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Original Articles

The Impact of Child Life Intervention on a Clinical Vaccine Trial

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Objective:
Needle-related procedures, such as vaccines, can be especially stressful for children. One children's hospital secured funding to staff a child life specialist to provide support to patients enrolled in a vaccine trial.
Method:
Data was collected to explore how participants coped through multiple nasal swabs, blood draws, and injections and the impact of providing child life support during a clinical research trial.
Results:
Children supported by a child life specialist for their vaccine exhibited low distress and utilized coping strategies frequently. Participant retention was higher than expected during the clinical trial.
Conclusion:
The study findings suggest including child life specialists as part of clinical trial teams in future studies.
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Pediatric clinical research is essential to improving clinical treatments. However, conducting pediatric research presents challenges. Children are considered a vulnerable population that deserve special protections. The ethical responsibility to protect children against the risks and discomfort of research procedures and treatment can make research design and approval challenging. It is the responsibility of institutional review boards to assess the risks and discomfort of research studies. However, the institutional review board's evaluation of whether the risks are acceptable may not give a representative view of children's experiences as few studies have explored children's perceptions on research participation.

Of the few studies that have explored pediatric patients' experiences being involved in research, one study found that children are more likely to participate in studies that do not involve painful procedures (Hunfeld & Passchier, 2012). In another study, the majority (86%) of children who participated in the clinical trial indicated they had limited understanding of the research study they were participating in despite physicians' explanations (Hein et al., 2015). Another study reported that many of the children felt minimally involved in the decision to enroll in clinical trials, with 38% of patients stating they did not feel they were free to decline participation in the study (Unguru et al., 2010). While ultimately pediatric participation in research is based on the parent or guardian's consent, ethically it is critical that children understand what they are agreeing to when they assent or consent to research and to determine their preferences for inclusion in research. When working with pediatric research participants, lack of understanding and psychosocial support during stressful or invasive study procedures or tests could lead to low assent and consent rates, poor participant retention, or high dropout rates (Bender et al., 2003).

To increase understanding and reduce fear, anxiety, and pain during stressful health care experiences, Certified Child Life Specialists (CCLS) are trained to provide developmentally appropriate interventions such as therapeutic play, procedural preparation, procedural coping support, and education. Patients prepared for what to expect during stressful healthcare encounters exhibit less distress and are more cooperative during procedures (Claar et al., 2002; Thompson, 1994; Tiedeman & Clatworthy, 1990). Child Life departments across the country have initiated many of their own research projects aimed at evaluating and de-

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scribing the benefits of child life services (Boik & Hall, 2020; Sanchez Cristal et al., 2018). CCLS preparation and support has been shown to significantly decrease the pain and distress levels of children and increase visit satisfaction while undergoing stressful and invasive procedures and tests (Brewer et al., 2006; Gursky et al., 2010; Sanchez Cristal et al., 2018; Schlechter et al., 2017). Specifically, previous studies support providing child life services to reduce children's distress during needle-related procedures (Diener et al., 2019; Sanchez Cristal et al., 2018).

When appropriate control of pain and distress is not provided during stressful and invasive medical procedures, children are more likely to experience posttraumatic stress symptoms, negative reactions, and noncompliance during subsequent medical encounters (Blount et al., 2009; Kain et al., 1996; McMurtry et al., 2015; Wintgens et al., 1997). A growing body of evidence supports that even minor, painful procedures, such as needle sticks, can affect a child's future response to stress, pain, and healthcare experiences (Young, 2005). Fear of needles is common and is associated with healthcare avoidance (McMurtry et al., 2015; Wright et al., 2009). Fear-induced avoidance of immunizations can compromise the success of immunization programs leading to sub-optimal coverage rates (Guerra, 2007).

While the potential benefits of providing child life intervention in a clinical trial setting is apparent, the use of CCLS as members of a clinical trial team and the impact they can have on participants' retention within the trial and patients' coping with the experiences of a trial has not been investigated. The research team from a national vaccine trial initially consulted the Child Life Department to provide recommendations for providing support for the nasal swabs, blood draws, and injections the trial would require. Through that discussion, the vaccine trial's research team identified the need for a full-time CCLS to provide support to trial participants. Funding to support a CCLS salary during the study enrollment was secured through the drug company who was funding the study. A primary CCLS was assigned to cover the clinical trial. When the primary CCLS was not available, backup CCLS covered the trial. The CCLS provided education, preparation, and procedural support to 5- to 11-year-old clinical trial participants. This descriptive, retrospective study aims to examine the impact that child life intervention provided to pediatric patients participating in the clinical vaccine trial had on participant retention, patient distress, and patient coping during trial visits.

Method

Participants

Over the course of 500 clinical visits, the CCLS was involved in educating, preparing, and supporting 5- to 11-year-old clinical vaccine trial participants undergoing several procedures including nasal swabs, blood draws, and injections. Children 5 to 11 years old participating in the vaccine trial who were seen and documented on in the electronic medical record by the primary CCLS during their initial two visits between June 7, 2021, to August 8, 2021, were included in the study. If a participant was not supported by the primary CCLS then they were not included in the study. A total of 224 patients were seen either for one or both trial visits by the CCLS.

Procedure

In preparing to see patients as part of the trial visits, the CCLS involved in this study conducted individualized chart reviews and assessed the need for child life support prior to the patient's arrival. Patients and families were also referred by the study team and research nurses for child life support. Reasons for referrals included patients who had an underlying diagnosis that might have affected their coping and patients who appeared or voiced being nervous or anxious about the study during the consent process. Other reasons for CCLS referral included patients who would benefit from developmentally appropriate preparation and education prior to signing their own assents, and patients who had started a procedure with the nurses and were unable to complete the procedures due to high levels of distress or uncooperativeness.

When either self-referred or referred by a member of the research team, a CCLS met with patients at the beginning of their visit to introduce services and offer support. Patient support was based on the patients' support needs and concerns and included developmentally appropriate explanations of the steps of the trial procedures, preparation for the three procedures (i.e., nasal swab, blood draw, and vaccination), development of a coping plan, and procedural support and coaching. Coping plans included deep breathing, distraction, positive self-talk, topical numbing (LMX 4 Cream), vibration at the injection site, counting, squeezing a stress ball, comfort holds, and other methods. The CCLS documented each patient encounter in a Smart Text that was developed for the study. Smart Texts are preset templates with dropdown lists to select from and areas to free text. The CCLS selected from drop down lists and added additional free text to the Smart Text to document on the patient. Documentation included time spent with patient, interventions provided, the patient's response/reactions, how the patient coped during their procedures, and the patient's distress level during their time with the CCLS. A research coordinator reviewed each participant's chart and recorded the demographic information. The average time the CCLS spent per patient, use of topical numbing cream (LMX 4), and the participant dropout rate for the clinical trial were also recorded and analyzed. All study data was collected and managed in REDcap (Research Electronic Data Capture; Harris et al., 2009, 2019). Approval for the study was obtained through the Institutional Review Board.

Data Analysis

A report was generated to identify the chart notes that met inclusion criteria for review. All progress notes documented in the electronic medical record by the primary CCLS for the clinical trial participants were reviewed as part of the study. Chart notes were independently reviewed by two research investigators. Investigators scored each note using a Coping Rubric (Figure 1) and Distress Rubric (Figure

Figure 1. Coping Rubric

Level	Operational Definition
1	Utilizes one or more coping strategies throughout the majority of the procedure.
2	Uses some coping strategies during procedure, but not consistently throughout the procedure. May need to be re-prompted or provided a break to reengage in coping.
3	Unable to utilize coping strategies during procedure. Ignores all prompts to encourage use of coping strategy.

Figure 2. Distress Rubric

Level	Operational Definition
1	Little to no distress exhibited during procedure, may grimace with pain, but does not protest, cry, or yell out. Calm and cooperative throughout the procedure.
2	Some distress exhibited. Patient may become tearful or express fear but remains cooperative for procedure.
3	Very distressed during the procedure as exhibited by crying, refusing to participate, resistant movement, verbally protesting, or yelling.

2). The Coping and Distress Rubric was developed by the research investigators to evaluate and quantify participant coping and distress during trial procedures based off of the documentation of the CCLS. Higher scores indicated less coping and more distress. Face validity for the Coping and Distress Rubric was established by having three experienced CCLS independently review the rubrics and provide feedback. Each CCLS agreed the components of the rubric were relevant to evaluating coping and distress based on a CCLS's chart note. Interrater reliability for the Coping Rubric was 93%. The interrater reliability for the Distress Rubric was 95%.

Research investigators were trained on how to use the scoring rubrics through review of the tool and practice sessions. Once scored independently, the research investigators compared their scores for each note. If the research investigators disagreed on the scores for any note, a third research investigator reviewed and scored the note. Investigators discussed the score until consensus was reached. Demographics and key variables were summarized with counts and proportions (if categorical) and median and interquartile range (if continuous). Chi-Square test or Fisher's Exact test were used to compare the observed proportions between groups. A one-way ANOVA and Tukey post hoc test were used to evaluate the relationship between race/ethnicity and distress and coping scores. Pearson correlations were used to compare relationships between variables.

Results

Participant Characteristics

Of the 224 children in the study, 58% were male. The average age of patients participating in the trial was 7.8 years (SD 1.92) as shown in Table 1. Of the entire sample, 52% were White, and 54% were non-Hispanic. Most of the patients did not have a topical numbing cream (LMX-4) applied prior to their blood draw (65%).

The average time spent by the CCLS with a patient during trial visits was 47 minutes. For the first visit, 122 patients received child life intervention for an average of 52 minutes (SD = 18.6). Broken down by procedures, 17 minutes (SD = 6) on average was spent providing child life support to participants for each procedure. At the second visit, 102 patients received child life intervention for an average of 43 minutes (SD = 15), with 22 minutes (SD = 7.2) spent per procedure. The difference between CCLS time spent per procedure between Visit 1 and Visit 2 was statistically significant, with more time spent per procedure for the second visit, t (221) = 4. 02, $p < .0001$.

Coping ratings correlated highly with distress ratings, r (222) = .82, $p < .00001$. Overall, coping during both visits was high, with 74% of patients receiving a rating of 1 for coping well during the procedures. Procedural distress was slightly higher with 63% of patients receiving a rating of 1 for demonstrating little to no distress during the study procedures. During procedures, the average coping score was rated 1.3 (SD = .65), and the average distress score was 1.5 (SD = .70). Coping and distress ratings were not significantly different between visit 1 and visit 2. Female patients had higher coping (M = 1.47, SD = .72) and distress (M = 1.61, SD = .74) ratings compared to male patient's coping (M = 1.28, SD = .60) and distress (M = 1.43, SD = .71) ratings, t (220) = 2.15, $p = .03$. Patient age had a significant negative correlation with coping ratings, r (221) = -.28, $p < .0001$. Patient age also had a significant negative correlation with distress ratings, r (221) = -.25, $p < .0001$. Coping and distress ratings did not vary significantly due to topical numbing use. The race and ethnicity of the patient had a significant effect on coping and distress ratings (Table 2). Coping ratings varied significantly by race (F (3,195) = 5.19, p =.002). Distress ratings also varied significantly by race (F (3,195) = 4.93, p =.003). Post hoc analysis using the Tukey HSD test revealed that coping scores for patients who identified as Native Hawaiian/Pacific Islander (M = 2.45, SD = 0.50) were significantly different than patients who identified as Caucasian (M = 1.34 SD = 0.62) or African American/Black/Caribbean ((M = 1.67, SD = 0.38) (p < .01). For distress scores there was a significant difference between patients who identified as Caucasian (M = 1.51, SD = 0.69) and pa-

Table 1. Demographics

Variable	Mean	SD	Range
Age	7.8	1.92	5-11
Variables		**N**	**Percentage**
Gender			
Male		130	58%
Female		93	42%
Race			
Caucasian		137	52
More than one race		41	16
Unreported		33	12
African American/Black/Caribbean		18	7
Asian		17	6
Other		14	5
Native Hawaiian/Other Pacific Islander		4	2
Ethnicity			
Non-Hispanic		121	54
Hispanic		68	31
Unreported		34	15
Topical Numbing (LMX)			
Yes		145	65
No		78	35

Table 2. Average Coping and Distress Scores by Race and Ethnicity

Race/Ethnicity	Average Coping Score (STD)	Average Distress Score (STD)
Caucasian/White	1.34 (0.62)	1.51 (0.69)
Hispanic	1.43 (0.60)	1.57 (0.66)
African American/Black/Caribbean	1.67 (0.38)	1.56 (0.51)
Asian	1.29 (.059)	1.53 (0.71)
More than one race	1.59 (0.77)	1.76 (0.77)
Native Hawaiian/Pacific Islander	2.25 (0.50)	2.5 (0.58)
Other	1.14 (0.36)	1.36 (0.50)

Table 3. Participant Dropout

	Withdrew Before Consent/ Assent	Withdrew After Consent/ Assent	Enrolled Randomization #	Completed
Total	2	3	256	253

tients who identified as Native Hawaiian/Pacific Islander (M = 2.50, SD = 0.58) or more than one race (M =1.76, S =0.77) ($p < .01$).

The dropout rate for the study was 3.5%. Two participants withdrew before consent/assent, and three withdrew after consent/assent (Table 3).

Discussion

Despite CCLS's long history of being part of multi-disciplinary teams and covering various areas in healthcare, there is little research detailing CCLS involvement as an integral part of a clinical trial team. It is a research investigator's ethical duty to mitigate the risk for emotional, psychological, and physical harm to participants. A CCLS can play a vital role in reducing the risk of harm by providing common child life interventions such as developmentally appropriate education, preparation, procedural support, and nonpharmacological pain management to participants.

When reviewing the data related to a patient's level of coping during the trial procedures, it was noted that overall, patients coped well with CCLS support and were able to use at least one coping strategy throughout the procedures. Patient distress was also recorded to be low with CCLS support. There was no significant difference between coping and distress ratings from visit 1 and visit 2, indicating that child life support may have helped mitigate the negative impact that repeated invasive procedures can have on patients' coping (Al-Jundi & Mahmood, 2010; Kain et

al., 1996; Rennick et al., 2004; Saylor et al., 1987). While coping and distress ratings were not significantly different from visits 1 and 2, this could be due to the fact that the CCLS spent more time on average with each patient during the second visit.

Our finding that younger age correlated negatively with distress and coping ratings is supported in the literature, which indicates that younger age is often associated with higher distress and non-compliance during medical procedures (Cahoon & Davison, 2014; Davidson et al., 2006; Kain et al., 2006; Klosky et al., 2007). Females in this study exhibited poorer coping and higher distress compared to males in the study. While some studies support this finding that females exhibit more distress during stressful healthcare experiences (Rennick et al., 2002; Small & Melnyk, 2006), other studies have demonstrated no differences between genders (Bossert, 1994; Hart & Bossert, 1994).

Race was a significant factor associated with distress and coping scores. While the study population was predominately White (52%), significant differences in coping and distress scores were observed. Patients who identified as Native Hawaiian/Pacific Islander had higher coping scores than patients who identified as Caucasian or African American/Black/Caribbean, indicating they used less coping strategies during the trial procedures. Native Hawaiian/Pacific Islanders also had higher distress scores than Caucasian patients. Patients who identified as more than one race also had higher distress scores than Caucasian patients. These results should be considered with caution, as the number of patients who identified as non-White was relatively small. Further research is warranted to more thoroughly explore the impact race and ethnicity may have on coping and distress during invasive medical procedures.

Coping and distress rating were highly correlated in the study, demonstrating the importance of having a coping plan and providing coping education and procedural coaching to help moderate procedural distress for patients. Previous research has highlighted the important role coping can play in the healthcare setting (Knight et al., 1979; LaMontagne et al., 1996, 1997; Staab et al., 2014). Specifically, vigilant coping in which a child actively seeks out information appears to be more effective in ameliorating the negative effects of a stressful healthcare experience than avoidant coping (Knight et al., 1979; LaMontagne et al., 1997). This further establishes the value of having a CCLS available to help prepare, educate, develop coping plans with patients, and provide procedural coaching during invasive research procedures.

The dropout rate for the study was 3.5% which is significantly less than the 10% anticipated dropout rate that was used to estimate the number of participants who would be needed for the clinical trial. Dropout rates in clinical trials are common and can impact the validity of the results. One review of attrition rates in pediatric randomized clinical trials found that 20% withdrew prior to the first follow-up session (Karlson & Rapoff, 2009). Another study found that children with increased distress and decreased psychological resources while participating in the clinical trial were at higher risk of missing visits or dropping out of the study (Bender et al., 2003). Previous studies have shown that greater knowledge about medical procedures is related to less child distress (Claar et al., 2002; Rodriguez et al., 2012). While numerous factors could be associated with the low dropout rate for the clinical trial, CCLS involvement in supporting the clinical trial participants may have impacted the trial's retention of participants by ensuring patients understood what to expect before assenting to participation and by supporting pediatric patients through the stressful aspects of study involvement.

Limitations

Prior to the first visits, when the CCLS was reviewing patients' charts, it was noted that many of the trial participants were either new to the hospital system or had limited notes that related to a patient's previous coping and distress with medical encounters. While a CCLS is trained to assess a patient's needs and prioritize, some patients may have been missed who would have benefitted from support during the study enrollment. To better prioritize patient needs, an assessment-based tool that helped identify the need for child life services could have been completed prior to the first visit with a patient and their family to identify the specific needs of individual patients and help plan proactively for child life support. After the initial visit for the clinical trial, nursing and child life staff were able to more easily identify patients who would benefit from child life support by conducting chart reviews of how the patient coped during their first visit. With the ability to plan more in advance, coverage for patients needing child life support was secured more effectively for patients during their second visit.

The coping and distress rubrics used to score patient's coping and distress level from the CCLS documentation was created by the research investigators. The rubrics have not been validated by previous studies and only face validity and interrater reliability were investigated as part of this study. This is a limitation of this study. However, a rubric for evaluating pediatric coping and distress during medical procedures from the documentation of a CCLS has not been developed previously. The rubrics both demonstrated high interrater reliability. While further exploration of the reliability and validity of the rubrics is warranted, these rubrics offer a promising standardized process for evaluating pediatric coping and distress from CCLS documentation.

Another limitation of the study included the timing of LMX-4 topical numbing cream. While it likely provided pain relief to patients, the length of time the cream was applied for prior to the blood draw was not tracked and was often only placed for a short amount of time versus the recommended time of 30 minutes for venipuncture procedures (Chumpitazi et al., 2022). If the LMX cream had been utilized according to the manufacturer recommendations, there could have been an increased number of patients who had lower distress and coped better due to decreased pain. Another limitation of the study was the lack of a comparison group. While some participants did not receive child life support during their clinical trial, the research investigators were unable to compare these participants to pa-

tients seen by the CCLS as coping and distress was only documented for patients who were seen by the CCLS. Future studies aimed at comparing participant outcomes for patients who receive child life support and those who are not supported by a CCLS would be highly valuable. According to one recent meta-analysis, the majority of children under the age of 10 report a fear of needles, so it is compelling that with child life support, participants exhibited low distress and coped well with the clinical trial procedures (McLenon & Rogers, 2019). Future studies should explore how child life support aimed at lessening distress and increasing coping impacts needle fear.

Without child and family participation in research, advancements in care are not possible. The medical and psychosocial communities rely on patient and family research participation to inform changes in practice. However, research participation can be stressful and confusing for children and families. To protect patients from additional stress, research investigators should introduce research opportunities in ways that make sure that patients consenting or assenting to research participation have a developmentally appropriate understanding of what their involvement entails and feel supported through the more stressful aspects of trial participation. Involving children and adolescents in research in this manner can transform the research participation experience from one that is stressful and uncertain into one that is positive and mutually beneficial to both participants and researchers. In turn, this could have a positive impact on trial participation and retention. Future studies should investigate how having a CCLS as a member of the clinical trial team influences understanding of clinical trial procedures, distress levels, and trial attrition for pediatric patients.

Conclusion

In this study, we saw high participation and low dropout rates, despite the invasive procedures involved in the trial. Needle fear and anxiety may be underestimated by healthcare professionals (Lidén et al., 2012). Since fear of needles occurs frequently and can impact vaccine acceptance (McLenon & Rogers, 2019), it is critical to ensure that patients' needle fear and anxiety is addressed and supported throughout their lifespan and especially in early childhood. The experience of having a CCLS available to provide support during this clinical trial demonstrated the potential impact that child life intervention can have on patients' coping and level of distress with difficult and painful procedures, patient compliance with study procedures, and the trial's retention of participants.

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