EARLY PEANUT INTRODUCTION IN INFANTS TO PREVENT PEANUT ALLERGY: IMPROVING GUIDELINE ADHERENCE THROUGH EMR STANDARDIZATION

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ABSTRACT

Lauren Herlihy: Early Peanut Introduction in Infants to Prevent Peanut Allergy: Improving Guideline Adherence Through EMR Standardization
(Under the direction of Elizabeth Walters)

Background: Peanut allergy in children is a population health problem affecting individuals, families, and healthcare systems. Strong evidence from the Learning Early About Peanut (LEAP) study suggests that early peanut introduction (EPI) for infants after four months of age but before 12 months can reduce the risk of developing peanut allergy (Du Toit et al., 2015; Fleischer et al., 2021; Obbagy et al., 2019; Togias et al., 2017). The success of peanut allergy prevention in infants is highly dependent on primary care providers (PCPs) incorporating the addendum guidelines into routine well-child check (WCC) encounters (Bilaver et al., 2019; Lai & Sicherer, 2019). Addendum guidelines recommending EPI have not been widely adopted in primary care settings. The Children's Primary and Specialty Clinic at UNC had notably low adoption of the addendum guidelines for EPI.

Methods: Using quality improvement (QI) methodology and the model for improvement, researchers developed and implemented a workflow protocol and clinical decision support (CDS) tools to improve guideline adherence through standardization. These tools, available in the electronic medical record (EMR), included smart lists, visit templates, and patient education handouts for home peanut introduction at 4, 6, and 9-month WCC encounters. Through plan-do-study-act (PDSA) cycles, the team executed changes and modifications to improve outcomes.

Results: The team collected data from 292 WCC encounters during the QI project. EMR documentation of clinically appropriate EPI guidance at 4, 6, and 9-month WCCs shifted from a

mean of 8.8% at baseline to 74.7% after 18 weeks of PDSA cycles ($p<0.001$). Mean provider adoption of smart lists and templates was 67.3%, and distribution of home peanut introduction handouts was 50.2% after 18 weeks of project implementation. There were no statistically significant changes in patient time-in-room ($p=0.795$). Rates of DTaP vaccination remained at 100% for 6M visits during the intervention.

Conclusion: QI methodology, PDSA cycles, and interprofessional collaboration in primary care settings improved documentation of EPI guidance at routine WCC encounters without impacting other measures. Broader PCP use of bundled CDS tools and EMR standardization could further improve guideline adherence to prevent peanut allergy in infants.

To my family and friends, who have endured and embraced the fine line of sanity I have walked through this journey; To my colleagues, mentors, and Chair, for believing my only possible outcome was a success.

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LIST OF ABBREVIATIONS

AAP	American Academy of Pediatrics
AD	Atopic Dermatitis
AHRQ	Agency for Healthcare Research and Quality
AVS	After Visit Summary
BPA	Best Practice Advisory
CDS	Clinical Decision Support
COI	Conflict of Interest
CRIF	Consolidated Framework for Implementation Research
CST	Clinical Support Technician
DNP	Doctor of Nursing Practice
EMR	Electronic Medical Record
EBI	Evidence-Based Intervention
EBP	Evidence-Based Practice
EPI	Early Peanut Introduction
IRB	Institutional Review Board
LEAP	Learning Early About Peanuts
NP	Nurse Practitioner
OFC	Oral Food Challenge
PCP	Primary Care Provider
PDSA	Plan Do Study Act
QI	Quality Improvement
RCT	Randomized Control Trial

sIGE	Serum Immunoglobulin E
SPCC	Statistical Process Control Chart
SPT	Skin Prick Test
UNC	University of North Carolina
WCC	Well Child Check
WIC	Special Supplemental Nutrition Program for Women, Infants, and Children

CHAPTER 1: EARLY PEANUT INTRODUCTION IN INFANTS TO PREVENT PEANUT ALLERGY: IMPROVING GUIDELINE ADHERENCE THROUGH EMR STANDARDIZATION

Problem Description

Peanut allergy is a common problem with significant morbidity amongst children. It affects 2% of the population in western nations (Lieberman et al., 2020). The prevalence of peanut allergy in children has increased by more than 50% from 2001 to 2017 in the United States (Togias et al., 2017). Only one in five children will outgrow peanut allergy (Cosme-Blanco et al., 2020), and allergic reactions to peanuts are the leading cause of anaphylaxis in children (Du Toit et al., 2015). Peanut allergy correlates with higher rates of accidental exposure, more severe allergic reactions, and approximately 7-14% of peanut-allergic individuals experience accidental ingestions each year (Lieberman et al., 2020). Families living with peanut allergies can suffer financial and psychological burdens, including needing to shop at expensive specialty stores for allergen-safe food, bullying at schools, friction in caregiver relationships, limitations in extracurricular activities, and the cost of epinephrine auto-injectors (Bilaver et al., 2016).

The atopic march refers to the typical progression of allergic diseases, often beginning with eczema in infancy (Wahn, 2015). Food sensitization is associated with moderate and severe eczema, also referred to as atopic dermatitis (AD), in the first year of life (Wahn, 2015). Early exposure to allergens through disrupted skin barriers, as in infants with eczema, can lead to the development of food allergies (Larson et al., 2017).

Strong evidence from the Learning Early About Peanut (LEAP) study suggests that early peanut introduction (EPI) for infants after four months of age but before 12 months can reduce

the risk of developing peanut allergy (Du Toit et al., 2015; Fleischer et al., 2021; Obbagy et al., 2019; Togias et al., 2017). However, addendum guidelines released in 2017 in response to the pivotal LEAP study have not been widely adopted in primary care settings. Six years after the LEAP study, clinicians, caregivers, and policy-makers struggle to optimize the guidelines' implementation strategies (Abrams et al., 2021).

Therefore, the purpose of this quality improvement (QI) project was to improve adherence to EPI guidelines by primary care providers (PCPs) during 4, 6, and 9-month well-child check (WCC) encounters. To facilitate guideline adherence, the QI team designed and implemented work protocols, electronic medical record (EMR) prompts, and educational patient handouts.

Available Knowledge

Search Strategies

Through the University of North Carolina (UNC) Health Sciences Library, the project lead searched the following electronic databases on 22Aug2021: PubMed, CINAHL, and Embase. The project lead used boolean modifiers such as 'AND' and 'OR' to search combinations of key phrases and concepts including, but not limited to the following: Peanuts, peanut hypersensitivity, atopic dermatitis, eczema, guidelines, adherence, non-adherence, compliance, implementation, quality improvement, and electronic health. Research studies published in a language other than English were excluded. The project lead set dates between 2015 and 2021 because the LEAP study, randomized control trial (RCT) publication that prompted the addendum guidelines' revision, was in 2015. The total number of results retrieved from the three databases was 133. The project lead manually reviewed references within the resulting articles to determine appropriateness for inclusion. Eighteen articles were identified as duplicates and removed. Titles and abstracts/introductions from the remaining 115 articles were screened for relevance to the research inquiry. Fifteen articles were included in this review.

Themes Identified

Overall, the body of evidence in the 15 articles is high quality. When synthesized, results across the 15 studies were consistent, and common themes were identified. These common themes are used as organizers for the review below.

Screening High-Risk Infants is Costly. The overall cost, time, resource utilization, and practice infrastructures are documented barriers to carrying out the addendum guidelines for screening high-risk infants (Abrams et al., 2020; Greenhawt et al., 2018; Koplin et al., 2016). While Abrams et al. (2020) argue the data supporting this claim are insufficient, there is concern that guideline implementation is not cost-effective. However, a strong counterargument encouraging providers to screen the most at-risk infants (those with severe eczema and/or egg allergy) will reduce the volume of infants needing guidance, testing, or referral.

The caveat to cost-conscious screening is the awareness that excess cost and resources should only occur if infants are 'over screened.' Since the guidelines maintain that severe eczema is rare, carefully selecting the infants who most need screening will lower costs (Abrams & Chan, 2018; Koplin et al., 2016; Togias et al., 2017). Lastly, Togias et al. (2017) argue that cost-effective measures such as peanut serum immunoglobulin E (sIgE) testing in at-risk infants and appropriate adherence to guidelines for EPI will reduce costs incurred by the individuals and the healthcare system in the long run. Preventing peanut allergy, per the guidelines, reduces the incidence of anaphylaxis to peanuts and the costs associated with long-term disease management.

Caregiver and Provider Hesitancy Around EPI Screening. Unlike the aforementioned cost-associated barriers to guideline adherence, some concerns over EPI center around caregiver and provider hesitancy to have young infants undergo screening tests and procedures. A general lack of provider confidence, time, willingness, knowledge around screening procedures, and

interpretation of sIgE, skin prick tests (SPT), and oral food challenges (OFC) to peanut are common throughout the literature (Abrams & Chan, 2018; Abrams et al., 2020; Pitt et al., 2020).

A frequent concern expressed by PCPs and parents is the fear of allergic reactions in young infants, but caregiver buy-in is vital in adhering to home peanut feeding, and providers need to be prepared to offer this support (Greenhawt et al., 2018; Gupta et al., 2020).

Interestingly, Lai & Sicherer (2019) identified a discrepancy between parental reports of little hesitancy around EPI and provider perception of great parental hesitancy. The implications of this may support the belief that some providers are overcautious and hesitant to screen. Still, parents may prefer testing before introduction, mainly if other children in the home are food allergic (Abrams & Chan, 2018).

Risk of 'Screening Creep' to Other Foods Not Included in the Guidelines. The concept of 'screening creep' is another casualty in EPI screening. It refers to either a provider or parental inquiry about potential allergies to foods other than peanut, none of which should be screened or tested before introduction. Well-meaning providers risk misusing screening data for clinical decision-making. It may be tempting to order sIgE levels to foods other than peanuts before dietary introduction. A combination of curiosity and fear takes hold of the dialogue between parents and providers. This practice is not indicated in the guidelines and can become a slippery slope of medicalizing food introduction into an infant's diet and is not recommended (Abrams & Chan, 2018; Hildebrand et al., 2017).

Furthermore, since the addendum guidelines publication, increased testing for peanut and other foods in non-high-risk infants may contribute to higher food allergy diagnosis rates. The implications of this practice are unintended consequences of the overall delayed introduction of

allergenic foods, false positives upon testing, and unnecessary avoidance of allergens (Lo et al., 2021).

Some experts share concerns that providers may interpret sensitization to peanut, represented by either positive SPTs or sIgE levels, as diagnostic of peanut allergy. The implications of making this assumption are incorrectly assigning a diagnosis of peanut allergy to a child who is not peanut-allergic, which carries a lifelong burden (Abrams et al., 2020). In contrast, a peanut OFC is the only confirmatory test to diagnose or exclude peanut allergy.

Additionally, over-testing other foods already tolerated in a child's diet can have a detrimental impact, resulting in removing a tolerated food from the diet based on sIgE or SPT. PCPs who assist with EPI evaluation should never order testing for tolerated foods in clinical practice (Abrams et al., 2020).

Generalized Knowledge Gaps. Other barriers to guideline adherence identified in the body of evidence were more generalizable knowledge gaps. Important findings from multiple survey instruments showed many providers do not fully understand how to implement the guidelines. Allergists adhere to EPI guidelines more frequently than PCPs, and caregiver buy-in, along with shared decision-making, is needed for successful follow-through of ongoing peanut consumption at home (Abrams et al., 2020; Abrams et al., 2019; Greenhawt et al., 2018; Lai & Sicherer, 2019). As will be detailed in a subsequent theme, inconsistent documentation of eczema remains a gap in primary care practice settings (Shea et al., 2018).

Suggestions to overcome barriers to adherence include feasibility planning for EPI guidance, supplying teaching materials for providers and parents, and incorporating EMR prompts for EPI screening. Additionally, adopting 'practice champions' to foster QI efforts can facilitate change (Gupta et al., 2020; Hespe et al., 2018; Koplin et al., 2016). One study showed

statistically significant differences in adherence to guidelines in primary care settings that used clinical decision support (CDS) tools, EMR prompts and order sets for evaluation of peanut allergy risk, and best practice alerts (BPAs) for infants with eczema and/or egg allergy (Bilaver et al., 2019).

Screening High-Risk Infants Perceived as Important to the Prevention of Peanut Allergy. Despite identifying barriers and limitations to addendum guideline implementation and adherence, many articles mentioned the importance of screening high-risk infants to reduce the incidence of peanut allergy per the addendum guidelines (Abrams & Chan, 2018; Bilaver et al., 2019; Du Toit et al. 2015; Greenhawt et al., 2018; Gupta et al., 2020; Hildebrand et al., 2017; Koplin et al., 2016; Lai & Sicherer, 2019; Pitts et al., 2020; Shea et al., 2018). Infants can have severe allergic reactions to allergens. Hence, home introduction or supervised feedings in a specialty setting following sIgE testing provide safe environments for EPI (Abrams et al., 2020; Bilaver et al., 2019).

While PCPs and allergists perceive preventing peanut allergy as important, there is a difference of opinion, mainly stemming from knowledge gaps, despite the explicit criteria in the guidelines (Togias et al., 2017), regarding how to handle high-risk infants in terms of procedural testing and referrals (Abrams et al., 2019). Gupta et al. (2020) collected responses from PCPs regarding what they would do under three different scenarios, one of which was high-risk infants. The results had wide variability, with deviations from the guidelines. Because of these findings, it is important to reiterate and discuss the different risk categories for the development of peanut allergy with PCPs (Pitts et al., 2020).

Screening Should be Done in Primary Care Settings. The success of peanut allergy prevention in infants is highly dependent on PCPs incorporating the addendum guidelines into

routine WCC encounters at 4 and 6 months of age (Bilaver et al., 2019; Lai & Sicherer, 2019). Several authors collected data on current primary care practices regarding guideline adherence. Still, all conclude that primary care settings are the first line of defense in identifying at-risk infants. Even infants with mild to moderate eczema, though not in the high-risk group for the development of peanut allergy, should be given guidance on EPI. (Abrams et al, 2019; Gupta et al., 2020; Hidebrand et al., 2017; Pitts, 2020).

While Gupta et al. (2018) pointed out that infrastructure may limit screening procedures such as SPTs and OFCs in the primary care setting, the guidelines acknowledge this limitation. Instead, the guidelines suggest that PCPs consider obtaining sIgEs to peanut as a first step in the screening process for infants with severe eczema and/or egg allergy (Hildebrand et al., 2017; Togias et al., 2017).

Consistent Classification of Eczema Severity in Infants. Accurate eczema classification determines the risk level for peanut allergy and subsequent steps in the guidelines' work protocol. A recurring, identifiable barrier to appropriately screening high-risk infants for peanut introduction is the classification system used to evaluate eczema as mild, moderate, or severe. Though Du Toit et al. (2015) showed infants with severe eczema are at the highest risk of developing peanut allergy, the SCORing Atopic Dermatitis (SCORAD) and the Eczema Area and Severity Index (EASI) instruments used in this RCT for eczema grading are complex and not feasible for routine clinic adoption, as noted by Shea et al. (2018) and Abrams et al. (2020). However, the addendum guidelines provide a more streamlined definition of 'severe eczema' as follows: 'Persistent or frequently recurring eczema with typical morphology and distribution assessed by a provider; the frequent need for topical corticosteroids, calcineurin inhibitors, or other anti-inflammatory agents despite emollients' (Togias et al., 2017).

It is also worth noting that Abrams & Chan (2018) and Koplin et al. (2016) found flaws with classifying eczema dependent on when a provider is evaluating the infant's skin, pre- or post-intervention with topical steroids and emollients. Suppose an infant initially presents with severe eczema at the 4-month WCC, but at the 6-month WCC, the same infant's physical exam reveals mild eczematous features due to good compliance with topical steroid use. Failure of the provider to document eczema severity at the 4-month WCC could mean misclassifying the infant as low-risk instead of high-risk.

The last consideration regarding eczema classification is how parents self-report their child's eczema. Hildebrand et al. (2017) point out that parents' use of 'severe' terminology to describe their child's eczema can lead to overdiagnosis of severe eczema. The downstream effects result in more infants requiring evaluation for peanut introduction, worsening the wait to receive a specialty allergy appointment. Therefore, PCPs need to adopt a more unified approach to eczema classification.

The Window of Opportunity to Screen. The addendum guidelines state that infants should be evaluated for EPI at 4 to 6 months of age (Togias et al., 2017). The LEAP study showed that peanut avoidance was associated with a higher frequency of peanut allergy than peanut consumption (Du Toit et al., 2015). The clinical implication of this lost opportunity to introduce peanut is that infants may miss a critical window before peanut sensitization solidifies into confirmed peanut allergy for some.

A common thread in the literature is that providers should avoid delays in recommending EPI for appropriately aged infants and avoid failing to identify at-risk infants. In particular, avoiding delays between identifying at-risk infants and evaluation for introduction has likely the best outcomes for peanut tolerance (Abrams & Chan, 2018). It is important to carefully screen

those most at-risk, refer only those meeting criteria for specialty evaluation, and gain confidence to make home introduction recommendations for low-risk infants. Funneling the correct infants for further evaluation will decrease the bottleneck of waiting time to get into allergy offices, as this window for the introduction of peanut is critical.

Hildebrand et al. (2017) and Abrams et al. (2020) argue that initiating unnecessary testing in low-risk infants may result in delayed peanut introduction as parents await allergy referral appointments to undergo sIgE, SPT, and OFCs. The PCP's role in screening infants during WCC encounters with sIgE draws can reduce the wait time for allergy visits. However, Abrams et al. (2020) suggest that screening might speed up introduction because the infants' families feel a sense of reassurance having undergone screening. However, many trials reported introducing peanuts up to 11 months of age may still protect against peanut allergy. While it is probably okay to have a month or two grace period for evaluation, high-risk infants benefit from introduction by 11 months of age (Abrams & Chan, 2018).

Rationale

Guidelines published in 2017 recommend EPI in the first year of life for infants, particularly infants identified as high-risk (those with severe eczema and/or egg allergy). The guidelines define severe eczema as persistent or frequent, with typical morphology and distribution requiring prescription-strength topical corticosteroids, calcineurin inhibitors, or other anti-inflammatory agents despite appropriate emollient use (Togias et al., 2017). More recently, a consensus approach to the primary prevention of food allergy through nutrition maintains that eczema is the highest risk factor for developing IgE-mediated food allergies (Fleischer et al., 2021).

The 2017 addendum guidelines replace the 2008 guidelines from the American Academy of Pediatrics (AAP), which recommended delaying the introduction of allergenic foods, including

peanuts (Greer et al., 2019). The LEAP study found an 86.1% relative reduction in the prevalence of peanut allergy between the peanut consumption group and the peanut avoidance group. Infants randomized to consume peanuts regularly, starting around 6 months of age, through 60 months of age, had lower rates of peanut allergy than infants randomized to delay the introduction of peanut until 60 months ($p<.001$) (Du Toit et al., 2015).

In a retrospective chart review of encounters at UNC from 2017 to 2020 for infants under 12 months of age presenting for either a WCC or eczema-focused visit, researchers found that 0.8% of those clinical encounters had documentation of EPI guidance (Iglesia et al., 2021). EPI guidelines have not been widely adopted or standardized at UNC primary care offices during WCCs during the first year of life. This QI project proposed to develop and implement the following to improve and facilitate EPI guideline adherence:

- A standardized work protocol regarding EPI guidance
- Modifications to EMR templates and smart lists at 4, 6, and 9-month WCC encounters.
- A peanut home introduction handout for caregivers of infants.

Eczema severity and clinical history prompted providers to follow one of two pathways in the work protocol: 1) Recommend home introduction of peanut at around 4-6 months of age for infants with absent or mild-to-moderate eczema; or 2) Order sIgE levels to peanut for infants with severe eczema and/or egg allergy. Peanut sIgE levels $\geq$0.35 ku/L (positive result) prompted providers to refer to UNC Pediatric Allergy for urgent evaluation. Furthermore, peanut sIgE levels <0.35 kU/L (negative result) prompted provider follow-up to recommend peanut introduction at home at 4-6 months but before 12 months of age to prevent missing a critical window of potential allergy development.

This QI initiative occurred at the UNC Children's Primary and Specialty Clinic. The clinic's previous successes with interdisciplinary team collaboration, use of the Model for Improvement, and PDSA (plan-do-study-act) cycles with other QI initiatives support its use for this project.

Improving adherence to the 2017 addendum guidelines for the prevention of peanut allergy requires a commitment from individual primary care offices, providers, nurses, and parents of young infants for whom EPI may be beneficial. Further dissemination and implementation of the guidelines require outcome-based frameworks to aid in the knowledge translation process (Abrams et al., 2021; Fleischer et al., 2021).

Framework

The Model for Improvement is a framework to help form teams and define project aims, measures, and changes. Tests of change occur through multiple PDSA cycles throughout QI initiatives. These cycles focus the team's efforts on devising the intervention (plan), carrying out tests on small scales (do), analyzing data for comparison against predictions and aims (study), and either modifying the test, increasing the sample size, or changing other variables before initiating the next cycle (act) (Institute for Healthcare Improvement [IHI], n.d.; Langley et al., 2009).

Additionally, the team used literature-supported translation methods in conjunction with the Model for Improvement framework. Implementing the EMR templates, which guided providers in evaluating eczema, and the work protocol prompts for the next steps following eczema classification are examples of CDS tools that support QI initiatives (White et al., 2016). A home peanut introduction handout is an example of an instructional design to carry out QI projects.

The guidelines and supporting research convey a sense of urgency to improve adherence to EPI recommendations to prevent the development of peanut allergy in high-risk infants. These guidelines have not been widely adopted at UNC primary care offices during WCCs during the

first year of life. Furthermore, no standardization in identifying at-risk infants during WCCs exists. The supporting body of literature on poor guideline adherence and common barriers justified the need to synthesize and appraise evidence regarding this important pediatric issue to improve guideline adherence and prevent new peanut allergy diagnoses.

Specific Aims

This DNP project aimed to improve adherence to EPI guidelines in infants 4-9 months of age to prevent peanut allergy through a QI initiative. The project targeted the following population: Infants of any race, gender, and ethnicity seen at the UNC Children's Primary and Specialty Clinic in Chapel Hill, presenting for WCC encounters at 4, 6, and 9 months.

The defined aims for this QI initiative were specific, measurable, achievable, realistic/relevant, and timely (SMART Aims). These aim features carry a better chance of successful QI project implementation and achievement of sustained, quality practice change based on a supported body of evidence to improve adherence to EPI guidelines in a primary care setting. Table 1 details the project aims.

Table 1

Project Aims

Aim Type	Description	Baseline to Goal	Timeframe
Primary	Increase mean documentation of clinically appropriate EPI guidance at 4, 6, and 9-month WCCs in patients' EMR	6.7% to 50%	Over 4-month QI initiative
Primary	Increase mean provider adoption of EMR changes evidenced by use of templates, smart lists, and documentation features as intended without deletions or substitutions at 4, 6, and 9-month WCCs	0% to 75%	Over 4-month QI initiative
Primary	Increase mean distribution of home peanut introduction handout in patients' AVS (after visit summary) for infants with no eczema or mild-moderate eczema	0% to 50%	Over 4-month QI initiative
Secondary	Increase provider adoption of standard work protocol evidenced by sIgE peanut orders placed and resulted during 4, 6, and 9-month WCCs for infants with egg allergy and/or severe eczema	0% to 75%	Over 4-month QI initiative

Methods

Context

The UNC Children's Primary and Specialty clinic was the site for implementing this QI project targeting EPI in infants at risk for the development of peanut allergy. The clinic is a satellite clinic of the UNC Healthcare system's medical umbrella. It offers primary care services, including WCC encounters from newborns up to age 21 years, for the surrounding counties of Orange, Durham, Chatham, and Wake and more remote locations across North Carolina.

The clinic staff includes 11 faculty providers, two research fellows, one preventative medicine resident, three chief residents, four nurses, and three clinical support technicians (CSTs). Additionally, the clinic is an academic-based teaching clinic with pediatric residents. Fifty-six first, second, and third-year residents are rotating through the clinic this academic year.

The demographic makeup of the clinic's patient population is broad. Spanish is the preferred language for approximately a quarter of the population. The standard of care at the UNC clinic is to conduct visits with a licensed Spanish interpreter or a provider fluent in medical Spanish. Therefore, providers conduct anticipatory guidance in Spanish or with a Spanish interpreter. The clinic also serves a large population of patients on Medicaid or self-pay (66%) and patients experiencing food insecurity.

The main barrier identified during the clinic's cultural assessment was that WCC encounters are already time-consuming for the providers and staff. Therefore, introducing another screening tool and counseling around EPI needed to be concise, easy to use, and offset by streamlining the overall approach to the conduct of WCCs for young infants.

During a typical month, the clinic conducts an average of 50 WCC encounters for infants 4, 6, and 9 months. Upon initial site evaluation, there were no current prompts, models, or standardized screening tools for EPI in this clinic setting. Thus, discussions between parents and providers about EPI were infrequent and inconsistent. This QI initiative targeted all infants of any race, gender, or ethnicity seen for routine WCC care at the 4, 6, and 9-month encounters.

Interventions

This QI initiative lasted from April 1, 2022, to August 11, 2022. The initiative incorporated CDS tools embedded in the EMR templates for 4, 6, and 9-month WCCs to prompt screening for EPI. The templates for these visits were consolidated and revised by the QI team as a part of pre-implementation planning. Additionally, we placed the project-developed standardized work protocol in the workrooms, easily accessible during provider charting, to prompt the appropriate course of action by the provider regarding EPI.

QI Team. The interdisciplinary QI team members included the DNP student, who served as the project lead. Other team members were the project Chair, who works as a Nurse Practitioner

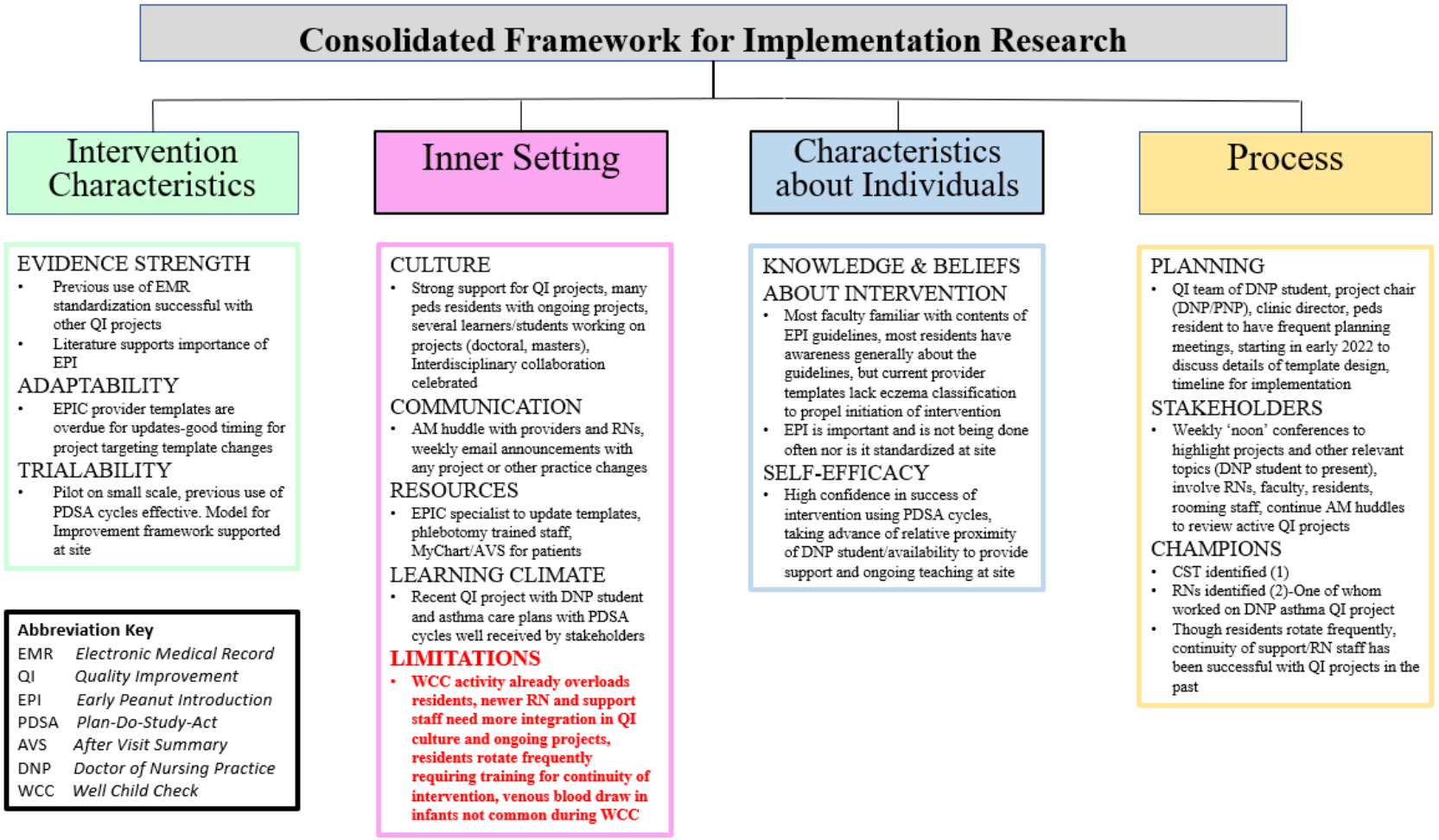
(NP) in the dedicated adolescent medicine area of the clinic. The QI team members with the most interface with the initiative were the clinic Director, full-time faculty members, and pediatric residents conducting the WCC encounters. One of the pediatric residents helped design the work protocol and served as a project champion.

Site Readiness Assessment. Assessing readiness for change is a systematic look into an organization's culture, team structure, motivation for change, and potential limitations to implementing an initiative (U.S. Department of Health and Human Services, 2015). A readiness assessment aims to determine potential barriers to success and allow the QI team or organization to overcome such obstacles before beginning or spreading the QI project (U.S. Department of Health and Human Services, 2015). In preparation for the initiative, the team lead assessed the clinical site for QI readiness using The Consolidated Framework for Implementation Research (CFIR), a practical and accessible structured format to evaluate cultural readiness for QI implementation. The tool embraces, consolidates, and unifies key constructs from published implementation theories (Damschroder et al., 2009).

The results of the site's assessment showed that The UNC Children's Primary and Specialty clinic demonstrates cultural readiness for the QI initiative based on its current team structure and prior successes with QI projects (Figure 1). The organizational structure, resources, and interdisciplinary collaboration have historically embraced the continuous QI model. The team identified barriers to implementation and addressed them in the context section.

Figure 1

Interview Results Using the CRIF to Assess Site Culture and Readiness



Baseline Data Collection. The project lead elicited the assistance of an information technology specialist at UNC to develop a report in UNC's EMR system, EPIC (Appendix A). This reporting feature allowed the project lead to access data specific to the Children's Primary and Specialty clinic and its patients of interest. Before implementing the intervention, the project lead used the EPIC report feature to collect three months of retrospective data, from January 1, 2022, to March 31, 2022, for the following: 1) The number of 4, 6, and 9-month WCC encounters conducted at the clinic; 2) The percentage of these visits where providers documented EPI (any language about 'early peanut introduction, 'peanut allergy,' 'allergy prevention, or similar guidance); 3) The number of sIgE peanut orders placed and collected during these encounters. After three months of implementing the standardized work protocol in the EMR, the researchers collected similar data for the 19 active weeks of the intervention.

Implementation Strategies. Evidence-based interventions (EBIs) are actions used to target factors contributing to health. Researchers refer to methods, tools, or techniques contributing to EBI adoption, implementation, scale-up, or sustainment as implementation strategies. (Leeman et al., 2017). For this project, the implementation strategies to improve adherence to EPI guidelines and this QI initiative included stakeholder engagement, practice facilitation, integration strategies, and PDSA cycles.

Stakeholder Engagement. As a part of the QI readiness assessment, the project lead identified a firm commitment from the clinic Director regarding the importance of EPI and standardizing an approach to implement the guidelines. Other stakeholders for the project included the clinic staff, pediatric residents, the project Chair, and other clinical faculty in practice. Engaging stakeholders is a continuous process targeted through the current climate of QI at the clinic. Ongoing morning staff huddles addressing current QI initiatives are daily

reminders for all stakeholders to prioritize ongoing projects mentally. Additionally, weekly noon conferences for the clinic staff and providers allow a more didactic approach for knowledge dissemination to key stakeholders about important primary care clinic topics. The project lead presented at a resident noon conference and a clinical faculty meeting, the timing of which aligned with the planned launch of the QI initiative and offered an opportunity to engage additional stakeholders.

Practice Facilitation. Primary care practices often lack the resources to invest in infrastructure and training, which are both crucial elements of QI success. While the UNC Children's Primary and Specialty clinic does have a successful model related to QI initiative implementation, it is likely due to its utilization of practice facilitation. Practice facilitation is an implementation strategy to assist clinics with developing capacity for sustained performance of QI interventions. The research literature supports that practice facilitation increases the likelihood of success in QI initiatives, increases provider adherence to evidence-based guidelines, and improves care quality metrics in many clinical settings (Walunas et al., 2021).

Facilitators support practice change by empowering clinic members to be involved in decision-making while creating an environment that promotes continuous improvement through respect, inclusion, and neutrality (Agency for Healthcare Research and Quality [AHRQ], 2013). In following suit with prior successes, the project lead served as the practice facilitator and engaged in activities consistent with its model, such as kickoff meetings, goal setting, maintaining initiative momentum, and planning for sustainability and transfer of project ownership.

***Integration Strategies*.** Integration strategies primarily target determinants at the level of individuals and the inner settings (Leeman et al., 2017). Collective integration strategies for this

QI initiative represented a QI toolkit known as a bundle. They were as follows: EMR changes, home peanut introduction handout, computer tags, printouts of the work protocol in workroom locations, academic detailing, and audit and feedback.

EMR Changes. There were three changes to the clinic's provider template for 4, 6, and 9-month WCC encounters. These changes addressed issues with the previous workflow established during process mapping. The time allotted to providers to conduct these visits was discordant with the time needed to collect a history, perform anticipatory guidance, conduct screening, and perform objective examination. Lack of time to address all developmental, age-appropriate activities is a known barrier to adopting a QI initiative targeted for these visits. Members of the QI team adapted the templates for these WCC encounters in EPIC to remove unnecessary history collection, objective assessments, and anticipatory guidance. The project lead's experience creating and adapting 'smart phrases' and 'smart lists' in EPIC allowed for a seamless rollout of EMR changes for providers adopting the CDS bundle (Appendix B).

Second, for each 4, 6, and 9-month WCC visit template or 'smart phrase' for the associated visit, the QI lead included an anticipatory guidance section for EPI screening around the same template section discussing nutrition. The EPI screening involved multi-select smart lists, including solid food introduction, peanut introduction, and other risk factors for the development of peanut allergy. The template then prompted the provider to select a low, moderate, or high-risk level for the infant related to the development of peanut allergy. Based on the risk stratification, the provider chose from another smart list to guide the family towards home introduction or direct the provider to order a sIgE to peanut. In rare cases, the work protocol prompts the provider to recommend peanut avoidance for concerns that a convincing history of allergic reaction already confirms the diagnosis of peanut allergy.

Third, we modified the EMR template's skin physical exam findings default from 'no rashes, bruising, or lesions' to a specific detailed skin assessment smart list detailing the presence or absence of typical morphologic features of eczema on specified areas of the infant's body. This focus on standardizing and improving eczema classification is essential to adequately stratify infants into the correct risk category for the development of peanut allergy.

Home Peanut Introduction Handout. 'Appendix D' (Appendix C) from the addendum guidelines (Togias et al., 2017) is intended to guide caregivers in executing home introduction of peanut for infants. However, after careful assessment, the QI team determined that these instructions, as written, were too complex and deterred caregivers from attempting home EPI, even if recommended. Therefore, the project lead simplified the instructions for home introduction of peanuts. The project lead removed complicated measurements for preparation in the handout's adaptation.

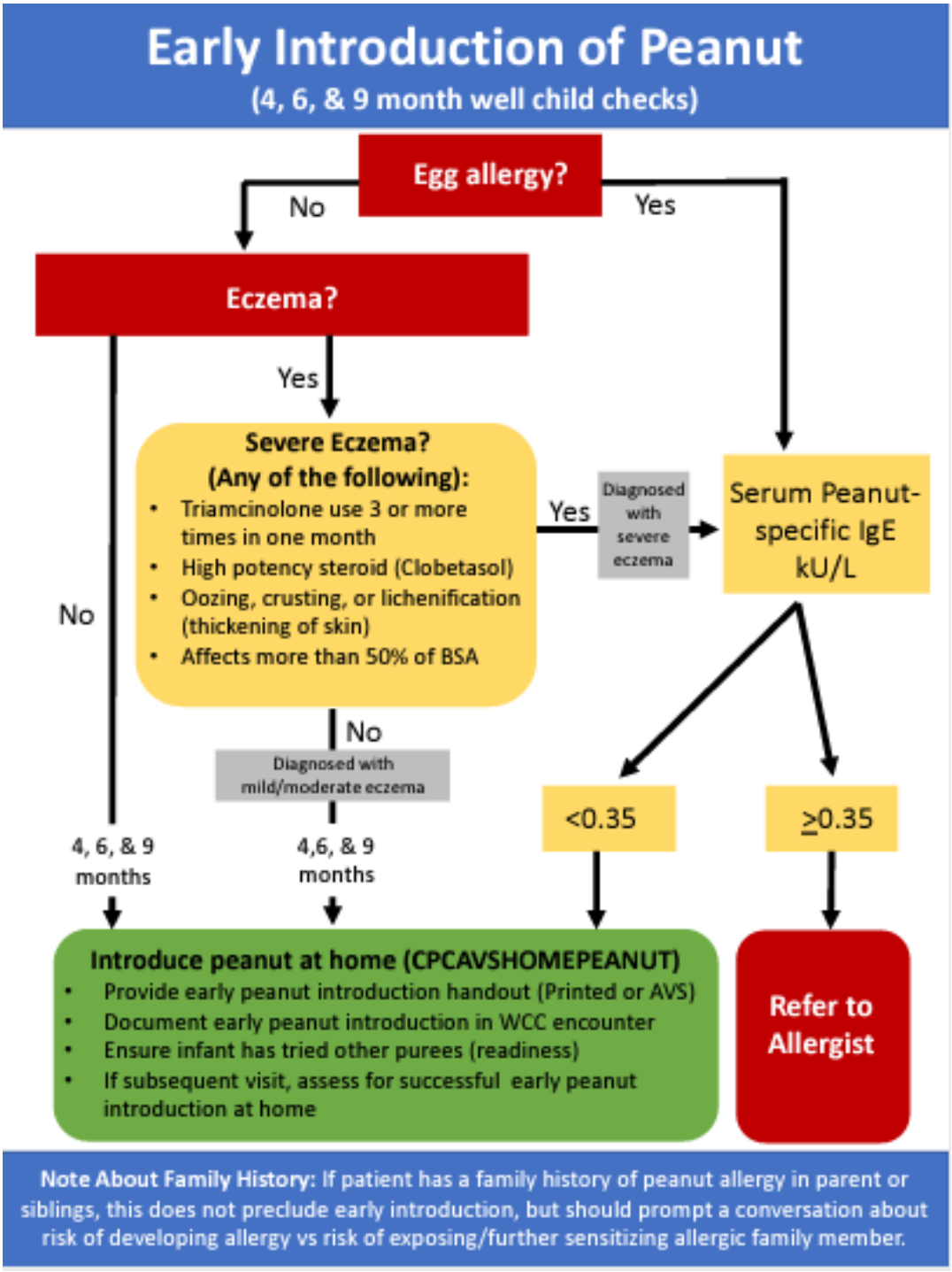
Additionally, the addendum guidelines offer three different types of peanut-containing foods. Still, the team felt the use of peanut butter was most practical and accessible to families, and thus we removed other forms of peanut-containing foods from the handout. The unique supplemental nutrition program known as WIC (Women, Infants, and Children) covers peanut butter, which aids in overcoming barriers to accessing this food. PORCH, a community organization collecting food donations, supplies the clinic with food, including peanut butter, ensuring access to those families without WIC or other assistance. The new handout captures the same safety guidance from the addendum guidelines and simplifies the critical information in the adapted handout (Appendix D). Providers inserted the handout in the patients' after-visit summary (AVS) using the associated smart phrase. The clinic utilized UNC translation services for a Spanish-translated version of the handout, which we implemented after the initial rollout of

the English version to address the population of Spanish-speaking families the clinic serves (Appendix E).

Standard Work Protocol. Because eczema classification is complex, this aspect of standardizing eczema assessment was a joint effort with the pediatric resident (QI team champion). First, the resident developed the portion of the work protocol to help providers correctly classify eczema severity based on physical exam findings, body surface area affected, and mid to high potency topical steroids usage. After that, the eczema classification directed the provider to follow the work protocol for the appropriate EPI guidance. The eczema classification and the EPI guidance resulted in one unified standard work protocol for the clinic providers (Figure 2).

Figure 2

Standard Work Protocol



Academic Detailing. Academic detailing, a process embedded within the practice facilitation model, is peer-to-peer educational outreach. These sessions between facilitators or QI team members can help build stakeholder buy-in with the ongoing QI initiative. The typical flow of academic detailing is as follows: introduction, needs assessment, key messaging, objection handling, and closeout (Knox et al., 2015). The project lead's proximity and access to the UNC Children's Primary and Specialty clinic allowed frequent detailing. The project lead visited the clinic weekly for routine check-ins and during new PDSA cycle changes. Feedback from key stakeholders and those members of the clinic most frequently interfacing with components of the QI initiative allowed for timely PDSA cycle changes to improve the intervention toolkit and minimize difficulties or burdens to the staff utilizing the CDS toolkit.

Audit and Feedback. The QI initiative tailored EPIC reports with chart audits and dashboard metrics and facilitated ongoing, real-time data collection. The project lead summarized the data weekly during the implementation period as a mechanism of feedback for the clinic providers. Results helped determine modifications for subsequent PDSA cycles and praised QI successes in the clinic. The clinic uses a data-driven change model through audits and feedback from other QI initiatives.

PDSA Cycles. As previously discussed, the team used the Model for Improvement as the framework for implementing this QI initiative. One of its main components is the use of PDSA cycles, which cater to the hallmark feature of QI: continuous changes and modifications to improve outcomes (IHI, n.d.; Langley et al., 2009).

Study of the Interventions

In addition to baseline data collection, the project lead compiled data through the tailored EPIC report designed for this QI initiative and conducted chart reviews to cover any gaps missed by running the EPIC report. The Medical Director circulated the data in clinic announcements to

the staff. The charts of interest were those of any 4, 6, and 9-month WCC seen during the intervention period. This process continued through subsequent PDSA cycles. As detailed in the integration strategies, the clinic rolled out updated WCC templates for the visits, embedded with several smart lists and provider prompts. As a result of the intervention, the team collected outcome data of providers' use of templates, smart lists, distribution of home peanut introduction handouts, and documentation of EPI guidance.

Measures

During typical QI initiatives, a family of measures is frequently used to evaluate the impact of multiple changes to an existing system. These include outcome, process, and balancing measures (IHI, n.d.). As previously stated, the team included infants of any race, gender, or ethnicity seen at the Children's Primary and Specialty care clinic for 4, 6, or 9-month WCC encounters. Table 2 details this QI initiative's outcome, process, balancing measures, clinical significance annotation, and planned analysis instruments.

Table 2

Project Measures

Measure Type	Description	Measure	Significance	Analysis
Outcome	EPI guidance from providers to patient caregivers	Mean percentage of documentation of clinically appropriate EPI guidance at 4, 6, and 9-month WCCs in patients' EMR	Measurement of QI initiative on provider behavior	Statistical Process Control Chart (SPCC) with statistical significance using Shewhart rule for Significance (McQuillan et al., 2016)
Outcome	Distribution of home peanut introduction handout for low-risk infants	Mean percentage of expected home peanut introduction handout inserted in AVS for infants with no eczema or mild-moderate eczema	Measurement of QI initiative on provider behavior	SPCC with statistical significance using Shewhart rule for Significance (McQuillan et al., 2016)
Process	Provider adoption of work protocol	Percentage of sIgE peanut orders placed and resulted during 4, 6, and 9-month WCCs for infants with severe eczema and/or egg allergy	Measurement of QI initiative on provider behavior	Descriptive analysis
Process	Provider adoption of revised 4, 6, and 9-month WCC templates and smart lists	Mean percentage of provider use of templates, smart lists, and documentation features as intended without deletions or substitutions at 4, 6, and 9-month WCCs	Measurement of QI initiative on provider behavior	SPCC with statistical significance using Shewhart rule for Significance (McQuillan et al., 2016)
Balancing	EPIC report of 4, 6, and 9-month WCCs conducted during intervention	Weekly average number of 4, 6, and 9-month WCCs conducted during intervention	Measurement of QI impact on WCC compliance	Independent t-test to assess statistically significant differences in the number of 4, 6, and 9M WCC encounters before and during QI initiative

Balancing	Patients receiving a 6-month DTaP vaccine (expected)	Rate of vaccination for DTaP at 6 months of age (EPIC dashboard data)	Measurement of QI impact on immunization compliance	Descriptive analysis
Balancing	Documentation of visit length in EMR (EPIC data report)	Average visit length (min) for 4, 6, and 9-month WCCs	Measurement of QI impact on length of provider-parent interaction	Independent t-test to assess statistically significant differences in mean visit duration (min) before and during QI initiative

Analysis

Data analysis for this QI initiative utilized SPCCs for outcome and process measures. These tools are more sensitive than run charts, offer additional rigor with control limits and mean lines, and accurately predict future performance. Analysis of control charts included observing the Shewhart Rules in determining clinical and statistical significance. This analysis methodology is well-suited to QI measures analysis. It plots data over time, allows for annotation during time points of implemented change, anchors baseline data as a point of reference for time zero, and reflects PDSA cycles (McQuillan et al., 2016). There were six PDSA cycles throughout the project (Table 3). The project lead used QI macros for Excel (KnowWare International Inc., n.d.) to generate charts and analyze data based on how they fell around control limits and the mean. The team leader updated data collection tools with the EPIC report feature to collect the team's data points of interest. The project lead also collected data on balancing measures using the report designed for this project.

Analysis of balancing measures used independent 2-tailed t-tests to assess for differences in variables at baseline compared to the intervention. Results without statistically significant differences indicated our project did not disrupt the established clinic workflow for these visits.

Table 3

PDSA Cycles

Date	PDSA Cycle	Changes to Improve Outcomes
4/1/22-4/28/22	#1	Clinic residents and faculty piloted the EMR templates and smart lists/phrases for user and logic errors Minor adjustments to smart phrase logic and usability in response to piloting feedback
4/29/22-5/19/22	#2	Project lead provided education to residents and faculty on the background of peanut allergy, LEAP guidelines, and QI project CDS toolkit and aims
5/20/22-6/2/22	#3	Project lead launched the approved EMR templates and CDS tools for two uninterrupted weeks to allow interface with the smart lists/phrases, home peanut introduction handout, and standard work protocol by multiple providers in the clinic
6/3/22-6/16/22	#4	UNC interpreter services translated the home peanut introduction handout into Spanish for AVS Modified work protocol to tighten classification of 'severe' eczema to exclude recurrent hydrocortisone use after feedback from faculty providers Expanded EMR accessibility to home peanut introduction handout through the EMR permissions feature
6/17/22-7/7/22	#5	Project lead visited the clinic weekly to answer questions and boost engagement with the project by providing candy and printed peanut allergy comic strips Laminated computer tags with visual text reminders of smart phrases for the English and Spanish home peanut introduction handout to increase distribution in AVS
7/8/22-8/11/22	#6	Placed in-text reminder embedded in the LEAP risk smart phrase/list section reminding provider to put home peanut introduction handout in the patient AVS for low to moderate-risk infants

Ethical Considerations

The team lead submitted the project to UNC's Institutional Review Board (IRB) for approval and listed QI team members as study personnel before beginning baseline data collection or implementation of the QI initiative. The IRB found no conflicts of interest (COI) during its review. While the IRB considers children a vulnerable population, this QI initiative did not seek new knowledge through original research. Instead, the QI initiative targeted better implementation of existing guidelines around EPI meant to reduce the incidence of peanut allergy in this population. Thus, the UNC IRB determined this QI initiative did not need further IRB approval.

Results

Baseline Data

During the baseline period, the clinic conducted 134 WCC encounters for 4, 6, and 9-month-old infants between January 1, 2022, and March 31, 2022. The average in-room time was 62 minutes, and DTaP vaccination rates for the 6-month WCC encounters were 100%. Providers documented EPI guidance during nine (6.7%) of these visits. Providers did not order sIgE levels to peanut in infants with severe eczema (no documented egg allergy at these encounters). Home peanut introduction handouts and smart lists/phrases were unavailable during baseline data collection.

Post-Implementation Data

During the intervention period, the clinic conducted 158 WCC encounters for 4, 6, and 9-month-old infants between April 1, 2022, and August 11, 2022. Providers documented EPI guidance during 89 (56.3%) of these visits, distributed the home peanut introduction handout in the AVS at 33 expected visits (34.4%), adopted the EMR changes for 76 (48.1%) visits, and

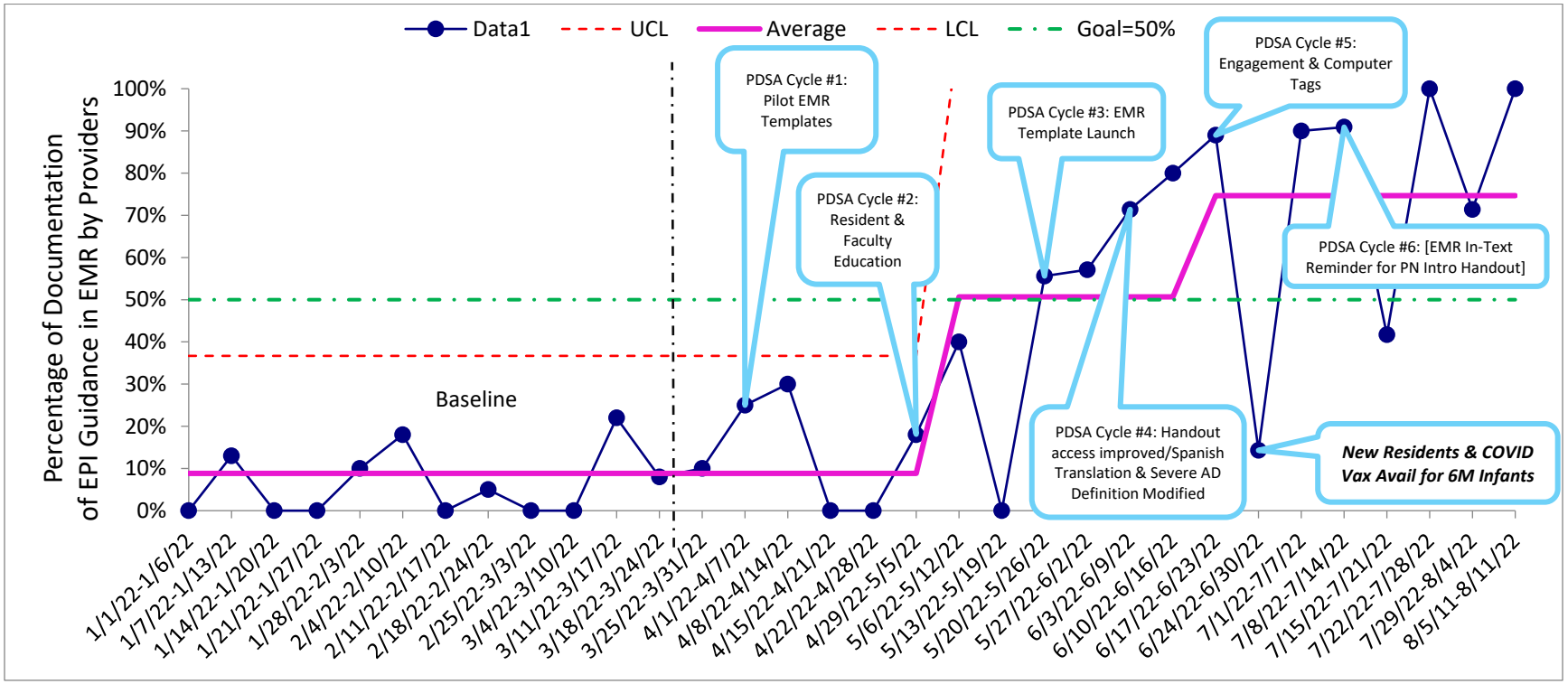
ordered one sIgE level to peanut for an infant with severe eczema. The average in-room time was 63 minutes, and DTaP vaccination rates for the 6-month WCC encounters were 100%.

Data Analysis

Outcome Measures. ***Documentation of Clinically Appropriate EPI Guidance at 4, 6, and 9-Month WCCs in Patients' EMR.*** Over the 19 weeks of the intervention, providers documented appropriate EPI guidance 56.3% of the time (n=89) compared to 6.7% (n=9) documentation during the 13 weeks of baseline data collection. Using the test of two proportions, these differences are statistically significant ($p<.001$). Using the Shewhart Rule for significance and SPCC, the mean documentation of this measure shifted twice from 8.8% to 50.7% during PDSA cycles #2-4 and again to 74.7% during PDSA cycles #5-6 (Figure 3). The significant shifts of the control line (mean) showed improvement in this measure and exceeded the project's 50% mean EPI documentation goal.

Figure 3

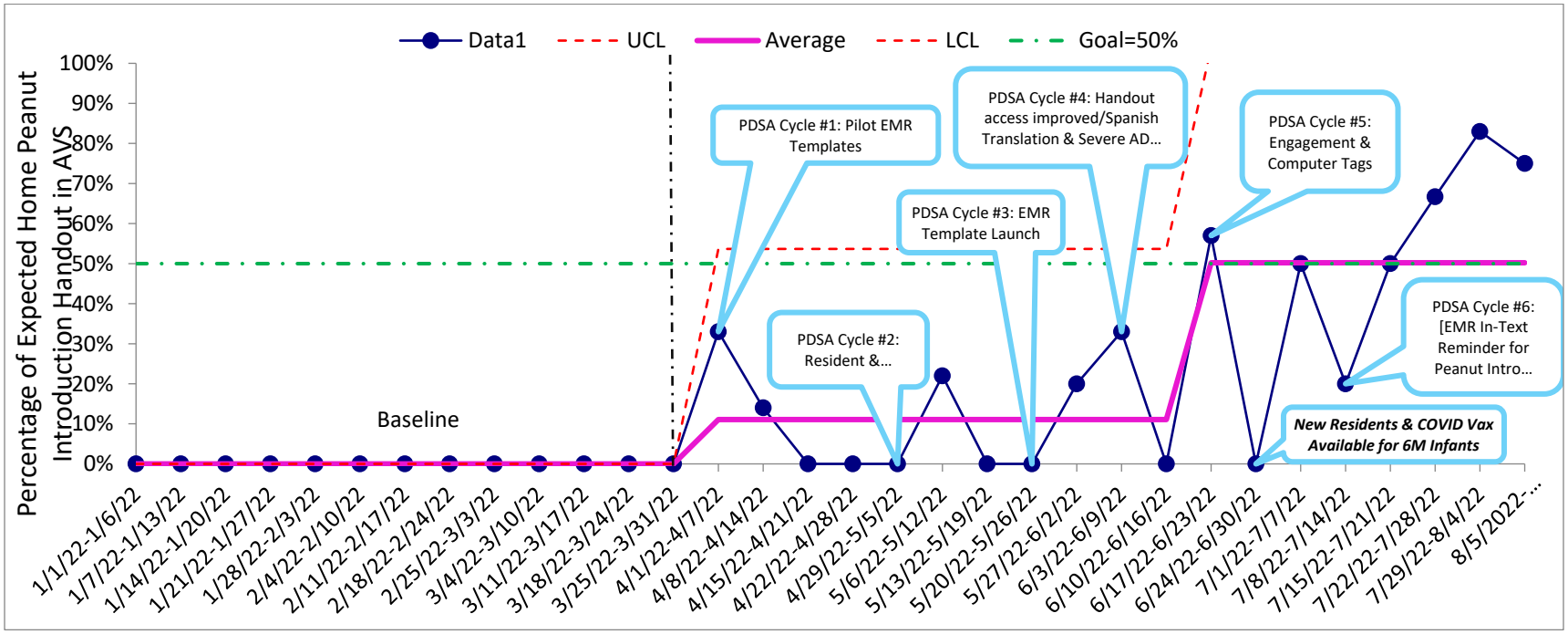
Percentage of Documentation of EPI Guidance in EMR



Providing Home Peanut Introduction Handout in AVS for Infants with no Eczema or Mild-moderate Eczema. Over the 19 weeks of the QI project, providers inserted the home peanut introduction handout for 33 (34.4%) infants with no eczema or mild-moderate eczema at 4, 6, and 9-month WCCs when we expected providers to distribute the handout compared to 0% when the handout was not available during baseline data collection. According to the standard work protocol, the handout would not be expected for infants not yet developmentally ready for purees/solids. The handout would also not be expected for infants already eating peanut. Using the Shewhart Rule for significance and SPCC, the mean distribution of the home peanut introduction handout into the patient AVS shifted twice from 0.0% to 11.1% during PDSA cycles #1-4 and again from PDSA cycles #5-6 to 50.2% during the QI project (Figure 4). Shifts in the mean showed statistically significant improvement in this measure, and we met our goal of 50% mean handout distribution for expected visits.

Figure 4

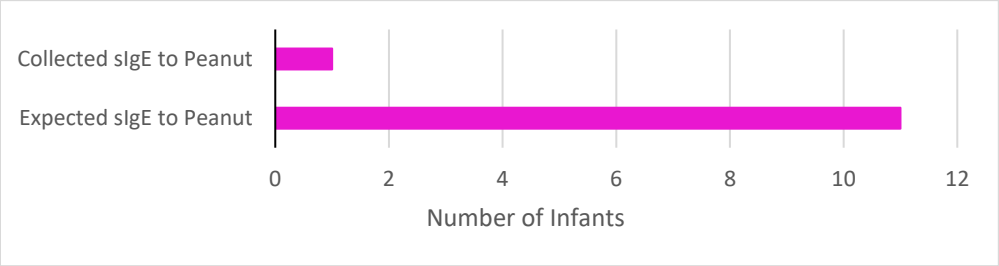
Percentage of Expected Home Peanut Introduction Handouts in AVS



Process Measures. ***Serum IgE to Peanut Orders Placed and Resulted During 4, 6, and 9-Month WCCs for Infants with Severe Eczema and/or Egg Allergy***. During the QI project, 11 infants met the work protocol criteria to have a sIgE to peanut drawn. Of these infants, one received a sIgE draw to peanut (9.1%), as shown in Figure 5, and the provider placed the home peanut introduction handout in the patient's AVS after peanut sIgE (<0.35 kU/L) was negative. In the other ten infants, providers documented exam findings consistent with the classifications of severe eczema according to the standard work protocol or topical steroid use consistent with severe eczema according to the work protocol.

Figure 5

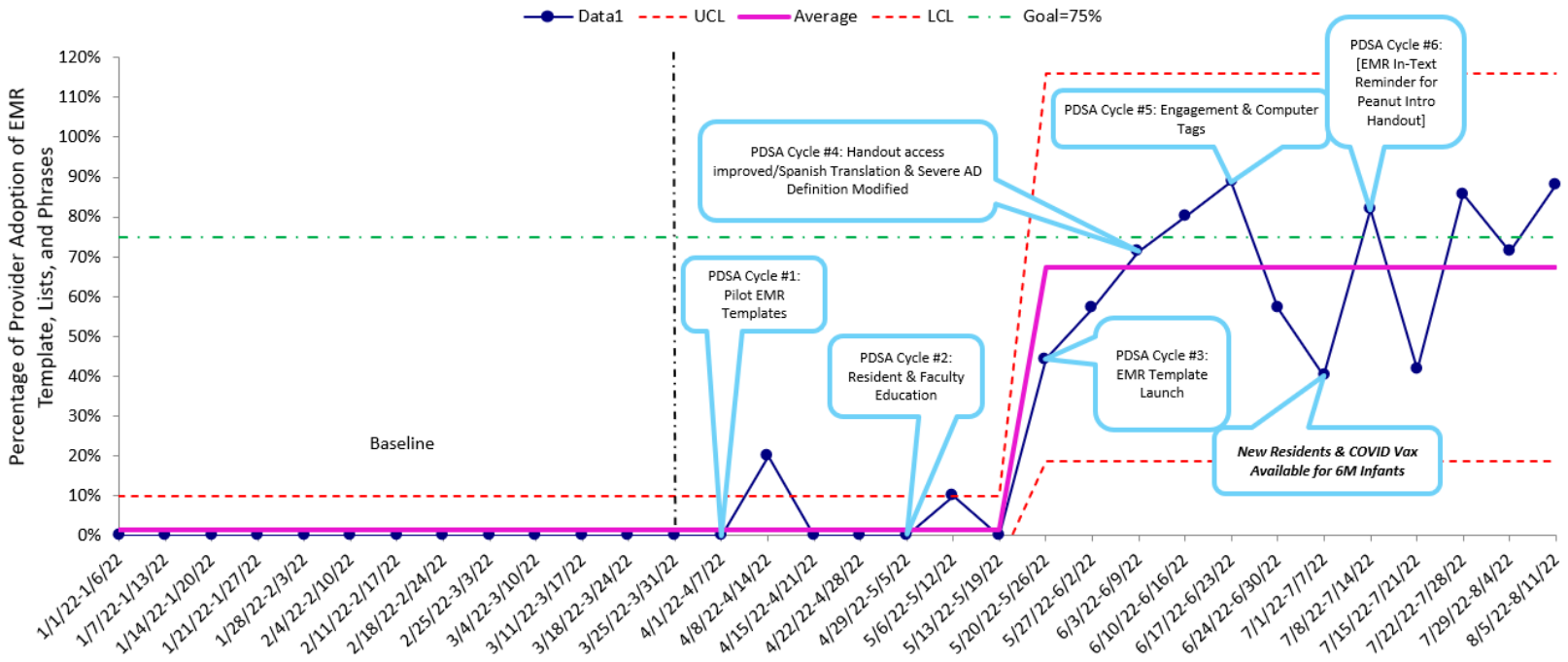
Serum IgE to Peanut in Infants with Severe Eczema or Egg Allergy



Use of Templates, Smart Lists, and Documentation Features as Intended Without Deletions or Substitutions at 4, 6, and 9-Month WCCs. Over the 19 weeks of the intervention, providers adopted the EMR templates, smart lists, and phrases as intended for 76 (48.1%) of the 158 WCCs at 4, 6, and 9 months as compared to 0% when the templates, smart lists, and phrases were not available during baseline data collection. Using the Shewhart Rule for significance and SPCC, the mean use of the EMR templates, smart lists, and phrases shifted from 1.5% to 67.3% during the QI project (Figure 6). Though this fell short of our goal of 75% adoption, the shift in the mean was statistically significant and showed outcome improvement.

Figure 6

Percentage of Provider Adoption of EMR Templates, Smart Lists, and Phrases



Balancing Measures. There were 134 WCC encounters for 4, 6, and 9-month-old infants during baseline data collection spanning 13 weeks, and 158 of the same visit type during the QI project spanning 19 weeks. The results indicate our initiative did not negatively impact the existing workflow procedures in place at the clinic. There were no significant changes to balancing measures from baseline through implementation, as shown in Table 4.

Table 4

Balancing Measures at Baseline and Project Implementation

	Baseline	QI Project	p-value*
DTaP Vaccination 6-month WCC	100%	100%	N/A
AverageTime In-Room (minutes)	62	63	.80
Weekly Avg. # of 4, 6, 9-month WCC encounters	10	8	.15

* Obtained using 2-tailed, independent t-test

Discussion

Using QI methodology and interprofessional collaboration for this QI project, we improved measures aimed at EPI in infants and preventing peanut allergy. The combined use of a standardized EMR bundle of CDS tools and concurrent engagement, facilitation, and feedback to the staff and providers conducting the targeted WCC encounters helped achieve project aims. Completing the QI project in an academic setting where QI and evidenced-based practice is broadly adopted and supported contributed to its success.

Unlike the other measures evaluated with SPCCs, in which project-specific tools were unavailable during baseline data collection, discussion of EPI guidance under the 2017 guidelines is a reasonable expectation in the primary care setting. Given the rationale for our project was that implementation of these guidelines was low, this particular outcome measure's

improvement from 6.7% to 74.7% throughout the project shows the positive impact of our intervention.

These two CDS tools were unavailable before the implementation on April 1, 2022. Notably, the control lines for both measures, adoption of smart phrases, templates, lists, and the home peanut introduction handout were zero during the baseline portion of the data represented. Not using the tools does not indicate poor compliance by providers.

For the measures analyzed with SPCCs, we exceeded our goal of 50% mean documentation of EPI guidance and met our goal of 50% mean distribution of the handout in the AVS. We fell short of our goal for mean provider adoption of the templates and smart lists by less than 10%, but the measure improved from baseline with a statistically significant shift in the mean.

Particular strengths of this QI project were the ease and efficiency of running the tailored EPIC report to capture these targeted infants and corresponding visits. Though the project lead still conducted individual chart audits, the EPIC report streamlined this process. It allowed for analysis of large sample sizes between WCCs during baseline and the project (n=292).

Additionally, despite changes to conduct and content of the 4, 6, and 9-month WCC encounters, other necessary balancing measures such as vaccination, overall time in the room, and the total number of visits were not significantly or negatively impacted by the project.

Other published QI work aiming to improve guideline adherence for EPI discusses projects that did not use EMR bundles. Two QI projects focused on improving PCP guideline adherence at infant WCC encounters and knowledge about EPI through education sessions and pre- and post-assessments (Pitts et al., 2020; Saini et al., 2021). While both projects documented increased provider awareness and knowledge about EPI guidelines, the projects lack supporting data that increased knowledge translated into practice changes during WCC encounters, both in

terms of patient education and EPI documentation. Remembering that infant WCCs are fast-paced and busy, the EMR templates and smart phrases in our QI project allowed for lapses in recall about EPI during a visit. The templates assisted with risk stratification, reminded providers to ask about peanut consumption, and enabled selecting physical exam features consistent with eczema. Additionally, the tools prompt providers to select appropriate guidance based on inputs into the template.

The QI project by Russo and Shih (2018) utilized emails to providers, small group education sessions, reminder cards at workstations, home introduction sheets placed in the clinic, and onsite assistance by an allergist to improve guideline adherence. Guideline adherence did not exceed 17% during the intervention cycles. While these interventions are CDS tools, they are neither standardized nor do any of the tools include EMR templates or smart phrases. Our standardized work protocol is the foundation for the EMR bundle of templates, smart lists, and prompts. The authors conclude that more concrete changes in the workflow are required to improve outcomes.

The most similar and arguably successful effort to improve EPI guideline adherence is the iREACH program, a CDS bundle utilizing EMR features and handouts to aid providers in early peanut introduction in primary care settings. Researchers provided the iREACH bundle to one primary care clinic and used a comparative control clinic that did not receive the bundle. In a sample of 143 WCC encounters at 4 and 6 months, results showed better adherence to guidelines (52.4%) with the use of the iREACH bundle compared to the control clinic (14.1%) without the bundle ($p<.001$) (Bilaver et al., 2019). This comparison used a similar sample size and population as our QI project and showed that using CDS tools, including EMR features, improved adherence in a primary care setting. Both initiatives support that a quick and effective

way to improve EPI guideline adherence in a single location can occur with EMR standardized bundles. QI projects without CDS tools in the EMR did not perform as well as those with EMR bundles.

Eczema is still considered the highest risk factor for developing IgE-mediated food allergy (Fleischer et al., 2021). Implementing this project in a primary care setting was appropriate because the providers most likely to interface with otherwise healthy infants in this age group are PCPs. They are the gatekeepers of overall wellness, and assessing infants for early atopy offers a unique opportunity to practice primary and secondary prevention.

Addressing poor eczema identification and misclassification exceeded the scope of this initiative. However, it remains of the utmost importance to continue to work towards standardized definitions of severe eczema. The standardized work protocol defined this for the providers interfacing with this QI project. The addendum guidelines (Togias et al., 2017) recommend assessing physical findings of the skin and topical steroid use. It is essential to ensure providers do not misclassify infants with well-controlled eczema on mid or high-potency topical steroids as infants with mild or moderate eczema rather than severe.

Koplin et al. (2016) showed that guideline adherence might only prevent up to 44% of peanut allergy diagnoses if providers restrict interventions to high-risk infants. There are no dietary contraindications to offer early peanut introduction to infants at low risk of developing peanut allergy. Diversification of infants' diet with allergenic foods without special precautions, absent screening, is encouraged. Therefore, continuing to use the home peanut introduction handout in infants with no eczema might be beneficial in preventing unnecessary peanut avoidance. Of note, in the baseline data collection and chart audits, according to the topical steroid use defined in the standard work protocol, six of 134 infants would have qualified for a

sIgE to peanut. These infants are at the most significant risk of missing a critical introduction window before sensitization.

While one primary aim of this QI project was to discuss home peanut introduction with low-risk infants, the infants most at risk for the development of peanut allergy observed during this initiative were the 11 infants who met the criteria for severe eczema according to the work protocol. Eleven infants had exam findings or documented use of topical steroids consistent with the standard work protocol's definition of severe eczema during the intervention. Of these 11 infants, only one received a sIgE to peanut (9.1%) in compliance with the work protocol. This infant, upon negative sIgE, received appropriate EPI guidance about home peanut introduction. The follow-through on EPI guidance by the provider for this particular infant was a successful execution of secondary prevention strategies. The findings of the ten infants who did not receive sIgE to peanut should be considered missed opportunities for secondary prevention in infants already showing atopic disease. Of note, for eight of the ten visits during which providers did not order sIgEs to peanut, they also did not use the templates and smart lists for these WCC encounters. We could argue that deletion of the prompts or failure to load the intended template contributed to poor adherence to this measure. Follow-up of these infants was beyond the scope of this project.

We did not collect data from providers about why they did not order sIgEs on the other ten infants. However, understanding the barrier to following this part of the standard work protocol may be necessary for the future sustainability of the project. Potential obstacles to following the process of the standard work protocol for venipuncture may be parental or provider hesitancy because, in addition to routine vaccination, a blood draw can be an additional uncomfortable procedure.

Identifying and tracking balancing measures remain essential parts of QI work. Targeting improvement to project measures should not come at the cost of sacrificing other vital outcomes already established in a practice setting. Overall, we made significant changes to the context of these WCC visits. Still, these changes did not impact room time, vaccination rates, or the number of visits. Process changes were not disruptive to these other visit aspects.

Vaccination compliance and education are essential measures for the clinic. DTaP at 6-month WCCs remained at 100% during baseline and throughout the project. This measure, first and foremost, shows the strength of the vaccination promotion already well-established by the clinic and its providers and staff. Our project did not decrease the vaccination rate at the 6-month WCC, despite the time when many infants began solid food introduction and received EPI guidance during the visit. During the project, the COVID vaccine became available for infants six months of age and older, which added another element of anticipatory guidance for providers to tackle in addition to EPI guidance.

The availability of the COVID vaccine for the 6 and 9-month-old patients in our target population and the new academic residents starting in late June and early July showed a decrease in our measures tracked with SPCCs. These findings are not unexpected but revamping towards education, engagement, and facilitation showed these measures rebounded, tracking towards the goal before the end of the project.

The remaining balancing measures which showed impressive results were the in-room time and number of visits for infants during these targeted visits. As previously indicated, there were no significant differences in the average in-room time during the QI project compared to baseline. Collecting data on this measure ensured that our aims to target early peanut introduction through provider education and discussion with families did not increase the overall

length of the visits. Increased visit length can bottleneck providers' workflow and be difficult for families with young infants. Longer visit times or family perceived burdensome discussions about EPI could risk the likelihood for that family to return and continue WCC care at subsequent visits. Our data show this was not the case and was reassuring.

Planning for Sustainability

Ongoing goals for the practice setting are to continue using the templates. The clinic Director reaffirmed the continued importance of the initiative. Before the launch, these WCC templates were edited and streamlined for non-allergy content as a part of concise charting and facilitating patient visits. The project leader granted access to the template, smart lists, and phrases to the clinic's Medical Director to make any ongoing adjustments needed for expected clinic changes and unforeseen circumstances. The project lead plans to seek funding and other QI support from the academic institution for continuing sustainability. The established EPIC report will be a source of future data collection for long-term projects and improvement.

Limitations

While this individual project at a single site showed improvements in our measures, the larger goal of generalizability of the QI initiative to the broader population remains an unmet need. Moving the needle on this initiative will require infiltrating more primary care clinics, some of which may not be as familiar with QI or evidence-based practice (EBP) in more remote and rural communities.

The standardized work protocol classifies severe eczema by skin exam findings and topical steroid use. Still, as previously mentioned, this marker will not capture everyone who will go on to develop a peanut allergy. Subjectivity remains in eczema severity assessments (Abrams et al., 2020). We attempted to mitigate this with the smart list by prepopulating typical eczematous features for provider use.

Also beyond this project's scope, but possibly a future research project is tracking the follow-up of infants provided the home peanut introduction handout. While this QI project focused on process measures of distributing the handout, we did not assess the successful home introduction of peanut in these infants who received the handout.

Lastly, COVID-19 remains a public health priority and is still an active concern in primary care offices. Questions from parents about COVID-19 vaccination and infection contribute to in-room time and increase provider anticipatory guidance requirements.

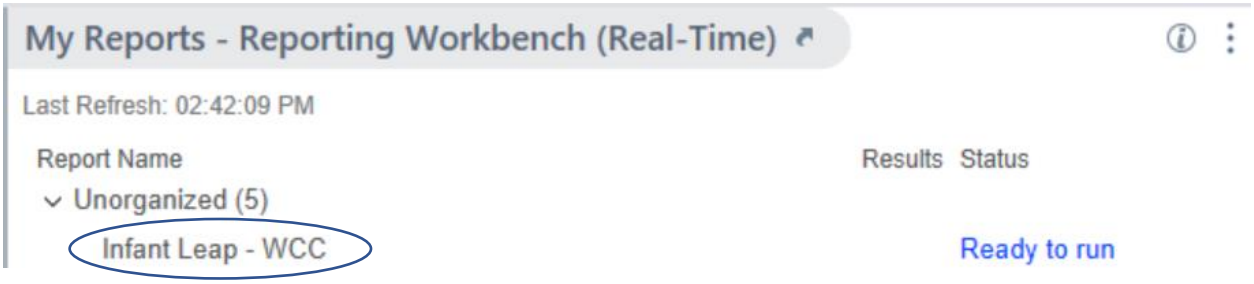
Providers at the UNC primary care clinic did not make referrals to the UNC allergy clinic per the standard work protocol. Though some infants should have received phlebotomy draws for sIgE to peanut, the implication is that early peanut introduction guidance prevents unnecessary allergy referrals by empowering PCPs to facilitate the conversation about early introduction with patient families independently. Most infants observed during this QI project met the criteria for immediate home introduction of peanut. As previously mentioned, unnecessary allergy referrals of low-risk infants may increase wait times for new patient appointments in more high-risk infants. PCPs should judiciously reserve referrals for infants who meet high-risk criteria according to the standardized work protocol and broadly promote EPI in all others showing developmental readiness for solid food introduction.

Conclusion

Peanut allergy in children is a population health problem affecting individuals, families, and healthcare systems. Research shows early peanut introduction can reduce the incidence of peanut allergy in young infants, but adoption of this practice remains low in primary care settings. QI methodology, PDSA cycles, and interprofessional collaboration in primary care settings improved documentation of EPI guidance at routine WCC encounters without impacting other

measures at the UNC Children's Primary and Specialty Clinic. Broader PCP use of CDS tools and EMR standardization could further improve guideline adherence to prevent peanut allergy in infants.

APPENDIX A: EPIC REPORT



APPENDIX B: SCREENSHOTS OF SMART LISTS, EMR TEMPLATES, AND DOCUMENTATION FEATURES

{Yes/NoEczema:82213}

{LEAPRISK:75908}

{LEAPPrimaryCare:75909

{LEAPATTEMPT:82539}

{EczemaHistory:82214}

{Eczemaclass:82607}

{PHR, LEAPFLOWCHART}

{Infantmilk:75906}

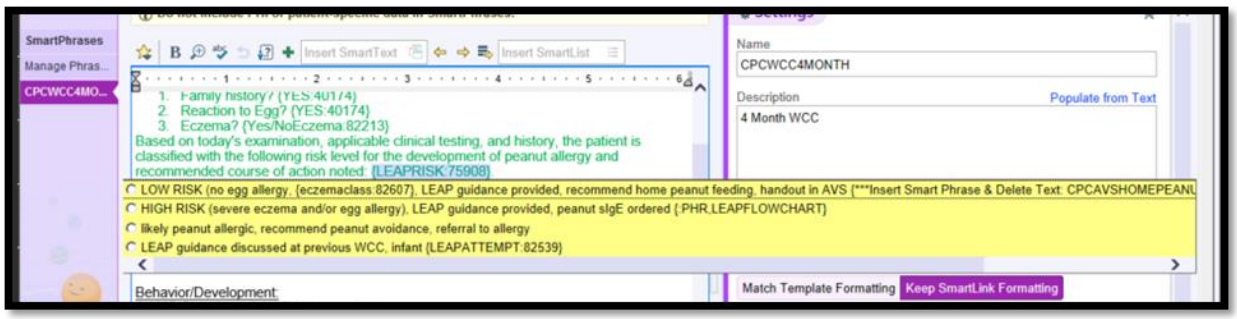
{SKINWCCInfants:82211::::1}

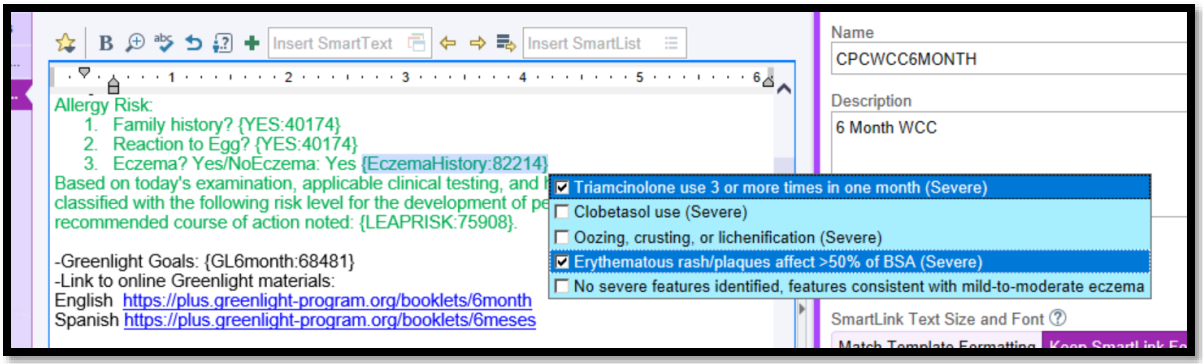
{SkinFeaturesWCC:82212}

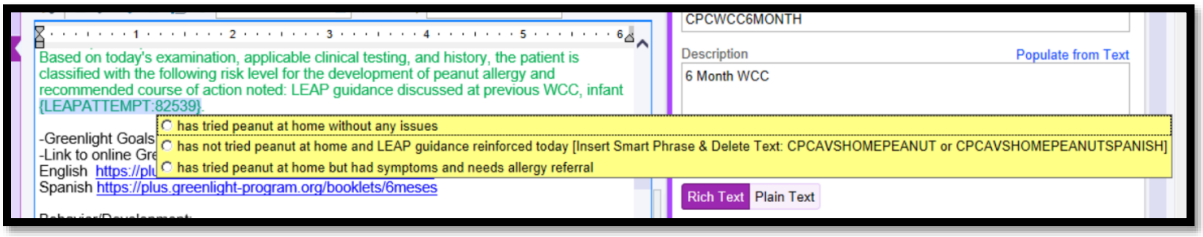
CPCAVSHOMEPEANUT	Early Peanut Introduction in Infants - English
CPCAVSHOMEPEANUTSPANISH	Early Peanut Introduction in Infants -Spanish
CPCWCC4MONTH	4 Month WCC
CPCWCC6MONTH	6 Month WCC
CPCWCC9MONTH	9 Month WCC

Nutrition and Growth:
- Infant nutrition & introduction of solids discussed
-Recommend no cow's milk or honey until 1 year of age
Early Peanut Introduction Assessment:
Allergy Risk:
1. Family history? {YES:40174}
2. Reaction to Egg? {YES:40174}
3. Eczema? {Yes/NoEczema:82213}

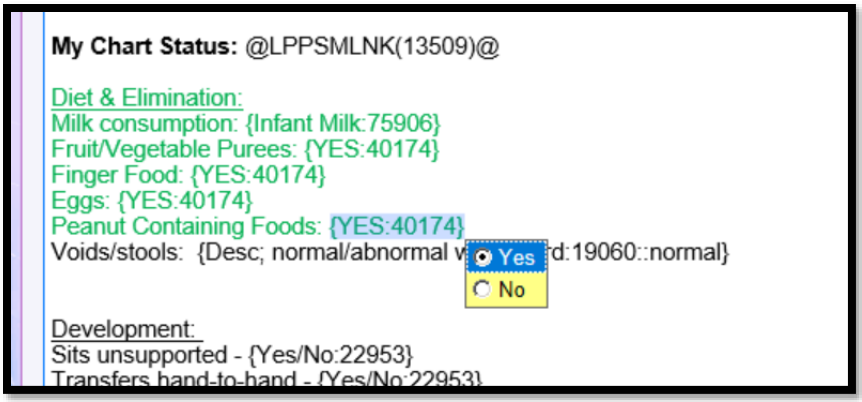
Based on today's examination, applicable clinical testing, and history, the patient is classified with the following risk level for the development of peanut allergy and recommended course of action noted: {LEAPRISK:75908}.



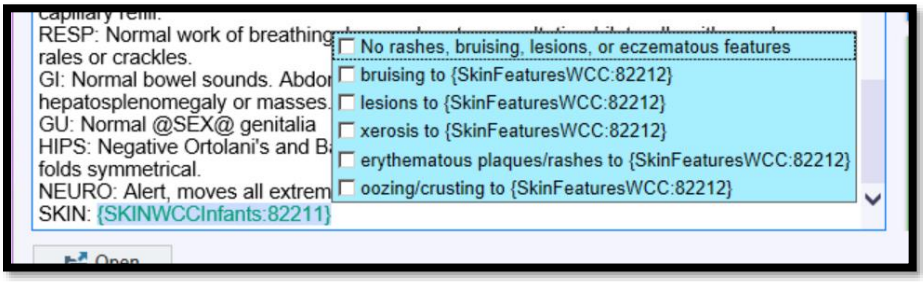

Insert SmartText
Insert SmartList
Allergy Risk:
1. Family history? {YES:40174}
2. Reaction to Egg? {YES:40174}
3. Eczema? Yes/NoEczema: Yes {EczemaHistory:82214}
Based on today's examination, applicable clinical testing, and
classified with the following risk level for the development of pe
recommended course of action noted: {LEAPRISK:75908}.
-Greenlight Goals: {GL6month:68481}
-Link to online Greenlight materials:
English https://plus.greenlight-program.org/booklets/6month
Spanish https://plus.greenlight-program.org/booklets/6meses
Triamcinolone use 3 or more times in one month (Severe)
Clobetasol use (Severe)
Oozing, crusting, or lichenification (Severe)
Erythematous rash/plaques affect >50% of BSA (Severe)
No severe features identified, features consistent with mild-to-moderate eczema
Name
CPCWCC6MONTH
Description
6 Month WCC
SmartLink Text Size and Font

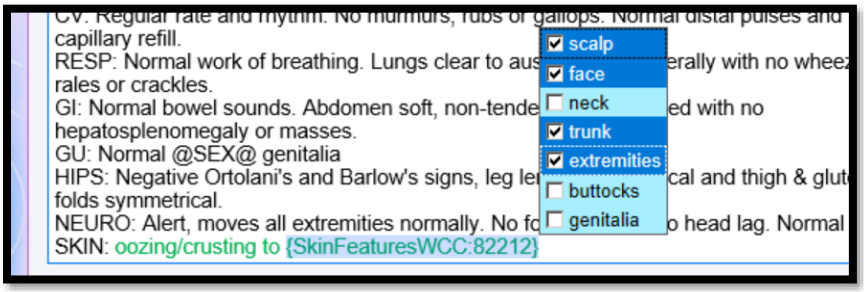

Based on today's examination, applicable clinical testing, and history, the patient is
classified with the following risk level for the development of peanut allergy and
recommended course of action noted: LEAP guidance discussed at previous WCC, infant
{LEAPATTEMPT:82539}.
has tried peanut at home without any issues
has not tried peanut at home and LEAP guidance reinforced today [Insert Smart Phrase & Delete Text: CPCAVSHOMEPEANUT or CPCAVSHOMEPEANUTSPANISH]
has tried peanut at home but had symptoms and needs allergy referral
Spanish https://plus.greenlight-program.org/booklets/6meses
CPCWCC6MONTH
Description
Populate from Text
6 Month WCC
Rich Text
Plain Text

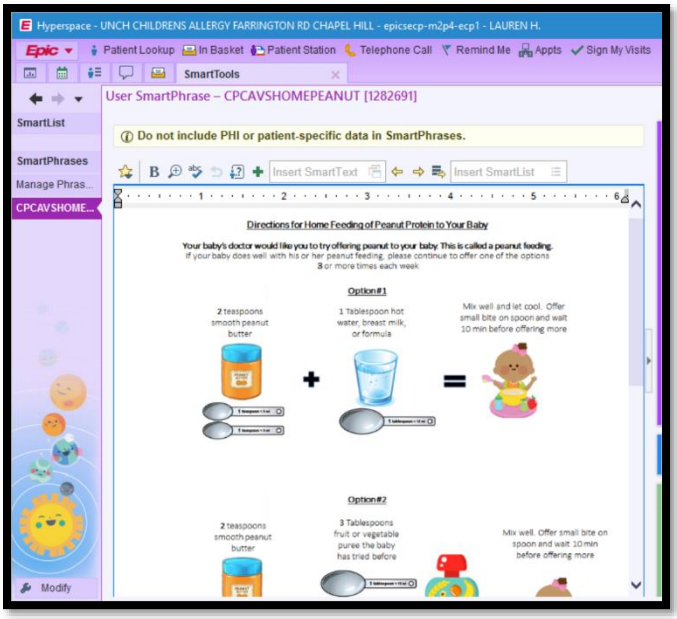

Diet & Elimination:
Milk consumption: {Infant Milk:75906}
Fruit/Vegetable Purees: {YES:40174}
Finger Food: {YES:40174}
Eggs: {YES:40174}
Peanut Containing Foods: {YES:40174}
Voids/stools: {Desc; normal/abnormal w/wildcard:19060::normal}


My Chart Status: @LPPSMLNK(13509)@
Diet & Elimination:
Milk consumption: {Infant Milk:75906}
Fruit/Vegetable Purees: {YES:40174}
Finger Food: {YES:40174}
Eggs: {YES:40174}
Peanut Containing Foods: {YES:40174}
Voids/stools: {Desc; normal/abnormal
Yes
No
d:19060::normal}
Development:
Sits unsupported - {Yes/No:22953}
Transfers hand-to-hand - {Yes/No:22953}

Physical Exam:
GEN: ***
HEAD:Normocephalic, atraumatic. Anterior fontanelle open, soft and flat.
Eyes: PERRL. Conjunctiva clear. Red reflex present bilaterally
ENT: Moist mucus membranes. Nares patent. Neck supple.
Dentition: ***
CV: Regular rate and rhythm. No murmurs, rubs or gallops. Normal distal pulses and capillary refill.
RESP: Normal work of breathing. Lungs clear to auscultation bilaterally with no wheezes, rales or crackles.
GI: Normal bowel sounds. Abdomen soft, non-tender, non-distended with no hepatosplenomegaly or masses.
GU: Normal @SEX@ genitalia
HIPS: Negative Ortolani's and Barlow's signs, leg length symmetrical and thigh & gluteal folds symmetrical.
NEURO: Alert, moves all extremities normally. No focal deficits. No head lag. Normal tone.
SKIN: {SKINWCCInfants:82211}






Hyperspace - UNCH CHILDRENS ALLERGY FARRINGTON RD CHAPEL HILL - epicsecp-m2p4-ecp1 - LAUREN H.
Patient Lookup
In Basket
Patient Station
Telephone Call
Remind Me
Appts
Sign My Visits
SmartTools
User SmartPhrase – CPCAVSHOMEPEANUT [1282691]
SmartList
SmartPhrases
Manage Phras...
CPCAVSHOME...
Do not include PHI or patient-specific data in SmartPhrases.
Insert SmartText
Insert SmartList
Directions for Home Feeding of Peanut Protein to Your Baby
Your baby's doctor would like you to try offering peanut to your baby. This is called a peanut feeding.
If your baby does well with his or her peanut feeding, please continue to offer one of the options
3 or more times each week.
Option#1
2 teaspoons smooth peanut butter
1 Tablespoon hot water, breast milk, or formula
Mix well and let cool. Offer small bite on spoon and wait 10 min before offering more
Option#2
2 teaspoons smooth peanut butter
3 Tablespoons fruit or vegetable puree the baby has tried before
Mix well. Offer small bite on spoon and wait 10 min before offering more
Modify

APPENDIX C: APPENDIX D FROM ADDENDUM GUIDELINES FOR HOME FEEDING OF PEANUT

APPENDIX D. INSTRUCTIONS FOR HOME FEEDING OF PEANUT PROTEIN FOR INFANTS AT LOW RISK OF AN ALLERGIC REACTION TO PEANUT

These instructions for home feeding of peanut protein are provided by your doctor. You should discuss any questions that you have with your doctor before starting. These instructions are meant for feeding infants who have severe eczema or egg allergy and were allergy tested (blood test, skin test, or both) with results that your doctor considers safe for you to introduce peanut protein at home (low risk of allergy).

General Instructions

1. Feed your infant only when he or she is healthy; do not do the feeding if he or she has a cold, vomiting, diarrhea, or other illness.
2. Give the first peanut feeding at home and not at a day care facility or restaurant.
3. Make sure at least 1 adult will be able to focus all of his or her attention on the infant, without distractions from other children or household activities.
4. Make sure that you will be able to spend at least 2 hours with your infant after the feeding to watch for any signs of an allergic reaction.

Feeding Your Infant

1. Prepare a full portion of one of the peanut-containing foods from the recipe options below.
2. Offer your infant a small part of the peanut serving on the tip of a spoon.
3. Wait 10 minutes.
4. If there is no allergic reaction after this small taste, then slowly give the remainder of the peanut-containing food at the infant's usual eating speed.

What are symptoms of an allergic reaction? What should I look for?

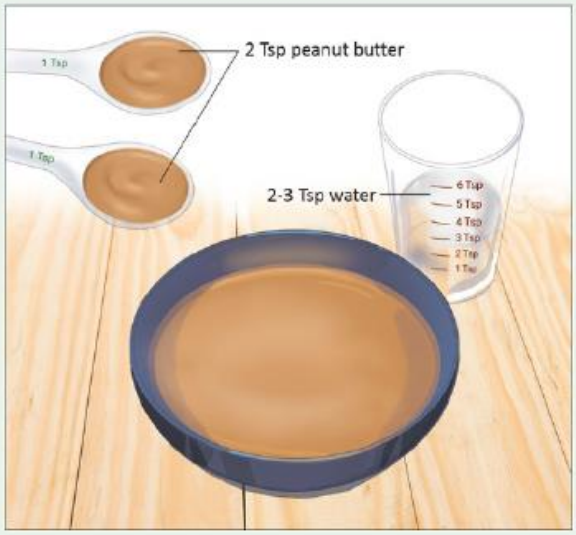
- Mild symptoms can include:
  - a new rash

    or
  - a few hives around the mouth or face
- More severe symptoms can include any of the following alone or in combination:
  - lip swelling
  - vomiting
  - widespread hives (welts) over the body
  - face or tongue swelling
  - any difficulty breathing
  - wheeze
  - repetitive coughing
  - change in skin color (pale, blue)
  - sudden tiredness/lethargy/seeming limp

If you have any concerns about your infant's response to peanut, seek immediate medical attention/call 911.

Four Recipe Options, Each Containing Approximately 2g of Peanut Protein

Note: Teaspoons and tablespoons are US measures (5 and 15 mL for a level teaspoon or tablespoon, respectively).



Option 1: Bamba (Osem, Israel), 21 pieces (approximately 2 g of peanut protein)

Note: Bamba is named because it was the product used in the LEAP trial and therefore has proven efficacy and safety. Other peanut puff products with similar peanut protein content can be substituted.

a. For infants less than 7 months of age, soften the Bamba with 4 to 6 teaspoons of water.

b. For older infants who can manage dissolvable textures, unmodified Bamba can be fed. If dissolvable textures are not yet part of the infant's diet, softened Bamba should be provided.

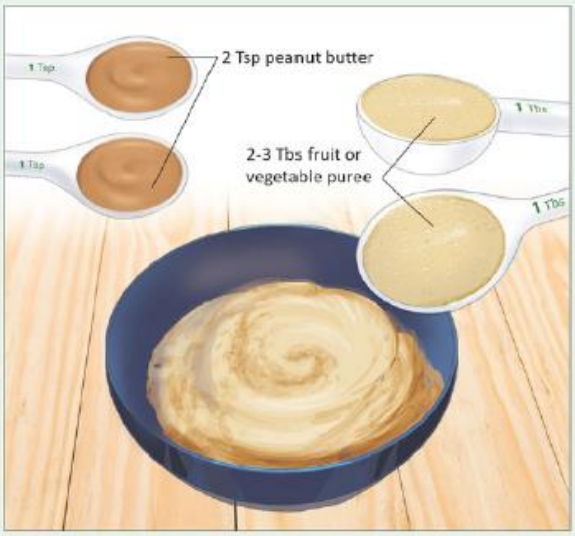
Option 2: Thinned smooth peanut butter, 2 teaspoons (9-10 g of peanut butter; approximately 2 g of peanut protein)

a. Measure 2 teaspoons of peanut butter and slowly add 2 to 3 teaspoons of hot water.

b. Stir until peanut butter is dissolved, thinned, and well blended.

c. Let cool.

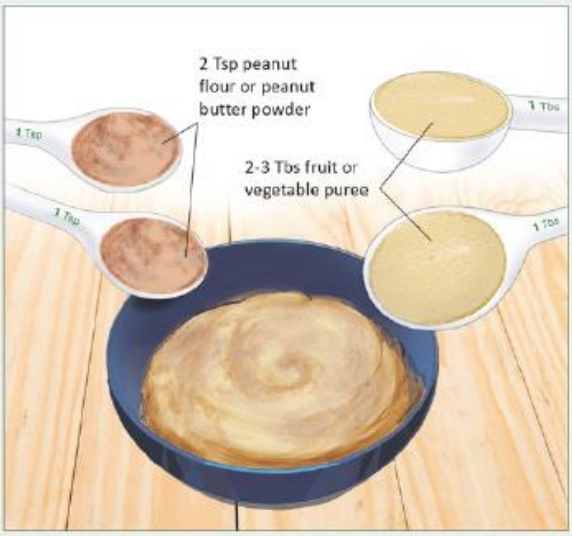
d. Increase water amount if necessary (or add previously tolerated infant cereal) to achieve consistency comfortable for the infant.



Option 3: Smooth peanut butter puree, 2 teaspoons (9-10 g of peanut butter; approximately 2 g of peanut protein)

a. Measure 2 teaspoons of peanut butter.

b. Add 2 to 3 tablespoons of pureed tolerated fruit or vegetables to peanut butter. You can increase or reduce volume of puree to achieve desired consistency.



Option 4: Peanut flour and peanut butter powder, 2 teaspoons (4 g of peanut flour or 4 g of peanut butter powder; approximately 2 g of peanut protein)

Note: Peanut flour and peanut butter powder are 2 distinct products that can be interchanged because they have a very similar peanut protein content.

a. Measure 2 teaspoons of peanut flour or peanut butter powder.

b. Add approximately 2 tablespoons (6-7 teaspoons) of pureed tolerated fruit or vegetables to flour or powder. You can increase or reduce volume of puree to achieve desired consistency.

APPENDIX D: HOME EARLY PEANUT INTRODUCTION HANDOUT ENGLISH

Directions for Home Feeding of Peanut Protein to Your Baby

Your baby's doctor would like you to try offering peanut to your baby. This is called a peanut feeding.
If your baby does well with his or her peanut feeding, please continue to offer one of the options
3 or more times each week

Option #1

2 teaspoons smooth peanut butter

1 Tablespoon hot water, breast milk, or formula

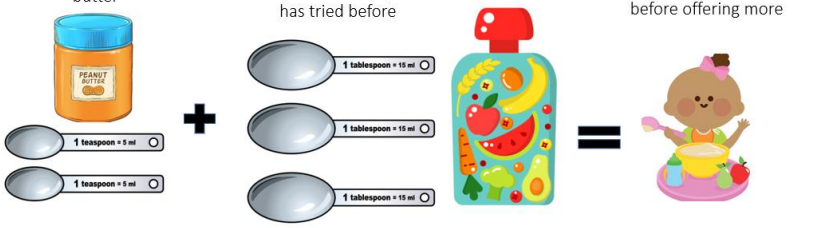
Mix well and let cool. Offer small bite on spoon and wait 10 min before offering more

Option #2

2 teaspoons smooth peanut butter

3 Tablespoons fruit or vegetable puree the baby has tried before

Mix well. Offer small bite on spoon and wait 10 min before offering more



Please remember a few things...

- Never Give your baby whole peanuts or peanut pieces or chunky peanut butter
- Give the first peanut feeding at home (not daycare or restaurant)
- Only feed your baby peanut butter when he or she is healthy
- Make sure 1 adult can focus his or her attention on the baby for 2 hours after feeding peanut the first time

What should you watch for? What are signs of an allergic reaction?

- A new rash or a few hives (welts) around the mouth

Stop feeding the peanut food and call your doctor's office or 911 if your baby has more serious symptoms of an allergic reaction...

- Lip, face, or tongue swelling
- Vomiting (throwing up)
- Many hives (welts) over the body
- Lots of coughing or trouble breathing
- Change in skin color (pale/blue)

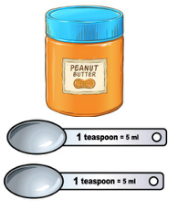
APPENDIX E: HOME EARLY PEANUT INTRODUCTION HANDOUT SPANISH

Instrucciones para alimentar a su bebé con proteína de cacahuate (maní)
Directions for Home Feeding of Peanut Protein to Your Baby

Al médico de su bebé le gustaría que usted intente incluir cacahuate en las comidas de su bebé.
Esto se llama alimentación con cacahuate.
Si su bebé come bien la proteína de cacahuate, siga ofreciéndole una de las opciones
3 o más veces por semana

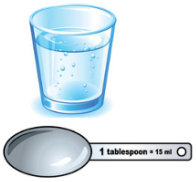
Opción 1

2 cucharadas de crema de cacahuate sin trozos



+

1 cucharada de agua caliente, leche materna o fórmula

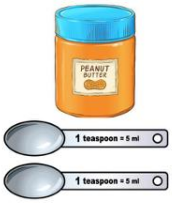


=

Mezcle bien y deje enfriar. Ofrecezca un bocado pequeño con una cuchara y espere 10 minutos antes de ofrecerle más

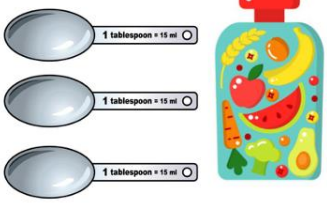
Opción 2

2 cucharadas de crema de cacahuate



+

3 cucharadas de puré de frutas o verduras que el bebé ha probado



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Mezcle bien. Ofrezca un bocado pequeño con una cuchara y espere 10 minutos antes de ofrecerle más

Recuerde algunas cosas...

- Nunca dé a su bebé cacahuate entero o trozos de cacahuate o crema de cacahuate con trozos
- Dé la primera alimentación con cacahuate en casa (no en la guardería o en un restaurante)
- Solo alimente a su bebé con crema de cacahuate cuando esté sano
- Asegúrese de que un adulto pueda centrar su atención en el bebé durante 2 horas después de alimentarlo con cacahuate la primera vez

¿A qué debería prestar atención? ¿Cuáles son las señales de una reacción alérgica?

- Un sarpullido nuevo o urticaria (ronchas) alrededor de la boca

Deje de darle alimento con cacahuate y llame al consultorio de su médico o al 911 si su bebé tiene síntomas más gaves de una reacción alérgica...

- Hinchazón de labios, rostro o lengua
- Vómitos
- Mucha urticaria (ronchas) en el cuerpo
- Mucha tos o problema para respirar
- Cambio en el color de la piel (pálido/azulado)

Translated by UNC Health Interpreter Services, 06/01/22

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