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The Efficacy of an Educational Toolkit to Enhance Knowledge of Pediatric Reflux Management among Occupational Therapists

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THE EFFICACY OF AN EDUCATIONAL TOOLKIT TO ENHANCE KNOWLEDGE OF PEDIATRIC REFLUX MANAGEMENT AMONG OCCUPATIONAL THERAPISTS

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Abstract

This manuscript describes a quality improvement project completed by a student in the University of Nevada Las Vegas Occupational Therapy Doctorate Program. The project tests the efficacy of an educational toolkit for occupational therapists staffed at an acute care hospital in Las Vegas, Nevada, to increase their perceived knowledge of and ability to educate families on conservative management techniques for pediatric reflux management. Results indicate that the toolkit demonstrated efficacy in achieving this objective. The toolkit provided useful staff education and parent handouts for the occupational therapists to utilize in patient care as appropriate. This project's ultimate aim was to promote the utilization of highly effective, evidence-based occupational therapy interventions for hospitalized infant and child patients experiencing gastroesophageal reflux. This manuscript describes the project's background, methods, and results- which may help to inform future capstone projects, research endeavors, and occupational therapy practice. Particularly those completed in the fields of infant and pediatric feeding therapy.

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Efficacy of an Educational Toolkit on Knowledge to Enhance Knowledge on Pediatric Reflux Management Among Occupational Therapists

The American Occupational Therapy Association and (AOTA) the American Occupational Therapy Foundation (AOTF) created an "Occupational Therapy Research Agenda" in which they set forth a paramount priority for the profession to ascertain the efficacy and effectiveness of occupational therapy interventions (The American Occupational Therapy Association [AOTA] & American Occupational Therapy Foundation [AOTF], 2011). This capstone project aimed to contribute to this vision through the creation of an evidence-based toolkit intended to help occupational therapists (OTs) at an acute care hospital in Southern Nevada provide evidence-based, effective interventions to patients ages 0-5 experiencing gastroesophageal reflux. The toolkit contained synthesized research findings on current OT interventions, access to evidence-based assessment tools, and evidence-based parent and patient handouts for the OTs to use within their practice. The rationale for, goal of, and outcomes of this toolkit are explained extensively throughout this manuscript.

PIO Question

This capstone project aimed to answer the following PIO question: "Among occupational therapists at Summerlin Hospital Medical Center (SHMC) in Las Vegas, Nevada, does the creation of an educational toolkit on pediatric reflux improve the perceived ability to implement and educate families on current guidelines for conservative management and treatment of gastroesophageal reflux (GER)?".

Operational Definitions

Gastroesophageal reflux is defined in the following ways:

- Conceptual definition: **“**The passage of gastric contents into the esophagus with or without regurgitation” (Rosen et al., 2018, p. 546).
- Operational definition: Confirmed or suspected reflux in infants and children at SHMC. Reported symptoms that align with clinically suspected reflux in the esophagus, such as irritability and crying related to infant feeding times or descriptions of heartburn and acid reflux in children.

Occupational therapists are defined in the following ways:

- Conceptual definition: An occupational therapist is defined in the state of Nevada as: “a person who is licensed [in accordance with Nevada state law] to practice occupational therapy” **(**Nev. Rev. Stat. 640A.040, 1991).
- Operational definition: Licensed and registered occupational therapists employed at Summerlin Hospital Medical Center in Las Vegas, Nevada, who work with patients in the pediatric intensive care unit (PICU), neonatal intensive care unit (NICU), and pediatric floors of the hospital

Conservative management is defined in the following ways:

- Conceptual definition: **“**Lifestyle changes and actions completed by an individual to improve and manage symptoms” (Stanford Healthcare Neuroscience, 2022, para. 1).
- Operational definition: Lifestyle changes, activity modifications, and simple techniques that do not involve surgery or pharmaceuticals that can be performed

by a majority of occupational therapists and caregivers upon simple education or training.

Statement of the Problem

Health professionals and parents are often unsure of the best practices for the management of pediatric gastroesophageal reflux (GER). The diagnostic criteria for reflux within infant and child populations is a topic of great uncertainty for healthcare professionals, including physicians and other leading experts in gastroenterology (Rosen et al., 2018). By definition, gastroesophageal reflux disease (GERD) is diagnosed based on subjective reports of symptoms. This has led to a lack of uniformity within its diagnosis. Further complicating measures is that infants are entirely unable to communicate their symptoms, and young children are often unable to communicate their symptoms effectively. Lastly, experts have not identified a singular diagnostic tool as the "gold standard" for objectively recording the occurrence of GER events (Rosen et al., 2018).

The lack of consensus for observing GER and defining GERD has led to a predictable lack of consensus in guidelines to manage the conditions. In 2009, the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition (NASPGHAN) and the European Society for Pediatric Gastroenterology, Hepatology, and Nutrition (ESPGHAN) developed clinical guidelines for the diagnosis and management of GER in infants and children (Vandenplas et al., 2009). However, these debatably lead to more questions than answers, highlighting the need for updated, more straightforward guidelines (Rosen et al., 2018). This led to a 2018 update of the guidelines which still does not have all of the answers but contains more straightforward recommendations for healthcare providers working with infants and children experiencing GER.

The guidelines recommend trialing and exhausting conservative measures for GER management before surgical and pharmaceutical methods (Rosen et al., 2018). However,

research trials on these conservative management techniques are scattered and non-uniform. The heterogeneous nature of the diagnostic criteria, outcome measures, and journals in which this literature is published makes pediatric reflux management a complicated research endeavor that most working health professionals simply lack the time to undertake. Occupational therapists consistently report a "lack of time" as the primary barrier to not using current research in their interventions despite a genuine interest and ethical desire to do so (Morrison & Robertson, 2011).

Significance of the Problem to Occupational Therapy

Complicated reflux can lead to reduced physical, mental, and occupational outcomes for both the pediatric populations experiencing it and their caregivers. This manuscript's literature review includes a robust discussion on mismanaged reflux complications. The co-occupation of feeding a young child consists of the activities of daily living (ADLs) of feeding, eating, and swallowing and the instrumental activities of daily living (IADLs) of child rearing and health management (AOTA, 2020). Furthermore, successfully nourishing one's child is a vital role for caregivers and a priority task in their daily routines (AOTA, 2020). The presence of reflux can lead to suboptimal ADL performance among infants and children and suboptimal role fulfillment and mental health among caregivers.

Solution

This capstone proposed the solution of the student creating an educational tool kit that contained accessible, easily digestible education on pediatric reflux for staff and families at SHMC. To create evidence-based resources, the capstone student performed scoping reviews of the current research on the efficacy of conservative management techniques for infant reflux.

This research was translated into the condensed education available to staff in both a physical and electronic version of the toolkit. The scoping literature review results were translated into parent-friendly language on appealing educational handouts placed in the toolkit for the SHMC OTs to disseminate to parents as appropriate. This quality improvement project hypothesized that the presentation of the toolkit to the OTs at SHMC would increase their perceived ability to implement and educate families on conservative management techniques for pediatric reflux.

Literature Review

Gastroesophageal Reflux is defined "as the passage of gastric contents into the esophagus with or without regurgitation" (Rosen et al., 2018, p. 546). Gastroesophageal Reflux Disease is defined as the condition when GER leads to troublesome symptoms or complications that affect daily functioning (Rosen et al., 2018).

Consequences of Mismanaged Reflux

Mismanaged GERD long-term can lead to a sequela of maladaptive behaviors, events, and development (Rosen et al., 2018). If the frequency, acidity, or amount of time that reflux remains in the esophagus is great enough, children can develop esophagitis, ulcerations, esophageal scarring and stricture, and Barrett's esophagus which is a precancerous condition (Rosen et al., 2018). If the reflux creates a high-calorie loss, children can experience poor weight gain and failure to thrive (Baird et al., 2015). Excessive reflux has also been correlated with adverse respiratory outcomes such as recurrent laryngitis, pneumonia, sinusitis, apnea spells, asthma, wheezing, stridor, and chronic cough (Rosen et al., 2018). Lastly, GERD has been linked with Sandifer syndrome, a movement disorder consisting of back arching and head and neck spasms, which are often accompanied by visible signs of discomfort (Patil, 2022).

Behavioral reports indicate that infants and children with GERD demonstrate increased irritability, fussiness, and discomfort following feedings compared to their non-afflicted counterparts (Eichenwald, 2018). These adverse physical and emotional experiences can cause a child to develop a feeding aversion which can carry several years into their development (Silverman et al., 2021). Feeding aversions are linked with poor calorie intake, stunted growth,

nutritional deficiencies, maladaptive feeding behaviors, and psychological distress within afflicted individuals (Silverman et al., 2021).

The adverse effects of reflux affect not only the infants and children experiencing them but also their caretakers. Infant reflux can cause bradycardia, oxygen desaturation, and cyanosis, which can be very frightening for caretakers (Eichenwald, 2018). Parents often report feelings of distress and inadequate role fulfillment when unable to successfully feed their infants (Silverman et al., 2021). Observation of their infant's discomfort and physical responses such as cyanosis and Sandifer syndrome is known to cause anxiety among caregivers (Patil, 2022). For example, Sandifer syndrome rarely leads to severe complications; however, caregivers often mistake the infant's movements for seizure activity. This leads to caregiver stress and sometimes unnecessary, expensive neurological testing when the actual condition was unmanaged GER (Patil, 2022).

Literature on the consequences of GER and GERD is plentiful and published in well-regarded journals. Additionally, the studies are supported by widely accepted anatomical, medical, and neurological knowledge and theories. However, the subjective nature of diagnosis leads to heterogeneous inclusion and exclusion criteria and study methodology. This weakens the evidence by introducing the likelihood of both over- and underreporting symptoms.

Conservative Management Techniques

The 2018 NASPGHAN/ESPGHAN guidelines recommend three conservative management techniques that fall into the OT scope of practice (Rosen et al., 2018). These techniques include positioning therapy, altered feeding regimens, and the elimination of cow's milk from the diets of infants and children with GERD (Rosen et al., 2018). The guidelines specifically recommend that providers consider the use of head elevation and left lateral

positioning (LLP) for children with GERD. For infants, the guidelines recommend feeding modifications in the case of overfeeding and eliminating cow's milk when appropriate.

The capstone student completed scoping reviews to obtain peer-reviewed scientific evidence on the efficacy of these three therapies when utilized on infants and children. Boolean searches were performed on Google Scholar, EBSCO, and PubMed databases; see Appendix A for each search's inclusion and exclusion criteria. The scientific rigor of each study was assessed using the 2009 Oxford Levels of Evidence, as these are the guidelines recommended by AOTA (AOTA, 2020; OCEBM Levels of Evidence Working Group, 2009). See Appendix B for a description of the levels of evidence. A literature review of the available evidence is discussed below; see Appendices C through F for tables describing various properties of the obtained articles on positioning therapy, adapted feeding regimens, and cow's milk elimination diet, respectively.

Positioning

Scoping reviews of positioning therapy for infants resulted in the obtainment of eight peer-reviewed, published scientific studies. Four of the articles exclusively compared left vs. right positioning, two exclusively compared supine vs. upright positioning, one discussed head elevation, and one compared left, right, supine, and prone positioning (Corvaglia et al., 2007; Jung et al., 2012; Loots et al., 2014; Omari et al., 2004; Quitada et al., 2020; Vandenplas et al., 2009; Van Wijk et al., 2007, 2009). Out of these articles, only authors Quitada et al. (2020) additionally discussed positioning in children; the rest studied infants exclusively.

All five articles comparing left vs. right positioning studied exclusively infants and found favorable effects of the LLP over the right lateral position (RLP) for reflux management. Of the five articles, one was of level "1B" scientific evidence, three were of level "3B" evidence, and

one was of level “4” evidence. In the obtained article of level 1B evidence, researchers Loots et al. (2014) completed a randomized control trial (RCT) of 51 infants with clinical symptoms of GER. The researchers found that LLP significantly reduced infants' total number of reflux episodes and vomiting (Loots et al., 2014). Among the articles of lower scientific rigor, three found LLP to be associated with lower frequencies of transient lower esophageal relaxations (TLESRs), which are known to be a primary mechanism of GER (Omari et al., 2004; Van Wijk et al., 2007; Van Wijk et al., 2009). In their pre-post study of level 3B evidence, researchers Van Wilk et al. (2010) found that TLESRs were triggered at significantly lower feed volumes in the LLP than in the RLP. This effect is hypothesized to be due to the fact that in the RLP, gastric contents pool just distal to the gastroesophageal junction, increasing the likelihood of GER (Van Wijk et al., 2007). Three studies specifically found the LLP to be associated with a lower total number of reflux episodes (Corvaglia et al., 2007; Omari et al., 2004; Van Wijk et al., 2009). Authors Corvaglia et. Al (2007) completed a quasi-experimental study of level 3B evidence and concluded that the LLP was associated with less acid-exposure time in the esophagus than the RLP.

The two articles comparing supine vs. upright positioning found mixed results (Jung et al., 2012; Quitada et al., 2020). Both were retrospective studies of level 3B scientific evidence. Authors Jung et al. (2012) studied 32 infants and found that although the upright position increased the total number of reflux events per hour (insignificantly), the upright position resulted in a statistically significant reduction in reflux-related respiratory symptoms per hour. Authors Quitada et al. (2020) studied 132 subjects and found a statistically significant higher total number of reflux events when infants, children, and teenagers were in an upright position compared to a supine position. Conversely, the authors found a statically significant longer

esophageal acid clearance time when participants were in a recumbent position (Quitada et al., 2020). Thus, in supine- participants experienced a lower frequency of reflux events, but each time they did reflux, the acid remained in the esophagus longer. Due to these competing factors, the authors concluded that upright vs. supine body positioning after feeding did not result in a statistically significant effect on total esophageal acid exposure time (Quitada et al., 2020).

Lastly, authors Vandenplas et al. (2010) conducted a preliminary pre-post study of level 4 scientific evidence on the efficacy of a specific commercial bed that places infants at a 40-degree incline from the supine position. Researchers found that this bed significantly reduced regurgitation and reflux symptoms among infants who previously had failed to respond to acid-suppressive drugs and feeding modification.

The obtained studies on body position are limited mainly by their low scientific rigor and small sample sizes. Only one of the studies is a randomized control trial RCT. Furthermore, this, and only one additional study were the only ones to utilize sample sizes greater than 50 participants. The remaining six studies were of relatively low scientific rigor and utilized sample sizes lower than 50.

In summary, all five articles that compared LLP vs. RLP found the LLP to have favorable effects on infant reflux. Within the three articles that compared upright vs. supine positioning, only one found exclusively positive benefits of the upright position. One study found positive results of the upright position for certain reflux symptoms but negative effects on others, and one concluded that upright vs. supine positioning did not create a statistically significant impact on reflux burden among infants and children.

The results of this scoping review are somewhat at odds with the recommendations of the ESPGHAN/NASPGHAN 2018 guidelines (Rosen et al., 2018). The guidelines recommend

consideration of upright and LLP positioning for children with GERD but do not make the same recommendation for infants. The guidelines discuss several research articles that suggest the benefits of LLP and upright positioning for infants with reflux. Each of these articles, plus an additional study from 2020 (Quitadamo et al., 2020), were obtained in the capstone student's scoping review. Synthesis of these articles showed the promising effects of LLP and supine positioning for infants with GERD. However, the guidelines firmly maintain that sleeping infants only ever be placed supine on a firm flat surface (Rosen et al., 2018). This is in adherence with repeated official statements from the American Academy of Pediatrics (AAP), which assert that this is best practice (Rosen et al., 2018). In an updated report on the topic from 2022, the AAP continues to only recommend the supine position for sleeping infants unless under specific conditions beyond this review's scope (Moon et al., 2022). The guidelines suggest that although the budding research on positioning therapy for infants and children with reflux appears promising, the staff at SHMC should always prioritize adherence to AAP guidelines for infant positioning in their patient care and parent education.

Adapting Feeding Volume and Rate

Scoping review methods utilized in this capstone paper resulted in the obtainment of five articles that discuss the alteration of feed volumes and frequency among infants with GER and GERD. However, of these five articles, Omari et al. (2002) were the only authors to exclusively manipulate feed volume and frequency within their intervention. The interventions of the other four authors involved additional treatments concurrent with volume manipulations which acted as confounding variables. Among these four studies, it is impossible to determine the exact effect volume manipulation alone had on the results.

Authors Omari et al. (2002) conducted a non-randomized control trial of level 3B scientific evidence on 32 infants, 14 of whom were suspected of having GERD. The authors concluded that reduced volume, higher frequency feeds resulted in a statistically significant reduction in reflux index among infant participants with GERD (Omari et al., 2002).

Of the four studies with confounding variables, three utilized a "feeding bundle" of multiple concurrent interventions (Jadchlera et al., 2021; Orenstein et al., 2008; Shalaby & Orenstein, 2003). One study had the exclusive confounding variable of additionally thickening the feeds (Kooshoo et al., 2002). Authors Kooshoo et al. (2002) completed a level 3B pre-post study in which they provided reduced volume, same calorie feeds thickened with rice cereal to six infants suspected of having GERD. These researchers found a significant reduction in vomiting, but no reduction in esophageal acid exposure upon intervention, suggesting that the reduced volume, thickened feeds reduced the frequency of GER but not the acidity (Koosh et al., 2002).

The "feeding bundles" in the remaining three studies involved reduced volume feeds thickened with rice cereal and positioning changes (Jadchlera et al., 2021; Orenstein et al., 2008; Shalaby & Orenstein, 2003). Authors Shalaby & Orenstein (2003) and Orenstein et al. (2008) additionally advised caretakers to limit the infant's exposure to tobacco smoke within their intervention bundle. One of these studies was of level "2B" scientific rigor, and the other two were retrospective studies of level 3B and 4 scientific evidence. Authors Jadchlera et al. (2021) conducted an RCT on 76 infants, providing a control group with acid-reducing medication only and the intervention group with acid-reducing medication plus a feeding bundle. Their feeding bundle included reduced volume, starch-thickened feeds and positioning the infant in the RLP during feeding and in supine position afterward. The authors found no significant benefit of

medication plus their feeding bundle over medication alone (Jadchlera et al., 2021). In their pre-post study of 37 infants, authors Orenstein et al. (2008) found that 68 percent of infants with GERD improved their scores on the I-GERQ-R in a clinically meaningful way. Furthermore, 24 percent increased their scores to ranges indicative of normal, non-GERD parameters (Orenstein et al., 2008). In their retrospective study of 395 participants, authors Shalaby & Orenstein (2003) found that parental education on their feeding bundle resulted in 24 percent of infants resolving their GERD symptoms. Resolution of symptoms was measured by parental report of satisfactory resolution and the infant not requiring subsequent medical intervention for their reflux following implementation of the feeding bundle.

The obtained articles had significant limitations. The main limitation was that four out of the five studies involved significant confounding variables along with reduced volume feeds that made it impossible to determine the effect that reduced volume feeds alone had on reflux burden. While the one study that exclusively manipulated reduced volume feeds did find statistically significant benefits, it was conducted with low methodological rigor, without controls, on a relatively low sample size of 37 infants.

In summary, four of the five obtained articles studying reduced volume feeds found statistically significant reductions in reflux burden on infant and child participants. Additionally, the 2018 NASPGHAN/ESPGHAN guidelines suggest modifying feed volume and frequency in the case of overfeeding (Rosen et al., 2018). The recommendation of the guidelines and results of the scoping review suggest the appropriateness of SHMC staff to recommend reduced volume, higher frequency feeds to infants whose current history and symptoms suggest that higher volume feeds are contributing to their reflux

Cow's Milk Elimination Diet

Scoping review methods resulted in the obtainment of three articles that addressed the elimination of cow's milk from the diet of infants with GERD symptoms (Borrelli et al., 2012; Famouri et al., 2016; Omari et al., 2020). These three articles were of level 2B, 3B, and 4 scientific evidence. Authors Borrelli et al. (2012) and Omari et al. (2020) conducted level 3B pre-post studies on infants whom they confirmed to have cow's milk allergy (CMA). These authors found that eliminating cow's milk from the formulas of formula-fed infants and the maternal diet of exclusively breast-fed infants led to improvement in GERD symptoms among infants confirmed to have CMA. Authors Omari et al. (2020) studied esophageal motility and found that eliminating cow's milk improved esophageal peristaltic function and mucosal integrity among study participants confirmed to have CMA. Authors Famouri et al. (2016) did not confirm CMA within their study participants. These authors conducted an RCT among 50 infants with GERD, allocating half to a control group that received acid-suppressive medication and half to an intervention group that received a hypoallergenic diet (Famouri et al. 2016). The hypoallergenic diet consisted of formula or maternal diets devoid of cow's milk, peanuts, fish, and soy. The interventions were provided over two weeks for all participants. The authors concluded that a hypoallergenic diet was just as effective as the acid-suppressive medication in reducing GERD symptoms among infants in the study (Famouri et al. 2016).

The articles studying cow's milk allergy have notable limitations. The RCT conducted by Famouri et al. (2016) had limited ability to demonstrate the effect of cow's milk elimination alone, as their intervention included the elimination of additional allergens which confounded the findings. The two studies which exclusively eliminated cow's milk were limited due to their low scientific rigor, lack of control groups, and low sample sizes of less than 50 participants.

In summary, all three of the obtained articles that studied the elimination of cow's milk found the practice to have statistically significant effects in lowering the reflux burden for infants and children up to 24 months of age with GERD. Concurrently, the 2018 NASPGHAN/ESPGHAN guidelines recommend a two-week trial of maternal avoidance of cow's milk in breastfed infants and extensively hydrolyzed or amino acid formula for formula-fed infants whose GERD has not responded to adapted feeding regiment and thickened feeds (Rosen et al., 2018). In extensively hydrolyzed and amino acid formulas, the protein that causes cows' milk allergy symptoms is inactive or absent. Thus, the evidence supports SHMC staff suggesting a two-week trial of cow's milk elimination from the diets of infant and child patients suffering from reflux who have trialed and not responded to thickened feeds and adaptive feeding regimens.

As discussed, there is a general dearth of high-quality evidence on conservative management techniques for infants and children with GERD (Rosen et al., 2018). Historically the condition has been overlooked and poorly defined. Furthermore, many of the obtained studies in this literature review were of low scientific evidence. This is likely because the participants were infants and children, which are both highly vulnerable and protected populations. Lower levels of scientific evidence are common among studies of infant and pediatric populations due to ethical considerations that dissuade the use of controls. Control groups require certain individuals to forgo potentially helpful treatment for the study duration, causing many researchers to avoid their use.

Despite and because of these challenges, the NASPGHAN and ESPGHAN task forces collaborated and set forth guidelines for the clinical management of infant and child GERD (Rosen et al., 2018). These guidelines, plus the results of the capstone student's scoping reviews,

offer extremely valuable information and insight to SHMC staff and families on evidence-based approaches to managing pediatric reflux.

Statement of Purpose

This capstone aimed to bridge the knowledge gap of conservative management techniques for reflux among SHMC staff and families. To achieve this, the student created a toolkit that contained education tailored to be most effective for the intended audience. This capstone hypothesized that after receiving education on the current literature for pediatric reflux management, OTs at SHMC would report a perception of improved ability to perform and educate families on best practices for pediatric reflux management.

Theoretical Framework

This capstone was grounded in the Occupational Adaptation Model of Practice. This commonly used model of practice (MOP) within the OT profession proposes that environmental demands and the human desire for occupational mastery may cause occupational breakdown (Schkade & Schultz, 1992). Within this MOP, OTs adapt certain occupational factors to produce an "adaptive response" from the client that helps them master the targeted occupation. Within reflux interventions, the OT facilitates the environment, client factors, and contexts surrounding feeding to help the caregiver-child dyad master this occupation while living with reflux.

The educational process in this capstone was grounded in cognitive learning theory. Cognitive learning theory emphasizes active learning (Matlin, 2013; Sternberg & Sternberg, 2017). Additionally, it emphasizes the importance of internal motivation, proper attention, encoding, and long and short-term memory (Roediger & McDermott, 1995). This capstone centers on educating a predominantly adult learning population. Education was provided to both the occupational therapy staff and the caretakers of infants and children experiencing reflux at SHMC. Research shows that adult learners are likely to be goal-oriented and generally prefer education that allows them to achieve clear and identifiable objectives (Knowles et al.,2015; Miller & Stoeckel, 2016). This consideration was implemented in the educational materials within the toolkit for both staff and parents. The materials utilized clear, concise language to meet the transparent objectives of increasing knowledge on how to help infants and children experiencing reflux.

Parent Handouts

Keeping in line with what is known about adult learning styles and cognitive learning theory, the parent handouts were created to be particularly clear and concise. Studies find that on average; U.S. adults read at an eighth-grade level, and thus health education materials should be written at a similar level (Hersch et al., 2015). Additional studies show that patients can better meet their health goals when they are provided with educational handouts that utilize clear language and attractive designs (Findeis & Patyk, 2020). The parent handouts in the toolkit were written in clear, simple language, without medical jargon. The handouts contained the necessary information to help parents know more about their child's condition or how to complete specific conservative management techniques. The handouts did not contain additional, excessive information as this is not in line with goal-oriented, actionable learning. The handouts included the scientific names of body structures, diseases, and diagnostics methods, to aid proper education. However, when used, these terms were always first explained in simple language.

Researchers Krasnoryadtseva et al. (2020) found that learners enjoy pictures in their medical handouts and looked deeper into what learners prefer in anatomical diagrams. They found that learners enjoy more detailed, anatomically correct medical diagrams than simpler images if adequately explained (Krasnoryadtseva et al., 2020). For this reason, anatomical diagrams of the upper GI tract were included in several parent handouts and were always accompanied by a clear, written explanation of what was depicted.

Staff Education

Compared to the parent handouts, education for staff was prepared in longer formats and written at higher health literacy levels. However, they still followed adult and cognitive learning

theories. The capstone student provided either a printed copy or the full reference for each original supporting document used to inform any given staff education topic. However, the capstone student was sure to create concise yet informative summaries of the main points of these documents that pertain to patient care at SHMC. This way, education for staff was goal-oriented, actionable, time efficient, and designed to keep readers engaged.

Methodology

Agency Description

Summerlin Hospital Medical Center is a joint commission accredited hospital with NICU, PICU, and pediatric floors. The OTs on these floors include trained, knowledgeable therapists who routinely perform feeding interventions with patients. This setting allowed the capstone student to generate knowledge in the specialty area of feeding therapy. Concurrently, the setting provided the opportunity to determine the toolkit's efficacy.

Study Design

The toolkit's efficacy was measured through what is known as a "one group-posttest only design" (Campbell &. Stanley, 1963). In this study design, a dependent variable is measured among one group of participants following a specific intervention (SAGE Publications, 2020). Within this capstone project, the "group of participants" was the neonatal and pediatric OTs at SHMC, and the "intervention" was presentation of the toolkit. Finally, the "dependent variable" was perceived knowledge and skill to follow and educate families on current guidelines for conservative management of pediatric reflux.

Instrumentation

Perceived knowledge and skill were measured using a post-intervention survey created by the capstone student and provided to the pediatric therapy staff at SHMC. The survey utilized Likert style, multiple choice, and opened ended questions that aimed to gain insight into the efficacy and staff perceptions of the toolkit. The two survey themes that most directly related to this capstone's PIO questions were: Increased knowledge of the 2018 NASPGHAN/ESPGHAN

guidelines and perception of increased knowledge and skill in evidence-based conservative management of reflux. The survey additionally evaluated the following themes: staff's perception of the parent and patient handouts and staff's opinions on implications for future capstone projects at SHMC.

Sample Description

The student conducted a 30-minute in-service on the toolkit's contents to the pediatric therapy staff at SHMC including three OTs, one physical therapist (PT), and one speech-language pathologist. Following the in-service, the student provided each attendee the survey. Three staff members responded to the survey, all of whom were OTs. Survey completion was completely anonymous and voluntary. Furthermore, the student explained the intended use of survey results to all participants before administration. See Table 1 below for the characteristics of the respondents.

Table 1

Participant Characteristics

Participant	Profession	Gender	Main Hospital Floor	Years Practicing OT
1	OT	F	NICU	30+
2	OT	F	NICU	20+
3	OT	F	Pediatrics/ PICU	Less than 1

Data Analysis

To answer the PIO question, statistical analysis was completed on survey questions that most directly related to the question. Descriptive statistics were utilized to summarize responses to additional Likert and multiple-choice questions in the survey. Lastly, content analysis was used to identify key themes in the open-ended, short-response questions in the survey. Within content analysis, one analyzes data for content and trends (Stanley, 2015).

Advantages of the Selected Methodology

This project's used a mixed method design, obtaining both qualitative and quantitive data. Mixed method designs are reported to aid data triangulation, strengthen findings, reduce bias, and increase generalizability to larger populations (Johns Hopkins Bloomberg School of Public Health, 2020). Health experts champion Likert scales to be versatile, adaptable, and appropriate for assessing beliefs, such as perceptions of increased knowledge and skilled assessed in this capstone (Centers for Disease Control and Prevention, 2012). Lastly, content analysis is viewed as an efficient, appropriate way to analyze short text sections, such as the short answers to the open-ended survey prompt (Stanley, 2015).

By utilizing both quantitative and qualitative data, the student gained a better understanding of the true perceived efficacy of the toolkit and the opinions of the OTs at SHMC. The main disadvantage to this study design was its low methodologic rigor. The one-group posttest design did not allow for a comparison of the staff's knowledge before the presentation of the toolkit. Furthermore, it did not allow for the use of controls. These factors plus the small sample size significantly limited the external validity of this study. Factors that increased the internal validity of this study include the mixed method research design and the anonymity of survey responses, which likely reduced participant bias and supported more honest responses.

Ethical and Legal Considerations

To ensure a safe, ethical, and legal process, the capstone team created and followed an action plan for the student's time at SHMC prior to their arrival. Student responsibilities, expectations, and limitations were clearly defined, formally agreed upon and strictly followed. The student completed all requested hospital trainings and followed hospital guidelines at all times. The UNLV OTD program provided the hospital with the student's immunization records, a clear background check, and negative drug screenings prior to the student's time on site. Throughout the entire capstone process, the student adhered to all Health Insurance Portability and Accountability Act (HIPPA) guidelines (Health Insurance Portability and Accountability Act [HIPAA] of 1996, Pub. L. No. 104-191). Throughout the process, the student recorded no patient information. The student understood that failure to adhere to any of the items in the action plan could result in the termination of the student's contract with the site. There were no breaches in this action plan within the student's 14 weeks at SHMC, ensuring a safe, legal, and ethical experience for all involved parties.

Vulnerable Populations

During the capstone experience, the student spent significant time around the vulnerable populations of hospitalized infants and children. All student interactions with patients and family were under the direct supervision of a physically present, licensed OT employed at SHMC. The student always wore a name tag stating their name and student status. The student collected no data from patients and families at Summerlin Hospital, negating the need for informed consent forms. Families were always asked if they were comfortable with the student's presence. Any

requests from families for the student to be absent during their care were immediately honored without question.

Results

Statistical Analysis to Test the Study Hypothesis

Three questions from the survey provided the most direct evidence to answer the PIO question. All three of these questions were in the form of a Likert scale with five options for respondents to choose from: “strongly disagree”, “somewhat disagree”, “neither agree or disagree”, “somewhat agree”, and “strongly agree”. The “exact test of goodness of fit” was used to create a null hypothesis and perform statistical analysis to answer the PIO question (Conover, 1980). The exact goodness of fit test is a non-parametric statistical test appropriate for studies with small sample sizes, and binary outcomes (Conover, 1980). The test is used to determine if observed results differ significantly from a known or expected result (McDonald, 2014). In order to use this test, responses to the three questions were categorized into one of two options: that the respondent agreed to the question or did not agree. Responses “somewhat agree” and “strongly agree” were categorized as the respondent agreeing, all other responses were categorized as not agreeing. The PIO question was translated into language that created a null hypothesis for each question that could be statistically tested. A response of agreeing was coded as a "success”. For each question, the expected result was that all three OTs would agree that the toolkit increased their ability to follow the 2018 NASPGHAN/ESPGHAN guidelines while providing care to infants and children at SHMC. The null hypothesis for each question was that the number of successes would be less than or equal to the number of “nonsuccesses.” The calculated p-value determined if the observed success rate of the toolkit was statistically significant or more likely to be due to chance. See Table 2 below to view the “expected” and “observed” successes for the three survey questions most directly related to the PIO question.

Table 2

Expected and Observed Successes Among Survey Responses

Survey Question	This toolkit increases my ability to provide patient care that follows the current guidelines for conservative management of infant/pediatric GERD at SHMC	This toolkit increases my ability to advocate for adherence to the current guidelines for conservative management of infant/pediatric GERD at SHMC	This toolkit will enhance the education that I provide to future patients and/or families of patients experiencing reflux
Expected Successes	3	3	3
Observed Successes	3	3	3

An exact test of goodness of fit was completed to examine if the relationship between the observed and expected successes was significant. All three questions had the same numbers of observed and expected successes; thus, the calculated p-values were identical. The calculated p-value for each of the three questions was 0.025, calling for the rejection of each null hypothesis.

Descriptive Analysis of Survey Responses

Survey items aimed to gain insight into the OTs' perceptions in four key areas: a) the toolkit's efficacy in increasing their ability to follow NASPGHAN/ESPGHAN guidelines; b) the toolkit's efficacy in increasing their knowledge of current evidence regarding pediatric reflux management; c) attitudes towards the student-made handouts; d) guidance for future capstone projects at the site. Results from the Likert scale and multiple-choice questions relating to these areas are discussed below.

Increased Ability to Adhere to Guidelines

All three respondents agreed that the toolkit increased their ability to provide care that followed the 2018 NASPGHAN/ESPGHAN guidelines; two participants selected strongly agree, and one selected somewhat agree. This exact response pattern was also seen for the questions asking if the participants agreed that the toolkit increased their ability to advocate for adherence to the guidelines within the hospital and that the toolkit would enhance the education they provide to staff and families. When asked to what degree they agreed the toolkit would enhance their hands-on patient care, two respondents strongly agreed, and one neither agreed nor disagreed.

Increased Knowledge of Pediatric Reflux Management

All three respondents agreed that the toolkit helped them stay up to date on the current research regarding infant and child reflux management, again with two participants selecting that they strongly agreed and one selecting that they somewhat agreed. Results were more mixed for the toolkit's efficacy in introducing the staff to new resources. When asked about their level of agreement that the toolkit introduced them to new publicly available resources to provide to parents, one respondent strongly agreed, one somewhat agreed, and one neither agreed nor disagreed. When asked if the toolkit introduced them to new symptom checklists to provide to parents, one strongly agreed, one neither agreed more disagreed, and one somewhat disagreed.

Attitudes Towards the Student-Made Handouts

All three participants strongly agreed that the student-made handouts appeared professional and appropriate for use at SHMC. Two strongly agreed that they plan to use the handouts with parents, and one somewhat agreed. On a 10-point scale of believing that the level

of information in the handouts was either far too simple or far too advanced, all three respondents selected a “five,” meaning that they felt the content was “just right.” This same scale was used to ask the respondent's perception of if the handouts looked too causal or too serious for their subject matters, and again all three respondents selected a five, just right.

Guidance for Future Capstone Projects

All three respondents neither agreed nor disagreed that in the future, SHMC staff should have more decision-making power in what goes into a student’s final capstone project. When asked the level to which they agreed that a toolkit is one of the most helpful projects to the staff and patients of SHMC that a student can make, one respondent strongly agreed, one somewhat agreed, and one neither agreed nor disagreed.

Content Analysis of Short Answer Responses

Responses to the open-ended, short-answer prompts were analyzed through content analysis. All responses were analyzed, and key themes were extracted from the data. The frequency of each theme was calculated by dividing the total number of participants who wrote a response within that theme by the total number of study participants overall. Content analysis results and accompanying quotes from respondents are shown below in Table 3.

Table 3

Identified Themes from Short Answer Responses

Theme	Frequency N (%)	Quotations
Overall, participants feel positively about the toolkit	3 (100%)	"The toolkit had an excellent range of evidence-based materials for practitioners, screening tools, and educational handouts…" "The toolkit looked incredible and was very informative on current research/practice guidelines. I look forward to using the materials in my practice!" "Great job!"
The toolkit is not lacking in any immediately identifiable areas	2 (66%)	"I cannot currently think of any additional comments to include." "Topics and needs are continually evolving. I feel [the need for additional components in future toolkits] would need to be assessed at that time."
Participants enjoy the handouts	1 (33%)	"The student-made handouts looked great. They were very professional and with an appealing design. They will be very helpful for my own reference as an OT and as educational materials with patients/families."
The staff would benefit from future toolkits with handouts on a broader range of topics	1 (33%)	"[An idea for future capstone projects is] Handouts in general covering multiple areas instead of one topic."

Discussion

The main finding of this study was that all three of the OTs agreed that they perceived the toolkit increased their ability to a) follow the 2018 NASPGHAN/ESPGHAN guidelines within patient care, b) advocate for adherence to the guidelines at SHMC, and c) provide education for families of infants and children experiencing reflux. Statistical significance was found between the expected results of an efficacious toolkit and the observed results in the sample for all three questions. This allowed for the rejection of the null hypothesis and acceptance of the hypothesis that the toolkit increased the staff's perceived ability to implement and educate families on evidence-based, conservative management techniques for pediatric reflux.

Application to the Occupational Therapy Profession

This capstone served as a pilot quality improvement project to promote the utilization of evidence-based, high-quality OT intervention for patients ages 0-5 experiencing gastroesophageal reflux. The results show that on a small sample of neonatal and pediatric OTs at an acute care hospital in southern Nevada, the toolkit demonstrated efficacy to do this. Results indicated that the toolkit increased the OTs' perceived ability to adhere to evidence-based clinical guidelines for pediatric GER management and to advocate for adherence among other staff in the hospital. The results indicated that the toolkit increased the OTs' perceived abilities to provide family education on reflux. Lastly, the results indicated that the toolkit increased the OT's perceived abilities to stay current on the most recent literature surrounding conservative management techniques. These results align with the AOTA and AOTF priority for the profession to ascertain the efficacy and effectiveness of occupational therapy interventions (AOTA & AOTF, 2011). This manuscript does not aim to provide large-scale suggestions to the

entire OT profession. Instead, this manuscript is intended to serve as a guide for future capstone projects and research studies that aim to contribute to the AOTA and AOTF priority research agenda for OT interventions for infants and children experiencing reflux.

Limitations of Study Results

All data within this capstone was collected from a small sample of OTs on specific floors of a singular hospital in Las Vegas, Nevada, in the spring of 2023. The toolkit, handouts, and surveys were all created for this specific population. Therefore, the generalizability of the results to larger populations is very limited.

The study design and small sample sizes greatly limited the options for statistical analysis and therefore limited what the results could suggest. The one-group posttest-only design did not allow for analysis of the degree to which the toolkit increased perceived knowledge and skill. Statistical analysis could only be completed on the toolkit's observed success rate vs. the expected success rate of a hypothetical, efficacious toolkit. Therefore, the analysis only increased the internal validity of the results and not their external validity to larger populations.

Limitations

This project's main limitation was the lack of time to create a more rigorous study design. The capstone student spent seven weeks in the hospital's NICU and seven weeks on the pediatric and PICU floors. This did not allow for sufficient time for the capstone student to recruit study participants from hospital staff other than OTs. At the time of the in-service presentation, only four neonatal and pediatric OTs were currently working at SHMC. One of these OTs was concurrently employed as a UNLV OTD faculty member and was therefore not asked to take the survey as this could have introduced avoidable bias to the results. These factors together limited the maximum possible sample size to three participants. This limitation made randomized selection procedures impossible. The small sample size and positive relationship built between the capstone student and the participants could have introduced participant bias. Participants may have felt pressure to respond how they felt the capstone student wanted them to, as opposed to providing more critical, honest perceptions. This could have introduced a type II error, implying that the toolkit created improvements that it did not.

Conclusion

Mismanaged GER can lead to detrimental developmental outcomes in the infant and pediatric population. Conservative techniques are recommended as the first line of defense; they can reduce reflux and several are well within the OT scope. Results of a survey provided to three neonatal and pediatric OTs at SHMC indicate that a student-made toolkit demonstrated efficacy in increasing perceived ability to implement and educate families on evidence-based conservative management techniques for pediatric reflux.

Recommendations

It is highly recommended that the UNLV OTD program and SHMC maintain a positive professional relationship and continue to partner for student capstone projects. The site provided an invaluable learning experience for the student and a sample on which to determine the efficacy of the toolkit. It is recommended that future UNLV OTD students review this capstone project and continue its potential to influence the community, the field, and the outcomes of families experiencing pediatric reflux.

Implications for Future Research

The main implication for future research is the need for additional high-quality studies with large sample sizes to be conducted. The current research on conservative management techniques for pediatric reflux is sparse. Research on caregiver confidence in implementing these techniques appears to be non-existent. The success of this pilot quality improvement project suggests the benefits of similar partnerships between universities and hospitals in communities. University students can supply the time to undertake rigorous research and resource creation, and

hospitals can provide study participants and expertise. The reported efficacy of this toolkit and the OT staff's positive perception of it suggests that future capstone students should consider creating similar resources for their sites.

Implications for Future Practice

The toolkit's apparent efficacy suggests that the SHMC OTs should continue to utilize this toolkit when preparing interventions for patients and families. The identification of frequently evolving research on conservative management techniques for reflux suggests that the SHMC OTs would benefit from continued efforts to stay current on these topics. The toolkit's efficacy supports the AOTA centennial vision for occupational therapy at SHMC to be a powerful, evidence-based profession that can meet the occupational needs of families experiencing infant reflux (AOTA, 2007).

Appendix A

Scoping Review Procedures

Database	Search Terms	Yield	Hits	Obtained
1. Google Scholar	**FEEDING REGIMEN SEARCHES**			
	Feeding regimen OR feeding volume AND GERD OR GORD AND Pediatric OR Infant	4,508	21	4
	Energy dense OR "higher frequency feeds" AND GERD OR GORD AND Pediatric OR infant	1,010	1	1
	COW's MILK ELIMINATION SEARCHES*			
	Food allergy AND reflux/gastroesophageal reflux disease since 2021	34	0*	0*
	Food hypersensitivity AND reflux/gastroesophageal reflux disease since 2021	27	0*	0*
	Non-IgE mediated allergies AND reflux/gastroesophageal reflux disease	26	0*	0*
	Non-IgE mediated allergies AND reflux/gastroesophageal reflux disease AND quality of life	7	0*	0*

2. EBSCO	**FEEDING REGIMEN SEARCHES**			
	Feeding regimen OR feeding volume OR ingested volume AND GERD OR Gastroesophageal reflux OR reflux AND pediatric OR Infant since 2017	340	0*	0*
	energy dense OR "higher frequency feeds" AND GERD OR GORD AND Pediatric OR infant	2	0*	0*
	BODY POSITIONING SEARCHES			
	Positioning therapy OR left lateral OR right lateral AND Reflux or GERD or GORD or gastroesophageal reflux AND infant OR pediatric OR child	539	22	7
	body position OR left lateral OR right lateral AND GERD OR GORD OR gastroesophageal reflux and Child OR Infants OR paediatric	38	15	1
	COW's MILK ELIMINATION SEARCHES*			
	Cow's milk allergy AND reflux AND infant	45	5	3
	Food allergy AND reflux (since 2021)	4	0*	0*
	Food hypersensitivity AND reflux/gastroesophageal reflux disease (since 2021)	11	0*	0*
	Non-IgE mediated allergies AND reflux/gastroesophageal reflux disease (since 2021)	2	0*	0*
	Non-IgE mediated allergies AND reflux/gastroesophageal reflux disease AND quality of life (since 2021)	0	0*	0*

3. PubMed	**FEEDING REGIMEN SEARCHES** (((GERD) AND (Feeding regimen))) AND (Pediatric)	2	0*	0*
	(((GERD) AND (volume OR feeding regimen))) AND (Pediatric OR infant)	40	0*	0*
	COW's MILK ELIMINATION SEARCHES**			
	Food allergy AND reflux/gastroesophageal reflux disease (since 2021)	12	0*	0*
	Food hypersensitivity AND reflux/gastroesophageal reflux disease (since 2021)	25	0*	0*
	Non-IgE mediated allergies AND reflux/gastroesophageal reflux disease(since 2021)	2	0*	0*
	Non-IgE mediated allergies AND reflux/gastroesophageal reflux disease AND quality of life (since 2021)	0	0*	0*

* Indicates articles were already obtained in previous searches.

**Searches on cow's milk elimination utilized a snowball method, in which were pulled from a 2022 position paper on the subject (Meyer et al., 2022). This article utilized exhaustive search methods to find all literature on food-allergy associated GERD up until February 2021. The capstone student reviewed all of the citations in this position paper and obtained articles relevant to the capstone literature review. The student completed scoping reviews utilizing the exact search terms in the position paper from 2021 and on the three databases mentioned above.

Appendix B

Oxford Levels of Evidence

Level	Type of Evidence
1A	Systematic review of homogeneous RCTs (similar population, intervention, etc.) with or without meta-analysis
1B	Well-designed individual RCT (not a pilot or feasibility study with a small sample size)
2A	Systematic review of cohort studies
2B	Individual prospective cohort study, low-quality RCT (e.g., <80% follow-up or low number of participants; pilot and feasibility studies); ecological studies; and two-group, nonrandomized studies
3A	Systematic review of case-control studies
3B	Individual retrospective case-control study; one-group, nonrandomized pre-posttest study; cohort studies
4	Case series (and low-quality cohort and case-control study)
5	Expert opinion without explicit critical appraisal

Note. RCT = Randomized controlled trial. Adapted from OCEBM Levels of Evidence Working Group. (2009). *The Oxford Levels of Evidence.* Oxford Centre for Evidence-Based Medicine.

Appendix C

Obtained Articles: Positioning Therapy

Article Title	Citation	Topic	Study Design	n=
A preliminary report on the efficacy of the Multicare AR-Bed in 3-week–3-month-old infants on regurgitation, associated symptoms, and acid reflux	(Vandenplas et al., 2009)	Elevated head of bed	Case Control	51
Body positioning and medical therapy for infantile gastroesophageal reflux symptoms	(Loots et al., 2014)	Left vs Right Sided	RCT	10
Effect of Body Position Changes on Postprandial Gastroesophageal Reflux and Gastric Emptying in the Healthy Premature Neonate	(Van Wijk et al., 2007)	Left vs Right Sided	Quasi Experimental	10
Paradoxical impact of body positioning on gastroesophageal reflux and gastric emptying in the premature neonate	(Omari et. al, 2004)	Left vs Right Sided	Case Control	22
Small Volumes of Feed Can Trigger Transient Lower Esophageal Sphincter Relaxation and Gastroesophageal Reflux in the Right Lateral Position in Infants	(Van Wijk et al., 2010)	Left vs Right Sided	Pre-Post	6

The Effect of Body Positioning on Gastroesophageal Reflux in Premature Infants: Evaluation by Combined Impedance and pH Monitoring	(Corvaglia et al., 2007)	Prone, Supine, Left, Right	Quasi Experimental	32
Association between body positioning and gastroesophageal reflux in pediatric age	(Quitadamo, 2020)	Supine vs upright	Retrospective	187
The efficacy of the upright position on gastro-esophageal reflux and reflux-related respiratory symptoms in infants with chronic respiratory symptoms	(Jung et al., 2012)	Supine vs upright	Retrospective	8

Appendix D

Obtained Literature Review Articles: Adapted Feeding Volume

Article	Citation	Subject	Study Design	n=
Mechanisms of gastro-esophageal reflux in preterm and term infants with reflux disease	(Omari et al., 2002)	PH monitoring of GERD vs non-GERD	Non-randomized control trial	36
Smaller Volume, Thickened Formulas in the Management of Gastroesophageal Reflux in Thriving Infants	(Khooshoo et al., 2000)	Thickening for lower volume feeds	Pre- Post	6

Appendix E

Obtained Literature Review Articles: Feeding Bundles

Article	Citation	Study Design	n=
Efficacy of Conservative Therapy as Taught in the Primary Care Setting for Symptoms Suggesting Infant Gastroesophageal Reflux	(Orenstein et al., 2008)	Pre-post	37
Efficacy of telephone teaching of conservative therapy for infants with symptomatic gastroesophageal reflux referred by pediatricians to pediatric gastroenterologists	(Shalaby & Orenstein, 2003)	Retrospective	395
Role of feeding strategy bundle with acid-suppressive therapy in infants with esophageal acid reflux exposure: a randomized controlled trial	(Jadchlera et al., 2021)	Retrospective	76

Appendix F

Obtained Literature Review Articles: Cow's Milk Elimination Diet

Article	Citation	Design	n=
Cow's Milk Challenge Increases Weakly Acidic Reflux in Children with Cow's Milk Allergy and Gastroesophageal Reflux Disease	(Borrelli et al., 2012)	Pre-Post	17
Comparison of Hypoallergenic Diet vs. Ranitidine in Treatment of Gastroesophageal Reflux Disease of Infants: A Randomized Clinical Trial	(Famouri et al., 2016)	RCT	50
Characterization of Upper Gastrointestinal Motility in Infants with Persistent Distress and Non-IgE-mediated Cow's Milk Protein Allergy	(Omari et al., 2020)	Pre-Post	43

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