Examining a New Scale for Evaluating Taste in Children (TASTY)

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OBJECTIVES Pediatric medication taste impacts adherence, and current recommendations advocate for direct input from pediatric patients on medication taste during drug development. However, the lack of a widely used, validated measurement tool limits taste assessments. This protocol examines the validity of, and preferences for, a newly created self-report taste rating scale designed with images centered on taste (TASTY), compared with 2 existing hedonic taste scales.

METHODS This study was a prospective, single-center, randomized survey of child-parent dyads recruited from pediatric ambulatory care clinics and ancillary service waiting rooms. Parents facilitated the survey by identifying foods that they perceived their child would recall as pleasant, neutral, and unpleasant. Children were asked to rate each of the 3 food items on each of 3 different faces scales presented in random order. Parents and children were also asked which scale they preferred and why.

RESULTS Ninety child-parent dyads completed this study (mean child age was 6.7 ± 2.9 years, 58% female). All 3 scales performed comparably with no significant differences ($p > 0.05$). However, concordance between parental assignment and child rankings was markedly lower in 3-year-olds ($r < 0.4$) and 4-year-olds ($r < 0.6$) than for children 5 years and older ($r > 0.9$). TASTY was preferred by both parents and children when compared with the other scales.

CONCLUSIONS This novel hedonic taste scale for pediatric use is equally valid and preferred to comparable faces scales. The TASTY scale may be beneficial in developing standardized methodology for evaluating drug palatability.

ABBREVIATIONS EMA, European Medicines Agency; FDA, US Food and Drug Administration; HIT, Human Intelligence Task; M-CERSI, University of Maryland's Center of Excellence in Regulatory Science and Innovation; MTurk, Amazon Mechanical Turk; TASTY, Tackling Assessment of Taste in Young children

KEYWORDS acceptability; hedonic scale; palatability; pediatrics; taste scale

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Introduction

Palatability, constituted by smell, taste, aftertaste, and mouth feel, is one of the most important factors influencing medication adherence and successful therapeutic outcomes in children.^{1–8} Better-tasting formulations are documented to simplify medication administration and improve adherence rates,^{9,10} yet many medications used for pediatric patients remain exceedingly unpalatable owing to bitter-tasting active pharmaceutical ingredients.^{11–15} Regulatory agencies and legislative bodies, including the FDA and the European Medicines Agency (EMA), have highlighted the importance of palatability in pediatric drug development where labeling is sought.^{7,16,17} However, there is no standardized methodology for assessing taste and no consistent guidance on taste performance standards.^{4,18} In fact, much of the knowledge relating to palatability assessment is concentrated in the food industry, which enjoys greater freedom to operate with regard to food

product taste testing than does the pharmaceutical industry.⁴ In a 2013 survey of pharmaceutical companies, respondents were overwhelmingly interested in advice from the FDA and EMA on validated tools and assessment criteria for evaluating pediatric medication taste preferences.¹⁶

A commonly used method for pediatric self-report of subjective experiences with taste are hedonic “faces” scales. Faces scales use a series of illustrations depicting varied facial expressions to demonstrate a spectrum of sensory experiences, thereby eliminating the need for the child to quantitate their experience numerically.¹⁹ There has been extensive research evaluating and validating faces scales for rating pain severity in children (e.g., the Wong-Baker FACES Pain Rating Scale),¹⁹ where faces scales are preferred to other methods including numeric and simple descriptive scales.^{20–23} However, faces pain scales have been criticized because of the relative challenge in discriminating between pain and emotional state, equating pain with sadness and

no pain with happiness.^{22,24–26} Notably, faces scales anchored with neutral versus smiling faces do not yield equivalent values of reported pain intensity.^{26,27} Despite these limitations, faces pain scales have been appropriated for other uses including the evaluation of medication taste.^{6,12,14,28–33} Some developers have attempted to address these limitations by removing the tearful face that anchors the pain scale, but emotion remains a component of their images.^{5,15,28} Moreover, children tend to prefer happy or cartoon-like faces as part of faces scales.²⁶ However, studies evaluating pediatric taste scales have focused on subjects' ability to use the scales without specifically commenting on purposeful scale design to be attractive to or preferred by children.³⁴ Therefore the existing scales are no more child friendly or engaging than those currently used for pain. Nonetheless, when taste studies are conducted on medicines, these faces scales are often the hedonic scales on which such studies rely. Sill, little is known about the validity and reliability of these scales.³⁵

The purpose of this study was to evaluate how a newly created, child-friendly, faces scale designed with images centered on taste (TASTY) performs relative to 2 commonly used faces scales used in taste assessment studies.^{16,28,34,36–38} A secondary objective was to examine patient and parent preferences related to these scales.

Materials and Methods

Scale Development and Selection. The draft TASTY scale was created in cooperation with pediatric clinicians and partner artists. A crowdsourcing mechanism was used to generate feedback as to how the scale was perceived by the lay public. Comments were solicited by using Web-based Human Intelligence Task (HIT) services under a protocol that was reviewed and approved by the Institutional Review Board at our hospital. The crowdsourcing marketplace Amazon Mechanical Turk (MTurk) was used to publish the HIT, recruit and compensate participants, and collect the data. An MTurk requestor account was created to deploy the HITs. With no context, respondents were asked to provide an open-ended interpretation of the scale. Context was then provided for the scale and respondents were asked to judge the effectiveness by using a 5-point Likert scale. Finally, respondents were asked how they would change the illustration to better depict the scale, using an open-ended format. Data from these responses were used to refine the illustrations.

With the lack of a widely used, validated measurement tool, a gold standard for comparison of pediatric faces taste scales does not exist. Two scales that have been used recurrently were chosen for comparison.^{16,28,35–38} Additionally, the scale developed by Chen et al,³⁴ which was used as one of the comparators, has been recommended to comparatively assess the palatability of oral dosage forms targeted for use in the pediatric populations by the Alliance Palatability

Working Group, under the guidance of the Global Alliance for Pediatric Therapeutics.¹⁶ Notably, reliability and validity data are lacking for both of the reference scales selected.

Study Design. This was a prospective, single-center, randomized survey of children-parent dyads. Children were distributed across 3 age cohorts (3–4 years, 5–8 years, and 9–12 years) and recruited from outpatient clinics and ancillary service waiting rooms at a major urban pediatric medical center in the Midwest (e.g., orthopedics, dentistry, otolaryngology, pharmacy, clinical laboratory). Participants were selected without regard for demographic and socioeconomic characteristics. Dyads were ineligible for participation if children were outside the age range of 3 to 12 years inclusive, were non-native language speakers, or were unwilling to participate in the study.

Procedures. After obtaining permission/assent/consent, limited demographic data were recorded including patient age, patient gender, and parent gender. The parent was then asked to facilitate the survey by considering a predefined list of foods and selecting 1 item each that he/she perceived their child would recall as very pleasant, neutral/bland, and very unpleasant tasting. The parents were offered a degree of flexibility in these selections to ensure that children were queried about food items to which they had been exposed. The selections were made silently without communication to the child.

The child was oriented to each scale prior to use. The child did not taste any food during the study but was asked to recall prior experience with the foods and rate each of the 3 food items on each of 3 different faces scales to include our novel scale TASTY and scales developed by Chen et al³⁴ and Ellis³⁷ (Figure 1), without assistance from the parent. The interviewer used a script to ensure consistency in wording during the interview process and maintain neutrality in an attempt to avoid influencing scale preference. Both the scales and the names of the food items were presented in random order as determined by a random number generator. The child was asked to consider the food item and then rate his/her perception of tastiness by pointing to the appropriate face on the scale. This was repeated until all foods were examined on all scales. Owing to reported differences in the ability of very young children to interpret longer hedonic scales,³² a 3-point version of each scale was used for children 3 years of age, a 5-point version for children 4 years of age, and either a 7-point (Scales 1 and 2) or a 5-point (Scale 3) version for children 5 years and older. All scales were printed to a similar dimension (relative to the height of the face), on white laminated paper, to ensure consistency between the faces and detail contained therein. No written descriptions or numbers accompanied the scales. At the conclusion of the survey, both the parent and child were shown all 3 scales

Figure 1. Seven-face and five-face study scales presented to subjects aged 5 years and older. Top to bottom: TASTY Scale, Chen Scale,³⁴ Ellis Scale³⁷ (Chen and Ellis scales reproduced with permission).

and asked which they preferred and why in the form of an open-ended question. All verbal communication as laid out by the script was simple and tailored for the youngest children in our study with the expectation that if a child of 3 years can understand the instructions so too can older children and their parents.

Statistical Analysis. A sample size of 30 participants in each pediatric age group was selected in accordance with the recommended 1:10 item to response ratio for each scale.³⁹ To enable comparison across all age groups, response data were transformed onto the same 7-point scale such that the anchoring faces were represented as 0 and 6, and the central face was represented by 3. Descriptive statistics were used to examine key survey data. Discriminant validity was determined by examining taste scores against parental assignment, using Spearman correlation. The Spearman correlation coefficient and the 95% confidence limit surrounding deviations in mean adjusted score were used to evaluate equivalence between scales. Associations between demographic data and preferences were examined by using the relevant parametric or non-parametric tests. Subjects unable to evaluate all 3 scales were excluded

from the data analysis. Responses to the open-ended question about scale preference were independently categorized by 2 researchers and reduced into major themes agreed upon by the authors. Data were analyzed in SPSS version 24 (IBM Analytics, Armonk, NY) and the a priori level of statistical significance for all tests was set at $\alpha = 0.05$.

Results

In total, 119 individuals responded to the MTurks survey. This strategy permitted us to gather opinions from a diverse audience at a lower cost and in a fraction of the time required for traditional focus groups. Approximately two-thirds (65.6%) indicated that the initial draft of the scale conveyed the concept very or fairly well. The remainder of respondents rated the scale somewhat effective (21%), slightly effective (5.9%), or not at all effective (7.6%). A representative sample of comments driving the modification of the scale that was ultimately used in this study include the following: “the middle three images are very similar, making it hard to identify which is the better option,” “remove

Table 1. Demographic Data

Population, Age, yr	Sample Size	Sex, Male:Female
All children	90	38:52
3	13	6:7
4	17	11:6
5	11	2:9
6	5	4:1
7	8	3:5
8	6	2:4
9	9	4:5
10	9	1:8
11	7	2:5
12	5	3:2

the numbering, it makes it appear like a time lapse or progression in a story,” “show a different object being tasted,” “make face #7 look a little less like the guy is high, and more like he enjoys the taste, more lip smacking,” and “change the color of the character.”

In total, 96 parent-child dyads were prospectively enrolled and 90 completed the study. Six participant pairs were excluded from the analysis because they were unable to complete the survey (e.g., they were called in from the waiting room prior to completion). Mean child age was 6.7 ± 2.9 years (median 6 years; range, 3–12 years; Table 1). Children were reasonably well balanced with respect to sex (58% female) though parents were largely represented by women (86%).

Across the entire cohort, and by age, all 3 scales performed comparably (Table 2). In the 3- and 4-year age groups, following normalization, values tended to be higher indicating a preference for faces showing more favorable tastes. When responses were evaluated against perceived parental assignments, there were no significant differences in the performance of the scales ($p > 0.05$, Figure 2). However, concordance between parental assignment and child ranking dropped markedly below the age of 5 years, irrespective of scale, suggesting reduced reliability in children 3 and 4 years of age. We did identify lower overall concordance be-

tween male parents and their children when compared with female parents (4%–40% lower depending on age and scale) though we were underpowered to determine the significance of this observation. We also observed a slight imbalance in randomization; however, sequence effects did not influence our findings.

Both parents and children preferred the TASTY scale over the 2 preexisting scales that were evaluated (Table 3). Factors contributing to their decisions about scale preferences are provided in Table 4. Collectively, children and their parents preferred scales that they perceived to convey a broader range of expressions and those that they found graphically more interesting. There was, however, a smaller group of participants that preferred images that were not too detailed. The Chen³⁴ scale found favor in selected participants who likened the images to emojis. Importantly, the incorporation of food/beverage in the TASTY scale resonated with several parents and children as did the incorporation of a body.

Discussion

In this study we evaluated a newly created faces scale (TASTY) designed specifically for the assessment of pediatric taste preferences. The results show that the instrument when administered as a 3-, 5-, or 7- point scale was equivalent to 2 commonly used faces scales that have also been applied for the assessment of taste in children. A high degree of correlation was found between the 3 instruments especially in children 5 years of age and older ($r > 0.9$, $p < 0.01$). Similarly, all 3 scales performed in an identical fashion when comparing parental perceptions of food preferences and pediatric responses. When compared with proposed requirements for interchangeability between scales (i.e., $r > 0.7$),^{40,41} our data suggest that there exists comparable validity between the 3 faces scales tested.

Importantly, all 3 of the faces scales that were examined appear less reliable in children under the age of 5 years where we observed limited concordance between parent and child. Whether the use of abbreviated scales (i.e., 3 faces for the 3-year-olds, 5 faces for the 4-year-olds) influenced this finding is unclear. However, reduced reliability in children under the age

Table 2. Comparison of Taste Scales in Different Age Groups

Population (Scales)	TASTY vs. Chen ³⁴		TASTY vs. Ellis ³⁷		Chen ³⁴ vs. Ellis ³⁷	
	Mean Difference (95% CI)	p value	Mean Difference (95% CI)	p value	Mean Difference (95% CI)	p value
All children	0.12 (−0.24, 0.48)	0.73 [†]	0.07 (−0.31, 0.45)	0.70 [†]	−0.05 (−0.38, 0.29)	0.77 [†]
5–12 yr (5 or 7 faces)	−0.07 (−0.24, 0.11)	0.93 [†]	−0.07 (−0.27, 0.13)	0.92 [†]	0.00 (−0.18, 0.17)	0.94 [†]
4 yr only (5 faces)	0.38 (−0.18, 0.94)	0.41 [†]	0.03 (−0.56, 0.62)	0.35 [*]	−0.35 (−0.84, 0.13)	0.56 [*]
3 yr only (3 faces)	0.62 (0.03, 1.20)	0.34 [*]	0.77 (0.17, 1.37)	0.29	0.15 (−0.43, 0.74)	0.39 [*]

* Scales significantly correlated at $p < 0.05$.

† Scales significantly correlated at $p < 0.01$.

Figure 2. Concordance between parental assignment and child ranking, based on child's age group.

of 5 years is consistent with reports on the use of similar pediatric scales.^{42,43} Though many studies have used self-report faces scales down to age 3 years, there is a lack of consensus regarding the number of increments that should be offered and the age where one can reliably and validly use self-report scales.^{22,28,44–47} Studies citing the successful use of pediatric self-report scales down to the age of 3 years often restrict participation to children who are first able to successfully perform a screening task or are given extra training on the scale, thus overestimating comprehension with these instruments in this age group.^{20,23,36,45,48} The simple differentiation of more, less, and the same can be comprehended by children as young as 2 to 3 years, whereas more advanced cognitive skills such as classification, seriation, matching, and estimation develop around age 3 to 4 years.²² Preschool years are also a period of rapid cognitive growth in the skills that underlie related vocabulary, recognition of symbols, and recognition of facial expressions, all of which may be important determinants of whether young children can estimate subjective experiences.^{49,50}

Memory, temperament, and attention span may also play important roles in contributing to children's use of self-report scales though this too is controversial.^{34,51} One study suggested that a child's age in months is the only significant predictor of children's self-report pain scale error scores, while another found that cognitive ability, as measured by estimated intelligence quotient combined with age is the best predictor of successful scale use.^{52,53} Our experience indicates that performance is highly child specific. Only 1 of thirteen

3-year-olds gave the anticipated answers for nearly all (8 of 9) anticipated selections and another could place the pleasant and unpleasant foods correctly on the scale but was indiscriminate when rating bland foods. Similarly, 1 of the seventeen 4-year olds in this study matched parental perceptions on all foods and another on all the pleasant and unpleasant foods. Though children under the age of 5 years could potentially improve with practice, we are in agreement with others that self-report faces scales should be used with caution in younger age groups.^{40,42,44,54}

We created the TASTY scale, in part, to dissociate perceptions of taste with emotion as is the norm for existing faces scales.^{12,32} We were also looking to create a scale that we perceived to be more child friendly. To that end, we were successful. Both children and parents favored the TASTY scale above the other scales that were evaluated. An unexpected finding was the preference, in some participants, for alternative scales that was driven by their similarity to emojis. This observation argues that the development of tools for patient reporting should be socially and culturally relevant for the population of interest at the time they are being

Table 3. Scale Preferences

Scale Name	Preferred by Children, %	Preferred by Parents, %
TASTY	48	66
Chen ³⁴	37	32
Ellis ³⁷	15	1

Table 4. Reasons Provided for Scale Preferences

Theme	Children Responses, n*	Parent Responses, n*
More descriptive/broader range of expressions	27	15
Graphically more interesting	18	33
Not too detailed	6	13
Easier to understand	4	13
Incorporates food/beverage	4	10
Recognizable/akin to emojis	2	4
Incorporates a body	2	2
More age appropriate	0	4

* Several participants provided more than 1 response.

applied. If the drug development and regulatory communities are interested in pediatric engagement, the community at large may need to revisit and, as necessary, update scales that are decades old. Our summary of the rationale driving participant preferences may offer a starting point for factors that should be taken into account when considering the development, or modification, of such tools.

Although the TASTY scale was developed for pediatric self-report during palatability testing, the current study was designed to associate food preferences by recall. This limits our ability to draw any conclusions about the utility and performance of the scale beyond the fact that TASTY displays comparable validity to existing faces scales. Subsequent studies conducted in the context of administered oral medicines or foods will be required to conclusively attest to the value of this scale. Another limitation is that this study was conducted with English-speaking families only. There may very well be cultural differences in the usability of, and preferences for, hedonic taste scales that we did not identify. Of note, we systematically evaluate all of the illustrations we develop for use in our research program with a crowdsourcing platform that solicits international respondents, so we do have some sense of how the TASTY faces were received in other countries.⁵⁵ Nevertheless, future prospective studies evaluating this scale should include non-English-language speaking populations. Finally, test-retest reliability remains to be established. Collaborations with food and beverage industry experts, as recommended by the University of Maryland's Center of Excellence in Regulatory Science and Innovation (M-CERSI) pediatric formulation workshop,¹ may facilitate the necessary validation and continual quality improvement of these and other scales.

Conclusions

Palatability plays a large role in pediatric medication compliance and risks associated with therapeutic failure. The FDA, EMA, and scientific community have

communicated the importance of evaluating the palatability of drugs before marketing authorization is granted, particularly for active substances with poor taste characteristics.¹⁴ Standardized methodology would permit comparisons of acceptability across studies and compounds, improving decision-making by developers, regulators, clinicians, and parents.⁵⁶ This study provides the first indication that our hedonic faces scale developed specifically for taste assessment is equally valid and more frequently preferred than comparable faces scales that were originally designed for other purposes.

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Ethical Approval and Informed Consent The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national guidelines on human experimentation and has been approved by the appropriate committees at Children's Mercy Hospital. All patients and/or parents/caregiver(s) provided written informed consent and/or assent (as applicable) at enrollment.

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