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ORIGINAL ARTICLE

The certified child life specialist: A novel resource in the pediatric primary care clinic for managing children's pain during routine immunizations

Seth W. Gregory[1,2] | Andrea J. Aul[2] | Tara M. Lodermeier[3] | Jennifer L. Rodemeyer[3] | Amy L. Weaver[4] | Brian A. Lynch[2]

[1]Department of Pediatric and Adolescent Medicine, Mayo Clinic Health System, Red Wing, Minnesota, USA

[2]Department of Pediatric and Adolescent Medicine, Mayo Clinic, Rochester, Minnesota, USA

[3]Department of Nursing, Child Life Program, Mayo Clinic, Rochester, Minnesota, USA

[4]Department of Quantitative Health Sciences, Mayo Clinic, Rochester, Minnesota, USA

Correspondence
Seth W. Gregory, Mayo Clinic Health System, 701 Hewitt Blvd, Red Wing, MN 55066, USA.
Email: gregory.seth@mayo.edu

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Abstract

This study evaluated the effect of the Certified Child Life Specialist (CCLS) on pediatric pain and pain management during routine immunization administration in the pediatric primary care clinic. Children 4–12 years of age ($n = 125$) presenting for a well child physical examination at a rural primary care clinic were selected to receive standard nursing care or standard nursing care plus CCLS support during routine immunization administration. Patient reported pain was measured using the Faces Pain Scale-Revised (FPS-R), and patient behavioral responses were measured during immunization administration using the Children's Emotional Manifestation Scale (CEMS). The performance of psychosocial interventions and administration of topical pain-relieving interventions were measured between both groups. CCLS support was associated with fewer negative emotional behaviors during immunization administration among 7- to 12-year-old children and a significantly higher provision of psychosocial interventions and topical pain-relieving interventions among all ages. This study demonstrates that the presence of a CCLS can increase the provision of psychosocial and pain-relieving interventions and reduce distress during immunization administration in a busy pediatric primary care clinic.

KEYWORDS
certified child life specialist, immunization, pain assessment, pediatric, psychosocial interventions

1 | INTRODUCTION

Immunizations are among the most common painful procedures performed in the pediatric primary care clinic. Multiple immunizations are commonly administered during a single visit to a child's primary care provider and are a major source of distress for children, caregivers, and the staff administering the immunizations.[1–3] A traumatic or emotionally charged immunization administration early in life may become a child's first memory of visiting the primary care clinic and become the foundation on which a child builds their expectations for future visits, resulting in preprocedural anxiety, needle fears, and healthcare avoidance that can last into adulthood.[4–6]

Certified Child Life Specialists (CCLSs) are trained professionals who help children cope and adjust with the stress and uncertainty of medical procedures, illness, injury, and hospitalization. They use developmentally appropriate strategies including play,

distraction, relaxation techniques, and psychological preparation. The Association of Child Life Professionals (ACLP) establishes and maintains professional standards for the child life field, including certification and ongoing recertification.[7] CCLSs partner with the medical team to meet the emotional, developmental, and cultural needs of children. They are often at the patient bedside with the medical team to provide support to the child during the performance of medical procedures and are a major advocate for pain-relieving interventions. In January 2021, the American Academy of Pediatrics released a joint policy statement endorsing CCLS support as essential to meeting the healthcare needs of children and that CCLSs are needed to educate healthcare team members and support developmentally appropriate patient- and family-centered practices.[8]

To our team's knowledge, this is the first study to investigate the impact of a CCLS consult during the administration of immunizations in the outpatient pediatric primary care setting. This study aimed to compare child-reported pain, observed behavioral responses, provision of psychosocial and pain-relieving interventions, and caregiver visit satisfaction between children receiving either standard nursing care or standard nursing care plus CCLS preparation and support during routine immunization administration. We hypothesized that CCLS support would reduce self-reported pain and reduce observed negative behavioral responses in children receiving immunizations and result in an increased provision of psychosocial interventions and offering of topical anesthetics.

2 | METHODS

2.1 | Design

This was a prospective clinical trial conducted at a single pediatric primary care clinic in Red Wing, Minnesota. The trial was divided into two consecutive phases which occurred over a 3-week period from June 28, 2021, to July 30, 2021.

During phase 1, nursing staff administered immunizations to children per current evidence-based standards of care. Nursing followed standardized procedures for safe immunization administration including: verification of patient identify, immunization status, physician orders, immunization integrity, correct immunization dosage, and correct immunization site administration.[9] Psychosocial interventions and vapocoolant spray were provided on a case-by-case basis to help the child cope with the discomfort of the injection while prioritizing safe immunization administration.

During phase 2, nursing staff administered immunizations to children per current evidence-based standards of care as described in phase 1 but with the support of a CCLS who was dedicated to the child's coping and comfort during the nursing procedure. The CCLS involved in the study is employed at a pediatric primary care clinic in Rochester, Minnesota, where the CCLS is integrated into the medical team.

Patients were not randomized individually or in clusters by day to either intervention in an effort to eliminate unwarranted influence of the CCLS on nursing practice. The study protocol was approved by the Institutional Review Board (IRB) at Mayo Clinic, Rochester, as well as by the Mayo Clinic Health System Office of Research.

2.2 | Participants

Eligible participants included children 4–12 years of age presenting for a well child examination by a pediatric healthcare provider and routine vaccine administration. Children with autism spectrum disorder or other severe developmental disabilities were excluded from the study. Caregivers of any age were eligible for inclusion. Caregivers and the eligible patients were not made aware of the possible presence of a CCLS at the time the well child examination appointment was scheduled. At the start of the visit, caregivers were informed by the research assistant that a study was taking place in the clinic to investigate the role of a CCLS in pediatric primary care. They were told that, if they chose to participate, a CCLS might be present during their child's immunizations and that the research assistant would observe the immunization process and ask questions of the patient and their caregiver. Prior to inclusion in the study, a research assistant obtained oral consent from a caregiver of eligible participants present during the visit. Additionally, oral assent was obtained directly from the child. Signed HIPAA authorization was obtained from the legal guardians of all participants prior to participation in the study.

2.3 | Study instruments

2.3.1 | Faces pain scale-revised (FPS-R)

The FPS-R is a self-report measure of pain for children ages 4–16 years of age and approved for the assessment of pediatric pain at the study site. The scale utilizes different faces to score the sensation of pain on a 0 (no pain)-to-10 (very much pain) metric.[10,11] The scale is quick and simple to use and requires minimal instruction. The scale is available free of charge (www.iasp-pain.org) and is available in more than 35 languages. The FPS-R is commonly utilized in the assessment of acute pediatric pain and demonstrates strong psychometric properties in children ages 4–16 years of age, including between subgroups based on age, sex, ethnicity, and primary language.[12]

2.3.2 | Children's emotional manifestation scale (CEMS)

The CEMS is a simple, objective, and consistent tool used to measure children's emotional responses during stressful medical procedures. The CEMS consists of five categories (facial expression, vocalization, activity, interaction, and level of cooperation) with each category scored from 1 to 5, with summed scores from 5 to 25. Higher scores represent more negative emotional behaviors. Observable

behaviors in each category of the CEMS is explained in detail with an operational definition providing relatively clear-cut criteria for the selection of the number that most closely represents the observed behavior. The scale is validated for children 7–12 years of age with satisfactory inter-rater reliability, high internal consistency reliability, good content validity and excellent convergent validity with the State–Trait Anxiety Inventory for Children.[13,14]

2.3.3 | Caregiver satisfaction survey

This survey was developed specifically for this study and consisted of 6 questions each with a 5-point Likert scale format (very satisfied, satisfied, neutral, dissatisfied, and very dissatisfied) that inquired about the following six areas: overall visit, overall vaccine experience, pain management, respect and compassion, medical staff teamwork, and quality of care.

2.4 | Objectives

The primary objective was to compare the two primary outcomes, FPS-R and CEMS, between all patients enrolled in the two phases. Given that the CEMS has only been validated for children 7–12 years of age, a secondary objective was to perform separate analyses of these two outcomes, stratified by age group (4–6 and 7–12 years). A secondary outcome objective was to compare the number and types of interventions and the caregiver satisfaction between the two groups.

2.5 | Study conduct

For all encounters in both phases, a dedicated research assistant was present who initially asked the patient how much they thought their poke(s) would hurt using the FPS-R prior to immunization administration. During immunization administration, the research assistant observed the behavioral responses of the child and scored their behavior using the CEMS. Immediately following immunization administration, the research assistant asked the patient how much their poke(s) hurt using the FPS-R. The caregiver completed a satisfaction survey at the conclusion of the visit.

Additional information recorded included patient age and sex, number of vaccines administered at the encounter, relationship of caregiver present at visit, presence of any siblings during the immunization administration, specialty of nurse administering immunizations (pediatric or family medicine), whether the caregiver treated the patient with acetaminophen or ibuprofen prior to the visit, and specific interventions (preparation, comfort position, offering and administration of a pain-relieving option, distraction, and relaxation techniques) provided in both phases.

The same CCLS was present for all patient encounters during phase 2. Patients and caregivers were blinded until the time of their immunizations as to whether they would receive standard nursing care or standard nursing care plus CCLS support. At the time of the study, no nurse participating in the study had previous experience working with a CCLS. The research assistant entered the study data real-time into a RedCap® database created for this project.[15]

2.6 | Statistical considerations

Comparisons between the two phases were evaluated using the two-sample t-test for age, the Wilcoxon rank sum test for the number of immunizations and the FPS-R and CEMS measures, and the chi-square test for all other variables. The primary outcomes were compared between the two groups using a non-parametric test given the skewed distributions. Ninety-five percent confidence intervals (95% CI) for the median difference in the primary outcome measures between groups were calculated using the Hodges–Lehmann estimation of location shift, also known as Moses confidence limits. All calculated p-values were two-sided and p-values <0.05 considered significant. Statistical analysis was performed using SAS version 9.4 (SAS Institute, Cary, NC, USA). The sample size was determined based on feasibility/availability of a CCLS and the results from an initial pilot study of deidentified children approved by the IRB. In this pilot study, FPS-R and CEMS data were collected for 22 children ages 4–12 years receiving immunizations with standard nursing care at a pediatric primary care clinic in Red Wing, Minnesota, and for 20 children ages 4–12 years receiving immunizations with standard nursing care plus CCLS support at a pediatric primary care clinic in Rochester, Minnesota, where use of a CCLS was already integrated into the clinical nursing practice. The group with CCLS support had a significant greater mean relative change (post minus pre) in their FPS-R compared to the group with standard nursing support (mean (SD), −4.3 [3.7] vs. −1.3 [4.3], $p = 0.02$). The mean (SD) CEMS was not significantly different between the two forementioned groups (11.7 [7.2] vs 10.1 [3.7], $p = 0.37$). Based on these results, we designed the prospective clinical trial with 30 patients per group in order to have 80% power to detect the effect size observed for FPS-R in the pilot study using a two-sided two-sample t-test. Furthermore, we proposed to enroll 60 patients per group, assuming half would be in each of the 4–6 and 7–12 age groups, in order to have sufficient power to evaluate the primary outcomes stratified by age group.

3 | RESULTS

During the 3-week period, 126 patients consented for this study. Four eligible participants declined participation. Of the 126 patients, 1 patient refused the vaccine leaving 125 patients for the analysis. Among the 125 patients, 62 (49.6%) had a CCLS present. Table 1 summarizes patient and visit characteristics, overall and by presence of CCLS. The mean age of the patient at the time of the visit was 8.1 years, and this was same in both groups. Despite the intervention assignment by study phase, there were

TABLE 1 Patient and visit characteristics.

Characteristic	CCLS present		
	No ($N = 63$)	Yes ($N = 62$)	p value[a]
Age at visit (years), Mean (SD)	8.1 (3.6)	8.1 (3.5)	0.96
Sex at birth			
Male	37 (58.7%)	27 (43.5%)	0.09
Female	26 (41.3%)	35 (56.5%)	
White race	58 (92.1%)	49 (79.0%)	0.038
Hispanic ethnicity	4 (6.3%)	4 (6.5%)	0.98
Insurance type			
Public only	9 (14.3%)	20 (32.3%)	0.09[b]
Commercial only	47 (74.6%)	38 (61.3%)	
Public and Commercial	6 (9.5%)	4 (6.5%)	
Not documented	1 (1.6%)	0 (0.0%)	
Patient knew they were receiving vaccines before the visit	32 (50.8%)	33 (53.2%)	0.79
Number of vaccines			
1	14 (22.2%)	11 (17.7%)	0.68
2	35 (55.6%)	37 (59.7%)	
3+	14 (22.2%)	14 (22.6%)	
Nurse specialty			
Pediatric	56 (88.9%)	59 (95.2%)	0.20
Family Medicine	7 (11.1%)	3 (4.8%)	

[a]Comparisons between the two groups were evaluated using the two-sample t-test for age, the Wilcoxon rank sum test for the number of vaccines, and the chi-square test for all other variables.

[b]Upon collapsing the categories into public only vs (commercial ± public), the results were 14.5% (9/62) vs. 32.3% (20/62), $p = 0.020$.

marked differences between the two groups in terms of race and insurance type. The group of patients with a CCLS present were more likely to be non-white (21.0% vs. 7.9%, $p = 0.038$) and to only have public insurance (32.3% vs. 14.5%, $p = 0.020$) compared to the group without a CCLS present. One patient had a grandparent present; otherwise, all patients had a parent present. Just two patients had a sibling present during immunization administration, and both patients were in the group without a CCLS present. Three patients received pain medication (Ibuprofen) prior to the visit, two in the group with a CCLS present and one in the group without a CCLS present. There were no statistically significant differences between the two groups in terms of whether the patient knew they were receiving vaccines before the visit or the number of vaccines administered.

At least one psychosocial intervention was utilized during all visits, except one patient without a CCLS present did not receive an intervention. When a CCLS was present, every patient received 3 or more psychosocial interventions. Figure 1a depicts the distribution of the total number of psychosocial interventions each patient received, separately for each group. The median number of psychosocial interventions each patient received was significantly higher when a CCLS was present (4 vs. 2, $p < 0.001$).

The types of psychosocial interventions utilized per group are summarized in Figure 1b. The proportion of patients who received each type of intervention was significantly higher in the group with a CCLS present. Verbal preparation was provided to 91.9% of children who were provided CCLS support prior to immunization administration compared to 30.2% of children receiving standard nursing care ($p < 0.001$). Comfort positioning was performed for 96.8% of children receiving CCLS support compared to 81% of children receiving standard nursing care ($p = 0.005$). Distraction techniques were utilized in 96.8% of children receiving CCLS support compared to 31.7% of children receiving standard nursing care ($p < 0.001$). Relaxation techniques were used for 93.5% of children receiving CCLS support during their immunizations compared to 30.2% of children receiving standard nursing care ($p < 0.001$). Lastly, a topical pain-relieving intervention was offered to 30.6% of patients in the CCLS support group whereas 6.3% of children were offered a topical pain-relieving intervention in the standard nursing care group ($p < 0.001$).

The primary outcomes, FPS-R and CEMS, are presented in Table 2. Of the 125 patients, 2 did not answer the FPS-R before or after immunizations and an additional 2 patients did not answer the FPS-R post-immunization. The FPS-R ratings ranged from 0 to 10, with higher scores indicating more pain. The median FPS-R for anticipated pain was 4 (IQR, 2–6) in the group with a CCLS present and 2 (IQR, 2–6) in the group without a CCLS present; however, this difference was not statistically significant ($p = 0.74$). The group medians were also 4 (IQR, 2–8) and 2 (IQR, 2–6) following the immunization (p = 0.46; 95% CI for median difference between groups, −2 to 0). The relative change (actual pain post-immunization minus predicted pain pre-immunization) in FPS-R ratings between the two groups was also not significantly different ($p = 0.34$, 95% CI for median difference between groups, −2 to 0). The distributions of the primary outcomes are shown in Figure 2.

The overall CEMS score ranges from 5 to 25, with higher scores representing more negative emotional behaviors. We did not observe a statistically significant difference in the overall median CEMS scores between the two groups ($p = 0.16$) with a median CEMS score of 9.5 (IQR, 7–17) for the group with a CCLS present and 10.0 (IQR, 7–17) for the group without a CCLS present (95% CI for the median difference between groups, 0 to 2). However, a significantly lower median CEMS score was observed during immunization administration among 7- to 12-year-old children that received CCLS support compared to standard nursing care alone (median (IQR), 7 (6–9.5) among 32 patients vs. 9 (7–11) among 33 patients, $p = 0.028$).

Caregiver satisfaction as measured by a 5-question patient satisfaction survey did not demonstrate a statistical difference between the two groups though higher ratings were observed in the group with CCLS support (Table 3).

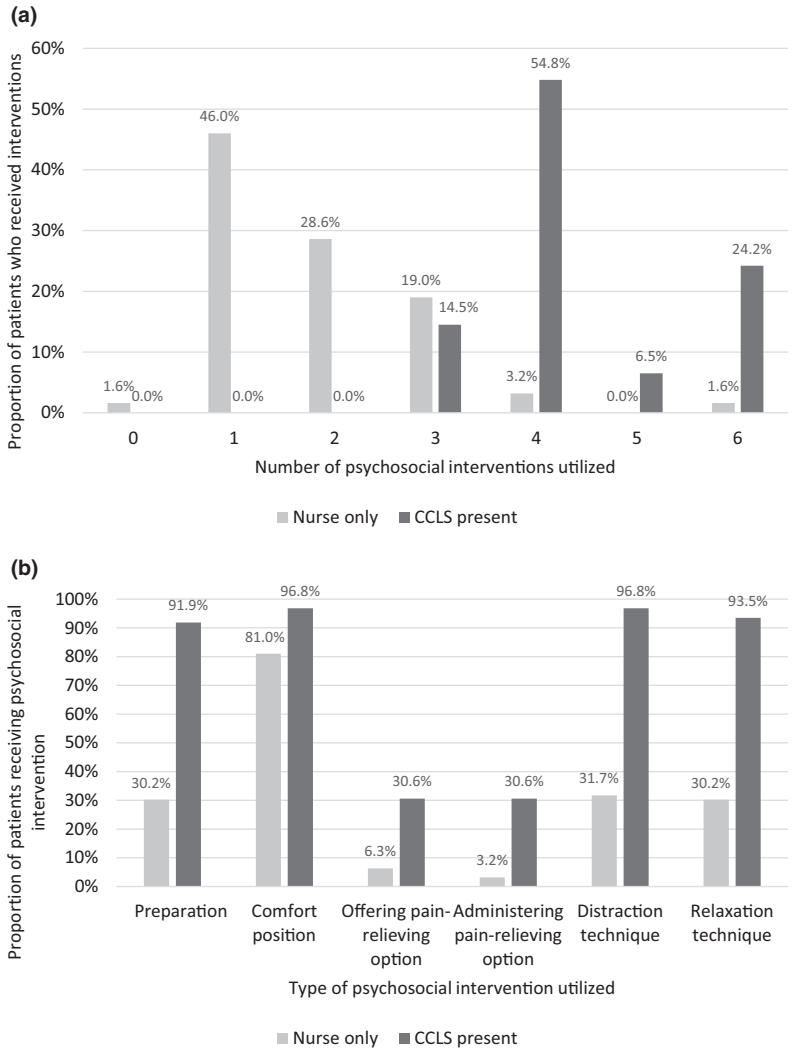

FIGURE 1 Proportion of patients who received psychosocial interventions by (a) number and (b) type.

4 | DISCUSSION

This study aimed to investigate the impact of CCLS support on pediatric pain and pain management during the administration of immunizations to 4- to 12-year-old children in the pediatric primary care setting. Our findings demonstrated that CCLS support resulted in fewer negative emotional responses during immunization administration, quantified using the CEMS, among 7- to 12-year-old children and a significantly higher provision of psychosocial interventions and topical pain-relieving interventions among all ages.

The CCLS in our study utilized psychosocial interventions to minimize the adverse experience of immunization administration. The benefits of psychosocial interventions such as preprocedural preparation, distraction, cognitive-behavioral coping techniques, and parental coaching in the reduction of distress and pain for children undergoing painful procedures are well established.[16–18] The specific interventions evaluated in this study included preparation, comfort positioning, distraction, offering and administration of a pain-relieving option, and relaxation techniques. Due to each individual patient interaction, the CCLS modified their approach based on the specific needs of the patient.

Procedural preparation occurs when children and their families are provided developmentally appropriate information about upcoming procedures. When provided with this information, children and families are better able to cope.[19] Studies have shown significant decreases in perceived, measured, and observed pain and distress in children receiving developmentally appropriate preparation and procedural support.[18,20–23] When looking specifically at immunizations, literature supports educational preparation of the parent and child, but higher quality studies are needed to further explore its impact on pain and distress.[24] In our study, 91.9% of children who were provided standard nursing care plus CCLS support received verbal preparation prior to immunization administration compared to 30.2% of children receiving standard nursing care alone ($p < 0.001$). The CCLS in this study prepared the patient by sharing the senses they would experience, talking through the sequence of events, and offering age-appropriate choices such as where the patient wanted to sit, if they wanted to watch or look away, or if the nurse should count prior to immunization administration.

Comfort positioning is the deliberate use of positive caregiver and child touch to provide safe immobilization during immunizations. Comfort positioning with a child sitting upright has been shown to

TABLE 2 Comparison of primary outcome measures between intervention groups, overall and by age group.

	All ages, 4–12 years			Ages 4–6 years			Ages 7–12 years		
	CCLS present			CCLS present			CCLS present		
Measure	No (*N* = 63)	Yes (*N* = 62)	*p*-value[a]	No (*N* = 30)	Yes (*N* = 30)	*p*-value[a]	No (*N* = 33)	Yes (*N* = 32)	*p*-value[a]
FPS-R, Pre-vaccine	*N* = 61	*N* = 62	0.74	*N* = 28	*N* = 30	0.50	*N* = 33	*N* = 32	0.76
Mean (SD)	3.9 (3.0)	3.8 (3.3)		4.6 (3.8)	3.9 (3.9)		3.3 (1.8)	3.8 (2.8)	
Median (IQR)	2 (2, 6)	4 (2, 6)		3 (2, 8)	3 (0, 8)		2 (2, 4)	4 (2, 5)	
FPS-R, Post-vaccine	*N* = 60	*N* = 61	0.47	*N* = 27	*N* = 30	0.68	*N* = 33	*N* = 31	0.65
Mean (SD)	4.0 (3.4)	4.4 (3.5)		5.1 (4.1)	5.5 (3.8)		3.0 (2.4)	3.3 (2.7)	
Median (IQR)	2 (2, 6)	4 (2, 8)		6 (0, 10)	6 (2, 10)		2 (2, 4)	2 (2, 4)	
FPS-R, Relative change[b]	*N* = 60	*N* = 61	0.34	*N* = 27	*N* = 30	0.37	*N* = 33	*N* = 31	0.81
Mean (SD)	0.1 (3.5)	0.6 (3.3)		0.7 (4.4)	1.6 (3.8)		−0.3 (2.7)	−0.5 (2.5)	
Median (IQR)	0 (−2, 2)	0 (0.2)		0 (−2, 2)	0 (0,4)		0 (−2, 0)	0 (−2, 2)	
CEMS score	*N* = 63	*N* = 62	0.16	*N* = 30	*N* = 30	0.46	*N* = 33	*N* = 32	0.028
Mean (SD)	12.1 (5.6)	11.1 (5.3)		14.9 (5.9)	13.8 (5.0)		9.5 (3.6)	8.6 (4.3)	
Median (IQR)	10.0 (7, 17)	9.5 (7, 17)		15.5 (9, 20)	14.5 (10, 17)		9 (7,11)	7 (6, 9.5)	

Abbreviations: CEMS, Children's Emotional Manifestation Scale; FPS-R, Faces Pain Scale-Revised; IQR, interquartile range (25th and 75th percentiles).

[a]Comparisons between the two groups were evaluated using the Wilcoxon rank sum test.

[b]Relative change calculated as post-vaccine score (0 to 10) minus pre-vaccine score (0 to 10).

reduce reporter-observed distress whereas traditional supine positioning and forcible restraint has been shown to increase fear and distress in children undergoing needle-related procedures.[25,26] In our study, upright comfort positioning was performed for 96.8% of children receiving standard nursing care plus CCLS support whereas comfort positioning was performed in 81% of children receiving standard nursing care ($p = 0.005$).

Distraction is the concerted effort to direct a child's attention away from painful stimuli. A variety of methods can be utilized, including the intentional use of diversional conversation, interactive games or toys, comfort items, and electronic devices. Distraction techniques have been shown to decrease self-reported perceptions of pain and reduce emotional distress during needle-related procedures and childhood immunizations.[18,27] Distraction was utilized in 96.8% of children receiving standard nursing care plus CCLS support in our study compared to 31.7% of children receiving standard nursing care ($p < 0.001$).

Topical anesthetics are numbing mechanisms that block pain signals from the site of injection. Studies have shown preparations such as EMLA (lidocaine/prilocaine) to be more effective than distraction alone in reducing child distress during immunizations.[4,28] EMLA, however, was not chosen as an offered topical anesthetic for our study given the time restraint for application. Instead, a topical vapocoolant spray was offered. Studies have shown that vapocoolant spray immediately before vaccination can reduce the short-term pain associated with injections and can be as effective as EMLA cream although more recent studies have shown conflicting results.[29,30] In our study, 30.6% of children receiving standard nursing care plus CCLS support were offered and received vapocoolant spray prior to immunization administration whereas 6.3% of patients receiving standard nursing care were offered vapocoolant spray ($p < 0.001$) and 3.2% had the spray administered ($p < 0.001$). These findings highlight the role of the CCLS as an advocate for pain-relieving interventions for the child. We did not investigate other in-office anesthetics such as the Buzzy® pain relief device as not all nurses had sufficient training in its use. The Buzzy® device has an ice pack and vibrating motor that provides distraction and topical anesthesia.[31] Future high-quality studies are needed to evaluate these different numbing mechanisms in conjunction with other psychosocial interventions to determine their efficacy in reducing immunization-related pain.

Relaxation techniques include but are not limited to deep breathing exercises, muscle relaxation, and imagery. A systematic review showed that deep breathing exercises, in particular, were effective in reducing children's self-reported pain, observer-rated distress, and nurse-reported distress during immunization administration.[27] In our study, relaxation techniques were used for 93.5% of children receiving standard nursing care plus CCLS support during their immunizations compared to 30.2% of children receiving standard nursing care ($p < 0.001$).

Our study showed an increased provision of psychosocial interventions and topical vapocoolant spray to children receiving standard nursing care plus CCLS support compared to standard nursing care alone. Our findings are in alignment with the AAP's

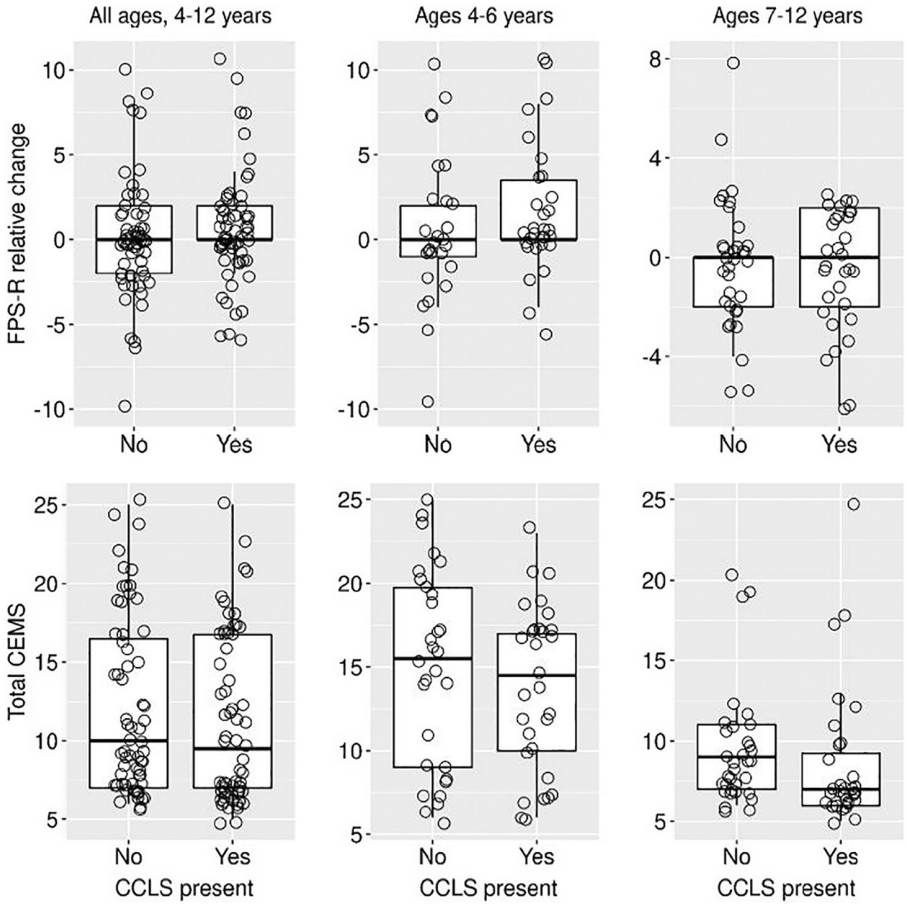

FIGURE 2 Distribution of primary outcomes, all ages combined and by age group.

policy statement highlighting the importance of CCLSs in the advocacy and provision of both evidence-based pain management and developmentally appropriate psychosocial support for the patient and family. CCLSs work with the entire healthcare team to facilitate coping and enhance the overall healthcare experience for the child while the primary focus of nursing is the safe administration of immunizations while trying to implement interventions to provide a more comfortable experience. When physically present, the CCLS provides targeted attention to the child allowing nursing to focus on safely administering immunizations. CCLSs also provide valuable education and training to nursing, physicians, and other healthcare team members in the provision of psychosocial interventions as CCLSs cannot be physically present for every patient encounter.[8] The presence of a CCLS in the primary care clinic is a relatively new phenomenon, and most clinics do not have access to an in-person CCLS. However, staff at smaller clinic sites within larger health systems can access CCLSs through telehealth or educational workshops. Future research is needed to determine the most effective strategy to incorporate the CCLS perspective in the provision of immunizations in the most child-friendly manner.

Surprisingly, the relative change in pre-immunization (predicted pain) and post-immunization (actual pain) FPS-R scores between those receiving standard nursing care compared to those receiving standard nursing care plus CCLS support was not clinically significant. There are several possible reasons for this finding. First, the two groups differed significantly in regard to race and insurance type (private vs public), with the group of patients with CCLS support more likely non-white (21.0% vs. 7.9%, $p = 0.038$) and to only have public insurance (32.3% vs. 14.5%, $p = 0.020$) compared to the group without CCLS support. Multiple studies have shown that pain assessment and its treatment are strongly influenced by race and ethnicity as well by the social and economic conditions in which patients live.[32] One study showed that minority and low-income children were less likely to have oral pain assessed and managed appropriately, especially if they had Medicaid insurance coverage.[33] Future studies are needed to see whether self-reported pain during immunizations differs based on race or socioeconomic standing; the current study was unable to assess this given the small numbers. Another possible reason for not finding a significant difference in the pre- and post-immunization FPS-R scores between the two groups is that a large percentage of both groups were 4 years of age (36.5% (23/63) in nurse only group, 30.6% (19/62) in CCLS support group). Studies have shown that many children 3 to 4 years of age cannot accurately self-report their pain.[33–35] Consequently, the use of self-reported pain as a primary outcome in this age range may not accurately reflect a child's actual pain. Future studies are needed to determine when a child is developmentally able to use a

TABLE 3 Summary of satisfaction items.

Item (5-point scale)	CCLS present			
	No ($N = 63$)	Yes ($N = 62$)	Total ($N = 125$)	p value[a]
Quality of care				
Very satisfied	58 (92.1%)	60 (96.8%)	118 (94.4%)	0.25
Satisfied	5 (7.9%)	2 (3.2%)	7 (5.6%)	
Pain management				
Very satisfied	54 (85.7%)	51 (82.3%)	105 (84.0%)	0.62
Satisfied	7 (11.1%)	10 (16.1%)	17 (13.6%)	
Neutral	2 (3.2%)	1 (1.6%)	3 (2.4%)	
Respect and compassion				
Very satisfied	59 (93.7%)	60 (96.8%)	119 (95.2%)	0.41
Satisfied	4 (6.3%)	2 (3.2%)	6 (4.8%)	
Medical staff teamwork				
Very satisfied	59 (93.7%)	60 (96.8%)	119 (95.2%)	0.41
Satisfied	4 (6.3%)	2 (3.2%)	6 (4.8%)	
Overall vaccine experience				
Very satisfied	59 (93.7%)	58 (93.5%)	117 (93.6%)	0.98
Satisfied	4 (6.3%)	4 (6.5%)	8 (6.4%)	
Overall visit today				
Very satisfied	58 (92.1%)	60 (96.8%)	118 (94.4%)	0.25
Satisfied	5 (7.9%)	2 (3.2%)	7 (5.6%)	

[a]Comparisons between the two groups were evaluated using the chi-square test.

self-reported pain scale versus a validated behavioral observation scale for this age group.

Our study did show reduced distress in children receiving immunizations with CCLS support as measured by the CEMS. Overall, a lower median CEMS score was seen in children receiving CCLS support during immunization administration compared to standard nursing care alone, but statistically significant differences were only demonstrated in the 7- to 12-year-old age group ($p = 0.028$). The lack of significance observed in children younger than 7 years of age may be attributed to our limited sample size. Additionally, the CEMS is only validated for 7- to 12-year-old children.[14] Further studies are needed to determine whether this tool can be validated in children younger than age 7.

4.1 | Strengths and limitations

A strength of our study is that we had consistency among primary care providers, nursing, and research staff during both phases of the study. Additionally, nursing staff had no previous experience working with a CCLS during phase 1 which enabled our team to evaluate psychosocial interventions utilized by nursing staff without unintentional influence of the CCLS on nursing practice.

A limitation of our study was a lack of randomization. As mentioned, the study was split into two phases to eliminate unintentional influence by the CCLS on nursing practice, but this led to an abrupt change in work flow for nursing during phase 2 with the introduction of the CCLS. This abrupt change may have indirectly influenced how nursing administered vaccines compared to the control group.

Another limitation is that asking subjects to rate how much they predicted their pokes to hurt prior to immunization administration may have caused anticipatory anxiety. This may have caused subjects to anticipate having more pain when asked to rate how much they thought their poke would hurt using the FPS-R and led to confirmation bias when reporting their pain after immunization administration. Additionally, the FPS-R is not validated for anticipatory pain although it has been used to assess hypothetical pain.[35] The FPS-R has been utilized prior to medical procedures in other studies to determine baseline pain before measuring post-procedural pain. Further studies are needed to better understand the role of the FPS-R in assessing preprocedural anticipatory pain in children.

Our statistical analysis did not evaluate individual psychosocial interventions in relation to self-reported pain and observer-rated distress. The potential confounding factor of topical vapocoolant spray being offered and administered with a much higher frequency in the group of children receiving CCLS support was not specifically accounted for. We chose to analyze the interventions together as the role of the CCLS is to advocate and utilize multiple psychosocial and pain-relieving interventions in combination and not individually. Future studies with larger sample sizes are needed to properly evaluate the effects of different topical anesthetics used in conjunction

with common psychosocial interventions in the reduction of immunization-related pain in children.

Another limitation is that we did not measure the order in which vaccines were administered. Studies have shown that administering the most painful injection last results in reduced reported pain.[36]

As mentioned previously, the control and intervention groups differed significantly by race and insurance type. Future studies with a larger sample size need to be conducted to evaluate the effect of these factors.

Lastly, we had the same CCLS present for all patient encounters during phase 2 whereas the nurse and nursing speciality (pediatrics or family medicine) was not consistent for each patient encounter in both phases. Due to staffing and financial restrictions, we could only have one CCLS available for our study. Future studies evaluating the impact of the CCLS on pediatric pain with immunizations should account for the variability of the individual CCLS, years of CCLS experience, nurse speciality, and years of nursing experience with administering childhood vaccines.

5 | CONCLUSION

The presence of a CCLS during immunization administration in the primary care clinic setting resulted in significantly more psychosocial interventions and topical vapocoolant spray being offered to children receiving routine immunizations. Additionally, CCLS support reduced observer-rated distress for children receiving immunizations. Further studies are needed to demonstrate the effect of CCLS support on self-reported pain among children in the 4- to 12-year-old age range. Based on our findings, we advocate for CCLS support and education of staff to promote psychosocial interventions and pain-relieving measures in all practices that provide immunizations to children.

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ORCID

Seth W. Gregory https://orcid.org/0000-0003-2496-3293

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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