South Africa - Impilo Enhle Study: The feasibility, reliability and validity of the health-related quality of life scale, EQ-5D-Y-5L, versus the EQ-5D-Y-3L and CHU9D in routine healthcare settings among adolescents living with HIV in KwaZulu-Natal, South Africa: a mixed

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Overview

Identification

ID NUMBER
ImpiloEnhleStudy

Overview

ABSTRACT
Executive summary

Background:

Maximising health-related quality of life (HRQoL) is now regarded as an important HIV programme goal, aligned with Sustainable Development Goal 3 (improving health and wellbeing). Thus, there is a need to monitor HRQoL in HIV programmes and measure this outcome in routine programme monitoring and in evaluations to capture the broader benefits of integrated HIV policies and interventions seeking to promote quality of life. However, there is lack of guidance on appropriate HRQoL scales that could be used in HIV programmes and evaluations in sub-Saharan Africa, particularly among adolescents living with HIV (ALHIV) who are at persistently high risk for HIV-related morbidity and mortality. The EuroQol five-dimensional youth HRQoL scale with five response levels (EQ-5D-Y-5L) has proven to be feasible among acute and chronic disease paediatric populations in developing countries. No study has compared its psychometric performance against the earlier 3L version and other generic adolescent HRQoL scales, such as the CHU9D among ALHIV aged 10-15 years.

Aim:

• Phase 1- To assesses cognitive understanding of the EQ-5D-Y 5L vs. 3L and CHU9D among ALHIV

• Phase 2- To establish the reliability and validity of the HRQoL scale, EQ-5D-Y 5L, vs. 3L and CHU9D among ALHIV

• Phase 3- To explore the acceptability and feasibility of implementation of the EQ-5D-Y 5L vs. 3L and CHU9D for use in HIV clinics from the perspective of HCWs and study staff.

Methods:

This mixed-method study was conducted between April 2021 and February 2022 , in seven healthcare facilities and eight schools within the eThekwini district of KwaZulu-Natal, an area with the highest HIV prevalence in South Africa. We first conducted a qualitative study (Phase 1) to explore adolescents' understanding of the English version of the EQ-5D-Y-5L. This was assessed via cognitive interviews (which entailed a ranking game, a recall assessment and individual interviews) with 24 purposively sampled adolescents aged 10-15 years (12 ALHIV sampled from HIV clinics, 12 adolescents sampled from public sector schools). Thereafter, we conducted a cross-sectional study with adolescents (Phase 2). In this phase, ALHIV (n=150, clinic arm) were consecutively sampled by WHO HIV clinical stage strata (1-4), (a marker for HIV disease progression) from HIV clinics, and a comparator group (n=150, school arm "general population"), was sampled from primary and secondary schools. A baseline questionnaire was administered to all participants. This questionnaire included a battery of HRQoL scales [Y-5L (IA, SC),Y -3L (IA, SC); CHU9D (SC)], which was reverse ordered for 50% of the sample in each arm. Those who completed interviewer-administered EQ-5D-Y scales at baseline were followed-up within 2 weeks after completion of the baseline questionnaire to assess test-retest reliability of the Y-5L versus Y-3L. In addition, HIV clinical data was extracted from clinic medical records for ALHIV. We used exploratory statistical techniques to examine our primary outcome (i.e. known-groups validity- degree to which the EQ-5D-Y-5L scale is able to distinguish between ALHIV in various WHO HIV clinical stages) and secondary outcomes (time to completion per scale, test-retest reliability, convergent validity, discriminatory power). Lastly, we conducted interviews with healthcare workers (n=10) to gain their perception on implementation of the scale in routine HIV clinics, and fieldworkers (n=5) to understand their experiences with administering the scales (Phase 3).

Results:

Phase 1: Cognitive interviews to explore adolescents' understanding of the English version of the EQ-5D-Y-5L

Cognitive interviews were complete n=24 adolescents. The median age of study participants for both the clinic (n=12) and school (n-12) arm was 13 years (IQR:11-14), with an even distribution by sex. The majority of ALHIV in the clinic arm (n=8) were in WHO HIV clinical stage 1. All participants in the clinic arm correctly ranked the order of severity for each of the Y-5L dimensions, compared to the school arms where approximately 6-8 participants correctly ranked each dimension. Recall of questions and responses was higher in the clinic (75%) vs. school (42%) arm. Most participants found the Y-5L (SC) easy to complete but reported challenges with understanding the following words pertaining to the Y-5L dimension (mobility) and response options (extremely, a little bit).

Phase 2: Psychometric Testing of Patient-Reported Outcome Measures in ALHIV

Survey recruitment was as follows (clinic arm: n=152, 91% followed-up; school arm= n=161, 86% followed-up). The median age of our survey participants was 13 years, with approximately 47% females in the clinic arm versus 57% females in school arm. Most ALHIV in the clinic were in asymptomatic to mild WHO HIV clinical stages (stage 1 (35%) and 2 (38%). On average it took just over 1 minute for completion of scales in the clinic[IA: Y-3L=1.26 min Y-5L=1.58 min; SC: Y-3L=1.71 min, Y-5L=1.35 min CHU9D=1.29 min] and school arm [IA: Y-3L=1.61 min Y-5L=1.41 min; SC: Y-3L=1.08 min, Y-5L=1.86 min CHU9D=1.34 min]. Missingness levels were highest for the Y-3L (SC), and this was highest in the school (21.74%) vs clinic (0%) arm. Overall, reporting of "no problems" for each dimension (11111) was the most prevalent response permutation and comparable between EQ-5D scales in the clinic arm [IA: Y-3L=66%, Y-5L=68%; SC: Y-3L=70%, Y-5L=70%], yet higher in comparison to the CHU9D (57%). This permutation pattern was similar in the school arm [IA: Y-3L=54%, Y-5L=76%; SC: Y-3L=73%, Y-5L=68%, CHU9D=55%], except for the Y-3L (IA) with 12% more 11111 The median VAS scores in the clinic arm were comparable between scales [IA: Y-3L=81, Y-5L=80; SC: Y-3L=80, Y-5L=85], and with the clinic arm reporting worst health compared to the school arm by 10%. In terms of discriminatory power, Usual activities (Shannon index H' = 0.387) and Mobility (Shannon index H'= 0.232) showed the greatest positive difference in spread of absolute information between the Y-5L and Y-3L (IA) in the clinic arm. Whereas in the school arm, the Y-5L (IA) did not show improvement in absolute informativity for most dimensions. For the SC version in the clinic arm, the Y-3L had systematically higher H' than the Y-5L, and the opposite trend was observed in the school arm.

Ceiling effects (11111) in the clinic arm increased by 1.6% when moving from the Y-3L (IA) to Y-5L (IA) ($p<0.001$) yet decreased by 0.2% from the Y-3L (SC) to the Y-5L (SC) ($p=0.002$).There were mixed ceiling effects results between the clinic and school arm. A difference of 11.8% was observed in the Y-3L (IA) between school and clinic arm, however it was not statistically significant ($p=0.258$). A significant difference of 7.9% in the Y-5L (IA) was observed between school and clinic arm, $p=0.012$. Overall, there was a reduction in ceiling effects in the clinic arm when moving from the Y-3L (SC) to CHU9D (16%) and Y-5L (SC) to CHU9D (12%). Results were similar in the school arm.

Test-retest reliability was assessed by following-up participants at 2 weeks. There was substantial agreement (>80%) in dimensions for both the Y-3L and Y-5L (IA) in the clinic arm, with Gwet ACs >0.80 for dimensions. Results were similar in the school arm. There was evidence of convergent validity mainly in the clinic arm, with more significant correlations between the Y-5L (IA) dimensions and the self-reported item of one's rating of their overall health (mobility, rho=0.23; looking after myself, rho=0.28; usual activities, rho= 0.37; pain or discomfort, rho=0.21) compared to the Y-3L (IA). For the SC version, convergent validity was exhibited mainly in the Y-3L for the school arm. However, only worried, sad or unhappy were significantly correlated with the EQ-VAS in both the Y-5L (IA) and Y-3L (IA) in the clinic arm; with Y-3L (SC) showing the most number of significant correlations in the school arm overall. Similarly, the Y-5L (SC) and CHU9D dimensions were strongly correlated in the clinic arm (worried, sad or unhappy, rho= 0.82; usual activities, rho=0.86), with the Y-3L (SC) showing the most number of significant correlations in both arms.

Known- groups validity was observed only in the Y-5L (IA), which showed a significant decrease in EQ-VAS score with increasing WHO HIV clinical stage (rho=-0.34, $p=0.001$). Although the study design and sample size did not facilitate a valid assessment of differential item functioning, we found that the clinic arm was less likely to score highly (indicating better health) on looking after myself (-1.75, $p = 0.002$), usual activities (-1.70, $p = 0.001$) for the EQ-5D-Y-5L (IA) and less likely to score highly on the worried, sad or happy dimension for the EQ-5D-Y-3L (SC) compared to the school arm.

Phase 3: Key informant interviews on implementation of scales in clinical and study setting

Healthcare workers indicated that the EQ-5D-Y scales were comprehensive in that it covered dimensions pertinent to adolescent HIV, were clear in terms of instructions, and could be administered by lay staff during their routine patient screening to inform patient management or completed by ALHIV during clinic waiting times. However, among healthcare workers and field staff, there was stronger preference for the EQ-5D-Y-3L given the fewer response options and concerns about literacy levels and cognitive delays among ALHIV. Several healthcare workers expressed the need for the scale to probe interpersonal relationships due to the impact of carer relationships and stigma among ALHIV in this setting. Key informants indicated that the following factors would promote implementation within routine HIV clinics: approval from management, training of staff with regards to administration and how to refer ALHIV based on the information gathered from the scale. Field staff noted that younger adolescence had difficulty with SC version of the scale.

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Discussion:

Overall our results indicate that the Y-5L may be a feasible, reliable and a valid extension of Y-3L to assess HRQoL among ALHIV. The EQ-5D-Y-5L was associated with favourable cognitive understanding by adolescents in the clinic arm only, and results indicated that the scale could be enhanced by simplifying key dimensions ("mobility") and response level ("extremely") wording. Feasibility of the Y-5L (IA) was supported by its short scale completion and low levels of missingness. However, key informants preferred the Y-3L for ease of implementation. Ceiling effects increased only marginally when moving from the Y-3L to Y-5L (IA) in the clinic arm. Test-retest reliability was comparable between the Y-5L and Y-3L, and there was good evidence of convergent validity in the Y-5L (IA) in the clinic vs. school arm. The Y-5L (IA) exhibited favourable discriminatory power for certain dimensions and stronger known-groups validity compared to the Y-3L (IA) in the clinic arm. Our findings suggests that the Y-3L and Y-5L could be appropriate for younger and older adolescents, respectively. Furthermore, the applicability of Y-5L scale could be enhanced by adding a bolt-on psychological dimension focused on inter-relationships for ALHIV and warrants further investigation.

Producers and Sponsors

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Sampling

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Reports

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