patients in the consulted EM CPP group were identified by a report generated within the EMR with an order for the "Sepsis Antibiotic Alert to Pharmacy". The "Sepsis Antibiotic Alert to Pharmacy" was an order available in the EMR and served as a formal EM CPP consult. Data was collected from study groups using consecutive sampling.

2.3. Study interventions

This facility's ED CPP collaborative agreement had previously only been applied to discharge culture review which involved the addition or modification of antimicrobial therapies if clinically indicated. For the purposes of this study, the ED CPP protocol was expanded to include empiric antibiotic ordering in the ED for sepsis and this change was approved by the institutional Pharmacy and Therapeutics Committee. The change enabled CPPs to prescribe first dose(s) of antimicrobials according to guideline-recommended empiric antibiotics under their scope of practice.

Following the expansion of the ED CPP protocol, the "Sepsis Antibiotic Alert to Pharmacy" order in the EMR was updated to require a source of infection to be selected by the consulting physician. The consult was purposefully designed to eliminate automatic ordering when the ED sepsis order set was utilized, making use of the consult more intentional. EM Physicians could consult EM CPPs by ordering the "Sepsis Antibiotic Alert to Pharmacy" consult from the institutional sepsis order panel or by a verbal consultation where the EM CPP would then order the consult. Previous practice required an EM clinical pharmacist to consult with the ordering physician prior to antimicrobial order entry. At times this resulted in delays in delivering recommendations as there was not always a documented source of infection at the time of consultation. An additional intervention was the implementation of a standardized documentation procedure following the completion of the "Sepsis Antibiotic Alert to Pharmacy" consult. Historically, there were no documentation requirements for sepsis consults. The EM CPP consulted group had a standardized pharmacy note documented in the chart with visibility to all members of the care team. The goal of requiring standard documentation was to outline the depth of consideration that goes into empiric antibiotic selection in the ED and to discourage inappropriate broadening of antibiotics on hospital admission.

2.4. Outcomes and data analysis

The primary outcome was the rate of appropriate empiric antibiotic utilization in the ED. Secondary outcomes included time-to-antibiotic administration, administration of antibiotic within 60 min, broadening of ED-initiated empiric antibiotics on hospital admission, hospital LOS,

and in-hospital mortality. Time zero for antibiotic ordering and administration was defined as patient arrival time to the ED. Electronic ED records, admission/ discharge summaries, laboratory and radiology reports were reviewed retrospectively to obtain data by trained abstracters. Data collected included patient demographics, medical and social history, management, and outcomes. A standardized extraction form with explicit definitions of study variables was used by two data collectors to record the data, and discrepancies were resolved by mutual agreement. All patients in the EM CPP consulted group had a Rapid Emergency Medicine Score (REMS) calculated at the time of consult using body temperature, mean arterial pressure, heart rate, respiratory rate, peripheral oxygen saturation, Glasgow Coma Scale score, and age, which was used to identify patients at risk of in-hospital mortality. REMS was also calculated retrospectively in the no pharmacist intervention group to contrast the severity of patients with sepsis across groups. Additional sub-analyses were performed to evaluate appropriate empiric antibiotic selection in the ED and inappropriate broadening of antibiotics on admission among the most common suspected sources of infection.

A previous study demonstrated a pharmacist-revised antibiotic sepsis bundle increased appropriateness of antibiotics by 20.9% [11]. Assuming EM physicians select appropriate empiric antibiotics in at least 50% of patients, we estimated a post-intervention increase to 75%. With power of 90% and alpha of 0.05, the sample size was calculated to require 77 patients in each group or a total of 154 patients. Chi-square test, student's *t*-test, and descriptive statistics were utilized where appropriate. Statistical significance was defined by a *p*-value of <0.05. Reliability of data abstracted was validated through a 10% medical record review by a co-investigator and an interrater agreement coefficient was reported using a kappa statistic.

3. Results

3.1. Baseline characteristics

Of the 298 patients screened for enrollment, 144 patients were included in the analysis (Fig. 1). No patients were included in the study more than once. Across study groups, the no pharmacist intervention group was significantly younger with a mean age of 59.7 vs 65.4 years ($p = 0.02$). The most common suspected sources of infection were pneumonia (47.9%), genitourinary (20.1%), and intra-abdominal (13.2%). Refer to Table 1 for complete baseline characteristics.

3.2. Primary and secondary endpoints

ED-initiated antibiotics were evaluated in both groups. Appropriate empiric antibiotic ordering significantly increased by 28.5% (57.5% no pharmacist intervention vs 86.0% EM CPP consulted; $p < 0.01$), as seen in Table 2. A 10% data review was performed and a kappa coefficient was calculated at 0.74, demonstrating substantial agreement among reviewers. On average, time-to-antibiotic administration was reduced by 64 min in the EM CPP consulted group ($p < 0.01$). There was no significant difference in the rate of antibiotics administered within 60 min, broadening of antibiotics on admission, hospital LOS, or in-hospital mortality across groups (Table 2). In the EM CPP consulted group, the mean time-to-antibiotics ordering was 25.2 ($\pm$ 24.7) minutes.

REMS was calculated for all patients in the pre- and post-intervention groups. The mean REMS was not significantly different across study groups. A total of 11 patients expired during hospital admission. The mean REMS for patients that expired compared to patients that survived to hospital discharge was 8.36 ($\pm$3.44) and 6.21 ($\pm$3.23), respectively, translating to a 3% risk of mortality across both groups [15]. Of those that expired during hospital admission, a total of 3 patients were categorized as having a 1% risk of mortality, 5 patients as a 3%, 2 patients as a 4%, and 1 patient as a 38%.

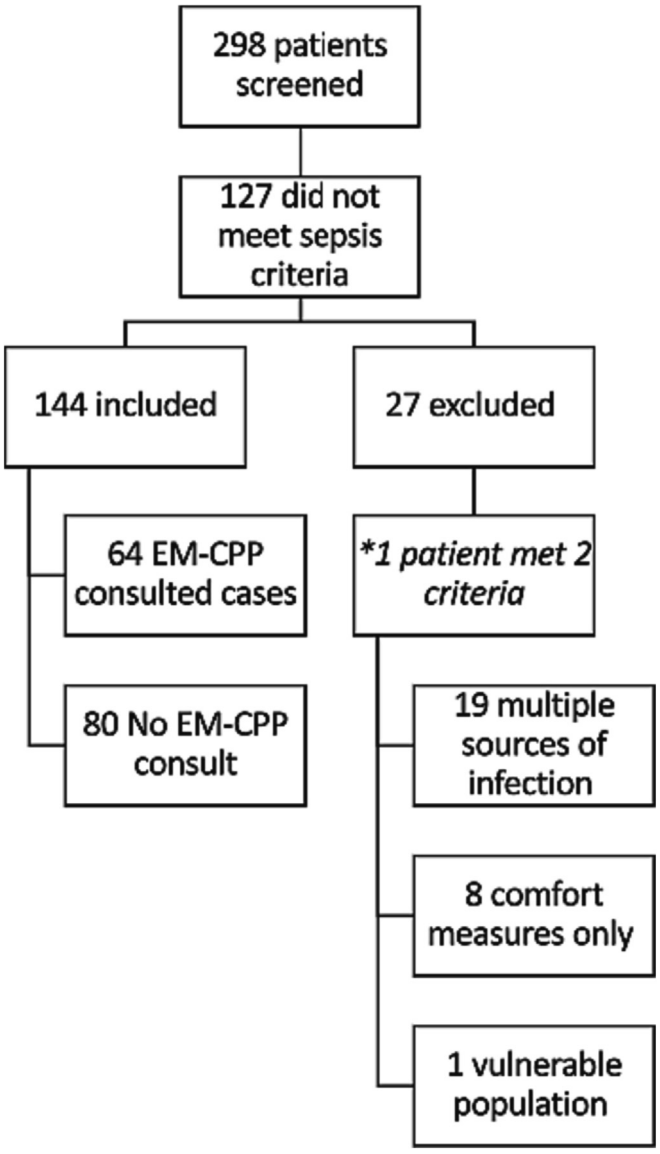

Fig. 1. Patient flow chart.
Patients >18 years of age with a sepsis diagnosis were included in this study.

3.3. Sub-group analyses

The most common suspected sources of infection within this study were pneumonia, genitourinary, and intra-abdominal. Appropriate empiric antibiotics were ordered in 57.5% of patients in the no pharmacist intervention group vs 86.0% ($p = 0.04$) in the EM CPP consulted group with pneumonia as the suspected source of infection, 76.5% vs 83.3% ($p = 0.65$) for genitourinary, and 46.1% vs 83.3% ($p = 0.13$) for intra-abdominal. There was nearly a 20% reduction in inappropriately broadened antibiotics on hospital admission for pneumonia (43.7% no pharmacist intervention vs 24.3% EM CPP consulted; $p = 0.09$). There was an increase in inappropriate broadening of antibiotics on admission for genitourinary (41.2% vs 41.7%; $p = 0.98$) and intra-abdominal (53.8% vs 66.7%; $p = 0.60$) between groups.

4. Discussion

4.1. Primary and secondary outcomes

To our knowledge, this is the first study highlighting the impact of EM CPPs on outcomes of patients presenting to the ED with sepsis.

Table 1
Patient demographics.

	No pharmacist intervention ($n = 80$)	EM CPP consulted ($n = 64$)	p-Value
Age, years	59.7 ± 15.2	65.4 ± 13.6	0.02
Male	39 (49)	38 (59)	0.20
BMI, kg/m^2	30.3 ± 8.4	28.0 ± 7.9	0.10
REMS	6.0 ± 3.4	6.9 ± 3.1	0.09
Suspected Source of Infection			
Pneumonia	32 (40)	37 (57.8)	
Genitourinary	17 (21.3)	12 (18.7)	
Intraabdominal	13 (16.2)	6 (9.4)	
Purulent SSTI	5 (6.2)	2 (3.1)	
Non-purulent SSTI	5 (6.2)	2 (3.1)	
URTI	3 (3.7)	0 (0)	
Diabetic Foot	2 (2.5)	2 (3.1)	
Osteomyelitis	2 (2.5)	0 (0)	
CNS	1 (1.2)	0 (0)	
Bacteremia	0 (0)	1 (1.6)	
Neutropenic Fever	0 (0)	2 (3.1)	

Continuous data are presented as mean and standard deviation. Binary and categorical data are presented as number and percentages of totals.
Abbreviations: BMI, body mass index; REMS, Rapid Emergency Medicine Score; SSTI, skin and soft tissue infection; URTI, upper respiratory tract infection; CNS, central nervous system.

This study demonstrated that an EM CPP-driven sepsis antimicrobial protocol significantly increased the rate of appropriate empiric antibiotic ordering. These findings reinforce that of a prior study which found that a pharmacist revised ED sepsis antibiotic bundle, based on a presumed infectious source, resulted in appropriate initial antibiotics being ordered more frequently (33.9% vs. 54.8%; $p = 0.03$) [11]. While data suggests a CPP-driven protocol increased the rate of appropriate empiric antibiotics in this study, it is important to recognize there was a continued collaborative practice among CPPs and physicians. Specifically, as a patient's clinical workup evolved, physicians would often re-consult CPPs so that antibiotics could be adjusted accordingly. While antibiotic ordering was left to the clinical judgment of the consulted CPP, appropriate empiric antibiotic selection could not have been as successful without a team-based approach to patient care.

This study also demonstrated that an EM CPP-driven protocol reduced time-to-antibiotic administration. These findings are consistent with previously published studies which found that a pharmacist's presence and participation in the care of patients with sepsis improve timeliness of antibiotic administration [12-14]. While this study found a significant reduction in time-to-antibiotic administration, many patients did not receive antibiotics within the SSC guideline's goal of 60 min. For the purposes of this study, time zero for antibiotic administration was defined as door-to-administration, which is a timelier goal than the CMS definition of physician-documented recognition of sepsis to administration [5]. It is also important to note a large standard deviation in time-to-first-antibiotic administration across groups. This variation can likely be attributed to patient acuity, nurse-to-patient ratio, and level of pharmacist involvement in procuring the ordered antibiotics at any given time. Higher acuity patients were more likely to have a pharmacist assist in preparing antibiotics at the bedside.

Table 2
Primary and secondary endpoints.

	No pharmacist intervention ($n = 80$)	EM CPP consulted ($n = 64$)	p-Value
Appropriate empiric antibiotic(s)	46 (57.5)	55 (86.0)	<0.01
Time-to-first-antibiotic administration (minutes)^	190.7 ± 9.7	127.0 ± 83.3	<0.01
Antibiotic administered within 60 min	6 (7.5)	10 (15.6)	0.12
Antibiotic(s) broadened on admission	35 (43.7)	22 (34.4)	0.25
Hospital LOS (days)	5.7 ± 4.9	5.9 ± 5.5	0.82
In-hospital mortality	6 (7.5)	5 (7.8)	0.94

Continuous data are presented as mean and standard deviation. Binary and categorical data are presented as number and percentages of totals.
^ Defined as ED presentation to first antibiotic administration.
Abbreviations: LOS, length of stay; ED, Emergency Department.

No significant difference was found in REMS for patients that expired compared to patients that survived to hospital discharge. A total of 11 patients included in this study expired during their admission. The original publication validating REMS in non-surgical patients in the ED found an increase of 1-point in the 26-point REMS scale was associated with an odds ratio of 1.40 for in-hospital mortality (95% CI: 1.36–1.45, $p < 0.01$) [15]. Furthermore, that study found that all patients with REMS <3 survived and all patients with REMS >24 expired [15]. Additional literature evaluating the utility of REMS in the setting of sepsis found the scoring tool to have 90.91% sensitivity and 88.57% specificity in mortality prediction [16]. This study did not find a meaningful difference in REMS between patients that expired or survived to discharge. Since no correlational analyses were performed in this study, we are unable to report reliability. Further studies are needed to evaluate the utility of REMS compared to standard mortality risk calculators and it's utility in triaging patients with sepsis in the ED.

4.2. Subgroup analyses

Specific sources of infection were identified that require further intervention to improve appropriate empiric antibiotic ordering and reduce inappropriate broadening of antibiotics on admission. While this study was able to reduce inappropriate broadening of antibiotics in patients with pneumonia as the suspected source of infection, there was a surprising increase in inappropriate broadening of antibiotics on hospital admission for genitourinary and intra-abdominal sources of infection. Identifying these sources of infection opened the door for guideline in-services, order-set interventions, and stewardship interventions.

This study did not find a significant difference in time-to-antibiotic ordering when CPP credentialed pharmacists completed the consult compared to non-CPP credentialed pharmacists. In evaluating this finding, a large standard-deviation was identified in time-to-antibiotic ordering within the CPP group. As a result, CPP-specific practice patterns were reviewed, and a standardized clinical practice was emphasized to further reduce time-to-antibiotic ordering when possible.

4.3. Limitations

This study was not without limitations. First, the retrospective study design introduces an inherent bias. More specifically, the no pharmacist intervention group was truly retrospective while EM pharmacists were aware of the study in the EM CPP consulted group. Second, this was a single center study with a small sample size that was unable to meet power. Despite not meeting power, this study was still able to identify a statistically significant difference in the primary endpoint which should translate into a clinically significant impact on patient-centered outcomes. Thirdly, it is important to recognize that the CMS-required antibiotics potentially confounded data in the no pharmacist intervention group as the required antimicrobials were often broader than guideline-recommended empiric antibiotic therapy for certain sources of infection. This largely impacted the grading of appropriateness across groups. Finally, in screening patients for study inclusion, only those identified to have two or more SIRS criteria with a clear source of infection were included. This inherently introduces a selection bias. To avoid a selection bias, clear-cut study definitions were followed by abstracters during data collection.

Overall, this study helped identify areas of opportunity at this institution. Future interventions at the study facility may include reviewing ED and admission sepsis antibiotic order sets to match EM CPP practice, continued inservicing on advances in guideline directed practice, and expanding inpatient CPP protocols to allow for better transitions of care.

5. Conclusions

In this small, single-center study, a Clinical Pharmacist Practitioner-driven protocol for patients with sepsis in the emergency department improved the rate of appropriate empiric antimicrobial selection and time-to-antibiotic administration. This study sets the stage for the expansion of CPP services and future CPP-driven protocols beyond the study facility. Further studies are needed to recognize additional positive outcomes associated with CPP-driven protocols in the ED.

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CRediT authorship contribution statement

Aubrie Hammond: Writing – original draft, Methodology, Formal analysis, Data curation, Conceptualization. **Regan Porter:** Writing – review & editing, Methodology, Conceptualization. **Kevin E. Lynch:** Writing – review & editing, Methodology, Conceptualization. **Taylor H. Cason:** Writing – review & editing, Methodology, Conceptualization. **Patrick Passaretti:** Validation.

Declaration of Competing Interest

Nothing to disclose.

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Aubrie Hammond: conceptualization, methodology, formal analysis, data curation, and writing Regan Porter: conceptualization, methodology, and writing- reviewing/ editing Kevin Lynch: conceptualization, methodology, and writing- reviewing/ editing Taylor Cason: conceptualization, methodology, and writing- reviewing/ editing Patrick Passaretti: data validation.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ajem.2023.11.012.

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