Report:

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<u>Impilo Enhle Study:</u> 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-method study

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Contents

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.

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.

1) Introduction

The burden of HIV and impact on health-related quality of life among adolescents in SSA

In 2019, there were an estimated 1,740,000 million adolescents living with HIV (ALHIV) worldwide; with almost 88% of this cohort residing in sub-Saharan Africa (SSA) (UNICEF, 2020). Epidemiological models predict that the adolescent HIV epidemic in SSA is expected to increase by approximately two-fold in 2050 as more HIV-positive children survive into adolescence and HIV incidence among adolescent girls continues to escalate in this region (Khalifa et al., 2019). Despite the remarkable progress in the scale-up of antiretroviral therapy (ART) in SSA, ART coverage among ALHIV remains sub-optimal (Enane et al., 2018). HIV/AIDS remains the leading cause of death among 10-15 year-olds in countries such as South Africa, which is home to nearly 20% of the global number of ALHIV (UNICEF, 2020). If the Sustainable Development Goal 3 ("improving health and wellbeing for all ages") is to be achieved in this region, then prioritising efforts to improve the quality of life among ALHIV is critical.

Emerging research suggests that the health-related quality of life, a construct that denotes functioning in key health and social areas affected by disease or treatment (Karimi and Brazier, 2016, Bakas et al., 2012), is under threat among ALHIV in SSA (Rukuni et al., 2018, Enimil et al., 2016, Coetzee et al., 2019). For example, a study conducted in Uganda found that peri-natal HIV-infection was associated with sustained deficits in HRQoL domains such as physical and cognitive functioning. Moreover, this study found that HRQoL scores was lower among ALHIV compared to HIV-negative controls (Nkwata et al., 2017), which concurs with findings from adult HIV population surveys (Miners et al., 2014). Whilst a Zambian study reported improvements in HRQoL dimensions among adolescents newly initiated on ART (Chitah et al., 2016), HRQoL may likely decrease as the duration on ART increases, as evidenced in adult HIV cohorts (Simms et al., 2019). Data from a South African study with ALHIV and on ART found that insomnia, anxiety and depression significantly predicted HRQoL (Kagee et al., 2018). The literature also suggests that HRQoL among ALHIV may be further impeded by broader psycho-social and structural issues that persist in this region (e.g. HIV-related stigma, caregiver illness, lack of social support services, household poverty, food insecurity) (Lowenthal et al., 2014, Skovdal and Belton, 2014, Williams et al., 2017).

Recent clinical research has highlighted the burden of multisystem comorbidities experienced among ALHIV in this region (e.g. lung, cardiovascular, musculoskeletal diseases, neurodevelopment delays, tuberculosis) (Frigati et al., 2020), and reported high incidence rates of hospital admissions (5.5-7.8%) linked to these conditions in South Africa (Frigati et al., 2020). In addition, a recent systematic review reported a high prevalence of emotional and behavioural difficulties (30-50%) among ALHIV in SSA (Dessauvagie et al., 2020). Several clinical observational studies have also found high levels depression and suicidality (Adeyemo et al., 2020, Casale et al., 2019, West et al., 2019), and disability among ALHIV (Rukuni et al., 2018). These co-morbidities together with the impacts of lifelong ART may have debilitating effects on HRQoL dimensions important for positive adolescent development such as physical, cognitive and mental health functioning (e.g. school concentration, interaction with peers, mood, physical activity etc.) (Rukuni et al., 2018). Hence, there is a need to monitor and enhance HRQoL among ALHIV in SSA.

Benefits of measuring health-related quality of life in routine HIV programmes and in the evaluation of complex HIV interventions for ALHIV

Currently ART programme performance is assessed on the basis of three key treatment-related goals: 95% of people living with HIV know their HIV status; 95% of people who know their status are on ART; and 95% of people on ART have suppressed viral loads (UNAIDS, 2020). However, with a shift in policy focus towards healthy ageing, aligned with SDG 3, there is now growing recognition for the need to examine the holistic effects of HIV programmes. Hence, there has been a call to add a 4th HIV programme goal related to improvement of quality of life, specifically HRQoL (Lazarus et al., 2016). Measurement of HRQoL within routine monitoring and evaluation activities could provide several benefits. Firstly, it could be used as a programme performance indicator in quality improvement activities. Secondly, as HRQoL is strongly predictive of HIV disease severity (Degroote et al., 2014), patient-level HRQoL data could be used as a low cost clinical management strategy to identify ALHIV in need of intensive rehabilitative care and follow-up within resource constrained settings (Chetty et al., 2018). Thirdly, measurement of HRQoL in HIV surveys or disease surveillance programmes could be used to assess the effectiveness new HIV policies or ART regimens (Gakhar et al., 2013). Lastly, HRQoL data from ALHIV could strongly enhance economic evaluations such as cost-utility analyses of new ART regimens or interventions (Robberstad and Olsen, 2010). Preference-based HRQoL measures are used in economic evaluations and in health technology assessments to derive utility

weights of states in these instruments. These data are subsequently used in the calculation of quality-adjusted life years in order to compare the cost per quality-adjusted life years gained in the intervention versus standard of care scenario.

Potential HRQoL scales for use in epidemiological and economic evaluations among ALHIV

According to Chan (2014), before a measure can be used in health research or clinical settings, it needs to undergo rigorous psychometric evaluations which includes an assessment of reliability (quality of the data), validity (quality of the decisions and inferences made based on the scores from measurement) and the patient's cognitive process during scale completion. Our previous scoping review found that the Pediatric Quality of Life Inventory tool is the most commonly used HRQoL scale among ALHIV in low- and middle- income countries (Govindasamy and Mathews, 2017). Whilst this scale has demonstrated favourable psychometric properties among paediatric HIV-positive patients in India (Banerjee et al., 2010), its use in economic evaluations is limited as it is not a preference-based measure. To date, the KIDSCREEN (-52, -27, -10 item) (Ravens-Sieberer et al., 2010) is the only HRQoL scale that has been psychometrically evaluated among ALHIV in SSA (Masquillier et al., 2012). However, this scale is not a preference-based measure, is perceived as being lengthy and has exhibited weak validity among ALHIV in Kenya and Uganda (Masquillier et al., 2012). Evaluations of appropriate preference-based HRQoL scale for among ALHIV could help fill an important research gap.

The EuroQol five-dimensional scale (EQ5D) is one of the most extensively used HRQoL scales in HIV research studies among adults living with HIV worldwide (Cooper et al., 2017), particularly in SSA (Robberstad and Olsen, 2010). This scale covers five dimensions of health: mobility; (ii) self-care; (iii) usual activities; (iv) pain/discomfort; and (v) anxiety/depression and includes a visual analogue scale (VAS) for the patient to rate their current health status. This scale has exhibited strong psychometric properties among adults living with HIV in Zimbabwe (Mafirakureva et al., 2016) and other LMICs (Tran et al., 2012), and is one of the recommended preference-based HRQoL measures for HIV economic evaluations (Tran et al., 2015, Robberstad and Olsen, 2010). However, experiences and patterns of HRQoL may differ between adults and adolescents living with HIV, given their unique developmental stage and socio-economic status (Kagee et al., 2018). Hence, it is important to assess the appropriateness of this scale with ALHIV in this region.

Several international and local studies have highlighted the feasibility and validity of EuroQol five-dimensional youth scale with a three response levels (EQ-5D-Y-3L), representing severity (i.e. no problems, some problems, a lot of problems) among general population samples (Ravens-Sieberer et al., 2010), and clinical samples of children and adolescents living with chronic conditions such as idiopathic arthritis in South Africa (Scott et al., 2019), cystic fibrosis in Germany (Eidt-Koch et al., 2009), functional disability in Sweden (Burström et al., 2014), asthma in Germany (Bergfors et al., 2015) and kidney disease in Taiwan (Hsu et al., 2018). In a longitudinal study conducted among children (mean age 10.5 years) with acute chronic and no health conditions in Cape Town, South Africa, the EQ-5D-Y-3L demonstrated good reliability based on a test-retest assessment (kappa varying from 0.365 to 0.653), and healthcare workers (HCWs) perceived the scale as being quick and easy to implement in clinic settings (Scott et al., 2017). However, convergent validity was stronger among the acutely ill group versus children with chronic conditions.

To increase the sensitivity and ceiling effects of the scale, a revised version with five severity response levels (i.e. no problems, a little bit of problems, some problems, a lot of problems and cannot/extreme problems) (i.e. the EQ-5D-Y-5L) was developed (Kreimeier et al., 2019). Recent quantitative studies have found that this extended version has demonstrated favourable psychometric properties compared to the EQ-5D-Y-3L version with regards to ceiling effects, reliability (Åström et al., 2020, Wong et al., 2019a) and responsiveness (Wong et al., 2019b) among adolescents with chronic conditions such as scoliosis and psychiatric disorders. A recent South African study conducted among children and adolescents with acute and chronic conditions found that the Y-5L was a valid and reliable extension of the Y-3L (Verstraete et al., 2022). The study reported a reduction in ceiling effects and improved relative informativity with the Y-5L. The convergent validity and test-retest reliability and convergent validity between the Y-5L and Y-3L was comparable (Verstraete et al., 2022). Moreover, the Y-5L and Y-3L showed comparable psychometric properties to Pediatric Quality of Life Inventory scale (PedsQL) (Verstraete and Scott, 2022). Furthermore, in a recent qualitative study with adolescent psychiatric inpatients, most participants reported that the EQ-5D-Y-5L scale was understandable and the dimensions and response levels adequately captured their health (Krig et al., 2020).

The Child Health Utility 9D (CHU9D) is another generic preference-based HRQoL measure that has shown favourable feasibility, reliability and validity among general population samples of children and adolescents, although only in developed countries (Ratcliffe et al., 2012, Furber and Segal, 2015, Chen et al., 2015, Stevens and Ratcliffe, 2012). Whilst it was originally developed for use among 7-11 year-olds, the scale has demonstrated good validity among adolescents up to the age of 17 years (Ratcliffe et al., 2012), specifically for adolescents living with chronic conditions (Furber and Segal, 2015, Petersen et al., 2019).

To date, no study has assessed the psychometric properties of the EQ-5D-Y-5L compared to other robust measures such as the EQ-5D-Y-3L and CHU9D among ALHIV in SSA. This information could inform scale selection in research and routine settings and improve the applicability and usability of this scale in this region.

2) Aim and objectives

Aim

To assess the feasibility, reliability and validity of the English version of the EQ-5D-Y-5L (IA, SC) compared to the EQ-5D-Y-3L (IA, SC) and CHU9D (IA) in routine healthcare settings among ALHIV versus general population sample (school sample) in South Africa

Purpose

The purpose of this evaluation was to add to the body of literature on appropriate HRQoL scales for use among ALHIV in HIV programme monitoring and economic evaluations. It specifically sought to provide technical recommendations to developers of the EQ-5D-Y-5L in order to improve the psychometric performance of this scale and ultimately ensure robust measurement of HRQoL among ALHIV in South Africa.

Research questions

i. What are adolescents' cognitive process when completing the EQ-5D-Y-5L and are their interpretations of the scale items consistent with intended meanings in the interviewer- versus self-administered scale ?

ii. Does the EQ-5D-Y-5L exhibit stronger psychometric properties compared to the EQ-5D-Y-3L and CHU9D among ALHIV?

iii. What are HCWs and study field staff perceptions regarding feasibility of the scale within routine healthcare settings ?

Objectives

i. To assess face validity by assessing whether ALHIV could comprehend the EQ-5D-Y-5L (IA) and was the scale acceptable to them.

ii. To examine the ceiling effects of the EQ-5D-Y-5L versus the EQ-5D-Y-3L and CHU9D by determining the percentage of respondents reporting level 1.

iii. To assess the test-retest reliability of interviewer-administered versions of the EQ-5D-Y-5L versus the EQ-5D-Y-3L by comparing scores taken within 2 weeks post-completion at baseline.

iv. To assess the convergent validity of the EQ-5D-Y-5L versus the EQ-5D-Y-3L and CHU9D by comparing the correlation coefficients between individual scale dimensions and self-rated overall health status or VAS score or CHU9D dimensions among ALHIV and the school sample.

v. To assess the known-groups validity of the EQ-5D-Y-5L versus the EQ-5D-Y-3L by assessing the effect size between scale scores (VAS, dimensions) and WHO HIV clinical stage among ALHIV.

vi. To assess differential item functioning in the EQ-5D-Y-5L versus the EQ-5D-Y-3L using logistic regression among ALHIV and the school sample.

vii. To assess examine results for the interview-administered versus self-completed EQ-5D-Y-5L.

viii. To understand HCWs perceptions on use of the scale in routine clinical care, and study fieldstaff experience with administering each scale.

3) Study setting and population

This study was conducted in the eThekwini Metropolitan Health District of the KwaZulu-Natal (KZN) province, South Africa. This province has the highest HIV prevalence in the country (27% among 15-49 year-olds) (HSRC, 2018). The eThekwini district has an HIV prevalence of 16.9% and high TB incidence (642.5 per 100 000 population) (Office of the Premier, 2020). It is a densely populated district (population count 3, 702, 231) , with 16% of individuals aged 10-19 years of age (Stats SA,

2016). It has high levels of income inequality (Gini co-efficient 0.63) and is currently in the medium human development category, with a Human Development Index score of 0.699 (COGTA, 2020). Recent studies have highlighted the high levels of functional difficulties within key domains (e.g. cognition, behavioural, concentration, learning) among children living with HIV in this setting (Maddocks et al., 2020).

The study was conducted within the south and central parts of the municipality. For the clinic arm, we conducted the study in four outpatient HIV clinics within regional and district public-sector hospitals, and three community clinics within the catchment areas. For the school arm, we conducted the study in eight public-sector schools located within the catchment areas of the clinics (five high schools and three primary schools).

The primary study population was 10-15-year-olds (younger adolescents as defined by (WHO, 2014)) who are living with HIV/AIDS. This age-range was chosen as it is a key target group in HIV programmes, given the poor ART outcomes among this group (Maskew et al., 2019), and it spans the recommended age-range for the EQ-5D-Y-5L scale (EuroQol, 2020). The comparator target group was 10-15 year-old school learners.

4) Research Methodology

a. Study design

We conducted a mixed-method study between April 2021 and February 2022 (Figure 1). In **Phase 1** (April-August 2021), we conducted semi-structured cognitive interviews (n=24) to assess adolescents understanding of the English-version of the EQ-5D-Y-5L scale (IA vs. SC). Cognitive interviewing is a qualitative method that is designed to assess whether scale items are comprehensive in that it covers aspects important to the quality of life of adolescents and well understood among participants (Willis, 2004). Measurement error can arise due to discrepancies between how a question is asked and interpreted at every stage of the cognitive process (interpretation, recall, motivation, response), thereby reducing the validity of the scale (Collins, 2003). Cognitive interviews were used in this study to test if there was a difference between respondent's recall ability on a Y-5L version. This was specifically due to the Y-5L being a high number in terms of response options for recall and whether the severity labels would be understood and remembered. It was further to test whether an English version was well understood in this setting. We used the EuroQoL VMC cognitive debriefing tool (Derrett et al., 2021) that comprised techniques such as think-aloud and verbal probing to assess the participant's comprehension of the question, information retrieved to respond to the question, decision process in answering the question, and selection of the response process.

In **Phase 2** (August 2021-February 2022), we conducted an observational cross-sectional study with repeat measures for a sub-sample to investigate the psychometric performance of the EQ-5D-Y-5L compared to the EQ-5D-Y-3L, and CHU9D. The following psychometric properties were assessed (ceiling effects, test- retest reliability, convergent validity, known-groups validity- *see section e for definitions*), using standard guidelines (Mokkink et al., 2010, Chan, 2014). Approximately N=300 adolescents aged 10-15 years were consecutively sampled from study sites (n=150 ALHV from five healthcare facilities, and n=150 adolescents from the general population selected from eight schools). A sub-sample from each arm were telephonically followed-up within two weeks to assess test-retest reliability of the interviewer-administered versions of the EQ-5D-Y-5L versus EQ-5D-Y-3L.

Parental permission together with minor assent were obtained for all potentially eligible adolescent participants prior to enrollment. All study procedures (recruitment, data collection) were piloted with a sample of ALHIV and school pupils.

Furthermore, **in Phase 3 (September 2021-December 2021)**, we conducted semi-structured key informant interviews (KIIs) with HCWs (n=10) (not involved in study implementation) to understand their perceptions on the feasibility of each scale for use among ALHIV in routine healthcare settings. In addition, we conducted n=4 interviews with fieldworkers who were involved in implementing the study (recruitment, questionnaires) to assess their experience with administering each scale. Key informant interviews allow one to obtain general and in-depth information from a diverse group of individuals who have expertise or knowledge about the context where the participants may have limited perspective or lack deep knowledge of a broader situation (e.g. factors affecting HRQoL among ALHIV in this setting) (Green and Thorogood, 2013).

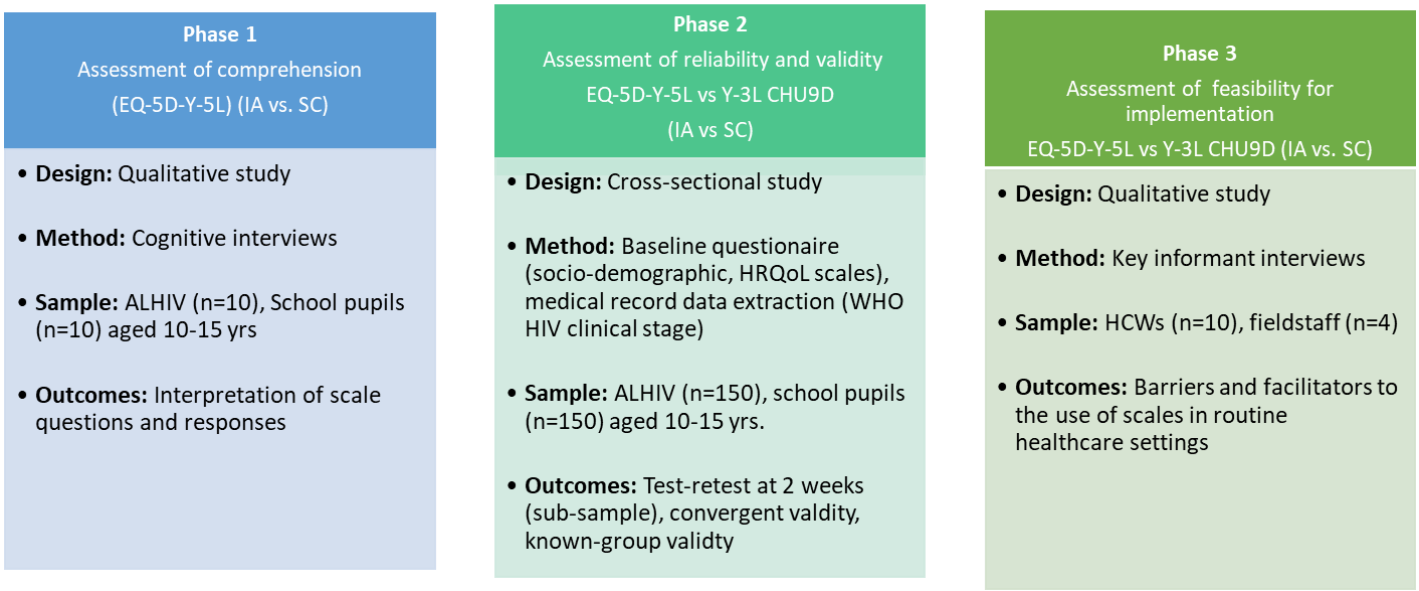

Figure 1: Overview of project design

b. *Participant recruitment and selection*

Phase 1: Cognitive interviews

ALHIV arm

We recruited n=12 ALHIV from study ART clinics. Potentially eligible participants were identified with assistance from HCWs (Table 1). Adolescents living with HIV (aged 10-15 years) who completed at least three years of schooling and had an English literacy levels equal to or above a Grade 3 learner were eligible to participate. English literacy levels were assessed at the point of screening via administration of an assessment sheet adapted from the South African National Department of Basic Education's Grade 3 assessments for second language students (DBE, 2020). We did not exclude participants on the basis of ART, adherence, WHO clinical stage or HIV disclosure status. We purposively sampled such that we had at least n=2 participants in each age-group (10, 11, 12, 13, 14, 15 years of age), and the sample was reflective of each WHO clinical stage distribution, with an even sex distribution, to capture a range of experiences. Clinical-related information that was needed to protect the ALHIV (e.g., HIV disclosure status) or for sampling purposes (WHO clinical stage) was obtained from discussion with the HCWs during pre-screening and not via accessing patient records. We required WHO clinical stage information to ensure that the sample is reflective of a wide spectrum of HIV clinical disease stages (based on WHO HIV clinical stage 1-4).

Potentially eligible participants and their parents were approached by our trained study fieldworkers after their clinical consult (ALHIV) (Figure 2). The fieldworker conducted a brief preliminary screen with each adolescent to verify certain eligibility criteria (i.e., the participant's sex, education status, COVID-19 symptom status) priori to explaining the study in-depth (Appendix 1a). If the parent was interested in the study, then the study fieldworker explained the study to the parent in their preferred language in a private space, using a standardised information sheet (Appendix 2). If the parent provided permission and sign a parental consent form, then the study was explained to the ALHIV in their preferred language, using an age-appropriate information sheet and assent form (Appendix 3). Once parental consent and child assent was obtained, participants were provided with an appointment card detailing the date for their one-on-one interview at the study office. Participants received telephonic reminders of their study appointment.

If ALHIV expressed interest in the study but a parent was not present at the clinic visit, then the adolescent received an envelope with a parental information sheet and consent form (with English and isiZulu copies) (Appendix 2) to take home to their parents for completion (Figure 2). Study contact cards were enclosed in the envelope should the parent wished to schedule a face-to-face or telephonic meeting prior to completion of the consent form. Child assent procedures (Appendix 3) were then conducted individually (face-to-face) with each potential participant who had signed parental permission to participate in the study. If a parent/child was unable to commute to the clinic or study office, then a home visit was conducted to complete consent and assent procedures.

School arm

We purposively sampled n=12 learners from form study school sites. Potentially eligible participants were identified, with assistance from teachers (Table 1). School pupils aged 10-15 years within Grades 4 to 10 and who had English literacy levels equal to or above a Grade 3 learner were eligible to participate. We purposively sampled such that we had at least 2 pupils in each age-strata (10, 11, 12, 13, 14, 15 years of age), and the sample was reflective of each school Grade and had an equal sex distribution.

Potentially eligible participants were approached by our trained study fieldworkers during non-learning period (Figure 2). The fieldworker conducted a preliminary screen with each adolescent to verify certain eligibility criteria (i.e., the participant's age, education status, COVID-19 symptom status) priori to explaining the study in-depth to the potential participant (Appendix 1a). Those adolescents interested in the study received an envelope with a parental information sheet and consent form (containing both English and isiZulu copies) (Appendix 2) to take home to their parents for completion. Study contact cards were enclosed in the envelope should the parent wish to schedule a face-to-face or telephonic meeting prior to completion of the consent form. The study information sheet and assent form (Appendix 3) was only be explained with the potentially eligible participant should they return a signed parental permission slip within a set timeframe. Once parental consent and child assent was obtained, participants were provided with an appointment card detailing the date for their one-on-one interview at our study office. Participants received telephonic reminders of their study appointment.

Phase 2: Cross-sectional quantitative study

Clinic arm

We sampled ALHIV (n=150) from study HIV clinics (*clinic arm*), on the days of their routine clinical appointment. Potentially eligible participants were identified, with assistance from HCWs. Those who completed at least three years of schooling and had English literacy levels equal to or above a Grade 3 learner were eligible to participate. English literacy levels were determined based on a brief assessment conducted by the fieldworker using a short test adapted from the National Department of Basic Education English test template for second language English learners. A fieldworker reviewed the clinic appointment roster for the week, and with advice from HCWs, identified potentially eligible participants that fulfilled the study criteria (Table 1). Clinical information that was needed to protect the minor (e.g., HIV disclosure status) and to aid in sampling (WHO clinical stage), was obtained from the HCW directly, and not via accessing patient clinic records. We required WHO clinical stage information to ensure that the sample was reflective of a wide spectrum of HIV clinical disease stages (based on WHO HIV clinical stage 1-4), and to avoid oversampling of specific groups.

Patients who met the pre-screen criteria were referred by the HCW on the day of their clinic visit after their clinical consult to the fieldworker. The fieldworker then introduced the study to the child and parent. If the parent was interested in the study, the study was explained in-depth with the parent in their preferred language, using the standardised information sheet. If parental consent was obtained (Appendix 5), then the study was explained to child (Appendix 6, Figure 3). Consent and assent procedures were conducted in either English or isiZulu, as indicated by the parent or child, respectively. Unaccompanied minors received an envelope with a parental information sheet and consent form to take home to their parents for completion (Figure 3). Study contact cards will be enclosed in the envelope for the parent to contact study staff to complete consent procedures either telephonically or face-to face at the study clinic or office. Once the child returned to the clinic with a signed parental consent form indicating that the parent provided permission only then were child assent procedure conducted.

If parental consent and child assent was obtained, only then will the ALHIV be enrolled into the clinic arm.

School arm

Pupils in the *school arm* (n=150) were sampled from Grades 4-10 based on those that were in class on the week of study recruitment. Those who had English literacy levels equal to or above a Grade 3 learner were eligible to participate which was assessed using the brief screening test used in the clinic arm. During non-learning periods, field staff conducted a brief introductory session with selected Grades per study school. Those school pupils interested in the study received an envelope with parental information sheet and consent form (Appendix 7) to take home to their parents for completion. Study contact cards were enclosed in the envelope if the parent wished to schedule a face-to-face or telephonic meeting prior to completion of the consent form. School pupils were provided with at least 2 weeks to return signed forms. Child assent procedures (Appendix 8) were then conducted individually (face-to-face) with each pupil who had signed parental permission to participate in the study.

Table 1: Study inclusion for adolescents participating in Phase 1 (cognitive interviews) and Phase 2 (cross-sectional survey)

Inclusion	Exclusion
• Adolescent aged 10-15 years	• Adolescent who was unable to comprehend the nature of the study (during the information and assent session) in either English or isiZulu
• Adolescent who completed at least three years of schooling	• Suicidal ideation, intoxication, or required urgent medical attention * Those excluded for medical reasons were referred to appropriate services
• Adolescent who had **adequate command in spoken AND written English as required for a Grade 3 learnerl ^^** ***^^ Assessed via probing of simple questions and completion of an English Literacy Assessment adapted from the National Department of Basic Education's assessments for English language (additional language, foundation phase, Grade 3). Those who score ≥ 70% will meet the criteria***	• **For ALHIV:** Listed as a person under investigation for COVID-19 based on HCW feedback, as per the NICD criteria • **For school pupils:** Screened positive for COVID-19 symptoms or reported being a current close contact of a confirmed or probable case of COVID-19, as per the NICD criteria
• **For ALHIV:** Diagnosed HIV-positive and attending any study HIV clinic,	

regardless of treatment, clinical, disclosure and co-morbidity status • **For school pupils:** Attending any study school site	
• Adolescent who was able to provide written [$$] informed assent and their parent/caregiver is able to provide written [$$] informed parental consent or a witness is available if the caregiver is illiterate. *$$ Individuals who experienced difficulty due to hearing or vision difficulties were accommodated via the use of an impartial witness to support them through the consent or assent process after which the respondent could provide a fingerprint to indicate consent or assent and to be signed by the witness.*	

Phase 3: Key informant interview

HCWs and study field staff

We conducted KIIs with HCWs (n=10) from all levels involved in HIV care delivery to assess their perceptions on each HRQoL scale and the feasibility of including the EQ-5D-Y-5L in routine monitoring. Clinic managers were approached for a staff list that details the role of each staff member. From this sample frame of approximately 25 HCWs, we purposively sampled 10 HCWs based on their experience working with ALHIV, and ensured all key cadres were represented (e.g., nurses, doctors, counsellors, community healthcare workers, rehabilitation care workers, social workers, occupational therapists, psychologists) (Table 2). Potentially eligible HCWs were approached (Appendix 4), and depending on their preference, consent procedures were conducted either face-to-face or telephonically, and interview dates scheduled with each participant. All study field staff (n=4) involved in questionnaire administration in Phase 2, were approached to participate in study exit interviews. Consent procedures were completed with each staff member (Appendix 4).

Table 2: Study inclusion for HCWs and fieldstaff participating in KIIs.

Inclusion	Exclusion
• HCWs providing HIV care and support to ALHIV within study clinics or in communities	• HCW/study field staff who was unable to comprehend the nature of the study in either English or isiZulu
• HCWs with at least two years of experience providing care and support to ALHIV	• Reported being listed as a person under investigation for COVID-19 based on HCW feedback, as per the NICD criteria
• Study field staff who administered at least n=20 questionnaires in Phase 2 (Cross-sectional survey)	
• HCWs/study field staff who were able to provide written informed consent	

c. Data collection

Phase 1:Cognitive interviews

A trained researcher assistant (post-graduate social science student) with support from a field staff (HIV counsellor) conducted one-on-one cognitive interviews with each adolescent participant (N=24: 12 ALHIV arm, 12 school arm) between April-August 2021 to assess their interpretation of scale items and ability to recall questions and responses of the English-versions of the EQ-5D-Y-5L interviewer-assessed (IA) and self-completed (SC) scales (Table 3). The researcher used a cognitive debriefing interview guide (Appendix 9), informed by the EuroQoL cognitive debriefing guide and standard guidelines (Collins, 2003).

The cognitive interviews were conducted in English and first entailed a ranking exercise whereby all participants per arm were asked to rank the response levels for each problem dimension on the EQ-5D-Y-5L scale (e.g., walking about, pain or discomfort). The ranking game was developed based on the EuroQol Group procedures to ensure the qualifiers were understood in the correct hierarchical order (Derrett et al., 2021). The ranking game was used to introduce participants to severity levels so that they would be better acquainted to- and understand- what was expected of them when responding to the dimensions of the EQ-5D-Y-5L scale. The game was explained- and administered- to participants by trained field team members. Briefly, participants were given four sets of cards, each set representing a HRQoL dimension (e.g. walking about, washing or dressing, pain or discomfort; and worried, sad or unhappy). Each deck of cards contained five cards representing the five levels of severity within that dimension. The severity levels ranged from not experiencing that dimension (score “1”), to experiencing extreme levels of that dimension (score “5”). Each participant was asked to rank the order of severity of response options for each dimension by placing the cards containing severity responses into boxes provided, where each box represented a different magnitude of severity (see Figure 1). Cards with response options were then removed from each box as per the degree of severity indicated by participants and used to generate response profiles for each participant. Based on the scoring of severity levels, a participant who correctly ordered the severity levels of a dimension, generated a profile of *1234* (i.e. correctly ranked severity from absence of- to extreme levels) for that dimension. Table 2 presents the frequency of participants who generated the correct profile (i.e. 1234) for each dimension of the ranking game per study arm.

Thereafter, 50% of the sample in each arm were asked to self-complete the EQ-5D-Y-5L, whereas field staff administered an interviewer-administered mode of the scale with the remaining 50% of participants per arm. The researcher then used think-aloud and verbal probing to assess their experience with completion of the scale (e.g., *I noticed you hesitated before you answered – what were you thinking about; Which words were confusing? Which words would you change, What are your thoughts on how the form is set-out? Did you remember all the response options? Could you repeat some of the questions or response options I mentioned/that were on the form?*). Interviews were conducted after the participant's clinic appointment (ALHIV) or non-teaching periods (school arm). The researcher discreetly timed and observed the participant during scale completion, taking notes at key points. The participant was given ample time to complete each activity, with sufficient breaks. Once each interview was complete, the researcher detailed the outcome of each activity in the cognitive debriefing interview guide (Appendix 9).

All qualitative interviews were conducted in a private and well-ventilated room. Furthermore, interviews were audio recorded, provided permission was obtained from the participant.

Table 3: Cognitive interviews- data collection interviews

	Ranking exercise EQ-5D-Y-5L	Scale completion EQ-5D-Y-5L (Self-administered)*	Scale completion EQ-5D-Y-5L (Interviewer-administered)*
Clinic arm (ALHIV, n=12)	All	N=6	N=6
School arm (pupils, n=12)	All	N=6	N=6

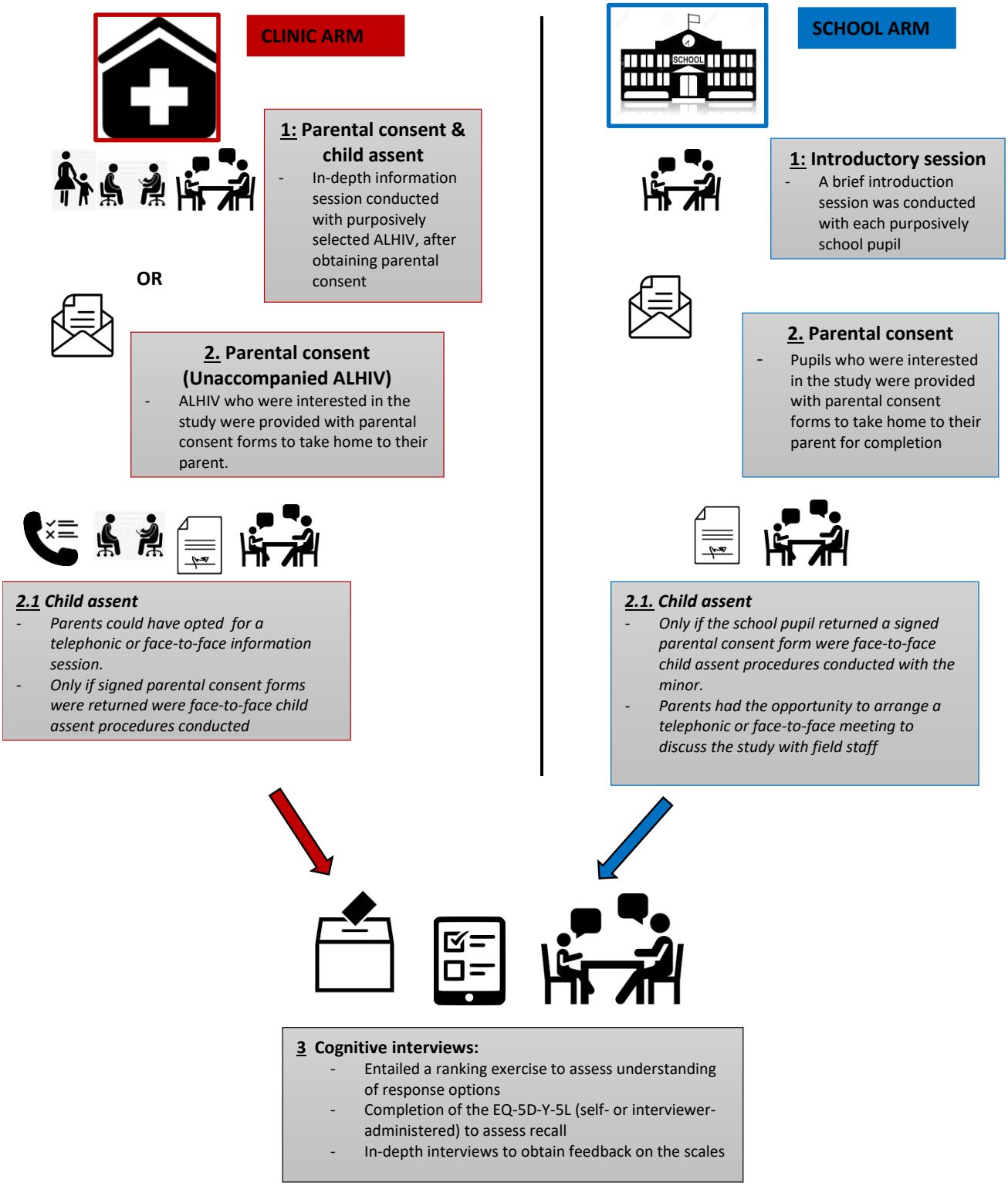

Figure 2: Cognitive interviews with adolescents: Illustration of key study processes, from enrolment through to data collection

Phase 2: Cross-sectional quantitative study

Once enrolled, all participants in each arm (clinic and school arm) underwent a brief electronic baseline questionnaire (Appendix 11). The baseline questionnaire contained the following modules: demographics (age, sex, education); living standards (household type, access to basic needs- water, electricity, food); overall self-rated health status; HRQoL scales). Socio-economic data was collected as these factors are known to impact HRQoL among ALHIV in SSA (Rukuni et al., 2018, Skovdal and Belton, 2014). A description of the HRQoL scales to be collected are detailed below:

I. EQ-5D-Y (5L, 3L)

Both versions of the EQ-5D-Y (5L and 3L) have five descriptive dimensions (*mobility, looking after myself; usual activities; having pain or discomfort; and feeling worried, sad or unhappy*) (Kreimeier et al., 2019). Scoring on the 5L is on a five-point Likert scale (1=no, 2=little bit, 3=some, 4= a lot, 5=extreme), whereas scoring for the 3L is on a 3-point Likert scale (1=no, 2=some, 3=a lot). Both the 5L and 3L include a VAS on which subjective overall health is self-rated, between 0 = worst health imaginable and 100 = best health imaginable. We used the EQ-5D-Y-5L as our primary outcome measure. In each arm, all participants completed either the EQ-5D-Y-5L and EQ-5D-Y-3L scale, using either the IA or SC versions as detailed below (Table 4).

II. CHU9D

This descriptive generic HRQoL measure consists of nine dimensions (worried, sad, pain, tired, annoyed, school work, sleep, daily routine and activities), each with five response levels (Ratcliffe et al., 2012). Scoring is on a five-point Likert scale (1=don't, 2= a little bit, 3= a bit, 4= quite a bit, 5=very). All participants in each arm completed the CHU9D scale, in self-completed mode as this is the only mode currently available.

To reduce ordering bias, the order of HRQoL scales and other modules in the questionnaire were reversed for 50% of the sample in each arm. Each HRQoL was separated by an ice-breaker activity (i.e., a simple stretch or breathing break with a cognitive task (e.g., "how many triangles do you see

on this laminated sheet?") (Table 4). The fieldworker used a stopwatch to discreetly time the participant's completion time for each scale.

Thereafter, field staff extracted HIV clinical data for all ALHIV enrolled in the clinic arm from electronic records (Tier.net) or patient files, provided permission was granted. The following information was extracted from records based on data from the most recent set of clinic visits (e.g., ART regimen, adherence levels based on pill count data, any co-morbidities, WHO clinical stage, viral load) (Appendix 12). WHO clinical staging for HIV/AIDS sorts patients into four stages of disease progression based on the presence of specific conditions or symptoms (WHO, 2013):

- **Stage 1 (asymptomatic):** *E.g., Asymptomatic or Persistent generalised lymphadenopathy*
- **Stage 2 (mild symptoms):** E.g., *Moderate unexplained weight loss (<10% of presumed or measured body weight), recurrent respiratory tract infections (sinusitis, tonsillitis, otitis media, pharyngitis)*
- **Stage 3 (advanced symptoms):** E.g., Unexplained severe weight loss (>10% of presumed or measured body weight), Unexplained chronic diarrhoea for longer than 1 month.
- **Stage 4 (severe symptoms):** E.g., HIV wasting syndrome, Pneumocystis pneumonia, Recurrent severe bacterial pneumonia

Finally, we sought to consecutively sample n=100 participants in each arm for a follow-up telephonic interview (Appendix 13). These follow-up interviews assessed the test-retest reliability of the IA version of the EQ-5D-Y-5L versus EQ-5D-Y-3L (Appendix 14). The aim was to conduct these interviews within two-weeks post-the baseline questionnaire (Table 4). We initiated follow-up within 48 hours post-baseline questionnaire completion. If the participant was uncontactable during the two-week period, after least 3-4 follow-up attempts, then he/she was deemed "lost-to follow-up", and additional participants was sampled until the target sample size is reached.

In psychometric evaluations, one has to first evaluate the scale in a new setting using the original language used in developing the scale, prior to translations (Bowden and Fox-Rushby, 2003). As there are no published data from psychometric evaluations of the EQ-5D-Y-5L among adolescents in South Africa at the study onset, we used the source language (English) for all scales (Y-5L & Y-3L: United

Kingdom English; CHU9D: United Kingdom English as there is no South African English version available). We did not use isiZulu versions for each scale type as this language was not yet available at the time of doing the study.

All questionnaire data was captured electronically on REDCap (Version 7.4.1) using electronic tablets. We used REDCap versions of each HRQoL scale that was supplied or approved by the developer of each scale.

For the clinic sample, questionnaire administration was conducted at our study office or a private space at the clinic. Given the lack of space within schools, we set-up medical tents with adequate ventilation on the school tarmac or sports field for staff to conduct study activities (i.e. assent procedures, questionnaire administration).

If a participant was unable to commute to the clinic, school or study office then a home visit was conducted to complete the questionnaire.

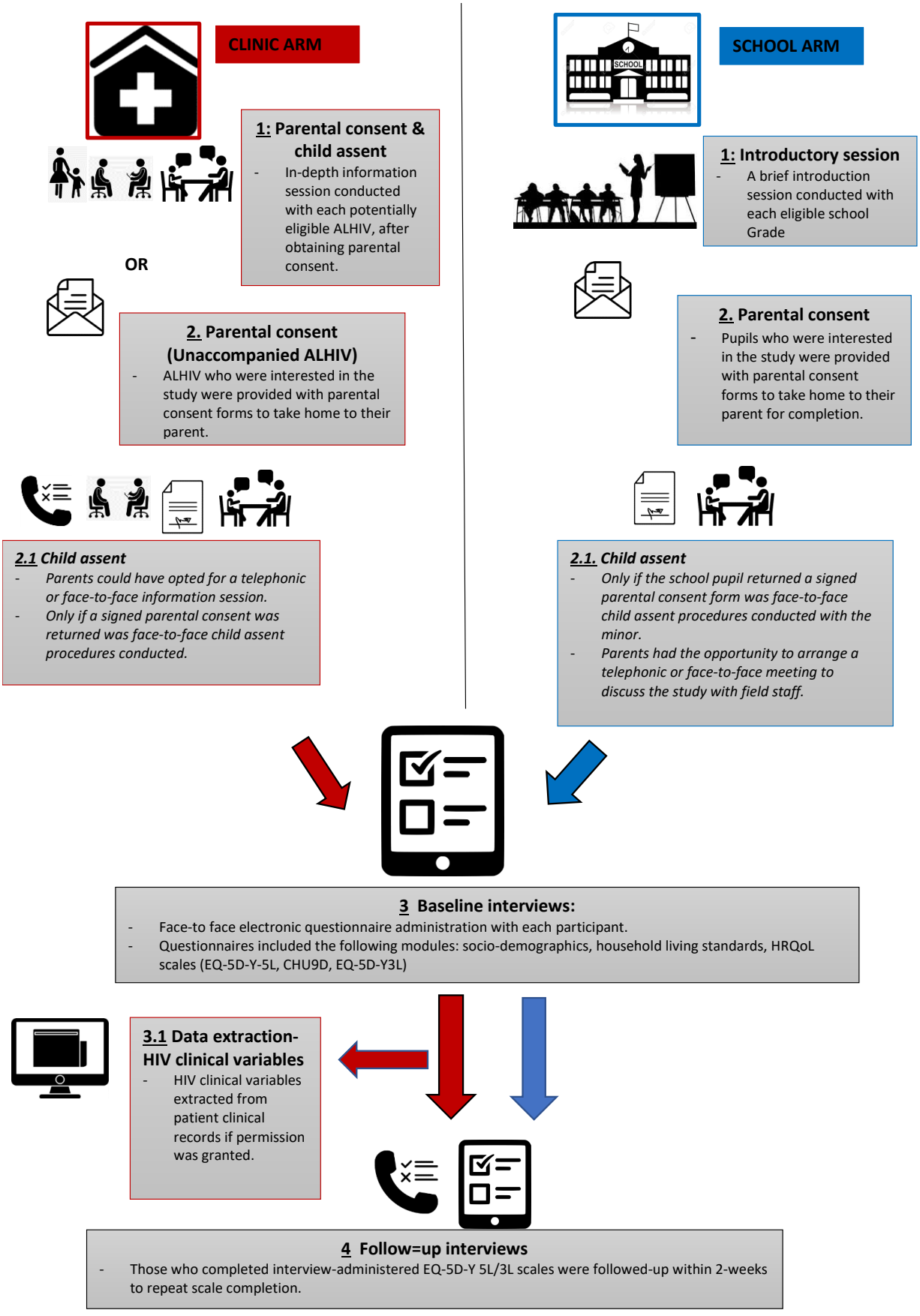

Figure 3:Cross-sectional survey : Illustration of key study processes from enrolment through to data collection

Table 4: Phase 2- Cross-sectional survey: Questionnaire structure

	BASELINE QUESTIONNAIRE**						DATA EXTRACTION-CLINIC RECORDS	FOLLOW-UP QUESTIONNAIRE
	Socio-demographics	EQ-5D-Y	ICE-BREAKER$	CHU9D	ICE-BREAKER$	EQ-5D-Y	HIV-related clinical variables	Test-retest EQ-5D-Y
Clinic arm (ALHIV)* N=150								
N=38 (HIV clinical Stage 1)	✓	✓ 3L-IA	✓	✓ SC	✓	✓ 5L-SC	✓	3L-IA (n=25)
N=37 (HIV clinical Stage 2)	✓	✓ 3L-SC	✓	✓ SC	✓	✓ 5L-IA	✓	5L-IA (n=25)
N=38 (HIV clinical Stage 3)	✓	✓ 5L-IA	✓	✓ SC	✓	✓ 3L-SC	✓	5L-IA (n=25)
N=37 (HIV Clinical Stage 4)	✓	✓ 3L-IA	✓	✓ SC	✓	✓ 5L-SC	✓	3L-IA (n=25)
School arm (Pupils) N=150								
N=38	✓	✓ 3L-IA	✓	✓ SC	✓	✓ 5L-SC	N/A	3L-IA (n=25)
N=37	✓	✓ 3L-SC	✓	✓ SC	✓	✓ 5L-IA	N/A	5L-IA (n=25)
N=38	✓	✓ 5L-IA	✓	✓ SC	✓	✓ 3L-SC	N/A	5L-IA (n=25)
N=37	✓	✓ 3L-IA	✓	✓ SC	✓	✓ 5L-SC	N/A	3L-IA (n=25)

* Groups were stratified by WHO HIV clinical stage for assessment of known group validity; ** The order of the modules were reversed for 50% of the sample in each arm; $: All ice-breaker activities were standardised across groups, it included a stretch or breathing break and a light cognitive task; IA= interviewer-administered, SC=self-completed

Phase 3:KIIs

Key informant interviews were conducted between September and December 2021 with HCWs (n=10) to assess their perceptions of the feasibility of each scale (EQ-5D-Y-5L, EQ-5D-Y-3L, CHU9D) for routine HIV care programmes. The researcher used a loose topic guide (Appendix 10), mapped on Slade et al. (1999) checklist for assessing feasibility of each scale (i.e. brevity, simplicity, relevance, acceptability, availability, value). Questions to be probed include *("What are your opinions on the layout and length of scale?; "Are the instructions and questions clear?"; "Would you recommend changes to specific questions or responses?; "Do you consider the dimensions relevant for ALHIV?"; "How should the scale be administered and which cadre would be best suited to administer the scale?"; "How would information derived from this scale improve your clinical management or evaluation of your programme?"; "What would be some of the challenges you would encounter in obtaining buy-in to implement this scale in the clinic?").* At the end of study activities related to Phase 2, brief exit interviews were conducted with the study field staff (n=4) to understand their experiences with completion of the scale (*"What worked or did not work with regards to the administration of each scale?"; "What questions/responses did participants have difficulty understanding and how would you have adapted this?"; "What would be you advice to HCWs who wish to implement this scale in clinics or community-based programmes?")*

d. Outcomes

Phase 1: Cognitive interviews

- **Content validity:** to qualitatively assess the extent to which the scale comprehensively measures concepts relevant to the condition, important to patients, and understandable for ALHIV
- **Face validity**- the acceptability and appropriateness of item wording, recall period and response options to patients

Phase 2: Cross-sectional quantitative study

Primary outcome

- **Known-groups validity:** the degree to which the EQ-5D-Y-3L vs. EQ-5D-Y-5L (IA, SC) and CHU9D (SC) are able to discriminate between groups that are known to different based on WHO clinical stage.

Secondary outcomes

- **Test-retest reliability:** the degree to which scale scores obtained from same participant remain consistent over brief periods (internal validity) for the EQ-5D Y- 3L (IA) and Y-5L (IA).
- **Convergent validity:** the degree to which two measures of constructs that are theoretically related are correlated for the EQ-5D-Y-3L vs. EQ-5D-Y-5L (IA, SC) and CHU9D (SC)
- **Ceiling effects:** the proportion of responses reflecting extreme problems for each dimension the EQ-5D-Y-3L vs EQ-5D-Y-5L (IA, SC) and CHU9D (SC).
- **Differential item functioning**: to assess the extent to which differential item functioning is present in the EQ-5D-Y-3L vs EQ-5D-Y-5L (IA, SC) (i.e. does the instrument perform differently by arm).

Phase 3: KIIs

- **Perceptions of the feasibility of each scale for use in routine HIV care programmes:** perceived factors that will facilitate or impede implementation of HRQoL scales within HIV clinics

e. Sample size justification: cross-sectional study

We aimed for a sample size of N=300 (n=150 ALHIV, n=150 school arm). This sample size was sufficient to satisfy the sample needed to assess our primary outcome (known-group validity). The total number of ALHIV estimated to establish known-group validity between the WHO HIV clinical stages (1, 2, 3, 4) and VAS scores was approximately n=128 (Table 1). The calculation was based on One-way ANOVA F-test, and moderate effect size of 0.3 between the VAS score on the EQ-5D-Y-5L and WHO clinical stage group (Scott et al., 2017). We estimated that a minimum sample size of 32 per arm was needed to have 80% power to detect an effect size (Table 5).

Table 5: Estimated sample size for one-way ANOVA

F test for group effect, Ho: delta = 0 versus Ha: delta != 0

alpha	power	N	N_per_group	delta	N_g	Var_m	Var_e
.05	.8	128	32	.3	4	.09	1
.05	.8	96	24	.35	4	.1225	1
.05	.8	76	19	.4	4	.16	1
.05	.8	60	15	.45	4	.2025	1
.05	.8	48	12	.5	4	.25	1
.05	.8	44	11	.55	4	.3025	1
.05	.8	36	9	.6	4	.36	1
.05	.8	32	8	.65	4	.4225	1
.05	.8	28	7	.7	4	.49	1

* STATA command: power oneway, ngroups(4) delta(.3(.05).7) power (0.8)

This sample size was also sufficient for assessing our secondary outcome (test-retest reliability of the EQ-5D-Y scales). Assuming a mean VAS score on the EQ-5D-Y-5L of 77.8 at baseline (Scott et al., 2019) and mean VAS score of 80.8 (Wong et al., 2019a) at follow-up , and intraclass correlation co-efficient (ICC) of 0.70-0.77 (Scott et al., 2017), we estimated we would need a minimum sample size of n=43 participants in each arm to have 80% power to detect an ICC of 0.7 (Table 6). We aimed to sample n=100 in each arm as we estimated that approximately 50% of participants will be lost-to follow-up. The remaining sample (n=50) will be sufficient to meet the minimum sample size requirements for test-retest reliability.

Table 6: Estimated sample size for repeated-measures ANOVA

F test for within subject with Greenhouse-Geisser correction. Ho: delta = 0 versus Ha: delta != 0

alpha	power	N	N/N_g	delta	N_g	N_rep	Var_w	Var_we	Var_e	Corr (rho)
.05	.8	56	56	.38	1	2	2.3	15	77	.6

.05	.8	49	49	.41	1	2	2.3	13	77	.65
.05	.8	43	43	.44	1	2	2.3	12	77	.7
.05	.8	36	36	.48	1	2	2.3	9.6	77	.75
.05	.8	33	33	.5	1	2	2.3	8.9	77	.77
.05	.8	29	29	.54	1	2	2.3	7.7	77	.8

* STATA command: power repeated 77.8 80.8, corr(0.7) varerror(77)

f. Analysis

Phase 1: Cognitive Interviews

Characteristics of the sample by arm (e.g. age, sex, school grade, household type) were presented using percentages and medians (IQR) for categorical and continuous data, respectively. Results from the ranking exercise, scale completion or recall assessment (e.g., percentage responses ranked correctly, percentage missing response, percentage of questions and dimensions recalled, median number of questions or responses recalled) were also described by arm.

We used a framework method for analysis of our qualitative data (Gale et al., 2013). In *Stage 1 (Transcription)*, all electronic audio-files were transcribed and checked by a member on the team. *Stage 2 (Familiarisation)* entailed listening to the audio, reading the transcript and fieldnotes and discussing this at regular meetings with the PI and qualitative research assistant. *Stage 3 (Coding)* entailed coding of a few transcripts on NVivo 12 (Gale et al., 2013). Thereafter, in *Stage 4 (Developing a working framework)*, codes that emerged from the initial transcripts were grouped into categories (e.g. Ranking game- meaning of dimensions, words that sounded strange, words not understood, recall of response options, recommendations for changing words, length of scale) which in turn were grouped into themes (ease of understanding, challenging words, key revisions). Once the framework was finalised, we applied this to the remaining transcripts via coding on NVivo and updated the file with any new codes and categories that emerge *(Stage 5: Applying the analytical framework)*. In *Stage 6 (Charting data into a framework matrix)*, we extracted key quotes from transcripts that exemplified a category, and a matrix (i.e., a summary of categories per transcript) was produced. The final stage, Stage 7 (Interpretation), was conducted jointly with both the field and investigator team. During this process, differences and similarities identified in the data (e.g., perceptions by age, arm) were discussed. Furthermore, relationships between categories and themes were mapped and discussed.

Phase 2: Cross-sectional quantitative study

All statistical analyses were conducted using Stata (V.16, Stata Corp, College Station, Texas, USA). Descriptive statistics were estimated to describe the socio-demographics characteristics (age, sex) of our sample and their household socio-economic status. Statistical differences (p value ≤ 0.05) in demographics, household socio-economic status, and perceived health status variables between the clinic and school arm were assessed by conducting a Chi-square test for categorical data and Kruskal-Wallis H test for continuous variables.

For the HRQoL data, the proportion of responses per dimension and response level and percentage missing were reported for each scale (EQ-5D-Y-5L, EQ-5D-Y-3L and CHU9D), stratified by group. In addition, the median (IQR) VAS score (EQ-5D-Y scales (5L, 3L), reflective of overall health status, were estimated. We estimated the median time to completion per HRQoL scale for each group. Wilcoxon ranksum test was used to assess differences in continuous variables between the school and clinic arm (e.g. age). Chi-square test was used to assess the associations between categorical variables by arm (e.g. sex).

We compared 3L and 5L responses within pairs of matched individuals within an identical stratum and used matched responses to examine inconsistency. We recoded 3L responses to the equivalent for the 5L, e.g. 1 = 1, 2 = 3, and 3 = 5, and assumed that in the absence of the version change, the 5L and recoded 3L responses within matched pairs would have been identical. Following Janssen et al. (2008)., we defined an inconsistent response for a domain as a response to the EQ-5D-3L that is at least two levels away from the EQ-5D-5L, e.g. an individual reporting ‘no pain or discomfort’ on the EQ-5D-3L but their matched respondent reporting ‘moderate pain or discomfort’ on the EQ-5D-5L.

The discriminatory power of the Y-3L and Y-5L dimensions was assessed using the Shannon Index (H') and Shannon Evenness Index (J') in terms of absolute and relative informativity (Janssen et al., 2008). The maximum H' index on the Y-3L and Y-5L, respectively, is 1.58 and 2.32, reflecting the descriptive system's ability to capture more information. No matter how many levels are included in the descriptive system, the Shannon Evenness Index (J') shows how the responses are distributed across the levels. The difference was calculated between Y-5L and Y-3L.

The test-retest reliability was assessed for the EQ-5D-Y-5L (IA) vs. EQ-5D-Y-3L (IA) by calculating Gwet AC to assess the agreement between baseline and follow-up responses for each dimension on EQ-5D-Y scales (5L, 3L). The Gwet AC was used due to relatively low variability in response options.

The convergent validity was explored using item-level correlation matrices (Spearman's rho) between the EQ-5D-Y dimension score , VAS, CHU9D dimension score (*worried, sad or unhappy; daily routines; school work; and pain or discomfort*), and self-rated health. Correlations were further assessed via linear regression techniques. We examined the p-values of β co-efficients to assess if scale items (e.g. EQ-5D-Y- "mobility") are statistically correlated with self-rated health (Boateng et al., 2018). We adjusted regression models for a priori confounders (age, sex). Summary scores were calculated as row totals and all zeros were considered as missing values because they did not answer the dimensions. Median summary scores (Y-3L [IA and SC], Y-5L [IA and SC], and CHU9D) were assessed Wilcoxon Rank Sum test between the two groups. The summary scores were not normalized on all the instruments. Due to lack of South African preference-weighted score for the Y-5L, Y-3L and CHU9D, only dimension level scoring was assessed.

The disease severity of ALHIV was categorised based on the international WHO HIV clinical staging criteria (WHO, 2010) (stages 1-4), which is routinely used in South Africa's HIV treatment programme (SAHCS, 2017). As an alternate measure of disease severity, we used HIV-virological suppression status of participants (based on biomarker HIV-RNA data: ≤40 copies/mL= suppressed; > 40 copies/mL= unsuppressed). As we had only 1 participant in stage 4, we merged this individual in the stage 3 group. The known group validity of the Y-3L, Y-5L was established by comparing the median differences between VAS scores or summary scores and disease severity . Kruskal Wallis test was used when the disease severity had three categories otherwise Wilcoxon rank sum was used.

As a secondary analysis, we used logistic regression techniques to assess differential item functioning (to examine how scores differ by group) or item performance (e.g. ordering and spread of levels across the latent trait, relative importance of items to underlying construct etc.) (Martinková et al., 2017). The score was a row total score obtained from summing all the responses of the dimensions per observation. The OLR approach for detecting DIF proposed by Zumbo (1999) was followed. Because of low sample size, we used the compete data for the development phase and randomized

95% of the data for validation phase of our results. The OLR DIF approach involves an iterative three-stage process enabling the detection of both uniform and non-uniform DIF. In Stage 1 a OLR is run with variable item score as the dependent variable and EQ LSS as the only independent variable (model 1). In Stage 2, the arm (clinic=0, school=1) independent variable is added to model 1. If the arm coefficient is statistically significant (assuming a Bonferroni corrected p-value of 0.05/5 items =0.01) then this item is considered to exhibit uniform DIF. In Stage 3, the observed health*arm interaction is added to model 2 (model 3). If the interaction is statistically significant, then the item is considered to exhibit non-uniform DIF. Items with significant p-values, and $\Delta R^2 \geq 2\%$, are considered to have meaningful DIF. This method has been widely used in the literature (Zumbo, 1999). R^2 differences between models 1 and 2 and models 2 and 3 can also be used to further investigate whether the majority of the DIF stems is uniform or non-uniform DIF. OLR analyses were conducted in SPSS version 27

Phase 3: Key informant interviews

We used the framework approach (described in Phase 1). Briefly, audio-recordings were transcribed, translated and checked for accuracy. A research assistant (RA) reviewed the first few transcripts in-depth and developed a codebook based on key questions and responses that emerged. All transcripts were then coded on NVivo and new codes added to the codebook as they emerged. Codes were then grouped into key categories (e.g. layout, clarity of instructions, questions, responses or VAS, suggestions for improving the scale, use in HIV clinics, challenges with implementing scales in the field). Thereafter, the RA and co-investigators (SC, DG) examined the data by scale and mode of administration, interpreted the data and identified supporting quotes.

5) Data management

a. Management

Data were managed at the SAMRC-Durban study office. Detailed data collection and quality assurance SOPs were developed and implemented, with regular SOP training provided to staff. Quantitative data was collected anonymously on an electronic database (REDCAP) on password protected Tablets. This database contained built-in skip patterns and validation checks to ensure internal integrity of the data. REDCAP data collection occurred in live mode with the assistance of wireless routers and built-in data cards. This facilitated real-time checking of data. Qualitative interview data was collected anonymously on a digital audio-recorder. All databases and forms were piloted and revised to reduce mistakes in completion and ensure reliability.

Data cleaning was conducted weekly by the by the PI using STATA (V 16). Electronic forms were screened to assess completeness and identify any inconsistencies or errors. Simple descriptive analyses were conducted to determine outliers, inconsistencies, strange patterns in the distribution, and missingness. Data management issues were addressed and resolved at regular quality control meetings. Identified missing fields were checked against the files or other source documents (e.g. routine clinic records). Audio-recordings of qualitative interviews were transcribed and translated and checked for accuracy by the qualitative research assistant. Transcripts were imported into NVivo and coded.

b. Storage

The REDCAP study database, data exports (.csv and .dta files), electronic audio-recordings (.mp3 files), and code files were stored on the SAMRC server, in a study folder with controlled access restricted to authorised study staff. This study folder was regularly backed-up onto an external electronic hard drive. Furthermore, once audio-recordings were uploaded, they were deleted from the digital device.

For both the quantitative and qualitative datasets, the PI developed an electronic data codebook.

All study forms and electronic devices (Tablets, digital recorders and hard drives) were stored in a locked cupboard at the study office with controlled access.

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6) Ethical considerations

Research ethics approval was sought from the SAMRC HREC. Approval to conduct this study within clinics and schools was sought from KwaZulu-Natal government bodies in health (Provincial Health Research Ethics Committee-Health Research and Knowledge Management), and education (The Research Unit, Resource Planning Department of Basic Education).

Voluntary written informed consent or assent was obtained from participants prior to participation. As this study involves minors (10-15-year-olds), parental consent (i.e. parental permission on behalf of the minor) together with child assent (i.e. affirmative agreement) was obtained for minors. Written parental consent was confirmed prior to enrolment of the minor in the school arm.

All adolescent participants in Phases 1 or 2 were provided with a school-related item pack which will include stationery and a lunch snack (total value of R100) in order to reimburse them for their time or any other opportunity costs. All parents or ALHIV who arrived at a study clinic specifically for the purposes of completing study-related activities (consent or assent procedures, questionnaires) were reimbursed for their transport costs (R30-45, return trip). Furthermore, healthcare providers and fieldworkers participating in the qualitative interviews will receive a water bottle (total value of reimbursement= R100).

7) Results

I. Phase 1- Cognitive interviews

a. Recruitment flow

The median age of study participants for both arms was 13 years (IQR:11-14) (Table 1). Sex was distributed evenly intra- and inter- study arm. The median school grade for the clinic arm was 7 years [IQR:5-8] and 8 years [IQR:6-8] for the school arm. The majority (n=8, 67%) of clinic arm participants were in WHO Stage 1. We were unable to enrol any participants who were in WHO stage 4 because all approached were at a very advanced stage of disease progression and hospitalised or being referred for hospitalisation at the time. It was, therefore, not possible to screen them for potential enrolment.

Table 1: Cognitive study participant demographic information

Demographic	Clinic (n=12)	School (n=12)
Median age (IQR)	13 (11-14)	13 (11-14)
Sex		
- Male	6	6
- Female	6	6
Grade	7 (5-8)	8 (6-8)
WHO Staging		
- Stage 1	8	-
- Stage 2	2	-
- Stage 3	2	-

b. Ranking game

All participants in the clinic arm correctly ranked the order of severity for each of the HRQoL dimensions (Table 2). In contrast, none of the dimensions had all 12 school arm participants correctly ordering the severity of responses. Instead, the highest correctly ranked responses were for the pain or discomfort dimension, which had 75% (n=9) participants ranking the order correctly. The poorest performing ranking was for the walking about dimension, with 50% (n=6) of school arm participants correctly ordering the severity levels, which suggests that perhaps school arm participants may have not understood what was expected of them initially.

Differences in these results could be explained by the limited time the interviewer had with the school arm participants due to COVID-19 restrictions in school settings, with a few ranking game activities completed by a second support fieldstaff when the main facilitator was attending to clinic arm participants.

Table 2: Ranking order game correct ordering of response levels

Dimension	Clinic (n=12)	School (n=12)
1. Walking about	12	6
2. Washing or dressing*	12	8
3. Pain or discomfort	12	9
4. Worried, sad or unhappy	12	8

* In the VMC Cognitive Debriefing Tool this dimension is referred to as washing or dressing

Figure 1: Ranking game exercise

***Participants placing cards containing severity responses into different sized boxes, each box representing a different severity level.**

c. Recall assessment

Recall of questions in the EQ-5D-Y-5L (IA) was higher in the clinic arm (75%) vs. the school arm (42%) (Table 3). Dimensions that participants were able to recall was “walking about” followed by “pain or discomfort”. Similarly, recall of response options was higher in the clinic arm (83%), with most participants being able to recall the “no problem” response level.

Table 3: Assessment of recall on the EQ-5D-Y-5L (IA)

EQ-5D-Y-5L	Clinic (n=12) n (%)	School (n=12) n(%)
Recalled a question		
Yes	9 (75%)	5 (42%)
No	3 (25%)	7 (58%)
Median number of questions recalled (IQR)	1 (1-1)	0 (0-1)
Dimension recalled		
Mobility (walking about)	8	3
Looking after myself	1	0
Doing usual activities	0	0
Pain or discomfort	3	3
Worried, sad or unhappy	2	0
Recalled a response		
Yes	10 (83%)	5 (42%)
No	2 (17%)	7 (58%)
Median number of responses recalled (IQR)	1 (1-2)	0 (0-1)
Response level recalled		
No problem	7	2
A little bit	2	4
Some	3	1
A lot of	3	1
Cannot/extreme	1*	0

- **Respondent recall extremely**

d. Perceptions of the EQ-5D-Y-5L scales

After being administered the SC and IA EQ-5D-Y-5L scales, participants were asked to give feedback of their experiences with using the scales. Specifically, they were asked to explain what the different dimensions meant to them and to highlight any words or phrases that they found a bit challenging in the instructions, dimensions and response options.

a. Understanding of scale dimensions

Participants from both study arms (n=24) were asked to explain their understanding of the meanings of the words used to describe each of the five dimensions of the EQ-5D-Y scales (i.e. mobility, looking after yourself, doing usual activities, having pain/discomfort; and feeling worried, sad or unhappy). Each participant was asked the meaning of a few dimensions (i.e. not all the dimensions were asked to any one participant). What follows are infographic representations of the frequently said words/phrases that participants used to describe each dimension (Figures 2 to 7). The size and boldness of the words in the infographics are a direct reflection of the frequency with which the word/phrase was used (i.e. larger and bolder suggests more frequent response).

Dimension 1: Mobility

Participants generally understood *mobility* to mean performing some sort of action or activity. The most frequently used words to explain *mobility* were “to move” or “to walk” (Figure 2). Less frequently used words/phrases to describe *mobility* were “to shake” and “to do something”.

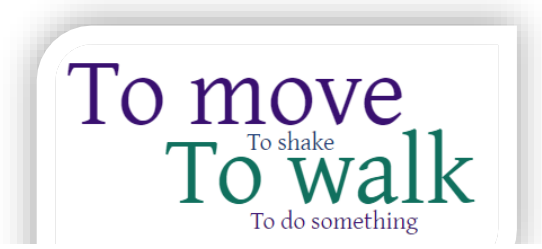

Figure 2: Meaning of “Mobility” infographic

Dimension 2: Looking after yourself

"Bathing" was the most frequently used word associated with "looking after yourself" (Figure 3). "Good health", "taking care of yourself" and performing "household chores" were the second most frequently cited group of words used to describe what "looking after yourself" meant. Other words associated with "looking after yourself" were "looking presentable" and "eating"

Figure 3: Meaning of "Looking after yourself" infographic

Dimension 3: Doing usual activities

Doing "Household chores", "playing" and "doing sport/exercising" were the dominant words/phrase used to describe what "doing usual activities" meant (Figure 4). Other words used to describe "doing usual activities" included "bathing", doing "homework, "eating", "sleeping", "watching TV"

Figure 4: Meaning of "Doing usual activities" infographic

Dimension 4: Having pain or discomfort

"Having pain or discomfort" was frequently understood to mean "not feeling well" or "hurting" or "uncomfortable" (Figure 5). "Body aches" and "bleeding" were also used to describe "having pain and discomfort".

Figure 5: Meaning of "Having pain or discomfort" infographic

Dimension 5: Worried, sad or unhappy

"Sadness" was the dominant word used to describe "feeling worried, sad or unhappy" (Figure 5). "Stressing" was also more frequently used compared to the other words in describing this dimension. Other words or groups of words included "missing loved ones", feeling unwell", "upset", "thinking a lot", "crying", "feeling fatigue", being "upset" and "feeling faint".

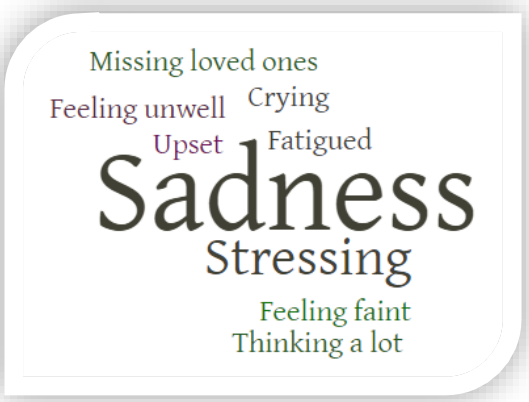

Figure 6: Meaning of "Worried, sad or unhappy" infographic

b. Challenging words

When asked which words they found a bit challenging or funny, “mobility” was often cited (Figure 7). “Extremely” and “a little bit” were also said to be a bit unclear or to sound funny. Given the opportunity, participants indicated that they would use different words. However, they were not asked to provide alternative words.

Figure 7: Challenging words

II. Phase 2- Survey

a. Recruitment flow

A total n=167 ALHIV were approached for participation in HIV clinics (Figure 1a). Of these, 3 parents refused consent, 4 did not meet the age criteria, and due to ethical reasons, 1 minor not on ART and 4 minors with severe mental health issues, could not be enrolled. Of the remaining n=155 that were potentially eligible, 2 minors failed the English comprehension tests and 1 could not comprehend the nature of the study, leaving n=152 in the clinic arm. We aimed to telephonically follow-up n=117 (77%) who completed the survey. Of these participants, 91% (n=106) could be reached.

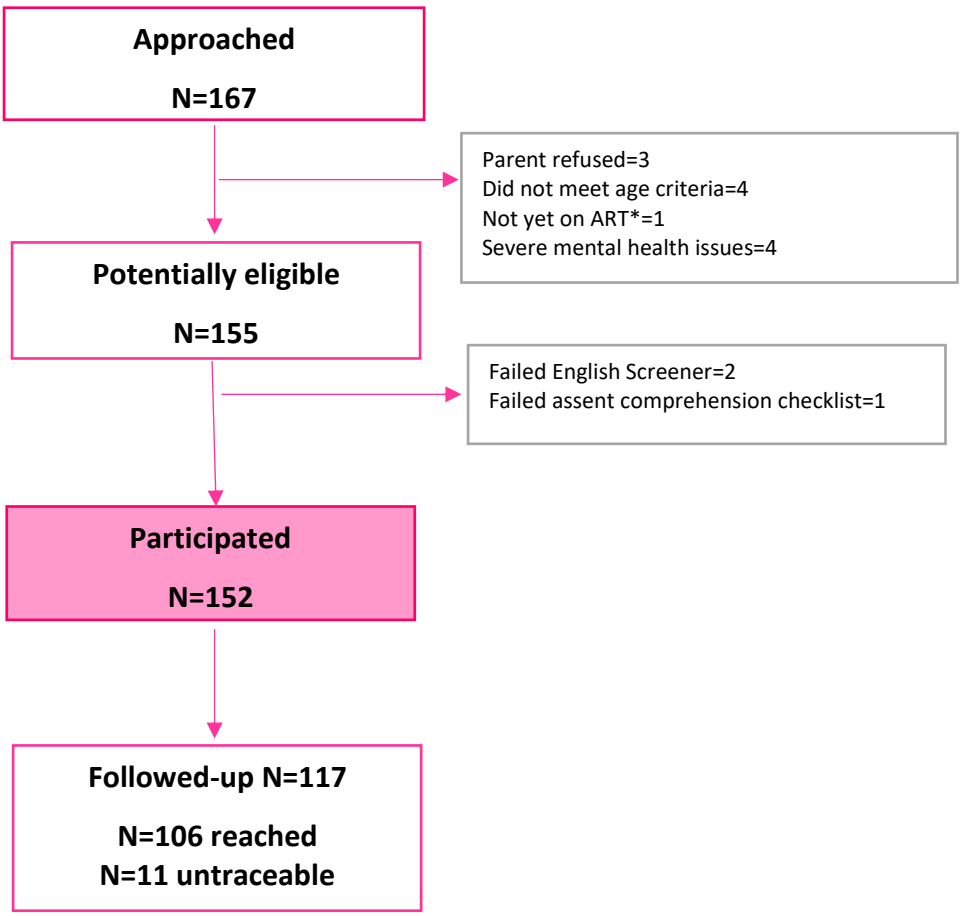

Figure 1a: Participant flow clinic arm

ART- antiretroviral therapy

Research packs were sent to eight schools (approximately 50-60 per school) (Figure 1b). Approximately n=177 were returned and these learners were approached for full screening and completion of consent procedures. Of these 17 were excluded, as they failed the English screener (n=11), did not meet age criteria on the day of enrolment(n=4), or could not comprehend the nature of the study (n=2). This resulted in n=161 participants in the school arm We aimed to telephonically follow-up n=115 (71%) who completed the survey. Of these participants, 86% (n=99) could be reached.

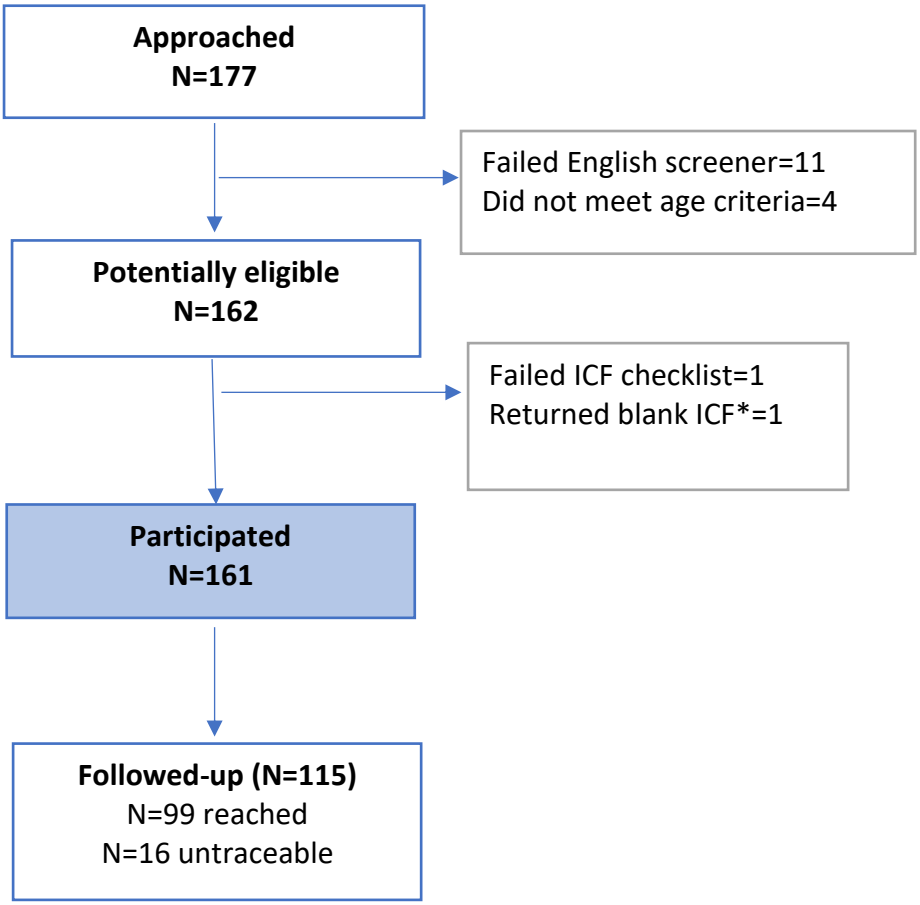

Figure 1b: Participant flow school arm

*ICF= Informed Consent Form

b. Baseline characteristics

Participants in the clinic arm were slightly older (median age 13.5 years, IQR: 12-15, p = 0.012) than those in the school arm (p=0.012) (Table 1). Just over half were male (53%) in the clinic arm, whereas in the school arm the majority were female (57%) (p=0.083). In each arm, the highest school grade completed was Grade 7 (primary level). and no significant difference was seen between the school and clinic arm (p = 0.870).

There was significantly higher report of excellent general health status in the school arm (43.5%) than the clinic arm (23.0%) (p<0.001). ALHIV in the clinic arm rated their health status as better compared to their friends (43%), whereas most school learners reported their health was the same (46%) as their peers. Just under 10% of ALHIV in the clinic arm reported having any other co-morbidities such as asthma, TB, diabetes, epilepsy, or depression. The majority of ALHIV in the clinic arm were in WHO HIV clinical stage 2 (38%) followed by stage 1 (35%) and stage 3 (27%). We were only able to recruit 1 participant in WHO HIV clinical stage 4 as most participants in this strata were seriously ill and could not be recruited or were in hospital and due to COVID-19 regulations we could not gain access to these patients. Median HIV-viral load level was 40 copies/mL, indicative of a suppressed or undetectable viral load.

More than two-thirds of participants in each arm resided in formal households, with an average 5 household members. There was a significantly lower number of participants in the clinic (48.7%) versus school (67.1%) arm who had access to piped water in the household (p=0.001). Furthermore, fewer number of participants in the clinic (49.3%) versus school (72.7%) arm who had access to flush toilet systems (p=<0.001).Over 80% of participants in both arms had access to electricity in the household. There was a significantly higher levels of food insecurity (defined as going to bed hungry often, sometimes, or rarely) in the clinic (38%) versus school (20%) arm (p=0.003).

Table 1: Description of each survey arm: clinic versus school arm

Variable		Clinic (n=152) n (%)	School (n=161) n (%)	p-value (statistic)
Demographics				
Median age (IQR)		13.5 (12-15)	13 (12-14)	0.012 (Z=2.50)

Gender	Male	81 (53.3%)	70 (43.5%)	0.083 ($X^2 = 3.01$)
	Female	71 (46.7%)	91 (56.5%)	
Median school grade (IQR)		7 (5.5-8)	7 (6-8)	0.87 (Z= -0.16)
Clinical				
General health status	Unsure	4 (2.6%)	1 (0.6%)	<0.001*
	Poor	3 (2.0%)	0 (0.0%)	
	Fair	29 (19.1%)	11 (6.8%)	
	Good	81 (53.3%)	79 (49.1%)	
	Excellent	35 (23.0%)	70 (43.5%)	
Health comparison to friend	Same	60 (39.5%)	74 (46.3%)	0.460*
	Better	66 (43.4%)	67 (41.9%)	
	Worse	2 (1.3%)	2 (1.3%)	
	Unsure	24 (15.8%)	17 (10.6%)	
WHO HIV Clinical Stage				
	Stage 1	53 (34.9%)	n/a	
	Stage 2	57 (37.5%)		
	Stage 3	41 (27.0%)		
	Stage 4	1 (0.6%)		
Viral load, median (IQR)		40 (20-250)	n/a	
Other health condition	Asthma	5 (3.3%)		
	TB	2 (1.3%)		
	Diabetes	1 (0.7%)		
	Epilepsy	5 (3.3%)		
	Depression	2 (1.3%)		
Household				
Household type	Informal/other	32 (21.1%)	39 (24.1%)	0.447 ($X^2 = 0.58$)
	Formal	120 (78.9%)	119 (75.3%)	
Median number of people living in household (IQR)		5 (5-7)	5 (4-7)	0.290 (Z=1.07)
Piped water	No	78 (51.3%)	53 (32.9%)	0.001 ($X^2 = 10.87$)
	Yes	74 (48.7%)	108 (67.1%)	
Flush toilet	No	77 (50.7%)	44 (27.3%)	<0.001 ($X^2 = 17.94$)
	Yes	75 (49.3%)	117 (72.7%)	
Electricity	No	20 (13.2%)	11 (6.8%)	0.061 ($X^2 = 3.51$)
	Yes	132 (86.8%)	150 (93.2%)	
Food insecurity	Often	5 (3.4%)	4 (2.5%)	0.003*
	Sometimes	30 (20.3%)	14 (8.8%)	
	Rarely	22 (14.9%)	14 (8.8%)	
	Never	91 (61.5%)	128 (80.0%)	

*Fischer's Exact Test- unable to produce a test statistics as cells with small sample size present (n≤5)

c. Scale completion and timing

Table 2a highlights the number of participants that completed each scale by study arm at baseline. Whilst the study aimed for an equal split of EQ-5D-Y scale completion by arm, on average, most data on the EQ-5D-Y-3L-IA came from the clinic arm (58.6%), whereas most data on the Y-5L-IA was from the school arm (60.9%). Of the total number of participants completing the Y-3L-SC, most were from the school arm (60.9%). Most records for the Y-5L-SC were from the clinic arm (58%). All participants in each arm completed the CHU9D.

Table 2a: Number of participants completing each scale at baseline by clinic vs. school arm

	Total	Clinic arm (n=152)	School arm (n=161)
EQ-5D-Y-3L-IA	111	65 (58.6%)	46 (41.4%)
EQ-5D-Y-5L-IA	223	87 (39.1%)	136 (60.9%)
EQ-5D-Y-3L-SC	223	87 (39.1%)	136 (60.9%)
EQ-5D-Y-5L-SC	112	65 (58.0%)	47 (42.0%)
CHU9D	313	152 (48.9%)	161 (49.1%)

Table 2b: Number of participants completing each scale at follow-up by clinic vs. school arm.

	Total	Clinic arm (n=152)	School arm (n=161)
EQ-5D-Y-3L-IA	98	60 (39.5)	38 (23.6)
EQ-5D-Y-5L-IA	109	46 (30.9)	63 (39.1)

Scale completion timing of IA scales in the clinic arm took on average 1 and a half minute to complete, with the Y-5L-IA taking slightly longer to complete (Table 3). In the school arm, the Y-3L-IA took about 20 seconds more time to complete versus the Y-5L-IA (1.41 minutes). However, there were no significant differences in completion times by arm in the Y-3L-IA (p=0.2259) and Y-5L-IA (p=0.3763).

For the SC scales in the clinic arm, the Y-3L-SC took the longest time to complete (1.71 minutes), followed by the Y-5L-SC (1.35 minutes) and CHU9D (1.29 minutes). Whereas in the school arm, the Y-5L-SC took the longest time to complete (1.86 minutes), followed by the CHU9D (1.34 minutes) and Y-3L-SC (1.08 minutes). There was only a significant difference in completion times by arm in the Y-3L-SC (p<0.001), with the school arm taking the shortest time to complete (1.08 minutes).

Table 3: Average time (minutes) of completion per scale by arm

Completion time	Clinic arm	School arm	p-value (statistic)
EQ-5D-Y-3L (IA)	1.26 (0.91-1.60)	1.61 (1.17-2.04)	0.2259 (T = -1.22)
EQ-5D-Y-5L (IA)	1.58 (1.27-1.89)	1.41 (1.17-1.64)	0.3763 (T = 0.89)
EQ-5D-Y-3L (SC)	1.71 (1.38-2.04)	1.08 (0.96-1.21)	< 0.001 (T = 3.91)
EQ-5D-Y-5L (SC)	1.35 (0.98-1.71)	1.86 (1.24-2.47)	0.1301 (T = -1.53)
CHU9D (SC)	1.29 (1.11-1.47)	1.34 (1.14-1.53)	0.7030 (T = -0.38)

d. Description of responses

Table 4a-c compares responses among participants by scale and arm. Most participants (80-92%) selected "no problems" in all dimensions for each scale. For the Y-3L (IA), between 10-28% in the clinic arm noted problems with *looking after yourself, having pain or discomfort or feeling worried, sad or unhappy* (Table 4a). Slightly more participants in the clinic arm reported problems in the Y-5L (IA), for the following dimensions (*mobility, looking after myself, usual activities, pain or discomfort*). Looking after oneself in terms of washing and dressing was a key problem area in the clinic arm, with approximately 15% reporting issues in this domain in the Y-3L (IA) and Y-5L (IA). There were significant differences in the clinic versus school arm for the *looking after yourself* dimension (Y-3L IA: p=0.030, Y=5L IA: p=0.011) and *usual activities* (Y-5L IA: p=0.006). Of note, no participant selected the most severe response option ("extreme") for the Y-5L (IA) in the clinic and school arm. For the Y-3L (SC) scale, there was significant differences in the clinic versus school arm for the *looking after yourself* dimension (p=0.011) and *usual activities* (p=0.006) (Table 4b). There were no significant differences in responses for the Y-5L (SC) in the clinic vs. school arm. For the CHU9D, between 10-15% reported problems with most dimensions, with most reporting problems with feeling tired and doing school activities (Table 4c). However, similar to the Y-5L (SC), there were no significant differences in distribution of responses between the clinic vs. school arm.

Point estimates for total missingness levels were highest in the school arm, particularly for the Y-3L (SC) [**IA:** Y-3L=0.%, Y-5L=3.72%; **SC:** Y-3L=21.74%, Y-5L=18.63%, CHU9D: 3.72%] compared to the clinic arm [**IA:** Y-3L=0.%, Y-5L=0%; **SC:** Y-3L=0%, Y-5L=0.66%, CHU9D: 0%].

Table 4a: Description of responses- EQ-5D-Y-3L (IA) vs. EQ-5D-Y-5L (IA) by study arm.

	Total (n=313), n (%)	Clinic arm (n=152), n (%)	School arm (n=161), n (%)	(Statistic), p-value
EQ-5D-Y-3L (IA)				
Dimension				
Mobility				(Z=0.297), 0.770
no problems	286 (92.6)	140 (92.1)	146 (93.0)	
some	23 (7.4)	12 (7.9)	11 (7.0)	
a lot	0 (0.0)	0 (0.0)	0 (0.0)	
Looking after myself				(Z=2.09), 0.030*
no problems	274 (88.7)	129 (84.9)	145 (92.4)	
some	34 (11.0)	22 (14.5)	12 (7.6)	
a lot	1 (0.3)	1 (0.7)	0 (0.0)	
Usual activities				(Z=1.16), 0.540
no problems	275 (89.0)	132 (86.8)	143 (91.1)	
some	33 (10.7)	20 (13.2)	13 (8.3)	
a lot	1 (0.3)	0 (0.0)	1 (0.6)	
Pain or discomfort				(Z=0.07), 0.870
no problems	264 (85.4)	130 (85.5)	134 (85.4)	
some	40 (12.9)	20 (13.2)	20 (12.7)	
a lot	5 (1.6)	2 (1.3)	3 (1.9)	
Worried, sad or unhappy				(Z=-0.42), 0.330
no problems	266 (86.1)	132 (86.8)	134 (85.4)	
a bit	39 (12.6)	19 (12.5)	20 (12.7)	
very	4 (1.3)	1 (0.7)	3 (1.9)	
Total missingness	0	0	0	
EQ-5D-Y-5L (IA)				
Dimension				
Mobility				(Z=-0.14), 0.888
no problems	278 (90.0)	136 (90.1)	142 (89.9)	
a little bit	21 (6.8)	12 (7.9)	9 (5.7)	
some	6 (1.9)	3 (2.0)	3 (1.9)	
a lot	2 (0.6)	0 (0.0)	2 (1.3)	
cannot	2 (0.6)	0 (0.0)	2 (1.3)	
Looking after myself				(Z=2.535), 0.011*
no problems	278 (89.4)	129 (84.9)	149 (93.7)	
a little bit	29 (9.3)	20 (13.2)	9 (5.7)	
some	3 (1.0)	2 (1.3)	1 (0.6)	
a lot	0 (0.0)	0 (0.0)	0 (0.0)	
cannot	1 (0.3)	1 (0.7)	0 (0.0)	
Usual activities				(Z=2.73), 0.006*
no problems	274 (88.1)	126 (82.9)	148 (93.1)	
a little bit	30 (9.6)	22 (14.5)	8 (5.0)	
some	6 (1.9)	3 (2.0)	3 (1.9)	
a lot	1 (0.3)	1 (0.7)	0 (0.0)	
cannot	0 (0.0)	0 (0.0)	0 (0.0)	
Pain or discomfort				(Z=0.813), 0.416

no problems	267 (85.9)	128 (84.2)	139 (87.4)	
a little bit	35 (11.3)	19 (12.5)	16 (10.1)	
some	9 (2.9)	5 (3.3)	4 (2.5)	
a lot	0 (0.0)	0 (0.0)	0 (0.0)	
extremely	0 (0.0)	0 (0.0)	0 (0.0)	
Worried, sad or unhappy				(Z=-0.74), 0.457
no problems	270 (86.8)	134 (88.2)	136 (85.5)	
a little bit	33 (10.6)	16 (10.5)	17 (10.7)	
quite	5 (1.6)	1 (0.7)	4 (2.5)	
really	2 (0.6)	0 (0.0)	2 (1.3)	
extremely	1 (0.3)	1 (0.7)	0 (0.0)	
Total missingness	6 (1.92)	0 (0)	6 (3.72)	

*** p<0.05**

Table 4b: Description of responses EQ-5D-Y-3L -SC vs. EQ-5D-Y-5L -SC

	Total (n=313), n (%)	**Clinic arm (n=152), n (%)**	**School arm (n=161), n (%)**	**(Statistic), p-value**
EQ-5D-Y-3L (SC)				
Dimension				
Mobility				(Z=-0.14),0.888
no problems	205 (91.9)	79 (90.8)	126 (92.6)	
some problems	18 (8.1)	8 (9.2)	10 (7.4)	
a lot	0 (0.0)	0 (0.0)	0 (0.0)	
Looking after myself				(Z=2.54),0.011*
no problems	204 (91.5)	74 (85.1)	130 (95.6)	
some problems	19 (8.5)	13 (14.9)	6 (4.4)	
a lot	0 (0.0)	0 (0.0)	0 (0.0)	
Usual activities				(Z=2.73), 0.006*
no problems	195 (87.4)	72 (82.8)	123 (90.4)	
some problems	27 (12.1)	15 (17.2)	12 (8.8)	
a lot	1 (0.4)	0 (0.0)	1 (0.7)	
Pain or discomfort				(Z=0.81), 0.416
no problems	189 (84.8)	72 (82.8)	117 (86.0)	
some problems	31 (13.9)	14 (16.1)	17 (12.5)	
a lot	3 (1.3)	1 (1.1)	2 (1.5)	
Worried, sad or unhappy				(Z=-0.74), 0.457
not worried	195 (87.8)	77 (88.5)	118 (87.4)	
a bit	25 (11.3)	10 (11.5)	15 (11.1)	
very	2 (0.9)	0 (0.0)	2 (1.5)	
Total missingness	35 (11.18)	0 (0)	35 (21.74)	
EQ-5D-Y-5L -SC				
Dimension				
Mobility				(Z=-1.66), 0.098
no problems	100 (91.7)	61 (95.3)	39 (86.7)	
a little bit	4 (3.7)	2 (3.1)	2 (4.4)	
some	3 (2.8)	1 (1.6)	2 (4.4)	
a lot	1 (0.9)	0 (0.0)	1 (2.2)	

cannot	1 (0.9)	0 (0.0)	1 (2.2)	
Looking after myself				(Z=0.58), 0.559
no problems	99 (89.2)	57 (87.7)	42 (91.3)	
a little bit	10 (9.0)	7 (10.8)	3 (6.5)	
some	1 (0.9)	0 (0.0)	1 (2.2)	
a lot	0 (0.0)	0 (0.0)	0 (0.0)	
cannot	1 (0.9)	1 (1.5)	0 (0.0)	
Usual activities				(Z=0.05), 0.961
no problems	100 (90.9)	59 (90.8)	41 (91.1)	
a little bit	8 (7.3)	5 (7.7)	3 (6.7)	
some	2 (1.8)	1 (1.5)	1 (2.2)	
a lot	0 (0.0)	0 (0.0)	0 (0.0)	
cannot	0 (0.0)	0 (0.0)	0 (0.0)	
Pain or discomfort				(Z=-0.04), 0.969
no problems	93 (84.5)	55 (84.6)	38 (84.4)	
a little bit	15 (13.6)	9 (13.8)	6 (13.3)	
some	2 (1.8)	1 (1.5)	1 (2.2)	
a lot	0 (0.0)	0 (0.0)	0 (0.0)	
extremely	0 (0.0)	0 (0.0)	0 (0.0)	
Worried, sad or unhappy				(Z=-0.24), 0.814
no problems	94 (83.9)	55 (84.6)	39 (83.0)	
a little bit	16 (14.3)	9 (13.8)	7 (14.9)	
some	1 (0.9)	0 (0.0)	1 (2.1)	
a lot	1 (0.9)	1 (1.5)	0 (0.0)	
extremely	0 (0.0)	0 (0.0)	0 (0.0)	
Total missingness	31 (9.90)	1 (0.66)	30 (18.63)	

*** p<0.05**

Table 4c: Description of responses- CHU9D

	Total (n=313), n (%)	Clinic arm (n=152), n (%)	School arm (n=161), n (%)	(Statistic), p-value
Dimension				
Worried				(Z=-1.00), 0.317
no problems	277 (88.5)	137 (90.1)	140 (87.0)	
a little bit	24 (7.7)	13 (8.6)	11 (6.8)	
a bit	6 (1.9)	1 (0.7)	5 (3.1)	
quite	5 (1.6)	1 (0.7)	4 (2.5)	
very	1 (0.3)	0 (0.0)	1 (0.6)	
Sad				(Z=0.44), 0.658
no problems	278 (89.1)	134 (88.2)	144 (90.0)	
a little bit	26 (8.3)	16 (10.5)	10 (6.3)	
a bit	3 (1.0)	0 (0.0)	3 (1.9)	
quite	4 (1.3)	1 (0.7)	3 (1.9)	
very	1 (0.3)	1 (0.7)	0 (0.0)	
Pain				(Z=0.53), 0.595
no problems	275 (87.9)	132 (86.8)	143 (88.8)	

a little bit	29 (9.3)	15 (9.9)	14 (8.7)	
a bit	5 (1.6)	4 (2.6)	1 (0.6)	
quite	3 (1.0)	1 (0.7)	2 (1.2)	
a lot	1 (0.3)	0 (0.0)	1 (0.6)	
Tired				(Z=-1.85), 0.064
no problems	239 (76.6)	123 (80.9)	116 (72.5)	
a little bit	57 (18.3)	24 (15.8)	33 (20.6)	
a bit	10 (3.2)	5 (3.3)	5 (3.1)	
quite	1 (0.3)	0 (0.0)	1 (0.6)	
very	5 (1.6)	0 (0.0)	5 (3.1)	
Annoyed				(Z=-0.99), 0.318
no problems	280 (89.7)	139 (91.4)	141 (88.1)	
a little bit	21 (6.7)	9 (5.9)	12 (7.5)	
a bit	5 (1.6)	3 (2.0)	2 (1.3)	
quite	5 (1.6)	1 (0.7)	4 (2.5)	
very	1 (0.3)	0 (0.0)	1 (0.6)	
School work				(Z=1.87), 0.062
no problems	257 (82.4)	119 (78.3)	138 (86.3)	
a little bit	35 (11.2)	20 (13.2)	15 (9.4)	
some	17 (5.4)	12 (7.9)	5 (3.1)	
a lot	1 (0.3)	1 (0.7)	0 (0.0)	
cannot	2 (0.6)	0 (0.0)	2 (1.3)	
Sleep				(Z=-0.06), 0.952
no problems	271 (86.9)	132 (86.8)	139 (86.9)	
few	30 (9.6)	16 (10.5)	14 (8.8)	
some	9 (2.9)	4 (2.6)	5 (3.1)	
a lot	2 (0.6)	0 (0.0)	2 (1.3)	
could not	0 (0.0)	0 (0.0)	0 (0.0)	
Daily routines				(Z=1.88), 0.061
no problems	273 (87.2)	127 (83.6)	146 (90.7)	
few	32 (10.2)	20 (13.2)	12 (7.5)	
some	7 (2.2)	5 (3.3)	2 (1.2)	
a lot	0 (0.0)	0 (0.0)	0 (0.0)	
cannot	1 (0.3)	0 (0.0)	1 (0.6)	
Join activities				(Z=1.03), 0.302
any	273 (87.5)	130 (85.5)	143 (89.4)	
most	20 (6.4)	10 (6.6)	10 (6.3)	
some	7 (2.2)	6 (3.9)	1 (0.6)	
few	4 (1.3)	3 (2.0)	1 (0.6)	
no	8 (2.6)	3 (2.0)	5 (3.1)	
Total missingness	6 (1.92)	0 (0)	6 (3.72)	

A breakdown of median total summary and VAS scores are presented in Table 5. As most participants report “no problems” the median total summary score for the Y-3L (IA) and Y-5L (IA) was 5. There

was no significant difference in these scores by study arm. Similar findings were found for the SC versions.

The median VAS scores for the Y-3L (IA) vs. Y-5L (IA) in the clinic arm was 81 (IQR: 65-100) vs 80 (IQR: 60-90), however, no statistical median differences was observed (p=0.420) Of note, there was statistically significant difference in median VAS scores (Y-5L-IA) by arm , with VAS scores almost 10 points lower in the clinic vs. school arm (p<0.001).

For the SC version, median VAS scores were slightly higher in the Y-3L (80) vs. Y-5L (85) in the clinic arm. There was statistically significant difference in median VAS scores (Y-3L SA) by arm, with VAS scores almost 10 points lower in the clinic compared to the school arm (p<0.001). The median VAS scores were different in the school arm between Y-3L (IA) and Y-3L (SC), (p=0.015). However, no difference was observed in the school arm between Y-5L (IA) and Y-5L (SC), (p = 0.445).

Table 5- Description of responses- median level summary score and VAS score by arm

	Missing, n (%)	Clinic arm, median (IQR)	School arm, median (IQR)	(Statistic), P value
Median summary score*				
EQ-5D-Y-3L (IA)		5 (5-6)	5 (5-6)	(Z=-1.24), 0.220
EQ-5D-Y-5L (IA)		5 (5-7)	5 (5-5)	(Z=1.51), 0.130
EQ-5D-Y-3L (SC)		5 (5-6)	5 (5-6)	(Z=0.71), 0.480
EQ-5D-Y-5L (SC)		5 (5-6)	5 (5-6)	(Z=0.18), 0.860
CHU9D (SC)		9 (9-12)	9 (9-12)	(Z=0.46), 0.650
Median VAS score (IQR)				
EQ-5D-Y-3L (IA)	0 (0.0)	81 (65-100)	92 (62-100)	0.420
EQ-5D-Y-5L (IA)	1 (0.4)	80 (60-90)	99 (80-100)	<0.001***
EQ-5D-Y-3L (SC)	0 (0.0)	80 (60-90)	99 (82-100)	<0.001***
EQ-5D-Y-5L (SC)	6 (5.3)	85 (66-100)	98 (70-100)	0.330

* Scoring for the descriptive system: Y-3L: 1= “No problem”, 2= “Some” , 3= “a lot”; Y-5L: 1=”No problem”; 2=”a little bit”; 3=”Some”; 4=”A lot”; 5=”Extreme”; CHU9D: 1= “don’t”, 2=”a little bit”, 3=”a bit”, 4= “quite”, 5=”very”; # scores were not normally distributed hence median is reported

e. Redistribution properties

The dimensions *Mobility and Usual Activities* had the highest number of inconsistent responses when moving from the Y-3L (IA) to the Y-5L (IA) for the school arm (Table 6). This analysis could not be conducted for the clinic arm as participants in this arm completed either a Y-3L or Y-5L (IA/SC).

Table 6: Cross tabulation for the EQ-5D-Y-3L (IA) and EQ-5D-Y-5L (IA) dimensions scores for school arm

	Y-5L					
Y-3L	**no**	**a little bit**	**some**	**a lot**	**cannot**	**Total inconsistent response, n**
Mobility						
no	15	1	**1**	**1**	0	**4**
some	**2**	0	1	0	0	
a lot	**0**	0	0	0	0	
Looking after myself						
no	15	3	**0**	**0**	**0**	**2**
some	**2**	**1**	0	0	**0**	
a lot	**0**	0	0	0	0	
Usual activities						
no	15	2	**0**	**0**	**0**	**4**
some	**4**		0	0	**0**	
a lot	**0**	**0**	0	0	0	
Pain or discomfort						
no	13	3	**0**	**0**	**0**	**3**
some	**3**	2	0	0	**0**	
a lot	**0**	0	0	0	0	
Worried, sad or unhappy						
no	16	3	**0**	**0**	**0**	**1**
a little bit	**1**	1	0	0	**0**	
a lot	**0**	0	0	0	0	

f. Discriminatory power

Absolute informativity did not show improvement on all dimensions on the Y-5L compared to the Y-3L (IA) in the clinic arm (Table 7). For the Y-5L vs. Y-3L (IA), H' is higher on the clinic arm for all dimensions except for *worried, sad or unhappy*. Whereas for the Y-5L vs. Y-3L (IA) in the school arm, H' is higher for all dimensions except for *looking after myself, usual activities, pain or discomfort.*

Table 7: Shannon Index (H') and Shannon Evenness Index (J') for the EQ-5D-Y-5L (IA) vs EQ-5D-Y-3L (IA) dimensions

IA	EQ-5D-Y-5L		EQ-5D-Y-3L			
	H′	J′	H′	J′	Difference in H′	Difference in J′
Mobility						
Clinic, n=65	0.463	0.288	0.231	0.333	0.232	-0.045
School, n=46	0.365	0.227	0.295	0.426	0.07	-0.199
Looking after myself						
Clinic, n=65	0.527	0.48	0.479	0.436	0.048	0.044
School, n=46	0.224	0.204	0.462	0.421	-0.238	-0.217
Usual activities						
Clinic, n=65	0.658	0.475	0.271	0.391	0.387	0.084
School, n=46	0.257	0.185	0.494	0.713	-0.237	-0.528
Pain or discomfort						
Clinic, n=65	0.537	0.489	0.386	0.351	0.151	0.138
School, n=46	0.428	0.39	0.563	0.512	-0.135	-0.122
Worried, sad or unhappy						
Clinic, n=65	0.342	0.247	0.479	0.436	-0.137	-0.189
School, n=46	0.473	0.341	0.489	0.445	-0.016	-0.104
Average difference	**Clinic**				**0.1362**	**0.0064**
	School				**-0.1112**	**-0.234**

For the SC version in the clinic arm, the Y-3L has systematically higher H' than the Y-5L, with much poorer spread in responses (J'). (Table 8). However, in the school arm, the Y-5L overall had higher H' and J'.

Table 8: Shannon Index (H') and Shannon Evenness Index (J') for the EQ-5D-Y-5L (SC) vs EQ-5D-Y-3L (SC) dimensions

SC	EQ-5D-Y-5L		EQ-5D-Y-3L			
	H′	J′	H′	J′	Difference in H′	Difference in J′
Mobility						
Clinic, n=64	0.219	0.136	0.307	0.443	-0.088	-0.307
School, n=45	0.57	0.354	0.263	0.379	0.307	-0.025
Looking after myself						
Clinic, n=65	0.419	0.302	0.422	0.609	-0.048	-0.044
School, n=46	0.344	0.248	0.181	0.261	0.238	0.217
Usual activities						
Clinic, n=65	0.349	0.318	0.46	0.419	-0.387	-0.084
School, n=45	0.35	0.319	0.341	0.31	0.237	0.528
Pain or discomfort						
Clinic, n=65	0.479	0.436	0.502	0.457	-0.151	-0.138
School, n=45	0.496	0.451	0.451	0.411	0.135	0.122
Worried, sad or unhappy						
Clinic, n=65	0.479	0.345	0.357	0.325	0.137	0.189
School, n=47	0.52	0.375	0.424	0.386	0.016	0.104
Average difference	**Clinic**				**-0.1074**	**-0.0768**
	School				**0.1866**	**0.1892**

g. Health profiles

Overall, reporting of "no problems" for each dimension was the most prevalent response permutation: the clinic arm IA: Y-3L=66%, Y-5L=68% (Table 9). The permutation was higher for the SC scales: Y-3L=70%, Y-5L=70%, and higher in comparison to the CHU9D (57%) in the clinic arm. In the school arm, there was a larger difference in % no problem, with it being highest in the IA scales for Y-5L and SC scales for Y-3L [**IA:** Y-3L=54%, Y-5L=76%; **SC**: Y-3L=73%, Y-5L=68%, CHU9D=55%].

Table 9: Prevalence of top ten permutations for each scale by arm

	Clinic arm	N (%)	School arm	N (%)		Clinic arm	N (%)	School arm	N (%)
EQ-5D-Y-3L (IA)	11111	43 (66.2%)	11111	25 (54.4%)	**EQ-5D-Y-5L (IA)**	11111	59 (67.8%)	11111	103 (75.7%)
	12111	5 (7.7%)	11211	4 (8.7%)		22221	6 (6.9%)	11121	4 (2.9%)
	21111	3 (4.6%)	11112	3 (6.5%)		11212	2 (2.3%)	12111	3 (2.2%)
	11112	2 (3.1%)	11121	3 (6.5%)		12111	2 (2.3%)	11112	3 (2.2%)
	11122	2 (3.1%)	12111	2 (4.4%)		12211	2 (2.3%)	11113	3 (2.2%)
	11113	1 (1.5%)	11122	1 (2.2%)		21111	2 (2.3%)	11122	2 (1.5%)
	11121	1 (1.5%)	12211	1 (2.2%)		11112	1 (1.2%)	11212	1 (0.7%)
	11211	1 (1.5%)	11233	1 (2.2%)		11122	1 (1.2%)	11131	1 (0.7%)
	11212	1 (1.5%)	12121	1 (2.2%)		11131	1 (1.2%)	11211	1 (0.7%)
	11221	1 (1.5%)	12221	1 (2.2%)		11211	1 (1.2%)	11222	1 (0.7%)
EQ-5D-Y-3L (SC)	11111	61 (70.1%)	11111	99 (72.8%)	**EQ-5D-Y-5L (SC)**	11111	45 (70.3%)	11111	30 (68.2%)
	22221	4 (4.6%)	11121	6 (4.4%)		11112	4 (6.2%)	11112	2 (4.5%)
	12111	3 (3.5%)	11112	5 (3.7%)		11121	2 (3.1%)	11121	2 (4.5%)
	11112	2 (2.3%)	21111	3 (2.2%)		11211	2 (3.1%)	31111	2 (4.5%)
	11121	2 (2.3%)	21222	3 (2.2%)		12122	2 (3.1%)	11131	1 (2.2%)
	11222	2 (2.3%)	11211	3 (2.2%)		11122	1 (1.5%)	12111	1 (2.2%)
	12221	2 (2.3%)	12122	2 (1.5%)		11131	1 (1.5%)	12222	1 (2.2%)
	21111	2 (2.3%)	12111	1 (0.7%)		11222	1 (1.5%)	11114	1 (2.2%)
	21222	1 (1.2%)	12221	1 (0.7%)		12111	1 (1.5%)	21122	1 (2.2%)
	22222	1 (1.2%)	11212	1 (0.7%)		12121	1 (1.5%)	22222	1 (0.6%)

CHU9D	111111111	87 (57.2%)	111111111	89 (55.3%)					
	111211111	4 (2.6%)	111211111	9 (5.6%)					
	111113111	3 (2.0%)	111112111	4 (2.5%)					
	111111121	2 (1.3%)	111111211	2 (1.2%)					
	111111211	2 (1.3%)	121111111	2 (1.2%)					
	111112122	2 (1.3%)	111211211	2 (1.2%)					
	111212111	2 (1.3%)	112211111	2 (1.2%)					
	112111111	2 (1.3%)	111212111	1 (0.6%)					
	111111115	1 (0.7%)	111212211	1 (0.6%)					
	111111221	1 (0.7%)	222121111	1 (0.6%)					

h. Ceiling effects

The proportion reporting a ceiling effect with no problems in each dimension (11111) showed a 1.6% increase from the Y-3L (IA) to Y-5L (IA) in the clinic arm (Table 10). This ceiling effect was substantially higher in the school arm (21%).

For the SC version, there was a smaller proportion (0.2%) increase in ceiling effect from the Y-3L to the Y-5L in the clinic arm (Table 11). However, there was slight reduction in this ceiling effect by 4% from the Y-3L to Y-5L in the school arm. When the Y-3L (SC) was compared to the CHU9D, the ceiling effect reduced by 16% in the clinic arm and 14% in school arm (Table 12). Similarly, there was a reduction in ceiling effects from the Y-5L to CHU9D, in the clinic (12%) and school (8%) arm (Table 13).

Table 10. Ceiling effect for the EQ-5D-Y-3L-IA and EQ-5D-Y-5L-IA across arms and for the total Sample

		Ceiling Y-3L (IA)		Ceiling Y-5L (IA)	Absolute reduction	Percentage reduction
	n	11111 (% [95% CI])	n	11111 (%[95% CI])		
Total	68	61.3 [0.52-0.70]	162	72.7 [0.66-0.78]	-11.4	-18.6
Clinic arm	43	66.2 [0.54-0.77]	59	67.8 [0.57-0.78]	-1.6*	-2.4
School arm	25	54.4 [0.40-0.68]**	103	75.7 [0.68-0.82]***	-21.3	-39.2

*P-value Y-3L vs Y-5L (IA) p<0.001; ** p value clinic vs school arm Y-3L (IA): p=0.258; ***p value clinic vs school arm Y-5L (IA): p=0.012

Table 11. Ceiling effect for the EQ-5D-Y-3L-SC and EQ-5D-Y-5L-SC across arms and for the total Sample

		Ceiling Y-3L (SC)		Ceiling Y-5L (SC)	Absolute reduction	Percentage reduction
	n	11111 (%[95% CI])	n	11111 (%[95% CI])		
Total	223	71.7 [0.65-0.77]	75	64.7 [0.58-0.75]	7	9.8
Clinic arm	61	70.1 [0.60-0.79]	45	70.3 [0.57-0.79]	-0.2*	0.3

School arm	99	72.8[0.65-0.80]	30	68.2 [0.49-0.76]	4.1	5.7

- P-value Y-3L vs. Y-5L (SC): p=0.002

Table 12: Ceiling effect for the EQ-5D-Y-3L-SC and CHU9D across arms and for the total sample

		Ceiling Y-3L (SC)		Ceiling CHU9D (SC)	Absolute reduction	Percentage reduction
	n	11111 (%)	n	111111111 (%)		
Total	160	71.8	127	57	14.8	20.6
Clinic arm	61	70.1	47	54	16.1	23.0
School arm	99	72.8	80	58.8	14	19.2

Table 13: Ceiling effect for the EQ-5D-Y-5L-SC and CHU9D across arms and for the total sample

		Ceiling Y-5L (SC)		Ceiling CHU9D (SC)	Absolute reduction	Percentage reduction
	n	11111 (%)	n	111111111 (%)		
Total	75	67	176	56.2	10.8	16.1
Clinic arm	45	70.3	87	57.2	13.1	18.6
School arm	30	63.8	89	55.8	8	12.5

i. Test-retest reliability

Test-retest was assessed in IA scale versions only. This analysis is based only on participants that were followed up within two weeks (n=14 days).

The Y-3L (IA) showed substantial agreement (>80%) for each dimension in the clinic arm, with the highest agreement and Gwet AC found in the *Mobility* (Gwet AC 0.96) and *Looking After Myself* (Gwet AC 0.92) dimensions (Table 14). Whilst mean scores did not change for the school arm for *the Mobility* and *Looking After Myself* dimension, agreement was higher in the school vs. clinic arm for *Usual activities (Gwet AC 0.94), Pain or discomfort(Gwet AC 0.94), Worried, sad or unhappy(Gwet AC 0.95).*

The Y-5L (IA) showed substantial agreement (>80%) for each dimension in the clinic arm, except for *Usual activities* with no change in the response. The highest agreement and Gwet AC was found in the *Pain or discomfort* (Gwet AC 0.93) and *Looking after myself* (Gwet AC 0.89) dimensions (Table 15). Agreement was higher in the school vs. clinic arm for *Mobility (Gwet AC 0.94), Looking after myself (0.90), Worried, sad or unhappy (Gwet AC 0.95).*

Table 14: Test-retest reliability for ED-5D-Y-3L (IA) dimension scores among those followed-up within two-weeks follow up

	Agreement		Gwet AC	
	Clinic (%)	**School (%)**	**Clinic**	**School**
Mobility, n=56	96	-	0.96	-
Looking after myself, n=52	92	-	0.92	-
Usual activities, n=56	85	95	0.84	0.94
Pain or discomfort, n=55	85	95	0.84	0.94
Worried, sad or unhappy, n=50	80	96	0.76	0.95

- means ratings did not vary.

Table 15: Test-retest reliability for ED-5D-Y-5L (IA) dimension scores among those followed-up within two-weeks follow

	Agreement		Gwet AC	
	Clinic (%)	School (%)	Clinic	School
Mobility, n=43	91	95	0.90	0.94
Looking after myself, n=43	90	91	0.89	0.90
Usual activities,n=43	-	-		-
Pain or discomfort, n=44	93	90	0.93	0.89
Worried, sad or unhappy, n=44	84	95	0.81	0.95

- means ratings did not vary.

j. Convergent validity

There was evidence of convergent validity with several Y-3L and Y-5L dimensions and the self-reported overall health measure, mainly in the clinic arm (Table 16). In the clinic arm, there were significant correlations (p< 0.05) in the Y-3L (IA), for *pain/discomfort* (*rho*= 0.26) and *worried/sad/unhappy* (*rho*= 0.31). In the Y-3L (SC), correlations were only significantly correlated for *pain/discomfort* (*rho*=0.22). Most dimensions in the Y-5L (IA) were significantly correlated with overall health, with the highest being observed for *looking after yourself (rho*=0.28) and *doing usual activities* (*rho*=0.37).

Table 16: Convergent validity of the ED-5D-Y-3L and EQ-5D-Y- 5L (IA vs. SC) by arm- correlation assessed with Spearman rank order coefficients between self-reported overall health status and dimension score

Dimensions	Clinic arm, rho (p-value)	School arm, rho (p-value)
Y-3L (IA), n=111		
Mobility	-0.07 (0.5610)	-0.01 (0.9651)
Looking after yourself	0.05 (0.6896)	0.10 (0.5034)
Usual activities	0.03 (0.7882)	0.20 (0.1765)
Pain or discomfort	0.26 (0.0348)*	0.01 (0.9395)
Worried, sad or unhappy	0.31 (0.0113)*	0.12 (0.4092)
Y-3L (SC), n=223		
Mobility	0.13 (0.2449)	0.08 (0.3272)
Looking after yourself	0.08 (0.4598)	0.22 (0.0087)**
Usual activities	0.17 (0.1122)	0.06 (0.4556)
Pain or discomfort	0.22 (0.0430)*	0.14 (0.0988)
Worried, sad or unhappy	0.15 (0.1736)	0.36 (0.0001)**
Y-5L (IA), n=223		
Mobility	0.23 (0.0291)*	0.10 (0.2463)
Looking after yourself	0.28 (0.0074)*	-0.02 (0.8374)
Usual activities	0.37 (0.0004)*	0.10 (0.2646)
Pain or discomfort	0.21 (0.0489)*	0.14 (0.1106)
Worried, sad or unhappy	0.17 (0.1072)	0.14 (0.1071)
Y-5L (SC), n=109		
Mobility	0.14 (0.2680)	-0.15 (0.3383)
Looking after yourself	0.13 (0.3185)	-0.01 (0.9295)
Usual activities	0.04 (0.7466)	-0.02 (0.8923)
Pain or discomfort	0.24 (0.0590)	0.13 (0.4061)
Worried, sad or unhappy	0.20 (0.1176)	0.16 (0.2735)

* p < 0.05; ** p<0.001

There was evidence of convergent validity with several Y-3L and Y-5L dimensions and the EQ-VAS (Table 17). For the ED-5D-Y-3L (IA), there were significant correlations for the *worried, sad or unhappy* dimensions only in the clinic (*rho* -0.34) and school (*rho* -0.30) arm. The Y-3L (SC) showed improved convergent validity, but this was only for the school arm. The Y-5L (IA) performed similarly to the Y-3L (IA) in the clinic arm, with significant correlations observed only for *worried, sad or unhappy* (*rho*= -0.34), yet more correlations found in the school arm (usual activities: *rho* -0.27, pain or discomfort: *rho*- 0.30, worried, sad or unhappy *rho*: -0.31) The Y-5L (SC) vs. Y-5L (IA), showed greater levels of convergent validity in the clinic arm only (looking after myself: *rho* -0.28, usual activities: *rho*- 0.28, worried, sad or unhappy *rho*: -0.37)

Table 17: Convergent validity of the ED-5D-Y-3L and EQ-5D-Y- 5L (IA vs. SC) by arm- correlation assessed with Spearman rank order coefficients for EQ-VAS score and dimension score

Dimensions	Clinic arm, rho (p-value)	School arm, rho (p-value)
Y-3L (IA), n=108		
Mobility	0.10 (0.4187)	-0.13 (0.4097)
Looking after yourself	-0.23 (0.0711)	-0.27 (0.0810)
Usual activities	0.05 (0.7022)	-0.06 (0.6846)
Pain or discomfort	-0.22 (0.073)	0.01 (0.9475)
Worried, sad or unhappy	-0.34 (0.005)*	-0.30 (0.054)*
Y-3L (SC), n=218		
Mobility	0.04 (0.7184)	-0.10 (0.2744)
Looking after yourself	-0.17 (0.1114)	-0.23 (0.009)*
Usual activities	-0.06 (0.5656)	-0.23 (0.0068)*
Pain or discomfort	-0.03 (0.7740)	-0.30 (<0.001)**
Worried, sad or unhappy	-0.09 (0.4307)	-0.43 (<0.001)**
Y-5L (IA), n=218		
Mobility	0.01 (0.9414)	-0.11 (0.1859)
Looking after yourself	-0.18 (0.0994)	-0.10 (0.2652)
Usual activities	-0.19 (0.0813)	-0.27 (<0.001)**
Pain or discomfort	-0.07 (0.5350)	-0.30 (<0.001)**
Worried, sad or unhappy	-0.34 (<0.001)**	-0.31 (<0.001)**
Y-5L (SC), n=105		
Mobility	-0.15 (0.2444)	-0.13 (0.4251)
Looking after yourself	-0.28 (0.0253)*	-0.13 (0.4362)
Usual activities	-0.28 (0.0243)*	-0.16 (0.3253)
Pain or discomfort	-0.16 (0.1972)	-0.08 (0.6107)
Worried, sad or unhappy	-0.37 (0.0025)*	-0.44 (0.0046)*

* $p < 0.05$; ** $p<0.001$

There was strong evidence of convergent validity between EQ-5D-Y (3L, 5L) and CHUD9 (SC) dimensions, (Table 18). Compared to the Y-5L (SC), the Y-3L (SC) exhibited more significant correlations with the CHU9D, and this was most pronounced in the clinic arm with the highest correlation observed in the clinic arm for *worried* (CHU9D) (rho=0.76) and *sad* (CHUD9) (rho=0.71). For the Y-5L (SC), significant correlations were mainly observed in the clinic arm, with the highest correlation observed for *worries* (CHU9D) (rho=0.82) and *daily routine* (CHU9D) (rho=0.86).

Table 18: Convergent validity of the ED-5D-Y-3L and EQ-5D-Y- 5L (SC) vs. CHU9D (SC) by each dimension with Spearman rank order coefficients for Y-3L, self-reported overall health and Y-5L, self-reported overall health for each dimension, by arm.

Dimensions	Clinic arm, rho (p-value)		School arm, rho (p-value)	
CHU9D	**Y-3L-SC**	**Y-5L-SC**	**Y-3L-SC**	**Y-5L-SC**
Worried [a]	0.76 (0.0001)**	0.82 (0.0001)**	0.45 (0.0001)**	0.78 (0.0001)**
Sad [b]	0.71 (0.0001)**	0.58 (0.0001)**	0.46 (0.0001)**	0.36 (0.0138)*
Daily routine [c]	0.29 (0.0065)**	0.86 (0.0001)**	0.07 (0.4399)	0.04 (0.8019)
School work [d]	0.37 (0.0004)**	0.18 (0.1408)	0.26 (0.0024)**	-0.12 (0.4488)
Join activities [e]	0.46 (0.0001)**	0.22 (0.0722)	0.43 (0.0001)**	0.06 (0.7005)
Pain or discomfort [f]	0.42 (0.0001)**	0.41 (0.0007)**	0.50 (0.0001)**	0.46 (0.0014)**

*p<0.05, **p<0.001

Dimensions : CHU9D vs. (Y-3L/Y-5L)

k. Pain/discomfort (CHU9D) vs. Pain or discomfort (Y-3L, Y-5L)
l. Worried (CHU9D) vs. worried, sad or unhappy (Y-3L, Y-5L)
m. Sad (CHU9D) vs. worried, sad or unhappy (Y-3L, Y-5L)
n. Daily routine (CHU9D) vs. looking after myself (Y-3L, Y-5L)
o. School work (CHU9D) vs. usual activities (Y-3L, Y-5L)
p. Able to join in on activities (CHU9D) vs. usual activities (Y-3L, Y-5L)

k. Known-groups validity

Results for known-groups validity are presented in Tables 19-23. Table 19 highlights the correlation between EQ5D VAS scores and WHO HIV clinical stage. Only the Y-5L (IA), showed a significant correlation with WHO HIV clinical stage and in the expected direction, a decrease in VAS score with increasing WHO HIV clinical stage. A similar trend was observed when we collapsed less severe HIV clinical stages (stage 1 and 2) and compared it against advanced stages (3 and 4) (Table 20). Similar patterns were found when we used medial summary scores (Table 20-21).

Table 19: Known-groups validity- Differences in median VAS scores and WHO HIV clinical stage in the clinic arm

VAS score	Total, n	WHO HIV clinical stage 1 median (IQR)	WHO HIV clinical stage 2, median (IQR)	WHO HIV clinical stage 3 and 4 , median (IQR)	p-value (statistic)
Y-3L (IA)	65	81 (65-100)	99 (79-100)	85 (50-97)	0.610 ($X^2 = 0.98$)
Y-3L (SC)	65	-	80 (62-98)	65 (50-89)	0.053 (Z = 1.94)
Y-5L (IA)	87	-	80 (75-91)	62 (50-80)	0.002** (Z = 3.14)
Y-5L (SC)	87	81 (70-100)	100 (100-100)	85 (51-94)	0.110 (Z = 0.12)

** p< 0.001

Table 20: Known-groups validity- Differences in median VAS scores and WHO HIV clinical stage in the clinic arm

VAS score	WHO HIV clinical Stage 1/2, median (IQR)	WHO HIV clinical Stage 3/4 median (IQR)	p-value (statistic)
Y-3L (IA), n=65	81 (67.5-100)	85 (50-97)	0.600 (Z = 0.52)
Y-3L (SC), n=65	80 (62-98)	65 (50-89)	0.053 (Z = 1.94)
Y-5L (IA), n=87	80 (75-91)	62 (50-80)	0.002** (Z = 3.14)
Y-5L (SC),n=87	85 (70-100)	85 (51-94)	0.500 (Z= 0.67)

* p < 0.001

Table 21: Known-groups validity- Differences in median summary scores and WHO HIV clinical stage in the clinic arm

summary score	HIV Stage 1/2, median (IQR)	HIV Stage 3/4 median (IQR)	p-value (statistic
Y-3L (IA)	5 (5-6)	5 (5-5)	0.434 (Z=0.781)
Y-3L (SC)	5 (5-5)	5 (5-7)	0.031 (Z=-2.16)
Y-5L (IA)	5 (5-6)	5 (5-7)	0.225 (Z=-1.21)
Y-5L (SC)	5 (5-6)	5 (5-5)	0.383 (Z=0.873)

CHU9D	9 (9-11)	9 (9-12)	0.010 (Z=-1.67)

** p < 0.001 * p < 0.05

When we look at HIV- virological suppression status as an alternate to WHO HIV clinical staging there was no significant correlation with the median VAS or summary score (Table 22-23).

Table 22: Known-groups validity- Differences in median VAS score and viral load in the clinic arm

VAS score	Suppressed (n=67), median (IQR)	Not suppressed (n=16), median (IQR)	p-value (statistic)
Y-3L (IA)	86 (70-100)	68 (61-85)	0.205 (Z=1.27)
Y-3L (SC)	80 (60-89)	75 (50-90)	0.332 (Z=0.740)
Y-5L (IA)	80 (60-88)	79.5 (50-80)	0.265 (Z=1.12)
Y-5L (SC)	87 (70-100)	75 (60-100)	0.387 (Z=0.87)

Table 23: Known-groups validity- Differences in median summary score and viral load in the clinic arm

Summary scores	Suppressed (n=67), median (IQR)	Not suppressed (n=16), median (IQR)	p-value
Y-3L (IA)	5 (5-6)	5 (5-6)	0.971 (Z=0.04)
Y-3L (SC)	5 (5-6)	5 (5-5.5)	0.473 (Z=0.717)
Y-5L (IA)	5 (5-6)	5 (5-7)	0.319 (Z=-0.995)
Y-5L (SC)	5 (5-6)	5 (5-6)	0.434 (Z=-0.783)
CHU9D	9 (9-10)	11 (9-13)	0.171 (Z=-1.39)

l. Differential item functioning

OLR Results: **EQ-5D-Y-3L (IA)**

After removing those with missing EQ-5D-Y-3L (IA) item data, 111 participants (65 in clinic arm; 46 in school arm) remained for analysis in the development sample (complete case analysis) and a random sample of 95% was used in the validation stage (60 in clinic arm; 45 in school arm). None of the items meet the 2% ΔR^2 cut-off for meaningful DIF (Table 24).

Table 24 – EQ-5D-Y-3L (IA) OLR results in the development and validation samples

	Model 1	Model 2 (uniform)		Model 3 (non-uniform)		
	R^2	Arm coefficient, e (p-value)	R^2	Arm* LSS coefficient, e (p-value)	R^2	ΔR^2
Development sample						
Mobility	0.313	0.092 (0.914)	0.313	0.522 (0.359)	0.331	0.018
Self-care	0.484	-0.512 (0.446)	0.490	-0.646 (0.250)	0.503	0.013
Usual Activities	0.399	1.114 (0.132)	0.430	0.412 (0.488)	0.437	0.007
Pain/discomfort	0.591	0.509 (0.479)	0.596	-0.509 (0.328)	0.605	0.009
Anxiety/depression	0.497	-0.502 (0.494)	0.502	-0.141 (0.758)	0.503	0.001
Validation sample						
Mobility	0.361	0.054 (0.957)	0.361	0.537 (0.394)	0.380	0.019
Self-care	0.459	-0.914 (0.219)	0.477	-0.724 (0.216)	0.495	0.018
Usual Activities	0.394	1.111 (0.134)	0.427	0.430 (0.468)	0.434	0.007
Pain/discomfort	0.591	0.465 (0.519)	0.596	-0.490 (0.344)	0.605	0.009

Anxiety/depression	0.487	-0.387 (0.571)	0.491	-0.085 (0.851)	0.491	0.000

*p-value<0.01. Bolded results signal items which met the cut-off for meaningful DIF. LSS = level sum score. P<0.01 and $\Delta R^2 \geq 0.02$

OLR validation

The results which were obtained from three different sets of 95% of the sampled data were consistent with the development stage results. No significant and meaningful DIF was obtained.

OLR Results: **EQ-5D-Y-5L (IA)**

After removing those with missing EQ-5D-Y-5L (IA) item data, 223 participants (87 in clinic arm; 136 in school arm) remained for analysis in the development sample and a sample of 95% was used in the validation stage (83 in clinic arm; 129 in school arm). The arm coefficient confirmed a uniform DIF for self-care and usual activities (Table 25). Thus, the clinic arm was less likely to score highly (indicating better health) on self-care (-1.75, p = 0.002), usual activities (-1.70, p = 0.001) as compared to the school arm. None of the items meet the 2% ΔR^2 cut-off for meaningful DIF because there were no responses on certain levels.

Table 25 – EQ-5D-Y-5L (IA) OLR results in the development and validation samples

	Model 1	**Model 2 (uniform)**	
	R^2	**Arm coefficient, e (p-value)**	**R^2**
Development sample			
Mobility	0.023	-0.935 (0.063)	0.051
Self-care	0.014	-1.747 (0.002)	0.110
Usual Activities	0.001	-1.704 (0.001)	0.106

Pain/discomfort	0.015	-0.619 (0.150)	0.030
Anxiety/depression	0.017	0.211 (0.658)	0.018
Validation sample			
Mobility	0.029	-1.074 (0.041)	0.065
Self-care	0.017	-1.684 (0.004)	0.107
Usual Activities	0.001	-1.665 (0.001)	0.102
Pain/discomfort	0.016	-0.510 (0.245)	0.026
Anxiety/depression	0.022	0.313 (0.534)	0.025

OLR validation

The results which were obtained from three different sets of 95% of the sampled data were consistent with the development stage results. Similarly, uniform DIF was obtained on mobility, self-care, and usual activities, however, none of the items showed meaningful DIF.

OLR Results: **EQ-5D-Y-3L (SC)**

After removing those with missing EQ-5D-Y-3L (SC) item data, 223 participants (87 in clinic arm; 136 in school arm) remained for analysis in the development sample and (82 in clinic arm; 130 in school arm) remained in the validation sample. Self-care had significant arm coefficient showing uniform DIF however, it was not indicating meaningful DIF (Table 26). The arm coefficients show that pupils in the clinic arm were 1.4 times less likely to score highly (indicating better health) on anxiety/depression as compared to the school arm. None of the items meet the 2% ΔR^2 cut-off for meaningful DIF.

Table 26 – EQ-5D-Y-3L (SC) OLR results in the development and validation samples

	Model 1	Model 2 (uniform)		Model 3 (non-uniform)		
	R^2	Arm coefficient, e (p-value)	R^2	Arm* LSS coefficient, e (p-value)	R^2	ΔR^2
Development sample						
Mobility	0.471	0.473(0.481)	0.476	-0.230 (0.632)	0.478	0.002
Self-care	0.471	-1.359 (0.038)	0.508	-0.331 (0.438)	0.513	0.007
Usual Activities	0.651	-0.176 (0.782)	0.652	-0.077 (0.868)	0.652	0.000
Pain/discomfort	0.640	0.619 (0.298)	0.645	0.112 (0.779)	0.645	0.000
Anxiety/depression	0.472	1.119 (0.067)	0.494	0.646 (0.095)	0.510	0.016
Validation sample						
Mobility	0.469	0.899 (0.224)	0.484	-0.619 (0.375)	0.493	0.009
Self-care	0.490	-1.232 (0.061)	0.519	-0.232 (0.600)	0.521	0.002
Usual Activities	0.644	-0.508 (0.442)	0.648	-0.227 (0.647)	0.649	0.001
Pain/discomfort	0.640	0.659 (0.268)	0.646	0.091 (0.819)	0.646	0.000
Anxiety/depression	0.499	1.010 (0.103)	0.516	0.603 (0.130)	0.530	0.014

OLR validation

Validation results (Table 27) were similar to those in the development sample except that on self-care there was no uniform DIF which was observed. However, the arm coefficient showed that pupils in the clinic arm were less likely to score highly (indicating poor health) in self-care and not statistically significant (p = 0.061).

OLR Results: **EQ-5D-Y-5L (SC)**

After removing those with missing EQ-5D-Y-5L (SC) item data, 111 participants (65 in clinic arm; 46 in school arm) remained for analysis in the development sample and 105 (59 in clinic arm; 46 in school arm) remained in the validation sample. Mobility, usual activities, and anxiety/depression met the 2% ΔR^2 cut-off for meaningful DIF. This was also confirmed in the validation sample. (Table 27).

Table 27 – EQ-5D-Y-5L (SC) OLR results in the development and validation samples

	Model 1	Model 2 (uniform)		Model 3 (non-uniform)		
	R^2	Arm coefficient, e (p-value)	R^2	Arm* LSS coefficient, e (p-value)	R^2	ΔR^2
Development sample						
Mobility	0.402	1.886 (0.061)	0.455	0.408 (0.182)	0.479	0.024
Self-care	0.679	-2.087 (0.084)	0.717	-0.730 (0.218)	0.733	0.016
Usual Activities	0.731	-1.409 (0.266)	0.747	3.312 (0.277)	0.778	0.031
Pain/discomfort	0.292	-0.367 (0.558)	0.296	-0.125 (0.681)	0.298	0.002
Anxiety/depression	0.406	-0.178 (0.772)	0.407	-0.690 (0.053)	0.452	0.045
Validation sample						
Mobility	0.429	0.725 (<0.001)	0.468	0.422 (0.183)	0.495	0.027
Self-care	0.697	-2.490 (0.069)	0.742	-1.021 (0.125)	0.768	0.022

Usual Activities	0.710	-1.877 (0.198)	0.736	4.357 (0.777)	0.897	0.161
Pain/discomfort	0.288	-0.322 (0.597)	0.292	-0.127 (0.675)	0.294	0.002
Anxiety/depression	0.409	-0.110 (0.859)	0.410	-0.678 (0.056)	0.455	0.045

OLR validation

The results obtained were almost similar to those in the development stage, mobility, usual activities, and anxiety/depression items met the 2% ΔR^2 cut-off for meaningful DIF and this was similar to the development stage.

III. Phase 3- Key informant interviews

In-depth interviews were conducted with Healthcare workers (n=10), to share their perceptions on the use of the scales in routine HIV clinics, and fieldworkers (n=4), to understand their experiences with administering the scales.

Table 1: Breakdown of respondents by profession

Healthcare worker cadre	Frequency (n)
Staff Nurse	2
Doctor	1
HIV Counsellor	2
Community caregiver	1
Paediatrician case manager	1
Social worker	2
Occupational therapist	1
Total	**10**

Their views are summarised in the upcoming sections.

a. Healthcare workers

Healthcare workers (HCWs) were presented with the five scales (EQ-5D-Y-5L (IA & SC), EQ-5D-Y-3L (IA & SC) and the CHU9D to review at least 2 weeks before being interviewed. The HCWs were not part of the fieldstaff employed on the study to conduct research activities. They were then asked about their overview of the scales (including instructions, questions), the dimensions of the EQ-5D-Y scales, and their preferred scale for use in their settings.

a. Clarity of instructions or layout

Healthcare workers mostly felt that the instructions of the EQ-5D-Y scales were clear and easy enough for 10–15-year-olds to understand within their settings. However, some were concerned that some words might be foreign to younger adolescents. It was also raised that an IsiZulu version of the scales would be ideal to accommodate the spectrum of people attending their facilities, most of whom come from IsiZulu-speaking backgrounds.

Overall

HCW5: *"Okay, I think they will understand very well especially young kids today are familiar with such feelings and such words and they are very expressive of how they feel. So, I think they'll understand very well what is expected of them."*

HCW8: *"I think there are words that they are not going to understand."*

HCW9: *"Okay I'd start off saying that the instructions are clear and make sense but are in English. English is a 'no' because children are not the same. We have children from Lamont, Umlazi (Black townships) and other hospitals from surrounding areas…the languages need to be mixed so that every child can understand."*

When asked to select the most appropriate scale based on layout, most HCWs opted for the EQ-5D-Y-3L, indicating that it is "straight to the point", and the tick options for the responses is something learners would be familiar with. Some indicated that they preferred the layout and the simplified wording used in the CHU9D.

Y-5L

HCW3: *"Yes, it is clear (Y-5L IA) 'cause when you hear like "mobility" maybe some will be confused mobility, mobility but they even put on brackets walking about so that there will be no confusion. I think that everything is explained very well."*

Y-3L

HCW1: *"the layout is okay simple, straight to the point"*

HCW5: *"It's the EQ-5D-Y-3L (SC), It's something I think they are familiar with from school, the way of answering and ticking boxes and whatnot, straight to the point questions and answers."*

CHU9D

HCW3: *"The layout is clear I think it is right it is very good cause you can see that it's a heading then they tick boxes where they tick whatever that is applicable to them …English is simple."*

b. Clarity of dimensions

The dimensions were perceived to be relatively clear, apart for younger children possibly not understanding what some of the dimensions meant. *Mobility* was often mentioned by HCWs as a possible confusing term for adolescents to comprehend. There was also concern about younger children not identifying with the word, *worried*. Furthermore, the indicated doing daily activities should consider taking medication for ALHIV. Some highlighted that the CHU9D covered a broader spectrum of dimensions, albeit it would be too long for younger children with lower concentration levels.

Y-5L & Y-3L

HCW3: *"Yes, it is clear. Maybe some will be confused with mobility."*

HCW5: *"Yes, it's 'mobility'. For a 10 year and 11-year-old, I doubt that they would understand such a word. Yes, just "mobility" I guess because I think the other ones, they are familiar with even from school, I doubt. It's just "mobility" that is a bit tricky for a 10-year-old, 11-year-old and a 12-year-old."*

HCW8: *"The word 'mobility', they won't understand it. I think some things are based on the vocabulary of each child."*

HCW4: *"When you go to question number five, you see, where it is under self-administered..However, when it comes to 'feeling worried, sad, or unhappy', I feel smaller children, like your 10- and 12- year-olds will not understand the term 'worried'. I think when they learn about emotions in school, they learn sad and happy, it's easier for children to understand. But when you talk about worry, this I feel is where adults understand… We are not taught to be worried at home; it is something that is for parents. You can be sad; you can be happy, but worried I feel that is too big and inappropriate for younger children."*

HCW3: *"No, I think the words are clear there is nothing I can change ….they talk about washing and dressing myself, but they never mentioned anything about their medication."*

HCW9*: "I'd remove mobility. It seems insensitive to them [and] they wouldn't understand. They would feel as if they were disabled because they had HIV and AIDS."*

CHU9D

HCW2: *" 9 dimensions. Cause the questions there its broad…"*

HCW4: *".. It is just that there is too repetition, you know of questions and I saw, yes, and I feel that even the questions that they answer are many for smaller children because of their concentration levels. We know most of them like your ten year olds and eleven year olds and twelve year olds, their focus span is very short".*

c. Clarity of responses

The questions/response options were considered to be clear by HCWs. Some HCWs indicated that the Y-5L provided "more choice" when it came to selecting the most appropriate severity level. However, most reported it created more confusion with lack of clarity between Y-5L options (" a little bit vs. some"). Similarly, HCWs highlighted that the CHU9D options ("really" vs. quite") were confusing. Based on clarity of response options in the Y-3L, most HWCs preferred this measure.

Y-5L

HCW1: *"Ya, I think it covers some gaps you know the threes one like mild, moderate, and severe so there might be something that is in between so the five one it covers… it covers that bridge, you know. So, I think it gives you more options"*

HCW1: *"I think five is more… more choice you know I'd choose the five the one with five options if possible .."*

HCW6: *"I felt in all the questions basically mean the same thing. 'I have a little bit problem walking or I have some problem walking"*

HCW6: *"You see the question "I have some problem in walking about", "I have a lot of problems walking about", 'I cannot walk about" (Y-5L SC) they would differ per child because there are children who have disabilities. You would find that the child is not handling the disability well maybe they are still angry over it, so it won't be easy for them to be asked those question. At least maybe if they questions were simpler and not so many questions. Maybe use words 'can you walk unassisted', either a yes or a no that simple right now it leaves them wondering if they have a problem. 'I have a little bit of a problem walking about' so to them it implies that not being able to walk is a problem. The way the word comes across it would be different on how they interpret it."*

Y-3L

HCW4: *"The responses are clear, they are very clear, like a child can tell you if they have pain or not. They can tell you if they are happy or not. They can tell you if they were able to dress themselves or not. So, I find them very clear and child friendly.*

HCW 10: *"I think I will go with the 3 levels because even though it is missing some information because the 5 level might get too confusing. You know, there are so many things what I say, what do I do, what does this mean.*

HCW9: *"1 to 3 because 1 to 5 is too much for a child they get irritable if you are going to ask too many things"*

CHU9D

HCW6: *"Like here I said, 'I am quite worried, sad or unhappy' or 'I am really worried…' so I think 'quite' and 'really' mean the same thing. I am quite worried, or I am really worried."*

d. Understanding of VAS activity

Several HCWs thought that 10-15-year-olds would be able to understand what was expected of them for the VAS activity on the EQ-5D scales. Two participants noted that the VAS activity could potentially pose a challenge to some ALHIV due to HIV-related cognitive delays or brain development.

HCW1*: "I'd say the majority but not all of them because kids are not the same and remember it's the patients here who are HIV positive and, in terms of when they started their medications, their brain development might ...[not] be the same with other peers of the same age. So, for the same age patient the scale might be interpreted otherwise."*

Some participants were of the view that ALHIV might not fully understand what was expected of them for the VAS activity. They suggested simplifying scale numbering and adding images to ease comprehension. This is what one of them had to say:

HCW8: *"I don't think it is going to be easy for a child to understand it. [It] would be better if maybe we say from zero to ten with maybe an image of sorts to show expression. It could be a sad or happy face. A child would be able to relate, and they would be able to respond accordingly to the scales as long as there are images there. Maybe use a sad face or a happy face, a tired person, or an active person those sorts of images that would be relatable for children. I think from 10 to 15 – the fifteen-year-old would understand the scale and would be able to understand but we would need to balance it with images."*

In similar vein, another HCW said:

HCW10: "*Rather [use] zero to ten because… normally with social work we have an emoji type of thing that we always use for anger and happiness… so those are things that are put on a scale for a child. So visually for a child to say, "I think this is how I am feeling"."*

HCW5: *"I think its this one because its less expressive. Ya section is it not the same as this one? it's the (Y-3L SC). The last statement where they have to rate themselves. I don't think rating*

themselves is within their level. Ya its not within their level so nje it's only an adult can just rate themselves. Like give me on a scale from zero to hundred how do you feel today, only an adult can understand like the wording of that not kids, not adolescents nah they won't understand that."

e. Suitability for assessing HRQOL in clinics

All HCWs indicated that all scales were appropriate for use in their clinics as they covered relevant dimensions for assessing HRQoL in ALHIV. However, several HCWs indicated that they would add a dimension that assessed support structures or interpersonal relationships. They felt that sometimes ALHIV in this setting did not have basic essential support structures, and at times were themselves heads of households. Moreover, the elders or caregivers were not supportive in some households, especially with clinic appointments and in ensuring that the adolescents took their medication. This is what HCWs had to say concerning this:

Overall

HCW1*: "I don't know whether its relevant, but it's the support structure of that particular adolescent because some adolescents… don't have their own biological parents. They are raised by some aunts or relatives of which sometimes they are not as supportive as… one would expect. … It's a challenge for those kids and some kids are actually… heading homes themselves. They don't have an elder at home to look after them. So maybe if somehow it can come up, do they have that kind of support. If I can give you an example, if you have a child that is not doing well in terms of virological suppression, you are picking up some issues and you ask for a caretaker or guardian or parent, then the child will come back alone in the next visit. Then they will tell you that "No, granny said 'hhayi', [i.e., no] she is busy with her own things". Then the child is in front of you alone. The child is worried about her health, is worried about somebody who is supposed to help her, but unfortunately cannot influence that older person or that caretaker. So, it is a challenge for those kids."*

***HCW3**: "Most of the time we are telling them that they must work hand-in-hand with their parents. If you know [that] at six o'clock you are taking your medication, you must make sure that you remind your mother or father 'hey now it's time for my medication'."*

***HCW10**: "I think add in something like interpersonal relationships. With adolescents that is part of their lives, their friends, how they are interacting with their peers. They may be experiencing bullying or [having] nice experiences. So, I think it's important to add interpersonal relationships somewhere… because even within the family you find that the adolescents are having a struggle with communication with their parents, with their caregivers, because they are at that point where they want to develop themselves and establish their own identity. So, there is that struggle. It's part of a process, so it's nice to know what they are going through at the moment, you know, if they need support."*

***HCW7**:"No, I think you have covered, but what I can perhaps add on my side, like, to educate them on how they should eat and the level of how they should live. Add Nutrition".*

In response to which scale they felt was best suited for assessing HRQoL at their clinic, three HCWs selected the EQ-5D-Y-3L based on clear and shorter list of response options. Six selected the CHU9D as their instruments of choice indicating that it appears to be more "child-friendly" and covers all important dimensions. Only one participant preferred the EQ-5D-Y-5L because it seemed a compromise between the simplicity of the EQ-5D-Y-3L and the comprehensiveness of the CHU9D.

Y-5L

HCW4: if the questions are separated like there is a heading, there is space, there are answers and there is a line separating. So, I feel that the first one is more friendlier, especially to small children because I found myself, even myself as an adult focusing more on EQ5DY5L than EQ5DY3L".

Y-3L

HCW3: *"Because you know when you are dealing with kids you don't need like more time to ask more questions… maybe you find that you ask only one question from here, but she will give all the answers before you even go to [option] number 3. Then to prevent that… they can get bored now if you are asking so many questions, they feel irritated sometimes."*

HCW10: *"The 3 levels because even though it is missing some information… because the 5 level might get too confusing. You know, there are so many things (e.g.) what I say, what do I do, what does this mean….. "I don't know. its hard ot say because the 9 levels kids will catch on things that are not clear you know so it will give you better but I think if you cut it down to three responses that might be good because this is going to tell you a little bit more about the child. But having five responses might confuse them"."*

CHU9D

HCW4: *"The questions they are clear, they are child-friendly, they are relevant. It is just that there is too repetition, you know of questions and I saw, yes, and I feel that even the questions that they answer are many for smaller children because of their concentration levels. We know most of them like your ten year olds and eleven year olds and twelve year olds, their focus span is very short".*

HCW 4*: "I like 9D the most… I find 9D most relevant because the children are able to express their feelings…I feel for me, it covers everything in terms of the social wellbeing."*

HCW 8*: "I Choose Child Health Utility 9D because the children would be able to express themselves better."*

f. Readiness for implementation in routine HIV clinics

When asked about scale implementation at the clinics, most thought that it was feasible, once they had received approval from higher structures at the clinics. Most opted for HCWs administering the scale within routine clinic appointments. They did, however, highlight that staffing might be a challenge and that staff might need some training to ease incorporating the

scale into their daily routine screening and knowing what to do about the data. One HCW also noted the challenges with implementing self-completion modes of scales, as adolescents may not accompany caregivers to all clinic appointments, especially if at medication pick-up appointments.

HCW 7: *"If you want to implement the scale… we need approval, but these general questions are the questions I ask every day, so I feel if I can implement it…Like I said…a person needs to be balanced physically, psychologically, emotionally and spiritually. We will need training for this. Well, to sharpen the skills, we always need training, but as I have said, these questions are questions I ask almost every day..."*

HCW 8: *"I think it would be the clinic manager that would grant a go-ahead. I also don't think there would be a cost involved because it would be a matter of certain days where the children are called over, gather their files, and have a scheduled day with a number of children expected maybe over the weekends. Then it would just be a matter of incentives for examples cake, juice for the day or health related pamphlets to read more information at home".*

HCW 9: *"If you can implement the scale firstly, the language, this hospital caters for different demographics so we can use both English and IsiZulu… The clinic manager will take it up to the CEO of the hospital who will need to approve your proposal because we don't make decisions on our own."*

HCW10: *"For the scale implementation, a simple form shouldn't be difficult to implement… [However], it can be time consuming, and it can need a person to be able to understand the form themselves… [to] know what it is that it is asking. So, I think people will need to be trained if you are thinking of using Department of Health staff in terms of the scales and the forms…"*

HCW 2: *Self-completion "The only problem is that in my clinic sometimes the mothers don't bring their children. At the clinic 'cause they are attending school, so we tell them not to bring the child maybe if its not for bloods but not for three visits so sometimes the child is in and out you know.*

b. Field staff

In-depth interviews were conducted with study field staff (n=4) who had administered the EQ-5D-Y-5L, EQ-5D-Y-3L (IA and SC) and CHU9D (SC) to participants in the cognitive interviews and survey phases of the study to assess their experiences administering the scales. Field staff were probed about the clarity and relevance of scale instructions, questions and responses; words that participants had difficulty understanding; and lastly, about the perceptions of the VAS activity based on their experiences with it. Their responses follow.

a. Clarity of instructions and layout

Overall, fieldstaff reported that the participants did not have any difficulties understanding the questions on the IA version. However, they indicated that 10–13-year-olds generally had some difficulties with understanding the instructions of the SC scales. Some fieldworkers highlighted that adolescents perceived the CHU9D to be too long.

Y-5L & Y-3L

FW1: *"To me they (Y-5L, Y-3L, SC) were not clear for 10- to 13- year-olds"*

FW2: *"For me, I'd say that it is unclear (Y-5L, Y-3L, SC) for 10- to 12- year-olds depending on the type of school they go to."*

CHU9D

FW3: "The kids would say that the questionnaire was too long and at times they would get irritable with completing it".

a. Dimensions

Words that participants found unclear or had difficulties understanding include *mobility, usual activity, extreme* and *discomfort*. They noted the need for pictures (as per the CHU9D) to facilitate adolescent's understanding of the dimension.

Y-5L & Y-3L

FW1: *"Mobility, maybe put words the young adolescents are familiar with… Usual activities, because a ten-year-old gets confused… Wording like mobility, usual activity, discomfort it's a no.... Extreme, they don't' understand that. So, you have to probe and probe maybe using examples and say, "okay this is extreme; this is not extreme" you get what I mean?"*

FW2: *"Also, the words like daily routine, a lot of our kids don't have a daily routine. I go home, I have chores, I don't have a daily routine...chores or anything…I still think… activities is a big word…."*

FW3: *"The words that were used, for example, mobility, I had to break it down for them to understand it …. And the adolescents are like, 'I've never heard of that word', we get that feedback 'but we've never heard of that word', 'we do know what moving around is but mobility we don't understand' ...also 'doing usual activities5', they'd ask when you have to break it down doing usual activities and explain and then they are like 'oh yes that means that, okay'....Discomfort, as well."*

FW4: *"Mobility is the first one. And also 'doing usual activities' like usual activities they didn't understand that most of them."*

CHU9D

FW2: "Firstly to… in order… for the dimensions to make sense I'd use colourful pictures (like the CHU9D)"

b. Clarity of questions/responses

The field team expressed that on the whole, response options were quite clear to participants. They did, however, mention that the wording of some of the terms used to depict severity levels were a bit confusing to participants. They also mentioned that participants were at times confused by some terms on the SC versions (Y-5L, Y-3L) because they seemed similar to each other (e.g. "a little bit" versus "some") and were asked to clarify these for participants

who were using the SC scales. In addition, the consensus view was that the 5L scales had too many response options for participants and at times they would select the first response option to avoid having to read all five options for each dimension. This is what they had to say:

Y-5L

FW1: *"The 5L had too many responses… Words like a lot, a little bit, some are also confusing to children."*

FW2: *"There are too many responses (Y-5L, SC). A lot of kids don't really understand, especially because of the language barrier. For example, they have difficulty understanding what's 'a lot', what's 'a little', 'some'. So it's difficult for them to differentiate. So, they end up ticking the first one… I think it would help if we had 'pics' like emojis especially for the younger kids."*

FW4: *"I felt like 'a little bit' and 'some' sounded the same to them. They'd just skip 'little bit' and go to 'some'."*

Y-3L

FW3: *"They always chose the first one ("no problem)...I think they just wanted to get over and done with the interview. I think they would prefer less options... it's like I was confusing them in a way."*

FW1: *"Instructions is clear because its 'walking about' its more direct in the sense I have no problems in walking about, I have some problems walking about. I am saying in the sense that its three options its clear 3 options".*

CHU9D

FW2: *There is too many responses*

c. Understanding of VAS activity

Y-5L & Y-3L

The VAS activity was perceived to be understandable for most participants. Only one of the field team suggested using visual aids to assist the younger participants. This is what they had to say:

> **FW1:** *"Not to 10- to 13-year-olds, but yes for 14- and 15-year-olds… Perhaps use visual aids to indicate 'this is the worst' and 'this is the best'… So, so if you are showing numbers like this it's difficult for them."*

8) Discussion

Tracking of health-related quality of life among ALHIV in treatment programmes is now regarded as a critical monitoring area as large cohorts of these patients survive into adulthood in SSA. However, the evidence on appropriate HRQoL measures to use within routine HIV clinical settings is scarce. Given the vast application of the EQ-5D in adult HIV research studies and the robust measurement properties associated with the EQ-5D-Y-3L in paediatric disease studies, we sought to assess the appropriateness of the EQ-5D-Y-5L for use within HIV clinics as part of adolescent HIV clinical monitoring. Our aim was to assess the feasibility, reliability and validity of the EQ-5D-Y-5L (IA, SC) versus the EQ-5D-Y-3L (IA, SC) and CHU9D (SC) for use in routine HIV clinical settings among ALHIV in KwaZulu-Natal, South Africa. Cognitive interviews revealed that there was better understanding of the EQ-5D-Y-5L scale among with ALHIV compared to school learners. This study found that the EQ-5D-Y-5L (IA) was associated with the strongest psychometric properties in terms of known-groups validity and convergent validity when compared to the Y-5L (SC), Y-3L and CHU9D. Test-retest reliability was similar in the Y-5L (IA) and Y-3L (IA). Whilst HCWs and field staff responded positively to the use of the EQ-5D-Y-5L in clinics, most preferred the EQ-5D-Y-3L largely due to its brevity. Overall, our findings suggest that the EQ-5D-Y-5L (IA) is a viable HRQoL scale for use in HIV clinical settings with ALHIV in SSA.

The feasibility of the Y-5L (IA) for ALHIV was confirmed in the cognitive interviews. Most ALHIV in our study understood the instructions, questions and response options in the EQ-5D-Y-5L (IA), and found the questionnaire easy to complete, which is in agreement with findings from a study among children and adolescents in psychiatric care in Sweden (Krig et al., 2020). Most participants were able to recall the dimension walking about and response option “no problem” However, ALHIV reported difficulty with understanding the word *mobility*, and response option “extremely” and “a little bit”. Of concern was the poorer understanding of the Y-5L scale among the school sample versus ALHIV, as demonstrated in the ranking and recall activities. The lack of a private setting, restricted time with learners at school during COVID-19 and differences in interviewer administration could have contributed to these findings in the school arm and warrants further investigation. Whilst the school arm showed sub-optimal results, we proceeded to Phase 2 (quantitative survey), based on favourable results from the clinic arm.

The feasibility of the EQ-5D-Y-5L scale was also supported by the relatively short duration for scale completion (IA: 1.58 minutes, SC: 1.35 minutes), which was similar to Y-3L scale completion times (IA: 1.36 minutes, SC: 1.71 minutes) in this and a previous South African study (Scott et al., 2019). However, for SC scales, the CHU9D had the shortest completion time overall in the clinic arm, whereas in the school arm, the EQ-5D-Y-3L had the shortest completion time. Evidence of feasibility of the EQ-5D-Y-5L (IA and SC) was further supported by its low levels of missing values (0-7%) across all dimensions and VAS in the in the clinic arm. The missingness in the SC version across all dimensions in the Y-5L (0-7%) versus Y-3L (0%) clinic arm, was similar to that reported in a recent South African study with chronic and acute paediatric groups (Verstraete et al., 2022). Missingness in the CHU9D was also very low (0-3%).

Our results show a higher reporting of problems in certain areas (*looking after myself, doing usual activities, pain or discomfort*) among ALHIV compared to the general population, and this pattern is most pronounced for the EQ-5D-Y-5L (IA) versus Y-3L (IA) or Y-5L (SC). However, this higher reporting could mean that ALHIV who had poorer socio-economic status compared to the general population interpreted these questions in light of their socio-economic status and not their health. Previous studies have reported lower HRQoL scores for similar scale dimensions in other paediatric HIV studies in this region (Nkwata et al., 2017, Kagee et al., 2018). Median VAS scores in the clinic arm ranged between 80-85, with the median VAS score 1-point lower in the Y-5L versus Y-3L (IA), yet 5-points higher in the Y-5L versus Y-3L (SC). As anticipated, the median VAS was significantly lower in the clinic versus school arm, albeit only for the Y-5L (IA) and Y-3L (SC). The reports of problems among the general population sample are aligned with findings from a previous South African studies (Scott et al., 2017, Verstraete et al., 2022) and could be linked to socio-economic determinants that were amplified during COVID-19 (i.e. household food insecurity, unemployment, lack of access to water and electricity, violence, lack of safety in high crime areas) and impacted adolescent HRQoL. Among the SC scales, the CHU9D was able to detect more problems for similar dimensions in the Y-5L and Y-3L (SC) (e.g. *pain or discomfort, worried, sad or unhappy, doing usual activities*). In addition, in the CHU9D there was a higher proportion of reporting problems among ALHIV compared to the general population for key psychological problems (*doing school work, daily routines, joining in on activities*)

lends support to previous paediatric HIV studies in the region that have highlighted the high burden of common mental problems and stigma (Pantelic et al., 2020, Kagee et al., 2018).

The redistribution of scores from the Y-3L to the Y-5L (IA) showed few inconsistencies across dimensions, with the highest observed for the *mobility and doing usual activities* dimensions. Note, this analysis could only be performed for the school arm due limited data for both scales in the clinic arm. Nevertheless, our results are in agreement with studies from South Africa (Verstraete et al., 2022) and China (Pei et al., 2021, Wong et al., 2019a). The absolute discriminatory power of the dimensions improved when moving from the Y-3L to the Y-5L (IA) for clinic arm for all dimensions except for *worried, sad or unhappy*. This is aligned with previous studies that reported higher absolute discriminatory power in the Y-5L than for the Y-3L version in all dimensions have been reported in paediatric studies from South Africa (Verstraete et al., 2022) and China (Lin et al., 2022). However, for SC scales, the Y-3L exhibited higher discriminatory power compared to Y-5L (SC) in the clinic vs. school arm. This could be due to poorer understanding of the Y-5L SC versus the IA in our sample. A previous study reported a slightly higher Shannon index ($H\_$) in the Y-3L compared to the Y-5L in paediatric patients with spinal conditions (Wong et al., 2019a). The relative discriminatory power with regards to the evenness of the distribution reduced slightly in the Y-5L compared to the Y-3L for both the IA and SC, similar to that found in previous studies (Verstraete et al., 2022, Lin et al., 2022). Nevertheless, the redistribution of scores and absolute discriminatory power in certain dimensions support the validity of the Y-5L (IA).

Regarding the distribution of EQ-5D-Y- 5L results, the ceiling effect in the sample was high, for both arms, clinic (IA: 68%, SC: 70%) and school (IA: 76%, SC: 68%). A similar ceiling effect for the EQ-5D-Y-5L-IA (>80%) has been also reported for the *mobility* and *looking after myself* dimensions in other studies with children and adolescents with scoliosis in China (Lin et al., 2022). This high ceiling effect could be partially explained by the more than two-thirds of ALHIV in this study in less severe HIV clinical disease stages (WHO HIV clinical stage 1-2) and stable on treatment based on viral load levels. A higher ceiling effect could be expected in children, taking into account their capacity of adaptation to chronic diseases and treatment routines, known as the wellbeing paradox or response shift effect (Ravens-Sieberer et al., 2006, Schwartz et al., 2007). When moving from the Y-3L to Y-5L there was an increase in relative ceiling effects: clinic (IA= -1.6%, SC= -0.2%), school (IA=- 21.3%, SC=4.1%). It is

plausible as a higher number of response options could have increased scale complexity and tiredness, as indicated by HCWs, resulting in more adolescents choosing extreme responses on a Likert scale (De Civita et al., 2005). This was most pronounced in the school arm and could be due to potential lower literacy levels in the school arm. Our findings differ from a recent South African study which demonstrated a significant relative reduction in ceiling effects when moving from the Y-3L to the Y-5L (SC) (Verstraete et al., 2022). Ceiling effects decreased when moving between the Y-3L (SC) to the CHU9D (clinic: 16%, school: 14%) and when moving from the Y-5L (SC) to CHU9D (clinic:13%, school: 8%). This suggests that adolescents may have had a better understanding of the response levels in the CHU9D, and perhaps tiredness and other psycho-social issues are common problems among adolescents with and without health conditions.

Our findings support good test-retest reliability in both the Y-5L and 3L (IA) dimensions for the clinic and school arm based on the high agreement for each dimension (Gwet AC 0.76-0.96), which is similar to that reported in a study with Chinese paediatric patients (Wong et al., 2019a). For both the Y-5L and Y-3L (IA), agreement was lowest for the feeling *worried, sad and unhappy* dimension, as evidenced in studies form South Africa (Verstraete et al., 2022) and China (Lin et al., 2022, Wong et al., 2019a), which could attributed to general changes in emotional functioning that typically occur in paediatric HIV populations (Vreeman et al., 2015).

Convergent validity of the Y-5L (IA) was supported by significant moderate correlation between dimensions as recorded by the level sum score and a self-reported general health status item (clinic: *rho* 0.37-0.21; school: none), and VAS score (clinic: *rho*- 0.34, school: *rho*: -0.31- -027). The results with the EQ-5D-Y-5L are in line with previous studies that assessed the correlation between EQ-5D-Y-3L and general health status measures among children and adolescents (Ravens-Sieberer et al., 2010, Burström et al., 2014). There was an improvement in convergent validity with the Y-5L (IA) compared to the Y-3L (IA) for all dimensions with the general health status item except for *pain or discomfort* and *worried, sad or unhappy*. Results were similar for the Y-5L IA vs. SC, albeit correlations were not statistically significant in the Y-SC. When convergent validity was assessed using the VAS score against the dimension score, results between the Y-5L (IA) and Y-3L (IA), however the Y-5L (SC) showed stronger evidence of convergent validity in the clinic arm compared to the Y-5L (IA).

Convergent validity between the EQ-5D scales and CHU9D was stronger in the Y-3L (SC) than the Y-5L (SC) as it had more significant correlations.. Of note, there were strong correlations between the Y-5L (SC) and CHU9D dimensions for *worried, sad or unhappy* (*rho* 0.82, p<0.001) and *looking after myself* (*rho* 0.86, p<0.001) in the clinic arm. Previous studies have also reported strong correlations between the Y-5L (SC) and other generic adolescent HRQoL measures such as the PedsQL (Verstraete and Scott, 2022) and KIDSCREEN-10 (Pei et al., 2021).

Overall, only the Y-5L (IA) showed evidence of known-groups validity as median VAS scores were able to discriminate between known-groups with differing WHO HIV clinical stages, which is accordance with recent evidence on the known-groups validity of the EQ-5D-Y-5L among children and adolescents with chronic condition (Verstraete and Scott, 2022, Lin et al., 2022, Mayoral et al., 2022) Our finding suggests that the EQ-5D-Y-5L (IA) could potentially be used as part of community-based health screening efforts operated by lay healthcare workers in resource limited settings (i.e. rural clinics, school healthcare programmes, juvenile detention centres) to detect and link to health services those ALHIB in need of care (Marcus et al., 2017).

Whilst our sample size was insufficient for any valid assessment of differential item functioning, we present results here for purposes of fulfilling report objectives. 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.

There was mixed results with regards to the feasibility of implementation of the EQ-5D-Y-5L. Key informants highlighted that the EQ-5D-Y scales were comprehensive in that it covered dimensions pertinent to HIV-infection and ART, were clear in terms of instructions, could be administered by HCWs during their routine patient screening and the information used in patient management. Our findings are aligned with results from a South African study which assessed perceptions of the Y-3L among HCWs (Scott et al., 2017). Some HCWs in our sample also indicated that adolescents could either complete the scale whilst in the clinic waiting area or take the form home to complete. However, there was stronger preference for the EQ-5D-Y-3L as HCWs were concerned about literacy levels in this setting. They highlighted the Y-3L would be simpler for completion given the fewer

response options and lack of clarity between responses in the Y-3L (a little bit, a bit, some). As per the interviews with adolescents, they also suggested alternate phrasing of certain terms (*mobility, discomfort, extremely*) to enhance understanding and to reduce distress associated with certain terms. Results suggest that adding a bolt-on dimension related to psychological functioning could improve the scales applicability for ALHIV. For example, several HCWs expressed the need for the scale to probe interpersonal relationships particularly with their caregivers given the major role they play in their treatment journey and reducing stigma (Shenderovich et al., 2021). The need for more psycho-social dimensions in the EQ-5D-Y-5L was also reported in a previous study among adolescents in inpatient care (Åström et al., 2020). Preference for the scale in both English and the local language (isiZulu) was expressed in several interviews given the poor levels of English literacy in this setting. Key facilitators to implementation of the scale within routine settings would be seeking approval from management, training on staff with regards to administration and how to refer ALHIV based on the information.

Our study had the following strengths: 1) our cognitive interviews used multiple methods (ranking exercise, discussion, observation), drawing on standardised EuroQoL guidelines, to assess adolescents' understanding of the EQ-5D-Y-5L; 2) in the cognitive interviews and cross-sectional survey, we sampled both ALHIV and a comparator general population group; 3) we employed two modes of scale administration (IA, SC), allowing us to assess differences in mode among the EQ-5D-Y scales; 4) ice-breaker exercises were inserted between scales in the questionnaire to reduce cognitive fatigue; 5) the SC mode was not influenced by teachers or parents as the participant completed this on the day of the interview in a private room under field staff supervision; 6) after each 25% of the sample in each arm completed the survey, we reversed ordered the scales in the questionnaire to reduce ordering effects.

Our results are subject to the following limitations: 1) we consecutively sampled adolescents accessing clinics and schools during the COVID-19 pandemic. Selection bias may have been present as adolescents with severe physical or mental health conditions, carer responsibilities or those from lower-socio-economic backgrounds, may have been absent on the day of recruitment; 2) the differences observed for the cognitive interviews in the clinic vs. school arm due could be due to differences in administration of the scales between fieldstaff. Due to COVID-19-related restrictions

in 2021, the field team had limited time and space to build rapport with participants; 3) As the EQ-5D-Y-5L and CHU9D are new instruments still requiring validation in the original language of development, we are unable to use the isiZulu versions of these scales. Once the validity and reliability of the English version of the EQ-5D-Y-5L is confirmed, future studies evaluating the translated isiZulu version of the scale will need to be conducted; 4) correlation between CHU9D and the Y-5L and Y-3L may have been influenced by ceiling effects; 5) due to sample size limitations we were unable to draw valid conclusions from our DIFF analysis; 6) the generalisability of our results to ALHIV with advanced HIV clinical stages is uncertain as our sample mainly included those in less severe HIV clinical stages.

9) Conclusion

Out study is the first to provide evidence on the psychometric performance of the Y-5L versus the Y-3L and CHU9D for ALHIV. Our results verify that the Y-5L version may be a feasible, reliable and valid extension of Y-3L to assess HRQoL among ALHIV, particularly if Zulu versions are made available. Cognitive interviews showed that there was good understanding of the English version of the EQ-5D-Y-5L among ALHIV but warrants further investigation for adolescents in the general population. The test-retest reliability and convergent validity was comparable between the Y-5L and Y-3L. The increased discriminatory power of the Y-5L for certain dimensions and know-groups validity of the Y-5L (IA) may result in greater sensitivity and responsiveness in measuring health status among ALHIV. There were strong correlations between the CHU9D and Y-5L compared to the Y-3L, and lower ceiling effects in the CHU9D which could be attributed to its ability in picking up cases with common mental health problems given its focus on psychological functioning. Overall, our findings suggest that the Y-5L IA version has potential for use in routine HIV disease monitoring, however the high ceiling effect suggest that it may be more appropriate for use among ALHIV with advanced disease and higher presence of problems. In addition, our results suggest that adding bolt-on dimensions focused specifically on psychological functioning as per the CHU9D may enhance the scales suitability for use among ALHIV given the high prevalence of mental health problems among this group in this setting. The application of the Y-5L versus Y-3L in future implementation studies should be guided by the

characteristics of the adolescent population. For younger adolescents, due to low literacy levels, the Y-3L IA may be the preferred option. For older adolescents the Y-5L (SC) could be the preferred option, and the Y-5L (IA) with bolt-on psychological dimensions for use among ALHIV with advanced HIV disease warrants further investigation.

10) Conflict of Interest

All investigators and staff on this study have no conflict of interest to declare. JV, JJ and AF are all members of the EuroQol group this did not influence the reporting of results. The views expressed in this report are not necessarily the views of the EuroQol research foundation.

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12) Appendices

Appendix 1- Screening form

SECTION A1: PRE-SCREEN (COGNITIVE INTERVIEWS: CLINIC & SCHOOL ARM)		
• *Section A1 is for the fieldworker to complete in conjunction with HCWs and teachers*		
1. Date of pre-screen assessment	____/_____/_____	
2. Fieldworker ID		
3. Screening ID		
4. Is the adolescent in the 10-15-year age-bracket?	☐ Yes ☐ **No**	
5. Is the adolescent in the following school Grade bracket (Grade 4-10)?	☐ Yes ☐ **No**	
6. Complete the English literacy assessment below- did the adolescent score ≥ 70%?	☐ Yes ☐ **No**	
7. Does the adolescent have any condition that will make it difficult for him/her to participate	☐ **Yes** ☐ No	
8. Is this adolescent classified as a person under investigation for COVID-19/has symptoms of COVID-19/close-contact of a COVID-19 case?	☐ **Yes** ☐ No	
9. Is the adolescent expressing signs of suicidal ideation, intoxication, or requires urgent medical attention	☐ **Yes** ☐ No	
ADDITIONAL QUESTIONS FOR ALHIV		
10. What is the adolescent's WHO Clinical stage?	☐ 1 ☐ 2	☐ 3 ☐ 4
11. Is the adolescent aware of his/her HIV status	☐ Yes- partially disclosed to ☐ Yes- fully disclosed to ☐ No	
12. Is their parent/guardian/foster parent/caregiver aware of the adolescent's HIV status?	☐ Yes ☐ No	

- **For Q4-9, if boxes that are highlighted then the participant is ineligible for participation. If unhighlighted then the participant is eligible to participate**

SECTION A2: PRE-SCREEN (CROSS-SECTIONAL SURVEY- CLINIC ARM)		
• *Section A2 is for the fieldworker to complete in conjunction with HCWs*		
1. Date of pre-screen assessment	____/_____/_____	
2. Fieldworker ID		
3. Screening ID		
4. Is the adolescent in the 10-15-year age-bracket?	☐ Yes ☐ **No**	
5. Is the adolescent in the following school Grade bracket (Grade 4-10)?	☐ Yes ☐ **No**	
6. Complete the English literacy assessment below- did the adolescent score ≥ 70%?	☐ Yes ☐ **No**	
7. Does the adolescent have any condition that will make it difficult for him/her to participate	☐ **Yes** ☐ No	
8. Is this adolescent classified as a person under investigation for COVID-19/has symptoms of COVID-19/close-contact of a COVID-19 case?	☐ **Yes** ☐ No	
9. Is the adolescent expressing signs of suicidal ideation, intoxication, or requires urgent medical attention	☐ **Yes** ☐ No	
ADDITIONAL QUESTIONS FOR ALHIV		
10. What is the adolescent's WHO Clinical stage? (For ALHIV only)	☐ 1 ☐ 2	☐ 3 ☐ 4
11. Is the adolescent aware of his/her HIV status	☐ Yes- partially disclosed to ☐ Yes- fully disclosed to ☐ No	
12. Is their parent/guardian/foster parent/caregiver aware of the adolescent's HIV status?	☐ Yes ☐ No	

• **For Q4-9, if boxes that are highlighted then the participant is ineligible for participation. If unhighlighted then the participant is eligible to participate**	

SECTION A3: PRE-SCREEN (CROSS-SECTIONAL SURVEY- SCHOOL ARM)	
• *Section A3 is for the fieldworker to complete in conjunction with HCWs*	
1. Date of pre-screen assessment	____/_____/_____
2. Fieldworker ID	
3. Screening ID	
4. Is the adolescent in the 10-15-year age-bracket?	☐ Yes ☐ **No**
5. Is the adolescent in the following school Grade bracket (Grade 4-10)?	☐ Yes ☐ **No**
6. Complete the English literacy assessment below- did the adolescent score ≥ 70%?	☐ Yes ☐ **No**
7. Is this adolescent classified as a person under investigation for COVID-19/has symptoms of COVID-19/close-contact of a COVID-19 case?	☐ **Yes** ☐ No
8. Is the adolescent expressing signs of suicidal ideation, intoxication, or requires urgent medical attention	☐ **Yes** ☐ No
• **For Q4-8, if boxes that are highlighted then the participant is ineligible for participation. If unhighlighted then the participant is eligible to participate**	

ENGLISH ASSESSMENT FORM			
1. **Interviewer to read:** How are you today? Do you like the weather today?			
SELF-COMPLETION			
2. **Circle the correct word on the right to complete the sentence**			
- **Winter is a very ____season**	hot	warm	cold
3. **Underline the correct word in brackets**			
- **Mother bought a bag of (potatoe/potatoes)**			

Read the story below and answer the questions below:

On the 16th of September 2021 New Town School will have its concert.

Grade 2 learners will sing and dance. First the choir will sing.
Thabo will do a gumboot dance. Thabo's sister, Nomsa , and her friends will also do a dance. Our teacher will play the piano.
Lastly, the principal will hand out prizes to all those who take part.
I hope that I will get a prize.

4. On what date and month **will the concert be held?**	Date:	Month:
5. **Name the school that will have the concert?**		

6. **Which Grade will sing and dance at this concert?**		
7. **What type of dance will Thabo do?**		
8. **Will Thabo's sister sing or dance?**		
9. **Will prizes be given to those taking part?**	Yes	No
10. **Who will play the piano?**	Teacher	Principal
To be completed by fieldworker: *** 1 point for each correct answer**	/10	Tally (%): ___ <70%= Ineligible

FOR STAFF TO COMPLETE		
1. Does the patient fulfill the pre-screen criteria?	☐ Yes ☐ No ☐ Already enrolled in this study	
2. Did you give the minor a parent brochure (letter and ICFs)?	☐ Yes ☐ No ☐ Minor refused	☐ N/A- parent is with minor
IF NO- DO NOT CONTINUE WITH FINAL SCREEN **THANK THE PATIENT AND PARENT FOR THEIR TIME**		

SECTION B: FINAL SCREEN

Note to the fieldworker:

- *Complete Section B on the day of recruitment.*
- *Please ensure the patient fulfils the pre-screen criteria before proceeding*
- *Commence by explaining who you are and briefly explain the study and ask the patient and/or parent/guardian/foster parent/caregiver if they are interested in knowing about the study in-depth*

1. Fieldworker ID	_____
2. Date of completion (dd/mm/yyyy)	_____
3. Did the patient and/or parent/guardian/foster parent/caregiver indicate that they would be interested in knowing more about the study?	☐ Yes ☐ No
3.1 If no, what was the reason for refusal?	_____

- ***If Q3 above=Yes, then proceed below***

I.	**PARENTAL PERMISSION- FACE-TO-FACE/TELEPHONIC (CLINIC/SCHOOL ARM)**	
	• ***Complete the INFROMATION SHEET with the parent/guardian/foster parent/caregiver*** • ***Complete the COMPREHENSION CHECKLIST with the parent/guardian/foster parent/caregiver*** • ***Complete the CONSENT FORM parent/guardian/foster parent/caregiver***	
1.	Is the parent/guardian/foster parent/caregiver present/on the call?	☐ Yes ***(Go to Q2)*** ☐ No *(provide the patient with a letter to take to their parent/guardian/foster parent/caregiver and schedule an appointment date with the patient and parent/guardian/foster parent/caregiver)*
2.	Who is undergoing this process	☐ Parent ☐ Guardian ☐ Foster parent ☐ Caregiver (grandmother, aunt, older sister) ☐ Other:_____
3.	Did you explain all the details on the information sheet with the parent/guardian/foster parent/caregiver present?	☐ Yes ***(Go to 4)*** ☐ No ***(Go to 3.1)***
	3.1 If no, why was the information sheet not completed with the parent/guardian/foster parent/caregiver?	☐ Parent/guardian/foster parent/caregiver indicated they were not interested ***(Go to Section C)*** ☐ Parent/guardian/foster parent/caregiver indicated he/she did not have time ***(Go to 3.2)*** ☐ Other:_____
	3.2 If the parent/guardian/foster parent/caregiver did not have time, was an appointment date set to continue the procedure?	☐ Yes ***(Go to Section C)*** ☐ No- parent did not have time, will try again at their next appointment **(Date:_____)** ***(Go to Section C)***
4.	Whilst explaining the information did the parent/guardian/foster parent/caregiver, exhibit any signs of distress or discomfort?	☐ Yes ***(Go to Section C)*** ☐ No ***(Go to 5)*** ☐ Other:_____
5.	Did you perform the comprehension checklist?	☐ Yes ***(Go to 6)*** ☐ No ***(Go to Section C)***
6.	Did the parent have a fair-good understanding of the study	☐ Yes ***(Go to 7)*** ☐ No ***(Go to Section C)***

7. Did the parent/guardian/foster parent/caregiver consent to their child (15-17 years) participating in this study?	☐ Yes ***(Go to ASSENT PERMISSION BELOW)*** ☐ No ***(Go to Section C)***

SECTION II: PARENT PERMISSION-SCHOOL ARM (SIGNED CONSENT FORM)

Note to the fieldworker:

- *Complete this section if the potential participant is in the school arm and has provided you with a signed parent consent form*

1. Verify with the child who signed the form	☐ Parent/caregiver/guardian/foster parent ☐ Other:_____
2. Was parental permission provided?	☐ Yes ***(Go to Assent section below)*** ☐ No ***(Go to C)***
2.1 Did the parent provide contact details for follow-up to verify signature	☐ Yes ☐ No
2.2 ***Random Verification***- did the parent indicate that he/she signed the form	☐ Yes ☐ No ☐ Other: _____

- ***If 4. above=Yes, then proceed below***

II.	**ASSENT PERMISSION—FACE-TO-FACE**	
• ***ONLY do this if the parent/guardian/foster parent/caregiver has provided consent for their child to participate*** • **Complete the INFROMATION SHEET** • **Complete the COMPREHENSION CHECKLIST** • **Complete the ASSENT FORM**		
1.	Did you explain all the details on the information sheet to the patient?	☐ Yes ***(Go to 2)*** ☐ No ***(Go to 1.1)***
	2.1 If no, why was the information sheet not completed with the patient?	☐ Patient indicated they were not interested to participate ***(Go to Section C)*** ☐ Patient indicated he/she did not have time ***(Go to 1.2)*** ☐ Other:_____
	2.2 If the patient did not have time, was an appointment date set to continue the procedure?	☐ Yes ***(Go to Section C)*** ☐ No- patient did not have time, will try again at their next appointment **(Date:_____)** ***(Go to Section C)***
2.	Whilst explaining the information did the patient exhibit any signs of distress or discomfort?	☐ Yes ***(Go to Section C)*** ☐ No ***(Go to 3)*** ☐ Other:_____
3.	Did you perform the comprehension checklist?	☐ Yes ***(Go to 4)*** ☐ No ***(Go to Section C)***
4.	Did the patient have a fair-good understanding of the study	☐ Yes ***(Go to 5)*** ☐ No ***(Go to Section C)***
5.	Did the patient assent to taking part in this study?	☐ Yes ***(Go to Section C)*** ☐ No ***(Go to Section C)*** ☐ Other:_____
• ***You may now proceed with the completing locator form and appointment care (Phase 1)/questionnaire (Phase 2)***		

SECTION C: OVERALL SCREENING OUTCOME	
• ***To be completed by fieldworker***	
1. Final screening outcome status?	☐ Eligible and enrolled ☐ Potentially eligible but parent did not have time to complete procedures/disinterested ☐ Potentially eligible but minor did not have time to complete procedures/disinterested ☐ Potentially eligible but minor refused to take the letter home to parent ☐ Potentially eligible but parent did not give permission ☐ Potentially eligible and parent gave permission, but minor did not want to participate ☐ Potentially eligible but parent did not come to clinic to complete consent procedures ☐ Ineligible- please specify (_____)
2. Please detail any feedback regarding the screening process below	

Appendix 2- ICF- Parental permission (Cognitive Interviews)

PART 1: INFORMATION SHEET

Introduction

- Good day. My name is _____. I work for the Health Systems Research Unit of the South African Medical Research Council (SAMRC).
- We do studies to help improve the health of children in South Africa. Your child is being invited today to take part in the Impilo Enhle study that is being done with 10 to 15 years in KwaZulu-Natal, South Africa.
- Dr Darshini Govindasamy, a scientist at the SAMRC, leads this study. This study is sponsored by the SAMRC.

Why are we doing this study?

- We want to identify an appropriate tool that can be used to understand how children in South Africa are functioning daily with regards to their health, school and home life.
- Thus, we want to test a few health-related quality of life tools with children to understand which one is best for this age-group in South Africa.

Why have we invited your child to take part in this study?

- We have chosen children from this community to attend our one-on-one interviews.
- Your child has been chosen as we think his/her feedback could help us identify a tool that will be easy for children to understand and complete.

What will happen if I decide to allow my child to take part in this study?

- First, because your child is between the ages of 10 to 15 years old, we need your permission to allow him/her to take part in the study.
- Then, we will get your child's agreement to take part in the study. Your child can only take part in this study if you 1) give us permission for him/her to take part and 2) your child agrees to take part. After you and your child have both agreed, I will:
- Give you and your child the date and time for this interview. This interview will take about 2 hours to complete and will be done at our study office at the local clinic.
- On the day of the interview, we will ask your child to complete a few health-related quality of life tools and obtain their feedback on each.
- Your child's name will not appear on any forms or next to anything he/she mentions. Instead, your child will be given his/her own study number.
- The interview will be voice-recorded on a device. The voice-recorded file will be copied onto a computer in our study office, and then deleted from the device. The voice-recorded file will be labelled with your child's study number and will not include his/her name. We will listen to the recording and write down all the information from our discussion.
- We will comply with government's COVID-19 protocols. Your child will be provided with a mask and hand sanitiser. Both the interviewer and your child will be screened for COVID-

19 symptoms before entering the interview room. The room will be well ventilated, and we will maintain social distancing at all times. Should either the researcher or your child present with COVID-19 symptoms, we will not proceed with the interview.

What are my rights and my child's rights?

- You can decide if you want your child to take part in the study or not, we will not force you to give permission or force your child to take part.
- You can choose NOT to allow your child to take part in the study. The choice that you make will not affect the services you or your child receives in this community.
- You can stop your child from taking part at any time. You can ask questions about this study.

What are the risks or inconveniences I or my child may experience?

- Some questions we ask your child might be hard for him/her to answer. We will not force your child to answer anything he/she cannot or does not want to answer.
- Allowing your child to take part might mean that your child will be taking time away from his activities and will need to travel to the clinic for this interview.
- Someone may overhear us during our interview. However, I will ensure that our interview is conducted in a private room where no can hear us.
- When I contact you or your child to confirm the meeting date, someone else could overhear us or pick-up the phone. When I contact you or your child, I will ensure I do not reveal any of your or your child's personal information to anyone. I will confirm the identity of the person picking up the phone to ensure it is only you or your child with whom I am speaking to. I will only continue our conversation on the phone if you or your child indicate that it is safe to talk.
- Study items (notes, recording device) could be misplaced or stolen. However, the research team will ensure all study items are stored in a locked cupboard.

What are the possible benefits of my child taking part in this study?

- Your child may not get anything out of our interview.
- The information we gather from all children participating in this study will help us understand how best to monitor health-related quality of life among children in in South Africa. This could help scientists develop new ways to improve their lives.

Will my child get anything for taking part in this study?

- Your child will receive a stationery set and lunch pack to the value of R100 at the end of the interview. This is to thank him/her for their time.
- At the end of the interview, you and/or your child will be provided with R50 each to cover any transport costs related to attending this interview.

Will the information my child gives be kept private?

- Your child's information will be kept on a computer file that will be protected with a password, which only staff working on this study will know. Others will not see information that your child provides me with in the interview.
- All my notes, forms and files from this interview will only have your child's study number on it and not his/her name. We will not link your child's name to the information he/she gives us. All the information your child provides us with will be kept private, and this information will be stored safely in a locked cupboard.
- If you tell us about plans to harm a person or yourself, I will need to take steps to protect that person or you. If your child informs us about plans to harm a person or themselves, I will need to take steps to protect that person or your child. Also, if you or your child informs us that they believe a person is going to harm you or him/her, steps will be taken to protect you or your child. If we suspect, or if you or your child tells us about any neglect or abuse in the household, we will have to report it to the authorities such as child welfare or the police.

Who do I contact if I have any questions about this study?

- If you have any questions about the study, you may contact the principal investigator: →	**Contact person:** Dr Darshini Govindasamy **Tel:** 031-203-4858 **Address:** 491 Peter Mokaba Ridge Road, Overport, Durban; PO Box 70380, 4091 Overport, South Africa **Email:** darshini.govindasamy@mrc.ac.za
- If you have any problems with the way the study was done/concerns about your rights in the study, you may contact the local research ethics committee which approved this study: →	**Contact person :** Prof D du Toit **Tel:** 021 938 0687 **Address:** South African Medical Research Council, PO Box 19070, Tygerberg 7505, Western Cape South Africa **Email:** adri.labuschagne@mrc.ac.za

PART 2: INFORMED VOLUNTARY CONSENT FORM

Please indicate whether you agree to your child taking part or not in the table below. If you agree, please kindly add your name, signature and date below

Please read and mark each statement below	Please mark with an X	
▪ I confirm that I have read and understood the information sheet (version number and date), for the above study and have had the opportunity to ask questions.	☐ Yes	☐ No
▪ I have received a copy of the information sheet in my preferred language	☐ Yes	☐ No
▪ I understand that my consent is voluntary and that I am free to withdraw this consent at any time, without giving any reason and without my legal rights being affected	☐ Yes	☐ No
Overall, I agree to my child taking part in this study	☐ Yes	☐ No
▪ I agree to the interview being voice-recorded	☐ Yes	☐ No
▪ I agree to quotes or other results arising from what my child says in this study being included in any reports, as long as my child cannot be identified	☐ Yes	☐ No
▪ I agree to share my contact details with the study staff should they need to contact me or my child to discuss any study matters or participation in a future caregiver study	☐ Yes	☐ No
As per the Protection of Personal Information Act 4 of 2013 (as amended), I agree:		
▪ To personal information (data) from me or my child being collected, processed, shared and stored as per the research protocol approved by South African Medical Research Council's Human Research Ethics Committee	☐ Yes	☐ No
▪ To data from my child that does not contain his/her names being shared, processed and transferred to other researchers in or outside South Africa;	☐ Yes	☐ No
▪ To results arising from what my child says in this study being included in any reports, as long as my child cannot be identified	☐ Yes	☐ No

For parent to complete:

_____	_____	_____
Name and surname of parent	Signature	Today's date (dd/mm/yyyy)

For study staff to complete:
I declare that I have explained the information given in this document to the parent and the parent was given ample time to ask questions

_____	_____	_____
Name and surname of study staff taking consent	Signature	Today's date (dd/mm/yyyy)

For witness to complete if parent is unable to write:
As a witness I confirm that all information about this study was given, and the parent verbally consented to their child participating in this study

_____	_____	_____
Name and surname of witness	Signature	Today's date (dd/mm/yyyy)

Appendix 3- ICF- Minor assent (Cognitive interviews)

PART 1: INFORMATION SHEET

Introduction

- Hello. My name is _____. I work for the South African Medical Research Council (SAMRC). We do work to help improve the health of children in South Africa.
- You are being invited today to take part in the Impilo Enhle study, which is being done with children in KwaZulu-Natal, South Africa.

Why are we doing this study?

- We want to know which tool will best help us understand how children in South Africa are coping with their health at home or at school.
- This information can help scientists develop solutions to improve the health of children in South Africa.

Why have I been invited to take part in this study?

- We have chosen children from this area to attend our interview (chat).
- You have been chosen as we think your feedback will help us select a tool that is easy for other children your age to understand and complete.

What will happen if I decide to take part in this study?

- After you tell me whether you want to take part or not, I will:
- Tell you the date, time and place we will meet and where we will meet to have this chat.
- On the day of the chat, I will ask you to complete a few tools and ask you how you felt completing these.
- I will not put your name next to anything you say.
- I will tape our chat on this gadget (voice-recorder) to listen to it again later and take notes. I will make sure I keep this voice-recorder safe and store its information on a safe computer.
- Due to COVID-19, we will check your temperature and ask you to wear a mask and sanitise your hands. We will sit in a room with open windows and will sit far apart.

What are my rights?

- You can decide if you want to take part in the study or not, we will not force you. You can choose NOT to take part in the study.
- You can ask questions about this study.

What are the risks or inconveniences I may experience?

- Some questions we may ask you might be hard for you to answer. We will not force you to answer anything you cannot or do not want to answer.
- Having to attend this chat might mean you will need to take time out from your activities after school, and travel to the clinic for this chat. However, we will ensure that we have this chat on a day that is good for you and does not affect your schoolwork.
- Someone may overhear us during our chat. However, I will ensure that our chat is conducted in a private room where no one can hear us.
- When I contact you to confirm the date of the chat, someone else could overhear us or pick-up the phone. However, I will ensure I do not reveal any of your personal information to anyone. I will only continue to talk to you on the phone if you indicate that you are in a safe space for us to talk.
- Study items (e.g., notes, recording device) could be misplaced or stolen. However, the team will ensure all study items are stored in a locked cupboard.

What are the possible benefits of taking part in this study for me?

- You may not get anything out of our chat.
- The information that we get from you and other children in this study will could help us understand how to measure and improve the health of children in South Africa.

Will I get anything for taking part in this study?

- You will receive a stationery set and lunch pack to the value of R100 at the end of the chat. This is to thank you for your time and for taking part.
- If you had to pay for transport to attend the interview you will be provided with R50 transport money to cover this.

Will the information I give be kept private?

- Your information will be kept on a computer file with a password, which only staff working on this study will know. Others will not see information that you provide me with.
- Our notes, forms and files from this chat will only have your own study number on it and not your name. We will not link your name to the information you give us. All the information you provide us with will be kept safe, and this information will be stored safely in a locked cupboard.
- We will use the information from this study in presentations and in reports. These presentations and reports will not contain your name.
- If you tell us that you plan to do something bad to a person or yourself, we will need to help that person or you. Also, if you tell us that a person is going to do something bad to you, we will have to ensure you are safe. If we think, or if you tell us that you or someone in your home is upset, being hit, shouted or abused we will have to report it to the right people.

Who do I contact if I have any questions about this study?

- If you have any questions about the study, you may call: →	**Contact person:** Dr Darshini Govindasamy **Tel:** 031-203-4858

	Address: 491 Peter Mokaba Ridge Road, Overport, Durban; PO Box 70380, 4091 Overport, South Africa **Email:** darshini.govindasamy@mrc.ac.za
- If you have any problems with the way the study was done, you can call: →	**Contact person :** Prof D. Du Toit **Tel:** 021 938 0687 **Address:** South African Medical Research Council, PO Box 19070, Tygerberg 7505, Western Cape South Africa **Email:** adri.labuschagne@mrc.ac.za

PART 2: INFORMED VOLUNTARY ASSENT FORM

Please indicate whether you would like to take part or not in the table below. If you agree, please kindly add your name, signature and date below

Please read and mark each statement below	Please mark with an X	
▪ I have read and understood the information sheet (version number and date), for the study and was given time to ask questions	☐ Yes	☐ No
▪ I have received a copy of the information sheet in my language	☐ Yes	☐ No
▪ I understand that I can stop taking part at any time in this study	☐ Yes	☐ No
Overall, I agree to take part in this study	☐ Yes	☐ No
▪ I agree to this chat being voice-recorded	☐ Yes	☐ No
▪ I agree to share my contact details with the study staff should they need to call me to discuss any study matters	☐ Yes	☐ No
As per the Protection of Personal Information Act 4 of 2013 (as amended), I agree:		
▪ To my personal information (data) being collected, processed, shared and stored as per the research protocol approved by South African Medical Research Council's Human Research Ethics Committee	☐ Yes	☐ No
▪ To my data that does not contain my name being shared, processed and transferred to other researchers in or outside South Africa;	☐ Yes	☐ No
▪ To results arising from what I say in this study being included in any reports, as long as I cannot be identified	☐ Yes	☐ No

For participant to complete:

_____	_____	_____
Name and surname of participant	Signature or initials	Today's date (dd/mm/yyyy)

For study staff to complete:

I declare that I have explained the information given in this document to the participant and the participant was given ample time to ask questions

_____	_____	_____
Name and surname of study staff taking assent	Signature	Today's date (dd/mm/yyyy)

For witness to complete if participant is unable to write:

As a witness I confirm that all information about this study was given, and the participant verbally assented to taking part

_____	_____	_____
Name and surname of witness	Signature	Today's date (dd/mm/yyyy)

Appendix 4- ICF- HCWs and study fieldworkers (Key informant interviews)

PART 1: INFORMATION SHEET

Introduction

- Hello. My name is _____. I work as a researcher for the Health Systems Research Unit of the South African Medical Research Council (SAMRC).
- You are being asked to participate in the Impilo Enhle study. This study is evaluating health-related quality of scales for use among adolescents living with HIV in KwaZulu-Natal, South Africa.
- Dr Darshini Govindasamy, a scientist at the SAMRC, leads this study. This study is sponsored by the SAMRC.

Why are we doing this study?

- Adolescents living with HIV are a vulnerable group. Recent scientific research has highlighted the burden of chronic health conditions among this population. These conditions may have severe impact on their health-related quality of life (i.e. physical, mental and social functioning).
- However, little is known about the health-related quality of life among this population as we lack valid scales to assess this.
- If we can accurately measure and monitor health-related quality of life among HIV-positive adolescents, then we can develop and evaluate interventions to promote their health and wellbeing.
- Therefore, we are doing this study to identify a robust health-related quality of life scale for use among adolescents living with HIV in South Africa.

Why have I been invited to take part in this study?

- You are being invited to take part in this study as we feel that your experience as a healthcare worker can add to our understanding of which scale would be most appropriate for use in routine HIV services.

What will happen if I decide to take part in this study?

After you have agreed (consented) to join the study I will:

- Schedule a date to conduct a one-on-one interview with you either in English or isiZulu. This interview will take about 45 minutes to complete and will be conducted either face-to face or telephonically.
- I will begin the interview by asking you what matters most for health-related quality of life among adolescents living with HIV in this setting. I will provide you with three international health-related quality of scales for adolescents to review prior to the interview. During the interview we will discuss your thoughts on each scale in terms of layout, wording and relevance, and which scale would be the most feasible to implement in your clinic.
- Your name will not be put on the interview documents or next to any of your responses. Instead, you will be given a unique study number that will identify your responses.
- The interview will be voice-recorded on an electronic device. The voice-recorded file will be copied onto a password protected storage device (USB) and computer server, and then deleted from the recording device. The USB will be stored in a locked cupboard at the

research study's office. The voice-recorded file will be labelled with a unique study number and will not include your name. Researchers working on the project will listen to the recording and write down all the information from the interview.

- We will comply with government's COVID-19 protocols. Should we conduct the interview face-to-face, you and the researcher will be provided with a mask and sanitiser. Both you and the researcher will be screened for COVID-19 symptoms before entering the interview room. The room will be well ventilated, and social distancing will be maintained at all times. Should either the researcher or you present with COVID-19 symptoms on the interview day, we will not proceed with the interview.

What are my rights?

- You can decide if you want to take part in the study or not. Your participation is voluntary.
- You can choose NOT to participate in the study. The choice that you make will not influence your job or any work-related evaluations or reports at this clinic.
- If you agree to participate now, you can stop taking part later.
- You can ask questions about this study.

What are the risks or inconveniences I may experience?

- Some questions we ask you might be hard to answer. We will not force you to answer anything you cannot or do not want to answer.
- Having to attend this study interview may impose on your work time and thus you may need to arrange for someone to take over your duties. Hence, we will arrange to conduct this interview at a time and date that is most convenient for you.
- Someone may overhear us during our interview. However, I will ensure that the interview is conducted in a private room with no disruption.
- Study items (e.g. my notes, recording device) could be misplaced or stolen. However, the research team will ensure all study items are stored in a locked cupboard with restricted access.

What are the possible benefits of taking part in this study for me?

- There will be no direct benefit to you, but your participation is likely to provide us with a more accurate picture of which health-related quality of life instrument could be used in HIV care programmes in South Africa.
- Findings could help policy makers and programme planners improve policies and interventions aimed at enhancing the health and wellbeing among adolescents living with HIV.

Will I get anything for taking part in this study?

- You will receive a lunch water bottle at the end of the interview to thank you for your time or any inconvenience costs incurred due to participation.

Will the information I give be kept private?

- Your information will be kept on a computer file that will be protected by a password, which only staff working on this study will know. Information that you provide us with will not be seen by other participants or staff.

- Notes, forms and electronic files from this interview will only have your unique study number on it and not your name. We will not link your name to the information you give us.
- All personal identifying information you provide us with will be kept confidential, and this information will be stored safely in a locked cupboard.
- Information from this study will be presented at scientific meetings and published so that the information can be useful to others such Department of Health, non-governmental organisations and scientists . This information will not contain your name.

Who do I contact if I have any questions about this study?

- If you have any questions about the study, you may contact the principal investigator: →	**Contact person:** Dr Darshini Govindasamy **Tel:** 031-203-4858 **Address:** 491 Peter Mokaba Ridge Road, Overport, Durban; PO Box 70380, 4091 Overport, South Africa **Email:** darshini.govindasamy@mrc.ac.za
- If you have any problems with the way the study was done/concerns about your rights in the study, you may contact the local research ethics committee which approved this study: →	**Contact person :** Prof D du Toit **Tel:** 021 938 0687 **Address:** South African Medical Research Council, PO Box 19070, Tygerberg 7505, Western Cape South Africa **Email:** adri.labuschagne@mrc.ac.za

PART 2: INFORMED VOLUNTARY CONSENT FORM

Please indicate whether you agree or not to participate in the table below and then add your name, signature and date below

Please read and mark each statement below	Please mark with an X	
I confirm that I have read and understood the information sheet (version number and date), for the above study and have had the opportunity to ask questions.	☐ Yes	☐ No
I have received a copy of the information sheet in my preferred language	☐ Yes	☐ No
I understand that my consent is voluntary and that I am free to withdraw this consent at any time, without giving any reason and without my legal rights being affected	☐ Yes	☐ No
Overall, I agree to take part in this study	☐ Yes	☐ No
▪ I consent to this interview being voice-recorded	☐ Yes	☐ No
In accordance with the provisions of the Protection of Personal Information Act 4 of 2013 (as amended), I hereby consent:		
▪ To my personal information (hereinafter 'data') being collected, processed, shared and stored in accordance with the research protocol as approved by the South African Medical Research Council's Human Research Ethics Committee (SAMRC HREC);	☐ Yes	☐ No
▪ To my anonymised data being shared, processed and transferred by third parties and between third parties, and where relevant beyond the jurisdictional borders of South Africa;	☐ Yes	☐ No
▪ To all findings and results flowing from my anonymised data being broadly shared and published on the conclusion of the research.	☐ Yes	☐ No

For participant to complete:

_____	_____	_____
Name and surname of participant	Signature	Today's date (dd/mm/yyyy)

For study staff to complete:

I declare that I have explained the information given in this document to the participant and the participant was given ample time to ask questions

_____	_____	_____
Name and surname of study staff taking consent	Signature	Today's date (dd/mm/yyyy)

For witness to complete if participant is unable to write:

As a witness I confirm that all information about this study was given, and the participant verbally consented to taking part

_____	_____	_____
Name and surname of witness	Signature	Today's date (dd/mm/yyyy)

Appendix 5- ICF- Parent permission (Cross-sectional survey, clinic arm)

PART 1: INFORMATION SHEET

Introduction

- Good day. My name is _____. I work for the Health Systems Research Unit of the South African Medical Research Council (SAMRC).
- We do studies to help improve the health of children in South Africa. Your child is being invited today to take part in the Impilo Enhle study that is being done with 10 to 15 years in KwaZulu-Natal, South Africa.
- Dr Darshini Govindasamy, a scientist at the SAMRC, leads this study. This study is sponsored by the SAMRC.

Why are we doing this study?

- We want to identify an appropriate tool that can be used to assess how children in South Africa are functioning daily with regards to their health, school and home life.
- Thus, we want to test a few health-related quality of life tools with children to understand which one is best for this age-group in South Africa.

Why have we invited your child to take part in this study?

- We have chosen children from clinics in this community to take part in this study.
- Your child has been chosen as we think his/her feedback could help us identify a tool that will be easy for children to understand and complete.

What will happen if I decide to allow my child to take part in this study?

- First, because your child is between the ages of 10 to 15 years old, we need your permission to allow him/her to take part in the study.
- Then, we will get your child's agreement to take part in the study. Your child can only take part in this study if you 1) give us permission for him/her to take part and 2) your child agrees to take part. After you and your child have both agreed, I will:
- Conduct an interview with your child in a private space. Your child will complete a form that asks about his/her school and home life, daily activities and how he/she is feeling. We may also schedule a second session with your child a few weeks later to complete the exact same form for us to further assess the tool.
- Thereafter, we will extract extra information from your child's clinic record should you give us additional permission to do so.
- Your child's name will not appear on any forms or next to anything he/she mentions. Instead, your child will be given his/her own study number.
- We will comply with government's COVID-19 protocols. Your child will be provided with a mask and hand sanitiser. Both the interviewer and your child will be screened for COVID-19 symptoms before entering the interview room. The room will be well ventilated, and

we will maintain social distancing at all times. Should either the researcher or your child present with COVID-19 symptoms, we will not proceed with the interview.

What are my rights and my child's rights?

- You can decide if you want your child to take part in the study or not, we will not force you to give permission or force your child to take part.
- You can choose NOT to allow your child to take part in the study. The choice that you make will not affect the services you or your child receives in this community.
- You can stop your child from taking part at any time. You can ask questions about this study.

What are the risks or inconveniences I or my child may experience?

- Some questions we ask your child might be hard for him/her to answer. We will not force your child to answer anything he/she cannot or does not want to answer.
- Allowing your child to take part might mean that your child will be taking time away from his daily activities.
- Someone may overhear us during our interview. However, I will ensure that our interview is conducted in a private room where no can hear us.
- Should I contact you or your child to confirm the meeting date, someone else could overhear us or pick-up the phone. When I contact you or your child, I will ensure I do not reveal any of your or your child's personal information to anyone. I will only continue our conversation on the phone if you or your child indicates that it is safe to talk.
- Study forms could be misplaced or stolen. However, the research team will ensure all study items are stored in a locked cupboard.

What are the possible benefits of my child taking part in this study?

- Your child may not get anything out of our interview. The information we gather from all children participating in this study will help us understand how best to monitor health-related quality of life among children in in South Africa.
- This could help scientists develop new ways to improve their lives.

Will my child get anything for taking part in this study?

- Your child will receive a stationery set and lunch snack to the value of R100 at the end of the interview. This is to thank him/her for their time.
- Should your child have to pay for transport to attend this interview at our study office then we will cover R50 transport costs at the end of the interview.

Will the information my child gives be kept private?

- Your child's information will be kept on a computer file that will be protected with a password, which only staff working on this study will know. Others will not see information that your child provides me with in the interview.

- All my notes, forms and files from this interview will only have your child's study number on it and not his/her name. We will not link your child's name to the information he/she gives us. All the information your child provides us with will be kept private, and this information will be stored safely in a locked cupboard.
- If you tell us about plans to harm a person or yourself, I will need to take steps to protect that person or you. If your child informs us about plans to harm a person or themselves, I will need to take steps to protect that person or your child. Also, if you or your child informs us that they believe a person is going to harm you or him/her, steps will be taken to protect you or your child. If we suspect, or if you or your child tells us about any neglect or abuse in the household, we will have to report it to the authorities such as child welfare or the police.

Who do I contact if I have any questions about this study?

- If you have any questions about the study, you may contact the principal investigator: →	**Contact person:** Dr Darshini Govindasamy **Tel:** 031-203-4858 **Address:** 491 Peter Mokaba Ridge Road, Overport, Durban; PO Box 70380, 4091 Overport, South Africa **Email:** darshini.govindasamy@mrc.ac.za
- If you have any problems with the way the study was done/concerns about your rights in the study, you may contact the local research ethics committee which approved this study: →	**Contact person :** Prof D du Toit **Tel:** 021 938 0687 **Address:** South African Medical Research Council, PO Box 19070, Tygerberg 7505, Western Cape South Africa **Email:** adri.labuschagne@mrc.ac.za

PART 2: INFORMED VOLUNTARY CONSENT FORM

Please indicate whether you agree to your child taking part or not in the table below. If you agree, please kindly add your name, signature and date below

Please read and mark each statement below	Please mark with an X	
▪ I confirm that I have read and understood the information sheet (version number and date), for the above study and have had the opportunity to ask questions.	☐ Yes	☐ No
▪ I have received a copy of the information sheet in my preferred language	☐ Yes	☐ No
▪ I understand that my consent is voluntary and that I am free to withdraw this consent at any time, without giving any reason and without my legal rights being affected	☐ Yes	☐ No
Overall, I agree to my child taking part in this study	☐ Yes	☐ No
▪ I agree to quotes or other results arising from what my child says in this study being included in any reports, as long as my child cannot be identified	☐ Yes	☐ No
▪ I allow the study staff to access my child's clinic records to extract further information	☐ Yes	☐ No
▪ I agree to share my contact details with the study staff should they need to contact me or my child to discuss any study matters or participation in a future caregiver study	☐ Yes	☐ No
As per the Protection of Personal Information Act 4 of 2013 (as amended), I agree:		
▪ To personal information (data) from me or my child being collected, processed, shared and stored as per the research protocol approved by South African Medical Research Council's Human Research Ethics Committee	☐ Yes	☐ No
▪ To data from my child that does not contain his/her names being shared, processed and transferred to other researchers in or outside South Africa;	☐ Yes	☐ No
▪ To results arising from what my child says in this study being included in any reports, as long as my child cannot be identified	☐ Yes	☐ No

For parent to complete:

_____	_____	_____
Name and surname of parent	Signature	Today's date (dd/mm/yyyy)

For study staff to complete:

I declare that I have explained the information given in this document to the parent and the parent was given ample time to ask questions

_____	_____	_____
Name and surname of study staff taking consent	Signature	Today's date (dd/mm/yyyy)

For witness to complete if parent is unable to write:

As a witness I confirm that all information about this study was given, and the parent verbally consented to their child participating in this study

_____	_____	_____
Name and surname of witness	Signature	Today's date (dd/mm/yyyy)

Appendix 6- ICF- Minor assent permission (Cross-sectional survey, clinic arm)

PART 1: INFORMATION SHEET

Introduction

- Hello. My name is _____. I work for the South African Medical Research Council (SAMRC). We do work to help improve the health of children in South Africa.
- You are being invited today to take part in the Impilo Enhle study, which is being done with children in KwaZulu-Natal, South Africa.

Why are we doing this study?

- We want to know which tool will best help us understand how children in South Africa are coping with their health at home or at school.
- This information can help scientists develop solutions to improve the health of children in South Africa.

Why have I been invited to take part in this study?

- We have chosen children from clinics in this area to attend our interview (chat).
- You have been chosen as we think your feedback will help us select a tool that is easy for other children your age to understand and complete.

What will happen if I decide to take part in this study?

- After you tell me whether you want to take part or not, I will:
- Ask you to complete a form to understand your home and school life and how you are feeling. We may also contact you in a week's time to complete the same form again.
- Should you give me permission, I will also get the extra information I need from your clinic records.
- I will not put your name next to anything you say.
- Due to COVID-19, we will check your temperature and ask you to wear a mask and sanitise your hands. We will sit in a room with open windows and will sit far apart.

What are my rights?

- You can decide if you want to take part in the study or not, we will not force you. You can choose NOT to take part in the study.
- You can ask questions about this study.

What are the risks or inconveniences I may experience?

- Some questions we may ask you might be hard for you to answer. We will not force you to answer anything you cannot or do not want to answer.
- Having to complete this form might mean you will need to take time out from your activities. However, we will ensure that we have this chat on a day that is good for you and does affect with your schoolwork.
- Someone may overhear us during our chat. However, I will ensure that our chat is conducted in a private room where no one can hear us.
- Should I contact you again to complete the forms, someone else could overhear us or pick-up the phone. However, I will ensure I do not reveal any of your personal information to anyone. I will only continue to talk to you on the phone if you indicate that you are in a safe space for us to talk.
- Study forms could be misplaced or stolen. However, the team will ensure all study items are stored in a locked cupboard.

What are the possible benefits of taking part in this study for me?

- You may not get anything out of our chat.
- The information that we get from you and other children in this study will could help us understand how to measure and improve the health of children in South Africa.

Will I get anything for taking part in this study?

- You will receive a stationery set and lunch snack to the value of R100 at the end of the chat. This is to thank you for your time and for taking part.
- If you had to pay for transport to attend the interview you will be provided with R50 transport money to cover this.

Will the information I give be kept private?

- Your information will be kept on a computer file with a password, which only staff working on this study will know. Others will not see information that you provide me with.
- Our notes, forms and files from this chat will only have your own study number on it and not your name. We will not link your name to the information you give us. All the information you provide us with will be kept safe, and this information will be stored safely in a locked cupboard.
- We will use the information from this study in presentations and in reports. These presentations and reports will not contain your name.
- If you tell us that you plan to do something bad to a person or yourself, we will need to help that person or you. Also, if you tell us that a person is going to do something bad to you, we will have to ensure you are safe. If we think, or if you tell us that you or someone in your home is upset, being hit, shouted or abused we will have to report it to the right people.

Who do I contact if I have any questions about this study?

- If you have any questions about the study, you may call: →	**Contact person:** Dr Darshini Govindasamy **Tel:** 031-203-4858

	Address: 491 Peter Mokaba Ridge Road, Overport, Durban; PO Box 70380, 4091 Overport, South Africa **Email:** darshini.govindasamy@mrc.ac.za
- If you have any problems with the way the study was done, you can call: →	**Contact person :** Prof D. Du Toit **Tel:** 021 938 0687 **Address:** South African Medical Research Council, PO Box 19070, Tygerberg 7505, Western Cape South Africa **Email:** adri.labuschagne@mrc.ac.za

PART 2: INFORMED VOLUNTARY ASSENT FORM

Please indicate whether you would like to take part or not in the table below. If you agree, please kindly add your name, signature and date below

Please read and mark each statement below	Please mark with an X	
▪ I have read and understood the information sheet (version number and date), for the study and was given time to ask questions	☐ Yes	☐ No
▪ I have received a copy of the information sheet in my language	☐ Yes	☐ No
▪ I understand that I can stop taking part at any time in this study	☐ Yes	☐ No
Overall, I agree to take part in this study	☐ Yes	☐ No
▪ I allow the study staff to get extra information from my clinic records	☐ Yes	☐ No
▪ I agree to share my contact details with the study staff should they need to contact me or my child to discuss any study matters	☐ Yes	☐ No
As per the Protection of Personal Information Act 4 of 2013 (as amended), I agree:		
▪ To my personal information (data) being collected, processed, shared and stored as per the research protocol approved by South African Medical Research Council's Human Research Ethics Committee	☐ Yes	☐ No
▪ To my data that does not contain my name being shared, processed and transferred to other researchers in or outside South Africa;	☐ Yes	☐ No
▪ To results arising from what I say in this study being included in any reports, as long as I cannot be identified	☐ Yes	☐ No

For participant to complete:

_____	_____	_____
Name and surname of participant	Signature or initials	Today's date (dd/mm/yyyy)

For study staff to complete:

I declare that I have explained the information given in this document to the participant and the participant was given ample time to ask questions

_____	_____	_____
Name and surname of study staff taking assent	Signature	Today's date (dd/mm/yyyy)

For witness to complete if participant is unable to write:

As a witness I confirm that all information about this study was given, and the participant verbally assented to taking part

_____	_____	_____
Name and surname of witness	Signature	Today's date (dd/mm/yyyy)

Appendix 7- ICF- Parent permission (Cross-sectional survey, school arm)

PART 1: INFORMATION SHEET

Introduction

- Good day. My name is _____. I work for the Health Systems Research Unit of the South African Medical Research Council (SAMRC).
- We do studies to help improve the health of children in South Africa. Your child is being invited today to take part in the Impilo Enhle study that is being done with 10 to 15 years in KwaZulu-Natal, South Africa.
- Dr Darshini Govindasamy, a scientist at the SAMRC, leads this study. This study is sponsored by the SAMRC.

Why are we doing this study?

- We want to identify an appropriate tool that can be used to assess how children in South Africa are functioning daily with regards to their health, school and home life.
- Thus, we want to test a few health-related quality of life tools with children to understand which one is best for this age-group in South Africa.

Why have we invited your child to take part in this study?

- We have chosen children from schools in this community to take part in this study.
- Your child has been chosen as we think his/her feedback could help us identify a tool that will be easy for children to understand and complete.

What will happen if I decide to allow my child to take part in this study?

- First, because your child is between the ages of 10 to 15 years old, we need your permission to allow him/her to take part in the study.
- Then, we will get your child's agreement to take part in the study. Your child can only take part in this study if you 1) give us permission for him/her to take part and 2) your child agrees to take part. After you and your child have both agreed, I will:
- Conduct an interview with your child in a private space. Your child will complete a form that asks about his/her school and home life, daily activities and how he/she is feeling. We may also schedule a second session with your child a few weeks later to complete the exact same form for us to further assess the tool.
- Your child's name will not appear on any forms or next to anything he/she mentions. Instead, your child will be given his/her own study number.
- We will comply with government's COVID-19 protocols. Your child will be provided with a mask and hand sanitiser. Both the interviewer and your child will be screened for COVID-19 symptoms before entering the interview room. The room will be well ventilated, and we will maintain social distancing at all times. Should either the researcher or your child present with COVID-19 symptoms, we will not proceed with the interview.

What are my rights and my child's rights?

- You can decide if you want your child to take part in the study or not, we will not force you to give permission or force your child to take part.
- You can choose NOT to allow your child to take part in the study. The choice that you make will not affect the services you or your child receives in this community.
- You can stop your child from taking part at any time. You can ask questions about this study.

What are the risks or inconveniences I or my child may experience?

- Some questions we ask your child might be hard for him/her to answer. We will not force your child to answer anything he/she cannot or does not want to answer.
- Allowing your child to take part might mean that your child will be taking time away from his daily activities.
- Someone may overhear us during our interview. However, I will ensure that our interview is conducted in a private room where no can hear us.
- Should I contact you or your child to confirm the meeting date, someone else could overhear us or pick-up the phone. When I contact you or your child, I will ensure I do not reveal any of your or your child's personal information to anyone. I will only continue our conversation on the phone if you or your child indicates that it is safe to talk.
- Study forms could be misplaced or stolen. However, the research team will ensure all study items are stored in a locked cupboard.

What are the possible benefits of my child taking part in this study?

- Your child may not get anything out of our interview. The information we gather from all children participating in this study will help us understand how best to monitor health-related quality of life among children in in South Africa.
- This could help scientists develop new ways to improve their lives.

Will my child get anything for taking part in this study?

- Your child will receive a stationery set and lunch snack to the value of R100 at the end of the interview. This is to thank him/her for their time.

Will the information my child gives be kept private?

- Your child's information will be kept on a computer file that will be protected with a password, which only staff working on this study will know. Others will not see information that your child provides me with in the interview.
- All my notes, forms and files from this interview will only have your child's study number on it and not his/her name. We will not link your child's name to the information he/she gives us. All the information your child provides us with will be kept private, and this information will be stored safely in a locked cupboard.
- If you tell us about plans to harm a person or yourself, I will need to take steps to protect that person or you. If your child informs us about plans to harm a person or themselves, I

will need to take steps to protect that person or your child. Also, if you or your child informs us that they believe a person is going to harm you or him/her, steps will be taken to protect you or your child. If we suspect, or if you or your child tells us about any neglect or abuse in the household, we will have to report it to the authorities such as child welfare or the police.

Who do I contact if I have any questions about this study?

- If you have any questions about the study, you may contact the principal investigator: →	**Contact person:** Dr Darshini Govindasamy **Tel:** 031-203-4858 **Address:** 491 Peter Mokaba Ridge Road, Overport, Durban; PO Box 70380, 4091 Overport, South Africa **Email:** darshini.govindasamy@mrc.ac.za
- If you have any problems with the way the study was done/concerns about your rights in the study, you may contact the local research ethics committee which approved this study: →	**Contact person :** Prof D du Toit **Tel:** 021 938 0687 **Address:** South African Medical Research Council, PO Box 19070, Tygerberg 7505, Western Cape South Africa **Email:** adri.labuschagne@mrc.ac.za

PART 2: INFORMED VOLUNTARY CONSENT FORM

Please indicate whether you agree to your child taking part or not in the table below. If you agree, please kindly add your name, signature and date below

Please read and mark each statement below	Please mark with an X	
▪ I confirm that I have read and understood the information sheet (version number and date), for the above study and have had the opportunity to ask questions.	☐ Yes	☐ No
▪ I have received a copy of the information sheet in my preferred language	☐ Yes	☐ No
▪ I understand that my consent is voluntary and that I am free to withdraw this consent at any time, without giving any reason and without my legal rights being affected	☐ Yes	☐ No
Overall, I agree to my child taking part in this study	☐ Yes	☐ No
▪ I agree to quotes or other results arising from what my child says in this study being included in any reports, as long as my child cannot be identified	☐ Yes	☐ No
▪ I agree to share my contact details with the study team should they need to contact me or my child to discuss any study matters or participation in a future caregiver study	☐ Yes	☐ No
As per the Protection of Personal Information Act 4 of 2013 (as amended), I agree:		
▪ To personal information (data) from me or my child being collected, processed, shared and stored as per the research protocol approved by South African Medical Research Council's Human Research Ethics Committee	☐ Yes	☐ No
▪ To data from my child that does not contain his/her names being shared, processed and transferred to other researchers in or outside South Africa;	☐ Yes	☐ No
▪ To results arising from what my child says in this study being included in any reports, as long as my child cannot be identified	☐ Yes	☐ No

For parent to complete:

_____	_____	_____
Name and surname of parent	Signature	Today's date (dd/mm/yyyy)

For study staff to complete:

I declare that I have explained the information given in this document to the parent and the parent was given ample time to ask questions

_____	_____	_____
Name and surname of study staff taking consent	Signature	Today's date (dd/mm/yyyy)

For witness to complete if parent is unable to write:

As a witness I confirm that all information about this study was given, and the parent verbally consented to their child participating in this study

_____	_____	_____
Name and surname of witness	Signature	Today's date (dd/mm/yyyy)

Appendix 8- ICF- Minor assent permission (Cross-sectional survey, school arm)

PART 1: INFORMATION SHEET

Introduction

- Hello. My name is _____. I work for the South African Medical Research Council (SAMRC). We do work to help improve the health of children in South Africa.
- You are being invited today to take part in the Impilo Enhle study, which is being done with children in KwaZulu-Natal, South Africa.

Why are we doing this study?

- We want to know which tool will best help us understand how children in South Africa are coping with their health at home or at school.
- This information can help scientists develop solutions to improve the health of children in South Africa.

Why have I been invited to take part in this study?

- We have chosen children from schools in this area to attend our interview (chat).
- You have been chosen as we think your feedback will help us select a tool that is easy for other children your age to understand and complete.

What will happen if I decide to take part in this study?

- After you tell me whether you want to take part or not, I will:
- Ask you to complete a form to understand your home and school life and how you are feeling. We may also contact you in a week's time to complete the same form again.
- I will not put your name next to anything you say.
- Due to COVID-19, we will check your temperature and ask you to wear a mask and sanitise your hands. We will sit in a room with open windows and will sit far apart.

What are my rights?

- You can decide if you want to take part in the study or not, we will not force you. You can choose NOT to take part in the study.
- You can ask questions about this study.

What are the risks or inconveniences I may experience?

- Some questions we may ask you might be hard for you to answer. We will not force you to answer anything you cannot or do not want to answer.
- Having to complete this form might mean you will need to take time out from your activities. However, we will ensure that we have this chat on a day that is good for you and does affect with your schoolwork.
- Someone may overhear us during our chat. However, I will ensure that our chat is conducted in a private room where no one can hear us.
- Should I contact you again to complete the forms, someone else could overhear us or pick-up the phone. However, I will ensure I do not reveal any of your personal information to anyone. I will only continue to talk to you on the phone if you indicate that you are in a safe space for us to talk.
- Study forms could be misplaced or stolen. However, the team will ensure all study items are stored in a locked cupboard.

What are the possible benefits of taking part in this study for me?

- You may not get anything out of our chat.
- The information that we get from you and other children in this study will could help us understand how to measure and improve the health of children in South Africa.

Will I get anything for taking part in this study?

- You will receive a stationery set and lunch snack to the value of R100 at the end of the chat. This is to thank you for your time and for taking part.

Will the information I give be kept private?

- Your information will be kept on a computer file with a password, which only staff working on this study will know. Others will not see information that you provide me with.
- Our notes, forms and files from this chat will only have your own study number on it and not your name. We will not link your name to the information you give us. All the information you provide us with will be kept safe, and this information will be stored safely in a locked cupboard.
- We will use the information and photos from this study in presentations and in reports. These presentations and reports will not contain your name.
- If you tell us that you plan to do something bad to a person or yourself, we will need to help that person or you. Also, if you tell us that a person is going to do something bad to you, we will have to ensure you are safe. If we think, or if you tell us that you or someone in your home is upset, being hit, shouted or abused we will have to report it to the right people.

Who do I contact if I have any questions about this study?

- If you have any questions about the study, you may call: →	**Contact person:** Dr Darshini Govindasamy **Tel:** 031-203-4858

	Address: 491 Peter Mokaba Ridge Road, Overport, Durban; PO Box 70380, 4091 Overport, South Africa **Email:** darshini.govindasamy@mrc.ac.za
- If you have any problems with the way the study was done, you can call: →	**Contact person :** Prof D. Du Toit **Tel:** 021 938 0687 **Address:** South African Medical Research Council, PO Box 19070, Tygerberg 7505, Western Cape South Africa **Email:** adri.labuschagne@mrc.ac.za

PART 2: INFORMED VOLUNTARY ASSENT FORM

Please indicate whether you would like to take part or not in the table below. If you agree, please kindly add your name, signature and date below

Please read and mark each statement below	Please mark with an X	
▪ I have read and understood the information sheet (version number and date), for the study and was given time to ask questions	☐ Yes	☐ No
▪ I have received a copy of the information sheet in my language	☐ Yes	☐ No
▪ I understand that I can stop taking part at any time in this study	☐ Yes	☐ No
Overall, I agree to take part in this study	☐ Yes	☐ No
▪ I agree to share my contact details with the study staff should they need to contact me or my child to discuss any study matters	☐ Yes	☐ No
As per the Protection of Personal Information Act 4 of 2013 (as amended), I agree:		
▪ To my personal information (data) being collected, processed, shared and stored as per the research protocol approved by South African Medical Research Council's Human Research Ethics Committee	☐ Yes	☐ No
▪ To my data that does not contain my name being shared, processed and transferred to other researchers in or outside South Africa;	☐ Yes	☐ No
▪ To results arising from what I say in this study being included in any reports, as long as I cannot be identified	☐ Yes	☐ No

For participant to complete:

_____	_____	_____
Name and surname of participant	Signature or initials	Today's date (dd/mm/yyyy)

For study staff to complete:

I declare that I have explained the information given in this document to the participant and the participant was given ample time to ask questions

_____	_____	_____
Name and surname of study staff taking assent	Signature	Today's date (dd/mm/yyyy)

For witness to complete if participant is unable to write:

As a witness I confirm that all information about this study was given, and the participant verbally assented to taking part

_____	_____	_____
Name and surname of witness	Signature	Today's date (dd/mm/yyyy)

Appendix 9- Topic guide (Cognitive Interviews)

NOTE TO INTERVIEWER

- The goal of this interview is to assess the wording and participant's understanding of the EQ-5D-Y-5L
- Ensure you do not show the participant the EQ5D-Y-5L scale before the interview.
- Ensure you have a private, quiet and well-ventilated room to conduct the interview.
- Ensure you have a fieldworker to assist you with the administration, filing, recording, refreshments and reimbursements.

Before starting the interview, make sure you have the following material:

- ***Ranking Game*** (Instructions, Card Sets and Data Collection Sheets): The rank ordering sheet (with the five numbered empty boxes ranging from smallest to biggest problem and the smiley faces) should have the top box ('Participant has the smallest problem') and bottom box ('Participant has the biggest problem'), and the page printed out.
- The boxes should then be cut out and kept together in the appropriate set.
- ***EQ-5D-Y-5L*** – interviewer-administered & self-administered versions
- ***EQ-5D-Y-5L*** for you to refer to in the interview.
- ***Interview Data Collection Form*** about the questionnaire, which includes the prompts to ask the participant about their understanding and interpretation of the wording in the EQ-5D-Y and is also where you record the participant's responses.
- ***A notebook and pens***.
- ***Two charged digital recording devices- to be placed at each end of the interview space***

Overall flow of activities for this interview:

1. Begin the interview with the **Ranking Game exercise with the main sample.** Go through the instructions and ask the participant to undertake the ranking exercise. Fill in the **Ranking game Data Collection Sheet** as each card set is completed.
2. Next, give the participant a copy of the **EQ-5D-Y-5L (self-administered/interviewer-administered) questionnaire.** Tell him/her that there are no right or wrong answers and that you are just interested in what they think of the questionnaire. Tell them they should try to complete the questionnaire on their own without asking any questions, but that if they become completely stuck, they should ask for your help.
3. Note the time of starting and finishing the self-completed EQ-5D-Y questionnaire.

4. Review the questionnaire with the participant, dimension-by-dimension using the prompts included in Data Collection Sheet 2.
5. Note time of completing the interview.
6. Fill in the information on **Demographic Data Collection Form.**

SECTION A: RANKING GAME

Instructions, Card Sets and Data Collection Sheets

Note to Interviewer: *The text in italics are instructions for you (interviewer) and should not be read to the participant. The words in* ***bold*** *should be read aloud to the participant. Before starting the ranking games, you should cut out the five cards for the Introductory Set, and for Sets 1, 2, 3 and 4. Keep the cards in their correct set, but shuffle the five cards in each set so they will be presented to the participant in a random order. The card sets can be used for testing with other participant. You may print the cards on thin cardboard or tape the printed cards to cardboard.*

INTRODUCTION

- **Thank you for meeting me today. The reason for meeting is to get your opinion on a questionnaire to measure health. The questionnaire will be used by children aged between 10 and 15 years.**
- **We think the wording will be easy to understand, but we want to make sure. That's why we asked if you could help us today.**
- **Before we begin, I would like to highlight that any information you provide will be kept safe and we will not include your name on any of the documents.**
- **If at anytime you need to take a break or have a question feel free to let me know.**
- **Do you have any questions to ask me at this stage?**

INSTRUCTIONS

We will go through a task (or game). There are no right or wrong answers; we are only interested in your opinion. Do you have any questions?

Show the participant the 'scale' with the empty five boxes and smiley faces on the page and say:

I am going to give you sets of five cards describing problems participant may have with different activities.

Shuffle the Introductory Set (Attending School) cards and give them to the participant.

I want you to sort the five cards in order from what you think is the smallest problem to what you think is the biggest on this scale *(indicate the page with five boxes)***. Put the cards in the boxes according to how big you think the problem on the card is, from the smallest problem here** *(point to box 1)* **to the biggest problem here** *(point to box 5).*

If any problems are the same, you can put them together in the same box.

You should read all 5 cards before placing them in the boxes.

The first set of cards shows problems a participant may have with going to school. The cards are not describing your own problems; you can think of, or imagine, any participant. After you have read these five cards you can begin placing them in the boxes.

When the participant has placed all five cards in the boxes, ask if they have any questions. If they do, answer their questions. Then check to see if the cards have been placed in the boxes correctly. If they haven't placed the cards correctly, check whether they understood the task and provide more instruction if necessary. This first ranking game is an introduction, and the participant's responses do not need to be recorded on the Data Collection Sheet.

Important Note: If the participant cannot understand the task after further instruction (e.g. because of literacy or comprehension difficulties), please thank him/her and proceed no further as they will find the rest of the exercise difficult.

Remove the Introductory Attending School cards and thank the participant.

The next cards show problems a participant may have Walking About. The cards are not about your own walking; you can think of, or imagine, any participant. Here are the five cards. After you have read these five cards, you can begin placing them in the boxes, and remember there are no right or wrong answers.

Give the participant the cards for Set 1 (Walking About) shuffled into a random order.

Important Note: For Sets 1, 2, 3 and 4, the participant may ask you to help them understand words such as 'Walking about' or 'Pain or Discomfort'. If this occurs, tell him/her that you will discuss those words with them later in the interview, and that now they need to place the cards in order from the smallest problem to the biggest problem.

When the participant has finished the task, ask if he/she had any difficulty in deciding the order of the cards and make a note of their response on the Set 1 (Walking About) section of participant's Data Collection Sheet. We are especially interested in knowing if they had any difficulty deciding which of two cards represented a higher (or lower) level of problems. You will be able to observe if respondents have difficulty deciding the order, as they may swap the cards around a lot, or they may take a long time to decide into which box to place the card/s. You should also note your own observations on the participant's Data Collection Sheet indicating whether the participant experienced any difficulty.

Enter the card order results onto the Data Collection Sheet, then take away the Walking About cards and give him/her the cards for Set 2 (Washing or Dressing).

The next cards show problems a participant may have with Washing or Dressing themselves. Here are the five cards. As you did before, please read all five cards before placing them in the boxes in order from the smallest problem to the biggest problem.

When the participant has finished the task, ask if he/she had any difficulty in deciding the order of the cards and make a note of their response, and your observations, on the Set 2 (Washing or Dressing) section of the Data Collection Sheet.

Enter the card order results onto the Data Collection Sheet, then remove the Washing or Dressing cards and give him/her the cards for Set 3 (Pain or Discomfort).

The next cards show problems a participant may have with Pain or Discomfort. Please read all five cards before placing them in the boxes in order from the smallest problem to the biggest problem and remember there are no right or wrong answers.

When the participant has finished the task, ask if he/she had any difficulty in deciding the order of the cards and make a note of their response, and your observations, on the Set 3 (Pain or Discomfort) section of the Data Collection Sheet.

Enter the card order results onto the Data Collection Sheet, then remove the Pain or Discomfort cards and give the participant the cards for Set 4 (Worried, Sad or Unhappy).

The last set of cards show problems a participant may have with feeling worried, sad or unhappy. Please read all five cards before placing them in the boxes in order from the smallest problem to the biggest problem.

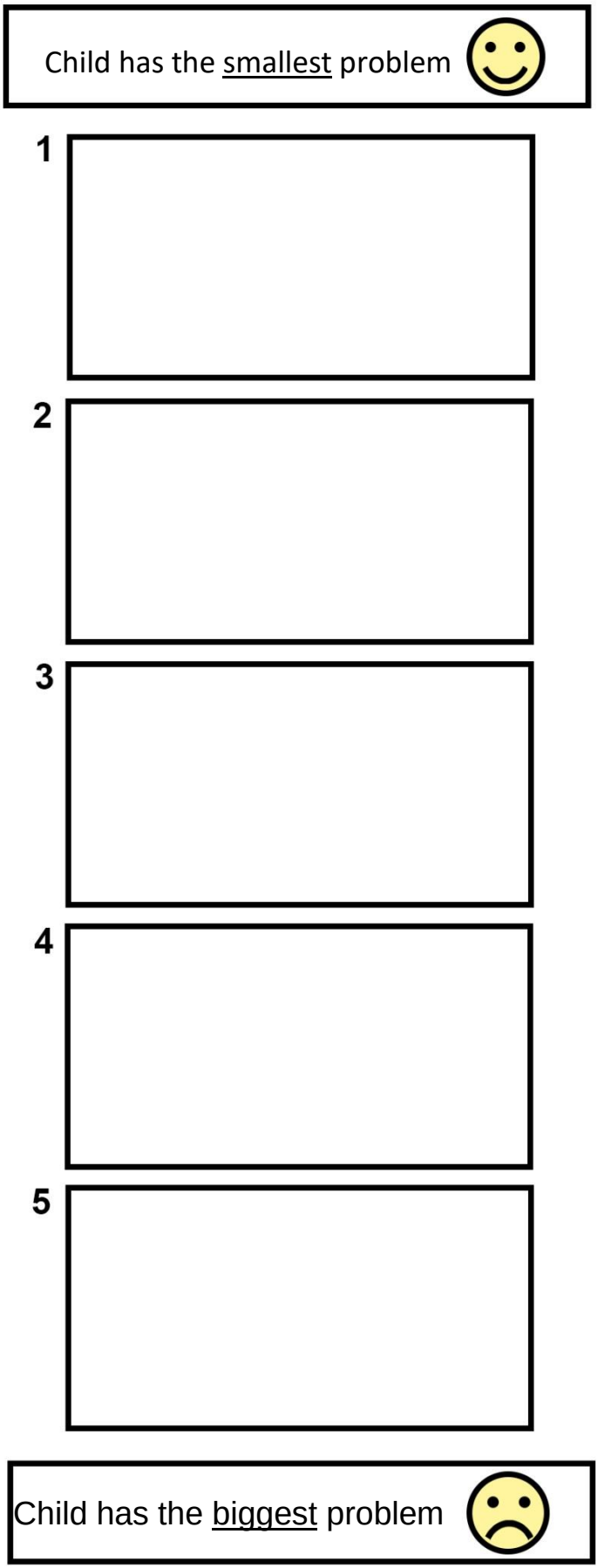
When the participant has finished the task, ask if he/she had any difficulty in deciding the order of the cards and make a note of their response, and your observations, on the Set 4 (Worried, Sad or Unhappy) section of the Data Collection Sheet.

Enter the card order results onto the Data Collection Sheet, then remove the Worried, Sad or Unhappy cards. Thank the respondent for completing the ranking game.

File all five cards sets carefully so the sets remain complete for future testing with other participant.

BREAK

- *Once the Ranking exercise is complete, ensure you and the participant take a 30-minute refreshment/stretch break before proceeding with the final activity.*


Child has the smallest problem
1
2
3
4
5
Child has the biggest problem

Introductory Set:
Attending (Going to) School

I am well and can attend school every day

I am unwell and cannot attend school for 2 days

I am unwell and cannot attend school for 3 days

I am unwell and cannot attend school for 4 days

I am unwell and cannot attend school on any day

Set 1: Walking About

I have no problems walking about

I have a little bit of a problem walking about

I have some problems walking about

I have a lot of problems walking about

I cannot walk about

Set 2: Washing or Dressing

I have no problems washing or dressing myself

I have a little bit of a problem washing or dressing myself

I have some problems washing or dressing myself

I have a lot of problems washing or dressing myself

I cannot wash or dress myself

Set 3: Pain or discomfort

I have no pain or discomfort

I have a little bit of pain or discomfort

I have some pain or discomfort

I have a lot of pain or discomfort

I have extreme pain or discomfort

Set 4: Worried, Sad or Unhappy

I am not worried, sad or unhappy

I am a little bit worried, sad or unhappy

I am quite worried, sad or unhappy

I am really worried, sad or unhappy

I am extremely worried, sad or unhappy

SECTION B: DATA COLLECTION SHEET

(ONE FOR EACH PARTICIPANT)

Respondent ID number: _____ ☐ ☐

Indicate the participant's age group: **10-11 years** **12-15 years**

Write the box number that the participant places each card into for each of the card sets. If he/she places two cards in the same box, enter the same box number for both cards.

	Box number	***In this column, write your comments about any problems the participant had with placing the cards***
Introductory Set (Attending School)		
I am well and can attend school <u>every day</u>	**1**	*You do not need to record respondents' responses for the Introductory Set about School Attendance, but we have entered the Box numbers as an example here.* *In our example, the participant has put all cards into boxes on the Rank Order Sheet in the order we intended, ranging from 'attending school every day' (Box 1) to 'not attending school on any day' (Box 5).*
I am unwell and cannot attend school for <u>2 days</u>	**2**	
I am unwell and cannot attend school for <u>3 days</u>	**3**	
I am unwell and cannot attend school for <u>4 days</u>	**4**	
I am unwell and cannot attend school <u>on any day</u>	**5**	

Continued on next page

	Box number	***In this column, write your comments about any problems the participant had with placing the cards***
Set 1 (Walking About)		
I have no problems walking about		*If the participant placed any cards in the wrong boxes, or in a seemingly random order, ask them why they ordered the cards the way they did, and write their responses here:* *If there were any card order mistakes: Do you think they were due to any of the following? (Select all that apply)* ☐ Participant misunderstood the translation of some words for this set. *Please specify:* _____ ☐ Participant misunderstood the game itself ☐ Other reasons (e.g. smileys are not culturally appropriate or questionnaires are ordered from the worst at the top to the best at the bottom in our culture). *Please specify:* _____
I have a little bit of a problem walking about		
I have some problems walking about		
I have a lot of problems walking about		
I cannot walk about		
Set 2 (Washing or Dressing)		
I have no problems washing or dressing myself		*If the participant placed any cards in the wrong boxes, or in a seemingly random order, ask them why they ordered the cards the way they did, and write their responses here:* *If there were any card order mistakes: Do you think they were due to any of the following? (Select all that apply)* ☐ Participant misunderstood the translation of some words for this set. *Please specify:* _____
I have a little bit of a problem washing or dressing myself		
I have some problems washing or dressing myself		
I have a lot of problems washing or dressing myself		

I cannot wash or dress myself		☐ Participant misunderstood the game itself ☐ Other reasons (e.g. smileys are not culturally appropriate or questionnaires are ordered from the worst at the top to the best at the bottom in our culture). *Please specify:* _____
Continued on next page		
	Box number	***In this column, write your comments about any problems the participant had with placing the cards***
Set 3 (Pain or Discomfort)		
Participant has no pain or discomfort		*If the participant placed any cards in the wrong boxes, or in a seemingly random order, ask them why they ordered the cards the way they did, and write their responses here:* *If there were any card order mistakes: Do you think they were due to any of the following? (Select all that apply)* ☐ Participant misunderstood the translation of some words for this set. *Please specify:* _____ ☐ Participant misunderstood the game itself ☐ Other reasons (e.g. smileys are not culturally appropriate or questionnaires are ordered from the worst at the top to the best at the bottom in our culture). *Please specify:* _____
Participant has a little bit of pain or discomfort		
Participant has some pain or discomfort		
Participant has a lot of pain or discomfort		
Participant has extreme pain or discomfort		
Set 4 (Worried, Sad or Unhappy)		
Participant is not worried, sad or unhappy		*If the participant placed any cards in the wrong boxes, or in a seemingly random order, ask them why they ordered the cards the way they did, and write their responses here:*
Participant is a little bit worried, sad or unhappy		

<table>
<tr><td>Participant is <u>quite</u> worried, sad or unhappy</td><td></td><td rowspan="4">If there were any <u>card order mistakes</u>: Do you think they were due to any of the following? (Select all that apply)

☐ Participant misunderstood the translation of some words for this set. Please specify: _____

☐ Participant misunderstood the game itself

☐ Other reasons (e.g. smileys are not culturally appropriate or questionnaires are ordered from the worst at the top to the best at the bottom in our culture). Please specify: _____</td></tr>
<tr><td>Participant is <u>really</u> worried, sad or unhappy</td><td></td></tr>
<tr><td>Participant is <u>extremely</u> worried, sad or unhappy</td><td></td></tr>
<tr><td></td><td></td></tr>
</table>

SECTION C: RANKING GAME SUMMARY REPORT

When all respondents have completed the ranking games, write the box scores for all respondents (R) into the following table. Please highlight in the table below where the card order was 'incorrect'.

	R1 Box order	R2 Box order	R3 Box order	R4 Box order	R5 Box order	R6 Box order	R7 Box order	R8 Box order	R9 Box order	R10 Box order
Participant's age (in years)										
Set 1 (Walking About)										
I have no problems walking about										
I have a little bit of a problem walking about										
I have some problems walking about										
I have a lot of problems walking about										
I cannot walk about										
Set 2: Washing or Dressing										
I have no problems washing or dressing myself										
I have a little bit of a problem washing or dressing myself										
I have some problems washing or dressing myself										
I have a lot of problems washing or dressing myself										
I cannot wash or dress myself										
Continued on next page										
	R1 Box order	**R2 Box order**	**R3 Box order**	**R4 Box order**	**R5 Box order**	**R6 Box order**	**R7 Box order**	**R8 Box order**	**R9 Box order**	**R10 Box order**
Set 3: Pain or Discomfort										
Participant has no pain or discomfort										
Participant has a little bit of pain or discomfort										

Participant has some pain or discomfort										
Participant has a lot of pain or discomfort										
Participant has extreme pain or discomfort										
Set 4: Worried, Sad or Unhappy										
Participant is not worried, sad or unhappy										
Participant is a little bit worried, sad or unhappy										
Participant is quite worried, sad or unhappy										
Participant is really worried, sad or unhappy										
Participant is extremely worried, sad or unhappy										

SECTION D1: FORM TO RECORD THE PARTICIPANT'S RESPONSES TO THE COGNITIVE DEBRIEFING (ED-5D-Y-5L (SA))

Give the participant the copy of the EQ-5D-Y-5L questionnaire and ask them to fill it in. Tell him/her that there are no right or wrong answers and that you are just interested in what they think of the questionnaire. Tell them they should try to complete the questionnaire on their own without asking any questions, but that if they become completely stuck, they should ask for your help.

Observe the participant carefully as they complete the questionnaire. **Note any point** at which the participant appears to struggle to understand, or complete anything, or where they go more slowly or have to re-read, etc.

If the participant asks for help, ask them what they think they are supposed to do at the point where they are asking for help and how they interpret any words or phrases they are having difficulty with. Encourage them to answer as best they can and tell them that you can talk more about problems they had when the participant finishes the questionnaire. **Make a note** of any *word*, *phrase* or *task* that the participant asks for help on.

⇒ **Note the time of finishing the self-completed EQ-5D-Y-5L questionnaire.**

To avoid asking every participant every question, we have divided the respondents into three groups which answer different parts of the questionnaire.

Please make sure that a younger participant is included in each group of responders. **The questions in grey should not be asked to the group of respondents that have been blanked out.**

For each dimension ask the following questions:

1. Were there any words which you did not understand, or found difficult or confusing? If so, what were these words?
2. Were there any words which you thought sounded strange or funny? Which ones?
3. Would you change any of the words or say anything in a different way? If so, which ones would you change?

If an answer is unsatisfactory, or the participant seems unsure how to respond, use probing questions to try to understand the problem further.

CLOSURE

- Thank the participant for their time. Ask them if they have any final questions for you.
- Assess the need for referral
- Provide them with their reimbursement and referral brochure.

SECTION D2: THE COGNITIVE DEBRIEFING ED-5D-Y-5L (INTERVIEWER-ADMINSITERED)

Note to the fieldworker: although allowance should be made for the interviewer's particular style of speaking, the wording of the questionnaire instructions should be followed as closely as possible. In the case of the EQ-5D-Y descriptive system of the questionnaire, the precise wording must be followed.

If the child (respondent) has difficulty choosing a response, or asks for clarification, the interviewer should repeat the question word for word and ask the child to answer in a way that most closely resembles his or her thoughts about his or her health today.

****DO NOT FORGET TO TIME PARTICIPANT COMPLETION FOR EACH SCALE**

INTRODUCTION

(Note to fieldworker: please read the following to the child.)

Narration:
We are trying to find out what you think about your health. I will explain what to do as I go along, but please stop me if you do not understand something or if things are not clear to you. There are no right or wrong answers. We are interested only in what you think.

Narration: *First, I am going to read out some questions. Each question has a choice of five answers. Please tell me which answer best describes your health TODAY.*

Do not choose more than one answer in each group of questions.

(Note to fieldworker: first read all five options for each question. Then ask the child to choose which one applies to him/herself. Repeat the question and options if necessary. Mark the appropriate box under each heading. You may need to remind the child regularly that the timeframe is TODAY.)

*****Refer to the EQ-5D-Y-5L (IA) SCALE******

- Observe the participant carefully as they complete the questionnaire. **Note any point** at which the participant appears to struggle to understand, or hear anything, or where they go more slowly or ask you to repeat, etc.
- If the participant asks for help, ask them what they think they are supposed to do at the point where they are asking for help and how they interpret any words or phrases they are having difficulty with. Encourage them to answer as best they can and tell them that you can

talk more about problems they had when the participant finishes the questionnaire. **Make a note** of any *word*, *phrase* or *task* that the participant asks for help on.

- **Note the time of finishing the self-completed EQ-5D-Y-5L questionnaire.**

For each dimension ask the following questions:

1. Did you understand what was expected from you when we began with the first question?
   - Could you repeat some of the questions I mentioned? [Probe- issues with instructions, confusing word/phrases]
2. For each question I asked (e.g. about pain/walking etc.), were you able to remember the options I provided you with to select from?
   - Could you repeat some of the responses I mentioned [Probe- issues with instructions, confusing word/phrases]
3. Were there any words which you did not understand, or found difficult or confusing? If so, what were these words?
4. Were there any words which you thought sounded strange or funny? Which ones?
5. Would you change any of the words or say anything in a different way? If so, which ones would you change?
6. How did you find the length of the questionnaire?
7. Do you have any advice on how we can improve the scale or how best to administer this scale to young people?

If an answer is unsatisfactory, or the participant seems unsure how to respond, use probing questions to try to understand the problem further.

CLOSURE

- Thank the participant for their time. Ask them if they have any final questions for you.
- Assess the need for referral
- Provide them with their reimbursement and referral brochure.

Source	Translation	Script	Respondent Age in years	Response to meaning questions	Response to example question (if applicable)	Interview-ers comments	Final consensus version	Project manager and VMC
Health Questionnaire English version for the UK			**R1**					
			R2					
			R3					
			R4					
			R5					
			R6					
			R7					
			R8					
			R9					
			R10					
Under each heading, please tick the ONE box that best describes your health TODAY		Could you explain what you were asked to do?	**R1**					
			R2					
			R3					
			R4					
			R5					
			R6					
			R7					
			R8					
			R9					
			R10					
MOBILITY (walking about)		What do you think 'Mobility' means? What do you think about when you see that word? What does 'walking about' mean for you? What did you think about when you saw those words?	**R1**					
			R2					
			R3-					
			R4					
			R5					
			R6					
			R7					
			R8					
			R9					
			R10					
I have <u>no</u> problems walking about		For each level ask the participant: Can you imagine, or do you know anyone who has had ('a little bit of a problem', 'some problems', a lot of problems') with walking about? Could you describe the problems they might have?	**R1**					
I have <u>a little bit</u> of a problem walking about			**R2**					
I have <u>some</u> problems walking about			**R3-**					
I have <u>a lot</u> of problems walking about			**R4**					
I <u>cannot</u> walk about			**R5**					
			R6					
			R7					
			R8					
			R9					
			R10					
LOOKING AFTER MYSELF		What do you think 'Looking after myself' means? What do you think about when you	**R1**					
			R2					
			R3					
			R4					

Source	Translation	Script	Respondent Age in years	Response to meaning questions	Response to example question (if applicable)	Interview-ers comments	Final consensus version	Project manager and VMC
		see those words? What do 'washing' and 'dressing' mean for you? What did you think about when you saw those words?						
			R5					
			R6					
			R7					
			R8					
			R9					
			R10					
I have no problems washing or dressing myself		For each level ask the participant: Can you imagine, or do you know anyone who has had ('a little bit of a problem', 'some problems', a lot of problems') with washing or dressing? Could you describe the problems they might have?	**R1**					
I have a little bit of a problem washing or dressing myself			**R2**					
I have some problems washing or dressing myself			**R3**					
I have a lot of problems washing or dressing myself			**R4**					
I cannot wash or dress myself			**R5**					
			R6					
			R7					
			R8					
			R9					
			R10					
DOING USUAL ACTIVITIES		What do you think 'Doing usual activities' means? What do you think about when you see those words?	**R1**					
			R2					
			R3					
			R4					
			R5					
			R6					
			R7					
			R8					
			R9					
			R10					

Source	Translation	Script	Respondent Age in years	Response to meaning questions	Response to example question (if applicable)	Interview-ers comments	Final consensus version	Project manager and VMC
I have no problems doing my usual activities		For each level ask the participant: Can you imagine, or do you know anyone who has had ('a little bit of a problem', 'some problems', a lot of problems') with doing their usual activities? Could you describe the problems they might have?	**R1**					
I have a little bit of a problem doing my usual activities			**R2**					
			R3					
I have some problems doing my usual activities			**R4**					
			R5					
I have a lot of problems doing my usual activities			**R6**					
I cannot do my usual activities			**R7**					
			R8					
			R9					
			10					
HAVING PAIN OR DISCOM-FORT		What do you think 'discomfort' means? What do you think about when you see that word?	**R1**					
			R2					
			R3					
			R4					
			R5					
			R6					
			R7					
			R8					
			R9					
			R10					
I have no pain or discomfort		For each level ask the participant: Can you tell me a little bit more about it? Do you know or can you imagine someone who would answer that they had ('no', 'a little bit', 'some', 'a lot of', 'extreme') pain or discomfort? Could you describe the problems that he or she might have?	**R1**					
I have a little bit of pain or discomfort			**R2**					
I have some pain or discomfort			**R3**					
I have a lot of pain or discomfort			**R4**					
			R5					
I have extreme pain or discomfort			**R6**					
			R7					
			R8					
			R9					
			R10					
FEELING WORRIED, SAD OR UNHAPPY		Could you explain in your own words what worried means? What does sad meant to you? Does this differ from unhappy? In what way?	**R1**					
			R2					
			R3					
			R4					
			R5					
			R6					
			R7					
			R8					
			R9					
			R10					

Source	Translation	Script	Respondent Age in years	Response to meaning questions	Response to example question (if applicable)	Interview-ers comments	Final consensus version	Project manager and VMC
I am not worried, sad or unhappy		For each level ask the participant: Can you imagine, or do you know a participant with a health condition who would answer that they are ('not', 'a little bit', 'quite', 'really', 'extremely') worried, sad or unhappy? Could you describe the problems that he or she might have?	**R1**					
I am a little bit worried, sad or unhappy			**R2**					
I am quite worried, sad or unhappy			**R3**					
I am really worried, sad or unhappy			**R4**					
I am extremely worried, sad or unhappy			**R5**					
			R6					
			R7					
			R8					
			R9					
			R10					
We would like to know how good or bad your health is TODAY.		Did you understand what you had to do? Were there any words that you did not know? Would you change any words?	**R1**					
This line is numbered from 0 to 100.			**R2**					
100 means the best health you can imagine.			**R3**					
0 means the worst health you can imagine.			**R4**					
Please mark an X on the line to indicate how your health is TODAY.			**R5**					
Now, write the number you marked on the line in the box below.			**R6**					
			R7					
			R8					
			R9					
			R10					

SECTION E: DEMOGRAPHIC DATA COLLECTION

Please complete the following table for each respondent (R).

	R1	R2	R3	R4	R5	R6	R7	R8	R9	R10
Date of interview										
Age in years										
School Grade										
Location*										
Describe Health Condition (ALHIV/ School sample)										
Time to complete EQ-5D-Y self-complete questionnaire (minutes)										
Ask participant: Was the questionnaire easy to answer? Was there anything you found difficult about the questionnaire?										
Interviewer's observations: Did the participant fill in the entire questionnaire independently without assistance? Did they ask for help at any point or appear to struggle with anything in the questionnaire?										
Time to complete the entire cognitive debriefing exercise – including the ranking game										

* The **location** should refer to the type of place of interview (e.g. school, clinic, respondent's home, etc.) and the town/city/region where the interview took place. Please do not include the detailed address.

SECTION F: QUESTIONS FOR INTERVIEWERS ABOUT THE RANKING GAME PROCESS

The ranking game is a new method for checking the level order within each of the five domains of the EQ-5D-Y-5L. To assess the appropriateness of this new method, we would appreciate interviewers answering the following questions:

1. **Did the participant understand what was required of them with regard to the ranking game?**

2. **Was the Introductory (Attending School) lead-in exercise useful? Was it necessary or would the participant have managed without doing it? If we do retain a lead-in exercise, was the use of Attending School appropriate? Was it difficult to translate this example?**

3. **If participant experienced problems in ordering the cards 'correctly', do you think we would have picked this up if we had not done the ranking exercise?**

Could you give us your overall opinion of the ranking game? Was it easy, enjoyable, useful, time consuming, etc

Appendix 10- Topic guide (Key informant interviews, HCWs and study fieldworkers)

NOTE TO INTERVIEWER

- The goal of the activity is to assess HCWs and fieldworkers' perceptions on the EQ-5D-Y-5L versus the 3L versions and CHU9D
- We want to know how feasible it would be to implement the EQ-5D-Y-5L within routine HIV clinics.
- Ensure you have given the HCW the pack of HRQoL scales to review at least 2 weeks before their interview date.
- Ensure you have a private, quiet and well-ventilated room to conduct the interview.

Before starting the interview, make sure you have the following material:

- ***EQ-5D-Y-5L, EQ-5D-Y-3L, and CHU9D***
- ***Interview Data Collection Form*** which includes the prompts to ask the participant about their perceptions regarding each tool and is also where you record the participant's responses.
- ***A notebook and pens***.
- ***Two charged digital recording devices- to be placed at each end of the interview room***
- ***Reimbursement item and form***

Overall flow of activities for this interview:

1. Probe the relevance of the dimensions addressed in each scale for ALHIV in this setting
2. Probe the wording and clarity of the instructions and questions in each scale, followed by the response options
3. Probe which scale would be most feasible for use in routine patient management and how could this be implemented?
4. Probe other relevant concerns regarding HRQoL among ALHIV in this setting.

TOPIC GUIDE FOR HCWs

INTRODUCTION

- Thank you for taking time out of your busy schedule for this interview. **Before we begin, I wish to remind you of the following:**
  - *In today's interview, we will discuss your feedback on the 3 HRQoL scales that I provided you with.*
  - *This interview will/will not be digitally recorded.*
  - *All information you share with me will be kept private and will not contain any personal identifiers. My notes and/or recordings will be kept in a locked cupboard at our study office.*
  - *Kindly place your phone on silent for the duration of the interview. If there is an urgent matter that you have to attend to, feel free to let me know so we can pause the interview and reschedule as needed.*
  - *If at any time you need a stretch break or need me to repeat the question, do not hesitate to ask.*
  - *Do you have any questions before we begin?*

1. Briefly describe your role and some of your key daily activities with patients at this clinic? *[Probe provision of services with ALHIV]*

2. When you hear the phrase "health-related quality of life", what comes to mind?

3. Which elements of HRQoL do you think matter most for adolescents aged 10-15-year-olds, particularly those living with HIV in this community? [Probe differences by sex, socio-economic status, disability status]

A. MAIN INTERVIEW

1. I am now going to obtain your feedback on each of the three HRQoL scales (English Version) in the pack that I provided you with. For each tool we will assess the following: layout, wording, relevance for ALHIV in this context.

- Are the <u>instructions</u> clear for a 10-15-year-old in this setting? *[Probe: suggestions for improvement]*
- Are the <u>questions</u> clear for a 10-15-year-old in this setting? *[Probe: suggestions for improvement]*
- Are the <u>responses</u> clear for a 10-15-year-old in this setting? *[Probe: suggestions for improvement]*
  - Do you prefer the 5 or 3 option response levels and why? *[For the EQ5D scales only]*
- Are there any <u>words</u> that are unclear OR a 10-15-year-old would not understand? *[Probe: suggestions for improvement]*

- For the EQ-5D scales, do you feel a 10-15-year-old would understand what is expected of them for the last question (VAS activity)? *[Probe: suggestions for improvement]*
- This tool probes the following HRQoL dimensions […].What dimensions would you add or delete to ensure it is relevant to ALHIV in this context?

2. From these 3 HRQoL scales,
- Which scale do you feel is best suited for assessing HRQoL among ALHIV who are accessing care at this clinic and why?
  - How easy would it be to implement this tool in your clinic, and want would one need to consider when implementing this scale ? [Probe: approvals, cost, administration (mode, language, frequency), time & resource constraints, training, usefulness for clinical care, referrals, M&E tool burden]
- Which scale do you feel is least suited for assessing HRQoL among ALHIV who are accessing care at this clinic and why?

B. CLOSURE

---

1. We have now reached the end of the interview. Thank you for your expert feedback. Before we close, this is a summary of what we discussed.
  - Is it an accurate summary?
  - Is there a key point I may have missed out on?

2. Is there anything else you wish to share? Or do you have any questions for the study team
- ❖ Provide participant with their reimbursement

TOPIC GUIDE FOR FIELDSTAFF ON THE STUDY

INTRODUCTION

- Thank you for taking time out of your busy schedule for this interview. **Before we begin, I wish to remind you of the following:**
  - *In today's interview, we will discuss your feedback on the 3 HRQoL scales that I provided you with, and that you administered to adolescents who participated in the survey.*
  - *This interview will/will not be digitally recorded.*
  - *All information you share with me will be kept private and will not contain any personal identifiers. My notes and/or recordings will be kept in a locked cupboard at our study office.*
  - *Kindly place your phone on silent for the duration of the interview. If there is an urgent matter that you have to attend to, feel free to let me know so we can pause the interview and reschedule as needed.*
  - *If at any time you need a stretch break or need me to repeat the question, do not hesitate to ask.*
  - *Do you have any questions before we begin?*

1. Briefly describe your role on the study and some of the activities you conducted?

A. MAIN INTERVIEW

1. I am now going to obtain your feedback on each of the three HRQoL scales you administered in the study (English Version) in the pack that I provided you with. For each tool we will assess the following: layout, wording, relevance for ALHIV in this context.

- Of the participants you interviewed, what was their overall reaction when you read the instructions on the form? *[Probe: clarifying questions they posed, self-administration, suggestions for improvement]*
- Of the participants you interviewed, what was their overall reaction when you read the questions? *[Probe: questions they asked/expressions on their faces, self-administration, suggestions for improvement]*
- Of the participants you interviewed, what was their overall reaction when you read the responses? *[Probe: questions they asked/expressions on their faces, self-administration, suggestions for improvement]*
  - Did you prefer the 5 or 3 option response levels and why? *[For the EQ5D scales only]*
- For the EQ-5D scales, what was your experience like administering this section (VAS activity)? *[Probe: self-administration, face-to-face interviews, telephonic interviews, suggestions for improvement]*
- Overall, were there any words which participants had difficulty in understanding? *[Probe: suggestions for improvement]*
- Are there any dimensions you would add or delete to ensure it is relevant to ALHIV in this context?

2. From these 3 HRQoL scales you administered,
    - Which scale do you feel is best suited for assessing HRQoL among ALHIV and why?
    - Which scale do you feel is least suited for assessing HRQoL among ALHIV and why?

3. Overall, what was you experience like working on this study? [Probe: Pros, cons, things they would have changed]

B. CLOSURE

---

1. We have now reached the end of the interview. Thank you for your expert feedback. Before we close, this is a summary of what we discussed.
    - Is it an accurate summary?
    - Is there a key point I may have missed out on?
2. Is there anything else you wish to share? Or do you have any questions for the study team
    - ❖ Provide participant with their reimbursement

Appendix 11- Baseline questionnaire (Cross-sectional survey)

SECTION A: INTRODUCTION	
Note to the fieldworker: Please kindly complete this section	
1. Participant study ID	_____
2. Fieldworker ID	_____
3. Date of interview (dd/mm/yyyy)	_____
4. Arm	☐ Clinic arm ☐ School arm
5. Quality controlled by (initials)	☐ _____
Narration: • *Good day. Thank you for agreeing to take part in this study* • *During our chat today, I will ask you a few questions on your background (home and school life, and your thoughts on your health and life)*	

SECTION B: PARTICIPANT'S BACKGROUND	
Narration: *First, I want to get to know you*	
1. How old are you?	_____
2. What Grade are you in currently? Key 1. Grade 3 2. Grade 4 3. Grade 5 4. Grade 6 5. Grade 7 6. Grade 8 7. Grade 9 8. Grade 10 9. Currently not in school 10. Stopped school after COVID-19 11. Don't know	☐ _____ (Choose from the key)
3. Which school do you attend? (For the Clinic arm only)	☐ _____
4. Who at home takes care of you (by this I mean, cooks your food, washes your clothes, takes care of you when you are sick? Key 1. Biological mother 2. Biological father 3. Sister 4. Brother 5. Uncle 6. Aunt	☐ _____ (Choose from the key) ☐ Other (please detail): _____ ☐ I take care of myself

7. Grandmother 8. Grandfather 9. Stepfather 5. 10. Stepmother			
6.	What do you want to be when your grow up? (ICE-BREAKER)	☐ Teacher ☐ Doctor ☐ Nurse ☐ Singer	☐ Police officer ☐ Chef ☐ Engineer ☐ Mechanic ☐ I do not know
7.	In general, how would you rate your overall health?	☐ Excellent ☐ Good ☐ Fair ☐ Poor ☐ Unsure	
8.	Compared to your friends, would you say your health is the same, better or worse?	☐ Same ☐ Better ☐ Worse ☐ Unsure	
9.	Do you have any health issues that you see anybody at the clinic? (School arm only)	☐ Yes ☐ No ☐ Unsure ☐ Prefer not to say	
9.1	If yes, could you explain to me the problem? (School arm only)	☐ Asthma ☐ Skin rash ☐ HIV ☐ TB ☐ Diabetes ☐ Diarrhoea	☐ Cancer ☐ Other (Specify:_____) ☐ Prefer not to say ☐ Unsure
10.	What do you do in your spare time? (ICE-BREAKER)	☐ Draw/colour/paint ☐ Read ☐ Play sport/other games ☐ Sing	☐ Dance ☐ Listen to music ☐ Watch TV ☐ Chat with friends ☐ Other
Narration: *Thank you for this information!*			

SECTION C: HOUSEHOLD INFORMATION		
Narration: *I am now going to ask you a few questions about the household you stay in*		
1. What material is your house made up of?	☐ Informal (house made of tin/zinc/wood/traditional material) ☐ Formal (house made of brick, cement, tiles) ☐ Homeless (no home, sleeps on the streets) ☐ Live in a hospice/childrens home/shelter	
2. How many people currently live in your household?	☐ Total:_____	
3. Where does the water you drink at home come from?	☐ Pipe water (tap) in dwelling ☐ Pipe water (tap) in yard ☐ Bottled water ☐ Water tank' ☐ Rainwater tank (Jo-Jo tank)	☐ Borehole, well or spring ☐ Dam/river or stream ☐ Public / communal tap ☐ Other (please detail):_____
4. Describe the type of toilet you use at home?	☐ Flushing toilet (for the house only) ☐ Flushing toilet (shared by > 1 house) ☐ Bucket latrine ☐ Pit latrine with ventilation	☐ Pit latrine without ventilation ☐ No toilet / bush / field ☐ Other (please detail):_____
5. What is used to make food at home?	☐ Electricity ☐ Gas ☐ Paraffin ☐ Charcoal	☐ Wood ☐ Dung ☐ Other (please detail):____
6. In the past 4 weeks, how often did you or any member of your household go to sleep hungry because of lack of food?	☐ Often ☐ Sometimes ☐ Rarely ☐ Never	
7. What is your favourite fruit ? (ICE-BREAKER)	☐ Apple ☐ Orange ☐ Banana ☐ Grapes ☐ Mango	☐ Pawpaw ☐ Litchi ☐ Strawberry ☐ I do not like fruit ☐ Other
Narration: *Thank you for this information!*		

SECTION D: HRQOL

Note to the fieldworker: although allowance should be made for the interviewer's particular style of speaking, the wording of the questionnaire instructions should be followed as closely as possible. In the case of the EQ-5D-Y descriptive system of the questionnaire, the precise wording must be followed.

If the child (respondent) has difficulty choosing a response, or asks for clarification, the interviewer should repeat the question word for word and ask the child to answer in a way that most closely resembles his or her thoughts about his or her health today.

****DO NOT FORGET TO TIME PARTICIPANT COMPLETION FOR EACH SCALE**

INTRODUCTION

(Note to fieldworker: please read the following to the child.)

Narration:
We are trying to find out what you think about your health. I will explain what to do as I go along, but please stop me if you do not understand something or if things are not clear to you. There are no right or wrong answers. We are interested only in what you think.

[THE PARTICIPANT WILL BE ALLOCATED SPECIFIC EQ-5D-Y 5L & 3L SCALES TO COMPLETE (IA/SA) AS PER TABLE 4 IN THE PROTOCOL- THE ORDER OF THE SCALES WILL BE REVERSED IN 50% OF THE SAMPLE IN EACH ARM]

SECTION D1: EQ-5D-Y-5L (SELF-ADMINISTERED)

Instructions (show the participant the questionnaire)

(Under each heading / On the following screens), please select the ONE box that best describes your health TODAY.

1. **MOBILITY** *(walking about)*
- ☐ I have no problems walking about
- ☐ I have a little bit of a problem walking about
- ☐ I have some problems walking about
- ☐ I have a lot of problems walking about
- ☐ I cannot walk about

2. **LOOKING AFTER MYSELF**
- ☐ I have no problems washing or dressing myself
- ☐ I have a little bit of a problem washing or dressing myself
- ☐ I have some problems washing or dressing myself
- ☐ I have a lot of problems washing or dressing myself
- ☐ I cannot wash or dress myself

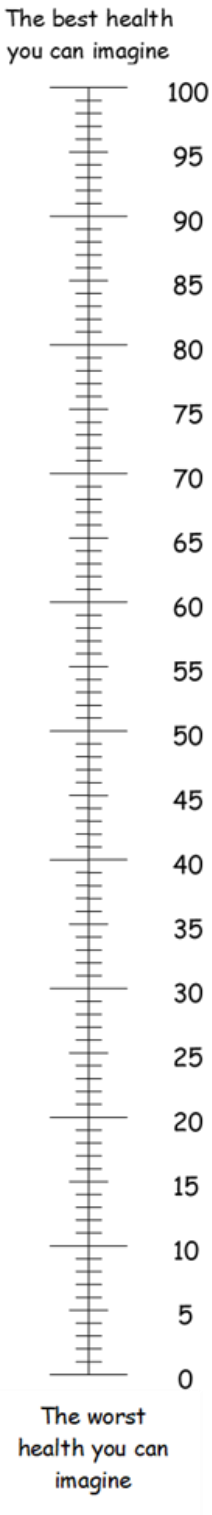
3. **DOING USUAL ACTIVITIES** *(for example, going to school, hobbies, sports, playing, doing things with family or friends)*
- ☐ I have no problems doing my usual activities
- ☐ I have a little bit of a problem doing my usual activities
- ☐ I have some problems doing my usual activities
- ☐ I have a lot of problems doing my usual activities
- ☐ I cannot do my usual activities

4. **HAVING PAIN OR DISCOMFORT**
- ☐ I have no pain or discomfort
- ☐ I have a little bit of pain or discomfort
- ☐ I have some pain or discomfort
- ☐ I have a lot of pain or discomfort
- ☐ I have extreme pain or discomfort

5. **FEELING WORRIED, SAD OR UNHAPPY**
- ☐ I am not worried, sad or unhappy
- ☐ I am a little bit worried, sad or unhappy
- ☐ I am quite worried, sad or unhappy
- ☐ I am really worried, sad or unhappy
- ☐ I am extremely worried, sad or unhappy

6. How good is your health TODAY

- We would like to know how good or bad your health is TODAY.
- This line is numbered from 0 to 100.
- 100 means the <u>best</u> health you can imagine.
  0 means the <u>worst</u> health you can imagine.
- Please mark with an X on the line to show how good or bad your health is TODAY.



7. Add participant completion time here (MM:SS): _____

** Let us do a small stretch together(depending on the participant 's physical ability, stand up and touch your toes/sit on the chair and move your neck from side to side (ICE-BREAKER)*

** How many starts can you spot in this row*

SECTION D2: EQ-5D-Y-5L (INTERVIEWER-ADMINSITERED)

Narration:

First, I am going to read out some questions. Each question has a choice of five answers. Please tell me which answer best describes your health TODAY.

Do not choose more than one answer in each group of questions.

(Note to fieldworker: first read all five options for each question. Then ask the child to choose which one applies to him/herself. Repeat the question and options if necessary. Mark the appropriate box under each heading. You may need to remind the child regularly that the timeframe is TODAY.)

First, I would like to ask you about WALKING ABOUT (MOBILITY). Would you say that:

You have no problems walking about	☐
You have a little bit of a problem walking about	☐
You have some problems walking about	☐
You have a lot of problems walking about	☐
You cannot walk about	☐

Next, I would like to ask you about LOOKING AFTER YOURSELF. Would you say that:

You have no problems washing or dressing yourself	☐
You have a little bit of a problem washing or dressing yourself	☐
You have some problems washing or dressing yourself	☐
You have a lot of problems washing or dressing yourself	☐
You cannot wash or dress yourself	☐

Next, I would like to ask you about DOING USUAL ACTIVITIES, for example, going to school, hobbies, sports, playing, doing things with family or friends. Would you say that:

You have no problems doing your usual activities	☐

You have a little bit of a problem doing your usual activities	☐
You have some problems doing your usual activities	☐
You have a lot of problems doing your usual activities	☐
You cannot do your usual activities	☐

Next, I would like to ask you about HAVING PAIN OR DISCOMFORT. Would you say that:

You have no pain or discomfort	☐
You have a little bit of pain or discomfort	☐
You have some pain or discomfort	☐
You have a lot of pain or discomfort	☐
You have extreme pain or discomfort	☐

Finally, I would like to ask you about FEELING WORRIED, SAD OR UNHAPPY. Would you say that:

You are not worried, sad or unhappy	☐
You are a little bit worried, sad or unhappy	☐
You are quite worried, sad or unhappy	☐
You are really worried, sad or unhappy	☐
You are extremely worried, sad or unhappy	☐

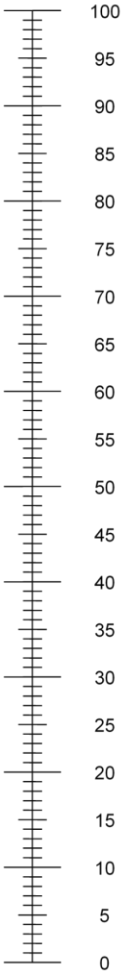
EQ-5D VAS

- **Now, I would like to ask you to say how good or bad your health is TODAY.**
- **I would like you to picture in your mind a vertical line that is numbered from 0 to 100.**
  (Note to interviewer: if interviewing face-to-face, please show the child the VAS line.)
- **100 at the top of the line means the <u>best</u> health you can imagine.**

  0 at the bottom of the line means the <u>worst</u> health you can imagine.
- **I would now like you to tell me the point on this line where you would put your health TODAY.**
  (Note to interviewer: mark the line at the point indicating the child's health today. Now, please write the number you marked on the line in the box below.)

THE CHILD'S HEALTH TODAY = ☐

The best health you can imagine



The worst health you can imagine

7. Add participant completion time here (MM:SS):

_____

** Let us do a small stretch together(depending on the participant 's physical ability, stand up and touch your toes/sit on the chair and move your neck from side to side (ICE-BREAKER)*

** How many starts can you spot in this row*

SECTION D3: CHILD HEALTH UTILITY-9D (SELF-ADMINISTERED)

Instructions (show the participant the questionnaire)

- These questions ask about how you are **today.**
- For each question, read all the choices and decide which one is most like you **today**.
- Then put a tick in the box next to it like this ☑. Only tick **one** box for each question.

Example
Today I feel quite upset so I will tick this box.

Upset

- ☐ I don't feel upset today
- ☐ I feel a little bit upset today
- ☐ I feel a bit upset today
- ☑ I feel quite upset today
- ☐ I feel very upset today

Now think about and answer the rest of the questions below

1. Worried

- ☐ I don't feel worried today
- ☐ I feel a little bit worried today
- ☐ I feel a bit worried today
- ☐ I feel quite worried today
- ☐ I feel very worried today

2. Sad

- ☐ I don't feel sad today
- ☐ I feel a little bit sad today
- ☐ I feel a bit sad today
- ☐ I feel quite sad today
- ☐ I feel very sad today

3. Pain

- ☐ I don't have any pain today
- ☐ I have a little bit of pain today
- ☐ I have a bit of pain today
- ☐ I have quite a lot of pain today
- ☐ I have a lot of pain today

4. Tired

- ☐ I don't feel tired today
- ☐ I feel a little bit tired today
- ☐ I feel a bit tired today

☐ I feel quite tired today ☐ I feel very tired today
5. Annoyed ☐ I don't feel annoyed today ☐ I feel a little bit annoyed today ☐ I feel a bit annoyed today ☐ I feel quite annoyed today ☐ I feel very annoyed today
6. School Work/Homework (such as reading, writing, doing lessons) ☐ I have no problems with my schoolwork/homework today ☐ I have a few problems with my schoolwork/homework today ☐ I have some problems with my schoolwork/homework today ☐ I have many problems with my schoolwork/homework today ☐ I can't do my schoolwork/homework today
7. Sleep ☐ Last night I had no problems sleeping ☐ Last night I had a few problems sleeping ☐ Last night I had some problems sleeping ☐ Last night I had many problems sleeping ☐ Last night I couldn't sleep at all
8. Daily routine (things like eating, having a bath/shower, getting dressed) ☐ I have no problems with my daily routine today ☐ I have a few problems with my daily routine today ☐ I have some problems with my daily routine today ☐ I have many problems with my daily routine today ☐ I can't do my daily routine today
9. Able to join in activities (things like playing out with your friends, doing sports, joining in things) ☐ I can join in with any activities today ☐ I can join in with most activities today ☐ I can join in with some activities today ☐ I can join in with a few activities today

☐ I can join in with no activities today

8. Add participant completion time here (MM:SS):

_____

** We have one more exercise to complete, let us take two breaths together (ICE-BREAKER)*

** How many triangles are in this row:*

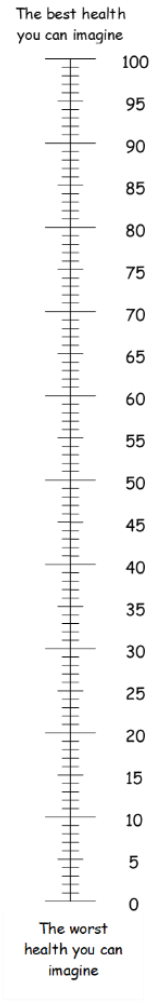
SECTION D4: EQ-5D-Y-3L (SELF-ADMINISTERED)

Describing your health TODAY

Under each heading, please tick the ONE box that best describes your health TODAY.	
1. Mobility *(walking about)*	
I have no problems walking about	❑
I have some problems walking about	❑
I have a lot of problems walking about	❑
2. Looking after myself	
I have no problems washing or dressing myself	❑
I have some problems washing or dressing myself	❑
I have a lot of problems washing or dressing myself	❑
3. Doing usual activities *(for example, going to school, hobbies, sports, playing, doing things with family or friends)*	
I have no problems doing my usual activities	❑
I have some problems doing my usual activities	❑
I have a lot of problems doing my usual activities	❑
4. Having pain or discomfort	
I have no pain or discomfort	❑
I have some pain or discomfort	❑
I have a lot of pain or discomfort	❑
5. Feeling worried, sad or unhappy	
I am not worried, sad or unhappy	❑
I am a bit worried, sad or unhappy	❑
I am very worried, sad or unhappy	❑

6. How good is your health TODAY

- We would like to know how good or bad your health is TODAY.
- This line is numbered from 0 to 100.
- 100 means the <u>best</u> health you can imagine.
  0 means the <u>worst</u> health you can imagine.
- Please mark with an X on the line to show how good or bad your health is TODAY.



7. Add participant completion time here (MM:SS)_____

ICE- BREAKER

How many hearts do you see?

Thank you for taking the time to answer these questions.

SECTION D5: EQ-5D-Y-3L (INTERVIEWER-ADMINSITERED)

Narration:

First, I am going to read out some questions. Each question has a choice of three answers. Please tell me which answer best describes your health TODAY.

Do not choose more than one answer in each group of questions.

(Note to fieldworker: first read all three options for each question. Then ask the child to choose which one applies to him/herself. Repeat the question and options if necessary. Mark the appropriate box under each heading. You may need to remind the child regularly that the timeframe is TODAY.)

1. **First, I would like to ask you about WALKING ABOUT (MOBILITY). Would you say that:**
   - You have no problems walking about? ❑
   - You have some problems walking about? ❑
   - You have a lot of problems walking about? ❑

Next, I would like to ask you about LOOKING AFTER YOURSELF. Would you say that:
   - You have no problems washing or dressing yourself? ❑
   - You have some problems washing or dressing yourself? ❑
   - You have a lot of problems washing or dressing yourself? ❑

Next, I would like to ask you about DOING USUAL ACTIVITIES, for example, going to school, hobbies, sports, playing, doing things with family or friends. Would you say that:
   - You have no problems doing your usual activities? ❑
   - You have some problems doing your usual activities? ❑
   - You have a lot of problems doing your usual activities? ❑

Next, I would like to ask you about HAVING PAIN OR DISCOMFORT. Would you say that:
   - You have no pain or discomfort? ❑
   - You have some pain or discomfort? ❑
   - You have a lot of pain or discomfort? ❑

Finally, I would like to ask you about FEELING WORRIED, SAD OR UNHAPPY. Would you say that:

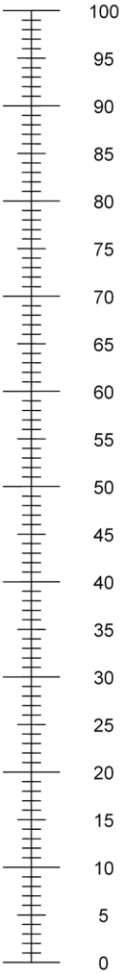
You are not worried, sad or unhappy?	❑
You are a bit worried, sad or unhappy?	❑
You are very worried, sad or unhappy?	❑

EQ-5D VAS

- **Now, I would like to ask you to say how good or bad your health is TODAY.**
- **I would like you to picture in your mind a vertical line that is numbered from 0 to 100.**
  (Note to interviewer: if interviewing face-to-face, please show the child the VAS line.)
- **100 at the top of the line means the <u>best</u> health you can imagine.**

  0 at the bottom of the line means the <u>worst</u> health you can imagine.
- **I would now like you to tell me the point on this line where you would put your health TODAY.**
  (Note to interviewer: mark the line at the point indicating the child's health today. Now, please write the number you marked on the line in the box below.)

The best health you can imagine



THE CHILD'S HEALTH TODAY = ☐

The worst health you can imagine

Thank you for taking the time to answer these questions.

SECTION E: CLOSURE

Narration:

- *Thank you for completing this activity with me.*
- *I appreciate your time.*
- *The information you have given us will not be shared with others, will not contain your name and will be stored in a locked cupboard.*
- *If you have any questions about the research we are doing or your participation in this study, or if you would like more information about any of the topics we have discussed in this interview, please feel free to contact us on the cellphone number listed on the study card you were given.*
- *Is there anything else you would like to share with us?*
- *[Refer as needed]*

Note to the fieldworker: Please kindly complete this section

1. Please write down anything unusual about this interview, your impressions of the participant or the interview, concerns you might have, or anything else that might help us to understand the information you have collected?

_____
_____
_____
_____
_____

Appendix 12- Data extraction form- HIV clinical variables (Cross-sectional survey, clinic arm)

- Data extracted from patient clinic folders and Tier.net records
- Data to be extracted only if parent and minor provided permission to access clinic information
- *Form based on 2019 NDoH Guidelines: 2019 ART Clinical Guidelines for the Management of HIV in Adults, Pregnancy, Adolescents, Children, Infants and Neonates*

SECTION I: INTRODUCTION	
Note to the fieldworker: Please kindly complete this section	
1. Participant study ID	_____
2. Fieldworker ID	_____
3. Date of data extraction (did/mm/yyyy)	_____
4. Facility code	_____
5. Patient clinic file number	_____
6. Patient Tier.net number	_____
7. Quality controlled by (initials)	☐ _____

SECTION II: CLINICAL INFORMATION		
A. PATIENT DETAILS		
1. Date of birth		
2. Sex	☐ Female ☐ Male ☐ Other (describe):_____	
3. Primary caregiver	☐ Biological mother ☐ Grandmother ☐ Aunt ☐ Sister ☐ Biological Father	☐ Grandfather ☐ Uncle ☐ Brother ☐ Other (describe): _____
B. CLINICAL HISTORY		
1. Date of HIV diagnosis		
2. Mode of HIV acquisition	☐ Vertically/MTCT/Perinatally ☐ Sexually ☐ Other (describe):_____	
3. Date of ART initiation		
C. CURRENT CLINICAL STATUS		
1. Current HIV disclosure status	☐ Fully disclosed ☐ Partially disclosed ☐ Not disclosed ☐ Other (detail): _____	
2. Currently on ART	☐ Yes ☐ No	
3. Current ART regimen	☐ First-line	

	☐ Second-line ☐ Third-line	
4. Current ARVs	☐ TLD (TDF +3TC+ DTG) ☐ TEE (TDF + FTC + EFV) ☐ Other (detail):_____	
5. Current clinical status	☐ Stable ☐ Unstable	
D. CURRENT SCREENING RESULTS		
6. Viral load	Result:	Date:
7. WHO Clinical stage (1, 2, 3, 4)	Result:	Date:
8. CD4 Count	Result:	Date:
9. Height	Result:	Date:
10. Weight	Result:	Date:
11. BMI	Result:	Date:
E. CURRENT CLINICAL STATUS		
1. Co-morbidities	☐ TB ☐ Asthma ☐ Diabetes ☐ Hypertension ☐ Epilepsy ☐ Depression	☐ Psychosis ☐ Mental illness ☐ Physical disability ☐ Cancer ☐ Other (detail):_____
2. Other conditions (tick all that apply)	☐ STI ☐ Pregnancy ☐ Hepatitis B infection ☐ Cryptococcal meningitis ☐ Anaemia ☐ Neutropaenia ☐ Thrombocytopaenia ☐ Virological failure ☐ ARV resistance ☐ Anxiety ☐ Suicidal ideation ☐ PTSD ☐ Non-consensual sexual violence ☐ Substance abuse ☐ Neurodevelopmental delay	☐ Obesity ☐ Nutritional issues ☐ ARV side-effects (rash, nausea, vomiting, fever, GIT issues, sleep disturbances, headache, weight loss, renal/liver complications etc.) ☐ Adherence issues/ Treatment fatigue ☐ Influence of peers ☐ Bereavement / Grief ☐ Unwell/unstable/varying caregiver ☐ No treatment supporter ☐ Food insecurity ☐ Disclosure issues ☐ Stigma ☐ Mental illness- patient ☐ Mental illness-caregiver ☐ Unstable home life

		☐ Other (detail):_____

Appendix 13- Locator and follow-up form

SECTION A: WHO ARE THESE LOCATOR DETAILS FOR	
1. Study ID?	☐ _____
2. Date (dd/mm/yyyy)	_____/_____/2021
3. Initials of FW completing this form	

SECTION B: TELEPHONIC FOLLOW-UP			
		Name	**Number**
1.	Could you kindly give us 1 or more mobile/landline number on which you can be reached?	**Participant**	
		Parent/Guardian	
		Other	
2.	Could you kindly give us the name and number of your emergency contact (i.e. person we should contact in the event of an emergency)	**Name:** **Relationship to you:**	**Number:**
3.	Is there a preferred time and date we can conduct the telephonic follow-up with you and/or your child?	☐ _____am ☐ _____pm	☐ Monday ☐ Tuesday ☐ Wednesday ☐ Thursday ☐ Friday ☐ Saturday ☐ Sunday ☐ Any day
4.	Is it OK to leave a voicemail message or SMS reminding you to contact us? • Note- we will not mention any information about this study • The message will read: *"Gooday ___, it is ___ calling. Please give me a*	☐ Yes ☐ No ☐ Other_____	☐ What name should we call you by: _____

	miscall/please call when you get this message and I will return the call. Thanks"		
5.	If someone else answers, can we leave a message with them reminding you to contact us? • Note- we will not mention any information about this study • The message will read: *"Gooday ___, my name is ___. When ___gets back, please can you tell him/her that I called, and that they can give me a miscall/please call when they get back, and I will return the call. Thanks"*	☐ Yes ☐ No	☐ What name should we call you by: _____
6.	To know it is you who I am speaking to, I will ask you 2 security questions? Choose 2 questions you would like me to ask?	☐ What is your study ID: _____ ☐ What is your favourite colour: _____ ☐ What is the name of your first primary school: _____ ☐ Other: _____	
7.	Other details	☐ _____	
8.	Any comments		

SECTION C: HOME VISIT		
1. What is your physical home address?	• House number: _____ • Street name: _____ • Zone/location number:_____ • Landmark: _____	
2. What type of home do you live in?	☐ Formal (brick, cement) ☐ Informal (Tin, wood)	
3. Is there a preferred time and date we could conduct the home visit?	☐ _____am ☐ _____pm	☐ Monday ☐ Tuesday ☐ Wednesday ☐ Thursday ☐ Friday ☐ Saturday ☐ Sunday ☐ Any day
4. If someone else answers the door, can we leave a message with them reminding you to contact us? • Note- we will not mention any information about this study • The message will read: *"Gooday ___, my name is ___. When ___gets back, please can you tell him/her that I stopped by, and that they can give me a miscall/please call when they get back, and I will return the call. Thanks"*	☐ Yes ☐ No	☐ What name should we call you by: _____
5. Other information	☐ _____	

SECTION D: FOLLOW-UP OUTCOME		
1. Reason for follow-up	☐ Parent follow-up (to explain the Information Sheet) ☐ Qualitative interview reminder ☐ CSS- Follow-up	
2. Follow-up outcome 1	☐ Number does not exist ☐ Voice-mail ☐ Rings but no one picks up	☐ Reached & appointment set ☐ Reached but cannot make the appointment ☐ Home visit- no one at home ☐ Home visit- cannot locate household
3. Follow-up outcome 2	☐ Number does not exist ☐ Voice-mail ☐ Rings but no one picks up	☐ Reached & appointment set ☐ Reached but cannot make the appointment ☐ Home visit- no one at home ☐ Home visit- cannot locate household
4. Follow-up outcome 3	☐ Number does not exist ☐ Voice-mail ☐ Rings but no one picks up	☐ Reached & appointment set ☐ Reached but cannot make the appointment ☐ Home visit- no one at home ☐ Home visit- cannot locate household
5. Follow-up outcome 4	☐ Number does not exist ☐ Voice-mail ☐ Rings but no one picks up	☐ Reached & appointment set ☐ Reached but cannot make the appointment ☐ Home visit- no one at home ☐ Home visit- cannot locate household
6. Total number of attempts made	☐	

7. Final outcome	☐ LTFU ☐ Traced but refused/ineligible ☐ Traced and enrolled
8. Any comments	

Appendix 14- Follow-up questionnaire (Cross-sectional survey)

SECTION A: INTRODUCTION	
Note to the fieldworker: Please kindly complete this section	
1. Participant study ID	_____
2. Fieldworker ID	_____
3. Date of interview (dd/mm/yyyy)	_____
4. Quality controlled by (initials)	☐ _____
Narration: • *Good day. Thank you for agreeing to take part in this study* • *During our chat today, I will ask you a few questions on your background (home and school life, and your thoughts on your health and life)*	

SECTION B: PARTICIPANT'S BACKGROUND	
1. Has anything major changed in your life since the last time we chatted such as	☐
a. Health	☐ Yes (explain:____) ☐ No
b. Home	☐ Yes (explain:____) ☐ No
c. School	☐ Yes (explain:____) ☐ No
d. Friends	☐ Yes (explain:____) ☐ No
e. Other	☐ Yes (explain:____) ☐ No
Narration: *Thank you for this information!*	

SECTION C: HRQOL

Note to the fieldworker: although allowance should be made for the interviewer's particular style of speaking, the wording of the questionnaire instructions should be followed as closely as possible. In the case of the EQ-5D-Y descriptive system of the questionnaire, the precise wording must be followed.

If the child (respondent) has difficulty choosing a response, or asks for clarification, the interviewer should repeat the question word for word and ask the child to answer in a way that most closely resembles his or her thoughts about his or her health today.

****DO NOT FORGET TO TIME PARTICIPANT COMPLETION FOR EACH SCALE**

INTRODUCTION

(Note to fieldworker: please read the following to the child.)

Narration:
We are trying to find out what you think about your health. I will explain what to do as I go along, but please stop me if you do not understand something or if things are not clear to you. There are no right or wrong answers. We are interested only in what you think.

[Note: The REDCAP data system will include the IA EQ-5D-Y (5L/3L) questionnaire that was completed at baseline]

SECTION C1: EQ-5D-Y-5L (INTERVIEWER-ADMINSITERED)

Narration:
First, I am going to read out some questions. Each question has a choice of five answers. Please tell me which answer best describes your health TODAY.

Do not choose more than one answer in each group of questions.

(Note to fieldworker: first read all five options for each question. Then ask the child to choose which one applies to him/herself. Repeat the question and options if necessary. Mark the appropriate box under each heading. You may need to remind the child regularly that the timeframe is TODAY.)

First, I would like to ask you about WALKING ABOUT (MOBILITY). Would you say that:

You have no problems walking about	☐
You have a little bit of a problem walking about	☐
You have some problems walking about	☐
You have a lot of problems walking about	☐
You cannot walk about	☐

Next, I would like to ask you about LOOKING AFTER YOURSELF. Would you say that:

You have no problems washing or dressing yourself	☐
You have a little bit of a problem washing or dressing yourself	☐
You have some problems washing or dressing yourself	☐
You have a lot of problems washing or dressing yourself	☐
You cannot wash or dress yourself	☐

Next, I would like to ask you about DOING USUAL ACTIVITIES, for example, going to school, hobbies, sports, playing, doing things with family or friends. Would you say that:

You have no problems doing your usual activities	☐

You have a little bit of a problem doing your usual activities	☐
You have some problems doing your usual activities	☐
You have a lot of problems doing your usual activities	☐
You cannot do your usual activities	☐

Next, I would like to ask you about HAVING PAIN OR DISCOMFORT. Would you say that:

You have no pain or discomfort	☐
You have a little bit of pain or discomfort	☐
You have some pain or discomfort	☐
You have a lot of pain or discomfort	☐
You have extreme pain or discomfort	☐

Finally, I would like to ask you about FEELING WORRIED, SAD OR UNHAPPY. Would you say that:

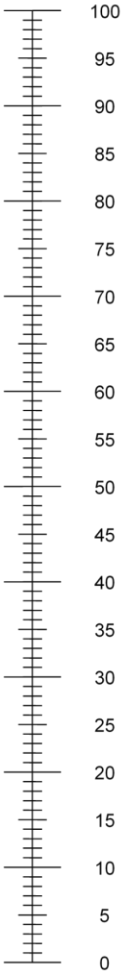
You are not worried, sad or unhappy	☐
You are a little bit worried, sad or unhappy	☐
You are quite worried, sad or unhappy	☐
You are really worried, sad or unhappy	☐
You are extremely worried, sad or unhappy	☐

EQ-5D VAS

- **Now, I would like to ask you to say how good or bad your health is TODAY.**
- **I would like you to picture in your mind a vertical line that is numbered from 0 to 100.**
  (Note to interviewer: if interviewing face-to-face, please show the child the VAS line.)
- **100 at the top of the line means the <u>best</u> health you can imagine.**

  0 at the bottom of the line means the <u>worst</u> health you can imagine.
- **I would now like you to tell me the point on this line where you would put your health TODAY.**
  (Note to interviewer: mark the line at the point indicating the child's health today. Now, please write the number you marked on the line in the box below.)

The best health you can imagine



The worst health you can imagine

THE CHILD'S HEALTH TODAY = ☐

7. Add participant completion time here (MM:SS)_____

SECTION C2: EQ-5D-Y-3L (INTERVIEWER-ADMINSITERED)

Narration:
First, I am going to read out some questions. Each question has a choice of three answers. Please tell me which answer best describes your health TODAY.

Do not choose more than one answer in each group of questions.

(Note to fieldworker: first read all three options for each question. Then ask the child to choose which one applies to him/herself. Repeat the question and options if necessary. Mark the appropriate box under each heading. You may need to remind the child regularly that the timeframe is TODAY.)

2. First, I would like to ask you about WALKING ABOUT (MOBILITY). Would you say that:

You have no problems walking about?	❑
You have some problems walking about?	❑
You have a lot of problems walking about?	❑

Next, I would like to ask you about LOOKING AFTER YOURSELF. Would you say that:

You have no problems washing or dressing yourself?	❑
You have some problems washing or dressing yourself?	❑
You have a lot of problems washing or dressing yourself?	❑

Next, I would like to ask you about DOING USUAL ACTIVITIES, for example, going to school, hobbies, sports, playing, doing things with family or friends. Would you say that:

You have no problems doing your usual activities?	❑
You have some problems doing your usual activities?	❑
You have a lot of problems doing your usual activities?	❑

Next, I would like to ask you about HAVING PAIN OR DISCOMFORT. Would you say that:

You have no pain or discomfort?	❑
You have some pain or discomfort?	❑
You have a lot of pain or discomfort?	❑

Finally, I would like to ask you about FEELING WORRIED, SAD OR UNHAPPY. Would you say that:

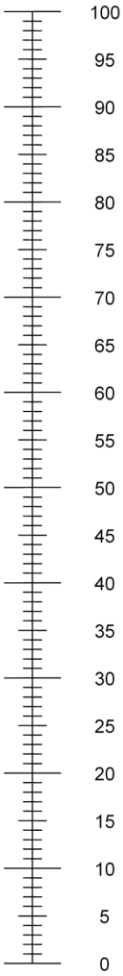
You are not worried, sad or unhappy?	❑
You are a bit worried, sad or unhappy?	❑
You are very worried, sad or unhappy?	❑

EQ-5D VAS

- **Now, I would like to ask you to say how good or bad your health is TODAY.**
- **I would like you to picture in your mind a vertical line that is numbered from 0 to 100.**
  (Note to interviewer: if interviewing face-to-face, please show the child the VAS line.)
- **100 at the top of the line means the <u>best</u> health you can imagine.**

  0 at the bottom of the line means the <u>worst</u> health you can imagine.
- **I would now like you to tell me the point on this line where you would put your health TODAY.**
  (Note to interviewer: mark the line at the point indicating the child's health today. Now, please write the number you marked on the line in the box below.)

The best health you can imagine



The worst health you can imagine

THE CHILD'S HEALTH TODAY = ☐

7. Add participant completion time here (MM:SS)_____

Thank you for taking the time to answer these questions.

SECTION D: CLOSURE

Narration:

- *Thank you for completing this activity with me.*
- *I appreciate your time.*
- *The information you have given us will not be shared with others, will not contain your name and will be stored in a locked cupboard.*
- *If you have any questions about the research we are doing or your participation in this study, or if you would like more information about any of the topics we have discussed in this interview, please feel free to contact us on the cellphone number listed on the study card you were given.*
- *Is there anything else you would like to share with us?*
- *[Refer as needed]*

Note to the fieldworker: Please kindly complete this section

2. Please write down anything unusual about this interview, your impressions of the participant or the interview, concerns you might have, or anything else that might help us to understand the information you have collected?

_____
_____
_____
_____
_____

Appendix 15- Comprehension Checklist-Information sheet

Purpose: To read to parent/minor to assess their understanding of the study prior to enrolment

Instruction (read): *Based on what we discussed; I am now going to ask you a few questions. This will help me understand which areas we discussed require further explanation.*

CHECKLIST FOR PARENT

QUESTION	SCORE
1. Could you describe what the goal of this study is in your own words?	☐ Good (2 points) ☐ Fair (1 point) ☐ Poor (0 point) ☐ Other:_____
2. Based on what we discussed, what will your child have to do if he/she participates in this study?	☐ Good (2 points) ☐ Fair (1 point) ☐ Poor (0 point) ☐ Other:_____
3. What are some of the potential risks and benefits if your child participates in this study?	☐ Good (2 points) ☐ Fair (1 point) ☐ Poor (0 point) ☐ Other:_____
4. Do you have any questions for me about the study?	☐ Good (2 points) ☐ Fair (1 point) ☐ Poor (0 point) ☐ Other:_____
○ **Based on score, is this individual eligible to participate (Use score below)**	☐ Yes ☐ No ☐ Other:_____
Total score= /8	
<1/8= DO NOT ENROL, >3/8=ENROL	

CHECKLIST FOR MINOR

QUESTION	SCORE
1. Imagine you had to explain this study to someone. How would you describe this study to this person?	☐ Good (2 points) ☐ Fair (1 point) ☐ Poor (0 point) ☐ Other:_____
2. What will young people have to do if they participate in this study?	☐ Good (2 points) ☐ Fair (1 point) ☐ Poor (0 point) ☐ Other:_____
3. Based on what we discussed, what are some of negatives and positives if young people take part in this study?	☐ Good (2 points) ☐ Fair (1 point) ☐ Poor (0 point) ☐ Other:_____
4. Do you have any questions for me about the study?	☐ Good (2 points) ☐ Fair (1 point) ☐ Poor (0 point) ☐ Other:_____
○ **Based on score, is this individual eligible to participate (Use score below)**	☐ Good (2 points) ☐ Fair (1 point) ☐ Poor (0 point) ☐ Other:_____
Total score= /8	
<1/8= DO NOT ENROL, >3/8=ENROL	

Appendix 16- Deliverables

1. Poster presentation: Nov 2021

YPWG Workshop:

'Where do we stand with the EQ-5D-Y-5L: what do we know about it's measurement properties and can we move it from experimental to beta status?'

Title: Impilo Enhle Study: The feasibility and acceptability 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

AUTHORS: Stanley Carries, Zibuyisile Mkhwanazi, Lovemore Sigwadhi, Janine Verstraete, Carl Lombard, Mosa Moshabela, Hannah Penton, Aureliano Finch, Jennifer Jelsma, Darshini Govindasamy

Background:

Globally, sub-Saharan Africa (SSA) has the largest number of adolescents living with HIV (ALHIV). Despite scale-up of antiretroviral therapy, ALHIV are at high risk for HIV-related morbidity. HIV policies recommend HRQoL monitoring among ALHIY. However, there is limited guidance on appropriate HRQoL scales for use among ALHIV in HIV clinics. The EQ-5D-Y-3L has proven feasible among chronic disease paediatric populations in SSA. However, no study has compared the content, face validity and factors affecting implementation of the scale's most recent version (EQ-5D-Y-SL) against the 3L and the CHU9D for ALHIV in SSA.

Aim:

To assesses the feasibility and acceptability of the EQ-5D-Y SL compared to 3L and CHU9D among ALHIV

Methods:

We conducted Phase 1 of the Impilo Enhle study between May-September 2021 in the eThekwini district of KwaZulu-Natal, South Africa. Phase 1 entailed cognitive interviews with n=24 purposively sampled adolescents aged 10-15 years (n= l2 ALHIV from HIV clinics; n= 12 school pupils), with two per age-strata and equal sex distribution in each arm.

These interviews explored adolescents' understanding and ability to complete the EQ-5D-Y-SL (English version). Cognitive interviews included a card ranking game, self- and interviewer-administration of the REDCAP EQ-5D-Y-SL, probing of participants' experiences with scale completion, and measurement of scale completion time.

Thereafter, we conducted 10 key informant interviews with healthcare workers (HCWs) to assess their perceptions of scale implementation in HIV clinics. This was followed by gaining feedback from fieldworkers of their experiences with administering the EQ-5D-Y-SL.

DATA ANALYSIS AND RESULTS

Data Analysis

Quantitative data were examined using descriptive statistics using STATA (V 17). Qualitative data were analysed using Framework Analysis on NVivo (V 12).

Results

Demographics

A total of34 adolescents were approached to participate in the study. All adolescents approached from schools (n= l2) met eligibility criteria and emolled into the study. Of the remaining 22 adolescents approached, 12 were emolled into the clinic arm, five refused to participate and five were ineligible because of the lack of comprehension of the English screener.

The median age for both study arms was 12.5 years (Table I). Sex was equally distributed in both arms, each arm having one male and one female per age category (i.e. 10-15 years). The median level of schooling was grade 7 for ALHIV and grade 8 for adolescents in the school arm.

Table I : Impilo Enhle participant demographics

Demographic	Clinic	School
Median Age (IQR)	13 (11-14)	13 (11-14)
Sex		
Male	6	6
Female	6	6
Median Grade (IQR)	4 (3-5)	5 (3-5)

The majority (66,7%) of ALHIV were in WHO HIV clinical stage!. Two ALHIV were in clinical stage 2 and two were in stage 3

Table 2: ALHIV WHO Clinical Staging

Demographic	Clinic	School
Median Age (IQR)	13 (11-14)	13 (11-14)
Sex		
Male	6	6
Female	6	6
Median Grade (IQR)	4 (3-5)	5 (3-5)

Ranking exercise

All ALHIV correctly ranked response levels for each problem dimension of the EQ-5D-Y-5L (Table 3). School pupils had the most difficulty with correctly ordering the "walking about" dimension, with only 50% getting the degrees of severity right. Most learners had difficulty with the "some" and "a lot" options of the "walking about" dimension.

Table 3: Ranking exercise

Demographic	Clinic	School
Median Age (IQR)	13 (11-14)	13 (11-14)
Sex		
Male	6	6
Female	6	6
Median Grade (IQR)	4 (3-5)	5 (3-5)

The average time to complete the debriefing exercise (including the ranking game) was 10.5 minutes (see Table 4). Overall, study participants described the ranking game as "fun", "easy" and "enjoyable".

Table 4: EQ-5D-Y-5L and debriefing exercise completion times

Demographic	Clinic	School
Median Age (IQR)	13 (11-14)	13 (11-14)
Sex		
Male	6	6
Female	6	6
Median Grade (IQR)	4 (3-5)	5 (3-5)

All adolescents reported understanding the EQ-5D-Y-5L instructions and recalled questions from this scale. However, participants commonly reported "mobility" and "extremely" as "difficult" or "confusing".

Participants also suggested that "mobility", "a lot", "extreme(ly)", and "walking-about" be reworded.

Healthcare workers and Fieldteam experiences with the EQ-5D-Y-5 scale

Most HCWs found the EQ-5D-Y-5L instructions, questions and responses clear and appropriate for ALHIV. A key concern was potential difficulty in completing the scale with ALHIV who have advanced disease. Most HCWs preferred the SL vs. the 3L because, as reported by one HCW, "it was more comprehensive and sensitive".

However, most HCW considered the VAS scale as potentially challenging to ALIIlV with cognitive delays. A comment by a

HCW on the VAS scale was " ... If they (ALHIV) see too many numbers, they will be confused ... because if they see this they will think of the number-line at school".

HCWs reported implementing the scale in HIV clinics would depend on proper training and assigning its administration to dedicated personnel.

Drawing from their exeriences with administering the scale, fieldstaff found that the instructions were clear and appropriate to ALHIV. They highlighted that participants found words like "extremely" and "mobility" confusing. They also mentioned that some adolescents bad difficulties with the VAS scale. In the words ofa fieldworker, "It is understandable to young kids. Instructions are clear. Participants seemed to have difficulties with the the words "extreme(ly)" and "mobility", and the phrasing of "doing your usual activities". Kids have a problem translating what their health is to a measurement on the VAS scale, even though they know how they felt. "

When asked to reflect on their experiences with administering the scale during the Covid-19 pandemic, one fieldworker said, "Implementing the study during Covid-19 was very challenging, especially at schools. However, we were able to overcome this by working collaboratively with amazing educators. "

Discussion

The EQ-5D-Y-5L scale was well received by study participants, healthcare workers and fieldstaff. Although participants had few difficulities with understanding words like "mobility" and "extremely", they were able to fully comprehend what the scale was about. It is likely that the ranking game played an important role in preparing participants to understand the scale. Healthcare workers and fieldstaff considered the scale to be clear and appropriate for adolescents. However, they felt that the VAS scale posed a challenge to many kids, especially ALHIY.

2. Oral presentation- February 2022

2nd EuroQol Africa Academy Meeting 2022 (Virtual)
Cairo, Egypt
9-10 February 2022.

TITLE: 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

AUTHORS: Stanley Carries, Zibuyisile Mkhwanazi, Lovemore Sigwadhi, Janine Verstraete, Carl Lombard, Mosa Moshabela, Hannah Penton, Aureliano Finch, Jennifer Jelsma, Darshini Govindasamy

ABSTRACT:

Background: Despite the scale-up of antiretroviral therapy, adolescents living with HIV (ALHIV) are at high risk for HIV-related morbidity. There is a lack of guidance on appropriate HRQoL scales for use among ALHIV in HIV clinics.The EQ-5D-Y-3L has proven to be feasible among chronic disease paediatric populations. However, there is a gap in knowledge on the content and face validity and factors affecting implementation of the EQ-5D-Y-5L vs. the 3L and the CHU9D. Furthermore, no study has compared the psychometric performance of EQ-5D-Y-5L vs. the 3L and the CHU9D, particularly among ALHIV in this region.

Aims:

a. Phase 1- To assesses the feasibility and acceptability of the EQ-5D-Y 5L vs. 3L and CHU9D among ALHIV
b. Phase 2- To establish the reliability and validity of the health-related quality of life scale, EQ-5D-Y 5L, vs. 3L and CHU9D among ALHIV
c.

Methods:

We conducted a mixed-methods study in KwaZulu-Natal, South Africa with 10-15 year-olds. Phase 1 (May-September 2021) entailed cognitive interviews with n=24 adolescents (n=12 ALHIV; n=12 school pupils). The interviews included a ranking exercise, administration of the REDCAP EQ-5D-Y-5L (English version) and probing of participants' experience with scale completion. We conducted 10 interviews with healthcare workers (HCWs) to assess their perceptions of implementing this scale in HIV clinics. Phase 2 (August 2021-January 2022) entailed a cross-sectional survey with ALHIV (n=150), and school pupils (n=150). REDCAP HRQoL scales (EQ-5D-Y: 5L, 3L CHU9D), either self- (SA) or interviewer- (IA) administered, were completed with participants on Tablets. Those who completed the EQ-5D-Y-5L (IA) at baseline were followed-up within 2 weeks.

Results:

Phase 1:

Most participants accurately ranked response levels for each dimension on the EQ-5D-Y-5L. “Mobility” and “extremely” were commonly reported as difficult or confusing. Most HCWs found the EQ-5D-Y-5L instructions, questions and responses clear and appropriate for ALHIV. Most HCWs preferred the 5L vs. the 3L as it was felt that it was more comprehensive and sensitive. However, most indicated that the VAS scale should be simplified due to the high prevalence of cognitive delays among ALHIV.

Phase 2:

To date, recruitment in the survey is as follows (clinic arm: n=125, 86% followed-up; school arm= n=152, 68% followed-up). Just over 50% were in WHO HIV clinical stage 2-3 in the clinic arm. The best health state (“1111”) reported per arm was as follows: [clinic arm- Y-5L-IA 35%; Y-5L-SA 36.4%]; [school arm- Y-5L-IA; 63%; Y-5L-SA 18%]. The highest ceiling effect in the clinic arm was reported for the worried dimension (Y-5L-IA) and mobility dimension (Y-5L-SA). The Gwet AC ranged from 0.87 to 0.78 for dimensions on the EQ-5D-Y-5L (IA). The analysis of variance did not reveal statistically significant differences between the VAS scores and WHO stages, for both the Y-5L and Y-3L.

Conclusion and Recommendations: The EQ-5D-Y-5L was associated with favourable content and face validity, including test-retest reliability, yet minimal known-group validity. The psychometric properties of this scale could be enhanced by simplifying key dimensions and response level wording. Scale implementation in HIV clinics is feasible provided HCWs are adequately trained.