Development of an International Odor Identification Test for Children: The Universal Sniff Test

Valentin A. Schriever, MD[1,2], Eduardo Agosin, PhD[3], Aytug Altundag, MD[4], Hadas Avni, MD[5], Helene Cao Van, MD[6], Carlos Cornejo, PhD[7], Gonzalo de los Santos, MD[8], Gad Fishman, MD[9], Claudio Fragola, MD[8], Marco Guarneros, PhD[10], Neelima Gupta, MD[11], Robyn Hudson, PhD[10], Reda Kamel, MD[12], Antti Knaapila, PhD[13,14], Iordanis Konstantinidis, MD[15], Basile N. Landis, MD[16], Maria Larsson, PhD[17], Johan N. Lundström, PhD[18,19], Alberto Macchi, MD[20], Franklin Mariño-Sánchez, MD[8,21], Lenka Martinec Nováková, PhD[22,23], Eri Mori, MD[24], Joaquim Mullol, MD[21], Marie Nord, MSc[17], Valentina Parma, PhD[18,25], Carl Philpott, MD[26,27], Evan J. Propst, MD[28], Ahmed Rawan, MD[12], Mari Sandell, PhD[29], Agnieszka Sorokowska, PhD[30,31], Piotr Sorokowski, PhD[30], Lisa-Marie Sparing-Paschke[1], Carolin Stetzler, MD[1], Claudia Valder[32], Jan Vodicka, MD[33], and Thomas Hummel, MD[1]

Objective To assess olfactory function in children and to create and validate an odor identification test to diagnose olfactory dysfunction in children, which we called the Universal Sniff (U-Sniff) test.

Study design This is a multicenter study involving 19 countries. The U-Sniff test was developed in 3 phases including 1760 children age 5-7 years. Phase 1: identification of potentially recognizable odors; phase 2: selection of odorants for the odor identification test; and phase 3: evaluation of the test and acquisition of normative data. Test—retest reliability was evaluated in a subgroup of children (n = 27), and the test was validated using children with congenital anosmia (n = 14).

Results Twelve odors were familiar to children and, therefore, included in the U-Sniff test. Children scored a mean ± SD of 9.88 ± 1.80 points out of 12. Normative data was obtained and reported for each country. The U-Sniff test demonstrated a high test—retest reliability ($r_{27} = 0.83$, $P < .001$) and enabled discrimination between normosmia and children with congenital anosmia with a sensitivity of 100% and specificity of 86%.

Conclusions The U-Sniff is a valid and reliable method of testing olfaction in children and can be used internationally. *(J Pediatr 2018;■■:■■-■■).*

Approximately 20% of people have a reduced sense of smell and 5% have functional anosmia.[1-3] The incidence of olfactory dysfunction is assumed to be lower in children and adolescents than in adults,[4] but reliable data to support this hypothesis are lacking. This may be due in part to difficulties performing olfactory testing in children. Anosmia in children may be congenital (among others: isolated disorder or Kallmann syndrome[5]) or acquired secondarily, such as from head trauma, adenoid hypertrophy, or cystic fibrosis.[6-9]

Many tests for evaluating olfactory function have been developed over the past few decades[10-13] because of an increasing appreciation of the importance of olfaction in everyday life. People with olfactory dysfunction experience an increased frequency of hazardous events, such as food poisoning or failure to detect smoke,[14] and have an overall decreased quality of life.[15] Olfactory function is most commonly evaluated orthonasally both clinically and for research purposes using the University of Pennsylvania Smell Identification Test (UPSIT)[11] and the Sniffin' Sticks battery—especially the odor identification subtest of the Sniffin' Sticks.[10] In addition to orthonasal olfactory assessment, measurements for retronasal olfactory testing such as using the "candy smell test" and the "taste powders" are available.[16,17] The range of stimuli for retronasal olfactory testing is limited due to simultaneous gustatory stimulation in a sweet (sorbitol) candy, and odors such as fish or cut grass cannot be used.[16] Even though the Sniffin' Sticks and the UPSIT test have been used in children as young as 5 years of age, they are suboptimal for evaluating olfaction in young children. In both odor identification tests, increases in test performance are observed from childhood through adolescence into adulthood.[18,19] However, the increment of performance is not due to actual increase in olfactory function. Children and adults perform equally well on olfactory threshold testing, but children's performance is lower than adults on odor identification tasks,[20,21] which may be attributed to "odor learning."[20,22-24]

AFC	Alternative forced choice
ICA	Isolated congenital anosmia
NIH	National Institutes of Health
ROC	Receiver operator characteristics
SCHOT	Sydney Children's Hospital Odor Identification Test
UPSIT	University of Pennsylvania Smell Identification Test
U-Sniff	Universal Sniff

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Odorants used in identification tests might not be familiar to children. In addition, the complexity of an olfactory test is considerable. For example, odor identification tests are commonly administered using a 4-alternative forced-choice (AFC) paradigm (ie, the presented odor has to be identified with the help of 4 descriptors).[11,25] These descriptors usually are presented in writing, which may not be optimal for children. To overcome these shortcomings, odor identification tests were developed for children.[21,26-31] However, only 2 tests have gained use, namely the Smell Wheel and the Sydney Children's Hospital Odor Identification Test (SCHOT).[27,28] The Smell Wheel has been used to evaluate olfactory function in children with a tracheostomy, and the SCHOT has been used to study children with cystic fibrosis, otitis media, renal disease, and following bone marrow transplantation.[32-36] These tests have not been used commonly likely because they were developed for children from a single country and are not translatable across cultures,[27,28] and most tests are not commercially available.

Cultural background also is of importance in odor identification. To counter this, the Cross-Cultural Smell Identification Test was developed for adults, which is based on the UPSIT.[37] Several country-specific, modified versions of the UPSIT and the Sniffin' Sticks odor identification test are used (eg, in Brazil, China, South Korea, Turkey, and Egypt).[38-42] Because of the child's development in odor learning, it is plausible that especially for children, the cultural background has substantial impact on odor identification tasks.

The aim of this multicenter study was to develop and validate an international odor identification test for children, called the Universal Sniff (U-Sniff) test, to enable the discrimination between normosmia and a reduced sense of smell with high sensitivity and specificity. We hypothesize that the study design enables the development of an odor identification test for children, can be used internationally, but that odor identification scores might differ across countries.

Methods

This study was performed in accordance with the Declaration of Helsinki on Biomedical Studies Involving Human Subjects. This study was approved by the local Ethics Committee of the Medical Faculty at the TU Dresden (EK 150042014, EK 383092015) and additionally by individual ethics committees of participating centers. Study details were explained to the children and their parents/legal guardians, and oral and/or written consent was obtained where required. In addition, children provided assent. The study was divided into 3 phases: phase 1—identification of potentially recognizable odor items; phase 2—selection of odorants for the odor identification test; and phase 3—evaluation of the test and acquisition of normative data.

Laboratories and clinics from the following countries participated: Europe: Czech Republic, Finland, Germany, Greece, Italy, Poland, Spain, Sweden, Switzerland, Turkey, and United Kingdom (only phase 3); America: Canada, Chile, Mexico, and the US. In addition Egypt (phases 2 and 3), India, Israel, and Japan contributed to this study.

Prior to phase 1, a pilot study was conducted whereby investigators from each contributing country submitted names of odor items that they believed would be well known to children in their country. A list of 42 odor items was generated. Items (n = 36) that were most common to all countries are listed in **Figure 1** (available at www.jpeds.com) and were subsequently used in phase 1.

Phase 1—Identification of Potentially Recognizable Odor Items

A total of 324 children with age ranging from 5 to 7 years from 17 countries participated. Each country interviewed 20 participants, except Finland (n = 17) and Canada (n = 7). The mean age was 5.9 ± 0.3 (SD) years. Slightly more girls (52.4%) than boys (47.6%) were included, but the difference was not statistically significant ($\chi^2_{[df = 1]} = 0.57$, $P = .45$). There was no difference in sex distribution across countries ($\chi^2_{[df = 13]} = 13.47$, $P = .41$). However, the sex of children from 3 countries (India, Israel, and Japan) was not recorded.

Photographs of each of the 36 odor items generated in the pilot phase of this study were presented to the children (**Figure 1**). For each item, a photograph representing the item was chosen. The majority of photographs were produced in the Smell and Taste Clinic in Dresden, Germany, and a few, copyright-free photographs were acquired from the internet.

Children were tested individually in a quiet room. The task was explained verbally to each child and 1 photograph at a time was shown to each child. Children were asked the following questions: Do you know what this is? (recorded as yes/no) and How does it smell? (responses written by the investigator).

Phase 2—Selection of Odorants for the Odor Identification Test

A total of 495 children aged 6 to 8 years from 18 countries were included; 30 children were tested from each country, except Egypt (n = 28), Turkey (n = 26), Finland (n = 25), US (n = 25), Greece (n = 21), and Czech Republic (n = 9). The mean age was 6.3 ± 0.5 years. There was an equal number of girls (n = 241) and boys (n = 254; $X^2_{[df = 1]} = 0.58$ $P = .45$), and there was no difference in sex distribution across countries ($\chi^2_{[df = 17]} = 14.98$, $P = .60$).

Based on results from phase 1, 17 odor items were used to create an odor identification test (**Figure 1**). Appropriate odorants were selected by a panel of experienced investigators to represent the visual items. Pen-like Sniffin' Sticks were used for odorant presentation. Pens were filled with 4 mL of each odorant and numbered 1-17. Details about the odorants are shown in **Table I** (available at www.jpeds.com). Odor identification was cued using a 4-AFC procedure. Four descriptors (1 target and 3 distractors) were used for each odor. One related and 2 unrelated items were chosen as distractors (eg, target: strawberry, distractors: flower [related], butter, cheese [unrelated] (**Figure 2**; available at www.jpeds.com). Photographs of odor items (from phase 1) with additional words were used as descriptors.

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The study was described in detail to each child and his/her parents/legal guardians. Each child was tested individually in a quiet, well-ventilated room. Odorants were presented one at a time by removing the cap from the Sniffin' Stick and holding it 2-3 cm in front of the nose for 3 seconds. Children were asked to identify the odor from the 4 given descriptors, which were shown to the children before odor presentation. If unsure, children were allowed to smell the odor again.

Phase 3—Evaluation of the Test and Acquisition of Normative Data

A total of 927 children aged 6 to 8 years from 19 countries participated. Fifty children were tested in each country, except United Kingdom (n = 41) and Canada (n = 36). The mean (SD) age was 6.9 ± 0.8 years. There was a significant difference in age across countries ($F_{[df = 18]} = 24.22$, $P < .001$). There was no significant difference in sex distribution (girls, n = 467, 51.7%; boys, n = 436, 48.3%; $X^2_{(df = 1)} = 1.06$, $P = .30$) or sex distribution across countries ($\chi^2_{[df = 18]} = 14.2$, $P = .71$). The sex of 24 children was not provided.

The newly created 12-item odor identification test, the U-Sniff test, was used based on results of phase 2 (**Figure 1**). As before, Sniffin' Sticks were presented in a 4-AFC procedure. To increase contrast between descriptors[43] based on the results from phase 2, the following descriptors were changed; a related distractor was changed to a nonrelated distractor: target: apple (orange changed to biscuit); target: onion (chocolate changed to strawberry and fish changed to banana); target: orange (lemon changed to flower); target: peach (strawberry changed to coffee) (**Table II**).

The task was explained to each participant and his/her parents/legal guardians. The U-Sniff test was administered in a similar manner as in phase 2. The sum of correct answers was computed as the odor identification score.

Test—Retest Reliability

A group of 27 children in Germany (17 girls, 10 boys; mean [SD] age 6.8 ± 0.7 years) was tested twice using the same testing procedure in 2 separate sessions. The minimum interval between sessions was 2 days.

Table II. Four alternative descriptors given to identify an odor are shown for each target odor (target written in bold)

Sniffin' Stick	Descriptor 1	Descriptor 2	Descriptor 3	Descriptor 4
1	**Apple**	Biscuit	Tomato	Cheese
2	Lemon	**Banana**	Fish	Flower
3	Cut grass	Flower	Strawberry	**Butter**
4	Peach	Biscuit	**Coffee**	Cut grass
5	Coffee	Banana	Biscuit	**Cut grass**
6	Strawberry	Honey	Coffee	**Fish**
7	Lemon	Banana	**Flower**	Orange
8	**Lemon**	Onion	Apple	Peach
9	Strawberry	Coffee	Banana	**Onion**
10	Banana	Honey	**Orange**	Flower
11	Coffee	**Peach**	Cut grass	Butter
12	**Strawberry**	Cheese	Flower	Butter

Test Validation in Olfactory Disorders

Fourteen children (8 girls, 6 boys, mean [SD] age 14.2 ± 3.1 years, range 6-17 years) with isolated congenital anosmia (ICA) from Germany were included for test validation. These children were previously tested in our Smell and Taste Clinic using the original Sniffin' Sticks test[18] (olfactory threshold, odor discrimination, and odor identification) and were diagnosed as having ICA. Children living in Dresden (n = 3) were retested using the new U-Sniff test in our Smell and Taste Clinic, and the test was mailed to children not living in Dresden (n = 11) with detailed instructions to be administered by their parents.

Statistical Analyses

Analyses were performed using IBM SPSS v 23.0 (SPSS Inc, Chicago, Illinois) with significance set at $P < .05$. Nonparametric tests were used to analyze data from phase1 because of the nature of the underlying data. An ANOVA with country, odor, and sex was performed. Bonferroni-corrected post-hoc tests were used for multiple pairwise comparisons. χ^2 tests were used to evaluate the sex distribution of the populations. The test was designed as a clinical screening test, meaning it had to distinguish between normal olfactory function and olfactory dysfunction. Therefore, the 10th percentile was used as a cut-off based on existing tests.[11,44] Receiver operator characteristic curve (ROC) was used in conjunction with the Youden index (Y = sensitivity+specificity-1)[45] to define the highest sensitivity and specificity of the new U-Sniff test. In addition, Pearson correlation was used to analyze test—retest reliability.

Results

Phase 1

All children were able to perform the task. To select the most highly recognizable odor items, items were ranked according to the children's answers for each country separately. The most highly recognizable odor item for children from a specific country was assigned a ranking score of 36, the second a ranking score of 35, and so forth to the least recognizable odor item which was assigned a ranking score of 1. Averaging the ranking scores of all 17 countries, "chocolate" was identified as the most recognizable odor and "rubber" as the least known to children (**Table III**; available at www.jpeds.com). The top 20 most recognizable odor items were selected for further analysis. From most to least recognizable, these items were: chocolate, apple, strawberry, banana, flower, biscuit, orange, lemon, milk, honey, coffee, fish, cola, tomato, onion, cheese, cigarette, butter, cut grass, and peach. Because we were unable to create suitable odorants for milk, cola, and cigarette, they were excluded from the study. There was a significant difference in ranking between the 17 selected odor items ($F_{[df = 16]} = 6.70$, $P < .001$). Although ranking of single odor items varied greatly between countries, there was no significant difference when average odor item rankings were compared ($F_{[df = 16]} = 0.70$, $P = .79$). A detailed description of the ranking analysis are shown in **Table III**. These 17 odors were used for phase 2 as seen in **Figure 1**.

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Phase 2

All children understood the task and were able to complete testing. No children were excluded from the study. The mean (SD) percentage of correct odor identification across all 17 odors was 73.4% ± 14.9%. There was a significant difference between countries on mean odor identification ($\chi^2_{[df = 17]} = 125.1$, $P < .001$) and across odors ($\chi^2_{[df = 16]} = 673.4$, $P < .001$). **Figure 3** displays the mean identification (and 95% CI) score for each odor. Lemon was most commonly identified correctly across countries, and honey was least commonly identified across countries.

For phase 3 odor selection, we selected only those odors that were identified >66% of the time in phase 2. The following odors were selected: lemon, banana, coffee, flower, strawberry, fish, cut grass, orange, onion, apple, and peach. Although there was a significant difference in correct identification of single odors between countries (except for lemon and flower) the mean correct identification of the selected 12 odors was >66% in all countries (mean 79.3% ± 6.6% range: 67.5%-92.2%).

Phase 3

All 927 children who participated in phase 3 were able to complete the task. No children were excluded from the study. The mean (SD) odor identification score across all children was 9.88 ± 1.80 points (range 2-12 points). The range of mean scores across countries varied from 8.2 to 11.2 points with a main effect of country ($F_{[df = 18]} = 4.94$, $P < .001$), meaning that odor identification scores differed significantly across countries. In addition, a main effect of sex was observed with girls (mean 10.1 ± 1.6 points) scoring higher on the U-Sniff test than boys (9.7 ± 1.9 points) ($F_{[df = 1]} = 7.85$, $P = .005$), but no main effect of age was found ($F_{[df = 2]} = 0.66$, $P = .52$). Further analysis showed no interaction between country and sex, country and age, or age and sex on the odor identification score (all $P > .1$). χ^2 analysis for single odors revealed a significant difference in correct odor identification of single odors between countries (all $P < .001$). In accordance with the results from phase 2, all odors except for butter (64%) were identified on average >66% of the time (range 64.0%-90.8%).

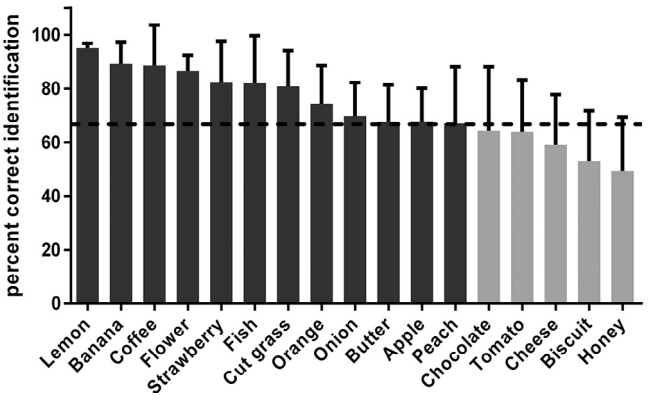

Figure 3. Odor identification phase 2, percent correct identification of odors used in phase 2 (mean + 95% CI). Twelve odors (*dark gray*) were identified correctly in 66% of cases and were selected for the U-Sniff test for children. The dashed line indicates the 66% odor identification.

Table IV. Normative data of the U-Sniff test for children by country

Regions	Identification score	Range	10th
All	9.86 ± 1.87	2-12	8
Europe	10.15 ± 1.65	2-12	8
Czech Republic	9.26 ± 1.55	6-12	7
Finland	9.82 ± 1.85	3-12	8
Germany	10.44 ± 1.62	6-12	9
Greece	10.32 ± 1.11	8-12	9
Italy	11.18 ± 0.75	9-12	10
Poland	9.64 ± 2.35	2-12	6
Spain	10.06 ± 1.52	5-12	8
Sweden	10.10 ± 1.99	2-12	7.1
Switzerland	10.68 ± 1.13	8-12	9
Turkey	9.84 ± 1.02	8-12	9
United Kingdom	10.34 ± 1.84	5-12	8
America	9.82 ± 1.78	3-12	7
Canada	9.50 ± 1.86	3-12	7
Chile	10.0 ± 1.65	5-12	8
Mexico	9.40 ± 1.65	5-12	7
US	10.30 ± 1.87	4-12	8
Egypt	9.02 ± 1.67	4-12	8
Israel	8.70 ± 2.29	3-12	6
India	8.24 ± 1.86	4-11	5.1
Japan	10.76 ± 1.04	9-12	9

Mean ± SD odor identification score, range, and cut-off to distinguish between normosmia and a reduced sense of smell by using the 10th percentile are shown.

Countries were grouped into continents to obtain normative data. On average, higher odor identification scores were reached in European compared with American countries ($t_{[df = 725]} = 2.21$, $P = .028$).

Europe

The mean (SD) odor identification score of European countries was 10.2 ± 1.7 points (range 9.3-11.2 points). A significant difference of odor identification scores across European countries was observed ($F_{[df = 10]} = 5.50$, $P < .001$); however, Bonferroni adjusted post hoc-tests revealed that only Italy (higher scores) and the Czech Republic (lower scores) were significantly different from each other. No other comparisons of odor identification scores between European countries reached significance. To define the cut-off between normal olfactory function and a reduced sense of smell, the 10th percentile of data distribution was used as a criterion. Across European countries, the 10th percentile on odor identification score was 8 points (**Table IV**). When analyzing the 10th percentile cut-off for each country individually, only cut-offs for the Czech Republic (7 points) and Poland (6 points) were lower (**Table IV**).

America

The mean odor identification score of the American countries was 9.8 ± 1.8 points (range: 9.4-10.0 points). A main effect of country on the odor identification test was found ($F_{[df = 3]} = 2.78$, $P = .042$), but Bonferroni adjusted post hoc tests

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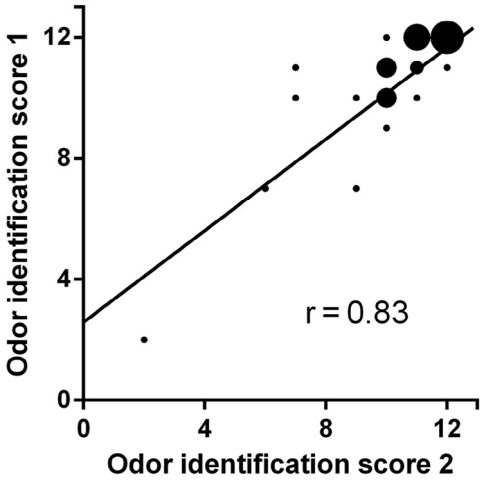

Figure 4. Reliability of the U-Sniff test, test—retest reliability (r = 0.83) of the U-Sniff test is shown. The size of dots represents the number of participants.

showed no significant difference for odor identification scores across the 4 American countries. When the 10th percentile criterion was applied, a score below 7 points on the U-Sniff test would indicate a reduced sense of smell (**Table IV**).

Other Countries

Children in Egypt scored a mean (SD) 9.0 ± 1.7 points on the U-Sniff test. The cut-off between normal olfactory function and a reduced sense of smell would be 8 points. Children in India scored a mean (SD) 8.2 ± 1.9 points on the U-Sniff test and a score below 5 points would indicate a reduced olfactory function. In Israel, children scored on average 8.7 ± 2.3 points on the U-Sniff test. The 10th percentile cut-off would be 6 points. The average odor identification score for children from Japan was 10.8 ± 1.0 points resulting in a 10th percentile cut-off of <9 points (**Table IV**).

Test—Retest Reliability

In the subgroup of 27 German children undergoing test—retest, the mean (SD) interval between tests was 57.6 ± 68.0 days (range: 2-229 days). Scores from the first (10.15 ± 2.33 points) and second tests (10.26 ± 2.12 points) did not differ significantly ($t_{[df = 26]} = 0.44$, $P = .66$). A strong positive correlation between odor identification scores from the first and second testing was observed ($r_{27} = 0.83$, $P < .001$) (**Figure 4**).

Test Validation

A group of 14 children who were previously diagnosed in our Smell and Taste Clinic as having ICA using the standard Sniffin' Sticks test including olfactory threshold, odor discrimination, and odor identification testing, were investigated. These children with anosmia previously scored a mean (SD) of 10.80 ± 3.30 points of a possible maximum of 48 points on the standard Sniffin' Sticks test (sum of threshold, discrimination, and identification tests) and now scored a mean (SD) of 3.57 ± 1.83 points on the U-Sniff test. Odor identification sores differed significantly between patients with ICA and the German study population ($t_{[df = 62]} = 13.7$, $P < .001$) (**Figure 5**, A). In addition, only 1 patient scored 7 points, and all other children with ICA scored ≤6 points. A ROC analysis to distinguish between ICA and healthy controls by means of the U-Sniff test showed an area under the curve of 0.99 ($P < .001$) (**Figure 5**, B). By using the highest Youden index, a sensitivity of 100% and a specificity of 86% to confirm a normal sense of smell were reached when a cut-off of ≥6 points was used. When a cut-off of ≥8 points was used. the sensitivity was 92% and the specificity was 100%, respectively.

Discussion

We developed an international odor identification test for children—the U-Sniff test. Normative data were generated, and the test's validity and test—retest reliability were evaluated.

We included children aged 6-8 years in this study. Previous studies have demonstrated that the ability to identify odors

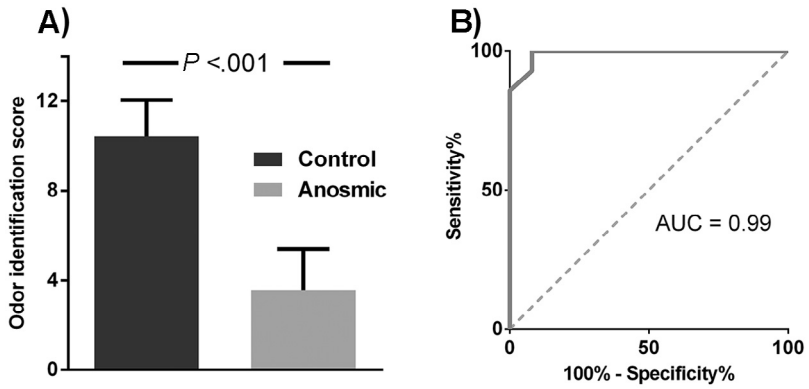

Figure 5. Comparison of areas for anosmia and control children, **A,** Mean ± SD odor identification scores for children with ICA (light gray) and controls (dark gray). Children with isolated congenital anosmia (ICA) scored significantly lower than controls (t = 13.7, $P < .001$). **B,** ROC analysis distinguishing between children with ICA and. Area under the curve was 0.99.

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increases with age in children.[26,30,46,47] This is due to an ongoing process of odor learning[20,23,24] rather than an actual increase in olfactory function.[46] Our aim during the development of the U-Sniff test for children was to only include odors that are well known and able to be correctly identified by a majority of children from different cultures around the world. To avoid the bias of age-dependent odor learning, we included young children who were old enough to understand and perform an odor identification task. Cavazzana et al reported odor identification tasks in children younger than 5 years of age to be unreliable[48] considering previous studies.[39,46] Although some studies have claimed that children as young as 3-4 years of age are able to perform an odor identification task,[28-30] results must be evaluated with caution. In the study by Dzaman et al, parents were allowed to explain the odor descriptors to the children, which may promote response bias.[29] Odors such as cinnamon and Play-Doh in the National Institutes of Health (NIH)-Toolbox were poorly identified by children with odor identification, reaching almost chance level.[30] Taken together, these studies suggest that measurements of odor identification in children younger than 5 or 6 years of age are unreliable. The upper age limit of 8 years in our study was chosen to minimize the possible influence of age on odor identification scores during the development of the U-Sniff odor identification test. Therefore, no age difference in odor identification was observed in the current study. Because we only studied this small age range, future studies should aim to test a broader age range in a more systematic manner, including both younger children and adolescents, to determine age dependent results of the U-Sniff test.

Of 927 children in phase 3, we found a difference in odor identification score between girls and boys. The literature regarding sex differences with respect to odor identification in children is contradictory. Richman et al and others found that girls outperformed boys, but Sorokowska et al and others, found no difference between girls and boys on an odor identification test. [21,26,27,29,31,47,49] Differences in these studies might result from the different age ranges of study populations as well as from use of different tests.

Odor identification scores differed significantly across countries despite the fact that all odorants were selected with data from all countries. The final odorant selection was based on average scores including all countries. Different cultural backgrounds might account for the difference in odor identification scores across countries. This is in line with previous studies in adults that have shown differences in odor identification scores across countries using the Sniffin' Sticks 16-item odor identification test.[38,50] Even though the odor identification scores differed significantly across countries in our study, children were able to perform the test in all countries and test scores of 69%-93% correct identification are comparable with previous studies in children (ie, NIH-Toolbox 72%, Dzaman et al 76%, Van Spronsen et al 62%, and SCHOT 85%-89%).[27,29,30,47]

Odor items for our U-Sniff test for children were selected in 3 phases, after piloting the possible odor items. First, familiar items were chosen by using photographs of odor items. In phase 2, the most well-known odorants were selected for an odor identification test, and only the items identified correctly in more than 66% of cases were chosen for inclusion. Previous studies used a slightly higher cut-off for including odors in an odor identification test. Hummel et al used 75% in the development of the Sniffin' Sticks odor identification test.[10] The same criterion was used by Dzaman et al in the development of a pediatric smell test.[29] We chose a lower criterion of 66% for odor identification because this test was developed internationally in a young population of children and, therefore, lower average odor identification scores are expected. The ranking of familiar odor items in phase 1 did not completely match the final odor identification scores (eg, chocolate was ranked as the most recognized odor item based on its photograph but was only the 13th most commonly identified odor in phase 2 and did not meet the criterion for inclusion in the final U-Sniff test version). A similar phenomenon was observed in children using the original Sniffin' Sticks 16-item odor identification test. In a study population of 537 children age 6-17 years, the item "apple" was only identified 34% of the time.[31] The difference between knowing the odor item and correct odor identification of the same might result from suboptimal odorant selection or poor- fitting picture-odor concept.[43] This is speculative, however, because no congruency rating of the odor—picture combination was measured in this study.

Test—retest reliability of the U-Sniff test was evaluated in a subgroup of 27 German children and found to be highly reliable ($r = 0.83$). This was more highly reliable than the majority of other pediatric smell tests (Sniffin' Kids [$r = 0.44$], NIH-Toolbox [$r = 0.45$], Smell Wheel [$r = 0.70$], and SCHOT" [$r = 0.98$]).[27,28,30,31] Its reliability is in the same range of the standard odor identification test in adults such as the UPSIT ($r = 0.92$) or the Sniffin' Sticks odor identification test ($r = 0.88$).[11,51]

Several odor identification tests have been developed for children to distinguish between normosmia and olfactory dysfunction. Only 2 tests, the Sniffin' kids odor identification test and the test developed by Richman et al, have been validated by including children with anosmia during test development.[26,31] The U-Sniff test was validated by including 14 children with diagnosed ICA into the study. Children with ICA scored significantly lower on the U-Sniff test than the control group. In addition, it was possible to distinguish between normal sense of smell and anosmia with high sensitivity and specificity. The test validation does not allow a separation between anosmia and hyposmia. To increase the number of children with anosmia in our test validation, the age range of this population was 6-17 years of age. Previous studies have reported an increase in odor identification score with age.[27,28,39,52] Such an increase is not expected in children with ICA. In fact, no correlation between age and odor identification score was observed in children with ICA in the current study ($\rho = -0.37$, $P = .194$). Therefore, the difference in age range between the study populations should not affect the study outcome.

By including a large study population of 927 children in phase 3, we are able to present normative data for children aged 6-8 years. We chose the 10th percentile as a cut-off, as the 10th

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percentile is commonly used to separate normosmia from a reduced sense of smell in olfactory testing.[11,18,26,31] Although, the 10th percentile value varied across 19 countries studied, country-specific values distinguished between normosmia and anosmia with high sensitivity and specificity. ROC analysis also was conducted. By using the highest Youden index, a cut-off of 6 points led to the highest sensitivity and specificity to distinguish between normosmia and a reduced sense of smell. Comparing the two cut-off criteria, the 10th percentile (≥8 points) lead to a higher specificity but slightly lower sensitivity than the ROC analysis (≥6 points) to confirm normosmia. Because of the lower frequency of olfactory dysfunction in children[4] this cut-off should be used as an orientation rather than a fixed value. Scores must be considered in regard to the whole clinical appearance of the patient (eg, medical history, including subjective reporting of the sense of smell, and other relevant investigations).

Limitations of this study are that most of the 19 countries included are from Europe and America, and, therefore, it is necessary to study the generalizability of this test to the rest of the world. In addition, odor identification has been shown to be associated with verbal fluency of children,[21] and the current study did not investigate verbal fluency of participants. Compared with the UPSIT and the Sniffin' Sticks extended odor identification test with 40 and 16 odor items, respectively, the final version of the U-Sniff test with only 12 items seems rather short.[10,11] However, previously it has been proven that 12 items are sufficient for an odor identification test (eg, the Cross-Cultural Smell Identification Test, Sniffin' Sticks 12-item odor identification test).[37,53] Considering the close range of odor identification scores across countries, the reliability of the U-Sniff test was only tested within the German subpopulation. Future studies should investigate the reliability of the U-Sniff test in additional countries. Odor items were suggested based on the experience of participating researchers and therefore, it might be possible that other odor items also would have been suitable for inclusion. The majority of children with ICA were tested at home with the test being administered by their parents. Although this method was not validated in the current study, previous research has demonstrated no difference in regard to odor identification scores between self-administered and examiner conducted tests using the Sniffin' Sticks in adults[54] and the Smell Wheel in children.[28]

The 12-item U-Sniff international odor identification test for children demonstrates a high test—retest reliability and was validated by including children with ICA. This test offers an efficient method of distinguishing with high sensitivity and specificity children with normosmia from those with a reduced sense of smell. ■

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Reprint requests: Valentin A. Schriever, MD, Abteilung Neuropädiatrie, Medizinische Fakultät Carl Gustav Carus, Technische Universität Dresden, Fetscherstrasse 74, Dresden 01307, Germany. E-mail: valentin.schriever@uniklinikum-dresden.de

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From the [1]Smell and Taste Clinic, Department of Otorhinolaryngology;

[2]Abteilung Neuropädiatrie, Medizinische Fakultät Carl Gustav Carus, Technische Universität, Dresden, Germany;

[3]Escuela de Ingeniería, Pontificia Universidad Católica de Chile, Santiago, Chile;

[4]Istanbul Smell and Taste Center, Istanbul, Turkey;

[5]Pediatric Feeding Disorders clinic, Dana Children's Hospital, Tel Aviv Medical Center, Tel Aviv, Israel;

[6]Pediatric Otolaryngology Unit, Department of Otorhinolaryngology, Head and Neck Surgery, University Hospitals of Geneva, Geneva, Switzerland;

[7]Escuela de Psicología, Pontificia Universidad Católica de Chile, Santiago, Chile;

[8]Unidad de Rinología y Cirugía de Base de Cráneo. Servicio de Otorrinolaringología. Hospital Universitario Ramón y Cajal. Madrid, Spain;

[9]Pediatric Otolaryngology, Dana Children's Hospital, Tel-Aviv Medical Center, Sackler School of Medicine, Tel-Aviv, Israel;

[10]Departamento de Biología Celular y Fisiología, Instituto de Investigaciones Biomédicas, Universidad Nacional Autónoma de México, Mexico;

[11]Department of Otorhinolaryngology, University College of Medical Sciences and GTB Hospital, Delhi, India;

[12]Department of Otorhinolaryngology, Head and Neck Surgery, Cairo University, Cairo, Egypt;

[13]Food Chemistry and Food Development, Department of Biochemistry, University of Turku, Turku;

[14]Department of Food and Environmental Sciences, University of Helsinki, Helsinki, Finland;

[15]Otorhinolaryngology Department, Aristotle University, Thessaloniki, Greece;

[16]Rhinology-Olfactology Unit, Department of Otorhinolaryngology Head and Neck Surgery, University Hospital of Geneva, Switzerland;

[17]Gösta Ekman Laboratory, Department of Psychology, Stockholm University, Stockholm, Sweden;

[18]Monell Chemical Senses Center, Philadelphia, PA;

[19]Department of Clinical Neuroscience, Karolinska Institutet, Stockholm, Sweden;

[20]ORL Clinica, Università of Insubriae Varese, ASST Settelaghi, Varese, Italy;

[21]INGENIO, Immunoal.lèrgia Respiratòria Clínica i Experimental (IRCE), Institut d'Investigacions Biomèdiques August Pi i Sunyer (IDIBAPS), Hospital Clínic, CIBERES, Barcelona, Catalonia, Spain;

[22]Department of Anthropology, Faculty of Humanities, Charles University;

[23]National Institute of Mental Health, Klecany, Czech Republic;

[24]Department of Otorhinolaryngology, The Jikei University School of Medicine, Tokyo, Japan;

[25]International School for Advanced Studies (SISSA), Neuroscience Area, Trieste, Italy;

[26]Smell and Taste Clinic, James Paget University Hospital, Gorleston;

[27]Norwich Medical School, University of East Anglia, Norwich, United Kingdom;

[28]Department of Otolaryngology—Head & Neck Surgery, Hospital for Sick Children, University of Toronto, Canada;

[29]Functional Foods Forum, University of Turku, Turku, Finland;

[30]Smell and Taste Research Lab, Institute of Psychology, University of Wroclaw, Poland;

[31]Department of Psychotherapy and Psychosomatic Medicine, TU Dresden, Dresden;

[32]Frey and Lau, Henstedt-Ulzburg, Germany; and

[33]Department of Otorhinolaryngology and Head and Neck Surgery, Pardubice Hospital, Faculty of Health Studies, University of Pardubice, Czech Republic

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Figure 1. Phases of odor item selection, the odor items and odors used in phase 1 (36 items), phase 2 (17 odors), and phase 3 (12 odors) are displayed.

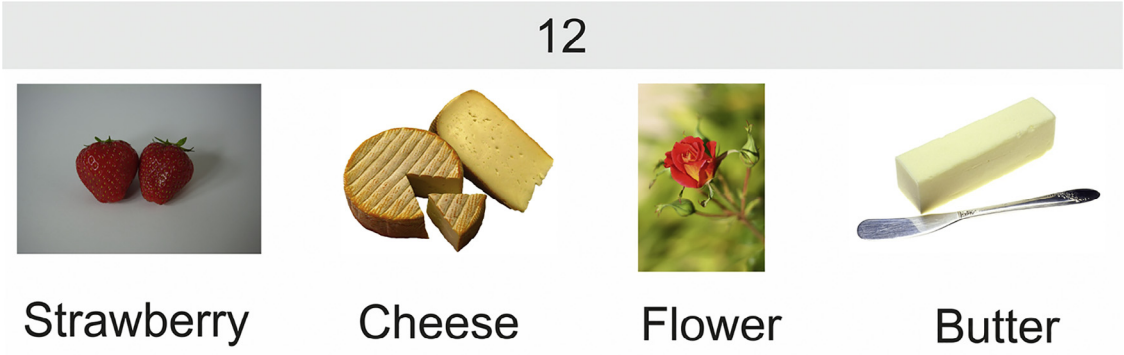

Figure 2. Descriptors for odor identification, an example for the usual descriptors for odor identification (strawberry being the target) is displayed.

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Table I. Details of the odorants used to create the U-Sniff odor identification test

Numbers	Odorant	Product number	Company	Dilution
1	Apple	P0602153	Frey&Lau, Henstedt-Ulzburg, Germany	Undiluted
2	Banana	P0604488	Frey&Lau, Henstedt-Ulzburg, Germany	1:10 in Propylene glycol
3	Cheese	B7906	Sigma-Aldrich Chemie Gmbh,Munich, Germany	1:10 in Propylene glycol
4	Butter	P0620830	Frey&Lau, Henstedt-Ulzburg, Germany	Undiluted
5	Chocolate	P0603444	Frey&Lau, Henstedt-Ulzburg, Germany	Undiluted
6	Biscuit	V1104	Sigma-Aldrich Chemie GmbH,Munich, Germany	3 g in 100 mL Propylene glycol
7	Coffee	P0604646	Frey&Lau, Henstedt-Ulzburg, Germany	Undiluted
8	Cut grass	H12900	Sigma-Aldrich Chemie GmbH,Munich, Germany	1:10 in propylene glycol
9	Fish	Fish sauce	Squid Brand, Bangkok, Thailand	1:10 in propylene glycol
10	Flower	1533250	Sigma-Aldrich Chemie GmbH,Munich, Germany	Undiluted
11	Honey	P0610351	Frey&Lau, Henstedt-Ulzburg, Germany	1:10 in propylene glycol
12	Lemon	P0119551	Frey&Lau, Henstedt-Ulzburg, Germany	Undiluted
13	Onion	Onion sauce	Knorr, Unilever GmbH, Hamburg, Germany	1:10 in propylene glycol
14	Orange	S0100099	Frey&Lau, Henstedt-Ulzburg, Germany	Undiluted
15	Peach	P0606040	Frey&Lau, Henstedt-Ulzburg, Germany	Undiluted
16	Strawberry	P0603875	Frey&Lau, Henstedt-Ulzburg, Germany	Undiluted
17	Tomato	P0631371	Frey&Lau, Henstedt-Ulzburg, Germany	1:10 in propylene glycol

Table III. Mean ± SD odor item ranking and range determined from phase 1 of study

Odor items	Mean ± SD	Range	Odor items	Mean ± SD	Range
Chocolate	34.06 ± 3.90	23-36	Cut Grass	20.00 ± 8.50	7-36
Apple	33.00 ± 4.65	24-36	Peach	19.24 ± 9.92	5-36
Strawberry	31.77 ± 7.36	9-36	Smoke	18.47 ± 7.62	7-36
Banana	30.82 ± 6.94	10-36	Glue	18.12 ± 7.34	7-36
Flower	29.53 ± 7.26	14-36	Bubble gum	18.00 ± 10.36	2-36
Biscuit	28.94 ± 8.07	11-36	Cherry	17.77 ± 9.74	3-36
Orange	28.65 ± 6.56	13-36	Peppermint	16.12 ± 9.73	3-36
Lemon	28.41 ± 8.97	4-36	Caramel	15.77 ± 7.04	3-36
Milk	27.82 ± 9.26	8-36	Peanut	15.06 ± 8.57	3-36
Honey	25.35 ± 9.33	7-36	Gasoline	14.53 ± 8.92	1-27
Coffee	23.35 ± 5.88	11-32	Manure	12.82 ± 13.15	1-36
Fish	23.00 ± 9.31	5-36	Vanilla	12.65 ± 7.98	5-36
Cola	22.88 ± 10.61	4-36	Mushroom	12.00 ± 8.28	3-36
Tomato	22.41 ± 10.30	7-36	Garlic	11.65 ± 7.15	3-26
Onion	20.77 ± 7.22	9-36	Coconut	9.59 ± 8.36	1-28
Cheese	20.71 ± 10.96	1-36	Cinnamon	7.53 ± 6.82	1-27
Cigarette	20.59 ± 8.72	8-36	Black Pepper	7.18 ± 6.57	1-28
Butter	20.18 ± 7.25	7-30	Rubber	6.12 ± 6.10	1-20

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