Introduction of Probiotics to Improve Eczema Symptoms in Children in one Pediatric Primary Care Practice: A Quality Improvement Project

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Introduction of Probiotics to Improve Eczema Symptoms in Children in one Pediatric Primary Care Practice: A Quality Improvement Project

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May 1, 2023

Submitted in Partial Fulfillment of the Requirements for the Doctor of Nursing Practice Degree

Project Committee

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Abstract

**Background:** There is emerging interest in alternative approaches to treating children with eczema because there is currently no allopathic cure. Non-pharmacological approaches are regarded as generally safe, well tolerated, and cost effective. Eczema is a chronic, relapsing inflammatory, itchy skin condition that adversely affects quality of life in many individuals, including children. Eczema interferes with sleep, leads to secondary skin infections, and causes intractable itching. Topical steroids are the current standard of practice in treating patients but, evidence suggests that they can cause unwanted side effects and can lead to serious systemic reactions. The purpose of this quality improvement project was to improve the quality of life and symptom management in children in the pediatric outpatient setting who have sub-optimally controlled eczema by implementing an eczema pathway that standardizes the use of probiotics as treatment.

**Methods:** Based on available knowledge, the most frequently identified alternative treatment modality to introduce for eczema patients in the literature was probiotics. The project was carried out at a holistic pediatric practice in an urban setting in Texas.

**Intervention:** Probiotics were introduced to pediatric patients (ages 0-15 years) with sub-optimally controlled eczema. To evaluate patient symptoms, quality of life, and adherence, a modified Patient Oriented Eczema Measure (POEM) questionnaire was completed by the parent/child dyads before the intervention and every four weeks during the 12-week implementation period.

**Results:** During the 12-week implementation period, 17 pediatric patients participated in the project. There were more males (n=10, 58.8%) than females (n=7, 41.2%). A baseline POEM questionnaire was obtained to track clinical progress, and a pre/post change score and percent improvement were calculated at the end of the project. The overall mean percent improvement in symptoms was 64%.

**Conclusion:** The initiation of probiotics was accompanied by a reduction in self-reported eczema symptoms and an improvement in quality of life in 82% of the participants. Ninety-four percent of patients took the probiotic without any noted side effects. The greatest improvement occurred in children with moderate to very severe symptom burden at baseline.
Introduction

There is emerging interest in alternative approaches to treating children with eczema because it is a chronic and debilitating condition for which there is currently no allopathic cure. Research in Complementary and Alternative Medicine (CAM) methods for eczema treatment and symptom control continues to be promising as individuals with eczema seek to improve their quality of life (Koo et al., 2020). Additionally, there is a general lack of knowledge among patients, parents, and healthcare providers that non-pharmacological approaches exist (Thandar et al., 2017).

Evidence has shown that CAM approaches appear to be generally safe, well tolerated, and effective in reducing symptoms in individuals struggling with eczema. CAM has been shown to improve the overall quality of life in children (Lu, et. al, 2019). Disturbances in sleep and itching are commonly associated with decreased quality of life in patients with eczema (Anderson et al., 2021). Moreover, non-pharmacological approaches are generally cost effective and can be considered alone or in conjunction with traditional approaches to treating persons with eczema (Lu, et. al, 2019).

Problem Description

Eczema, a type of atopic dermatitis (AD), is a chronic, relapsing inflammatory, itchy skin condition that adversely affects quality of life in many individuals, including children. It commonly occurs before the age of 5 years and is often located on the arms and behind the knees but can be found anywhere on the body (Atopic dermatitis (eczema)-Symptoms and causes - Mayo Clinic, n.d.). Atopic Dermatitis can interfere with sleep, lead to secondary skin infections, and cause intractable itching. Pruritus, or itching, is the most burdensome symptom affecting eczema patients and is the symptom most likely to interfere with a patient’s quality of life. Sleep
quality, energy level, mood, physical health, and mental health are additional factors that guide a patient’s quality of life (Anderson et al., 2021).

Eczema can last across the lifespan for some individuals and can lead to other social issues, increased healthcare costs, and decreased quality of life (Szari & Quinn, 2019). According to the National Eczema Association, 31.6 million people (10.1%) in the United States (US) suffer from AD and of those, approximately 9.6 million are children under the age of 18 years (“Eczema Prevalence”, n.d.). One-third of those children have moderate to severe disease, and nearly 60% experience disrupted sleep greater than five nights a week, leading to daytime irritability, inattention, and moodiness (“Eczema Prevalence”, n.d.). Eczema, the most common skin condition affecting children, is a non-contagious condition that affects an estimated 15–30% of children in developing countries (Jaffary et al., 2015). Because there is no known cure for eczema at this time, patients are forced to seek treatment modalities to assist in easing symptoms as a long-term solution.

Topical steroids are the current standard of practice in treating patients with eczema. However, evidence suggests that topical steroids can cause unwanted side effects such as localized burning, itching, dryness, and skin atrophy in some cases, and can lead to serious systemic side effects for other individuals. Untreated or worsening eczema symptoms can lead to missed school or workdays, the need for visits to the primary care physician, necessary additional prescriptions, and social problems, all of which can increase financial burden and decrease overall quality of life for families dealing with chronic diseases (Anderson et al., 2021 & Jaffary et al., 2015).
Local Problem

In the Dallas-Fort Worth metroplex, there is increasing demand for holistic and integrative healthcare approaches aimed at treating the underlying causes of inflammatory diseases such as atopic dermatitis (Ramachandra, 2021). Families frequently seek out holistic healthcare clinics based on their willingness to explore non-traditional approaches to prevention and disease management. Additionally, families are looking for alternative approaches to ailments due to frustration and dissatisfaction with conventional treatments, and failure to see improvement in their chronic conditions (Shi & Lio, 2019). In the holistic pediatric primary care clinic, which served as the site for this project, children are treated for a host of acute and chronic conditions. Sub-optimally managed eczema is among the most common reasons patients present to the clinic for treatment. Maintaining good quality of life is important to parents and families and holistic healthcare clinics are a good fit for meeting their needs.

Available Knowledge

Guidelines for a Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) served to guide this systematic review of the literature. The review was conducted to determine what non-pharmacological interventions and strategies were effective in combating eczema symptoms in the outpatient population. Twenty-one studies (randomized controlled trials n=14, quasi-experimental n=1, meta-analysis n=2, systematic review n=2, and expert opinion/guidelines n=2) were included in this review spanning twelve countries globally (Australia, China, Egypt, Finland, Germany, Iran, Japan, Mongolia, Netherlands, Spain, United Kingdom, and United States). Participants were recruited from local hospitals, medical centers, and academic centers. Most of the studies (n=15) investigated non-pharmacological interventions...
in reducing eczema symptoms and one evaluated effects of a customized Integrative Body-Mind-Spirit on atopic dermatitis.

Among the sixteen studies that reported age, the range of ages was 0 to 79 years. Most of the total participants, approximately 85%, were children less than 18 years old (n=4,310). Of the total participants (N=5,034), there were eight studies (n=473) that reported gender, and within this group there were more females (n=241, 51.2%) than males (n=232, 48.8%) who participated. Additionally, a little more than half of the articles (n=13) discussed ethnicity of participants (American, Asian, British, Dutch, Egyptian, Finish, German, Iranian, Japanese, and Spanish) and none reported economic status of the participants.

Non-pharmacological treatments identified as effective in reducing itching and eczema symptoms were probiotics (n=8 studies), Vitamin D (n=3 studies), melatonin (n=1 study), stress reduction techniques (n=2 studies), homeopathics (n=1 study), prebiotics (n=1 study), acupuncture (n=2 studies), acupressure (n=1 study, p=0.05), Gamma-Linolenic acid (GLA) (n=2 studies), Tzu-Yun ointment (TYO treatment) (n=1 study), Whey associated with dodder seed extract (n=1 study), Chinese (n=1 study) herbal medicine, and Vitamin E (n=1 study). Most of the studies showed marked improvement in eczema symptoms, while some studies indicated the need for further research.

Instruments used to collect data included: Dermatology Life Quality Index (DLQI), Eczema Area and Severity Index (EASI), α=6.6, Eppendorf Itch Questionnaire (EIQ), α=0.82–0.98, ImmunoCAP Infant blood test, Nottingham Eczema Severity Score (NESS), Patient-oriented Eczema Measure (POEM), Scoring Atopic Dermatitis (SCORAD) index, Six Area Six Sign Atopic Dermatitis (SASSAD) score, Three Item Severity (TIS) scores, and Visual Analogue scale (VAS). The studies are synthesized by intervention (see Appendix A).
All the alternative, or non-pharmacological approaches for treating eczema in the studies reviewed were shown to decrease the severity and frequency of daily symptoms, decrease incidence of eczema flares, and aid in increasing the individual’s immune system. Despite the growing body of evidence investigating alternative therapies to treating eczema, commonly the studies lack randomized controlled trials or have smaller sample sizes (Shi & Lio, 2019). Alternative approaches for the treatment of eczema were shown to be promising, but probiotics had the most substantial studies and were shown to have significant effect compared to placebo (Lu, et. al, 2019).

The human intestinal tract contains microorganisms that are collectively referred to as the microbiome. These organisms may be healthy or harmful and are composed of bacteria, fungi, or viruses that live in or on the human host. The microbiome plays a significant role in the health of the individual’s immune system. Probiotics are healthy microorganisms that provide an overall benefit to the host’s microbiome (Szari & Quinn, 2019). Probiotics are described as live, microbial food products whose ingredients aid in improving overall health benefits, including improving eczema symptoms, for the consumer and have been reported to be well-tolerated and safe for use in the pediatric population. (Wollina, 2017). The higher the population of healthy probiotics in the intestinal tract, the less likelihood that harmful bacteria will abundantly multiply leading to a decreased immune system or decline in the health of the host (Szari & Quinn, 2019).

Individuals with eczema have been shown to have reduced colonization of gut microbiome compared to healthy individuals (Szari & Quinn, 2019). Probiotics are found naturally in some food products such as yogurt, kefir, kombucha, sauerkraut, pickles, miso, tempeh, kimchi, sourdough bread, and some cheeses (Parker et al., 2016). Additionally, probiotics naturally originate in breastmilk and are frequently added to infant formulas to aid in
colonizing the infant’s microbiome with healthy bacteria (Maldonado et al., 2019). Probiotics have been shown to have no known negative consequences in healthy, full-term babies and are generally regarded as safe and effective for use in children (Cruchet et al., 2015, Karkhaneh et al., 2020, & Lu et al., 2019).

Multiple randomized controlled trials have been conducted to examine the effects of probiotics (healthy bacteria) on the human body in treating and preventing numerous medical conditions. There have been no adverse events identified in children using probiotics, and their use is generally recognized as safe in healthy children. In some studies, only minor effects, if any, were reported in children such as mild bloating and flatulence which subside quickly with continued use (Cruchet et al., 2015, Karkhaneh et al., 2020, & Lu et al., 2019).

Rationale

Conceptual model

In the studies examining probiotics as a treatment modality, no underlying theory emerged as a main theme throughout the literature. Therefore, multiple models and frameworks were reviewed to select the best framework for implementing an intervention. One multidimensional model, the Rogers’ Diffusion of Innovation (DOI) theory, aligned well with this proposal and was used to guide implementation of the change for both patients, parents, and the healthcare team.

The Diffusion of Innovation (DOI) Theory was developed by Rogers in 1962 and is an implementation model designed to show how, over time, an idea or product gains momentum and spreads, or diffuses, through a specific group of people. The innovation-decision process involves five steps: 1) knowledge, 2) persuasion, 3) decision, 4) implementation, and 5) confirmation (Rogers, 2003). The first step, knowledge, refers to the exposure to the new
information or innovation and its functions. The persuasion step occurs when an individual develops an attitude towards the innovation, favorable or unfavorable. The third step, decision, occurs when the individual takes actions towards acceptance or rejection of the innovation. Implementation takes place when the individual uses the new innovation in the daily routine. Finally, confirmation takes place when an individual recognizes the benefits of the new innovation, integrates it into an ongoing routine, and promotes it to others within the organization, despite possibly facing resistance to adoption by others (Rogers, 2003).

An important assumption of this theory is that each group and organization is unique in the ways in which they absorb and disseminate information. Therefore, the slow rate at which new information is adopted can be challenging in many organizations. Early adopters of new information are viewed as opinion leaders and are identified as an asset in the organization to assist in circulating new concepts to other peers within the group. Opinion leaders are regarded as change agents, initiating change among peers by exerting their influence through communication, networking, and role modeling (Rogers, 2003). The DOI theory assists in predicting the adoption of information within the established group, specifically adoption intention by the advanced practice providers.

The model is helpful in implementing non-pharmacological approaches to a specific chronic disease modality in an outpatient primary care clinic. The project leader used the steps of the DOI theory to share information about the intervention with the other Advanced Practice Registered Nurses (APRNs) at the proposed project site to assist with integrating a new modality into their practice. Additionally, the DOI was useful to patients and their parents or caregivers in making the decision whether to use probiotics in the treatment plan by gaining knowledge and
attitudes towards the intervention, followed by shared decision making and implementation of
the intervention and finally, confirmation or adopting the use of the intervention.

**Specific Aims**

The purpose of the proposed quality improvement (QI) project was to improve the quality
of life and symptom management in children in the pediatric outpatient setting who have sub-
optimally controlled eczema. Below were three specific aims of the project:

- Develop and implement an eczema pathway that standardizes the introduction of
probiotics into the management of eczema for children with sub-optimally controlled
eczema. Secure ≥ 90% of eligible patients offered probiotics.

- Of the participants who initiated probiotics and participated in the pathway, 60% will
adhere to the treatment and 75% will have a decrease in eczema symptoms and
improvement in quality of life.

- Advanced Practice Registered Nurses will report the introduction of probiotics to be
feasible and add value to patient care.

**Methods**

The framework used to report this quality improvement project is the Standards for
QUality Improvement Reporting Excellence (SQUIRE 2.0) which provides guidelines for
evidence-based interventions projects (Ogrinc et al., 2016). The methodology guiding the
development, implementation and evaluation of the proposed improvement project was the
model for improvement depicted in Figure 1. The Plan-Do-Study-Act (PDSA) cycle is a four-
step method used to take ideas and turn them into actions, and further connect those actions to
learning. The rapid cycles of improvement in this model focus on learning and assist in building
knowledge, testing a change, and implementing that change within a complex system (Langley et
al., 2009). The model defines the improvement objectives, assesses if a change was an improvement, and identifies changes that need to be made that will lead to improvement. The PDSA model was chosen because it allowed for ongoing assessment, reassessment, observation, and improvement to initiate a change.

**Context**

The project was carried out at a holistic pediatric practice in an urban setting in Texas. The primary care clinic is the context in which pediatric patients receive care at the project site. A microsystem map was constructed to outline the environment, social roles, and relationships of the clinic and patient (see Appendix B). The clinic is pictured at the center of the microsystem map with contributing elements identified in the surrounding box. Internal contributors included administrative staff, medical assistants, nurse practitioners, and billing/Electronic Health Record (EHR) systems. External contributors included laboratory, pharmacy.supplement store, and home. Each contributing component provided a connection with the clinic.patient that affected patient outcomes (Nelson et al., 2011). Pediatric practices are unique because children are the patients, but parents and caretakers are also involved in all shared decision making for treatment approaches.

The pediatric practice is a privately owned outpatient facility that services a variety of diverse pediatric patients 0-18 years of age. The organization offers wellness examinations, sick or acute visits, immunizations, natural and holistic treatments, and preventative healthcare recommendations to its patients and families. The clinic is financially supported by private insurance reimbursement or from families who privately pay for care received.
Several factors are associated with a child’s environment. There is a correlation between a child’s environment, quality of life, and sub-optimally controlled eczema (Gabes et al., 2020). Children with eczema face long-term health challenges that can impact their health into adulthood. To evaluate this further, a cause-and-effect diagram was completed to examine the factors associated with poorly controlled eczema in the project setting (see Appendix C). Health beliefs and opinions of caretakers and primary care providers can affect health outcomes in patients. For example, does the caretaker or primary care provider trust alternative therapies or are they open-minded about the use of such approaches? Additional barriers to well managed eczema include lack of parental education about alternatives to traditional therapies, lack of resources or time to obtain proper care, non-compliance with treatment regimens, lack of patient tolerance to medications including adverse side effects and ineffective prescription management, and lack of access to care. Other barriers in the healthcare setting include provider health beliefs and past experiences, lack of education or guidelines on managing childhood eczema, time constraints, and lack of provider experience (Siegfried et al., 2020).

Patients with poorly controlled eczema have often exhausted traditional modalities but have little access to information about alternative modalities or approaches to treatment. If they are familiar with alternatives, frequently they are not knowledgeable about administration or utilization. They seek guidance from an experienced practitioner who is well-acquainted with specific options, brands, and dosages that can guide them through the process.

Contextual factors can influence the organization’s readiness to change. A force field analysis was conducted to identify current and potential driving and restraining forces within the organization that could impact the success of implementing probiotics use with eczema patients (see Appendix D). Current driving forces included organizational buy-in, patient and parent
desire for improvement in their health, and historical safety of probiotics use. Potential driving forces were team support at the organization, efficacy of the treatment, and increased awareness of treatment options. Only two current restraining forces were identified: out-of-pocket cost for probiotics and lack of insurance reimbursement. Patient tolerability and compliance, team training and lack of education were identified as potential restraining forces. With organizational buy-in and parents’ desire for improvement as major driving forces, it appeared that this was an optimal time to initiate the project. Although restraining forces were present, they were not viewed as impossible and the potential driving forces were strong.

**Intervention**

Based on available knowledge, the most frequently identified alternative treatment modality to introduce for eczema patients in the literature was probiotics. Implementing the use of probiotics into the pediatric population with sub-optimally controlled eczema may lead to improved health outcomes, decreased symptoms, improved immune system, and improved quality of life. Forms of probiotics include liquid, powder, chewable, and capsule and are administered by mouth once daily. Probiotic supplements can be taken alone or mixed into water, breastmilk, or formula for administration (Szari & Quinn, 2019). For this project, professional, commercially available probiotics were recommended to the patients by the APRNs such as Klaire Labs Ther-biotic Infant probiotic powder, Klaire Labs Ther-biotic Chewable children’s probiotics, or Klaire Labs Ther-biotic Complete capsules depending on the age of the patient and administration preferences (Prebiotics and Probiotics for Gut Health, n.d.). The probiotics were available for purchase at the clinic site or at the local health food store.
Description of the Intervention

Initially, the patient presented to the outpatient clinic for a scheduled appointment with the APRN. Figure 2 illustrates the process for the pathway. The patient checked in with the front office staff and was brought to the room by the medical assistant (MA). Vital signs were measured and a past and current medical history, including review of systems, were obtained by the MA, and documented within the patient’s chart in the Electronic Health Record (EHR). Additionally, the MA documented what, if any, previous interventions for eczema the patient had tried in the past for treatment, if the intervention was well tolerated, and effective. The information was helpful for the clinician in the decision-making process to determine which patients may be eligible for initiation of probiotics. Ineligible patients included patients that were born prematurely (due to their immature gastrointestinal tract), had previous failure with taking probiotics, were currently taking probiotics, or patients who refused to take oral supplements.

Next, the APRN assessed the patient and determined an appropriate diagnosis based on a baseline physical examination and presenting symptoms. Since there is no laboratory test to diagnose eczema, the clinician made a diagnosis based on objective assessment of the skin and the evaluation of the skin included visual inspection, texture, size, and location of rashes on the body. The APRN used their clinical judgment to establish an appropriate diagnosis and documented both the diagnosis and physical assessment in the patient’s chart within the EHR.

If eczema was diagnosed, the APRN administered a modified Patient Oriented Eczema Measure (POEM) questionnaire for the parent/child dyad to complete (see Appendix E). The POEM survey, a seven-item questionnaire, developed by the University of Nottingham, addresses how often the patient has experienced sleep disturbance, itching, bleeding, weeping, flaking, and cracked skin over the past week (Grinich et al., 2018). This clinical tool was
modified by the project administrator by adding three additional questions to assess for adherence, and possible barriers, and then moreover used to determine subjective symptoms reported by the parent/child dyad (see Appendix F). Data from the modifications to the questionnaire were not calculated into the final POEM score and therefore did not affect the final patient POEM scores. The results from the POEM score helped guide the parent/child dyad and clinician in determining the burden of disease as well as a conversation with them about appropriate goals and treatment plans. The discussion about treatment options included the use of probiotics as an alternative to traditional approaches. It was important for the clinician to provide both conventional and alternative options to families for the treatment of eczema to increase their knowledge base, optimize clinical outcomes, and acknowledge the health beliefs and preferences of the individual parent/child dyad.

Additionally, the clinician discussed any barriers to treatment with probiotics, their willingness to comply with the use of probiotics, and their ability to afford the probiotic supplement when they determined the next steps in the treatment pathway. If the parent/child dyad chose not to participate in the utilization of probiotics for treatment, then traditional approaches to treatment were used and the APRN documented the decision in the EHR. In addition, the APRN documented if there was a possibility of using probiotics as a treatment modality in the future.

If the parent/child dyad made the decision to use probiotics as an alternative approach to treating their eczema, the APRN discussed the plan, including specific probiotic recommendations, locations for purchase, dosages, instructions for use, any noted side effects, intended outcomes, and answered any questions the parent/child dyad may have had. The probiotics were then prescribed to the patient and the form was selected based upon the patient’s
age and capability of ingesting the specific formulation. The detailed care plan was documented within the patient’s EHR. The Diffusion of Innovation (DOI) theory involves sharing knowledge, persuasion, and discussion to obtain the parent/child dyad buy-in to participating in the implementation of the project. Refer to Figure 2 for a depiction of the intervention flowchart. A larger version of the flowchart is found in Appendix G.

**Figure 2**

*Intervention Flowchart*

![Intervention Flowchart](image)

The POEM questionnaire was completed before initiating probiotics to establish an objective baseline of patient symptoms and to make shared decisions about the treatment and treatment goals between the parent/child dyad and APRN. The questionnaire was used to assess progress toward treatment goals at each follow-up appointment (four weeks, eight weeks, and
twelve weeks post implementation). Results from the survey were used to clinically assess the child’s progress and to guide the treatment plan and care pathway. The results were recorded in the patient’s chart during the initial visit and for each follow-up thereafter during the 12-week intervention period.

Upon completion of the appointment with the APRN, the patient checked out with the front desk personnel and was encouraged to schedule a follow-up appointment in four weeks to evaluate adherence and symptom monitoring. Adherence was monitored by self-reporting from the parent/child dyad and documented within the patient’s chart along with the POEM results. Adherence was described as utilizing prescribed doses of probiotics for at least five of seven days in each week. If barriers to adherence were present, the clinician discussed options for overcoming those barriers to fully optimize the treatment plan. Following the patient’s initial appointment, the parents purchased the probiotic supplement from the clinic or the health food store and administered it by mouth daily to the child as directed based upon the prescribed dosage and formulation.

Lastly, the patient followed up in the clinic or via phone call or email with the APRN or project administrator as scheduled (every 4 weeks for 12 weeks) and symptoms and adherence were reassessed utilizing the modified POEM questionnaire and parent/child dyad interview process. A physical examination was also performed to assess skin improvement during in-person follow-up appointments. Results of the repeated POEM questionnaires and physical examination were documented in the patient chart for later comparison.

**Implementation of the Intervention**

Based on the stages of the Diffusion of Innovation (DOI) theory, sharing knowledge, persuasion, and discussion are important initial steps in implementing a new treatment pathway
within an organization. Training was provided by the project leader to any APRN in the organization who was not familiar with the safety, effectiveness, and utilization of probiotics. The project leader allowed for open discussions to address clinician health beliefs, lack of education in treatment of eczema, and lack of clinician experience with the utilization of probiotics in the eczema pathway.

A logic-model identifying resources, activities, outputs, and expected outcomes, was created, and shared with stakeholders to guide implementation of the project (see Appendix H). Developing a flowchart of the intervention process identified a step-by-step progression of the project which was the first phase of the Plan-Do-Study-Act cycle. The healthcare clinician and the parent/child dyad worked together in direct partnership throughout the process. The project director obtained support from the organization’s leadership team and the details of the intervention were presented to the other team members, specifically medical assistants (MAs) and Advanced Practice Nurse Practitioners (APRNs). Conferring with the team and obtaining a group consensus to adopt and carry out the intervention was key in initiating the improvement project. Stakeholders buy-in was vital since the project leader was implementing a novel concept for the organization.

The project director obtained permission to utilize the Patient Oriented Eczema Measure (POEM) questionnaire from the University of Nottingham. The university requested that organizations or individuals register their intended use of their tool including how the clinic was using the tool and in which country it was used. Registration was completed by the project leader and emailed to the University of Nottingham prior to the start of the intervention. Training on how to utilize, score, and document the results of the questionnaire was conducted within the
An eczema pathway was implemented in the clinic among the stakeholders. All questions or concerns from the team were addressed before implementation began.

A post implementation focus group was held with the APRNs to determine clinician opinions and feedback about the implementation process. The clinicians were asked specifically what worked with the implementation process and what did not work with the process, feasibility of the intervention, helpfulness of the POEM questionnaire to patient care, and their opinions of value added to patient care. Furthermore, they were asked to provide their opinions on what needed to be changed or adapted with the process for future application. The answers were recorded in a log for later analysis.

**Evaluation of the Intervention**

Multiple approaches were used to assess the impact of the intervention. The evaluation was guided by the Study-Act phases of the PDSA cycle and was applied to evaluate and adapt the implementation, while the Rogers’ Diffusion of Innovation (DOI) theory assisted in the implementation gaining momentum and buy-in throughout the organization among the APRNs and patients and parents. The framework guided change agents in evaluating whether a change had resulted in an improvement. Commonly, interventions experience multiple rounds of PDSA cycles before finalizing an outcome that is suitable for the organization.

**Measures**

There were multiple expected process outputs and outcome measures with implementation of an eczema pathway. A measures table was developed to clearly outline the objectives and measures. Refer to Appendix I for a detailed outline of the measures and Table 1 for a summary of the measures.
### Objective 1: Implement an eczema pathway that standardizes the introduction of probiotics into the management of eczema in children with sub-optimally controlled eczema.

Implementation was defined as evidenced in the patient’s EHR that each child who presented to the clinic diagnosed with sub-optimally controlled eczema by the clinician or APRN, was introduced to the addition of probiotics to improve symptoms and quality of life. The daily schedule was reviewed within the EHR by the project leader to determine the number of patients who presented with or had a new diagnosis of eczema and the number who were deemed to have inadequate control and would benefit from probiotics. If the patient was diagnosed with eczema, the clinician documented within the patient’s chart if the patient would benefit from probiotics, if probiotics were offered, and if probiotics were chosen as the treatment plan. The goal was that 90% of eligible patients would be offered probiotics. Frequencies and proportions were used to determine adherence to the protocol and participation in the pathway.

### Objective 2: Of the patients who decide to use probiotics and participate in the pathway, 60% will adhere to the treatment and 75% will have a decrease in eczema symptoms and

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**Table 1**

**Measures Table**

<table>
<thead>
<tr>
<th>Outcomes/outputs</th>
<th>How operationalize/ measure</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Introduce probiotics to each eligible patient</td>
<td>• # of patients who present with eczema (eligibility) who are offered probiotics</td>
</tr>
<tr>
<td>• Patients choose to participate</td>
<td>• # of patients who choose to participate</td>
</tr>
<tr>
<td>• Adherence with use of probiotics (did pts fill prescription for probiotics and take the supplement?)</td>
<td>• Frequencies and percentage of adherence/participation (self-reporting) on modified POEM (added 3 additional questions). Adherence=≥ 5 of 7 days, tracked on a weekly basis. Document barriers if applicable.</td>
</tr>
<tr>
<td>• Improved symptoms and QoL (improved patient care)</td>
<td>• POEM Questionnaire (total of 7 questions and score from 0-28)</td>
</tr>
<tr>
<td>• APRN Satisfied with QI project</td>
<td>• Document post implementation comments from focus group (was project feasible and added value to patient care?)</td>
</tr>
</tbody>
</table>
improvement in quality of life. This objective was evaluated by tracking adherence to taking probiotics and improvement in eczema symptoms and quality of life. Evidence of adherence was drawn from the modified POEM questionnaire. At each follow-up visit, the parent estimated the average number of days a week the child was utilizing probiotics. The APRN documented patient adherence on the modified POEM questionnaire utilizing the concept of self-reporting within the EHR system. If the patient did not adhere to the prescribed probiotic, the rationale was documented as cost, side effects, taste, or other on the questionnaire. Evidence of improvement in symptoms and quality of life were drawn from the POEM results in the medical record during each visit over the 12-week implementation period. The goal was that 60% of patients would adhere to the treatment and that 75% of patients who initiated probiotics would self-report improvement in their symptoms and quality of life. The project leader developed a tracking tool to record adherence rates and POEM results in a spreadsheet that assessed baseline, 1-, 2-, and 3-month values for comparison.

The POEM questionnaire is a validated tool used clinically to assess symptom control and quality of life (Grinich et al., 2018). There are seven questions that ask the parent how many days over the last week has their child experienced the specific stated symptom(s). The symptoms include (itching, sleep disturbance, skin bleeding, skin weeping, cracked skin, flaking, and dryness) and the range for symptom frequency is from no days to every day (0 to 4). Refer to the tool in Appendix E for specific scoring questions. Once the questionnaire was completed, the parent returned the form to the APRN for scoring and discussion about their symptom management.

The individual questions were then summed by the medical assistant or APRN, and a total score of 0 to 28 was assigned based on the answers provided. The following is the
individual POEM scores: 0-2 is clear or almost clear, 3-7 is mild eczema, 8-16 is moderate eczema, 17-24 is severe eczema, and 25-28 is very severe eczema. The results of the questionnaire were shared with the parent and discussed in detail to assist the parent in increasing their knowledge about their child’s condition, level of severity, and in hopes of persuading them towards utilizing probiotics as a treatment option. The results of the questionnaire were then recorded into the EHR system within the encounter for documentation purposes and utilized to determine if symptoms had improved since starting the probiotics.

Objective 3: Evaluate Advanced Practice Registered Nurses’ (APRN) satisfaction with the quality improvement project. At the conclusion of the 12-week implementation period, the APRNs within the organization (n=6) participated in a semi-structured focus group to discuss their perceptions and opinions of the feasibility of adding probiotics to standard care as well as the value added. Understanding feasibility and value added were important predictors of sustainability. Feedback, themes, and areas of improvement were abstracted from the focus group transcript. They were able to share their opinions about successes and challenges of implementation. The focus group was conducted by an APRN within the practice who was not the project leader. Stakeholder perceptions and opinions were important in determining the feasibility and likelihood of sustainability of the intervention.

APRN feedback was paramount when determining if any adjustments in the process needed to be made. Informal, intermittent huddles were conducted with the project administrator and the APRNs throughout the course of the 12-week implementation to address this need and provide any coaching needed. This ongoing assessment was important to brainstorm about ideas or suggestions for changes to the process.
**Analysis**

Descriptive statistics including frequency, proportion for categorical measures and means for continuous measures were calculated as well as pre/post change and percent improvement. Analysis of these results provided information about the adherence to probiotic use, implementation, use of the POEM questionnaire, and APRNs feedback on implementation. Qualitative measures were used to describe APRN satisfaction in the post-implementation focus group. This analysis aided in establishing whether the aim(s) of the quality QI project were accomplished.

**Ethical Considerations**

As evidenced by the completed quality improvement checklist (see Appendix J), the project met the criteria for clinical quality improvement and did not meet the definition of human subjects’ research because it was not designed to generate generalizable findings but rather to provide immediate and continuous improvement feedback in the local setting in which the project was carried out. The University of Massachusetts Boston IRB determined that quality improvement projects did not need to be reviewed by the IRB.

There was no formal ethics review or Institutional Review Board (IRB) at the clinic location. The project was vetted by the leadership members of the organization and approved as quality improvement by administration before implementation. The leadership members remained in communication with the project leader before, during, and at the completion of the project.

No ethical concerns were identified, and the parent or caregiver was involved in the decision-making process. The literature demonstrated that probiotics are safe to administer to
children and participation in the intervention was offered to all eligible patients in the clinic. All patient information remained protected and was not used outside of the EHR system.

**Results**

**Implementation of the Pathway**

During the 12-week implementation period, a total of 93 patients presented to the practice for eczema. Of the 93 pediatric patients, 54% (n=50) of patients met the criteria to be offered probiotics and participate in the pathway. Patients were not eligible if they were born prematurely, were currently taking probiotics at the time of the appointment, had previous failure with taking probiotics, or refused to take oral supplements. Of the eligible patients, 86% (n=43) were offered probiotics by the APRN. Refer to Table 2 for a breakdown of eligible patients who were offered probiotics and the total that chose to participate in the project during the 12-week implementation period.
Table 2

Weekly proportion of eligible patients who were offered probiotics and total that chose to participate in the project

| Weeks | Patients offered probiotics (n)/(%) | Patients that participated in project (n)/(%)
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>4 / 6 (67%)</td>
<td>2 / 4 (50%)</td>
</tr>
<tr>
<td>2</td>
<td>3 / 3 (100%)</td>
<td>3 / 3 (100%)</td>
</tr>
<tr>
<td>3</td>
<td>1 / 1 (100%)</td>
<td>0 / 1 (0%)</td>
</tr>
<tr>
<td>4</td>
<td>4 / 4 (100%)</td>
<td>2 / 4 (50%)</td>
</tr>
<tr>
<td>5</td>
<td>1 / 1 (100%)</td>
<td>0 / 1 (0%)</td>
</tr>
<tr>
<td>6</td>
<td>7 / 10 (70%)</td>
<td>2 / 7 (29%)</td>
</tr>
<tr>
<td>7</td>
<td>6 / 6 (100%)</td>
<td>1 / 6 (17%)</td>
</tr>
<tr>
<td>8</td>
<td>2 / 3 (67%)</td>
<td>0 / 2 (0%)</td>
</tr>
<tr>
<td>9</td>
<td>6 / 6 (100%)</td>
<td>4 / 6 (67%)</td>
</tr>
<tr>
<td>10</td>
<td>4 / 5 (80%)</td>
<td>1 / 4 (25%)</td>
</tr>
<tr>
<td>11</td>
<td>3 / 3 (100%)</td>
<td>1 / 3 (33%)</td>
</tr>
<tr>
<td>12</td>
<td>2 / 2 (100%)</td>
<td>1 / 2 (50%)</td>
</tr>
<tr>
<td>Total:</td>
<td>43 / 50 (86%)</td>
<td>17 / 43 (40%)</td>
</tr>
</tbody>
</table>

Eligible patients: (not born prematurely, have not failed with probiotics previously, currently taking probiotics, or refuse to take oral supplements) n=50

Participation: # participants/# offered probiotics
Of the 43 patients who were offered probiotics, 17 (40%) parent/child dyads agreed to participate in the quality improvement project. Parents were asked to evaluate their child’s current eczema symptoms and complete the POEM questionnaire before initiating the intervention. Figure 3 illustrates the demographic characteristics of the children who participated. Participants were well distributed by gender with slightly more males (n=10, 58.8%) than females (n=7, 41.2%). Approximately 76% (n=13) of the patients had private insurance, while the remaining 24% (n=4) were self-pay (cash-pay). Most of the participants, 65% (n=11), were infants under two years of age, and children ages 2-4 years (17%, n=3). See Figure 3 for a detailed breakdown of participant ages.

**Adherence**

During implementation, adherence was assessed and recorded on the modified POEM questionnaires at three points in time (4 weeks, 8 weeks, & 12 weeks). If the parent/child dyad self-reported taking probiotics for an average five or more days of the week and took the probiotics for at least 50% of the 12-week implementation period, the participant was considered adherent to the protocol. If they reported four or less days a week, or less than 50% of the 12-week implementation period, they were considered not adherent. As illustrated in Figure 4, the majority of children (76%, n=13) were successful in taking the probiotics for much of each week. See Figure 4 for a depiction of percentages of adherence. For those children whose parents reported barriers to taking their probiotics for most of the week, a rationale was selected from the
list (cost, side effects, taste, or other) and those barriers were recorded on the data tracking form.

**Figure 4**

*Adherence to taking probiotics*

![Adherence to probiotics protocol](image)

The most frequently reported rationale was “other” (n=6), followed by “cost” (n=3), “side effects” (n=2), and “taste” (n=1).

**Symptom improvement**

As described previously, symptoms were reported at four points in time; Prior to beginning treatment, parents completed the subjective self-report of symptoms for their child with the child’s input if age appropriate. As illustrated in Table 3, the POEM score was recorded at each point in time and then a pre/post change score and percent improvement were calculated. Percent improvement was defined as pre minus post divided by pre. Once the individual scores were calculated, a mean score for the participants (n=17) was calculated for the pre-POEM score and post-POEM score and used to calculate the mean change and mean percent improvement. The overall mean score improved by 54% and the overall mean percent improvement was 64% over the 12 weeks of the project. The lowest preliminary POEM score was 1 and the highest preliminary score was 23.

There was no noted attrition since each parent/child dyad participated through the end of the entire 12-week implementation period. Every parent completed POEM questionnaires 1, 2, and 4. Only three parents (18%), did not complete POEM questionnaire number 3 in the allotted time frame, therefore their response was left blank in the data set.
Table 3

*POEM scores, change score, % improvement, and symptom reduction*

<table>
<thead>
<tr>
<th>Participant Number</th>
<th>POEM #1</th>
<th>POEM #4</th>
<th>Change score</th>
<th>% Improvement (from POEM #1 to POEM #4)</th>
<th>Symptoms reduced?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>12</td>
<td>3</td>
<td>-9</td>
<td>75%</td>
<td>Yes</td>
</tr>
<tr>
<td>2</td>
<td>2</td>
<td>1</td>
<td>-1</td>
<td>50%</td>
<td>Yes</td>
</tr>
<tr>
<td>3</td>
<td>12</td>
<td>10</td>
<td>-2</td>
<td>17%</td>
<td>Yes</td>
</tr>
<tr>
<td>4</td>
<td>8</td>
<td>0</td>
<td>-8</td>
<td>100%</td>
<td>Yes</td>
</tr>
<tr>
<td>5</td>
<td>12</td>
<td>8</td>
<td>-4</td>
<td>33%</td>
<td>Yes</td>
</tr>
<tr>
<td>6</td>
<td>14</td>
<td>5</td>
<td>-9</td>
<td>64%</td>
<td>Yes</td>
</tr>
<tr>
<td>7</td>
<td>7</td>
<td>4</td>
<td>-3</td>
<td>43%</td>
<td>Yes</td>
</tr>
<tr>
<td>8</td>
<td>5</td>
<td>5</td>
<td>0</td>
<td>0%</td>
<td>No</td>
</tr>
<tr>
<td>9</td>
<td>23</td>
<td>9</td>
<td>-14</td>
<td>61%</td>
<td>Yes</td>
</tr>
<tr>
<td>10</td>
<td>3</td>
<td>3</td>
<td>0</td>
<td>0%</td>
<td>No</td>
</tr>
<tr>
<td>11</td>
<td>11</td>
<td>0</td>
<td>-11</td>
<td>100%</td>
<td>Yes</td>
</tr>
<tr>
<td>12</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0%</td>
<td>No</td>
</tr>
<tr>
<td>13</td>
<td>7</td>
<td>2</td>
<td>-5</td>
<td>71%</td>
<td>Yes</td>
</tr>
<tr>
<td>14</td>
<td>14</td>
<td>6</td>
<td>-8</td>
<td>57%</td>
<td>Yes</td>
</tr>
<tr>
<td>15</td>
<td>9</td>
<td>4</td>
<td>-5</td>
<td>56%</td>
<td>Yes</td>
</tr>
<tr>
<td>16</td>
<td>19</td>
<td>1</td>
<td>-18</td>
<td>95%</td>
<td>Yes</td>
</tr>
<tr>
<td>17</td>
<td>18</td>
<td>1</td>
<td>-17</td>
<td>94%</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>MEAN:</strong></td>
<td>10.41</td>
<td>3.7</td>
<td>-6.74</td>
<td>54%</td>
<td>14/17 (82%)</td>
</tr>
<tr>
<td><strong>MEAN % IMPROVEMENT:</strong></td>
<td></td>
<td></td>
<td></td>
<td>64%</td>
<td></td>
</tr>
</tbody>
</table>

*Advanced Practice Registered Nurses’ (APRN) Satisfaction*

A post-implementation focus group was assembled, composed of APRNs (n=6), all of which were female, within the practice. One hundred percent of the APRNs within the practice...
participated in the project and focus group during the entire implementation period. In a semi-structured, open-discussion format, the APRNs were asked a series of five questions written by the project administrator about the QI project. Questions explored the providers' perceptions of feasibility, helpfulness in decision making and planning for patient care, value added to patient care, area of improvement, and any additional feedback that would be useful for future implantation. Table 4 provides sample feedback related to the questions asked.

Table 4

Post Implementation Semi-Structured Focus Group (APRNs) (n=6)

*Focus group was conducted by an APRN at the practice site who was not the project leader.

<table>
<thead>
<tr>
<th>Question</th>
<th>APRN feedback</th>
</tr>
</thead>
<tbody>
<tr>
<td>Was the implementation of probiotics feasible in patient care?</td>
<td>Very easy to follow</td>
</tr>
<tr>
<td></td>
<td>Feasible for patients</td>
</tr>
<tr>
<td></td>
<td>Low cost, low effort for patients, easily accessible, available on site</td>
</tr>
<tr>
<td></td>
<td>Questionnaire easy to read and follow, not overwhelming</td>
</tr>
<tr>
<td>Was the POEM questionnaire helpful in your decision making and planning for your patient?</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>Helpful if determining if root cause was gut related</td>
</tr>
<tr>
<td></td>
<td>Helped providers to see direct correlation</td>
</tr>
<tr>
<td></td>
<td>Mostly, read only one time (didn’t look at poem results)</td>
</tr>
<tr>
<td>Do you feel there was value added to patient care with this project if we continue to use the POEM form and utilize probiotics? If so, explain?</td>
<td>Yes, helped parents identify correlation – promoted patient adherence</td>
</tr>
<tr>
<td></td>
<td>Follow ups helped with consistency</td>
</tr>
<tr>
<td></td>
<td>Difficult with patients who did not follow up in office</td>
</tr>
<tr>
<td></td>
<td>Yes, would help if I was the one following up with the POEM.</td>
</tr>
<tr>
<td>Areas of improvement for the project? If the organization continues to use the protocol, what suggestions or changes do you propose?</td>
<td>Qualifications of probiotic - # of cultures, strains. Switching probiotics could also decrease symptoms</td>
</tr>
<tr>
<td></td>
<td>Questions geared towards follow up</td>
</tr>
<tr>
<td></td>
<td>Very simple to implement</td>
</tr>
<tr>
<td></td>
<td>Small sample size</td>
</tr>
<tr>
<td></td>
<td>Increased project length of time</td>
</tr>
<tr>
<td></td>
<td>Time of year</td>
</tr>
<tr>
<td></td>
<td>Algorithm more accessible</td>
</tr>
<tr>
<td>Other feedback for the project?</td>
<td>No barriers to providers to implement</td>
</tr>
<tr>
<td></td>
<td>Sooner follow up</td>
</tr>
<tr>
<td></td>
<td>Increased flexibility for follow up time</td>
</tr>
<tr>
<td></td>
<td>Offering incentive to increase follow up (could skew results)</td>
</tr>
</tbody>
</table>
Discussion

Summary

The introduction of a pathway that standardized the use of probiotics in children with eczema was associated with a reduction in overall eczema symptoms and an improvement in quality of life in the participants. Of the parent/child dyads who participated in this project, the majority were able to adhere to the use of probiotics and experienced an improvement in symptoms, with the greatest improvement occurring in those children with moderate to very severe symptom burden at baseline. Furthermore, the APRNs were satisfied with the QI project and perceived an increase in value added to patient care.

Ninety-four percent of the patients took the probiotic without any noted side effects. Only one patient reported having unwanted side effects which were described as experiencing “mild gassiness and bloating after taking the probiotic supplement”. The symptoms subsided once the patient discontinued its use. Another notable comment from one parent/child dyad was “she loves it” when asking if the patient was taking the probiotic daily. Much of the time if the parent/child dyad selected “other” as a rationale for not adhering, the main comments were that they forgot or ran out of the probiotic. Many parents included comments on the form that they were really motivated by an improvement in their child’s symptoms. Cost of the probiotic was a factor for some families. Estimated cost of probiotics for chewable tablets are $5.25 per week or $22 dollars per month and infant powder $2.00 dollars per week or $8.75 per month. Prices vary by brand, formulation, and ingredients. Tracking barriers was useful for sustainability of the intervention and for future potential projects.

The first aim, to secure at least 90% of eligible patients be offered probiotics when presenting to the clinic with eczema, was nearly met but fell short by only 4%. The goal that at
least 60% of participants would adhere to the treatment was surpassed since 76% of participants reported adherence to the protocol during the project. The symptom improvement goal of 75% of participants will show a decrease in symptoms and have an improvement in quality of life was also met and surpassed since 82% of patients showed a reduction in symptoms. Sixty-four percent of participants showed an overall mean percent improvement from the initial POEM questionnaire to the final POEM questionnaire.

The final objective of the project was to evaluate APRN satisfaction with the quality improvement project which was completed by collecting subjective qualitative data via a semi-structured focus group. The consensus among the APRNs was that the project was perceived as being valuable and quite feasible to follow, conduct, and implement among their patients. The APRNs shared that the POEM questionnaire and QI project was helpful in determining root cause and correlation of improvement among those patients who were utilizing probiotics. Additionally, it was sensed that the follow-up POEM questionnaires were helpful in both promoting patient adherence and consistency with taking probiotics when patients could see their scores improve over time. When patients chose to follow-up via phone call or email with the project administrator rather than in-person visits to complete subsequent POEM forms, it was noted as less valuable to the APRN. The most likely reason for this is because the APRN was not able to evaluate the improvement scores herself.

Many rapid PDSA cycles were executed over the 12 weeks of project implementation period and the project was revised accordingly. For example, there were a few modifications made to the intervention process over time to include: a) change in available follow-up format from in-person to phone call or email, b) slight modification to the POEM questionnaire to include the addition of the date of completion to assist with proper data tracking, c) initiating a
chart alert pop-up within the EHR to alert the APRNs of which patients were participating in the project so a follow-up POEM questionnaire could be provided, and finally, d) adding check boxes for preferred form of follow-up by the parent (email, phone call, or in-person). The changes were made in hopes to avoid attrition, improve data tracking, and improve response rate of parents.

When exploring areas of improvement for the project and other feedback from the APRN perspective, they would like to continue this over a longer period of time so they can get experience with more participants and see if there is any seasonal variation. Furthermore, the APRNs shared that they might suggest switching probiotic brands and strains of probiotics throughout the project to see if that affected the outcomes in patients who did not demonstrate a reduction in symptoms on the initial probiotic. In future, it was suggested to offer increased flexibility in the follow-up time and possibly offer an incentive to the patients to complete their follow-up questionnaires, however they agreed that this may lend itself to possible bias and skew results.

There were some unexpected problems that arose during the project. First, some APRNs neglected to offer the protocol to their patients who presented with eczema, possibly it was not on the forefront of their thoughts as time progressed and they simply forgot. Second, some patients were receptive to adding probiotics into their daily routines but were not agreeable to participating in the project. It was anticipated that there would be more participation from this patient population and a larger participant cohort would be helpful to evaluate trends. Third, consistent follow-up by the parent was the ultimate challenge faced by the administrator during the improvement project. Often, it took multiple attempts via email or phone call to obtain the subsequent POEM questionnaires in the time set forth by the outlined project. Parents are busy
and some have full-time jobs and do not have extra time to return to the clinic for a follow-up visit, which is what necessitated the adjustments to the project to allow for email follow-up in lieu of in person follow-up. Offering telehealth appointments as a means of follow-up could be an option for the future. Affordability of the probiotic supplement and co-pays or expenses for follow-up visits could also have been a factor which led to inconsistencies in follow-up and non-adherence with the protocol throughout the project.

The time of year may play a role in eczema symptom management. The QI project took place in the fall and winter in the Dallas area which are known to be drier months for the area. It would be interesting to conduct the improvement project during different times of the year to compare outcomes among patients.

Strengths of the project include parental motivation to participate in the project and improvement in their child’s symptoms which greatly discouraged attrition. Probiotics were available for purchase within the clinic site, thus convenience to the parent was an additional advantage. The APRNs in the clinic were enthused to participate due to their inherent interest in alternative healthcare approaches. Additionally, the project administrator was motivated, well-organized, and able to maintain and meet timeline requirements of the project.

Roger’s Diffusion of Innovation (DOI) model provided the framework for introducing the pathway to the parent/child dyads via the APRNs (2003). Utilizing the DOI model to address barriers in a quality improvement project increases the likelihood of adoption of the new process (Bostwick & Champion, 2022). Elements of the DOI model were realized when the project gained momentum over time among the collective group. The results of the questionnaire were shared with the parent and discussed in detail to assist the parent in increasing their knowledge about their child’s condition and level of severity in hopes of persuading them towards utilizing
probiotics as a treatment option. There were some early adopters of the project among the APRN group who were the change agents and aided in persuading the rest of the group to participate in the project. Knowledge was instilled easily within the group and there was minimal persuasion needed to encourage participation. Over time, as the DOI model is achieved, it is anticipated that more parent/child dyads will make decisions to adopt change leading to a higher participation rate.

Even though the participation rate was only 40%, in the end, seventeen families were highly motivated to participate, the APRNs within the clinic had buy-in, and many families were enthused to continue use of probiotics because they were recognizing improvement in their child’s symptoms and the positive benefit realized in their everyday life. Moreover, the APRNs realized the benefits of the POEM questionnaires in having a tangible improvement score to gauge their patient’s progress. The empirical outcomes led to confirmation by the group. The overall feasibility, sustainability, and affordability of the project are motivating factors for future implementation within the clinic.

**Interpretation**

Literature suggests the higher the initial symptom burden or score, the more opportunity for improvement over time (Mazza et al., 2022). In comparison, lower initial symptom scores are often associated with less change over time. When the participants were sorted by symptom burden, it was found that this was true for the patients in this project. Participants with a low symptom burden (nearly clear/mild; POEM scores ≤ 7; n=6) had a mean percent improvement of 36%. Conversely, participants with a high symptom burden (moderate/severe/very severe; POEM scores ≥ 8; n=11) had a mean percent improvement of 69%. By the end of the implementation period, no participants were classified as “severe” or “very severe eczema” and
only three participants (18%) were classified as “moderate eczema” and the remaining participants (n=14, 82%) were characterized as having “clear” or “mild” symptoms. Overall, each participant had either the same or a decrease in their symptom burden compared to baseline and improvement in quality of life.

Limitations and Challenges

Because this was a quality improvement project and not research, the improvement in symptoms experienced by the participants should be interpreted as clinical improvement, but a causal relationship between the probiotic and the outcome cannot be assumed. Eczema is a multifactorial disease process necessitating a multifaceted approach to optimize clinical outcomes therefore, other factors and confounders may have contributed to the outcome which could create potential for bias (Shi & Lio, 2019). For example, the patients may have been taking other medications such as antibiotics or have food or other allergies that could affect their skin. Additional research needs to be conducted in this area and should explore dosages and types of probiotics. Research investigating whether there is any significant correlation between percent improvement and age of the child would be of interest.

Conclusions and Recommendations

Improving quality of life and eczema symptoms in children suffering from sub-optimally controlled eczema was the overarching goal of this quality improvement project. The nurse-driven initiative was successfully implemented and met most of the established aims, ultimately demonstrating objective improvement in children’s health and overall quality of life. Of the patients that elected to take the probiotics, the pathway was well received and there was a high rate of adherence. The project was positively perceived as overall safe, simple, and sustainable for future use within the clinic setting. The participants showed overall positive improvement
and stakeholders were encouraged by the results and motivated to continue regular use of probiotics. The implications in clinical practice could fill the gap of lack of existing knowledge about alternative approaches to treating eczema, especially as a safe, first-line option for the treatment of eczema.

Should the intervention be continued in the clinic setting, the project administrator would propose sharing POEM results with the APRNs frequently so they could appreciate improvement in symptoms sooner. For example, a monthly presentation of individual participant progress may be advantageous and appreciated. Furthermore, future hires should be educated on the potential benefits and usefulness of probiotics in combating eczema symptoms and encouraged to introduce them for use in their patients.

Recommended next steps include exploring other improvement projects focusing on education for parents and healthcare providers on eczema prevention or utilizing additional, non-pharmacological approaches to combating eczema. Moreover, other alternative approaches to managing health challenges faced in the pediatric population may be of interest to explore such as combining supplements leading to a synergistic effect. Further consideration in this area is warranted. Longer term, the principal goal is to expose more healthcare providers and patients to alternative approaches in treating chronic ailments in children.

**Funding**

The project did not require much financial support outside of printed materials and cost of probiotic supplements. The organization’s leadership team and project administrator provided funding for expenses of printed materials. Individual families who participated in the project were responsible for purchasing probiotics for their own use. Payment for initial and follow-up visits at the practice location were provided by the parent or responsible party via self-pay or
private insurance payments. There was no fee assessed to participants for follow-up phone calls or emails when completing POEM questionnaires.
References


Cheng, H.M., Chiang, L.C., Jan, Y.M., Chen, G.W., & Li, T.C. (2011). The efficacy and safety of a Chinese herbal product (Xiao-Feng-San) for the treatment of refractory atopic


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https://doi.org/10.1186/s12887-019-1753-7


https://doi.org/10.1002/prp2.679


Alternative and Complementary Medicine, 22(3), 237–243.

https://doi.org/10.1089/acm.2015.0324
## Appendix A

### Evidence Summary

What are the most effective non-pharmacological strategies to improve symptoms for persons with eczema?

<table>
<thead>
<tr>
<th>Studies</th>
<th>Intervention</th>
<th>Significant Findings and Outcomes</th>
<th>*Level/Quality of Evidence and Sample Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Foolad et al (2013)</td>
<td>Probiotics</td>
<td>A. Researchers found a significant reduction in AD severity after supplementation. Majority of studies found that certain nutrition supplementation was able to prevent the development or severity of AD</td>
<td>A. 5/B N= 21 studies (n=6859 participants, children &lt;3 y/o, 4134 infants or mothers served as controls).</td>
</tr>
<tr>
<td>B. Fuchs-Tarlovsky et al (2016)</td>
<td></td>
<td>B. Authors found enough evidence to recommend the use of probiotics in specific conditions in dermatology practice (esp w/AD).</td>
<td>B. 5/B N= 42 studies</td>
</tr>
<tr>
<td>C. Institute for Functional Medicine (IFM) (n.d.)</td>
<td></td>
<td>C. Probiotic supplementation has a reported benefit for children with AD</td>
<td>C. 5/A</td>
</tr>
<tr>
<td>D. Kim et al (2014)</td>
<td></td>
<td>D. Treatment with a mixture of different bacterial species or of Lactobacillus species showed greater benefit than did treatment with Bifidobacterium species alone.</td>
<td>D. 5/A N=25 RTCs (n=1,599 participants) (n=1143 children)</td>
</tr>
<tr>
<td>E. Lu et al. (2019)</td>
<td></td>
<td>E. Probiotics showed significant effect compared with placebo</td>
<td>E. 1/A N=24 RTCs (2233 children &lt; 14 y/o)</td>
</tr>
<tr>
<td>F. Navarro-Lopez et al (2018)</td>
<td></td>
<td>F. The mixture of probiotics was effective in reducing SCORAD index and reducing the use of topical steroids in patients with moderate AD</td>
<td>F. 1/B N=50 children. 26 [50%] female; mean [SD] age, 9.2 [3.7] years) participated</td>
</tr>
<tr>
<td>G. Schmidt et. al (2019)</td>
<td></td>
<td>G. Observed a significantly lower incidence of eczema in the probiotic group compared to the placebo group</td>
<td>G. 1/A N=290 infant participants. n=144 in the probiotic group and n=146 in the placebo group. Mean age at intervention start was 10.1 months</td>
</tr>
<tr>
<td>H. Li, et al., (2019)</td>
<td></td>
<td>H. Oral probiotic use (with Lactobacillus, Bifidobacterium, and Propionibacterium) during gestation and infancy has been found to decrease AD risk.</td>
<td>H. 1/A</td>
</tr>
<tr>
<td>I. Camargo et. al (2014)</td>
<td>Vitamin D</td>
<td>I. Vitamin D supplementation produced a clinically and statistically significant improvement in EASI score</td>
<td>I. 1/A N=107 children. Median age of subjects was 9 years (range 4 years to 14 years), and 59% were male</td>
</tr>
<tr>
<td>J. Institute for Functional Medicine (IFM) (n.d.)</td>
<td></td>
<td>J. Vitamin D supplementation has been found to decrease eczema severity</td>
<td>J. 5/A</td>
</tr>
<tr>
<td>K. Mansour et. al (2020)</td>
<td></td>
<td>K. The mean EASI score was significantly lower in the treatment group compared to placebo group (P = .035). The percent change in EASI score</td>
<td>K. 1/B N=86 children, aged from 5 to 16 years old</td>
</tr>
<tr>
<td>Study (Year)</td>
<td>Treatment</td>
<td>Evidence Statement</td>
<td>Evidence Details</td>
</tr>
<tr>
<td>------------------------------</td>
<td>------------------</td>
<td>-------------------------------------------------------------------------------------</td>
<td>---------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Chang et. al (2016)</td>
<td>Melatonin</td>
<td>Melatonin supplementation is a safe and effective way to improve disease severity in children with AD</td>
<td>N=48 patients, aged 1 to 18 years with physician-diagnosed AD involving at least 5% of the total body surface area. n=24 placebo group, n=24 melatonin group</td>
</tr>
<tr>
<td>L. Schachner (1998)</td>
<td>Stress reduction techniques</td>
<td>L. Massage, progressive muscle relaxation, education, cognitive behavioral therapy, autogenic training can be helpful for reduction of AD symptoms</td>
<td>L. 1/A</td>
</tr>
</tbody>
</table>
| M. Xie et. al (2020)         | N/A              | M. Stress reduction techniques were effective in improving skin symptoms and psychosocial well-being among 6–12-year-old children living with AD | M. 1/A
|                              |                  | N=163 children, primary school age                                                   |                                             |
| Itamura (2007)               | Homeopathics     | 88.3% of patients reported over 50% improvement after individualized homeopathic treatment | N=60 pts (15 men and 45 women aged 14–77 years, mean age: 59) |
| Foolad et. al (2013)         | Prebiotics       | Researchers reported reduction in AD incidence by greater than 50%. Prebiotic use was effective in reducing the development of AD | N=21 studies (n=6859 participants, including infants/mothers) |
| N. Pfab et. al (2010)        | Acupuncture/Acupressure | N. Subjects showed significant reduction in itch                                      | N=30 (mean age: 28.6)                      |
| O. Pfab et. al (2012)        |                  | O. Marked itch intensity reduction                                                   | O. 1/A
| P. Lee et. al (2011)         |                  | P. Significant improvement in symptoms                                               | P. 1/B
|                              |                  | N=15 (10=men, median age=36; Caucasian=4)                                           |                                             |
| Q. Foolad et. al (2013)      | GLA (gamma-Linolenic acid) | Q. 13 studies focused on infants with a family history of atopic disease. For infants or children w/AD, GLA may have a positive effect on reducing AD severity | Q. 1/B
| R. Jaw Van Gool et. al (2003)| TYO treatment (Tzu-Yun ointment) | R. Early supplementation w/ GLA tends to alleviate severity of AD in later infancy in children at high familial risk; decrease in severity of AD | R. 1/A
|                              |                  | N=121 children (GLA group n=61 (55% girls); Placebo group n=60 (53% girls))         |                                             |
| Jaffary et. al (2015)        | Vitamin E        | This study suggests that vitamin E can improve the symptoms and the quality of life in patients with AD | N=70 participants with mild-to-moderate AD (aged 10-50 years old) |
| Yen & Hsieh (2016).          | TYO treatment    | TYO (Tzu-Yun ointment) may be as effective as TS (topical steroids) therapy for AD; has potential as alternative tx for AD | N=31; TS group (n=16); 6 female, age 39.6 (+/- 12.3)
|                              |                  | TYO group p= (n=15); 5 female, age 32.9 (+/- 13.4)                                    |                                             |
| Mehrbani et. al. (2015)      | Whey associated with dodder seed extract | Significant difference regarding the pruritus after 15 days of receiving tx          | N=42 (36 female, age= 26.47) |
| Cheng et. al (2011)          | XFS (Chinese herbal product) | Decrease in the total lesion score in the tx group was significantly greater than that of the placebo group. | N=69 (Age=XFS 12.2, Placebo 13.6; Male=XFS 25, Placebo 12) |

1. **Clinical Microsystem Name**: Outpatient primary care center
2. **Subpopulation of patients**: Pediatric patients with eczema

### Appendix B

#### Administrative Staff

#### Medical Assistants

#### Nurse Practitioner

#### Laboratory

#### Free Standing Primary Care Clinic/Patients

#### Home/Parents

#### Pharmacy/Supplement store

#### Billing Dept/EHR System

**3. List the specific health care needs**

- Assessment
- Diagnosis/Testing
- Prescriptions/Recommendations
- Patient & parent/caregiver education regarding disease management/shared decision making
- Follow up appointments

**Improvement Ideas**: Provide patient/parent/caregiver education to increase awareness of non-pharmacological approaches to eczema to patients/parents/caregiver and other primary care providers. Improve eczema symptoms in children by implementing probiotics into management plan.
Appendix C

Fishbone diagram worksheet

Name: Christie Potter
Date: March 2022
Appendix D

Current driving forces
- Organizational buy-in
- Pt/parent desire for improvement
- Safety of product

Potential driving forces
- Increased awareness of options for tx
- Team support
- Efficacy of tx

Current restraining forces
- Cost
- No insurance reimbursement

Potential restraining forces
- Team Training
- Pt tolerability/compliance
- Lack of education

Implementing probiotics use with eczema pts
Appendix E

### POEM Patient-Oriented Eczema Measure

**POEM (Proxy) for POEM completion (e.g. by parent)**

**Patient Details:**

<table>
<thead>
<tr>
<th>Age</th>
<th>Sex</th>
<th>Height (cm)</th>
<th>Weight (kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Date:**

---

Please circle one response for each of the seven questions below about your child’s eczema. If your child is old enough to understand the questions then please fill in the questionnaire together. Please leave blank any questions you feel unable to answer.

1. Over the last week, on how many days has your child’s skin been itchy because of their eczema?
   - No days
   - 1-2 days
   - 3-4 days
   - 5-6 days
   - Every day

2. Over the last week, on how many nights has your child’s sleep been disturbed because of their eczema?
   - No nights
   - 1-2 nights
   - 3-4 nights
   - 5-6 nights
   - Every night

3. Over the last week, on how many days has your child’s skin been bleeding because of their eczema?
   - No days
   - 1-2 days
   - 3-4 days
   - 5-6 days
   - Every day

4. Over the last week, on how many days has your child’s skin been weeping or oozing clear fluid because of their eczema?
   - No days
   - 1-2 days
   - 3-4 days
   - 5-6 days
   - Every day

5. Over the last week, on how many days has your child’s skin been cracked because of their eczema?
   - No days
   - 1-2 days
   - 3-4 days
   - 5-6 days
   - Every day

6. Over the last week, on how many days has your child’s skin been flaking off because of their eczema?
   - No days
   - 1-2 days
   - 3-4 days
   - 5-6 days
   - Every day

7. Over the last week, on how many days has your child’s skin felt dry or rough because of their eczema?
   - No days
   - 1-2 days
   - 3-4 days
   - 5-6 days
   - Every day

---

**Total POEM Score (Maximum 28):**

---

### How is the scoring done?

Each of the seven questions carries equal weight and is scored from 0 to 4 as follows:

- No days = 0
- 1-2 days = 1
- 3-4 days = 2
- 5-6 days = 3
- Every day = 4

**Note:**

- If one question is left unanswered this is scored 0 and the scores are summed and expressed as usual out of a maximum of 28
- If two or more questions are left unanswered the questionnaire is not scored
- If two or more response options are selected, the response option with the highest score should be recorded

---

### What does a POEM score mean?

To help patients and clinicians to understand their POEM scores, the following bandings have been established (see references below):

- 0 to 4 = Clear or almost clear
- 5 to 7 = Mild eczema
- 8 to 16 = Moderate eczema
- 17 to 24 = Severe eczema
- 25 to 28 = Very severe eczema

---

### Do I need permission to use the scale?

Whilst the POEM scale is protected by copyright, it is freely available for use and can be downloaded from [www.nottingham.ac.uk/dermatology](http://www.nottingham.ac.uk/dermatology). We do however ask that you register your use of the POEM by e-mailing cepb@nottingham.ac.uk with details of how you would like to use the scale, and which countries the scale will be used in.

---

### References


© The University of Nottingham. The Patient Oriented Eczema Measure (POEM) scale is free to use. Permission is granted to reproduce and/or redistribute this material in its entirety without modification. Any use which falls outside this remit requires the express consent of the copyright owner.
Appendix F

POEM
Patient-Oriented Eczema Measure

Patient’s Name: 
DOB: 
Date: 

Please select one response for each of the seven questions below about your child’s eczema. If your child is old enough to understand the questions, then please complete the questionnaire together. Please leave blank any questions you feel unable to answer.

1. Over the last week, on how many days has your child’s skin been ITCHY because of their eczema?
   - No days
   - 1-2 days
   - 3-4 days
   - 5-6 days
   - Every day

2. Over the last week, on how many nights has your child’s SLEEP BEEN DISTURBED because of their eczema?
   - No days
   - 1-2 days
   - 3-4 days
   - 5-6 days
   - Every day

3. Over the last week, on how many days has your child’s skin been BLEEDING because of their eczema?
   - No days
   - 1-2 days
   - 3-4 days
   - 5-6 days
   - Every day

4. Over the last week, on how many days has your child’s skin been WEEPING or OOZING clear fluid because of their eczema?
   - No days
   - 1-2 days
   - 3-4 days
   - 5-6 days
   - Every day

5. Over the last week, on how many days has your child’s skin been CRACKED because of their eczema?
   - No days
   - 1-2 days
   - 3-4 days
   - 5-6 days
   - Every day

6. Over the last week, on how many days has your child’s skin been FLAKING off because of their eczema?
   - No days
   - 1-2 days
   - 3-4 days
   - 5-6 days
   - Every day

7. Over the last week, on how many days has your child’s skin felt DRY or ROUGH because of their eczema?
   - No days
   - 1-2 days
   - 3-4 days
   - 5-6 days
   - Every day

8. Was the PAST WEEK a typical week for your child’s eczema symptoms (if not, was it better or worse than usual)?
   - Typical
   - Better than usual
   - Worse than usual

9. On average over the past month, how many days per WEEK would you say that your child took the probiotic?
   - Number of days: 

10. If your child did NOT take the probiotic over the past month, why?
    - Cost
    - Side Effects
    - Taste
    - Other

Total POEM Score (Maximum 28): 

For Office Use Only
Appendix G

**Intervention Flowchart**

1. **In person visit to clinic (patient & caregiver)**
   - Pt is checked in and roomed for APRN
   - Physical exam and diagnosis by APRN (eczema)
   - Is probiotic appropriate for the patient?
     - Yes
     - APRN & parent engage in shared decision making about probiotic use
       - No: May offer at a later date
     - No: POEM Questionnaire administered/scored & documented
       - No: Pt to check out from clinic
       - Yes: Choose probiotic/care plan
   - Yes: May consider at a later date (if appropriate)

2. Pt to schedule follow up appt for adherence & sx monitoring
3. Pt to purchase probiotic
4. Pt to initiate probiotic
   - Yes: Follow up appt to evaluate every 4 weeks + re-administer POEM questionnaire
   - No: Routine follow up & care

5. Reassess effectiveness in 3 months + final POEM
Appendix H

Problem: Sub-optimally managed eczema is among the most common reasons patients present to the outpatient pediatric clinic for treatment.

Goal: Improve quality of life (QoL) and eczema symptoms in children suffering from eczema.

APPENDIX G: LOGIC MODEL

**Inputs**
- Organizational support
- MAs and APRNs
- Parent buy-in & resources
- POEM questionnaire
- Workflow/time
- Leadership

**Activities**
- Review the current tx protocols for patients with eczema
- Review POEM questionnaire for pre/post treatment w/team
- Identify probiotics to use for implementation
- Send email w/details of how the POEM tool will be used to Univ. of Nottingham

**Outputs**
- Identity patients to participate
- Implement pathway including pre/post POEM questionnaires
- Implement standardized holistic pathway

**Short-term outcomes (4 weeks)**
- Increased utilization of probiotics in eczema patients (90% pt participation)
- Pts participate in monthly follow-up appts
- Improvement in patient outcomes (sx and QoL)

**Intermediate outcomes (12 weeks)**
- Providers will be satisfied with implementation
- 90% of pts still utilizing probiotics in tx
- 75% of pts keep their follow-up appointments
- Increased number of patients with symptom improvement

**Long-term outcomes (future)**
- Sustained improvements in eczema symptoms/QoL
- Improved patient care in eczema patients (75% of pts w/decreased sx and improved QoL)
- Probiotics becomes standard of care in use with eczema pts

**Impact:** Reduce symptoms and improve overall quality of life in children with eczema.
Appendix I

Measures

**Goal:** Improve quality of life (QoL) and eczema symptoms in children suffering from sub-optimally controlled eczema

**Aims:**
- Develop and implement an eczema pathway that standardizes the introduction of probiotics into the management of eczema for children with sub-optimally controlled eczema. Secure ≥ 90% of eligible patients offered probiotics.
- Of the participants who initiated probiotics and participated in the pathway, 60% will adhere to the treatment and 75% will have a decrease in eczema symptoms and improvement in quality of life.
- Advanced Practice Registered Nurses’ (APRN) will report the introduction of probiotics to be feasible and add value to patient care.

<table>
<thead>
<tr>
<th>Aim or Objectives</th>
<th>Outcomes/outputs</th>
<th>How operationalize/measure</th>
<th>Where will you get the information</th>
<th>Will you have a comparison</th>
<th>Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Develop/implement an eczema pathway and secure ≥ 90% of eligible patients would be offered probiotics. Offer participation in the project to eligible patients</td>
<td>Offer probiotic use to each patient diagnosed with eczema at routine visits</td>
<td>Chart reviews and documentation</td>
<td>EHR System/daily schedule</td>
<td>No</td>
<td>Frequencies and proportions will be used to determine prevalence and participation in the pathway.</td>
</tr>
</tbody>
</table>
| Of the participants who initiated probiotics and participated in the pathway, ≥ 60% will adhere to the treatment and ≥ 75% will have decrease in eczema symptoms and improvement in quality of life | - Continue use of probiotics  
- Improved symptoms and QoL                                                       | POEM Questionnaire (total of 7 questions and score from 0-28). POEM modified to include 3 additional questions about adherence & barriers. | POEM Questionnaire completed by parent and documented into EHR system | Pre/Post POEM Questionnaire for clinical comparison | Document adherence to taking probiotics & improvement in eczema sx and QoL. Evidence of adherence will be drawn from the modified POEM questionnaire. Evidence of improvement in symptoms and QoL will be drawn from the POEM results in the EHR over the implementation period. |
| APRNs satisfaction with QI project / implementation                              | - Improved overall patient care and value added  
- APRNs satisfied with QI project                                                  | - Log perceptions/opinions, feasibility in transcript from group meeting                | - APRN huddle/focus group post implementation | No                           | Feedback, themes, and areas of improvement will be abstracted from the focus group transcript. |
Appendix J

**CLINICAL QUALITY IMPROVEMENT CHECKLIST**

<table>
<thead>
<tr>
<th>Date: April 2022</th>
<th>Project Leader: Christie Potter</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Project Title:</strong> Introduction of Probiotics to Improve Eczema Symptoms in Children in one Pediatric Primary Care Practice: A Quality Improvement Project</td>
<td></td>
</tr>
<tr>
<td><strong>Institution where the project will be conducted:</strong> pediatric primary care clinic, Frisco, TX</td>
<td></td>
</tr>
</tbody>
</table>

Instructions: Answer YES or NO to each of the following statements about QI projects.

<table>
<thead>
<tr>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>The specific aim is to improve the process or deliver of care with established/accepted practice standards, or to implement change according to mandates of the health facilities’ Quality Improvement programs. There is no intention of using the data for research purposes.</td>
<td>X</td>
</tr>
<tr>
<td>The project is NOT designed to answer a research question or test a hypothesis and is NOT intended to develop or contribute to generalizable knowledge.</td>
<td>X</td>
</tr>
<tr>
<td>The project does NOT follow a research design (e.g. hypothesis testing or group comparison [randomization, control groups, prospective comparison groups, cross-sectional, case control]). The project does NOT follow a protocol that over-rides clinical decision-making.</td>
<td>X</td>
</tr>
<tr>
<td>The project involves implementation of established and tested practice standards (evidence-based practice) and/or systematic monitoring, assessment or evaluation of the organization to ensure that existing quality standards are being met. The project does NOT develop paradigms or untested methods or new untested standards.</td>
<td>X</td>
</tr>
<tr>
<td>The project involves implementation or care practices and interventions that are consensus-based or evidence-based. The project does NOT seek to test an intervention that is beyond current science and experience.</td>
<td>X</td>
</tr>
<tr>
<td>The project has been discussed with the QA/QI department where the project will be conducted and involves staff who are working at, or patients/clients/individuals who are seen at the facility where the project will be carried out.</td>
<td>X</td>
</tr>
<tr>
<td>The project has NO funding from federal agencies or research-focused organizations, and is not receiving funding for implementation research.</td>
<td>X</td>
</tr>
<tr>
<td>The clinical practice unit (hospital, clinic, division, or care group) agrees that this is a QI project that will be implemented to improve the process or delivery of care.</td>
<td>X</td>
</tr>
<tr>
<td>The project leader/DNP student has discussed and reviewed the checklist with the project Course Faculty. The project leader/DNP student will NOT refer to the project as research in any written or oral presentations or publications.</td>
<td>X</td>
</tr>
</tbody>
</table>

**ANSWER KEY:** If the answer to ALL of these questions is YES, the activity can be considered a Clinical Quality Improvement activity that does not meet the definition of human research. UMB IRB review is not required. Keep a dated copy of the checklist in your files. If the answer to ANY of these questions is NO, the project must be submitted to the IRB for review.