1061

Evaluation of Measures for the Assessment of COVID-19 Signs and Symptoms in Children and Adolescents

Carla Romano,[1,*] Margaret Mayorga,[1] Javier Ruiz-Guiñazú,[2] Géralyn C. Trudel,[3,†] Sheri Fehnel,[1] Kelly McQuarrie,[4,†] Eric K.H. Chan,[3] Eva G. Katz[3]

[1]RTI Health Solutions, Research Triangle Park, NC, USA; [2]Janssen Research & Development, Beerse, Belgium; [3]Janssen Global Services, LLC, Raritan, NJ, USA; [4]Janssen Global Services, LLC, Horsham, PA, USA.

*Presenting author.

†Affiliation at the time of the study.

Introduction/Background

- Since the emergence of SARS-CoV-2 in the United States, >1,000 COVID-19–related deaths have been reported in children and adolescents aged 0 to 17 years[1]
- With the recent eligibility of children and adolescents to receive COVID-19 vaccinations in the United States,[2,3] it is important to capture detailed data regarding their experience of COVID-19 and potential responses to vaccines
- PRO measures can be used to monitor initial infection, disease progression, and treatment response[4,5]
- The SIC is a PRO measure used to assess the presence and severity of COVID-19 signs/symptoms in adults[6]
- At the time of this study, no disease-specific PRO measures were available for self-completion by adolescents or caregivers of young children to evaluate patients' symptomatic experience of COVID-19

Objectives

- To evaluate a version of the SIC for adolescents aged 12 to 17 years based on the adult SIC, with reference materials to facilitate self-completion
- To develop a pediatric adaptation of the SIC (PedSIC) for caregiver assessment of children aged <12 years

Methods

Measures

- The SIC includes 30 items marked as present or absent, 25 of which are followed by an 11-point numerical rating scale to capture severity within the past 24 hours
  - The SIC is written at a sixth-grade reading level
  - A reference card, providing definitions of symptoms addressed in SIC items, was developed to further facilitate self-completion by adolescents
- The PedSIC is an observer-report measure adapted from the SIC for the pediatric population aged newborn to <12 years and includes 2 sections
  - The first section is completed by caregivers based on observations alone, including 15 signs of COVID-19 marked as present or absent and assessed using a 5-point verbal rating scale (none, mild, moderate, severe, or very severe)
  - The second section, which includes 11 items assessed as present, absent, or not able to report, is completed by caregivers with input from children aged 3 to 11 years, later updated to 5 to 11 years

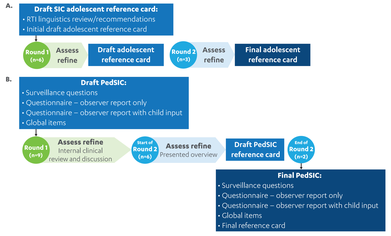
Cognitive Debriefing Interviews

- Two iterative rounds of cognitive debriefing interviews were conducted from November 2020 through January 2021 to test and refine the adolescent version of the SIC, as well as the PedSIC
- Study participants included healthy adolescents aged 12 to 17 years (**Figure 1A**) and caregivers of healthy children aged <12 years located in the United States (**Figure 1B**)
  - A reference card to aid caregivers in collecting child input for the PedSIC was developed and tested in Round 2 interviews

Data Analysis

- Interview data were analyzed via standard qualitative methods using a thematic approach
- Demographic variables were reported in aggregate using descriptive statistics

Figure 1. Cognitive debriefing process for (A) adolescents and (B) caregivers. In panel B, surveillance questions refer to an item designed to monitor children for initial infection and medically emergent signs and symptoms of COVID-19.

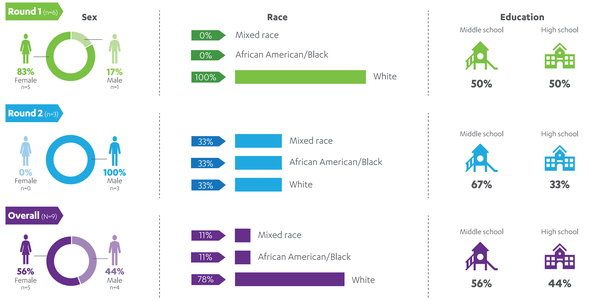


Results

Participant Demographics

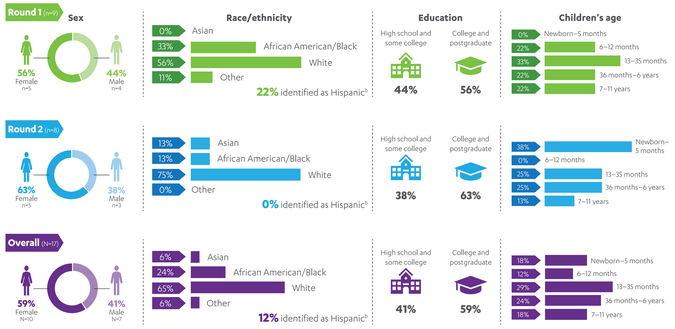
- Among participating adolescents (N=9), mean age was 14 years (SD, range: 1.76, 12–17 years), with 56% being in middle school (**Figure 2**)
- Slightly more female (5/9; 56%) than male adolescents were interviewed, with the majority being White (7/9; 78%)

Figure 2. Demographic characteristics of healthy adolescents aged 12 to 17 years reported at screening.



- Among participating caregivers (N=17), mean age was 34 years (SD, range: 6.28, 26–41; **Figure 3**)
  - 59% were female, and 36% were non-White
  - Children of participating caregivers ranged in age from newborn to 11 years
  - 29% (5/17) were caring for >1 child

Figure 3. Demographic characteristics[a] reported at screening of caregivers of children aged <12 years.

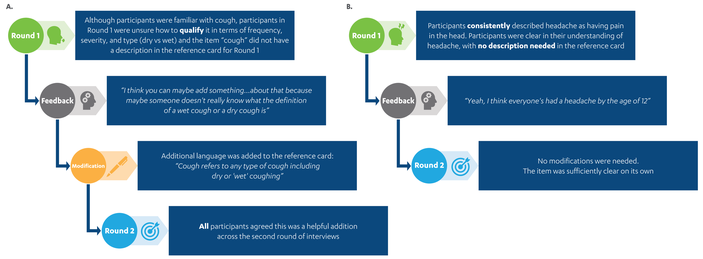


[a]Percentages may not total to 100% due to rounding.
[b]Ethnicity was captured separately from race.

Healthy Adolescents (SIC and Reference Materials)

- All adolescents understood and completed the SIC, which required no modifications
- Feedback suggested adolescents understood 22 of the 30 SIC items
  - Definitions were added to the reference card for Round 2 for cough, chest congestion, fever, red or bruised-looking feet or toes, and wheezing (wheezing was further refined in Round 2)
  - Adolescents required clarification to the reference card definitions of problems thinking clearly or brain fog, feeling faint, and skin rash
  - Two examples of the process for incorporating adolescent feedback are presented in **Figure 4**

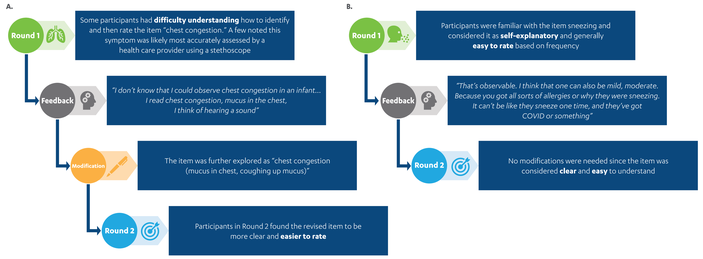
Figure 4. Incorporation of adolescent feedback to the reference card for the SIC items (A) cough and (B) headache, with representative quotations from participants.



Caregivers (PedSIC and Reference Materials)

- Caregivers reported the PedSIC instructional text, questions, and response options to be clear
- For items intended to monitor children for emergent signs/symptoms, 5 items were updated or revised, 4 items were added, and 1 item was removed after interview Round 1 (eg, increased work of breathing was simplified to trouble breathing)
- After interview Round 2, 2 items were further revised based on caregiver feedback
- For observer-reported items, 7 were modified following feedback received during both rounds of interviews
- After completion of 9 interviews, a reference card with standardized instructions was created for caregivers to read to their children aged <3 years to capture the child's symptomatic experience of COVID-19
  - Based on caregiver feedback, caregivers would report observations but would consider child input for older children (aged <5 years) when recording symptom-specific responses to the PedSIC
  - Three items were clarified based on caregiver feedback: "Do you feel sick to your stomach/belly?", "Can you smell things like usual?", and "Can you taste things like usual?"
  - Following inclusion of the reference card, caregivers expressed greater confidence that younger children (aged <5 years) could accurately respond
- Two examples of the process for incorporating caregiver feedback are presented in **Figure 5**

Figure 5. Process diagram for incorporating caregiver feedback for the PedSIC items (A) chest congestion and (B) sneezing.



Limitations

- A limitation of this study included potential caregiver bias
- The study evaluated a small number of participants; however, useful feedback regarding inclusion/clarifications of SIC definitions was obtained

Conclusions

- All adolescents were able to read and respond to each SIC item without modification and found the reference card to be useful
- Caregiver interviews supported the content validity of the PedSIC
- A reference card facilitated PedSIC completion by caregivers, including the collection of input from children in their care aged ≥5 years
- The minimum age for child input was raised from 3 to 5 years based on caregiver feedback
- Expanding the use of the SIC and implementing the PedSIC will provide measures for the collection of COVID-19 signs and symptoms in adolescents and younger children for vaccine and treatment clinical trials
- Quantitative assessment demonstrating the psychometric properties of the PedSIC in children with COVID-19 is planned

Abbreviations

COVID-19, coronavirus disease 2019; PedSIC, Pediatric Symptoms of Infection with Coronavirus-19; PRO, patient-reported outcome; RTI, Research Triangle Institute; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2; SD, standard deviation; SIC, Symptoms of Infection with Coronavirus-19.

References

1. Centers for Disease Control and Prevention. Weekly updates by select demographic and geographic characteristics. https://www.cdc.gov/nchs/nvss/vsrr/covid_weekly/index.htm. Accessed June 1, 2022.
2. Centers for Disease Control and Prevention. COVID data tracker. COVID-19 vaccinations in the United States. https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-total-admin-rate-total. Accessed June 1, 2022.
3. Centers for Disease Control and Prevention. Stay up to date with your vaccines. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html. Accessed June 1, 2022.
4. Mercieca-Bebber R, et al. *Patient Relat Outcome Meas*. 2018;9:353–367.
5. Alyegbusi OL, Calvert MJ. *Lancet*. 2020;396(10250):531.
6. Romano C, et al. *J Patient Rep Outcomes*. 2022;6(1):85.

Acknowledgments

This work was supported by Janssen Vaccines & Prevention. Medical writing support was provided by Sadie Van Dyne, PhD, and Jill E. Kolesar, PhD, of Lumanity Communications Inc. and was funded by Janssen Global Services, LLC.

Disclosures

CR, MM, and SF are salaried employees of RTI Health Solutions, which received research funding from Janssen during the conduct of this study. JR-G, EKHC, and EGK are employed by Janssen Pharmaceuticals, a Johnson & Johnson company, and may be Johnson & Johnson stockholders. GCT and KM were employees of Janssen at the time of the study.

Scan the QR code
https://www.congresshub.com/IDW/IDW2022/EarlyInvestigationalProducts/Romano
The QR code is intended to provide scientific information for individual reference, and the information should not be altered or reproduced in any way.

Presented at the 11th Annual IDWeek Congress; October 19–23, 2022; Washington, DC.