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Clinical Focus

Clinical Focus: Findings and Clinical Implications for Thickening Formula With Infant Cereal Using the International Dysphagia Diet Standardisation Initiative Flow Test

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ABSTRACT

Purpose: The International Dysphagia Diet Standardisation Initiative (IDDSI) framework was established to provide standardized terminology and objective measures to assess foods and liquids for persons with swallowing difficulties. This clinical focus article reports the findings and clinical implications of the flow testing of infant formulas thickened with infant cereal completed as part of the transition process to IDDSI for one large pediatric quaternary care hospital.
Method: To determine a common recipe that could be used to thicken formulas with infant cereal to the appropriate IDDSI levels, three clinicians completed flow testing on 94 infant formulas. To examine intra- and interclinician variability in the process, they repeated flow testing with three commonly used formulas and infant cereal.
Results: Clinicians were unable to identify a standard recipe (infant formula + infant cereal combination) that consistently thickened different formula brands to a desired IDDSI thickness level, as there was pronounced variability across and within infant formulas. Reliability testing revealed that, overall, clinician mixers were consistent in replicating similar results to themselves and to each other and that, instead, greater variability lies within the formula (and infant formula + infant cereal combination).
Conclusions: Based on findings of pronounced variability within and across infant formulas, our institution determined that the creation of a standard recipe for achieving IDDSI thickness levels of formula mixed with infant cereal was not feasible or clinically appropriate. We offer recommendations for similar institutions for advancing clinical management of infant dysphagia using the IDDSI flow test and directions for future research.

Dysphagia is difficulty moving food, liquids, saliva, and medications safely from the mouth to the stomach (Cichero, 2013). It affects up to 8% of the world's population and can impact overall nutrition and hydration for those affected (Cichero et al., 2013). In pediatric populations, dysphagia may negatively affect the safe feeding and hydration of children with developmental disorders (Arvedson, 2008; Gosa et al., 2011; Lefton-Greif, 2008), infants born prematurely, and those with complex medical conditions (Dodrill & Gosa, 2015; Lefton-Greif, 2008).

There is limited evidence to guide a practitioner in best practice treatment for infants with dysphagia. Infants who exhibit dysphagia may require modifications to their diet, including thickening formula or human milk so these liquids are easier and safer to swallow. The common

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practice of thickening helps to slow the liquid to allow additional time to engage laryngeal vestibule closure before the bolus arrives at the entrance to the airway. Thickened liquids provide other benefits, including increasing sensory input and normalizing the swallow pattern timing during respiration (Gosa et al., 2011). As a challenge to clinical practice, thickening practices vary widely across institutions, where clinicians may recommend using artificial thickeners and/or infant cereal as the preferred thickening agent (Madhoun et al., 2015). Research has found variability in thickening recipes and methods for measuring, mixing, and warming thickened feeds (Madhoun et al., 2015). Cichero et al. (2013) conducted a survey with 2,050 respondents across 33 countries to gather information about standard clinical care for persons with dysphagia. Participants reported 54 different names for modified foods and 27 different names for levels of modified liquids. These inconsistencies in clinical practice patterns lead to difficulty in making the most evidence-based recommendations to caregivers of infants with swallowing difficulties.

The International Dysphagia Diet Standardisation Initiative (IDDSI) was developed to establish common dysphagia terminology across the life span, institutions, and cultures (Steele et al., 2018). The IDDSI framework includes characteristics and examples of food and liquid at each specified diet level and describes testing methods to confirm the flow or characteristics of these particular foods and drinks (The IDDSI, 2019). The food testing methods use common eating utensils, whereas the drink testing methods use a gravity flow test. The standardization of dysphagia diets using the IDDSI framework allows clinicians to provide more consistent communication and better care for their patients through the establishment of common terminology and standardized meal preparation methods. Specifically, for clinicians and caregivers of infants with dysphagia, IDDSI provides an objective procedure to modify liquids via flow testing to ensure the liquid meets the desired thickness prior to the administration of the feeding.

Despite the standardization offered by IDDSI regarding the testing of liquid flow rates, it does not make recommendations as to the way liquids are thickened. There is inconsistent evidence in the literature regarding the ideal thickener to use when thickening formula and/or human milk for infants with dysphagia. In their systematic review, Gosa et al. (2011) reported that three of six studies used rice cereal as the thickening agent, whereas one used cornstarch; two studies did not specify the thickener that was used. McCallum (2011) conducted a review of the impact of various thickeners on nutrient density and found that the type of thickener used in different liquids (i.e., formula, human milk) impacts the caloric density of the fluid. For example, some thickeners increase the load of carbohydrates but consequently also reduce the volume of liquid, which impacts the availability of required nutrients for growth and development. Xanthan gum gel thickener was introduced as a possible solution to thickening for infants with dysphagia; however, due to the possible link between xanthan gum and necrotizing enterocolitis, xanthan gum is no longer recommended for use in infants (Beal et al., 2012; Gosa & Corkins, 2015; Tutor & Gosa, 2012). Other thickening options such as carob bean gum are also readily available; however, research has shown that the established manufacturing thickening instructions/recipes do not consistently yield the appropriate thickness for ready-to-feed (RTF) infant formulas, leading to persistent safety concerns (Gosa & Choquette, 2021). Lack of clear evidence-based guidelines related to thickening procedures for infants with dysphagia leads to inconsistent practices across institutions, making it challenging to educate caregivers and medical providers regarding the best way to thicken formula for infants with swallowing impairments.

IDDSI Implementation at One Large Pediatric Hospital

The IDDSI framework was established to provide standardized terminology and objective measures to assess foods and liquids; however, each implementing institution was tasked with deciding how to transition from their current dysphagia diet to IDDSI. At our large pediatric medical institution, this transition was initiated through multidisciplinary collaboration with key stakeholders involved in dysphagia care. These stakeholders included nursing leadership, information systems, electronic medical record specialists, project coordinators, nursing informatics, physician informatics, nursing educators, clinical nurses, occupational therapists (OTs), speech-language pathologists (SLPs), and registered dietitians. Prior to IDDSI, clinical practice at our institution followed general understanding of the best available evidence that involved thickening formula with infant cereal for patients under 12 months of age (corrected for premature birth) and the use of hospital-approved artificial thickeners for patients over 12 months of age (corrected). With the transition to IDDSI and the recommended practice of flow testing to determine the correct level of thickness of all liquids, the IDDSI Transition Team at our institution was tasked with identifying new standardized thickening recipes using infant cereal that met IDDSI requirements. The stated goal was that the simple standardized thickening recipes could then be used by staff on the hospital floors and in ambulatory clinics, as well as taught to parents for easy replication of the desired and recommended thickness.

This clinical focus article reports the findings and clinical implications of the flow testing completed as part of the transition process to IDDSI for one large pediatric quaternary care hospital. On the basis of these findings, we offer recommendations for similar institutions for advancing clinical management of infant dysphagia and directions for future research.

Method

This work was completed as a business process improvement initiative and did not require institutional review board approval as it did not involve human subjects. The process described in this clinical focus article includes two specific steps. First, clinicians completed initial flow testing to determine a standard recipe for thickening formula using infant cereal for each IDDSI level. As a result of variations noted in replicating the recipes during initial flow testing, reliability flow testing was then completed with a small number of formula and infant cereal combinations.

Initial Flow Testing

The clinical lactation and nutrition team within the organization identified the most frequently ordered formulas across all patient units. One SLP and two OTs completed flow testing using the standardized IDDSI protocol. Clinician feeding and swallowing experience ranged from 10 to 22 years.

The gravity flow test was used for testing the thickness of liquids, as specified in the IDDSI flow testing methods (The IDDSI, 2019). Briefly, clinicians poured 30 ml of room temperature infant formula into a Volu-Feed (Abbott Laboratories) bottle. Clinicians measured Beech-Nut rice or oatmeal infant cereal using measuring spoons and then added the cereal to the bottle that contained the infant formula. The formula and infant cereal were then shaken for 30 s. Clinicians then immediately drew up 10 ml of thickened formula from the middle of the mixture into a 10-ml Luer slip tip syringe (BD). Clinicians stopped the liquid flow after it drained by gravity for 10 s. The amount of liquid left in the syringe following the 10-s flow test was measured to assign the corresponding IDDSI level (i.e., Level 0 = *thin*, Level 1 = *slightly thick*, Level 2 = *mildly thick*, Level 3 = *moderately thick*, Level 4 = *extremely thick*). Following the flow test, the 10-ml mixture was then returned to the bottle to be used for testing at 15 and 30 min. These same formula mixtures were then retested using the same procedures at 15 and 30 min. Initial trials for each formula included 1 tsp of rice or oatmeal infant cereal added to 30 ml of infant formula. Once flow testing was completed, if the designated IDDSI level was not achieved, clinicians adjusted the amount of infant cereal added in 0.25-tsp increments until the target IDDSI thickness level was achieved. The three clinicians tested the IDDSI thickness level on a total of 94 formulas, each thickened with infant cereal until they achieved recipes for each formula + infant cereal combination for three IDDSI levels (Levels 1, 2, and 3). Because the institution is not adopting IDDSI Level 4 (extremely thick), clinicians did not complete the flow testing for this thickness level.

This process was completed over approximately 51 sessions in 2- to 4-hr increments starting in December 2018 and ending in January 2020. Clinicians used flow testing first with all formulas in their pure form, at room temperature, to determine their IDDSI level prior to adding oatmeal or rice infant cereal. Then, flow testing was completed as described above. Other variables recorded for each flow testing/formula combination included formula brand, form (i.e., RTF, powder, and concentrate), caloric density, amount and type of infant cereal added, and IDDSI thickness level in its pure state (i.e., no infant cereal added) and after thickening with infant cereal. Clinicians tested most infant formulas with both rice and oatmeal infant cereal and recorded results accordingly. Clinicians recorded data on audit sheets at the time of testing and transferred to a shared spreadsheet for reference and tracking over the course of the implementation project.

Reliability Flow Testing

Following the initial flow testing and to help confirm next steps and recommendations for successful IDDSI implementation, three of the institution's commonly used RTF formulas were selected for reliability flow testing where clinicians could evaluate the consistency of their flow testing within and across formulas and clinicians. RTF formulas were chosen to reduce variability that comes with powder and concentrate mixtures that require further preparation of the formula. To help understand if the results found during the initial flow testing were due to clinician variability, the follow-up testing allowed for both an examination of any differences between measurers (interclinician variability) as well as within measurer (intraclinician variability). All formulas included for reliability testing had a caloric density of 20 cal/oz, and flow testing confirmed each as an IDDSI Level 0 (thin) in its unaltered/pure state at room temperature. The RTF formulas were thickened using the specified amount of Beech-Nut rice infant cereal (prior to rice cereal recall) found during the initial flow testing procedures to achieve an IDDSI Level 1 (slightly thick):

- Gerber Good Start Gentle 20 cal/oz RTF (30-ml room temperature formula mixed with 1½-tsp Beech-Nut rice infant cereal)
- Similac Alimentum 20 cal/oz RTF (30-ml room temperature formula mixed with 1-tsp Beech-Nut rice infant cereal)

- Enfamil NeuroPro Infant 20 cal/oz RTF (30-ml room temperature formula mixed with 2-tsp Beech-Nut rice infant cereal)

The formula was prepared by mixing the specified amount of infant cereal with 30 ml of the specified formula. To test a predetermined recipe for an IDDSI Level 1 (slightly thick) liquid, each clinician tested all three formulas individually using a consistent measuring spoon to add the designated amount of infant cereal for each recipe. Clinicians used the flow testing process as outlined above for this phase of reliability testing. To control for variability in the number of times that the mixture was reshaken, prior to flow testing at 15 min and 30 min, each clinician shook the formula 3 times.

Statistical Analysis for Reliability Testing

The three clinicians performed three experimental runs for each of the three different brands of RTF formula for a total of nine experimental runs for each brand of RTF formula. Measurements were taken at each of three time points (0, 15, and 30 min) for every experimental run. To explore consistency in results within and between individuals, they produced a plot of the minimum and maximum amount of formula remaining in the syringe for all runs of the experiment at 0, 15, and 30 min by clinician and formula brand. If the plot showed general consistency in results within and between clinicians across the experimental runs and at each time point, they decided, a priori, to collapse results among clinicians to assess the median, minimum, and maximum IDDSI level produced by each brand over time. To further assess the inter- and intrarater reliability of the measurements, they calculated the intraclass correlation coefficient (ICC) both between clinicians and within each clinician. An average-agreement, two-way random-effects model assessed between-clinicians ICC. For the within-clinician ICC, an average-agreement, two-way mixed-effects model assessed each of the three clinicians (Koo & Li, 2016). Of interest is whether clinically significant differences were noted between the formulas over time, which would be assessed using the flow test. All data analyses and graphs were produced in R Version 4.0.

Results

IDDSI Thickness Level Testing

A portion of the results from the initial flow testing is shown in Table 1. The table shows all key variables recorded during flow testing, including the specific formula, caloric density, form (i.e., RTF, concentrate, and powder), recipe used, IDDSI level achieved, and type of infant cereal (i.e., rice and oatmeal). The larger spreadsheet, detailing the 94 formulas, thickening agent, and recipes for each IDDSI level at time of flow testing (0 min) and at 15 and 30 min postmixing, is available upon request. As shown in Table 1, a different amount of cereal was required for formulas to reach the desired IDDSI thickness level. For example, to achieve an IDDSI Level 1 thickness level, Gerber Good Start Gentle 20 cal/oz RTF formula required 1.5 tsp of oatmeal infant cereal, whereas Gerber Good Start Gentle 20 cal/oz powder formula required 2 tsp of oatmeal infant cereal. As the testing of various formulas continued, clinicians found that they could not use the same recipe across or within formula brands. They noted variability among the formula + infant cereal combinations required to achieve a specific IDDSI thickness level, which is specifically illustrated in the cereal-per-ounce column in Table 1.

Recipe Testing for Inter- and Intramixer Reliability

Because of variability observed during the initial flow testing process, the same three clinicians who participated in the initial flow testing process completed reliability testing. The aim of this testing was to determine if flow testing was consistent within and across clinicians and also within formula + infant cereal combinations. Figure 1 illustrates that all three clinicians produced an IDDSI Level 1 (slightly thick) for Similac Alimentum 20 cal/oz RTF formula over three separate trials. Initial testing with Enfamil NeuroPro Infant 20 cal/oz RTF flow-tested to an IDDSI Level 1 (slightly thick); however, during reliability testing across three clinicians, this recipe produced an IDDSI Level 2 (mildly thick) for all three clinicians across three separate trials. Gerber Good Start Gentle 20 cal/oz RTF proved to show the most inconsistency across the three clinicians using the recipe identified during initial flow testing to result in an IDDSI Level 1 (slightly thick). When mixing this formula using the predetermined 1½-tsp Beech-Nut rice infant cereal with 30 ml of room temperature formula, two clinicians found this to flow test to an IDDSI Level 0 (thin) over three separate trials. Clinician 3's flow testing revealed the formula fluctuated between IDDSI Level 0 (thin) and IDDSI Level 1 (slightly thick) at the 0-, 15-, and 30-min testing marks (see Table 2 and Figure 1). Table 2 specifically shows the variation in the amount of formula remaining in the syringe at these three time points. Of note, the clinicians discovered that this formula was changed from Gerber Good Start "Gentle" to Gerber Good Start "GentlePro" in November 2019. The change may have implications for modifications in composition of the formula that impact the mixing of the formula and infant cereal and the ability to achieve the

Table 1. Recipes identified in initial International Dysphagia Diet Standardisation Initiative (IDDSI) thickness level testing for Enfamil, Gerber, and Similac formula in ready-to-feed, concentrate, and powder forms.

Formula	Calories per ounce	Form (ready-to-feed, concentrate, or powder)	Recipe (infant cereal per ounce)	IDDSI level	Type of Beech-Nut infant cereal
Enfamil NeuroPro Infant	20	Ready-to-feed	2 tsp	1	Rice
Enfamil NeuroPro Infant	20	Ready-to-feed	2 tsp	2	Rice
Enfamil NeuroPro Infant	20	Ready-to-feed	2.5 tsp	2	Rice
Gerber Good Start Gentle	20	Powder	2 tsp	2	Rice
Gerber Good Start Gentle	20	Ready-to-feed	1.5 tsp	1	Oatmeal
Gerber Good Start Gentle	20	Ready-to-feed	2 tsp	2	Oatmeal
Gerber Good Start Gentle	20	Powder	1.75 tsp	1	Rice
Gerber Good Start Gentle	20	Powder	2 tsp	1	Oatmeal
Gerber Good Start Gentle	20	Powder	2.5 tsp	2	Oatmeal
Gerber Good Start Gentle	20	Ready-to-feed	2 tsp	1	Rice
Gerber Good Start Gentle	20	Ready-to-feed	2.75 tsp	2	Rice
Similac Alimentum	20	Ready-to-feed	1.25 tsp	1	Oatmeal
Similac Alimentum	20	Ready-to-feed	1.5 tsp	2	Oatmeal
Similac Alimentum	20	Powder	1.75 tsp	1	Oatmeal
Similac Alimentum	20	Powder	2.25 tsp	2	Oatmeal
Similac Alimentum	20	Ready-to-feed	1.5 tsp	2	Rice
Similac Alimentum	20	Powder	1.75 tsp	1	Rice
Similac Alimentum	20	Ready-to-feed	1 tsp	1	Rice
Similac Alimentum	20	Powder	2.5 tsp	2	Rice
Similac Alimentum	22	Powder	1.5 tsp	1	Oatmeal
Similac Alimentum	22	Powder	2 tsp	2	Oatmeal
Similac Alimentum	22	Powder	2.25 tsp	2	Oatmeal
Similac Alimentum	22	Powder	1.5 tsp	1	Rice
Similac Alimentum	22	Powder	1.75 tsp	2	Rice
Similac Alimentum	22	Powder	2.25 tsp	2	Rice
Gerber Good Start Gentle	24	Concentrate	2 tsp	2	Rice
Gerber Good Start Gentle	24	Concentrate	1.75 tsp	1	Rice
Gerber Good Start Gentle	24	Concentrate	2.5 tsp	2	Oatmeal
Gerber Good Start Gentle	24	Concentrate	2 tsp	1	Oatmeal
Similac Alimentum	24	Powder	1.5 tsp	1	Oatmeal
Similac Alimentum	24	Powder	2 tsp	2	Oatmeal
Similac Alimentum	24	Powder	1.5 tsp	1	Rice
Similac Alimentum	24	Powder	1.75 tsp	1	Rice
Similac Alimentum	24	Powder	2.25 tsp	2	Rice
Gerber Good Start Gentle	27	Concentrate	2 tsp	2	Rice
Gerber Good Start Gentle	27	Powder	2 tsp	2	Rice
Gerber Good Start Gentle	27	Concentrate	1.75 tsp	1	Rice
Gerber Good Start Gentle	27	Concentrate	1.75 tsp	1	Oatmeal
Gerber Good Start Gentle	27	Powder	2.25 tsp	2	Oatmeal
Gerber Good Start Gentle	27	Powder	1.75 tsp	1	Rice
Gerber Good Start Gentle	27	Powder	1.75 tsp	1	Oatmeal
Gerber Good Start Gentle	27	Concentrate	2.5 tsp	2	Oatmeal
Similac Alimentum	27	Powder	1.25 tsp	1	Oatmeal
Similac Alimentum	27	Powder	1.75 tsp	2	Oatmeal
Similac Alimentum	27	Powder	1.5 tsp	1	Rice
Similac Alimentum	27	Powder	2 tsp	2	Rice

desired IDDSI level. These changes may help explain the differences from initial flow testing to reliability testing in the amount of infant cereal required to reach IDDSI Level 1.

Figure 1 illustrates that clinicians were generally consistent across their three trials, meaning that intraclinician variability was low as each clinician mixed and flow-tested each of the three RTF formulas three separate times. There was no clinically significant interclinician variability noted either, as all three formulas remained either within or near their designated IDDSI thickness levels across the three trials for each clinician. Although one clinician was on the border of IDDSI Levels 0 and 1 for the Gerber RTF formula, the difference was small in absolute volume. The ICC for the interrater reliability was excellent (ICC = 0.98; 95% CI [0.97, 0.99]), and the ICC for the intrarater reliability for each clinician was also excellent with the lower bounds of the 95% CIs exceeding 0.90 for all three clinicians. While there are no clinically significant intra- or interclinician differences with mixing and flow testing of the formulas tested, there are notable differences across the different RTF formulas themselves.

Figure 2 shows a plot of the median, minimum, and maximum volume of formula remaining in the syringe after flow testing, over time, and for each of the nine runs of each formula, illustrating that the formulas remained

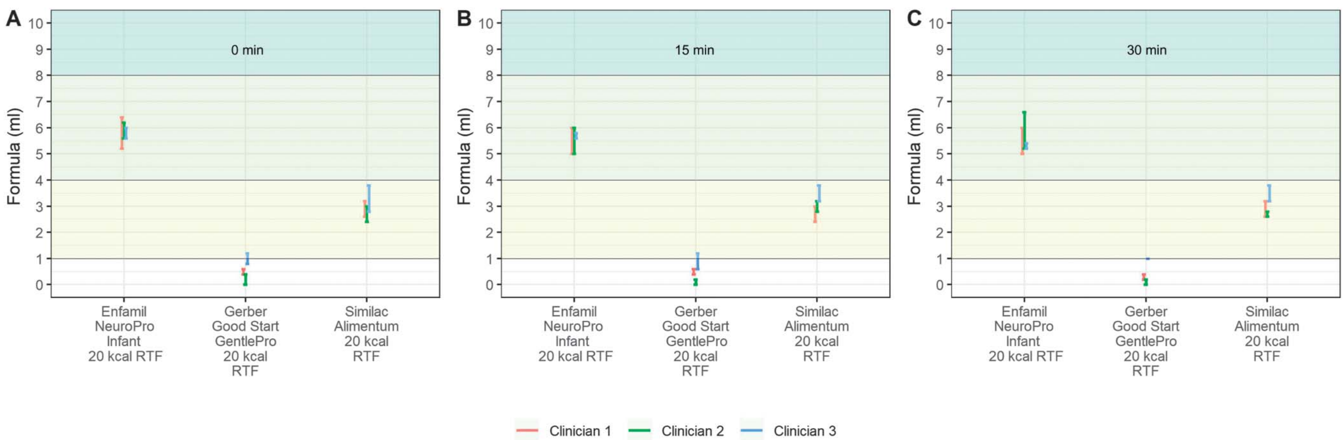


Figure 1. Minimum and maximum (amount of formula remaining in the syringe at each flow testing) for each formula at 0 min (A), 15 min (B), and 30 min (C). There appears to be little interclinician and intraclinician difference over the three time periods. Horizontal lines indicate the different International Dysphagia Diet Standardisation Initiative levels (0–1 ml = Level 0; 1–4 ml = Level 1; 4–8 ml = Level 2; 8–10 ml = Level 3). RTF = ready-to-feed.

consistent over time. In other words, the formula maintained the same IDDSI thickness level at the time of testing (0 min) and at 15 and 30 min, except for Clinician 3's mixing of the Gerber Good Start RTF. The clinician mixers intended to replicate Level 1 recipes for all three formulas, using predetermined recipes from their initial flow testing. They expected the formulas to all be plotted between 1 and 4 ml, but as shown initially in Figure 1 and reinforced in Figure 2, only Similac RTF formula thickened to the desired thickness level using the original recipe determined in the initial round of flow testing. Across all three clinicians, during this reliability testing, Enfamil thickened to a Level 2, and Gerber met criteria for an IDDSI Level 0.

Discussion

As our large pediatric institution transitioned to using the IDDSI framework, a group of key stakeholders was tasked with identifying a standardized recipe for thickening infant formula by adding infant cereal in designated amounts to reach each IDDSI level. After testing over 90 different formulas, a clinically notable finding from this project was the variability among different infant formulas and infant cereal combinations. Results from this project are consistent with a growing body of research indicating that there are many factors that can impact the thickening of infant formula for infants with dysphagia (Gosa & Choquette, 2021; Gosa & Dodrill, 2017; Kumar, 2019; Madhoun et al., 2015; Pados et al., 2016).

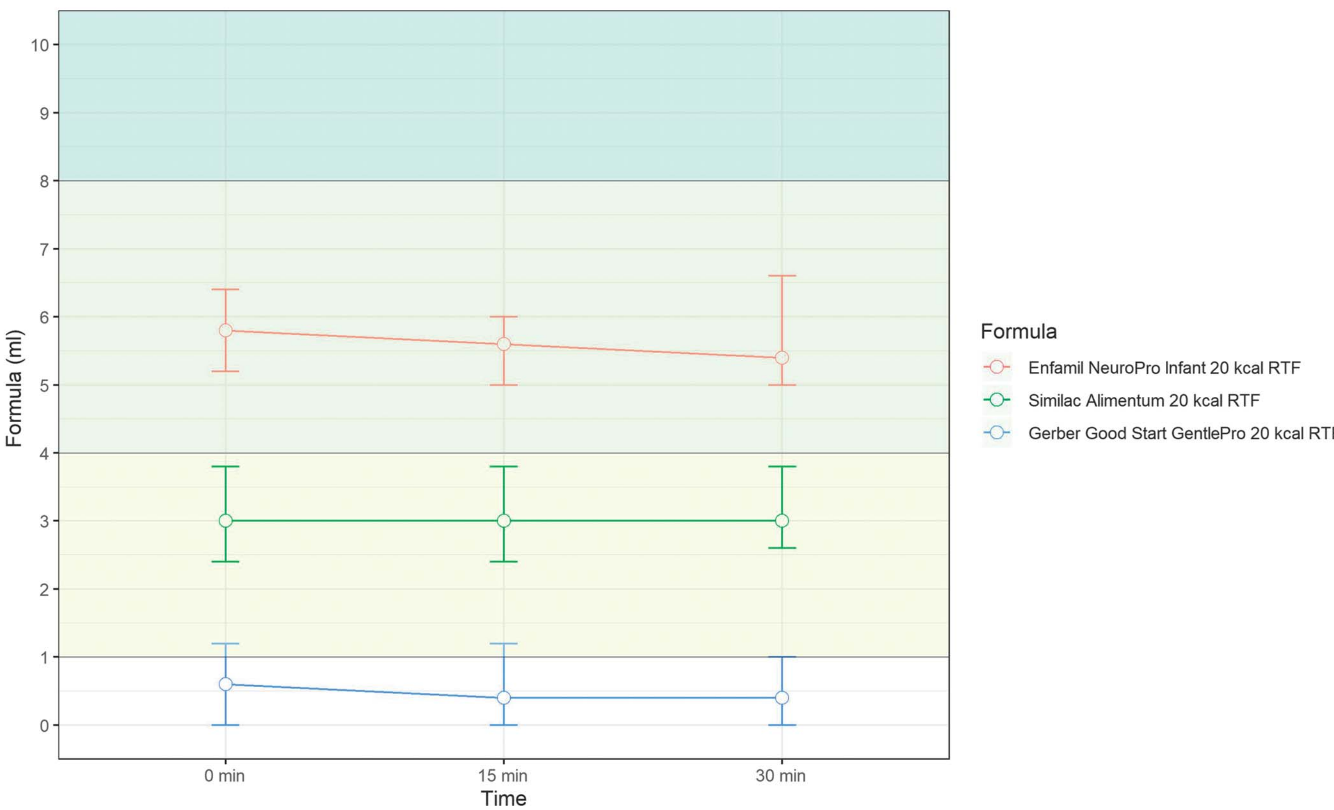
Inter- and intraclinician reliability testing revealed that formulas remained within a distinct IDDSI level from the time of preparation (0 min) to after flow testing at 15 and 30 min, except for one formula mixed by one clinician, which showed minimal absolute change but still affected IDDSI thickness determination. These findings demonstrate that the IDDSI level achieved upon initial mixing for an infant feeding is likely to remain consistent throughout a 30-min feeding. This is important as it ensures that the infant is receiving formula at an appropriate thickness level through the duration of the feeding to promote safe oral intake.

However, when taken with the overall results of the flow testing trials, results showed that thickness can change from feeding to feeding if relying on a standard recipe, without completing specific flow testing before each feeding. Although the clinicians attempted to be consistent in the reliability testing procedures, it appears that even slight variations in the procedures or products used can lead to differences in thickness and the corresponding

Table 2. Results of reliability mixing for Clinician 3 with Gerber Good Start GentlePro Ready to Feed. (Minutes refer to time after initial mixing when flow testing was completed, per standard International Dysphagia Diet Standardisation Initiative [IDDSI] guidelines.)

Trial	Recipe (tsp/oz)	IDDSI level	0 min (ml)	15 min (ml)	30 min (ml)	Cereal
1	1.5	0	1.2	0.6	1	Rice
2	1.5	0	0.8	1.2	1	Rice
3	1.5	0	1.2	0.8	1	Rice

Figure 2. Median, minimum, and maximum (amount of formula remaining in the syringe at each flow testing) by formula over time. Each formula was tested 9 times consisting of three trials performed by three different clinicians. There appears to be consistency among the trial runs within each formula with large differences between the formulas. Horizontal lines indicate the different International Dysphagia Diet Standardisation Initiative levels (0–1 ml = Level 0; 1–4 ml = Level 1; 4–8 ml = Level 2; 8–10 ml = Level 3). RTF = ready-to-feed.



IDDSI level achieved for each feeding. For example, the recipes that the IDDSI Implementation Team identified in the initial flow testing to achieve IDDSI Level 1 were not replicated when clinicians completed reliability flow testing. Furthermore, before the recall of Beech-Nut rice cereal, the specific type of infant cereal used (rice vs. oatmeal) led to differences in thickness of the same type of formula. While previous studies (e.g., Gosa & Choquette, 2021; Kumar, 2019) demonstrate variability across different formulas and thickeners, this clinical focus article is the first to show the variability that results when trained clinicians attempt to replicate a targeted thickness (IDDSI Level 1) using a recipe previously determined to achieve that target thickness.

There are several possible explanations for these differences, as numerous variables must be considered when thickening formula for infants with dysphagia. The first variable is the type of infant cereal used to thicken the infant formula. The size of the grains/flakes of infant cereal and the ability for the cereal to pass through the syringe for accurate flow testing is an important consideration. Findings from this project replicate findings from Kumar (2019), who similarly showed that the same amount of Beech-Nut and Gerber oatmeal infant cereals thickened formula to different IDDSI levels. When completing the testing described in this clinical focus article, both pulverized Beech-Nut rice and oatmeal infant cereals were small enough to successfully pass through the syringe during the flow test, whereas a larger, flaked grain-like Gerber clogged the syringe and precluded accurate testing. While Beech-Nut no longer manufactures infant rice cereal, oatmeal and mixed-grain cereal are still commercially available, although grain size may vary between and within brands. When instructing families about thickening infant formula for their infants, clinicians are encouraged to work with the family to identify the brand of infant cereal that they are likely to use at home, as the variability described here may be seen across brands and cereal types within brand.

As testing continued, new containers of cereal were needed. The type and batch of cereal used may add to the variability of reproducing consistent thickening results. Additionally, specificity of measuring the cereal to mix with the formula could cause variability in thickening results. In the procedures described in this clinical focus article, the clinicians used a standard measuring spoon but did not weigh the cereal to determine exact amounts. While this is likely more representative of what parents would do when mixing cereal with formula (vs. requiring a kitchen scale to determine a specific weight of cereal), this offers a potential area for inconsistency between feedings. It is possible that even a few more grains of cereal could impact the way that a formula thickens for a given feeding. As shown with Clinician 3's flow testing of Gerber RTF formula (see Figure 1), even very small differences may lead to a formula crossing from one IDDSI level to another.

The composition of the formula and how it interacts with the infant cereal poses an additional consideration when attempting to identify a standardized recipe for thickening formula (Gosa & Choquette, 2021). Each brand of infant formula is available in several different forms (i.e., RTF, concentrate, and powder) and types (e.g., Gerber Good Start Gentle vs. Gerber Good Start Extensive HA), with all of them having different ratios of micronutrients and macronutrients that could affect how they react with the cereal for thickening. Additionally, formulas that are concentrated to higher caloric density or have a different protein base may react differently to the various thickening agents, as described in previous work by Pados and Feaster (2021), where they tested multiple formulas and the variability in the flow rates among types and preparations of infant formulas. Similarly, Gosa and Choquette (2021) demonstrated that the choice of thickening agents (including single-grain oatmeal cereal and two different artificial thickeners) can impact the resulting thickness of an infant formula.

Clinical Implications Resulting From IDDSI Implementation at One Large Pediatric Hospital

Previous work by Madhoun et al. (2015) recommended further research and standardization are needed to guide thickening practices for infants with dysphagia. The establishment of IDDSI with the recommendation for standardized flow testing of liquids may be the most prudent method of ensuring safe and appropriate thickening of formula using infant cereal. Inappropriate thickening can result in dehydration or nutritional problems if an infant is not able to extract a thickened liquid from a particular bottle nipple (Pados et al., 2016), and infants are potentially at risk for aspiration if formula is underthickened. While common recipes are ideal in the overall ease of carryover for families and staff, the information gained from this testing revealed that standardized recipes may not be the safest or most appropriate option. Given the significance of the slight differences in thickness found in this investigation are unclear, the multidisciplinary IDDSI team at this institution determined to move forward conservatively and instead create a policy requiring flow testing prior to all feeds. Therefore, for all infants who require thickened formula at this institution, a new policy indicates that a flow test using the standardized IDDSI protocol must be completed prior to each feeding.

To facilitate this practice and consistency in thickening outcomes, staff was trained in flow testing, and the hospital stocked only one specific brand of pulverized cereal to promote consistency. Despite the potential inconvenience for staff and families, the institution reinforced the need to flow-test each time thickened formula is being prepared for an infant to confirm the thickness of the formula rather than relying on a standard recipe. When implementing the transition to IDDSI, the institution put significant emphasis on the importance of educating families and other care providers about flow testing and supporting problem solving for infants who require thickened formula. Family education materials were created with visual aids to assist in educating caregivers (Nationwide Children's Hospital, 2021). Direct parent and staff instruction is also recommended to ensure understanding of the flow testing process. Staff education consisted of a competency checklist completed via hands-on training with expert clinicians. Various staff educational resources are also available via the institution's internal intranet system. At all points, education to hospital staff and caregivers reinforces the importance of both infant swallowing safety and feeding efficiency, especially when utilizing infant cereal as the thickening agent.

As the IDDSI framework is implemented worldwide, clinicians should be aware of all the different sources of variability that can lead to inconsistencies when thickening formula with infant cereal. In addition to specificity of measuring both formula and cereal, other sources of variability (as discussed above) include but are not limited to type and batch of cereal, brand of formula, caloric content of formula, temperature of formula, and type of bottle/nipple being used to feed the infant. Leveraging multiple tools for staff and family education may help families navigate scenarios that require they thicken their infant's formula and how to do this for each feeding most effectively and safely. Considering a caregiver's preferred learning style, education could include video-based learning, return demonstration, pictures, and written directions. As infants discharge home, leveraging a telehealth modality for continuation of care and parent coaching of flow testing could be considered to limit the burden of return hospital/clinic visits but ensure that the infant is tolerating the feeds and that parents are successfully managing the thickening process (Tanner et al., 2020).

Future quality improvement projects and prospective research should examine how best to train staff and families to ensure consistent mixing and use of flow testing. Adverse outcomes, such as readmission rates for dehydration, failure to thrive, or aspiration pneumonia, should be monitored for infants who require thickened feeds. The feasibility of flow testing in hospital-based settings should continue to be examined regarding nurse workflow and patient acuity levels. Prospective research would help to inform the implementation process to ensure success for staff and family alike

Limitations

There are several limitations to this work that should be considered as we move forward with IDDSI implementation for bottle-feeding infants. First, this project was not planned as a research study, although part of the standardization of IDDSI requires strict methodology for flow testing. When clinicians reassessed flow testing for reliability purposes, they only repeated the procedures with three formulas and were not able to control for every possible variable during the reliability measurements. For example, although they used the same formula brand, type, and caloric density, because reliability testing was completed several months after the rounds of initial flow testing, these formulas were not from the same case/batch as the original formulas tested, introducing the potential for variability. Additionally, reliability testing was only completed for the IDDSI Level 1 range. Reliability testing for the thicker consistencies may yield different results. However, it is important to note that the purpose of reliability testing was not just to compare to the flow testing results from the first attempts but also to ensure that the variability observed was not related to the mixer and was likely due to the inherent properties of the formula and/or the infant cereal used as a thickener. It is possible that any change to the formula composition affected differences found between the initial flow testing and reliability flow testing for all three formulas tested in the reliability process. Many factors can influence the variation noted, which is why our institution made the conservative decision to utilize the IDDSI flow test prior to each feed when thickening infant formula using infant cereal. Unfortunately, we do not know the clinical significance of slight variations that result in the flow testing falling between two IDDSI levels, but only varying by 1 ml for example, or how the broad IDDSI categories compare with the barium tested in fluoroscopy. Further research is needed on what is clinically significant within these slight variations through practice-based experience.

Conclusions

This clinical focus article shares the experiences of one large pediatric institution's attempt to transition to IDDSI. Specifically, we describe the challenges to produce a standardized recipe to thicken infant formulas with infant cereal and suggest that one standard recipe may not be the ideal practice standard. Variables such as the brand and form of the formula (e.g., powder vs. RTF), caloric composition of the formula and how it interacts with the infant cereal, the temperature of the formula (Gosa & Choquette, 2021; Gosa & Dodrill, 2017), and the type and batch of infant cereal used to thicken the formula can lead to variability that prevents the identification of a standardized recipe to achieve a particular IDDSI level (Kumar, 2019). We found that intra- and interclinician variability was minimal, but variability across different formulas was pronounced. Reliability testing also reinforced that the recipes identified in our initial flow testing procedures did not consistently thicken these formulas to the same IDDSI thickness level, reinforcing that variability exists across formulas and mixing trials. On the basis of the findings of this rigorous quality improvement project, our institution determined that the most cautious response was to implement the IDDSI flow test before every infant feeding. As a result, clinicians and families are able to ensure the appropriate thickness level of formula for an infant with dysphagia. Utilizing a standardized recipe of infant cereal and formula may pose a safety risk to the infant and does not appear to be an effective method for ensuring that a specific formula is thickened to the appropriate level. Future, prospective studies are needed to explore infant outcomes related to thickening with infant cereal and the feasibility and fidelity of using the IDDSI flow testing tool across settings and patient populations to ensure good health literacy and equitable outcomes.

Author Contributions

Melanie Stevens: Conceptualization (Equal), Data curation (Equal), Formal analysis (Equal), Writing – original draft (Supporting), Writing – review & editing (Equal). **Sara O'Rourke:** Conceptualization (Equal), Data curation (Equal), Formal analysis (Equal), Writing – original draft (Supporting), Writing – review & editing (Equal). **Shelley Coleman Casto:** Conceptualization (Equal), Data curation (Equal), Formal analysis (Equal), Writing – original draft (Supporting), Writing – review & editing (Equal). **Jason Benedict:** Data curation (Equal), Formal analysis (Equal), Writing – review & editing (Supporting). **Jennifer P. Lundine:** Data curation (Supporting), Formal analysis (Supporting), Writing – original draft (Lead), Writing – review & editing (Equal).

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