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Development of a Blenderized Tube Feeding Recipe for Inpatient Use at Seattle Children's Hospital

A Capstone Report

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Chapter I: Introduction

Blenderized tube feeding (BTF), tube feeding in which whole foods are blended and then put through a feeding tube, has been gaining in popularity in recent years.[1-4] Many families of pediatric patients are drawn to BTF for a variety of reasons, among them improved tolerance of tube feeding, an increased ability to include a child in family meals, feelings of nurturing elicited, and a perception that BTF is more natural or more in line with their family food values.[1,5] While families who use BTF report overall satisfaction with their decision, the use of BTF can add strain to these families if their child is inpatient for any period of time. While Seattle Children's Hospital (SCH) has a policy to allow BTF while inpatient, there have been difficulties with implementation of BTF during inpatient stays in the past. The current policy allows families to make and bring in their own formula - adding a time and travel burden - or have the SCH kitchen make a BTF formula for their child. While SCH does have standard BTF recipes, these have found little use as they frequently contain baby food or other items that patient families find unacceptable. Attempts to make family BTF recipes in the SCH kitchen have proven problematic, as they often clog the tubes, leading to frustration on the part of nurses, dietitians, and families.

The goal of this capstone project was to determine what families would be most receptive to in regard to inpatient BTF - would they prefer to use a food combo tool to develop a recipe while inpatient or would they prefer to order a standard recipe, and then based on the information received, develop either a tool or recipe. If adoption of the new product is successful, this project has the potential to ease the stress burden of families who rely on BTF while their children are inpatient. Additionally, the project also has the potential to push the boundaries of current BTF practice, if a standard recipe can be shown to work well with smaller feeding tube sizes than the current recommended standard of 14 French. If successful, the developments from this project will positively impact the nutritional status of tube-feeding children while inpatient, hopefully eliminating gaps and delays in feeding while ensuring the patients are receiving balanced nutrition.

Chapter II: A History of Blenderized Tube Feeding/Practices and Policy at Seattle Children's Hospital

Evidence of enteral provision of food and liquid has been found as early as ancient Egypt and Greece, with enemas of broths, wine, and milk used to treat patients.[1,5,6] Tube feeding was first used in the 16th and 17th centuries, though these were primarily naso- and oropharyngeal tubes used to provide liquids.[6] The first gastric tube feedings occurred in the 1700s, with provision of eggs, milk, broth, and whiskey.[1,6] Occasionally gastric tube feeding continued through the 18th and 19th centuries, but rectal tube feedings of beef and other foods were the primary method of nutrition support until 1910, when the first nasoduodenal tube feeding was performed and experiments to improve tube feeding tolerance were seen. At this time, eggs and milk were still the most common foods fed via tube, though butter, sugar, salt, and various types of alcohol were also used.[1,6] Commercial formula development began in the 1940s, with increasing adoption of commercial formulas in the 1960s and 70s due to continued adoption of antiseptic procedures, the ability to add modular components to commercial formulas, and the

decreased labor costs associated with the new formulas.[6] At this time, BTF use decreased dramatically, and has only reemerged recently.

Blenderized tube feeding came to the forefront at SCH in 2006 when an SCH dietitian published a paper on the topic in the Pediatric Nutrition Practice Group *Posts* publication. Dietitians were beginning to work with families to support BTF in the outpatient setting, but little focus was placed on BTF in the inpatient setting at this time. In 2011, a multidisciplinary team was created to focus on feeding tube practices and policies generally, which provided an opportunity to elevate the issue of BTF to a broader audience. The first inpatient BTF policy was implemented in 2014, based on recommendations in the literature that it be used only with G-tubes 14 French or larger and that boluses were preferred, but that if pumps or continuous feeds were used, bags should be changed every two hours for food safety reasons. Over time, families have pushed the boundaries of these policies, successfully using BTF in 8 French NG tubes when at home, leading to discordance with the inpatient policy when their child is admitted and they want to continue using their home BTF. This has led to adaptations to the inpatient BTF policy, allowing 14 French G-tubes and minimum 8 French NG tubes and providing inpatient BTF options that include the family bringing their own formula from home daily, using standard SCH BTF recipes, or having their home formula recipe made on site at SCH. As the standard SCH formula recipes grew outdated, they fell out of use, and more families began to ask that their home recipe be made on site.

Making individual patient BTF recipes on site has created many difficulties, increasing burdens on dietitians, kitchen staff, and nurses. Current SCH policy requires that the dietitians document the patient's home recipe and let the family know if any substitutions will need to be made. In practice, this process can take hours, as the dietitian talks with the family to verify their current recipe(s) and any food allergies, then communicates with the diet technicians or kitchen staff to determine which recipe ingredients are available at SCH. If any ingredients are unavailable, potential substitutions need to be identified and then proposed to the family. This cycle is repeated until a satisfactory recipe is documented. Having gone through this process, there is no guarantee that the recipe will work in the patient's tube once they are admitted. Families that have attempted to have SCH make their home formula recipe have frequently noted difficulties with clogged tubes. When this occurs, significant nursing, dietitian, and kitchen staff time is spent trying to resolve the issue. Often, more formula cannot be made until hours later, leading to long delays and interruptions in nutrient delivery. These families often resort to bringing their own formula from home, which can add stress to their stay and which is often only feasible for families that live or are staying near the hospital. Due to these frustrations, the current project to update the standard BTF recipe was proposed.

Chapter III: Literature Review Summary

Prevalence of BTF in Patient Populations and RD Support for BTF

Long-term home enteral nutrition is increasing worldwide, and with it, the number of tube-fed patients using some amount of BTF is also increasing. It is estimated the patients receiving home enteral

nutrition has increased from 34,000 in 1989 to 344,000 in 2014 and that over 50% of adult patients use some BTF to supplement their commercial formula.[7] While the prevalence of BTF use in the tube-fed population is not entirely certain, a recent survey of tube-fed adult and pediatric patients was conducted by the Oley Foundation and Mayo Clinic researchers attempting to quantify BTF use. The Oley Foundation is a non-profit organization that supports people on home parenteral and enteral nutrition, providing education, networking, resources, and advocacy. The foundation has over 16,000 members, 3,748 of whom were recorded as enteral nutrition patients at the time of the survey. 125 pediatric and 91 adult participants were recruited for the survey through the Oley Foundation website. Survey results indicate that nearly 90% of the pediatric population use BTF for an average of 71% of their intake, while approximately 70% of the adult population uses BTF for an average of 56% of their intake. 75% of pediatric patients use self-prepared BTF, while 24% use a combination of self-prepared BTF and commercial blended formula.[4] Despite increasing use of BTF among patients, many providers are hesitant to support BTF use among their patients. An unvalidated survey of the AND Pediatric Nutrition Practice Group found that approximately half of RDs surveyed use BTF in their practice, with nearly 30% indicating a lack of knowledge as a barrier to their using BTF in clinical practice. Of those who use BTF, 75% reported an overall positive experience.[8]

Reasons for BTF Use

Most reasons for choosing BTF are based on personal beliefs about food or on anecdotal evidence, as very little research has been conducted comparing outcomes of BTF to commercial formulas. Reasons for choosing BTF include the recent popularity of the “whole foods” concept and perceived health benefits from whole and less processed foods, the ability for BTF to adapt to specific diet preferences or needs, that it allows patients to eat the same foods as their family, increased feelings of nurturing among caregivers, monetary savings, and perceived improvement in feeding tolerance and decrease in oral aversion.[1,5,7,9,10] The adaptability of BTF to individual needs has been noted as particularly useful in the pediatric population, where there are often complex food allergies or intolerances in conjunction with complex disease states.[4] Additionally, its adaptability allows patients and families to use BTF in a way that works for them, with some patients opting to add pureed foods to commercial formulas, others to blend whole foods at one meal per day, while yet others make home-blended formula for all meals.[2,3,11]

Few studies have looked at outcomes of BTF use in patients. Of those that have, one study noted a significant decrease in gagging and retching among children who used BTF after fundoplication surgery, though this was based on parent report and therefore may be susceptible to reporter bias.[12] Adults self-report improvement in stooling and decreased nausea, bloating, and vomiting with BTF compared to commercial formulas.[7] Children with intestinal failure who were transitioned from elemental formula to a food-based commercial formula were observed to have parent-reported improvement in stooling, were able to discontinue supplemental fibers, and maintained age-appropriate weight gain at 6

and 12 months after transitioning to the real-food-based formula.[9] These results are based on a small sample size and, again, are heavily reliant on parent report. A recently published study followed patients transitioning from commercial formula to BTF. This study found that 50% more calories were required on BTF than on commercial formula in order to maintain BMI throughout the study.[13] Contrary to common anecdotal report and previous studies, no changes were seen in stool frequency or consistency and a significant increase in use of stool softeners was observed. However, vomiting and the use of acid suppression medications decreased on BTF, which aligns with the findings of Pentiuk et al.[12,13] This study is unique, as the first study to look at changes in patient microbiome with the transition to BTF; bacterial diversity and richness significantly increased in patient stool samples after transition to BTF.[13] These results show an overall positive effect of transitioning patient to BTF when feasible, while also highlighting the need for patients to work closely with their RD during this transition to ensure adequate macro- and micronutrient intake and age-appropriate growth. Common limitations in all studies on BTF to date are small sample size, potential for reporter bias, lack of randomization, and lack of a control group. However, the compelling results may provide support for larger randomized controlled trials going forward.

Concerns About BTF Use

Several concerns have been raised about the use of BTF, concerns which primarily mirror the reasons for which commercial formulas initially rose to prominence. Opposition to BTF typically centers around potential contamination, adequate nutrient provision, costs, viscosity and clogged tubes, and compatibility with the proposed ENFit connectors. Patients at risk for microbial contamination include neonates, the elderly, and any immunocompromised patients, and this risk is among the most commonly cited reasons for lack of BTF use in clinical practice.[8,14] Three studies comparing microbial composition of hospital or home prepared BTF with commercial formula found BTF to have increased incidence of contamination compared to commercial formula.[15-17] Studies have noted higher rates of contamination in powdered commercial formulas compared to liquid commercial formulas and noted that the increase in contamination with BTF and powdered formula may be due to increased food handling, with increased risk for contamination due to inadequate hygiene of personnel or poor equipment sanitation.[15,17] Another study noted that refrigerators in which BTF was stored were not kept at optimal temperatures and that prepared formula was often stored outside of the refrigerator for extended lengths of time.[16] Much of the literature acknowledges this concern, but the impact of contamination on patient outcomes has not been studied.[1] Recent papers do not discourage immunocompromised patients from using BTF; rather, they encourage adequate education and attention to food safety in BTF preparation and use within two hours if being given via pump or gravity bag.[1-3,18] Surveys of adult patients using BTF have not found foodborne illness to be a problem, however, these may not be reliable as they are based solely on patient report, and studies around safety of BTF are very limited.[7]

Adequate nutrient provision has also been called into question when BTF is used, as some studies have found the nutritional content of BTF to be highly variable and lower than expected.[15,17-20]

However, in some studies, patients strained their formula to remove large food particles and often had to add water to the formula after straining to decrease the viscosity and allow administration through the tube.[15,17] These practices will decrease the nutrient provision of the formula, with straining contributing to variability among BTF nutrient provision. Other reasons for variability include patients altering what foods are used in the formula each day and a lack of standardized recipes available to patients.[1]

BTF are known to have greater viscosity than commercial formulas, which can cause them to flow through tubes more slowly. If patients add water or other fluid to the formula to aid delivery, this could impact the nutrient content the patient receives.[1,15,19] Use of feeding pumps is common among the pediatric population, but these pumps are developed to accommodate commercial formulas, not the thicker blended formulas, thus the actual flow rate of BTF through the pump may be slower than what the pump is set to.[5] This would lead to a longer time required to provide adequate formula volume, and could decrease nutrient provision if sufficient formula is not delivered through the day.[11] Additionally, some home infusion providers have noted pump failures due to use with BTF, which could impact the ability to feed patients and increase costs.[5] The potential for variability in nutrient composition of BTF and the concerns this introduces around micronutrient deficiencies and malnutrition suggest that special attention should be paid to nutrient content and method of delivery when creating a BTF recipe. Straining and adding water to the formula should be avoided where possible. If additional fluid must be added to decrease viscosity, using a fluid that adds nutritional value, such as broth, juice, or milk, will likely be preferable to water; the nutritional content of the formula should be evaluated including this additional fluid.

Formula viscosity and clogged tubes are of particular concern in the pediatric population, where many patients have smaller diameter G or NG tubes. Aside from the problems that could arise with nutrient provision, discussed above, if the formula is too thick and clogs the tube, there is a possibility that the clog could not be cleared, and the tube would need to be replaced. Additionally, if a patient needs a more calorically dense formula, it may be difficult to achieve this without increasing the viscosity of the formula.[20] Patients on BTF have been observed to require additional calories compared to when using commercial formulas to maintain their BMI, which could pose challenges if the patient is unable to tolerate the higher volume required to meet these needs with BTF.[13]

In recent years, an effort has been made to develop new enteral tube connectors to eliminate compatibility between feeding tubes and other lines and tubes, as this compatibility has led to misconnections that can have deadly consequences.[5,21] Enteral connectors have typically had a male to female connection with feeding tubes, which has allowed them to connect with central venous catheters, tracheostomy tubes, and other non-enteral tubing.[22] The proposed ENFit connectors have a female to male orientation, eliminating the possibility of such misconnections, but have drawn criticism and concern over their compatibility with BTF, especially given the growing prevalence of BTF use among adult and pediatric patients.[7,21,22] The proposed connectors have a smaller diameter, at 3 mm, compared to the 14 French tubes typically recommended for BTF use, which have a 4.7 mm diameter.[21] A study comparing

the force required to syringe bolus various types of BTF through the new connectors compared to commercial formula show significantly increased pressure needed for all BTF, especially homemade blends, to move through the connector.[21] A study assessing the compatibility of BTF given via gravity bag with two proposed ENFit connectors found that the administration time was significantly longer with one of the connectors, while it was not significantly increased with the other. This raises concerns about patients not administering their full feeding if it is taking too long.[22] Finally, Mundi et al pointed out that changing to a female syringe tip fitted to a male connector will increase the amount of volume in the dead space, which could cause dosing complications for medication. A proposed solution to this has been to further reduce the bore of the connector, which the authors pointed out would further complicate viscous formula administration.[21]

Recommendations for Creating and Transitioning to BTF

Although there is limited evidence to guide recommendations around BTF, the literature detailing current practice contains many suggestions for determining appropriate patient populations, how to create BTF, and how to transition to BTF. ASPEN has also produced safe practice guidelines for enteral nutrition, based on consensus recommendations, which include some guidelines for BTF.[23] There are many points to consider when determining if BTF is appropriate for a patient, summarized in Table 1 below. BTF can be introduced as table foods would typically be introduced, providing partial nutrition starting at 6 months of age and full nutrition from 1 year of age onward.[2] Prior to transitioning to BTF, patients must be medically stable, with appropriate growth for their age.[1-3,10,11,24] Multiple severe food allergies may make adequate nutrition provision solely through BTF difficult. Additionally, patients who are volume-restricted or have complex dietary needs, such as with metabolic disorders, may have difficulty meeting needs through BTF.[1-3,23,24]

Support of the medical team and the ability of the RD to closely follow and support the family as they transition to BTF is essential to success.[2,3,23,24] The ability of the family to take the time to prepare the formula and follow food safety guidelines in the preparation, storage, and transport of the formula should be taken into consideration. If the family has limited time or other resources, there are commercial BTF products or simplified ways to prepare BTF using baby food purees that may be more appropriate while still fulfilling their desire for BTF.[2,3,23,24] Most of the current literature recommends using BTF with a 14 French or larger G-tube, with syringe bolus feedings preferred.[1-3,10,11,23,24] However, families are pushing these recommendations, with many families using BTF through NG tubes as small as 8 French. Gallagher et al. included patients with 12 French or larger G-tubes and Bhow et al. developed recipes that would easily flow through a 10 French tube by gravity, a sign of clinics gradually responding to patient and family preferences in this area.[13,25] The Oley Foundation notes that BTF can be given via gravity, bolus, or pump, and that while administration through an NG tube is not common and is difficult, it is possible.[10]

Table 1. Criteria to consider prior to transitioning patients to BTF. Adapted from Bobo, Walia, and Zettle.[1-3]

Age	Patient should be at least 1 year of age if BTF to provide 100% of nutrition. BTF may provide <25% of nutrition starting at 6 months.
Growth	Growth should be adequate and stable prior to initiating.
Medical Stability and Conditions	Medically stable. Certain medical conditions (multiple food allergies, renal disease, metabolic disorders) may make BTF use difficult and will need careful monitoring.
Feeding Tube	Gastrostomy tube of 14 French or greater, with site of tube well-healed.
Feeding Method	Syringe bolus preferred and known ability of patient to tolerate bolus feeds. If pump or gravity bag used, change bag every 2 hours to limit risk of foodborne illness.
Team Support	Careful follow-up and monitoring is required by the RD, with recipe adjustments made as necessary. Ideally, the RD has access to nutrition analysis software. Medical team support should be present.
Family Resources	Health literacy - understanding of food safety, clean food preparation space, ability to care for tube site. Space and equipment to prepare and store BTF. Time for preparation. Resources to pay for food and necessary equipment.

Recipes for BTF formulas should take into account the patient and/or family goals.[2,26] A nutrition assessment of the patient should be performed to ascertain appropriateness of BTF and the patient's nutrition needs.[2,3,24] Most literature recommends using the MyPlate recommended portion sizes for the patient's calorie goal as a starting point or referencing the *Homemade Blended Formula Handbook*, which provides formula worksheets adapted from the USDA Choose My Plate.[2,24,26] Alternatively, sample BTF recipes can be found through the University of Virginia School of Medicine's GI Medical Nutrition Support team website.[27] After creating an initial draft recipe, it should be evaluated in nutrient analysis software to determine if it meets the patient's fluid, macro- and micronutrient needs.[2,3,24]

Transitioning to BTF should be done slowly if the patient has never had food before, just as one would introduce new foods to an infant.[2] If the patient is already on a commercial formula, the BTF formula should be gradually increased as the commercial formula is decreased. Time to fully transition will depend on the patient's tolerance.[2,26] Close follow-up with the patient and family is needed during this time period to ensure appropriate growth, tolerance, provide continued reinforcement of food safety education, and to make adjustments to the initial recipe as needed.[2]

Chapter IV: Interviews of Nurses and Families with Inpatient BTF Experience

Interview Recruitment and Methodology

IRB approval was obtained in June 2017 to conduct interviews with the families of patients identified by SCH RDs as having experience using BTF while inpatient. Approval was also granted to interview nurses who had interacted with patients using BTF. Interviews were conducted between June 2017 and November 2017. Informed consent was obtained from all family (n=6) and nurse (n=3) participants. The interviews were recorded and transcribed, with all identifying information removed.

Interviews with nurses had a duration of approximately 15 minutes each and attempted to ascertain the impact of inpatient BTF on nursing time and workflow. Interviews with families had a duration of approximately 45 minutes each and attempted to determine how SCH could best facilitate inpatient BTF in the future. Sample interview questions can be found in Appendix I.

Nursing Interviews

Three nurses were interviewed, two from cancer units and one from ICU. Experience with BTF was limited and ranged from working with patients using Nourish or Liquid Hope to patients using homemade formula. They primarily saw patients using BTF with NG tubes, and all patients were using pump delivery.

When asked about frustrations with BTF, nurses all agreed that increased frequency of bag changes (related to two-hour hang time) was difficult with home BTF, primarily due to the added time out of their workday to change bags. On average, the nurses noted it takes five minutes to change a bag, which adds up to 30 minutes in a 12-hour shift. One RN estimated it takes as much as ten minutes per bag change, or 1 hour of a 12-hour shift. If use of BTF were to become widespread, this could significantly impact nursing workflow and labor costs. In response to this, nurses were supportive of allowing families to perform bag changes, as they are experienced with doing this at home. They also recommended research to determine if the hang time for BTF could be safely increased.

Other frustrations amongst nurses included frequency of tube clogging, especially with homemade BTF (it was noted this was rarely a problem with commercial BTF such as Nourish). One nurse noted that a hindrance of successful inpatient BTF was the hospital not having BTF to provide, highlighting the poor use of the current BTF formulas and the need for the hospital to provide an in-house option that appeals to families.

All nurses expressed support for BTF use in the hospital, noting that they saw improved formula tolerance and tolerance of higher feeding rates in children on BTF than in those on commercial formula. They noted they would like BTF to be offered to more families and be more affordable for families. Overall, nurses expressed a desire to learn more about BTF and its potential for increasing enteral nutrition tolerance as well as a desire for increased training on BTF administration.

Family Interviews

Six parents of SCH patients were interviewed. All parents reported using a pump to deliver BTF, with 2 parents reporting their child had a 14 French G-tube and 4 parents reporting their child had an NG tube. All but one family reported having a back-up formula that they used in case of emergency or if BTF did not work while inpatient. Three families would use Nourish as their back-up, with the other three using a variety of commercial formulas, despite these options often producing decreased tube feeding tolerance. Reasons for using BTF over standard commercial formula were primarily related to feeling that the nutrition provided by commercial formula is inferior to that of BTF, including concerns about sugar as the primary ingredient in commercial formula. Half of parents reported using BTF due to food sensitivities or allergies. Flexibility to add supplements they think are beneficial and BTF aligning with their current family diet were mentioned by one third of participants.

All participants noted benefits to using BTF, primarily improved tolerance of tube feedings and treatment (decreased nausea, vomiting, diarrhea, and constipation). Other perceived benefits include improved growth, child participation in food selection, shortened recovery time, and decreased reflux. One parent noted that improved tolerance led to the ability to give bolus feeds, allowing feeds to occur at mealtimes with family and school peers, thereby aiding in maintaining a sense of normalcy for both parents and child at home and at school. Multiple parents noted that BTF also benefits parents by providing something to feel a sense of control over and giving parents an increased sense of nurturing and caring for their child. Despite all families being staunch advocates for BTF, they each acknowledged some disadvantages to BTF. The primary drawback, discussed by all participants, is the time required to blend the formula. Other common disadvantages include the expense due to not being reimbursed for by insurance, potential for clogging the tube, and difficulty when traveling.

Some noted difficulties with BTF were inpatient-specific. These included nurses having to control the pump and do bag changes, leading to feelings of loss of control and frustration around delays in bag changes. Additional difficulties arise when bringing BTF into the hospital from home, as this needs to be blended fresh daily, and adds time, travel, and stress to the hospital stay. Because of this, many families were eager to have BTF options that work well provided by the hospital kitchen, especially for families coming from long distances. Multiple families noted that when they tried to order their home recipe made in the SCH kitchen, clogged tubes were a common problem despite the recipe working without clogging at home. They noted that this increased the RN workload around troubleshooting, caused poor sleep due to the pump alarming throughout the night, and led to an overall increase in stress during their stay, especially if their child did not have a commercial back-up formula they could tolerate well. It was also noted to result in decreased provision of nutrition to their child, as they often could not get a new batch of formula made for several hours. While there were difficulties with BTF while inpatient, five out of six families expressed appreciation that staff were willing to work with and enthusiastically support BTF. Families also felt that having RDs available to ensure their child was meeting their needs and to provide guidance when needed was vital to their overall positive BTF experience.

When presented with a choice between a menu of set BTF recipes versus a food combo tool while inpatient, one parent had no preference, two parents preferred the idea of the food combo tool, and three parents preferred set recipes. One parent that preferred the food combo tool also stated that as long as there were several recipes available, it would be likely one of these would meet a child's dietary needs. Four parents expressed a preference for organic ingredients in their BTF, with two parents stating they would not consider using a recipe made at SCH if the ingredients were not organic. This is a concern for recipe adoption and will need to be considered as data is collected after implementation.

Chapter V: Recipe Development

Recipe Goals

Once interviews were complete, a recommendation was made to the inpatient clinical manager and other inpatient RDs that the project focus on creating a single recipe that would not clog tubes and would meet desired nutrition goals. A meeting was held to discuss goals for the new formula, which were decided to be as follows:

- Recipe makes approximately 1000 mL batches
- 25 kcal/oz
- No more than 30g protein per 1000 kcal
- Fat at 40% of total calories (no more than 50% of total calories)
- Fiber no more than 12g/L
- Vitamin A no more than 250% of DRI or Upper Limit
- 75% of DRI for all nutrients for 4-8 years old at 1000 kcal
- Adequate sodium to be safe
- Dairy free
- Gluten free
- "Pacific Northwest" ingredients (i.e. Salmon, apples, kale)

The recipe needed to include only foods available in the Forest Kitchen and not place an undue burden on kitchen staff (i.e. be overly time-consuming or labor-intensive to make). To ensure this, a list of available foods was obtained from the informatics RD. Discussions verifying the availability of selected foods and ease of preparation were had with the buyer supervisor and sous chef.

Recipe Creation

Recipe guidelines found in Walia et al. and *Homemade Blended Formula Handbook* were used as initial guides for amounts of each food group needed.[2,26] Analysis of recipes was done in Food Processor. Results were then compared to the macro and micronutrient goals calculated from the DRIs for 4-8 year olds (see Appendix II). In anticipation that keeping vitamin A below the goal limit would be

difficult, and that vitamin D, calcium, phosphorus, and sodium might be difficult to reach goal, particular attention was paid to results for these nutrients.

Initial drafts included sweet potato, but not only did this provide excessive amounts of vitamin A, but it was later discovered to be unavailable in the kitchen. Instead, butternut or delicata squash was used (dependent on seasonal availability), providing a more ideal vitamin A profile. Low-sodium chicken broth was added to decrease viscosity and increase sodium. While vegetable broth was higher in sodium than chicken broth, vegetable broth contained fewer calories per cup, leading to a decision to optimize calories, as the formula was already near-goal for calories per ounce and dropping below goal was a concern.

Sodium needs proved particularly difficult to meet, as the SCH kitchen no longer carries full-sodium broths. Potassium, as anticipated, was also a difficult goal to meet. Based on feedback from the clinical manager that the DRIs for these minerals are known to be high and that, clinically, patients do not need the amount listed in the DRIs, the decision was made to adjust these goals.The sodium goal was adjusted to meet the content range of other pediatric enteral formulas: 380 mg/L (Pediasure with Fiber) to 760 mg/L (Compleat Pediatric). Additionally, the potassium goal range was adjusted to mimic that of other enteral formulas: 1477 mg/L (Pediasure with Fiber) to 1640 mg/L (Compleat Pediatric).

Vitamin D remained a problem, especially as the goal was to make the formula dairy free. The rice milk available in the kitchen is not enriched, so contains no vitamin D. In addition, the salmon is farmed salmon, which has been observed to have lower levels of vitamin D than wild salmon.[28] Food Processor lists the salmon as containing no vitamin D, however, the results of Lu et al. indicate this is not accurate.[28] Thus, while the vitamin D content of the formula is higher than assessed by Food Processor, it is still inadequate to meet needs. However, this was an expected result, due to the known difficulty of meeting vitamin D needs through food. In the end, this deficiency is one that had to be accepted, acknowledging that if patients are on this formula for a lengthy time, supplemental vitamin D will be needed.

Viscosity Testing Procedure

To ensure that the formula would flow through feeding tubes, the International Dysphagia Diet Standardisation Initiative (IDDSI) Flow Test was performed on each batch of formula using a NeoMed 12 mL oral/enteral syringe. This test can be used to assess the viscosity of fluids for patients with dysphagia, but has also been used to assess viscosity for BTF, and is validated using a 10 mL Luer lock syringe. The NeoMed 12 mL oral/enteral syringe is not validated with the IDDSI Flow Test, however when testing began validated 10 mL Luer lock syringes could not be found in the hospital. While these circumstances were not ideal, performing the test with the syringes available provided valuable feedback and general guidance related to viscosity. Per test protocol, the syringe was filled to 10 mL, allowed to flow for 10 seconds, and the remaining volume was recorded. This test was completed 3 times immediately after production for each batch of formula, with the three tests averaged. The formula was then refrigerated for

24 hours before it was tested another three times. The average test results initially and 24 hours after production were used to assign an IDDSI level to each recipe. If no formula flows through the syringe, IDDSI level 4 is given. Level 3 is 8-10 mL remaining with some formula flowing through the syringe, Level 2 is 4-8 mL remaining, Level 1 is 1-4 mL remaining, and Level 0 is no fluid remains after ten seconds.[29] SCH policy does not permit the formula to be kept longer than 24 hours, so testing again at this point allowed determination of maximum thickening occurring prior to a batch of formula being discarded. If less than 4 mL remained in the syringe after the flow test, the formula should work in a 14 French tube or greater (L. Epp, personal communication, November 21, 2017). This provided a goal below which to aim for, as this formula needed to flow through 8 French tubes, a commonly used tube size for children. As current recommendations advise against using BTF in tubes smaller than 14 French, more specific benchmarks for viscosity testing were not available.

Viscosity Testing Results

Several recipe versions were created prior to testing, with some of these eliminated without testing due to not meeting goals during Food Processor analysis. Initial viscosity test results were performed on two formula versions. Tests on recipe 1 indicated an IDDSI classification of Level 3 (see Table 2). After 24 hours, no noticeable thickening had occurred, with no change in IDDSI results. This recipe made 36 ounces of formula and provided 28 kcal per ounce. Recipe 2 made 38 ounces of formula and provided 24 kcal per ounce. Results of the IDDSI classified this recipe as a Level 2. It was decided to pursue modifications to recipe 1, as it was well above the calorie goal and below the volume limit of the blender carafes, allowing room for adjustment.

A second round of testing was completed on recipe 3, a variation of version 1. Testing was complicated by clogging. Initial tests were run after blending for one minute, but all of these clogged the syringe immediately. The formula was then blended for another minute (two minutes total) and tested again. Two of the tests experienced clogging, with an average of 7.7 remaining. Fifteen minutes later, one more test was performed, with a result of 4.0. The average of all tests was 6.8, or Level 2. Upon retesting 24 hours later, no clogs occurred and indicated an IDDSI classification of Level 2.

Next, vegetable broth was substituted for chicken broth and blackstrap molasses was added. Clogging continued to be an issue when blending for one minute. This recipe was then blended for an additional two minutes (three minutes total). Viscosity testing resulted in a Level 2 classification. It was determined during testing that pieces of rice were causing the clogs, likely due to having increased the amount of rice in the recipe. Based on this, the amounts of rice and broth were adjusted to achieve a thinner consistency that would not clog.

Recipe 4 was tested after blending for one minute. This gave a Level 3 result, with near immediate clogging. Adding thirty seconds to the blend time improved results to a Level 1. Some clogging and slowing of flow occurred during this test. This recipe made 38-40 ounces (foaming after blending interfered with an accurate measurement), providing 26-27.5 kcal per ounce. Because of continued

issues with clogging, the amount of rice in the recipe was decreased further. The chicken broth was also decreased in an attempt to prevent overflow while blending.

This final recipe (recipe 5) was tested after blending for one minute. It received a Level 2 classification due to clogging. An additional thirty seconds of blending was added, resulting in a Level 1 classification and an average of 1.1 mL remaining. After 24 hours, an average of 2.1 mL of formula remained. Due to foaming, the total volume of the formula was highly uncertain, from 35-39 ounces, providing between 25 and 28 kcal per ounce. Because of this, another batch of formula was made and tested. After blending, the formula volume was measured using standard measuring cups, and produced approximately 37 ounces, providing approximately 26.5 kcal per ounce. Viscosity testing results were the same as previous tests, with a Level 1 classification and an average of 1.1 mL remaining. Clogs were no longer occurring during the flow test and there were no longer visible pieces of grain after blending, so testing with gravity bags and feeding tubes was begun.

Table 2. Viscosity testing results, both in IDDSI levels and in average volume remaining over three tests both immediately after production and 24 hours after production, estimated volume and calories per ounce of each recipe

Recipe Version	IDDSI Level	Average Volume Remaining in Syringe (mL) (Initial production/24 hours after production)	Volume (oz)	Kcal/Oz
1	3	9.53/9.53	36	27
2	2	7.8/7.73	38	24
3	2	6.8/4.53	39	26.5
3 (veg broth)	2	5.3/6.1	40	26.1
4 (1'30 blend)	1	2.6/2.9	38-40	26-27.5
5 (1' blend)	2	4.4/NA	37	26.5
5 (1'30 blend)	1	1.1/2.1	37	26.5

Gravity Bag Testing

Once the final recipe was developed, attempts were made to test it on 10 and 12 French tubes. However, no gravity bags could be found on SCH floors. The only connection tubing found on site was smaller than 8 French, which was tried, but did not work well with the formula. A makeshift connection was made between a syringe and the 10 and 12 French tubes, and the formula flowed well through these tubes. Remaining formula was stored for four days until the clinical manager received a 1200 mL gravity bag and an 8 French tube from a Homecare RD.

The formula was tested with the gravity bag and 8 French tube. An initial clog occurred but was able to be flushed out. After this, the formula flowed through the tube well, with a drip rate of 250 mL/hour.

Due to the delays in testing this batch of formula and the initial clog, further testing was performed on formula batches blended for one minute thirty seconds and two minutes. The formula with the shorter blend time had a drip rate of 225 mL/hour and experienced significant clogging. The two-minute blend had a drip rate of approximately 300 mL/hour. While it experienced some initial clogging, such issues were less frequent. It was decided to trial blending the formula for three minutes, with a break halfway through to scrape the sides of the blender carafe to catch any large particles and ensure a smoother blend. A test would also be performed on a batch that had been put through a sieve after blending.

For this round of testing, 1000 mL gravity bags and 8 French tubes were obtained from Central Services. The non-sieved formula ran at a rate of 470 mL/hour (157 drips/min) and the sieved formula at a rate of 495 mL/hour. Both formulas experienced an initial clog, though this clog did not appear to be a food particle as seen previously, but rather a thickened or compressed “plug” of formula that was discovered near the end of each feeding tube. This “plug” was easily squeezed out, after which both formulas flowed easily at the rates above and without further clogging. Hypotheses about the cause of this plug formation include the potential of something coating the interior of the bag and/or tube causing a thickening of the initial formula flow (bags and tubes were new), or the change in pressure required when moving between the bag tubing and the 8 French tube compressing initial formula flow into a plug. Bags and tubing were rinsed and flushed with water to allow reuse during retesting 24 hours later.

Upon retesting, water was placed in the bags and run through the tubing prior to testing to ensure that no residue remained from the previous day and that nothing was clogging the tubing. The non-sieved formula ran at a rate of 340 mL/hour while the sieved formula ran at a rate of 450 mL/hour. Neither formula experienced any clogging, further indicating that the clogging during the previous tests was not due to the formula. Another batch of formula was made and tested, with a 15-20 mL water flush used on the NG tube prior to connecting the gravity bag. This eliminated the initial plug formation, with the formula flowing at 350 mL/hour 24 hours after formula production.

Chapter VI. Final Product

As recipe volume during the testing stages was noted immediately after blending, the volumes above are not representative of the delivered volume after the formula has settled and some formula has been lost to viscosity testing performed for quality control. The final recipe, delivered to the informatics RD and the head chef, produces approximately 1050 mL of formula after the formula settles, which provides 28-28.5 calories per ounce depending on the type of squash used in production. It is anticipated this recipe will have approximately 1000 mL available for delivery after some formula loss to viscosity testing and transferring the formula from the blender to the delivery jug. The final recipe is as follows:

Ingredients:

2 cups vanilla classic rice milk

¾ cup low-sodium chicken broth

2 ounces salmon

½ cup cooked brown rice

½ cup chopped kale

½ cup baked, peeled, and cubed butternut or delicata squash

½ cup diced pears, juice and all

1 packet (32 g) almond butter

4 teaspoons olive oil

1 tablespoon blackstrap molasses

Instructions:

Poach the salmon. Steam 1/2 cup of kale. After baking the squash, cut off and discard any crisped/browned sections prior to measuring. Place all ingredients in blender carafe. Blend at 100% for 1 minute 30 seconds. Scrape the sides of the carafe and blender lid with a spatula. Blend at 100% for an additional 1 minute 30 seconds.

Table 3. Nutrition Information Quick Reference (Butternut squash version, per 1050 mL)

Technical Data		Calories	1001	Niacin, mg	8.8
Nutrient Density (Cal/mL)	0.95	Protein, g	28.2	Choline, mg	29.9
Protein (% Cal)	11.3				
Carbohydrate (% Cal)	49.4	Total Carbohydrate, g	123.7	Biotin, mcg	3.9
Fat (% Cal)	42.6				
n6:n3	6.7:1	Dietary Fiber, g	10.3	Pantothenic Acid, mg	1.5
Gluten-Free	Yes				
Dairy-Free	Yes	Total Fat, g	47.4	Sodium, mg	440
Viscosity					
Level 1		Water, g	956.6	Potassium, mg	1620.6
Minimum Tube Size for					
Gravity/Pump Feeding, Fr	8/8	Vitamin A, RAE, mcg	643.8	Calcium, mg	425.1
		Vitamin D, IU	0	Phosphorus, mg	480.8
		Vitamin E, mg	13.7	Magnesium, mg	187.7
		Vitamin K, mcg	58	Manganese, mg	1.9
		Vitamin C, mg	27.5	Copper, mg	0.68
		Folic Acid, mcg	65.3	Zinc, mg	2.29
		Thiamin (Vit B_1), mg	0.34	Iron, mg	15.8
		Riboflavin (Vit B_2), mg	0.47	Selenium, mcg	14.4
		Vitamin B_6, mg	0.70	Chromium, mcg	0.40
		Vitamin B_{12}, mcg	1.5	Molybdenum, mcg	0.40

The site will also be provided with a nutrition information quick reference chart (Table 3), similar to those provided by companies for all formulas in their line. This chart provides a quick way for dietitians to determine the nutrient density, macronutrient distribution, and micronutrient content of the recipe.

Chapter VII. Project Summary and Roll-Out

Interviews with nurses and families at SCH have shown that there is broad support for improvements to the provision of BTF at the hospital. Families are eager to have access to a BTF formula made on-site that will flow without complication through their child's feeding tube and continue to provide the whole-foods nutrition that these families value and which they have observed to positively impact their children's tube feeding tolerance. Nurses have observed improved tolerance of tube feeding in children receiving BTF and are supportive of increasing access to BTF for tube-fed patients. Clogged tubes are a frustration to both families and nurses in the inpatient setting, thus avoiding such complications is paramount. The product of this project, a gluten-free, dairy-free BTF formula to be produced in the SCH kitchen, flows through an 8 French NG tube via gravity and, if the tubing is primed with 15-20 mL of water prior to administration, should not clog the tube.

Work is currently underway to update the standard work for inpatient BTF, update the inpatient BTF policy, create a diet order, and update any workflows necessary to successful roll-out of the new formula. Once these key components are in place, the formula will be ready to offer to all tube-fed patients using BTF while they are inpatient. Updates to the inpatient BTF policy have been proposed, received support from the interdisciplinary Nutrition Support Committee in May 2018, and are awaiting finalization.

A hand-off summary of the project results, nutrition information quick reference, and next steps required for roll-out will be presented to the inpatient clinical nutrition manager and other stakeholders. Transcriptions of nurse and family interviews have already been provided to the inpatient clinical nutrition manager. Additionally, findings from interviews and the formula development process were presented to dietitians attending the Assuring Pediatric Nutrition in the Hospital and Community conference in May 2018.

Chapter VIII. Future Recommendations

The results of this project are simply a first step in development of a potentially robust system of BTF support at SCH. To meet the varied needs of patients and their families, it is recommended that SCH assess patient adoption of the new formula, adapting the formula or its production process as needed in response to unforeseen complications that may occur in production or delivery. This could be accomplished both through tracking orders of the formula amongst the BTF patient population and by conducting interviews with families using inpatient BTF one year after implementation. Additionally, if this formula is well-accepted, SCH should consider developing several other BTF formulas to create a BTF menu. Doing so would allow some variety for patients and their families, as well as provide the

opportunity to meet an array of common dietary needs. Future formulas could be made to be general diet, vegetarian, or nut-free.

It has been recommended to the head chef that the kitchen consider batch preparing the squash, as this is the most time-consuming ingredient in the recipe, taking 45 to 60 minutes to bake. Preparing large volumes of squash and freezing it after it has been peeled and cubed would allow kitchen staff to increase efficiency of formula preparation. Additionally, the buyer supervisor may wish to consider purchasing enriched rice milk to increase calcium and vitamin D provision of the recipe. If lack of organic ingredients proves to be a major hurdle to adoption of the formula, a cost analysis of purchasing some or all of the ingredients in organic form should be undertaken.

There is a great need for further research on BTF - its outcomes compared to commercial formula, cost comparisons, and food safety concerns. SCH should plan to complete a cost analysis of BTF, comparing the new standard formula costs to that of standard commercial formula and commercial BTF formulas. This analysis should take into account nursing labor required with 2-hour bag changes. Additional research could be conducted around patient outcomes when using BTF compared to standard commercial formulas and potential solutions that might safely allow an increase in the hang time of BTF, which could decrease labor costs of BTF and further increase nursing support of inpatient BTF.

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Appendix I. Sample Interview Questions for Families and Nurses

Families

- What led you to choose BTF over commercial formula? What are the benefits that you have found? Any disadvantages?
- Do you use a syringe, pump, or gravity bag to deliver the feeding? What tube size is your child using for their BTF?
- If the hospital had a robust menu of blenderized tube feeding recipes to choose from, how likely would you be to order from this menu during your stay? Follow up question: Would you prefer a BTF menu or to order off the regular menu and have it blended?
- What difficulties have you found with trying to provide your child with blenderized tube feeding in the hospital?
- What could make the transition between feeding at home and feeding in hospital smoother?
- What has contributed to a successful inpatient BTF experience for your family?
- Do you have a commercial backup formula that you use at home? During your child's hospital stay would you consider moving to a backup commercial blended formula, such as Compleat Pediatric?

Nurses

- What tube types (NG, G) and sizes have you seen the most BTF success with? What method of delivery?
- What current hospital practices do you feel lead to successful inpatient BTF? What current practices hinder success?
- For the nurses, what about the BTF process is most difficult/frustrating? What would you like to see done that could ease these difficulties?
- How much time does BTF require of nurses compared to commercial tube feeding?

Appendix II. Recipe Goals and Results

Macronutrients	Recipe Goal	Recipe Analysis (Butternut)	Recipe Analysis (Delicata)
Kcal/oz	25	28.5	28
Protein (g/1000 kcal)	<30	26.8	26.6
Fat (% total kcal)	40-50	43%	43%
Fiber (g/L)	</=12	9.8	7.3

Vitamins	DRI	Recipe Goal	Recipe Analysis (Butternut)	Recipe Analysis (Delicata)	Upper Limit
Thiamine (mg)	0.6	0.45	0.34	0.27	
Riboflavin (mg)	0.6	0.45	0.47	0.46	
Niacin (mg)	8	6	8.76	7.77	15
Biotin (mcg)	12	9	3.9	3.9	
Pantothenic Acid (mg)	3	2.25	1.53	1.16	
B6 (mg)	0.6	0.45	0.7	.57	40
Folate (mcg)	200	150	65.31	45.83	400
B12 (mcg)	1.2	0.9	1.51	1.51	
Choline (mg)	250	188	29.88	29.88	1000
Vitamin C (mg)	25	19	27.52	18.04	650
Vitamin A (mcg)	400	<1000	643.76	188.73	900 (IU, preformed)
Vitamin D (IU)	600	450	0	0	3000
Vitamin E (mg)	7	5.25	13.65	12.33	300
Vitamin K (mcg)	55	41.25	57.95	56.93	

Minerals	DRI	Recipe Goal	Recipe Analysis (Butternut)	Recipe Analysis (Delicata)	Upper Limit
Sodium (mg)	1200	380-760 mg/L	440	435.9	1900
Potassium (mg)	3800	1477-1640 mg/L	1620.61	1329.51	--
Calcium (mg)	1000	750	425.1	396.41	2500

Phosphorus (mg)	500	375	480.79	453.12	3000
Magnesium (mg)	130	98	187.67	157.94	--
Iron (mg)	10	7.5	15.83	15.45	40
Zinc (mg)	5	3.8	2.29	2.16	12
Iodine (mcg)	90	68	--	--	300
Selenium (mcg)	30	23	14.35	13.84	150
Copper (mcg)	440	330	680	610	3000
Manganese (mg)	1.5	1.1	1.94	1.76	3
Fluoride (mg)	1	0.75	--	--	2.2
Chromium (mcg)	15	11	0.4	0.4	--
Molybdenum (mcg)	22	16.5	0.4	0.4	600

Appendix III. Executive Summary

Updating Inpatient Blenderized Tube Feeding Practices

Blenderized tube feeding (BTF), tube feeding in which whole foods are blended and then put through the tube, has been gaining in popularity in recent years.[1-4] Many families of pediatric patients are drawn to BTF for a variety of reasons, among them improved tolerance of tube feeding, an increased ability to include a child in family meals, feelings of nurturing elicited, and a perception that BTF is more natural or more in line with their family food values.[1-4] While Seattle Children's Hospital (SCH) has a policy to allow BTF while inpatient, attempts to make individual patient's BTF recipes in the SCH kitchen have proven problematic, as they often clog the tubes, leading to frustration on the part of nurses, dietitians, and families.

Current Guidelines:[1-6]

- **Use BTF with a 14 French or larger G-tube**
- **Patient is medically stable, 1 year of age if getting 100% BTF, and tolerates bolus feeds**
- **Syringe bolus administration preferred. If pump or gravity used, limit hang time to 2 hours**
- **Discard unused formula after 24 hours**

While much of the evidence supporting BTF has been anecdotal, a recent study has reported decreased vomiting and use of acid suppressive medications after transitioning to BTF, as well as increased diversity and richness of stool microbiota.[7] Other studies have reported improvement in stool consistency and frequency and decreases in gagging and retching.[8-10] Patients are pushing recommendations regarding tube size. This has led to recent research including participants with 12 French G-tubes and attempts to develop BTF for 10 French tubes.[7,11] These cases support the approach at SCH to accommodate families using BTF with smaller tubes. Concerns for food safety, adequate nutrient provision, and clogged tubes have been observed and need to be considered when implementing BTF in both outpatient and inpatient settings.[1-5,12-17]

Recommendations:

- **Continue policy of 2-hour bag changes when pumps or gravity bags are used.**
- **Eliminate production of individual BTF recipes in SCH kitchen except in cases of clinical necessity to minimize risk of clogged tubing.**
- **Offer a standard BTF recipe made in SCH kitchen during inpatient stays.**
- **Interview families one year after roll-out of recipe to assess success and re-align with patient needs.**

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