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Patient-Reported Outcomes

Psychometric Evaluation of the Proxy-Reported Pediatric Quality of Life Inventory Generic Core Scales Across the Childhood Lifespan in Australian Children and Adolescents With Specified Health Conditions

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ABSTRACT

Objectives: Current generic childhood health-related quality-of-life instruments lack comprehensive psychometric evidence across all ages. The Pediatric Quality-of-Life Inventory v4.0 Generic Core Scales (PedsQL GCS) covers ages 2 to 18 years old, but evidence on its psychometric properties is limited to restricted age groups. This study aimed to evaluate the proxy-reported PedsQL GCS across the entire childhood lifespan.

Methods: The study used data from the Longitudinal Study of Australian Children for children aged 2 to 17 years with 1 of 6 health conditions: high weight status, eczema, attention deficit hyperactivity disorder, vision problems, hearing problems, and learning difficulty. Psychometric properties of the proxy-reported PedsQL GCS were assessed in early childhood, middle childhood, and adolescence against established criteria.

Results: In analyses of 9317 children with 50 934 total observations, the PedsQL GCS demonstrated good acceptability across the childhood lifespan, except for high rates of missing data in 2 to 9 year olds (range = 12%-30%). Strong internal consistency was evident across health conditions and age (α range = 0.72-0.93; item-total correlations range = 0.28-0.80). Known group validity was strong with differentiation between children with/without the condition across all ages, except for eczema. Responsiveness was variable with inconsistencies mainly in early childhood.

Conclusions: This study adds to the PedsQL psychometric evidence base, finding that the proxy-reported PedsQL GCS demonstrated robust reliability and known group validity, good acceptability, and mixed responsiveness in Australian children with health conditions across age. We propose the PedsQL GCS as a robust instrument to take forward for valuation to directly generate utility values for use in economic evaluations.

Keywords: Australia, children and adolescents, pediatric quality of life, Pediatric Quality of Life Inventory v4.0 Generic Core Scales (PedsQL GCS), psychometric evaluation.

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Highlights

- Current preference-based pediatric health-related quality-of-life (HRQoL) instruments have a limited target age range and variable psychometric evidence base across the childhood lifespan. The Pediatric Quality-of-Life Inventory v4.0 Generic Core Scales (PedsQL GCS) has a wide target age range (2-18 years old) and a significant psychometric evidence base. However, its psychometric performance has not been established for health conditions across different age groups, and it cannot directly generate utility values.
- This study determined that the proxy-reported PedsQL GCS instrument demonstrated robust reliability and known group validity, good acceptability, and mixed responsiveness in Australian children with specified health conditions (high weight status, eczema, attention deficit hyperactivity disorder, vision problems, hearing problems, and learning difficulty) across the childhood lifespan.
- We propose the PedsQL GCS as a sound instrument for country-specific valuation to enable the direct generation of utility values. The availability of a value set for the PedsQL GCS would address the challenge of consistent measurement and comparison of HRQoL across childhood, which is critical for economic evaluations and cost-utility analysis in many pediatric decision-making contexts.

Introduction

Patient-reported outcome measures (PROMs) that aim to assess health-related quality of life (HRQoL) are crucial tools for health outcomes research in children and adolescents. They have been used in various contexts, such as informing clinical care decisions, clinical trials, health system evaluations, and health policy decision making.[1,2] Generic PROMs designed to assess HRQoL across different populations are useful because they enable comparisons across clinical conditions and between clinical and general populations.[3,4] Some generic HRQoL instruments can also be used with valuation algorithms (value sets) that provide preference-based HRQoL on a utility scale (in which 0 = death to 1 = full health).[5–7] This enables the calculation of quality-adjusted life years, which is a standardized measure to compare HRQoL across different populations using the same utility scale.[5–7]

Challenges of measuring HRQoL in children and adolescents include the availability of PROMs (nonpreference and preference-based) that have been developed specifically for them (rather than applying adult measures), are age appropriate, reflect different disease stages and developmental changes, the ability of young children to self-report, and the resulting challenge of

consistency between child self-reports and proxy-reports.[8-10] An additional challenge is identifying PROMS that have been appropriately appraised, including the robust assessment of the psychometric properties. Psychometric assessment guidelines are well established and endorsed for use across research, clinical and industry practices.[11-15] Evidence of the performance of HRQoL measures (including self- and proxy-reported versions) over a comprehensive range of psychometric properties within general and clinical populations, and across many settings, is essential to determine if the instruments are fit for purpose and provide valid, reliable, and responsive measurement of HRQoL. This evidence is crucial to ensure the effective application of HRQoL measures and the credibility of the decisions that they inform.

A recent systematic review identified 17 preference-based HRQoL measures (HRQoL utility instruments) for use in children and adolescents (aged ≤18 years old).[1] However, they all had truncated target age ranges and did not cover the whole childhood lifespan from 0 to 18 years old.[1] Another systematic review also highlighted the variable psychometric evidence base.[16] The absence of a preference-based HRQoL instrument that spans the whole childhood lifespan highlights the challenge of consistent measurement and comparison of HRQoL across childhood, which is critical for economic evaluations and decision-making contexts.

Although not a preference-based measure, the Pediatric Quality-of-Life Inventory v4.0 Generic Core Scales (PedsQL GCS) is the most widely used generic childhood PROM that assesses HRQoL and is part of the PedsQL measurement model.[17,18] It is a favored childhood HRQoL measure because it was developed and validated as a generic measure for use in general and clinical populations of children and adolescents aged 2 to 18 years old using the same descriptive system. This facilitates consistent and comparable HRQoL measurement across childhood.[19,20] Although there is variation between self- and proxy-reported PedsQL GCS scores,[4] the proxy-reported PedsQL GCS is valuable for younger populations and conditions that preclude self-completion. The systematic review by Janssens et al[4] identified a larger psychometric evidence base for the PedsQL GCS (self- and proxy-reported) compared with other HRQoL measures, and highlighted evidence gaps for its psychometric properties, such as internal consistency reliability, test-retest reliability, and responsiveness.[4] Although recent work has provided evidence of the psychometric performance of the PedsQL GCS within the Australian context, including the often lacking test-retest reliability and responsiveness properties,[21-23] the performance of the PedsQL GCS in children and adolescents with a range of health conditions has not been assessed across all age groups.

This study aimed to address some of these evidence gaps by evaluating the psychometric properties of the proxy-reported PedsQL GCS within distinct age groups across the childhood lifespan in a national sample of Australian children and adolescents (2-17 years old) with specified health conditions.

Methods

Study Population

We conducted a secondary analysis of the Longitudinal Study of Australian Children (LSAC) data.[24] The LSAC is an ongoing population-representative longitudinal survey of children and their families, which collects data on child well-being and development over the childhood life course. The LSAC initiated recruitment in 2004 (wave 1), using clustered sampling methods to enroll 2 distinct cohorts: the Baby (B) cohort, consisting of 5107 children, and the Kindergarten (K) cohort, comprising 4983 children.[25] Children and their caregivers were interviewed every 2 years with the most recent wave of data available for analysis collected in 2021.[24] Various methods and modes of data collection have been used for the LSAC, including self-completion, interviewer administered, mail-out, in-person, telephone, and computer-assisted methods for the parent-reported and child-reported questionnaires.[24]

This study used HRQoL data obtained using the parent proxy-report version of the PedsQL GCS instrument from the LSAC. The resulting longitudinal data set included PedsQL GCS data from 2004 to 2020 for 7 waves of data from the B cohort (children aged 2-15 years old) and K cohort (children aged 4-17 years old), respectively. The data set for analysis was pragmatically categorized as early childhood (2-5 years old), middle childhood (6-11 years old), and adolescence (12-17 years old), based on typical definitions of these age groups.[26]

PedsQL GCS

The PedsQL GCS is a generic nonpreference-based PROM specifically designed to measure childhood HRQoL and is developmentally appropriate for those aged 2 to 18 years old.[20] Age-appropriate versions of the PedsQL GCS were used in the LSAC and included the following parent proxy-report versions: Toddlers (ages 2-4 years), Young children (ages 5-7 years), Children (8-12 years), and Teens (13-18 years). We noted that for children aged 10 to 11 years (wave 4) in the K cohort, the LSAC used the PedsQL GCS Young Children (ages 5-7) version. The age-specific PedsQL GCS versions have the same core constructs with some questions worded to be age appropriate. Except for the Toddler version, the PedsQL GCS consists of 23 items within 4 summary functional subscales: physical (8 items), emotional (5 items), social (5 items), and school (5 items).[20] The Toddler version only contains 21 items with 2 of the items removed from the school functioning subscale. Each item is scored on a 5-point Likert scale. All item responses are reversed scored and transformed onto a linear scale in which the total score is the sum of item scores divided by the number of items answered (thus accounting for missing data).[20] The PedsQL GCS total score ranges from 0 to 100, with higher scores indicating better HRQoL.[20]

Health Conditions

We assessed the psychometric properties of the PedsQL GCS within common childhood health conditions and across different child age groups. The LSAC includes objectively measured weight status and a range of health conditions that are proxy-reported by a parent or caregiver. This study focused on those with any of the following 6 health conditions: high weight status (overweight and obesity), eczema, attention deficit hyperactivity disorder (ADHD), vision problems, hearing problems, and learning difficulty. Children in the LSAC may have multiple health conditions, and this study examined the presence of any of the 6 specified conditions. Children without any of these conditions were included for comparison where appropriate. The 6 health conditions were selected based on the availability of data across child age groupings in the LSAC and feedback and prioritization from the study end-user group, which consisted of pediatric and nonpediatric clinicians, health economists, and policy and funding decision makers (14 members in total).

Evaluation of Psychometric Properties

We evaluated acceptability, internal consistency reliability, known group validity, and responsiveness of the PedsQL GCS using criteria from best-practice guidelines and established standards.[11-15,27-29] The psychometric evaluation for each health condition used complete observations for the specified condition,

the PedsQL GCS, and sociodemographic variables, except when assessing the acceptability of missing data levels. Acceptability and internal consistency reliability analyses were conducted separately for children with each of the 6 health conditions and children without any of the 6 conditions, across available age groups. Known group validity and responsiveness were assessed separately for children with each of the 6 health conditions and across available age groups.

Acceptability was assessed based on data quality, specifically, the proportions of missing data and ceiling and floor values, using thresholds of <5% (missing data) and <10% (ceiling and floor values).[28] Assessment of feasibility, practicality, comprehension, and completion burden[15,27,28] were not possible with our data.

Reliability was assessed using internal consistency, which measures the interrelatedness of items within the same scale, providing insights into how consistently the items within each scale or subscale measure the same underlying construct.[12,29] We assessed internal consistency reliability for the physical health, emotional, social, and school functioning subscales and the total score scale of the PedsQL GCS using Cronbach's alpha and item-total correlations. Cronbach's alpha values ≥ 0.7 and item-total correlations ≥ 0.2 and ≤0.8 were selected as minimum standards for internal reliability consistency.[28-31]

Known group validity assessed the ability of the PedsQL GCS total scores to differentiate between health conditions.[15] We hypothesized that children with any 1 of the 6 conditions would have lower PedsQL GCS total scores compared with those without the specified condition. General estimating equations (GEEs) were used to account for the repeated measures of the PedsQL GCS and health conditions among the same children and were adjusted for age (continuous), sex, whether participants identified as an Aboriginal or Torres Strait Islander person or culturally and linguistically diverse (CALD), and low socioeconomic position, all of which are known to be associated with HRQoL.[32,33] More details of the methods and sociodemographic variables are provided in previous studies.[23,34] Separate GEE models were estimated for the presence of each of the 6 health conditions compared with the absence of the condition (eczema vs no eczema, ADHD vs no ADHD, etc). Significance levels were set at $P < .05$ for main effects and $P < .01$ for interaction terms. Interaction terms for each health condition and sociodemographic variables that were significant in the initial multivariate models were explored. Finally, we used the fitted models to predict the marginal effects of the health condition on HRQoL.

Responsiveness assessed the ability of PedsQL GCS total scores to detect change over time in the 6 health conditions.[12,28,35] We hypothesized a negative change in total scores for a child moving from absence to presence of the condition (eg, no eczema to eczema); a change close to 0 for no change in presence or absence of the condition and a positive total score change if the condition resolved (eg, eczema to no eczema). Children were classified based on whether each selected clinical condition manifested (categorized as "worse"), resolved ("better"), or persisted ("same") between consecutive waves of the LSAC data set. When reported, the B and K cohorts provided data on the change in total scores for individual children over 2-year intervals for age group progressions from 2-3 to 4-5 years old all the way up to 14-15 to 16-17 years old. Responsiveness was evaluated using effect sizes (ESs), calculated by dividing the change in the mean PedsQL GCS total score by the baseline score's standard deviation (SD), which accounts for the PedsQL GCS total score change relative to the baseline score's SD.[36,37] Effect sizes were interpreted using accepted thresholds of small (ES = 0.2), moderate (ES = 0.5), and large (ES ≥ 0.8).[31,38]

Results

Study Population

Abbreviated characteristics of the study sample are summarized in Table 1 (see Appendix Table 1 in Supplemental Materials found at https://doi.org/10.1016/j.jval.2025.03.018 for complete descriptive characteristics). The data set for this study, derived from the LSAC and based on available PedsQL GCS data, included 50 934 observations from 9317 children across both cohorts: 25 305 observations from 4544 children in the B cohort and 25 629 observations from 4773 children in the K cohort. The health conditions were not reported for all age groups; ADHD and vision problems were not reported for 2-to-3-year olds, and hearing problems were only available for children between 4 and 15 years old. Overall, the most prevalent conditions reported were high weight status (including overweight and obesity), eczema, and vision problems. The least prevalent conditions were ADHD, hearing problems, and learning difficulty.

The distribution of sociodemographic characteristics varied across the 6 conditions. A higher proportion of boys had ADHD or learning difficulty across all age groups compared with the other health conditions and those without any of these conditions. The distribution of CALD status across age groups for most of the conditions were similar to the CALD distribution by age groups reported for children in the 2021 Australian population census when "language other than English spoken at home" was used to define CALD status.[39]

Psychometric Properties

Acceptability

Across the 6 health conditions, acceptability of the PedsQL GCS assessed through missing data was poor in early childhood as it exceeded the <5% threshold criteria (B and K cohort range = 12%-30%), variable in middle childhood (B cohort range = 0%-4%; K cohort range = 0.4%-28%) and acceptable in adolescence (B and K cohort range = 0%-5%) (see Appendix Tables 2 and 3 in Supplemental Materials found at https://doi.org/10.1016/j.jval.2025.03.018). The floor and ceiling effects were <10% across all the health conditions and throughout childhood and adolescence (floor effects = 0%; ceiling effects range = 0%-5%).

Internal consistency reliability

The PedsQL GCS total score scale and 4 summary score subscales showed strong internal consistency across the 6 health conditions throughout childhood and adolescence (α range = 0.72-0.93; item-total correlations range = 0.28-0.80) (Table 2). The only exception was the school functioning subscale, in which Cronbach's alpha was below the threshold for overweight, obesity, eczema, ADHD, vision problems, and learning difficulty in early childhood (α range = 0.52-0.69), and for those with ADHD in middle childhood (α = 0.64). The lower range of the item-total correlations for the school functioning subscale in children with ADHD in early childhood (item-total correlations range = 0.18-0.40) also fell slightly below the lower threshold of 0.2.

Known group validity

Known group validity was very good for the PedsQL GCS as the mean total scores differentiated between children with and without 5 of the 6 conditions throughout childhood and adolescence (Fig. 1). Known group validity was not significant for overweight compared with healthy weight in early childhood and was less clear for eczema over all age groups in which a predicted PedsQL GCS score decrement of <1 point was associated with eczema. Known group validity for overweight and obesity was

Table 1. Abbreviated descriptive characteristics of analysis sample by health condition status and age group.

Age group	Variables	Sample without any of the 6 conditions	High weight status		Eczema	ADHD	Vision problems	Hearing problems	Learning difficulty
			Overweight	Obesity					
Early childhood (2-5 years old)									
2-3 years old: *N* = 3510 (B cohort wave 2)	*N* for complete cases of demographics and individual health condition†	3510	3450	3450	3510	-	-	-	3510
	n (%)	1677 (48)	1063 (31)	416 (12)	631 (18)	-	-	-	27 (0.8)
	PedsQL mean total score (SD)	81.8 (9.8)	82.4 (9.8)	81.1 (10.6)	80.7 (10.3)	-	-	-	60.5 (16.1)
	Female *n* (%)	852 (51)	511 (48)	181 (44)	293 (46)	-	-	-	7 (26)
4-5 years old: *N* = 7996 (B cohort wave 3 and K cohort wave 1)	*N* for complete cases of condition in cohort and wave†	7996	7916	7916	7996	7996	7996	7996	7996
	n (%)	4392 (55)	1922 (24)	669 (9)	1091 (14)	60 (0.8)	218 (2.7)	214 (2.7)	123 (2)
	PedsQL mean total score (SD)	81.4 (10.2)	81.3 (10.7)	79.3 (12.3)	79.9 (10.6)	67.5 (15.7)	77.5 (14.0)	75.2 (13.3)	63.5 (17.0)
	Female *n* (%)	2284 (52)	816 (42)	296 (44)	542 (50)	14 (23)	103 (47)	81 (38)	35 (28)
Middle childhood (6-11 years old)									
6-7 years old: *N* = 7606 (B cohort wave 4 and K cohort wave 2)	*N* for complete cases of condition in cohort and wave†	7606	7520	7520	7604	7604	4143*	4143*	7606
	n (%)	4469 (59)	1454 (19)	648 (9)	967 (13)	114 (1.5)	281 (7)	118 (3)	154 (2)
	PedsQL mean total score (SD)	80.0 (12.8)	79.2 (12.9)	75.3 (15.1)	78.0 (13.1)	64.6 (16.7)	75.9 (15.5)	72.3 (16.4)	66.3 (16.7)
	Female *n* (%)	2234 (50)	704 (48)	272 (42)	494 (51)	29 (25)	143 (51)	50 (42)	51 (33)
8-9 years old: *N* = 7726 (B cohort wave 5 and K cohort wave 3)	*N* for complete cases of condition in cohort and wave†	7726	7631	7631	7719	7719	7719	7719	7719
	n (%)	3984 (52)	1599 (21)	868 (11)	896 (12)	202 (3)	724 (9)	183 (2)	242 (3)
	PedsQL mean total score (SD)	81.7 (11.8)	79.6 (12.9)	75.5 (15.2)	78.7 (13.7)	67.0 (15.5)	76.6 (13.9)	71.2 (15.5)	64.6 (17.2)
	Female *n* (%)	2007 (50)	813 (51)	354 (41)	474 (53)	43 (21)	371 (51)	75 (41)	77 (32)
10-11 years old: *N* = 7699 (B cohort wave 6 and K cohort wave 4)	*N* for complete cases of condition in cohort and wave†	7699	7414	7414	7693	7693	7693	7693	7696
	n (%)	3757 (49)	1645 (22)	893 (12)	850 (11)	227 (3)	1096 (14)	152 (2)	130 (2)
	PedsQL mean total score (SD)	81.1 (13.4)	78.3 (14.4)	74.0 (16.0)	78.5 (14.4)	66.8 (15.9)	76.6 (14.8)	71.6 (16.4)	66.3 (17.1)
	Female *n* (%)	1898 (51)	808 (49)	329 (37)	459 (54)	51 (22)	592 (54)	65 (43)	46 (35)
Adolescence (12-17 years old)									
12-13 years old: *N* = 7061 (B cohort wave 7 and K cohort wave 5)	*N* for complete cases of condition in cohort and wave†	7061	6812	6812	7051	7051	7051	7051	7050
	n (%)	3710 (53)	1494 (22)	714 (10)	671 (10)	239 (3)	801 (11)	113 (1.6)	175 (2)
	PedsQL mean total score (SD)	82.9 (12.5)	80.0 (14.2)	74.9 (15.9)	79.4 (14.3)	67.1 (16.0)	77.3 (14.9)	73.9 (16.8)	65.0 (17.9)
	Female *n* (%)	1821 (49)	747 (50)	286 (40)	369 (55)	60 (25)	456 (57)	45 (40)	53 (30)
14-15 years old: *N* = 6400 (B cohort wave 8 and K cohort wave 6)	*N* for complete cases of condition in cohort and wave†	6400	6039	6039	6392	6392	6392	6392	6392
	n (%)	3473 (54)	1245 (21)	588 (10)	579 (9)	220 (3)	813 (13)	112 (1.8)	166 (3)
	PedsQL mean total score (SD)	81.2 (14.8)	78.0 (15.7)	72.7 (18.1)	77.3 (16.2)	66.9 (17.0)	77.3 (15.9)	73.3 (16.8)	62.7 (17.0)
	Female *n* (%)	1657 (48)	656 (53)	244 (42)	332 (57)	62 (28)	491 (60)	48 (43)	57 (34)
16-17 years old: *N* = 2936 (K cohort wave 7)	*N* for complete cases of condition in cohort and wave†	2936	2742	2742	2936	2936	2936	-	2936
	n (%)	1667 (57)	529 (19)	296 (11)	214 (7)	84 (3)	356 (12)	-	77 (3)

continued on next page

Table 1. Continued

Age group	Variables	Sample without any of the 6 conditions	High weight status		Eczema	ADHD	Vision problems	Hearing problems	Learning difficulty
			Overweight	Obesity					
	PedsQL mean total score (SD)	82.4 (13.2)	79.9 (14.3)	74.6 (17.1)	79.6 (14.5)	68.7 (16.5)	76.4 (15.1)	-	63.0 (19.2)
	Female *n* (%)	786 (47)	265 (50)	142 (48)	116 (54)	17 (20)	228 (64)	-	24 (31)

Note. Numbers and percentages are calculated from the *N* for complete cases of demographics and individual health condition columns. PedsQL mean total score scale = 0-100
ADHD indicates attention deficit hyperactivity disorder; SD, standard deviation.
*N = 4143 because no data were collected for vision problems or hearing problems in K cohort wave 2.
†Note that the samples are complete cases for the following variables: PedsQL, low socioeconomic position, culturally and linguistically diverse and being Aboriginal/Torres Strait Islander overall, and then additionally complete cases for each of the health conditions (ie, eczema, high weight status of overweight or obesity, vision problems, attention deficit hyperactivity disorder [ADHD], hearing problems, and learning difficulty).

stronger for adolescents and children in middle childhood than in early childhood, whereas for ADHD, learning difficulty, hearing difficulty, and vision problems were similarly strong for children across all age groups studied. Having ADHD in middle childhood and adolescence resulted in a lower PedsQL GCS total score of around 10 points, learning difficulty was associated with an 8 to 9 points lower total score and hearing problems with a 4 to 5 points lower score (see Appendix Table 4 in Supplemental Materials found at https://doi.org/10.1016/j.jval.2025.03.018). Interaction terms for clinical conditions and sociodemographic variables were not significant, suggesting little evidence that known group validity for a particular condition was modified by these factors in the LSAC sample. The marginal predictions for the adjusted PedsQL GCS total scores and GEE model outputs are summarized in Appendix Tables 4 and 5 in Supplemental Materials found at https://doi.org/10.1016/j.jval.2025.03.018.

Responsiveness

Appendix Figure 1 in Supplemental Materials found at https://doi.org/10.1016/j.jval.2025.03.018 summarizes the estimated mean ES and trend across 2 consecutive waves of data for age group progressions for those who moved to a "worse" category, stayed the "same" or moved to a "better" category. If the PedsQL GCS was responsive, the ES for "worse," "same," and "better" would be expected to be negative, close to 0, and positive, respectively. The responsiveness of the PedsQL GCS was variable for most of the 6 conditions across childhood and adolescence.

The responsiveness in children with learning difficulty was as hypothesized, except for progression from 2-3 to 4-5 years old and the adolescent age groups. The change in ES in children with changing weight status and vision problems, respectively, were as hypothesized for the age progressions from 8-9 to 10-11 years old and 14-15 to 16-17 years old, and were less consistent within early childhood and the progressions from 10-11 to 12-13 years old and 12-13 to 14-15 years old. Responsiveness was less consistent for children with eczema, with results close to the hypothesized trend in ES only evident in progressions from 2-3 to 4-5 years old, 6-7 to 8-9 years old, and 12-13 to 14-15 years old, although with overlapping 95% CIs. The expected pattern was seen for the middle childhood age group progressions in children with ADHD and hearing problems, respectively; however, there were large and overlapping CIs due to smaller sample sizes for the "worse" and "better" categories.

In situations where responsiveness was consistent with the hypothesis, the ES estimates were relatively small. The ES point estimates and 95% CIs for the PedsQL GCS for the 6 health conditions and age group progressions are summarized in Appendix Tables 6 to 11 in Supplemental Materials found at https://doi.org/10.1016/j.jval.2025.03.018.

Discussion

The findings of this study indicate that overall the PedsQL GCS demonstrated strong psychometric performance. There was good acceptability with either no or low floor and ceiling effects (<10%) and mostly low missing data (<5%) over the childhood lifespan, except for high levels of missing data (12%-30%) before the computer-assisted self-interview (CASI) method. The higher levels of missing data were noted in our study for waves 2 and 3 (B cohort) and waves 1 to 3 (K cohort) and may be due to the initial data collection modes in the LSAC, before the transition to the CASI method from wave 4 onward.[24] Missing data were acceptable (<5%) for data collection in wave 4 and beyond. Low levels of missingness (<5%) were observed for the PedsQL GCS (self- and proxy-reported) in other psychometric assessments across multiple clinical conditions and contexts for children aged 2 to 18 years.[19,20,40-42] The lack of floor and ceiling effects (<10%) for the PedsQL GCS demonstrated in this study is consistent with other studies and suggests no issues with measurement variability at the upper and lower ends of its scale.[21,22,42,43]

The PedsQL GCS demonstrated strong internal consistency reliability and known group validity for most of the reported health conditions throughout childhood and adolescence for this cohort of children for whom PedsQL GCS data were available. This provides users with confidence that the items within the PedsQL GCS subscales and total scale consistently measure the overall construct of HRQoL as developed. Our study noted that internal consistency for the school functioning subscale was slightly below the acceptable Cronbach's alpha threshold for most health conditions in early childhood (2-5 years old). The LSAC did not administer 2 out of 3 items from the school functioning subscale of the 21-item Toddler version to 2-to-3-year olds. Although no reason was provided, not administering the instrument as intended could explain our finding of lower internal consistency in early childhood. The PedsQL GCS can discriminate between groups of children based on health condition status. This distinction is less pronounced among children with eczema, suggesting that the PedsQL GCS may be less sensitive to this condition. However, this finding could also be attributed to the lack of condition severity in the LSAC. Our conclusion regarding the strong known group validity of the PedsQL GCS aligns with other studies.[4,21,22,40-43] Australian

Table 2. Internal consistency reliability results for PedsQL GCS in early childhood, middle childhood, and adolescence by health condition.

Condition	PedsQL GCS variable	Early childhood (2-5 years old)			Middle childhood (6-11 years old)			Adolescence (12-17 years old)		
		N	Cronbach's alpha value*	Item-total correlations range†	*N*	Cronbach's alpha value*	Item-total correlations range†	*N*	Cronbach's alpha value*	Item-total correlations range†
1. Sample without any of the 6 conditions	Total score scale	6069	0.8563	0.3044-0.5326	12210	0.8970	0.3831-0.5965	8850	0.9106	0.4394-0.6161
	Physical health summary score subscale	6069	0.7433	0.3367-0.5440	12210	0.8380	0.3399-0.7475	8850	0.8580	0.3779-0.7758
	Emotional functioning summary score subscale	6069	0.7300	0.3646-0.5551	12210	0.7760	0.4698-0.6057	8850	0.8258	0.5551-0.7089
	Social functioning summary score subscale	6069	0.7544	0.5050-0.5505	12210	0.7789	0.4717-0.6194	8850	0.8117	0.5511-0.6560
	School functioning summary score subscale	6069	0.5916‡	0.2144-0.5186	12210	0.7218	0.3913-0.5990	8850	0.7686	0.4109-0.6497
2. High weight status										
• Overweight	Total score scale	2985	0.8657	0.3082-0.5630	4698	0.8985	0.3644-0.5952	3268	0.9168	0.4639-0.6143
	Physical health summary score subscale	2985	0.7458	0.3146-0.5595	4698	0.8404	0.3105-0.7523	3268	0.8616	0.4152-0.7727
	Emotional functioning summary score subscale	2985	0.7201	0.3242-0.5383	4698	0.7820	0.4641-0.6312	3268	0.8384	0.5683-0.7275
	Social functioning summary score subscale	2985	0.7749	0.5191-0.5973	4698	0.7952	0.5188-0.6380	3268	0.8238	0.5698-0.6817
	School functioning summary score subscale	2985	0.6003‡	0.2309-0.5063	4698	0.7227	0.3655-0.6136	3268	0.7765	0.4530-0.6412
• Obesity	Total score scale	1085	0.8841	0.3295-0.6171	2409	0.9111	0.4045-0.6418	1598	0.9242	0.4485-0.6639
	Physical health summary score subscale	1085	0.7755	0.3620-0.6294	2409	0.8506	0.3412-0.7671	1598	0.8643	0.4345-0.7644
	Emotional functioning summary score subscale	1085	0.7286	0.3531-0.5550	2409	0.8006	0.4832-0.6554	1598	0.8505	0.5843-0.7404
	Social functioning summary score subscale	1085	0.8030	0.5573-0.6331	2409	0.8135	0.5675-0.6530	1598	0.8309	0.5790-0.6925
	School functioning summary score subscale	1085	0.6401‡	0.2860-0.5443	2409	0.7569	0.4404-0.6370	1598	0.7603	0.4328-0.6430
3. Eczema	Total score scale	1722	0.8631	0.3185-0.5419	2713	0.9013	0.3827-0.6181	1464	0.9205	0.4371-0.6520
	Physical health summary score subscale	1722	0.7270	0.3155-0.5082	2713	0.8373	0.2889-0.7494	1464	0.8603	0.3884-0.7866
	Emotional functioning summary score subscale	1722	0.7374	0.3550-0.5642	2713	0.7852	0.4611-0.6372	1464	0.8310	0.5580-0.7073
	Social functioning summary score subscale	1722	0.7645	0.4860-0.5862	2713	0.7980	0.5054-0.6426	1464	0.8325	0.5901-0.6844
	School functioning summary score subscale	1722	0.6003‡	0.1950‡-0.5351	2713	0.7249	0.3845-0.5997	1464	0.7765	0.4653-0.6459
4. ADHD	Total score scale	60	0.8675	0.2822-0.5946	543	0.8891	0.3261-0.5732	543	0.8994	0.3681-0.5940
	Physical health summary score subscale	60	0.8097	0.2777-0.7509	543	0.8227	0.3268-0.7213	543	0.8415	0.3963-0.7422

continued on next page

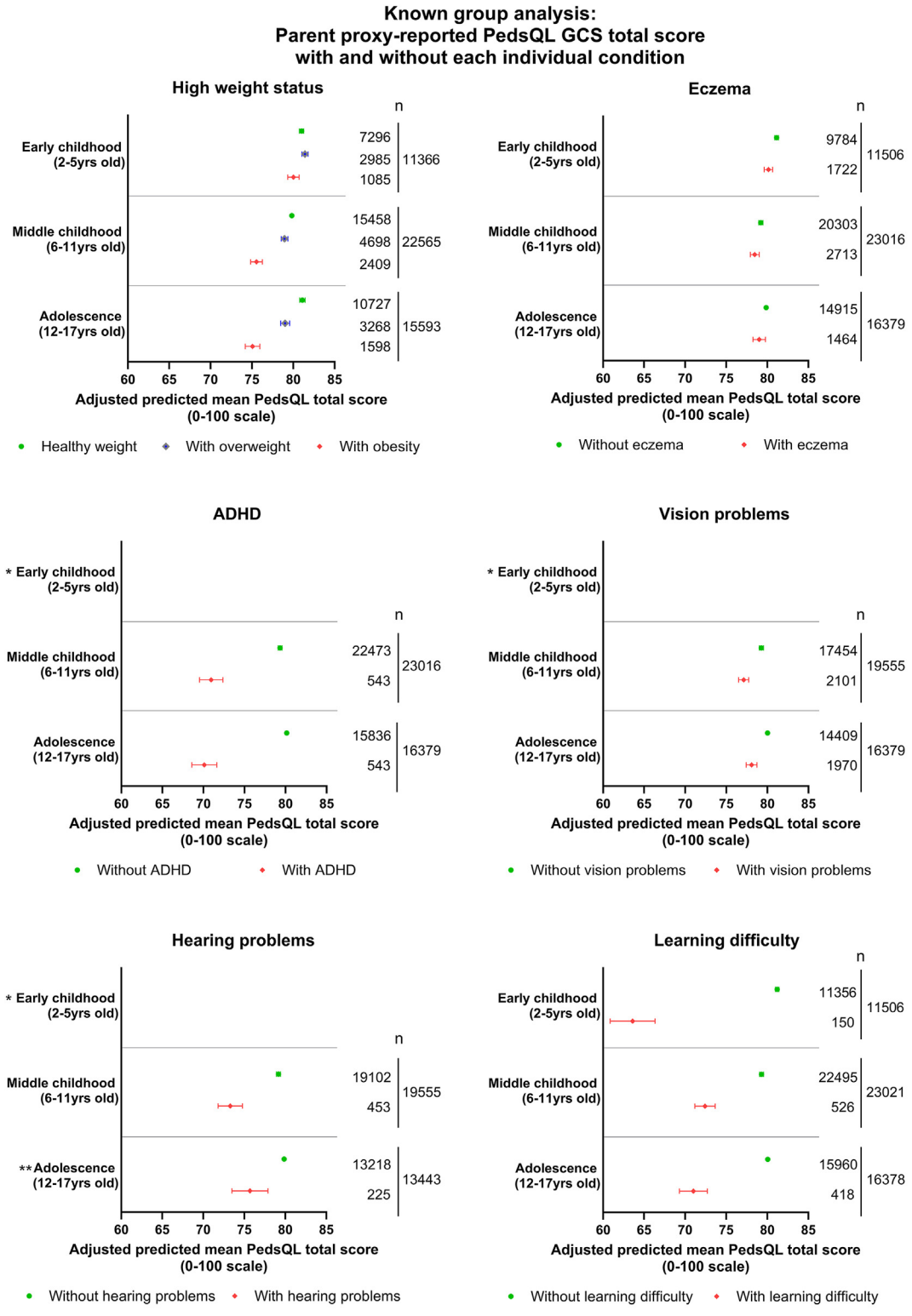
Table 2. Continued

Condition	PedsQL GCS variable	Early childhood (2-5 years old)			Middle childhood (6-11 years old)			Adolescence (12-17 years old)		
		N	Cronbach's alpha value*	Item-total correlations range†	*N*	Cronbach's alpha value*	Item-total correlations range†	*N*	Cronbach's alpha value*	Item-total correlations range†
	Emotional functioning summary score subscale	60	0.7935	0.5300-0.6593	543	0.7827	0.4704-0.6338	543	0.8043	0.4779-0.6929
	Social functioning summary score subscale	60	0.7924	0.4991-0.6539	543	0.8065	0.5078-0.7196	543	0.8272	0.5447-0.7350
	School functioning summary score subscale	60	0.5213‡	0.1751‡-0.4042	543	0.6382‡	0.2976-0.5253	543	0.6975	0.3850-0.5171
5. Vision problems	Total score scale	218	0.9125	0.3199-0.6997	2101	0.9033	0.3968-0.6095	1970	0.9224	0.4202-0.6336
	Physical health summary score subscale	218	0.8220	0.3626-0.7345	2101	0.8362	0.3009-0.7471	1970	0.8560	0.4198-0.7690
	Emotional functioning summary score subscale	218	0.7778	0.4085-0.6322	2101	0.8075	0.5167-0.6558	1970	0.8405	0.5591-0.7338
	Social functioning summary score subscale	218	0.8281	0.5946-0.6875	2101	0.8155	0.5376-0.6844	1970	0.8387	0.5952-0.7032
	School functioning summary score subscale	218	0.6954‡	0.3638-0.6486	2101	0.7236	0.3580-0.5958	1970	0.7922	0.4862-0.6840
6. Hearing problems	Total score scale	214	0.8891	0.3416-0.6618	453	0.9068	0.3980-0.6400	225	0.9282	0.3898-0.6575
	Physical health summary score subscale	214	0.7990	0.2645-0.7282	453	0.8404	0.2678-0.7451	225	0.8762	0.4695-0.7994
	Emotional functioning summary score subscale	214	0.7548	0.4016-0.5859	453	0.7841	0.4757-0.6404	225	0.8074	0.4699-0.7146
	Social functioning summary score subscale	214	0.8007	0.5451-0.6213	453	0.7949	0.5254-0.6263	225	0.8384	0.5748-0.7063
	School functioning summary score subscale	214	0.7375	0.4875-0.5955	453	0.7540	0.4130-0.6239	225	0.7958	0.4546-0.7086
7. Learning difficulty	Total score scale	150	0.8951	0.3075-0.7089	526	0.8965	0.3845-0.6139	418	0.9066	0.3572-0.6635
	Physical health summary score subscale	150	0.8242	0.3507-0.7472	526	0.8476	0.3634-0.7337	418	0.8628	0.4385-0.7672
	Emotional functioning summary score subscale	150	0.7496	0.4175-0.6404	526	0.7971	0.4750-0.6514	418	0.8442	0.5552-0.7597
	Social functioning summary score subscale	150	0.8011	0.5273-0.6274	526	0.8256	0.5519-0.7284	418	0.8224	0.5403-0.7082
	School functioning summary score subscale	150	0.6859‡	0.3027-0.6265	526	0.7086	0.3452-0.5917	418	0.7396	0.4167-0.5948

Note. The samples are combined B and K cohorts for the 3 age groups and include complete cases for the following variables: PedsQL, low socioeconomic position, culturally and linguistically diverse, and being Aboriginal/Torres Strait Islander overall and then additionally complete cases for each of the health conditions (ie, eczema, high weight status of overweight or obesity, vision problems, ADHD, hearing problems, and learning difficulty.
ADHD indicates attention deficit hyperactivity disorder; PedsQL GCS, Pediatric Quality-of-Life Inventory v4.0 Generic Core Scales.
*Acceptable Cronbach's alpha threshold ≥ 0.7.
†Acceptable Item-total correlations threshold ≥ 0.2.
‡Indicates values below the threshold criteria.

studies by O'Loughlin et al[22] and Jones et al[21] demonstrated strong known group validity for the PedsQL GCS by age groups (4-6 years, 7-12 years, and 13-18 years) and report type (proxy and self-report). O'Loughlin et al[22] also demonstrated strong known group validity in specific health conditions (ADHD or anxiety/depression). Most of these studies focused either on a single health condition and/or limited pediatric age ranges; in contrast, our evaluation included multiple health conditions across age groups and addressed the gap in our understanding of age-specific known group validity.

Figure 1. Known group marginal predictions for PedsQL GCS total score and health conditions from final adjusted GEE models.



n=number of observations for each sub-category.
*No data available for children with these conditions in early childhood (2-5 years old). **No data available for children aged 16–17 years old with hearing problems.

GEE indicates general estimating equation; PedsQL GCS, Pediatric Quality-of-Life Inventory v4.0 Generic Core Scales.

The responsiveness of the PedsQL GCS varied across ages with inconsistencies mainly within early childhood. Potential reasons include smaller sample sizes for some health conditions, proxy-reported health conditions (except for weight status), and a lack of condition severity (except for weight status) as only absence or presence was reported. Lack of condition severity may account for poorer responsiveness in eczema because it is associated with negative HRQoL when severity is considered.[44,45] Inconsistent responsiveness for high weight status in early childhood could be due to its potential lack of impact on HRQoL at this age.[46,47] Other Australian studies, which combined various health conditions, noted inconsistent PedsQL GCS responsiveness due to small sample sizes.[21,22,43]

Currently available child-specific utility instruments can only be applied to limited age ranges within the childhood age span and are constrained by a paucity of evidence of their psychometric properties.[1,16] The potential ramifications of these limitations are the lack of consistent quality-adjusted life year derivation across the childhood lifespan and the implications for modeling decisions within economic evaluations. Our study demonstrates the good psychometric performance of the PedsQL GCS at different ages and child development stages across the childhood lifespan (2-17 years old) in children with and without health conditions. These are desirable characteristics for consistent measurement and comparisons in pediatric economic evaluations. However, the PedsQL GCS cannot be used in cost-utility analyses because it does not have an accompanying preference-based value set. This barrier has also been identified in the recent literature.[22] One strategy to address this is the development of mapping algorithms from the PedsQL GCS to pediatric HRQoL utility instruments, such as the Child Health Utility Index-9 Dimension (CHU9D),[48-52] albeit with a limited target age range (ie, 7-11 years old), for the CHU9D.[1,53,54] Others have also explored mapping algorithms for the PedsQL GCS to the EQ-5D utility instrument and suggested that these algorithms would likely be robust for children aged 11 to 15 years old.[55] However, one concern with this approach is that the EQ-5D was developed for use in adults rather than in childhood populations. The established psychometric performance of the PedsQL GCS and its wide target age range provides a strong case for developing country-specific value sets for PedsQL GCS, rather than mapping to other measures, so that it can be directly used to generate utility values for children and adolescents aged 2 to 18 years. This would enable the consistent generation and comparison of health utility values within the pediatric context, based on the same construct for HRQoL, and underpin robust economic evaluation and decision making.

Strengths and Limitations

Strengths of this study include its large, diverse, and population-representative sample (n = 50 934 observations from 9317 children) drawn from longitudinal data that enabled the assessment of multiple psychometric properties for the PedsQL GCS in a single sample of Australian children and adolescents. The longitudinal nature of the data allowed us to assess psychometric properties within age groups across the childhood lifespan and to investigate responsiveness—a psychometric property that is seldom reported.[4] The methods used to evaluate the psychometric properties of the PedsQL GCS were rigorous and based on established practice guidelines and criteria.

The PedsQL GCS data were, however, limited to parent/caregiver proxy reporting. There is some contention regarding the use of and comparability between self-report and proxy-report responses when generating HRQoL and utility values for children and adolescents.[35] In addition, the health conditions (except weight status) were also parent/caregiver proxy-reported and not supported by other clinical data. Furthermore, the severity of the conditions, except for weight status, was unknown. Finally, this was a secondary analysis using an existing data set from the LSAC; therefore, some analyses and methods were constrained by the availability of PedsQL GCS and health condition data across all age groups. Including children with each of the health conditions individually and excluding the presence of multiple health conditions was not implemented because this would have substantially decreased the relevant sample sizes for some of the analyses, thereby limiting the statistical power of the methods used. Test-retest reliability was not assessed for the proxy-reported PedsQL GCS in this study because of data constraints. However, other Australian studies have demonstrated acceptable test-retest reliability for the PedsQL GCS (self- and proxy-reported).[21,22]

Conclusions

Against established criteria, this study determined that the proxy-reported PedsQL GCS instrument demonstrated robust reliability and known group validity, good acceptability, and mixed responsiveness. This study is a valuable addition to the evidence base around the psychometric performance of the PedsQL GCS by demonstrating its psychometric performance in a large representative cohort of Australian children and adolescents with specific health conditions. We put forth the PedsQL GCS as a sound instrument to consider for country-specific valuation to directly generate utility values for economic evaluation and decision making within the pediatric context.

Author Disclosures

Author disclosure forms can be accessed below in the Supplemental Material section.

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Data Availability: The data from the Longitudinal Study of Australian Children used in this study are available by application to the data custodians: Longitudinal Studies, Data Strategy Branch, Australian Government Department of Social Services.

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