mhc MENTAL HEALTH CLINICIAN

ORIGINAL RESEARCH Open Access

Community pharmacy attitudes and behaviors following a buprenorphine best practices dissemination

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How to cite: Roth W, Dadiomov D. Community pharmacy attitudes and behaviors following a buprenorphine best practices dissemination. Ment Health Clin [Internet]. 2025;15(2):43-50. DOI: 10.9740/mhc.2025.04.043.

Submitted for Publication: September 7, 2024; **Accepted for Publication:** January 8, 2025

Abstract

Introduction: Opioid overdose deaths continue to rise despite available safe and efficacious treatments for opioid use disorder, such as buprenorphine. Whereas provider-level access to buprenorphine has improved, community pharmacy-level barriers remain, related to patient stigma and regulatory concerns. Education programs improve pharmacist comfort in dispensing naloxone. Because naloxone education improves naloxone dispensing comfort, buprenorphine education may improve stocking and dispensing of buprenorphine.

Methods: An evidence-based, best practices continuing education (CE) program about buprenorphine, including regulatory agency truths, was delivered to an audience of community pharmacists. To develop this CE program, interviews were conducted with key regulatory stakeholders including the Drug Enforcement Agency, board of pharmacy, and pharmaceutical distributors. Community pharmacist attendees completed a postsession anonymous survey on their knowledge about and comfort level toward buprenorphine following this CE program. Represented community pharmacies were contacted by phone approximately 1 month following this session to determine the immediate availability of buprenorphine and naloxone products.

Results: At least 75% of pharmacists reported feeling knowledgeable and comfortable about buprenorphine and its related regulations following an evidence-based CE program though buprenorphine was immediately available in only 25% of represented community pharmacies when contacted 1 month following the educational session.

Discussion: There are additional needs outside of pharmacist education to support consistent and timely buprenorphine access. Policy adjustments and board of pharmacy support may assist in improving timely and consistent buprenorphine access.

Keywords: buprenorphine, opioid use disorder (OUD), medication access, opioid overdose, education, naloxone

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Disclosures: The authors declare that they have no financial or nonfinancial interests to disclose.

Introduction

During the last 2 decades, greater than half a million individuals have died from an opioid overdose. These overdose deaths continue to rise and have remained over 100,000 deaths per year for the last 3 years.[1,2] These overdose deaths are preventable with available safe and efficacious treatment options for opioid use disorder (OUD) and widely available opioid overdose reversal agents.

Opioid antagonists reverse opioid overdoses by displacing full mu opioid agonists from the mu opioid receptor to restore breathing. Naloxone is a widely available, efficacious opioid antagonist that was recently FDA approved for over-the-counter use.[3] Prior to its over-the-counter approval, naloxone could be furnished by the community pharmacist without a prescription in some states, including California. Even with this capability, naloxone was still not consistently readily available at community pharmacies with 40% of community pharmacies in high-overdose areas of Los Angeles not furnishing naloxone.[4] A majority of pharmacists have expressed positive attitudes toward naloxone dispensing though pharmacist confidence affects their willingness to dispense naloxone, which is improved by participation in naloxone training and education programs.[5-9]

Pharmacologic first-line treatment options for OUD include buprenorphine and methadone.[10] Though not first-line, naltrexone is FDA approved for the treatment of OUD and may be appropriate in a subset of patients (eg, those already abstinent from opioids to prevent relapse and/or those unwilling or unable to take methadone or buprenorphine).[10] Whereas methadone must be dispensed from an opioid treatment program, buprenorphine may be dispensed from a community pharmacy and, therefore, has fewer regulatory access barriers. Buprenorphine is a partial mu opioid agonist with an incredibly high affinity for the mu opioid receptor.[11,12] Due to its pharmacology, it is effective in treating opioid withdrawal symptoms, reducing opioid cravings, preventing opioid overdose, increasing retention in treatment for OUD, and reducing high-risk behaviors among individuals using intravenous drugs.[12-15] It has a number needed to treat for suppressing illicit opioid use of 2 at doses of at least 16 mg daily.[16]

Provider-level access to buprenorphine has improved with the removal of the Drug Addiction and Treatment waiver in 2023. Currently, any provider with a Drug Enforcement Agency (DEA) number may prescribe buprenorphine for OUD for any number of patients.[17] Even with these provider-level improvements, barriers persist at the community pharmacy level, and many patients are unable to fill their prescription due to insufficient stocking or dispensing refusal.[18,19] In fact, a third of patients taking buprenorphine for OUD reported problems with picking up their prescription with one of the most common reasons cited as pharmacist refusal.[20] Previous literature investigates community pharmacy barriers to buprenorphine access and finds them to be twofold: (1) stigma and (2) regulatory concerns.[19,21-25] Stigma for patients using buprenorphine involves the untrue belief that these patients will misuse or divert the medication. Whereas this belief is pervasive, the majority of individuals who use buprenorphine illicitly do so for treatment of cravings and withdrawal symptoms—the medication's intended purpose.[20,26] Regulatory concerns stem from a pharmacist-perceived cap on buprenorphine ordering and dispensing set by the DEA. It is believed that reaching this cap will result in investigation and citation by the DEA or the state's board of pharmacy though these caps have not been found to exist.[23] Community pharmacist positive attitudes toward buprenorphine have not been found to predict dispensing behaviors[24] though negative attitudes have been related to increased prescription refusal and dispensing cap perception.[19] There are, therefore, additional needs to support pharmacist comfort in consistently stocking and dispensing this life-saving medication with clarity on regulatory bodies and their role in buprenorphine ordering being especially important.[19] Due to the evidence of improved confidence in dispensing naloxone associated with education and clear educational gaps associated with community pharmacy buprenorphine access, it is advantageous to determine the effect of community pharmacist buprenorphine training on pharmacist attitudes and behaviors toward buprenorphine stocking and dispensing.

In this study, we interviewed regulatory bodies, including the DEA, the board of pharmacy (BOP), and the Healthcare Distribution Alliance (HDA)—which oversees pharmaceutical distributors nationally—to determine their individual roles in buprenorphine access. We included regulatory agency roles and buprenorphine best practices in our evidence-based continuing education (CE) program that was delivered to a group of community pharmacists. We subsequently assessed attendees' attitudes toward buprenorphine via self-report survey and stocking behaviors of buprenorphine at represented community pharmacies via "secret shopper" calls. We hypothesized that knowledge about and comfort level toward buprenorphine in the treatment of OUD would be positive following the educational session; therefore, buprenorphine stocking at the represented community pharmacies would also increase with a majority of pharmacies having buprenorphine immediately available at the time of phone call.

Methods

Design

We conducted a descriptive study in the Orange County, California, area assessing community pharmacy attitudes and behaviors toward buprenorphine following an evidence-based educational session. Our CE program on buprenorphine included (1) myths of buprenorphine use; (2) regulatory truths endorsed by the DEA, California BOP, and HDA; and (3) principles of harm reduction.

To determine these regulatory truths, we developed interview questions for the DEA, BOP, and pharmaceutical distributors on the following topics: (1) controlled substance distribution caps, (2) history of sanctions against pharmacies for buprenorphine ordering and/or dispensing, and (3) the agency's role in buprenorphine access. See Table 1 for a full list of interview questions. Each agency was contacted via email to participate in a 30-minute video interview.

TABLE 1: Scope and enforcement of buprenorphine ordering and dispensing for each interviewed regulatory agency

	DEA	BOP	Pharmaceutical Distributors
Scope	Monitor, regulate, and investigate all handlers of controlled substances	Promote health and safety of patients in their state No requirements to report excessive controlled-substance ordering or dispensing	Set pharmacy-specific thresholds Report suspicious ordering to the DEA
Enforcement	Review suspicious orders for possible follow-up investigation or action No known reports of investigation or action related to buprenorphine alone	No known reports of investigation or action related to buprenorphine	Cut off controlled substance ordering if above pharmacy-specific threshold Report excessive orders to DEA
Interview Questions[a]	What are the requirements for reporting excessive controlled-substance ordering? What is the process for reviewing these reports? What are the requirements for reporting excessive buprenorphine ordering? What is the process for reviewing these reports? What is the role of the DEA/BOP when a distributor cuts off the controlled substance shipment to a pharmacy? How often have sanctions been applied to distributors, pharmacies, or other stakeholders as a result of excessive buprenorphine distribution or dispensing?		What are the limits on controlled-substance ordering? Buprenorphine ordering? What elements of pharmaceutical ordering are assessed in the development of "red flags?" How often are pharmacies flagged for excessive ordering?

[a]All interviewees were asked (1) What are the reporting requirements for controlled substances to your agency? (2) What is the history of pharmacies/pharmacists being punished (citation, license suspension, controlled-substance shipment cutoff) for buprenorphine ordering if any? (3) What is the history of pharmacies/pharmacists being punished (citation, license suspension, controlled-substance shipment cutoff) for buprenorphine dispensing if any? (4) How is buprenorphine assessed differently from other controlled substances, such as full opioid agonists, if at all?

Interviewees were recommended by each agency based on their expertise. Interviews were transcribed and reviewed by the investigators for themes, which were included in the CE program to describe regulatory agency roles in buprenorphine access.

The CE program also included evidence-based information on buprenorphine and harm-reduction strategies, including using naloxone to reverse opioid overdoses and its over-the-counter availability, compiled from clinical guidelines[10] and primary literature.[4,14,15,18,21-23,25-38] This program was delivered at an Orange County Pharmacists Association medication for OUD (MOUD) event organized by 5 Southern California schools of pharmacy. Attendees were recruited through association with their schools of pharmacy and the Orange County Pharmacists Association as well as via social media (ie, LinkedIn, Facebook) marketing. One hour of CE credit was awarded for attending this presentation, which was delivered by a PGY2 psychiatric pharmacy resident and overseen by a Board-Certified Psychiatric Pharmacist.

Following the educational session, attendees were instructed to complete an anonymous postsession survey on their knowledge about and comfort level toward buprenorphine. Approximately 1 month following delivery of this educational programming, community pharmacies represented at the educational session were contacted via phone by the principal investigator (PI) posing as a new patient requesting buprenorphine/naloxone 8/2 mg sublingual films. The PI requested to speak with the pharmacist for a stock check. If out of stock of buprenorphine/naloxone films, the pharmacist was asked whether other brand or generic formulations were available, including buprenorphine monoproducts. Pharmacists were also asked if naloxone was immediately available either over the counter or by prescription. Phone calls followed a semistructured script, and responses were anonymously documented.

Analytical Strategy

Our analyses utilized descriptive statistics to determine attitudes toward buprenorphine following a targeted educational session as well as the percentage of pharmacies with buprenorphine and naloxone products currently in stock at community pharmacies represented at the MOUD event. This study was approved by the University of Southern California institutional review board as exempt (#HS-21-00044).

Results

Each regulatory agency has its own scope for community-pharmacy buprenorphine access. Distributors establish pharmacy-specific thresholds to monitor controlled-substance ordering and must report suspicious orders to the DEA. The DEA reviews these reports to determine any necessary follow-up action. Distributors also may cut off pharmacy

TABLE 2: Pharmacy immediate availability of buprenorphine and naloxone products stratified by pharmacy type

Pharmacy Type	Chain, n (%)	Independent, n (%)	Total, n (%)
Buprenorphine			
In Stock	1 (16.67)	3 (30)	4 (25)
Not in Stock	4 (66.67)	6 (60)	10 (62.5)
Unable to Assess	1 (16.67)	1 (10)	2 (12.5)
Naloxone			
In Stock	5 (83.33)	6 (60)	11 (68.75)
Not in Stock	1 (16.67)	2 (20)	3 (18.75)
Unable to Assess	0 (0)	2 (20)	2 (12.5)

controlled-substance ordering if the threshold is reached as a business decision without involvement from the DEA. The BOP does not mandate that pharmacies stock buprenorphine, but supports increased access to MOUD and may become involved if there is a delay in care reported to the BOP. All agencies were unaware of sanctions—DEA investigation, pharmacist or pharmacy license suspension, controlled-substance shipment cutoff—related to buprenorphine ordering or dispensing.

A total of 44 pharmacists that represented 16 unique community pharmacies were included in analyses of knowledge about and behavior toward buprenorphine following the delivery of an educational session.

Knowledge

Forty-two participants (95.5%) reported either agreeing or strongly agreeing that they felt more knowledgeable about MOUD, whereas 2 participants (4.5%) neither agreed nor disagreed with this statement. No participants disagreed or strongly disagreed.

In terms of buprenorphine regulatory knowledge, both knowledge level about buprenorphine thresholds and suspicious order reporting were assessed. Forty-one participants (93.2%) reported either agreeing or strongly agreeing that they felt more knowledgeable about buprenorphine thresholds, 2 participants (4.5%) neither agreed nor disagreed, and 1 participant (2.3%) disagreed with this statement. Thirty-eight participants (86.4%) reported either agreeing or strongly agreeing that they felt more knowledgeable about buprenorphine suspicious order reporting, 5 participants (11.4%) neither agreed nor disagreed, and 1 participant (2.3%) disagreed with this statement.

In terms of harm reduction, 42 participants (95.5%) reported either agreeing or strongly agreeing that they felt more knowledgeable, whereas 1 participant (2.3%) neither agreed nor disagreed; 1 participant (2.3%) did not respond to this question.

Comfort Level

Thirty-three participants (75%) reported either agreeing or strongly agreeing that they felt more comfortable stocking and ordering buprenorphine products. Eleven participants (25%) neither agreed nor disagreed that they felt more comfortable in stocking buprenorphine products. Ten participants (22.7%) neither agreed nor disagreed that they felt more comfortable ordering buprenorphine products. No participants disagreed or strongly disagreed that they felt more comfortable stocking or ordering buprenorphine products. One participant (2.3%) did not respond to the buprenorphine dispensing comfort level question.

Thirty-seven participants (84.1%) reported either agreeing or strongly agreeing that they felt more comfortable dispensing buprenorphine products to an already known patient, whereas 7 participants (15.9%) neither agreed nor disagreed with this statement. No participants disagreed or strongly disagreed that they felt more comfortable dispensing buprenorphine products to an already known patient.

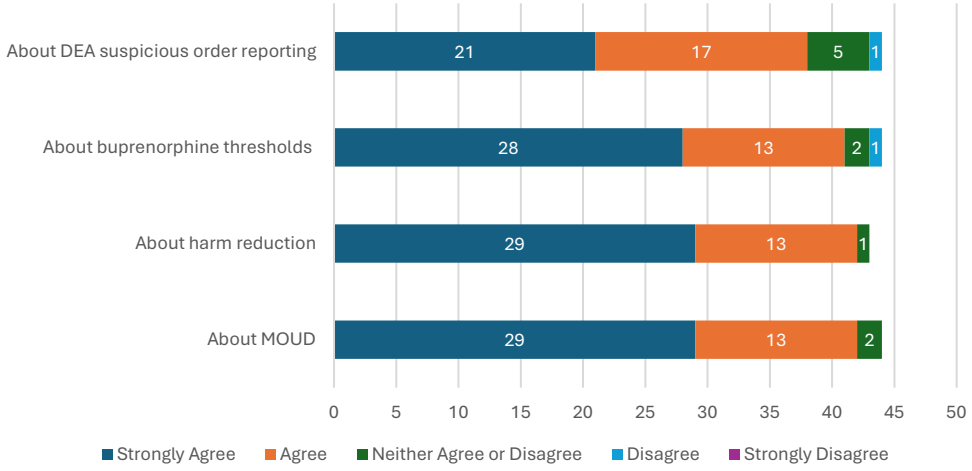

FIGURE 1: Community pharmacy participant improvements in knowledge following buprenorphine educational programming (n = 44)

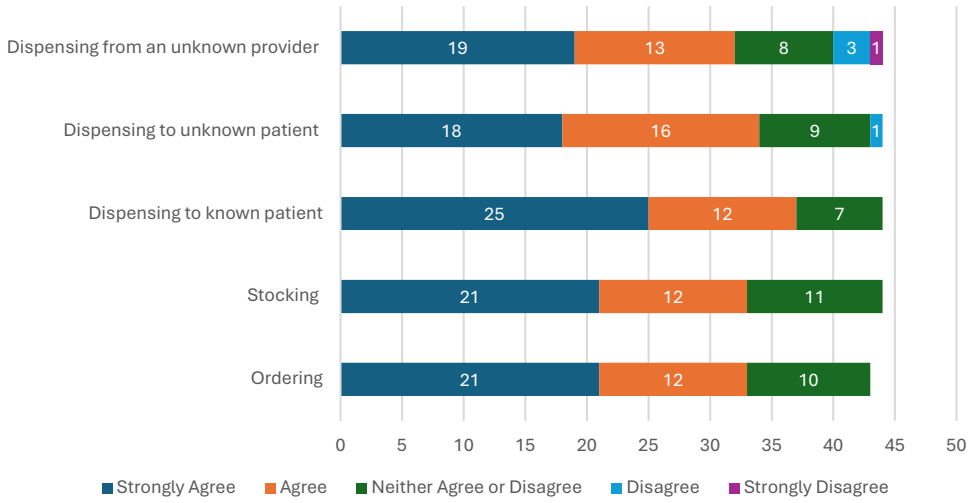

FIGURE 2: Community pharmacy participant improvements in comfort level following buprenorphine educational programming (n = 44)

Thirty-four participants (77.3%) reported either agreeing or strongly agreeing that they felt more comfortable dispensing buprenorphine products to an unknown patient, 9 participants (20.5%) neither agreed nor disagreed, and 1 participant (2.3%) disagreed with this statement. Thirty-two participants (82.7%) reported either agreeing or strongly agreeing that they felt more comfortable dispensing buprenorphine products from an unknown provider, 8 participants (18.2%) neither agreed nor disagreed, and 4 participants (9.1%) disagreed or strongly disagreed with this statement.

Behavior

Of the 16 represented community pharmacies, 6 (37.5%) were chain pharmacies and 10 (62.5%) were independent pharmacies. Across all pharmacies, buprenorphine was immediately available at 4 pharmacies (25%), 1 chain pharmacy and 3 independent pharmacies. Buprenorphine was not available at 10 pharmacies (62.5%), 4 chain pharmacies and 6 independent pharmacies. Availability of buprenorphine was not able to be assessed at 2 pharmacies (12.5%), 1 chain pharmacy and 1 independent pharmacy, due to pharmacy unwillingness to provide stocking information to a patient or immediate hang up by pharmacy staff. Across all pharmacies, naloxone was immediately available at 11 pharmacies (68.75%), 6 independent pharmacies and 5 chain pharmacies. Naloxone was not available at 3 pharmacies (18.75%), 1 chain pharmacy and 2 independent pharmacies. Availability of naloxone was not able to be assessed at 2 pharmacies (12.5%), which were both independent pharmacies.

Discussion

We assessed community pharmacist attitudes and behaviors toward buprenorphine following an evidence-based educational session and found that, though attendees felt knowledgeable about and comfortable with buprenorphine, buprenorphine was not immediately available at the majority of represented community pharmacies when contacted 1 month following the educational session. Knowledge about and comfort level toward buprenorphine and its related regulations were subjectively positive in at least 75% of attendees across all measured domains; in particular, 95.5% of all attendees felt knowledgeable about MOUD. Additionally, more than 75% of attendees felt more comfortable dispensing buprenorphine products to both known and unknown patients, highlighting a possible reduction in stigma for patients with OUD. Consistent with previous literature, additional training and education on pharmacotherapy related to OUD and opioid overdose is associated with positive pharmacist attitudes toward medication dispensing.[8] However, these positive attitudes were not associated with stocking and dispensing behavior, which is consistent with previous survey-based studies[24] as buprenorphine products were not immediately available in a majority of the represented community pharmacies when contacted after the educational session.

Buprenorphine was immediately available in 4 community pharmacies, which represented 25% of our sample. Notably, 3 of these 4 pharmacies (75%) were independent community pharmacies. Previous literature has found that buprenorphine products are more consistently available at chain pharmacies rather than independent community pharmacies,[4,19,25] which was not consistent with our findings. However, it is important to note that the majority of the represented pharmacies (62.5%) in our study were independent community pharmacies, which may have contributed to this finding.

Naloxone was immediately available in nearly 70% of surveyed community pharmacies either by prescription or for purchase over the counter. The availability of naloxone products found in this study is higher than detailed in

previous literature,[4,8] which may be related to the recent FDA approval of over-the-counter naloxone products, which lessens pharmacist responsibility by removing their need to furnish the medication. This behavioral change of increased naloxone availability represents a policy-level adjustment—FDA approval for over-the-counter use—that likely resulted in improved access to life-saving medications at the community pharmacy level.

Such policy-level changes related to buprenorphine may support similarly improved access to buprenorphine at the community pharmacy level. Regulatory concerns, including pharmacist perception of DEA caps, are commonly cited barriers to community pharmacy buprenorphine access.[19,22,23] Whereas pharmacy-specific controlled-substance thresholds are required to be established by pharmaceutical distributors,[39] the DEA and BOP do not have controlled-substance ordering thresholds set by their agencies to trigger investigation. Additionally, neither agency was aware of actions against pharmacies related to buprenorphine alone and reinforced the belief that buprenorphine should remain accessible for public health during our interviews. In fact, each agency highlighted its desire to increase MOUD access and to not punish pharmacies for increased buprenorphine ordering and dispensing. However, reaching these pharmacy-specific thresholds can result in a suspicious order report from the pharmaceutical distributor to the DEA[40] or pharmacy controlled-substance shipment cutoff.[41] Due to buprenorphine's classification as a controlled substance, it is subject to these thresholds and the fear of controlled-substance shipment cutoff, and DEA reports associated with increased ordering are still prevalent regardless of DEA statements in support of MOUD access.[42] The disconnect between regulatory agencies' support of MOUD and pharmacist perception of regulatory agencies as barriers to stocking MOUD highlights additional policy-related needs to support consistent and timely buprenorphine access.

This study is one of the first to (1) interview regulatory agencies directly to determine their role in buprenorphine access and (2) investigate pharmacist attitudes and behaviors toward buprenorphine following an educational session including the role of these regulatory agencies. However, there are limitations. First, our regulatory agency interviews were conducted with representation of 1 individual from each regulatory agency. Though the comments from our DEA participant were endorsed by the national DEA, BOP requirements may differ between states. Attempts to interview representatives from the largest pharmaceutical distribution companies were made without success though our representative of pharmaceutical distributors represents these companies nationally. In terms of our assessment of community pharmacy attitudes and behaviors, whereas attendees were associated with the contacted pharmacy, the attendee may not have been working at the time of the call or the policy of their pharmacy may not reflect the attendees' belief reported on the subjective, anonymous postsession survey. This survey was only administered following the CE program, and there is, therefore, no baseline data to assess any changes in attitudes. Additionally, pharmacies were contacted 1 month following the delivery of the CE programming. This 1-month follow-up may not have allowed sufficient time for an updated buprenorphine policy to be drafted, reviewed, and approved if attendees contacted their pharmacy's leadership team in support of increased buprenorphine access. Also, because buprenorphine is an opioid, some pharmacists were not comfortable discussing stock over the phone with a patient and, therefore, were unable to be assessed. Finally, whereas a majority of pharmacies did not have buprenorphine immediately in stock, secret shopper calls were not made prior to the educational programming session; there is, therefore, no baseline stocking behavior to compare the postprogramming buprenorphine availability. It is possible that the educational session did improve immediate accessibility to buprenorphine products, which was not seen due to our study methods. However, immediate availability of buprenorphine in 4 out of 16 pharmacies is still far below optimal and demonstrates clear care disparities for patients with OUD despite a lack of comparison baseline availability.

Despite these limitations, this study captures endorsed regulatory agency roles in buprenorphine access, subjective attitudes following a buprenorphine educational session, and subsequent stocking practices of represented pharmacies. Future studies should investigate pharmacy-level policies related to buprenorphine stocking and dispensing as well as attitude and behavioral changes after whole staff pharmacy on-site education.

Conclusion

At least 75% of pharmacists reported feeling knowledgeable and comfortable about buprenorphine and its related regulations following an evidence-based CE program, but close to the same proportion (62%) work for a community pharmacy that does not have immediate buprenorphine availability. These findings highlight additional needs outside of pharmacist education to support consistent and timely buprenorphine access. Policy adjustments, such as descheduling buprenorphine or removing buprenorphine from community pharmacy controlled-substance threshold calculations, may improve pharmacist comfort in consistently ordering and stocking the medication as both actions would remove the requirement of pharmaceutical distributors to submit a suspicious order report for excessive ordering of buprenorphine. Additionally, leveraging state BOP support for patients unable to receive their prescription in a timely manner may be advantageous in ensuring consistent buprenorphine access.

Acknowledgments

All authors worked together to design the study, analyze the data, interpret the results, and revise the manuscript. Dr Roth collected the data through secret shopper calls, drafted the manuscript, and prepared figures. Dr Dadiomov assisted with the analysis of results as well as reviewed and edited the manuscript. The human investigation committee (institutional review board) of the University of Southern California approved this study as exempt (#HS-21-00044). This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors. The data sets generated and analyzed during the current study are not publicly available, but are available from the corresponding author upon reasonable request. The CE program and attendee questionnaire are also available from the corresponding author upon reasonable request.

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