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Gerber Food Product Guide for Caregivers and their Infants With PKU Following the Simplified Food Plan

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GERBER FOOD PRODUCT GUIDE

FOR CAREGIVERS AND THEIR INFANTS WITH PKU FOLLOWING THE SIMPLIFIED FOOD PLAN

By

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Phenylketonuria (PKU) is an autosomal recessive inborn error of metabolism caused by a deficiency in the hepatic enzyme phenylalanine hydroxylase (PAH).[1] Phenylketonuria can have many forms, ranging from mild to severe (i.e., classic PKU) based on an individual's Phenylalanine Hydroxylase (*PAH)* mutation.[1] Phenylalanine Hydroxylase is a hepatic enzyme that converts the essential amino acid Phenylalanine (Phe) to tyrosine with the help of the cofactor tetrahydrobiopterin (BH4).[1]A deficiency in PAH or its cofactor BH4 results in Phe accumulation. An accumulation of Phe can be neurotoxic and lead to severe cognitive disabilities if left untreated.[1] Newborn screening for inborn errors of metabolism is done 24-48 hours after birth.[1]If a newborn is confirmed of testing positive for PKU, they are brought to a metabolic clinic for confirmatory testing. The confirmatory testing tests the blood for plasma amino acids, or at a minimum plasma Phe and tyrosine (Tyr).[2] The average cutoff for a positive screening based on is a PHE of 360 μmol/L and a PHE: TYR ratio >3.[2] The mutation analysis is not required but recommended when screening newborn babies.

The primary treatment for PKU is through dietary restriction of Phe and supplementation with specifically designed medical foods (i.e., protein substitutes) to meet nutrient needs for growth and development.[1,2]The low Phe diet was established in 1953 by Bickel and colleagues.[1] Phenylalanine is an essential amino acid that serves as a building block for high protein foods, such as red meats, milk, eggs, and yogurt.[1,3] Most individuals with classical PKU have a dietary protein tolerance of less than 10 g/day (~500 mg Phe/day.[3]It is recommended that people with PKU maintain blood PHE between 120-360 μmol/L throughout their lifetime.[3] The consequences of untreated PKU are brain dysfunction, mood alteration, nutritional deficiencies and severe brain damage.[3] To prevent nutrient deficiencies in people with PKU, they consume fortified formulas and some do not track certain fruits and vegetables that are low protein to

consume the nutrients that cannot consume in high protein foods.[3] There are different types of diets that a person with PKU can follow depending on the severity of their PKU diagnosis. There is a low-protein diet and a simplified diet. The low-protein diet is the traditional treatment for PKU. The low-protein diet avoids all high protein foods and requires people with PKU to take an amino acid supplement to ensure nutrient requirements, growth, and health.[4] The Simplified Diet Method is a specific a certain type of dietary management for the PKU population that allows unrestricted intake of foods low in Phe. These foods may include certain fruits, vegetables, and low-protein medical foods that would be considered, "free" or "unaccounted for".[5] The low Phe diet is a mainstay for treatment but there are challenges with it being too restrictive for people with PKU leading to poor quality of life and decreased adherence to diet. Current research has encouraged the development of simplified strategies in metabolic clinics to improve these aspects of life for the PKU population.[2,3]

There are different types of diets for people with PKU. The traditional diet is the most common where the individual with PKU must follow a Phe restricted diet according to their PKU diagnosis. The Simplified diet differs from the traditional diet in that the intake of Phe is reduced by approximately 30%, so they do not have to account for all Phe foods while tracking. So, there are different diets for individuals with PKU depending on their severity of diagnosis and how they prefer to manage their PKU.

There are very few educational materials on the use of the Simplified Diet as a dietary treatment for PKU infants 6-12 months. There is no data analyzing the relationship between the education of caregivers with PKU infants and the use of the Simplified Diet method. The creation of this educational handout for mothers with PKU infants 6-12 months will open more opportunity for new data to assess if diversifying a PKU infant earlier in their life would increase

adherence to diet later in life, metabolic control, and increased nutrients consumption of fruits and vegetables that do not need to be counted in dietary Phe.

The specific aims of this project are: 1) to conduct a review of the literature to identify different strategies that increase dietary adherence, improve quality of life, and quality of the diet without reducing metabolic control. 2) to develop a simplified diet guide for caregivers with infants with PKU to try to increase adherence to diet later in life, metabolic control, and nutrient consumption of fruits and vegetables that do not need to be counted in dietary Phe.

Literature Review

Nutrition Recommendations for Infants without PKU

The American Academy of Pediatrics recommends exclusive breastfeeding for six months of age with continued breastfeeding along with complimentary foods for up to one year of age and beyond.[3] At approximately six months of age, infants can be introduced to semi-solid foods. Depending on the infant's gross motor, oral, and fine motor skills, the infant can start eating complementary semi-solid foods around 4-6 months of age.[4] The signs infants do once they are ready to eat complementary foods are controlling their head and neck, sitting up alone or with support, bringing objects to their mouth, and showing interest in food.[3]The complementary foods must be nutrient-dense, meet calorie and nutrient requirements, and stay within limits of dietary components such as added sugars and sodium.[4] Nutrient-dense foods options are fruits, vegetables, high protein foods, dairy, and iron-fortified grains. When introducing new foods, there are timelines to start to introduce foods. At 4-6 months, purred or smashed food like oatmeal, green beans, avocado, and pears can be offered to an infant.[5] At 8-10 months, infants can have more solid food options such as broccoli, spinach, blueberries, yogurt, and

turkey.[5]Repeatedly offering foods such as fruits and vegetables is recommended to increase the likelihood of an infant accepting them. A demographic and health survey was conducted on infant feeding and household and environmental factors for 76,641 children in 42 low- and middle-income countries.[6]This survey provided data on early infant eating and diet patterns. The survey concluded that the parents/caregivers who provided a more diversified diet to their infants were from wealthier families, had higher maternal education, and had better food environments to improve diet quality.[6]This study suggests that income can affect diversifying an infant's diet. The lack of maternal education on what to provide for their infant can lead to a less diverse diet. Infants not introduced to a diversified diet early on can lead to picky eating, poor diet quality, and growth and development issues later in life.

Dietary Management for Infants with PKU

Compared to infants without PKU, infants with PKU have a similar experience from weening to introducing food items. Both have similar timelines introducing complementary foods, different textured foods, and the importance of diversifying their diet at a young age.[4,7] The difference is the traditional PKU diet has restrictions of the amount of Phe the infant is allowed to consume. A dietitian speaks to the parents or caregivers of the infant with PKU about dietary requirements and suggestions to help introduce foods into the infant's diet. Healthcare professionals will suggest when the infant is ready to start eating the complimentary foods to begin with "free foods" as their complementary food items.[7] The free food items can be fruits, vegetables, and grains that contain low amounts of Phe in which the parent or caregiver does not need to count.[7] The infants with PKU would eat their complementary foods with their individually designed formula or breast milk because the PKU formulas supply the Phe requirement for the infant. Free foods help the infant with PKU accustomed to new tastes and

textures without affecting blood Phe control. Infants with PKU are required to drink a Phe-free protein substitute formula along with their breastmilk or formula and the complementary foods.[8] The Phe free formula provides certain amino acids, carbohydrates, fats, vitamins, and minerals that are not consumed from not eating a high protein diet.[8]

There are challenges in managing dietary restrictions for an infant with PKU. The challenges could be resistance to drinking formula, nonadherence to dietary restrictions, and lack of parent or caregiver education on diversifying their infant's diet. When the infant does not adhere to their dietary requirements can lead to Phe accumulation which leads to cognitive disabilities, malnourishment, and death. Adhering to Phe restrictions and diversifying a PKU infant's diet earlier on is crucial to the infant with PKU because it will help with diet adherence and improved diet quality.

Tracking Methods

Individuals with PKU must follow a diet prescription to maintain metabolic control of their Phe blood concentrations. They must follow this prescription because if their blood Phe levels fluctuate it can cause neurological issues and potentially a shortened life.[1,2]The recommended diet prescription that individuals with PKU follow is the low Phe diet. The dietary recommended range in the US for Phe blood concentration is 120-360 μmol/L to maintain metabolic control.[1,2] To abide the dietary restrictions, one must track their daily PHE. Tracking Phe allows an individual with PKU to adhere to their dietary needs and maintain metabolic control. There are three main tracking strategies that individuals with PKU use. These strategies are tracking grams of protein, mg of Phe, and using an exchange system to convert protein to Phe. There are challenges that arise with various exchange system differences and inaccuracy of nutrition labels to count Phe concentration accurately. Research regarding which tracking

method is the “best” is limited. The PKU restricted diet overall brings challenges with psychosocial health, diet quality, and metabolic control.

General Challenges of Adhering to a Restricted Diet

The PKU Restricted Diet not only comes with the challenges of compliance issues, but issues with psychosocial, behavioral, diet quality, and metabolic control. The PKU restricted diet makes individuals with PKU face issues with food when they are outside their homes that can put stress, frustration, and eating problems in social situations. The social restrictions and eating problems have been found to be prevalent in the children with PKU that has affected their psychosocial health.[9] Studies have been conducted on the barriers of social aspects of eating in children with PKU, but there are also challenges with their caregivers that can induce the children with PKU to not being in metabolic control and having a poor quality diet.[9,10] The social aspect of eating has been studied in children with PKU to understand what barriers they face when eating in social situations. A study was conducted to evaluate the social restrictions and eat problems in children with PKU and caregivers face with dietary treatment.[9] It was a web-based questionnaire, based on the Behavioral Pediatrics Feeding Assessment Scale (BPFAS) with additional PKU-specific questions.[9] The caregivers of children with PKU completed the survey. The results included that there was more difficulty in offering food variety, more stress when eating an evening meal outside the home and during vacation, and concerns about (accidental) spilling of food during dinner by the child.[9] The caregivers also reported to being angrier, more frustrated, and more anxious when feeding their child, and they more often felt that their child’s eating pattern had a negative influence on the child’s general health.[9] The study research team reported that the BPFAS showed a higher level of anxiety and insecurity among caregivers of children with PKU.[8]This might be explained by the consequences of poor metabolic control in the child with

PKU; however, we did not evaluate metabolic control.[1]The study results suggest that not only do the PKU children face frustration and limit their food choices due to the restrictions, but also the caregivers face a lot of stress and frustration as well. The higher the anxiety in the caregivers, the more anxiety the children with PKU will have. Higher stress can lead to poor diet quality, metabolic control, and higher stress in social situations to eat. The limitations to this study were that these questions were not validated, the researchers did not perform a sample-size calculation for this pilot study, and the questions were only available in Dutch, so no other country that was not Dutch speaking could use these questions in another survey.[9] This study was also a very large study population having children ages 1-16 years old participate.

Yilmaz et al (2023) conducted a study with a narrower age group in children with PKU ages 1-5 years old to evaluate abnormal eating patterns in these children with their dietary treatment.[11] The children with PKU were compared to a control group of children without PKU in the same age group.[11]The mothers of all the children completed a validated feeding assessment questionnaire examining maternal perceptions of the incidence and type of feeding problems, feeding behavior and parental management.[11] A scored video recording of each child eating a midday meal was made, and mothers recorded a 3-day dietary assessment.[11] The main problems reported in the PKU group were slowness to feed, poor appetite, dislike of sweet foods, and limited variety of foods consumed. The parents of the children with PKU found that they experienced more feeding problems than the children without PKU's mothers. The researchers found that caregivers of children ages 1-5 years old with PKU were more likely to get frustrated during mealtime than in the control group, and more often prepared alternative food when their child did not like what was being served.[11] The PKU group were also found to separate their child with PKU from the rest of the family to eat their midday meal and received less parental

feeding directed verbalization to begin to eat their meals.[11]This study concluded that when children with PKU are then isolated from their families at meals can lead to not finishing their meals, poor social interactions during meal time, and resisting food variety that can lead to poor diet quality. The awareness of these aspects of being on a restricted diet should prove that there needs to be better ways to manage these aspects to improve diet, metabolic control, and psychosocial aspects of eating.

Individuals with PKU can determine which method of tracking they want to use to maintain metabolic control, improve diet quality, be able to not track all their foods, and have an improved quality of life (QOL). Weighing food record was known to be the "golden standard" of tracking Phe in the restricted dietary treatemnet.[12]However, self-reporting food records have been known to be unreliable due to the patient's ability to be truthful of their foods they have eaten either unintentionally or purposefully.[12]When counting mg of Phe there has been limited information of Phe content on commercialized food items and with more accurate dietary exchange systems there can only be an approximate estimation of Phe content. This makes tracking mg of Phe more restrictive and complex to follow. There are exchange systems available in countries such as the UK, US, and Australia use to convert Phe exchanges from food items.[12] These exchange systems have been researched and some of them have been known to be less rigorous, improve quality of diet due to excitement of choosing more foods, and not counting all of the Phe foods because it is below a certain mg that does not affect the blood Phe concentration.[12] Due to the lack of research done to compare all of these tracking methods for managing PKU dietary restriction, it is up to the individual to determine what they think is the best way to track their Phe intake. It all comes down to which tracking method they believe to be the least difficult to

abide their dietary treatment and provides the improved QOL, diet quality, metabolic control, and diversity in their diet.

Tracking Grams of Protein

To track protein intake, people with PKU are using food references, protein content on nutrient labels, and using protein/Phe exchange systems to calculate their Phe intake. Specific exchange systems can be used to convert grams of protein to mg of Phe based on the protein in the food. The challenges of protein tracking are the inconsistency of the nutrient label information, the lack of knowledge of how to interpret the nutrition label to calculate a protein exchange and lack of knowledge of low protein options to consume. A cross-sectional online survey was sent to individuals with PKU or their caregivers residing in the UK about their experience when calculating protein exchanges from the food labelling on prepackaged foods.[13]There were 246 respondents in the study.[13] Thirty-one percent of the responders found it difficult to interpret food protein exchanges from food labels.[12]The respondents listed that the main issues with protein labelling were the non-specification of whether the protein content was for the cooked or uncooked weight, labels stating foods contained zero grams of protein but then included protein sources in the list of ingredients, and the non-clarity of whether the protein content was for the weight of prepared or unprepared food.[13] This study suggest that's with the inconsistency of the nutrient labels and the information on the labels about the protein content is making PKU individuals and families frustrated and confused on what is actually accurate on these labels to calculate their protein exchanges. This inconsistency can lead to adherence issues, decreased QOL and poor diet quality if these industry labels continue to not put accurate information on their products for people who need restricted dietary needs. The limitations to

this survey were that the recruitment process was advertised on social media and did not reach a broad spectrum of PKU individuals and there was a low response rate of adults with PKU.

When put on a low Phe diet, people with PKU lack knowledge of what types of foods they are allowed to eat.[14] A 12-week randomized controlled study assessed the efficacy of a new app titled PKU Bite.[14] The app provided guides to low protein food choices, label interpretation, and protein calculation. The study participants were 60 parents/caregivers of children with PKU, aged 1−16 years, and 21 adolescents with PKU.[14] The results concluded that there was an increase of metabolic control in the 12 weeks Metabolic Control lower mean blood Phe levels at 12 weeks compared to baseline, in both groups, possibly associated with increased attention to diet in the initial weeks of the study.[14] When subjects were asked what improvements could be made to the app, they recommended an exchange tracker, a barcode/label scanner, more recipes and menu ideas, and a bigger range of branded food.[14] The results of this study suggests that when PKU patients are given tools such as an app provided with a vast amount of food choices and tools to help with calculating protein, their dietary adherence and metabolic control improved. Tracking protein with the right tools and calculations can be a strategy to improve adherence and metabolic control. The limitations of the study were that participants would have liked to see more Phe exchange calculators on the app suggesting some of these participants enjoy using Phe exchange systems instead of tracking solely protein. Tracking grams of protein can become difficult to maintain metabolic control and poor diet quality. The limited information on nutrient labels can lead to unreliable protein information to make the calculations less precise than counting mg of Phe.

Tracking mg of Phe

To count mg of Phe, individuals with PKU can use food references, protein/Phe exchange systems and weighing their food to calculate the Phe content. The benefits of this tracking method are that it is a precise way of calculating Phe intake. The challenges of this tracking method are compliance issues, difficulty of counting every mg of Phe, diet quality could be poor due to strict tracking, and not all data has been identified on the Phe content of foods which leads to inaccuracy of concentrations in different foods.[15] As a result, the diet may be more restrictive and could inadvertently reduce energy intake.[15]

The benefit of tracking Phe is that it is a more precise measurement than protein content. In recent studies, there has been more research done to improve this tracking method by using multipliers which help estimate the Phe content of foods from the protein content. This way, the multipliers give a range of Phe content that can improve adherence to their dietary needs and metabolic control due to the flexibility of the range and more precise measurements.[16]A study was done to assess new multipliers for estimating the phenylalanine content of foods from the protein content.[16] In this study the researchers compared the statistical distribution of the Phe: protein ratio in two databases, namely the USDA National Nutrient Database and the Danish Food Composition Databank.[16] Based on their data, they concluded that replacing the 30–50 multipliers with the 20–65 multipliers can lead to more accurate results. The Phe content from the protein content, these multipliers yield estimates that are correct for more than 97% of the data analyzed (as opposed to less than 76.3% for the multipliers 30–50).[16] This study justifies that it is impossible to know how much Phe a food contains solely from its protein content. More specifically, it is possible to discover new multipliers that can give a more accurate Phe measurement for tracking. This study suggests that tracking mg of Phe may be more accurate

than protein tracking because these multipliers give a specific range of Phe for certain foods rather than counting grams of protein based on nutrient labels.

Research has been conducted since the MacDonald article on PKU dietary changes on fruits and vegetables that have been measured for their Phe content based on their protein content. A table of the Phe contents of fruits and vegetables in Brazil has been created based exclusively on the chemical analysis of protein content, considering that proteins contain 3–4% Phe (TCFA/ANVISA).[17] A study compared the protein and Phe contents of vegetables and fruits provided by the TCFA/ANVISA with those listed in international food composition tables. The Phe content of 71 fruits and vegetables listed in TCFA/ANVISA was classified into four subgroups, and the Wilcoxon nonparametric test compared the Phe and mean protein contents provided by the FCTs.[17] The results were that 55 out of the 71 studied fruits and vegetables had a mean Phe content of 50 mg/100 g or less, and 100 mg/100 g or less. [17] The researchers suggested that other clinical trials suggest that fruits and vegetables with Phe content of 50 mg to 100 mg/100 g are safe for patients with phenylketonuria, these fruits and vegetables could be classified as unrestricted for these individuals.[17]Also, 70% of the studied fruits and vegetables had very similar Phe content. The other 30% of fruits and vegetables that were different in Phe content could have been different because of factors such as accuracy of protein and Phe estimates, origin of the food, genetic variability, climate, degree of maturation, time of harvest, and even a transcription error of raw data, which cannot be omitted.[17] This study can suggest that individuals with PKU cannot always rely on the protein content of certain fruits and vegetables to find mg of Phe. The variability of Phe content in foods such as fruit and vegetables should constantly be reassessed to allow these foods to be considered “free foods” and to be able to find multipliers for PKU individuals to calculate Phe from protein content. So, knowing Phe content

variability in fruits and vegetables may help to reduce uncertainty, create accurate multipliers to use to count protein, improve metabolic control, and expand the dietary guidelines of foods for patients with phenylketonuria.

Phe Exchange Systems

Phe Exchange Systems differ in Europe and the US. In the US, PKU dietary guidelines suggest counting every mg of Phe or using a two-tiered exchange system. MacDonald (1994) explained how the original assumption that 50mg Phe equals one gram of Protein came from the first supplement of McCance and Widdowson's Composition of foods by Paul et al. in 1979.[18,19] The UK has been using this exchange system since the 1980's.[18,19]MacDonald (1994) also explained that the exchange system of 50mg of Phe equals one gram of protein is outdated due to the inaccuracy of the exchange in other food groups that are not breads and grains. The author emphasized that there needs to be more research done on fruits and vegetables that have one gram of protein in them but less than 50mg of Phe.[19]

In recent studies, this standardized exchange rate has been challenged by researchers that it has become an outdated exchange system because it does not provide enough information on fruits and vegetables that may not affect Phe blood concentration.[18,19,20] This recent finding possibly can provide PKU individuals with a diverse food selection of fruits and vegetables and less Phe to track in their daily intake. There have been studies done that have found that foods that provide 20-50mg or less of Phe are considered "free foods". The "free foods" are foods that individuals with PKU do not have to track have been found to not affect Phe blood concentrations and diversified their diets.[1] Multiple studies have come out of analyzing the Phe content in numerous fruits and vegetables now that are either over or under 50mg of Phe that do not affect the Phe blood concentration. This provides more evidence that this standard exchange

system needs to be updated with recent data on fruits and vegetables that could be unaccounted for in the dietary tracking that can lead to improved diet quality, adherence, and maintaining metabolic control.[17,21,23] This tracking method of using exchange systems could possibly lead to better metabolic control, diet adherence, and improved diet quality and QOL if the standard exchange is updated with recent research on fruits and vegetables that do not have to be accounted for when tracking Phe.

Phenylalanine Tolerance

Phenylalanine tolerance is the amount of phenylalanine that can be eaten by an individual with PKU to maintain blood phenylalanine concentrations within the target treatment range.[24] Phenylalanine tolerances can be different based on the severity of the PKU. For example, people with mild or moderate PKU will tolerate more protein. Factors such as adherence, daily distribution of protein substitute, drug therapy, and any other treatment supplementing the dietary restriction can alter an individual Phe tolerance.[24] It is also influenced by growth, pregnancy, and catabolic state during illness. Individuals with moderate PKU can tolerate 350-400 mg of dietary phenylalanine per day. Individuals with mild PKU can tolerate 400-600 mg of dietary phenylalanine per day. infants with mild hyperphenylalaninemia (MHP) that have a plasma Phe concentration <600 µmol/L (10 mg/dL) can be put on a normal diet.[24] These ranges besides the MHP are based on adults with PKU. *Children* with classical *PKU can tolerate* less than 500 mg of Phe per day.[24]

Information on initial neonatal management of PKU, when Phe tolerance is still unknown. [25] There have been studies that suggest that with age, Phe tolerances can increase, and adult patients tolerate more Phe than prescribed by their health professionals. [26,27] So, this suggests that if there was more research done on Phe tolerances for younger infants, could

possibly improve their knowledge of their Phe tolerance and possibly have an opportunity to increase their dietary Phe and choose to be on a dietary treatment such as the Simplified Diet in which they do not have to count everything in their diet.

The Simplified Diet

The Simplified Diet Method does not increase the Phe intake of the individual with PKU prescribed diet, but it allows the counted Phe allowed in the diet to be slightly offset by low Phe foods that do not have to be counted in the overall Phe intake.[14] The Simplified Diet method's goal is to allow more flexibility, maintain metabolic control, and encourages people with PKU to eat a diverse number of low-Phe foods such as fruits and vegetables.[14] This method tales away the stress and burden of tracking every Phe filled foods in their diet without putting themselves in any health-related risks.

To be able to do the Simplified Diet Method, the individual with PKU must speak with their metabolic dietitians to take safe and precautioned steps to do this method correctly. There may be cases where the PKU diagnosis of an individual may be too restricted to be able to do this dietary method. The first step that the dietitian takes is reduce the patient's current Phe prescription up to 30%.[26] This allows wiggle room for the person with PKU to not account the low-Phe foods without going over their Phe prescription. The second step is that the dietitian then provides a list of low-Phe fruits and vegetables that they do not need to count towards the daily Phe/protein allowance. A lot of clinics have their own low Phe food lists for their patients with PKU, so there is not a standardized lists of low Phe foods, although a lot of the lists have similar food choices.[26] Once they start the Simplified Diet, the dietitian watches their Phe blood concentration a lot closer than usual. The dietitian wants to make sure there is no fluctuation in their blood concentration. The dietitian then would suggest the individual with PKU writes down

their food in a food record and hands it in more frequently to watch their intake. So, starting the Simplified Diet doesn't mean the low-Phe foods are Phe-free, but rather that the Phe prescription has been reduced to accommodate the amount of those foods that the patient consumes.[26]

The foods that are not accounted for in the Simplified diet are usually certain fruits and vegetables. These fruits and vegetables have low Phe content that have been studied to have no negative effects on the Phe blood concentration and metabolic control.[22,23,29] A cross-over study was conducted with fourteen children with PKU ages 2-10 years old on whether free consumption of fruits and vegetables containing less than 75 mg Phe per 100 g affects metabolic control in children with PKU.[23]A detailed food record was written daily and a dried- blood Phe concentration. The results were that the two-week period of consuming fruits and vegetables less that 75mg of Phe did not have any effect on the study participant's metabolic control.[23] The study participants commented that they enjoyed the freedom of eating certain foods and it encouraged them to keep trying different fruits and vegetables that were under 75mg of Phe.[23] The limitations to this study were that this study only observed two weeks and the dietary needs for the age range was not specific enough to get good data compared to if the researchers selected a certain age group that are similar in dietary needs. This study suggests that when experimenting with low Phe content fruits and vegetables, there can be more opportunities to allow individuals with PKU to eat certain "free" foods and this encourages adherence to diet, metabolic control, and encourages PKU patients to try different types of fruits and vegetables to improve their diet quality.

The Simplified diet method comes with many health benefits for the PKU population. As mentioned above, this dietary method provides flexibility, encourages food diversity, and maintains metabolic control. There was a survey conducted to U.S. Metabolic Dietitians that

implement the Simplified diet in their practices for the PKU population.[28]There were 93 study respondents that were included in the study. Ninety-eight percent of the 93 dietitians use some sort of Simplified Diet method in their practices.[28]There was a mixture of study respondents that use certain Phe criteria to use as their "uncounted" foods for their PKU patients. When asked about when the introduce the Simplified Diet to a patient with PKU, 68% of survey respondents reported they would introduce the Simplified Diet approach at 6 months, which is when many infants in the U.S. start solid foods.[28]An additional 26% of participants (n = 16/62) reported they would introduce the Simplified Diet at the earliest with children ages 12 months or older. Regards to the simplified diet method used on their PKU patients, 78% of the respondents said that it reduces the stress and anxiety related to food and mealtimes.[28]And 79% "agreed" or "strongly agreed" that patients on a Simplified Diet maintain similar blood.[28] The survey results suggest that the simplified diet is becoming more a mainstream of dietary management around the U.S. for patients with PKU. Dietitians are implementing this method because it helps decrease stress and anxiety of eating for these patients with PKU and it does not affect metabolic control of Phe blood concentration. The survey implied that a lot of dietitians are introducing this dietary method earlier on in the individuals with PKU's life which can help improve dietary adherence and decrease anxiety of food early on.

The Simplified Diet method for PKU dietary management provides more benefit than harm for the PKU population. There is still not enough research on the effects of introducing the Simplified Diet method earlier than 6 months of age, the Phe tolerances of an adult versus an infant to engage in the Simplified Diet and how to teach mothers of younger infants with PKU on how to implement the Simplified diet while the infant is transitioning from weening to soft foods.

Conclusion

There is no research conducted on infants under the age of 6 months on their Phe tolerances and the use of the Simplified Diet. The parents and caregivers of infants with PKU should understand how to introduce more fruits and vegetables to their infants with formulas and breast milk. Once there is data on infants with PKU Phe tolerances and the use of the Simplified diet there would be an improvement in adherence to dietary restrictions later in the infant with PKU's life. This data would provide an educational baseline for these parents and caregivers of infants with PKU to introduce a diverse diet to their infants.

Methodology

I created a Gerber product guide for caregivers with 6-12 months infants PKU. I researched Phe tolerances for adults and children to see if there were similarities and differences. I looked at studies that assessed Phe amounts in fruits and vegetables to see what ranges individuals with PKU do not have to count while maintaining their Phe blood concentrations. I researched the differences between weaning infants with PKU versus those without PKU to understand how to introduce foods to an infant. I went through infants (over six months of age) with PKU's diet records to count the Phe intake from fruits and vegetables. I created a reduction factor to give an estimated range of these foods' infants with PKU 6-12 months can eat and maintain their Phe blood concentrations. Finally, I created a handout specifically for caregivers with infants with PKU of examples of Gerber food items that fit into the reduction factor created to follow a simplified diet plan.

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***Provider Guide for Capstone Project**

Green Zone

< 50mg of Phe)

Gerber 1st Foods:

Gerber Food Item	Serving Size (per label weight)	Weight (g)	Phe (mg)	Protein (g)	Calories (kcal)
Apple	1 tub	113	10	0.4	35
Carrot	1 tub	56	40	0.5	40
Mango	1 jar	113	20	0.5	70
Mixed Carrots	1 jar	113	30	0.5	40l
Peach	1 tub	56	10	0.6	45
Pear	1 tub	56	10	0.3	40
Prune	1 tub	56	40	1	60
Squash	1 tub	56	40	0.7	25

Gerber 2nd Foods:

Gerber Food Item	Serving Size (per label weight)	Weight (g)	Phe (mg)	Protein(g)	Calories (kcal)
Apple	1 tub	113	10	0.3	60
Apple Berry Mixed Cereal	1 tub	113	40	0.8	80
Apple Blueberry	1 tub	113	10	0.3	60
Apple Blueberry Spinach	1 pouch	99	20	0.5	50
Apple Carrot Squash	1 pouch	99	20	0.5	50
Apple Cherry	1 tub	113	10	0.3	70
Apple Mango with Rice Cereal	1 tub	113	30	0.6	80
Apple Peach Squash	1 tub	113	30	0.5	60

Apple Raspberry Acai Berry	1 pouch	99	30	0.4	60
Apple Strawberry Banana	1 tub	113	10	0.4	60
Apple Strawberry Beet	1 jar	99	10	0.4	50
Apple Sweet Potato	1 tub	99	10	0.4	60
Apple Zucchini Spinach Strawberry	1 pouch	99	10	0.5	50
Apples & Summer Peaches	1 pouch	99	10	0.4	80
Apricot Mixed Fruit	1 tub	113	30	0.5	80
Carrot Apple Mango	1 pouch	99	30	0.5	50
Carrot Pear Blackberry	1 tub	113	40	0.8	60
Fruit & Grain Apple Pear Apricot with Mixed Grain	1 pouch	99	40	0.9	80
Fruit & Grain Pear Peach Oatmeal	1 pouch	99	30	0.8	80
Mango Apple Twist	1 tub	113	40	0.6	90
Peach	1 tub	113	20	1.1	60
Pear	1 tub	113	10	0.5	70
Pear Blueberry Apple Avocado	1 pouch	99	40	0.5	70
Pea Carrot Pea	1 pouch	99	30	0.9	60
Pear Peach Strawberry	1 pouch	99	10	0.5	60
Pear Pineapple	1 tub	113	20	0.5	70
Pear Purple Carrot Raspberry	1 jar	113	20	0.5	60
Pear Spinach	1 pouch	99	20	0.5	60
Pear Zucchini Mango	1 pouch	99	20	0.6	60
Pear Zucchini Corn	1 tub	113	30	0.8	70
Prune Apple	1 tub	113	40	0.7	80
Root Veggies & Quinoa	1 pouch	99	40	1	70

Gerber Lil ’Bits:

Gerber Food Item	Serving Size (per label weight)	Weight (g)	Phe (mg)	Protein (g)	Calories (kcal)
Broccoli Carrot Banana Pineapple	1 pouch	99	40	1.3	60
Mixed Carrot Corn & Butternut Squash	1 tub	142	10	1.9	70
Oatmeal Apple Cinnamon Cereal	0.25cup	15	10	1.6	60
Oatmeal Banana Strawberry Cereal	0.25cup	15	10	1.6	60
Orchard Fruit Medley	1 tub	142	20	0.7	100
Pear Apple Berry	1 tub	142	20	0.6	90
Pear Apple Sweet Potato & Oatmeal	1 tub	142	20	1	90
Sweet Potato Mango Pear Kale	1 pouch	99	40	0.9	70

Gerber Graduate Squeezable:

Gerber Food Item	Serving Size (per label weight)	Weight (g)	Phe (mg)	Protein (g)	Calories (kcal)
Apple Carrot Pineapple	1 pouch	120	10	0.6	60
Apple Pear Peach	1 pouch	120	10	0.5	70
Banana Blueberry	1 pouch	120	40	1.2	100
Apple Mango Strawberry	1 pouch	120	10	0.4	60
Apple Strawberry Banana	1 pouch	120	10	0.5	60
Pear	1 pouch	120	20	0.5	70
Apple Peach Spinach	1 pouch	120	20	0.7	70
Apple Peach Spinach	1 pouch	120	20	0.7	70
Banana Pear Zucchini	1 pouch	120	40	0.9	90
Apple Blueberry	1 pouch	120	10	0.4	70
Pear Squash	1 pouch	120	10	0.6	70

Gerber Other:

Gerber Food Item	Serving Size (per label weight)	Weight (g)	Phe (mg)	Protein (g)	Calories (kcal)

Gerber® Organic Veggie Crisps Farm Greens	1 package	15	10	1.9	70
Gerber® Lil' Beanies® Original	26 pieces, 173 pieces per 100mg of food item	15g	10	1.9	70
Gerber® Lil' Beanies® White Cheddar Cheese and Broccoli	26 pieces, 173 pieces per 100mg of food item	15g	10	1.9	70

Yellow Zone

(Phe 50-75mg/serving)

Gerber 1st Foods:

Gerber Food Item	Serving Size (per label weight)	Weight (g)	Phe (mg)	Protein (g)	Calories (kcal)
Banana	1 jar	113	60	1.3	40
Green Bean	1 tub	56	50	1.1	25

Gerber 2nd Foods:

Gerber Food Item	Serving Size (per label weight)	Weight (g)	Phe (mg)	Protein (g)	Calories (kcal)
Banana	1 tub	113	60	1.2	100
Banana Blueberry Blackberry Oatmeal	1 pouch	99	70	1.4	80
Banana Mango	1 pouch	99	50	1.1	80
Banana Squash	1 pouch	99	50	0.9	100
Butternut Squash	1 tub	113	60	0.8	40
Carrot	1 tub	113	70	1	40
Carrot Zucchini and Broccoli	1 pouch	99	50	1	30
Fruit and Grain Bananas, Red Berries & Granola	1 pouch	99	60	1.2	80

Garden Veggies Brown Rice with White Bean	1 pouch	99	50	1.2	60
Hawaiian Delight	1 tub	113	70	2.1	120
Mango Apple Carrot Kale	1 pouch	99	50	0.6	70
Peach Mango with Oatmeal Cereal	1 tub	113	60	1	80
Pumpkin Banana Carrot	1 pouch	99	60	1.5	60
Sweet Potato Apple Carrot Cinnamon	1 jar	113	60	0.1	60

Gerber Lil 'Bits:

Gerber Food Item	Serving Size (per label weight)	Weight (g)	Phe (mg)	Protein (g)	Calories (kcal)
Apple Sweet Potato with Cinnamon	1 pouch	99	60	0.4	50

Gerber Graduates and Squeezable Foods:

Gerber Food Item	Serving Size (per label weight)	Weight (g)	Phe (mg)	Protein (g)	Calories (kcal)
Fruit and Graduates® Grabbers Yogurt Peaches & Cream	1 pouch	120	70	1.4	80
Graduates® Grabbers Fruit and Vegetables	1 pouch	120	70	1.7	100
Fruit and Graduates® Grabbers Yogurt Very Berry	1 pouch	120	70	1.7	100
Graduates® Grabbers Fruit Banana Squeezable	1 pouch	120	60	1.3	100
Squeezable Graduates® Grabbers Fruit Banana Apricot	1 pouch	120	60	1.4	100

Red Zone

(Phe >75mg/serving)

(all food that should be avoided)

This includes foods items with high Phe content, such as chicken, cheese, ham, turkey, yogurt, and beans.

Gerber 2nd Foods:

Gerber Food Item	Serving Size (per label weight)	Weight (g)	Phe (mg)	Protein (g)	Calories (kcal)
Apple Chicken Dinner	1 tub	113g	80	1.5	100
Beef and Gravy	1 tub	113	350	9.1	70
Chicken Noodle Dinner	1 tub	113	130	2.5	80
Chicken Rice Dinner	1 tub	113	120	2.8	80
Ham and Gravy	1 tub	113	360	8.9	80
Mac and Cheese with Vegetable Dinner	1 tub	113	130	2.8	90
Turkey and Gravy	1 tub	113	330	8.4	80
Turkey Rice Dinner	1 tub	113	140	3.3	80
Vegetable Chicken Dinner	1 tub	113	120	2.3	70

Gerber Lil 'Bits

Gerber Food Item	Serving Size (per label weight)	Weight (g)	Phe (mg)	Protein (g)	Calories (kcal)
Autumn Vegetables Turkey with Lil' Bits® Dinner	1 tub	142	190	4.5	120
Chicken Itty-Bitty Noodle with Lil' Bits® Dinner	1 tub	142	170	3.9	90
Garden Vegetable & Beef with Lil' Bits® Dinner	1 tub	142	190	4	120
Purple Carrot Greek Yogurt Mixed Grains	1 pouch	99	140	2.7	70

SIMPLFIED FOOD PLAN FOR INFANTS WITH PKU

The goal of the PKU Simplfied Food Plan guide:

This Gerber food product guide was created for infants aged 6-12 months with PKU. This guide can aid caregivers in shopping for their infants with PKU and diversifying the diets of their infants with PKU following the Simplified Diet.

Keys to using the guide:

Color of Zones

- Green Zone: **Gerber foods below 50mg of phe per serving are considered "free"**
  - Do not count in daily intake.
- Yellow Zone: **Gerber Foods that are 50-75mg of phe per serving.**
  - These foods are similar to the green zone, but some vegetables and grains can be higher in protein than others.
  - allowed one serving per day, but must be counted in daily phe intake.
- Red Zone: **Foods that should be avoided**
    - Includes Gerber foods with meats, yogurt, cheese, nuts, legumes, fish, and poultry.

Gerber Food Types

- **Gerber 1st Foods**
  - Stage 1 baby foods are very smoothly pureed and are soupy enough to drip off of a spoon.
- **Gerber 2nd Foods**
  - Stage 2 foods may be roughly pureed, blended or strained.
- **Graduate Grabber or Squeezbles**

Gerber Graduate Grabbers: Meals with solid food items

Squeezable Graduates

Gerber Lil'Bits

Green Zone (Phe < 50mg/serving)

Gerber 1st foods items:

- Apple
- Butternut Squash
- Peach
- Pear
- Mango
- Mixed Carrots

Gerber 2nd foods items:

- Apple
- Apple Banana with Mixed Cereal
- Apple Berry Mixed Cereal
- Apple Blueberry
- Apple Blueberry Spinach
- Apple Carrot Squash
- Apple Cherry
- Apple Mango with Rice Cereal
- Apple Peach Squash
- Apple Raspberry Acai Berry
- Apple Strawberry Banana
- Apple Strawberry Beet
- Apple Sweet Potato
- Apple Sweet Potato with Cinnamon
- Apple Zucchini Spinach Strawberry
- Apples & Summer Peaches
- Apricot Mixed Fruit
- Banana Apple Pear
- Banana Carrot Mango
- Banana Orange Medley
- Banana Plum Grape
- Blended Fruits with Oatmeal
- Carrot Apple Mango
- Carrot Pear Blackberry
- Fruit & Grain Apple Pear Apricot with Mixed Grain
- Fruit & Grain Pear Peach Oatmeal
- Mango Apple Twist
- Peach
- Pear
- Pear Blueberry Apple Avocado
- Pear Carrot Pea
- Pear Cinnamon with Oatmeal
- Pear Peach Strawberry
- Pear Pineapple
- Pear Purple Carrot Raspberry
- Pear Spinach
- Pear Zucchini Corn
- Pear Zucchini Mango

- Prune Apple
- Pumpkin
- Pumpkin Banana
- Root Veggies & Quinoa
- Sweet Potato

Gerber Lil'Bits:

- Banana Apple Mango
- Banana Apple Strawberry
- Broccoli Carrot Banana Pineapple
- Mixed Carrot Corn and butternut Squash
- Orchard Fruit Medley with Lil' Bits
- Pear Apple Berry with Lil' Bits
- Pear Apple Sweet Potato & Oatmeal

Gerber's Squeezable:

- Apple Carrot Pineapple
- Apple Peach Spinach
- Apple Pear Peach
- Apple Mango Strawberry
- Apple Strawberry Banana
- Banana Blueberry
- Banana Apricot

Yellow Zone (Phe 50-75mg/serving)

Gerber 1st food items:

- Banana
- Carrot
- Green Bean
- Prune
- Squash

Gerber 2nd food items:

- Banana
- Banana Blueberry Blackberry Oatmeal
- Banana Mango
- Banana Squash
- Butternut Squash
- Carrot
- Carrot Zucchini and Broccoli
- Fruit and Grain Bananas, Red Berries & Granola
- Garden Veggies Brown Rice with White Bean
- Hawaiian Delight
- Mango Apple Carrot Kale
- Peach Mango with Oatmeal Cereal
- Pumpkin Banana Carrot
- Sweet Potato Apple Carrot Cinnamon

- Hawaiian Delight
- Mango Apple Carrot Kale
- Peach Mango with Oatmeal Cereal
- Pumpkin Banana Carrot
- Sweet Potato Apple Carrot Cinnamon

Gerber Lil'Bits

- Apple Sweet Potato with Cinnamon
- Oatmeal Apple Cinnamon Cereal
- Oatmeal Banana Strawberry Cereal

Gerber Other food items:

- Lil' Beanies® Original
- Lil' Beanies® White Cheddar Cheese and Broccoli
- Organic Veggie Crisps Farm Greens

Gerber Graduates and Sqeezables:

- Graduates Fruit and Vegetables
- Graduates Grabbers Fruit Banana Squeezable
- Graduates Grabbers Yogurt Very Berry
- Graduates Yogurt Peaches & Cream

Red Zone (Phe >75mg/serving)

Gerber 2nd food items

- Apple Chicken Dinner
- Beef and Gravy
- Chicken Noodle Dinner
- Chicken Rice Dinner
- Ham and Gravy
- Mac & Cheese with Vegetable Dinner
- Turkey and Gravy
- Turkey Rice Dinner
- Vegetable Chicken Dinner

Gerber Lil' Bits Dinners

- Autumn Vegetables Turkey with Lil' Bits® Dinner
- Chicken Itty-Bitty Noodle with Lil' Bits® Dinner
- Garden Vegetable & Beef with Lil' Bits® Dinner
- Purple Carrot Greek Yogurt Mixed Grains