
Article:
Poku, E. orcid.org/0000-0001-6549-5081, Franklin, M. orcid.org/0000-0002-2774-9439, Simpson, E. et al. (3 more authors) (2025) An international compendium of health state utilities in people with HIV: a systematic review. Quality of Life Research. ISSN 0962-9343

https://doi.org/10.1007/s11136-025-03966-3

Quality of Life Research
https://doi.org/10.1007/s11136-025-03966-3

REVIEW

An international compendium of health state utilities in people with HIV: a systematic review

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Accepted: 24 March 2025

Abstract

Purpose Measuring health-related quality of life across different health states for people with HIV (PWH) using direct or indirect preference-based values can inform decision-analytic models evaluating cost-effectiveness of different care strategies. This systematic literature review collates comprehensive international evidence on health state utility values (HSUVs) in PWH to inform economic modelling of antiretroviral therapies (ARTs).

Methods This review aligns with PRISMA standards (PROSPERO: CRD42022346286). Searches from multiple sources (e.g. MEDLINE, EMBASE) identified HSUVs for PWH from 2000. We categorised HSUVs using ISPOR's Task Force criteria from low (high bias risk) to high (low bias risk) quality, alongside National Institute for Health and Care Excellence (NICE) suitability grading from Grade 3 (did not meet necessary criteria) to 1 (no concerns). Tabular and narrative syntheses were undertaken.

Results Overall, 53 studies from 22 countries were identified. Study sizes ranged from 32 to 4137 participants. HSUVs were from cross-sectional (n = 45) or longitudinal (n = 10) datasets, stratified by infection stage, CD4 count, viral load, and treatment status. EQ-5D three-level (n = 29) and five-level (n = 18) estimates were most common. Although 28 included studies were 'high' quality, most were Grade 3 for NICE suitability, mainly indicating that the HSUVs for these studies were not representative of a UK population. Extensive methodological and clinical heterogeneity precluded meta-analysis.

Conclusions Greater clarity in treatment regimens, preference-weighting methods, and different HIV clinical stages could improve interpretation and applicability of HSUVs in economic models. Despite this, our compendium and taxonomy of HSUVs can inform ART economic modelling within relevant populations and different jurisdictions.

Keywords Antiretroviral therapy · Health state utility values · HIV · Preference-based measures · Systematic literature review

Introduction

The introduction of antiretroviral therapies (ARTs) and highly active ARTs has greatly reduced morbidity and mortality for people with HIV (PWH), with marked improvements in life expectancy seen since 1996 [1]. ARTs, however, are currently unable to cure PWH, instead suppressing the viral load (VL) without complete elimination of the virus [2]. Therefore, increasingly higher proportions of individuals now live with chronic HIV infection compared with those with severe morbidity associated with a significantly reduced life expectancy [3].

The World Health Organization's strategy on HIV is to end acquired immunodeficiency syndrome (AIDS) and achieve universal health coverage and healthy lives and well-being for all ages by 2030 [4]. Additionally, it has been advocated that at least 90% of PWH with VL suppression maintain a good health-related quality of life (HRQoL) [5]. As such, HRQoL in PWH is an important outcome when assessing the overall benefits of ARTs. HRQoL can be operationalised within modelling-based economic evaluations by quantifying health state utility values (HSUVs). HSUVs represent a quantified value of the preference for different health states on a cardinal scale,

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Published online: 17 April 2025

often referred to as a quantification of HRQoL. Therefore, it is possible to suggest to what extent a specific health state is potentially 'preferred' to another based on the HSUV. HSUVs are used to inform cost-effectiveness analyses (CEAs) and are a key component of economic decision making. Additionally, HSUVs can be used to inform and guide clinical priorities [6] and policy development; however, while this is possible, the use of HSUVs in this manner needs to be considered against a range of other relevant information, such as life expectancy as well as equality and equity considerations, among political, socioeconomic, and cultural requirements and expectations [6].

HSUVs can be obtained via direct elicitation of an individual's preference for different health states using elicitation techniques like the standard gamble (SG) or time trade-off (TTO) techniques. Alternatively, such outcomes can be indirectly obtained via preference-based measures (PBMs); i.e. health-related patient-reported outcome measures, such as EuroQol's EQ instruments (e.g. EQ-5D) or the Short-Form 6 Dimensions (SF-6D) [7]. Overall, these preferences represent HRQoL on a cardinal scale, commonly anchored between 0 (dead) and 1 (perfect health) [8]. While some PBMs may be less responsive to HRQoL changes and adverse events (AEs) during ART than HIV-specific measures [9], the shorter and easier administration of generic PBMs makes them a valuable method for assessing HRQoL, and tools such as EQ-5D have shown validity in PWH [10].

HSUVs can be combined with survival time to estimate quality-adjusted life-years (QALYs) [7]. QALYs represent morbidity and mortality in a single metric as a key health-related outcome for CEAs. CEA is commonly recommended by Health Technology Assessment (HTA) agencies to provide 'value-for-money' evidence of new healthcare technologies and interventions compared with any alternative to guide efficient allocation of finite healthcare resources. Although both direct and indirect preference-based methods are potentially suitable for obtaining HSUVs, the latter using PBMs where preferences are based on a representative sample of society (as opposed to only individuals with the health condition of interest) are often preferred by HTA agencies internationally (such as the National Institute for Health and Care Excellence [NICE] for England and Wales) [11].

Previous systematic reviews have provided an overview of methods for estimating HRQoL or HSUVs for specific health states in PWH [12–14]. There is, however, still limited evidence on preference-based estimates for PWH. Additionally, HSUVs for all relevant health states required to represent the disease or care pathway of PWH in cost-effectiveness models have not yet been comprehensively identified and critiqued, particularly for newer treatments (e.g. atazanavir). Therefore, there is an opportunity to identify and collate recent evidence on HSUVs to improve understanding and quantification of HRQoL across different health states for PWH that can help inform economic modelling and development of future studies assessing new treatments in PWH.

This de novo systematic literature review was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidance [15], alongside recommendations by The Professional Society for Health Economics and Outcomes Research (ISPOR) [16], the Centre for Reviews and Dissemination (CRD) [17], and the NICE Decision Support Unit [18]. Our aim was to systematically consolidate the wealth of information on heath utilities in PWH, particularly for new ARTs, through identifying, appraising, and collating up-to-date evidence. Additionally, this review presents information to assist with understanding the context and nature of the HSUV, including how these values represent preference-based HRQoL related to the underlying study population and setting.

Methods

The protocol was pre-registered on PROSPERO (CRD42022346286) [19].

Eligibility criteria

We included interventional (randomised controlled trials [RCTs] and non-randomised trials) and observational (cohort, cross-sectional, case–control) studies with full-text articles published since 2000, with no geographic restrictions. Systematic reviews, case series, case reports, editorials, and cost-effectiveness studies were excluded.

Studies needed a well-defined population or subgroup of adolescents (14–17 years) or adults (≥ 18 years) with a reported HIV diagnosis. Interventions of interest were ARTs (any formulation) administered as first- or second-line therapy, or as a treatment switch. Additionally, treatment-naïve PWH were included where studies also had a comparator arm of relevant ART interventions. Studies reporting HSUVs for PWH with co-infections or comorbidities receiving ARTs were included if adjustments were made for co-existing conditions or concomitant treatments. Treatments for HIV-related co-infections, complications or adverse effects, non-pharmacological treatments, and complementary or alternative management were excluded.

The primary outcome of interest was HSUVs obtained either directly or indirectly, reported as point estimates alongside distributional statistics and p-values (when reported and relevant). Data relating to the entire study population or subset based on health states, including stage of infection, treatment status, or pre-specified clinical parameters (i.e. CD4 count and VL) were included. Additional outcomes

of interest were disutilities, as coefficients from regression models when the outcome of interest was a utility value, which are also useful to explore the relationship between population characteristics and HSUVs. Relevant estimates reported by mapping studies were considered if the search produced limited data of relevance. Subsequently, due to the volume of available data from directly elicited estimates, estimates derived from mapping (i.e. studies reporting on non-preference-based methods of HRQoL) were not included. HRQoL obtained from proxies (i.e. clinicians, carers) or vignettes, or measures of person satisfaction were also excluded.

Search strategy

Bibliographic database searches were initially conducted on 27 June 2022 in MEDLINE, EMBASE, Cochrane Library, NHS Economic Evaluation Database (NHS EED), International Network of Agencies for Health Technology Assessment (INAHTA), Epistemonikos, and Clinicaltrials.gov. A publication year limit from 2000 onwards was applied to capture studies reflecting current medical practice management of HIV in PWH. Search terms included subject headings and words that represented HIV infection, antiretroviral treatment, HRQoL, and HSUVs. The MEDLINE search strategy (Supplementary File 1) was adapted for other databases. Additionally, a Google Scholar alert with the search terms 'health utilities' in 'people living with HIV' was set up from June 2022 to February 2023 to identify publications following the initial search. No additional relevant publications were identified following a Google Scholar search on 26 March 2024.

Supplementary searches included checking reference lists of potentially relevant systematic reviews, cost-effectiveness studies, and included papers. Authors of potentially relevant conference abstracts were contacted when feasible.

Selection process

Based on pre-specified eligibility criteria, study selection was undertaken by two reviewers in a three-stage process. Firstly, both reviewers examined titles of retrieved articles and excluded duplicate articles or records that did not meet the agreed criteria. Secondly, reviewers independently examined titles and abstracts of a mutually exclusive set of remaining records. Early in this stage, both reviewers checked each other's selection decisions to ensure consistency. Differences were discussed and agreed between reviewers for subsequent examination of records. If an agreement could not be reached, then a third researcher who was an expert in utility measurement was consulted by the reviewers to achieve a resolution.

Full-text articles were obtained and split into half for detailed examination and checked for relevance by each reviewer. Afterwards, both reviewers discussed and validated each other's decisions. Uncertainties and discrepancies were resolved in consultation with the team's utility measurement and health economics expert.

Data extraction and assessment

Using a bespoke Microsoft Excel data extraction form, one reviewer extracted data from included studies. Items related to all extracted data were checked by the second reviewer. Differences and inconsistencies were resolved by discussion between the researchers. Abstracted data items included study design, study period, follow-up period, inclusion and exclusion criteria of study population, classification of HIV stage, CD4 count, HIV-RNA VL, antiretroviral treatment (previous and ongoing) and HSUV measurement information.

In the absence of a standardised approach for assessing the methodological quality of the health utilities literature, an 8-item review-specific quality assessment tool was developed and utilised in line with recommendations from the ISPOR Task Force quality assessment criteria for HSUVs in cost-effectiveness models. Items for assessment of study quality related to the following: (1) recruitment and selection of participants; (2) sample size of study; (3) response rate; (4) length of follow-up; (5) HSUs elicitation methods; (6) source of preference weights; (7) loss to follow-up; and (8) reported variance of HSUs (as a proxy for precision of reported estimates) (Supplementary File 1) [16]. Studies were considered as 'high', 'moderate', or 'low' quality if there were ≥ 6, 4–5, and ≤ 3 'yes' responses, respectively. In some cases, a study could be rated 'yes' or 'no'. For example, when examining the item, 'acceptable response rate $\geq 60\%$ for HSU measurement?', a study reporting HSU data for the entire study population (if 100%) and subgroup relating to a defined health state (if $< 60\%$) was rated 'yes' or 'no'. Based on the cumulative counts of responses, some studies were assigned dual ratings. Preliminary independent quality assessment and grading were completed by two members of the review team. Revised criteria were agreed following discussion and input from an expert health economist. Subsequently, quality assessment and grading were undertaken by one researcher and checked by a second researcher.

The review sought to identify HSUVs in PWH to inform cost-effectiveness models of treatments in various reimbursement settings. For pragmatic reasons, the authors agreed to use recommendations from NICE [20] and the ISPOR Task Force [16] for the grading of studies. The grading method reflected the approach reported by Cooper 2020 [21], (Supplementary File 1). Items assessed included the methodological quality of the study, representativeness of

the study population and/or health states and the appropriateness of HSU data for cost-effectiveness modelling. Studies were classified according to whether the study met all criteria of NICE (noting NICE's perspective is for England and Wales, with an acceptable broader remit of the UK) [20] with no concerns (Grade 1), met most but not all criteria with some concerns (Grade 2), or did not meet the criteria (Grade 3). NICE's perspective was used to represent a specific HTA agency's perspective for grading HSUVs for use in decision-analytic models as it would be a substantial task to represent the perspective of all HTA agencies internationally [22, 23]. Preliminary independent quality assessment and grading were completed by two members of the review team. Revised criteria were agreed following discussion and input from an expert health economist. Subsequently, quality assessment and grading were undertaken by one reviewer and checked by a second reviewer.

Data synthesis

Due to the methodological and clinical heterogeneity of included studies, it was not appropriate to undertake a meta-analysis. Available data are presented in narrative and tabular summaries.

Results

Study characteristics

In total, 53 studies were identified from database (n = 45) and supplementary (n = 8) searches (Fig. 1; Table 1) [10, 24–75]. Study sizes ranged from 32 to 4137 participants, with most studies being cross-sectional (n = 45). Studies were conducted in single or multiple settings of 22 individual countries (Fig. 2A), with a further 24% being conducted in ≥ 2 countries (i.e. international studies). Most studies did not provide details relating to ARTs to establish treatment regimens.

Included studies reported HSUV data using two direct methods (SG, TTO) and six indirect methods: EQ-5D three-level (EQ-5D-3L), EQ-5D five-level (EQ-5D-5L), Health Utilities Index Mark 2 (HUI2), HUI Mark 3 (HUI3), SF-6D (obtained from SF-12 and SF-36), and 15D (Fig. 2B). EQ-5D-3L (n = 29) and EQ-5D-5L (n = 18) were the most frequently reported. In total, 10 studies reported > 1 HSUV estimation method and ~ 50% reported regression coefficients representing disutilities.

Study quality

A total of 29 studies were rated as 'high' and six as 'moderate' quality. One study was rated 'low' owing

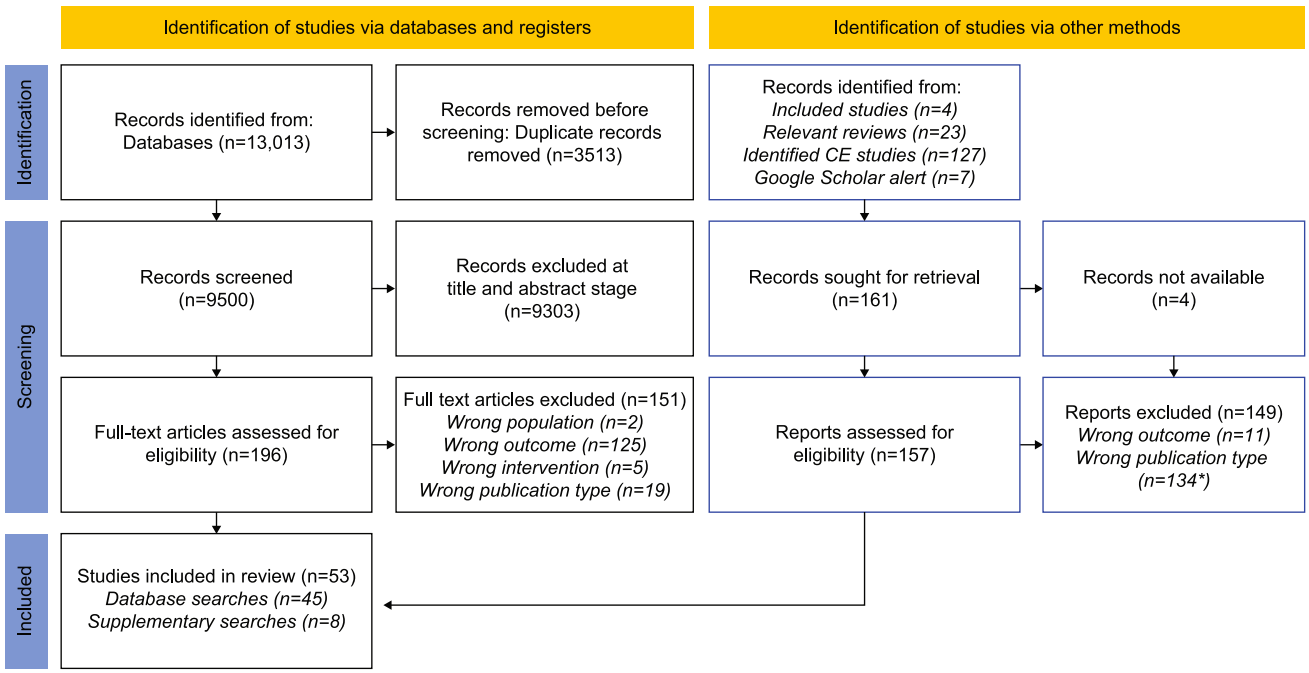

Fig. 1 PRISMA flowchart of literature search and screening. *Includes CE studies available only as abstracts (n = 39), CE studies with no relevant data/primary studies (n = 84) and excluded primary studies from reviews (n = 1). *CE* comparative-effectiveness

Table 1 Characteristics of included studies

Study ID	Data source/study design	Study period	Study setting	Brief description of study eligibility criteria/population	PWH contributing HSUV data, n	HSUV measure(s)	Preference source(s)*
Non-randomised studies							
Ahmed (2021) [24]	Cross-sectional study	2019	Pakistan	PWH and AIDS HIV diagnosis ≥ 6 months	602	EQ-5D-3L	UK
Anderson (2022) [25] BRIGHTE study NCT02362503	Cross-sectional and longitudinal data	2015–2016	Multicentre (n = 108; 23 countries)	Heavily treatment-experienced or multidrug-resistant PWH	371	EQ-5D-3L	UK
Anis (2009) [26] OPTIMA trial	Longitudinal data (Secondary analysis, subgroup with ADEs)	2001–2007	USA, Canada, UK	PWH, treatment failure†	368	EQ-5D-3L HUI3	US Canada
Joyce (2009) [39] OPTIMA trial	Cross-sectional data (Secondary analysis: UK and US value sets)	2001–2006				EQ-5D-3L HUI3 TTO SG	US Canada
Joyce (2012) [40] OPTIMA trial	Cross-sectional data (Secondary analysis: Baseline HRQoL of treatment groups)	2001–2007				EQ-5D-3L HUI3 TTO SG	USA Canada
Bansback (2008) [28] OPTIMA trial	Cross-sectional data (Secondary analysis: subgroup with adverse events)	2001–2007				EQ-5D-3L HUI2, HUI3	USA Canada
Nosyk (2009) [53] OPTIMA trial	Cross-sectional study	2001–2007				EQ-5D-3L HUI3	USA Canada
Anosike (2021) [27]	Cross-sectional study	2016	Nigeria	PWH and AIDS	352	EQ-5D-5L	Zimbabwe
Belay (2021) [29]	Cross-sectional study	2019	Ethiopia	PWH and AIDS	511	EQ-5D-5L	Ethiopia
Castro (2019) [30]	Cross-sectional study	2014–2016	Brazil	PWH	1480	EQ-5D-3L	Brazil
Delate & Coons (2001) [34]	Cross-sectional study	1999	USA	PWH	242	EQ-5D-3L	UK
Gow (2013) [35]	Cross-sectional study	2008	South Africa	PWH (subgroup)	47	EQ-5D-3L HUI3	NR Canada
Honiden (2006) [36]	Cross-sectional study	1997	USA	PWH and AIDS	66	TTO	NR
Huang (2007) [37]	Cross-sectional study	NR	USA	PWH and AIDS	1126	EQ-5D-3L	UK US
Isogai (2013) [38]	Cross-sectional study	2007–2009	Canada	PWH and AIDS	841	HUI3	NR
Kall (2021) [41]	Cross-sectional study	2019–2020	Romania Spain	PWH	570 Romania, n = 170 Spain, n = 400	EQ-5D-5L	Spain
Keaei (2016) [42]	Cross-sectional study	2014	Columbia	PWH, receiving ART	138	EQ-5D-5L	Spain

Table 1 (continued)

Study ID	Data source/study design	Study period	Study setting	Brief description of study eligibility criteria/population	PWH contributing HSUV data, n	HSUV measure(s)	Preference source(s)*
Lenert (2002) [43]	Cross-sectional study	NR	NR	PWH	75	SG TTO	NA
Lopez-Bastida (2009) [44]	Cross-sectional study	2003	Spain	PWH	572	EQ-5D-3L	Spain
Louwagie (2007) [45]	Cross-sectional study	Not specified	South Africa	PWH‡	371 On HAART, n = 268 Yet to start HAART, n = 103	EQ-5D-3L	UK
Mafirakureva (2016) [46]	Cross-sectional study	2013	Zimbabwe	PWH, on ART	257	EQ-5D-3L	Zimbabwe
Maheswaran (2017) [48] ISRCTN02004005	Longitudinal data (Secondary analysis of cluster RCT of HIV testing strategy	2013–2015	Malawi	PWH (subgroups on ART and yet to start ART)	325 HTC, n = 265; HIVST, n = 60	EQ-5D-3L	Zimbabwe
Maheswaran (2018) [47]	Cross-sectional study	2014	Malawi	PWH (subgroup)	447	EQ-5D-3L	Zimbabwe
Miners (2014) [49] ASTRA study Health Survey for England (HSE) 2011	Cross-sectional data (Secondary analysis: subgroups, on ART and not receiving ART)	ASTRA: 2011–2012 HSE: 2011	UK	PWH	3151	EQ-5D-3L	UK
Miners (2001) [50]	Cross-sectional study	NR	UK	Advanced PWH§	132	EQ-5D-3L	UK
Mrus (2006) [51]	Cross-sectional study	2002–2003	USA	PWH and AIDS	450	TTO SG	NA
Mwangi (2022) [52]	Cross-sectional study	2015–2016	Kenya	PWH, pregnant women	100	EQ-5D-3L	Zimbabwe
Okhai (2022) [54]	Cross-sectional study	2016–2017	UK	PWH, women only aged 45 to 60 years	813	EQ-5D-3L	NR
Oliva (2003) [55]	Cross-sectional study	NR	Spain	PWH and AIDS	32	EQ-5D	NR
Patel (2017) [56]	Cross-sectional study	2007–2009	Kenya	PWH, treatment-naïve¶	538	SF-6D**	Kenya (based on a Kiswahili translated and adapted SF-12)
Podzamczer (2018) [57] PRO-STR study	Longitudinal data (secondary analysis, open-label study)	NR	Spain	PWH, treatment switch††	300	EQ-5D-3L	NR

Table 1 (continued)

Study ID	Data source/study design	Study period	Study setting	Brief description of study eligibility criteria/population	PWH contributing HSUV data, n	HSUV measure(s)	Preference source(s)*
Popping (2021) [58]	Cross-sectional data (Secondary analysis)	2016–2018	Netherlands	PWH	n = 895	EQ-5D-5L	Netherlands
England, Positive Voices		2017	England		n = 4137		England
Stichting HIV monitoring database (ATHENA project)							
Quach (2022) [59]	Cross-sectional data (Secondary analysis, cohort study)	2020–2021	Uganda	PWH (subgroup); age ≥ 49 years	298	EQ-5D-5L	Zimbabwe
Quality of Life and Ageing with HIV in Rural Uganda Study							
Sakthong (2009) [60]	Cross-sectional study	2004	Thailand	PWH and AIDS	120	EQ-5D-3L	UK
						SG	NA
Sakthong (2014) [61]	Cross-sectional study	2010	Thailand	PWH	210	EQ-5D-3L	Thailand
Shimels (2022) [62]	Cross-sectional study	2020	Ethiopia	PWH	371	EQ-5D-3L	Zimbabwe
Stavem (2005) [63]	Cross-sectional data and longitudinal data (cohort study)	1995–1998	Norway	PWH and AIDS	60	15D	Finland
						SF-6D‡‡	Norway
						EQ-5D	UK
Surah (2013) [64]	Cross-sectional study		Northern Ireland	PWH, intravenous drug users and non-engaging§§	55	EQ-5D-3L	UK
						SF-6D	SF-36 (UK)
Suryana (2020) [65]	Cross-sectional study	2019–2020	Indonesia	PWH and AIDS	584	EQ-5D-5L	Spain
Thomas (2017) [66]	Cross-sectional data (Secondary analysis of cluster RCT)	2013–2015	Zambia, South Africa	PWH (subgroup)	Zambia, n = 4128 South Africa, n = 4012	EQ-5D-5L	NR
HPTN 071 (PopART) study							
Tran (2018) [67]	Cross-sectional study	2017	Vietnam	PWH and AIDS	482	EQ-5D-5L	Vietnam
Tran (2011) [68]	Cross-sectional study	2008–2009	Vietnam	PWH, advanced stage	400	EQ-5D-3L	UK
Tran (2012) [10]	Cross-sectional study	2012	Vietnam	PWH and AIDS	1016	EQ-5D-5L	Crosswalk value set of Thailand
Treskova (2022) [69]	Cross-sectional data (Secondary analysis of baseline data)	2009–2012	Germany	PWH, receiving ART	1056	EQ-5D-3L	Germany
Cost and Resource Utilisation Study in Antiretroviral Therapy (CORSAR)							
Van Duin (2017) [70]	Cross-sectional data	2014	Columbia	PWH, with or without comorbidities	138	EQ-5D-5L	Spain
Wang (2021) [73]	Cross-sectional study	2019–2020	China	PWH and AIDS Age ≥ 16 years	1997	EQ-5D-5L	China
Wang (2022a) [72]	Siyaphambili study (NCT03500172)	2018–2020	South Africa	PWH, female sex workers	1363	EQ-5D-3L	Zimbabwe

Table 1 (continued)

Study ID	Data source/study design	Study period	Study setting	Brief description of study eligibility criteria/population	PWH contributing HSUV data, n	HSUV measure(s)	Preference source(s)*
Wang (2022b) [74]	Cross-sectional study	2019–2020	China	PWH and AIDS	1797	EQ-5D-5L	China
						SF-6D[¶¶]	US
Weng (2022) [75]	Cross-sectional study Extending the QALY (E-QALY)	2019	China	PWH and AIDS (subgroup)	101	EQ-5D-3L/5L	China
Randomised studies							
GEMINI-1 [33] NCT02831673 GEMINI-2 [32] NCT02831764 studies	RCTs	2016–2018	Multicentre (n = 187 centres in 21 countries)	PWH, treatment-naïve or on ≤ 10 days previous ART***	DTG + 3TC, n = 719 DTG + TDF/FTC, n = 722	EQ-5D-5L	NR
TMC125-C216-W96 2006 (DUET-2) [31] NCT00255099	RCT	2005–2006	Various countries	Treatment-experienced PWH[†††]	591	EQ-5D[‡‡‡]	NR
Velvanathan (2016) [71]	RCT	NR	Malaysia	PWH and AIDS	120 FRC, n = 60 FDC, n = 60	EQ-5D-5L	UK

*Country related to general population; [†]Treatment failure following ≥ 2 different standard multidrug regimens, or laboratory evidence of resistance to either NRTIs; NNRTIs or PIs; on current ART for ≥ 3 months; laboratory crtieria:CD4 + counts < 300 cells/mm^3; pVL > 5000 copies per mL (Roche Amplicor v1.0) or ≥ 2500 copies per mL (bDNA Bayer v3.0/Chiron v3.0; or PCR Roche Amplicor Monitor/COBAS v1.5; [‡]2 months post-HAART initiation or yet to start HAART; CD4 count < 200 cells/µl or WHO stage 4; [§]Diagnosis of AIDS in 30% of the study population; [¶]Viral load ≥ 55,000 copies/mL; **Derived from SF-12; [††]Treatment switch due to intolerance (grade 2 to 4 adverse event or laboratory abnormality based on WHO criteria) to previous treatment; switch from a cART regimen of two nucleoside analogues plus a boosted PI or one integrase inhibitor + two nucleoside analogues) to the short treatment regimen i.e. rilpivirine (RPV)/emtricitabine (FTC)/tenofovir (TDF): EVIPLERA®/COMPLERA® to STR (EVIPLERA®); [‡‡]Derived from SF-36; [§§]Those who had missed ≥ 2 outpatient appointments over the past year or nonattendance in the preceding 6 months; [¶¶]Derived from SF-12; ***Laboratory criteria:CD4 + < 200/µL, HIV-1 RNA ≤ 1000–500,000 copies per mL; No evidence of resistance mutations to PIs, NRTIs or NNRTIs; [†††]Those with > 5000 RNA copies/mL; on a stable ART ≥ 8 weeks; [‡‡‡]Number of dimensions, not reported

3TC lamivudine, *ADE* AIDS-defining event, *AIDS* Acquired Immunodeficiency Syndrome, *ART* antiretroviral therapy, *cART* combination ART, *CDC* Centers for Disease Control and Prevention, *DTG* dolutegravir, *EQ-5D-3L*, EuroQol-5 Dimensions-3 Levels, *EQ-5D-5L* EuroQol-5 Dimensions-5 Levels, *FDC* fixed-dose combination, *FRC* free-dose combination, *FTC* emtricitabine, *HAART* highly active antiretroviral therapy, *HIV* Human Immunodeficiency Virus, *HIVST* HIV self-testing, *HRQoL* health-related quality of life, *HSE* Health Survey of England, *HSUV* health state utility value, *HTC* HIV testing and counselling, *HUI* Health Utilities Index, *n* number, *NA* not applicable, *NRTI* nucleoside reverse transcriptase inhibitor, *NNRTI* non-nucleoside reverse transcriptase inhibitor, *NR* not reported, *PI* protease inhibitor, *PWH* people living with HIV *QALY* quality-adjusted life-years, *RCT* randomised controlled trial *SF-6D* Short-Form 6 Dimensions, *SF-12* 12-Item Short-Form Survey *SG* standard gamble *TDF* tenofovir disoproxil fumarate, *TTO* time trade-off, *WHO* World Health Organization

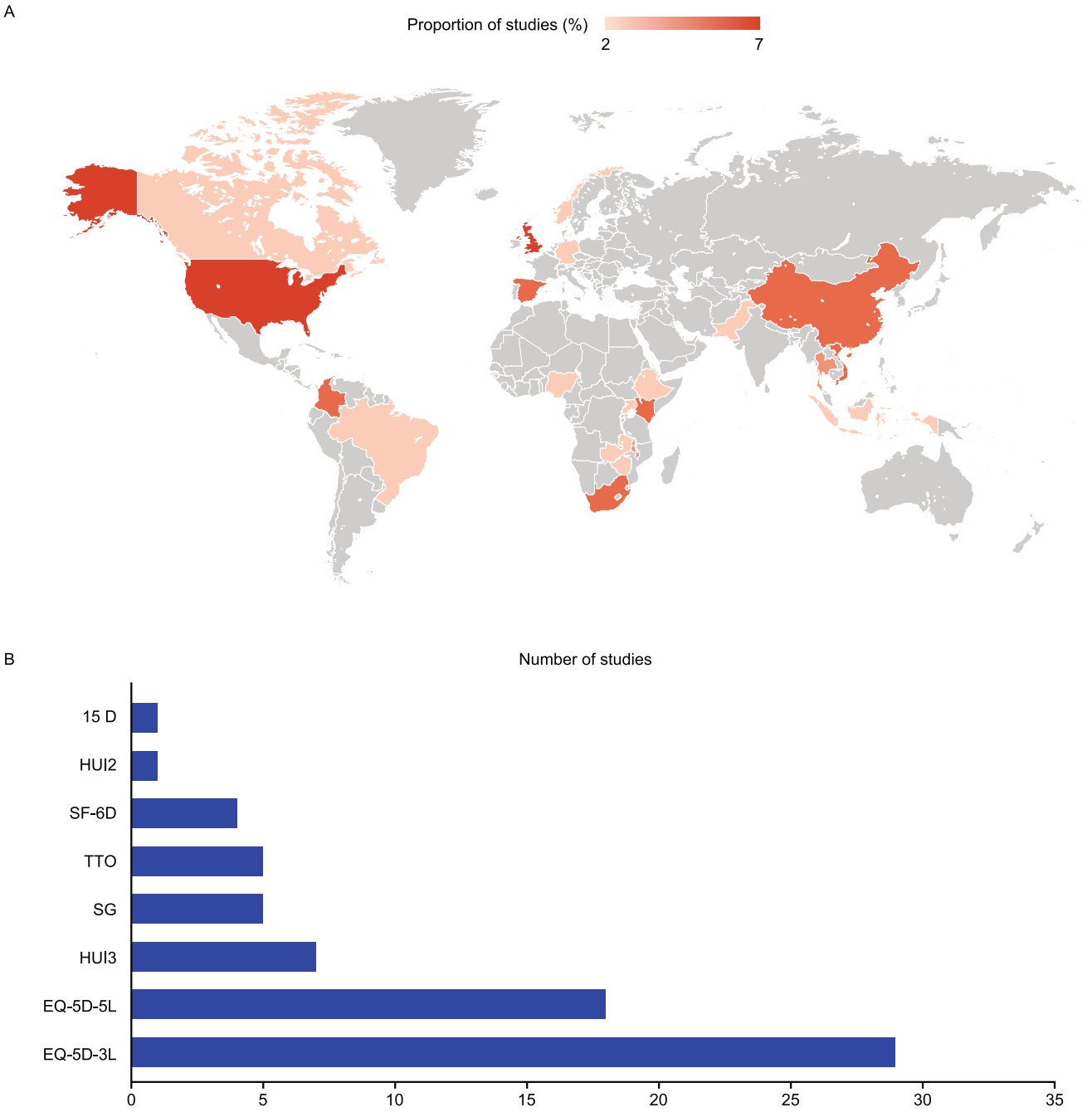

Fig. 2 Summary of study locations* (**A**) and estimation methods (**B**) reported in included studies. *Studies in individual countries were available from Brazil, Canada, China, Colombia, Ethiopia, Germany, Indonesia, Kenya, Malawi, Malaysia, Nigeria, Norway, Pakistan, South Africa, Spain, Thailand, Uganda, UK, USA, Vietnam, Zambia, and Zimbabwe. Additionally, a further 24% of studies reporting on ≥ 2 countries. *EQ-5D* EuroQol-5 Dimensions, *HUI* Health Utilities Index, *SF-6D* Short-Form 6 Dimensions, *SG* standard gamble, *TTO* time trade-off

to sample size and limited reporting of the estimation approach. All remaining studies were rated as moderate/high (n = 15) or low/high (n = 2). One study reporting disutilities relating to AIDS-defining events (ADE) and non-ADE serious AEs (SAEs) for PWH with advanced disease was the only Grade 1 study [28]. One study based on the Positive Voices survey was rated as Grade 2 [58]. Overall, 43 studies were rated exclusively as Grade 3, four

were rated as Grade 1 or 3, and a further four were rated as Grade 2 or 3. Most Grade 3 studies included participants who often used utility measures and/or preference weights not recommended by NICE (Supplementary File 1). Extensive heterogeneity was seen regarding the source populations and preference value sets used in studies.

Cross-sectional HSUV data

ART experience

Data were available from six studies using EQ-5D-3L [45, 68, 72] and EQ-5D-5L [30, 41, 74] estimates (diverse populations/value sets) in treatment-naïve PWH. Means (standard deviation [SD]) ranged from 0.69 (0.4) to 0.90 (not reported) (Table 2; Supplementary File 2).

One study reported on treatment-experienced PWH with eight specified ART regimens. The median (interquartile range) EQ-5D-5L estimate (Ethiopian population/value set) was 0.94 (0.87–1.0), with individual treatment HSUVs differing significantly between ART regimens ($p = 0.004$), ranging from 0.82 (0.77–1.0) for PWH on TDF + 3TC + ATV/r to 0.97 (0.94–1.0) for PWH receiving AZT/3TC/EFV [29].

Remaining studies reporting on ART regimens provided limited or no information on specific interventions (Table 2). A 2012 study provided EQ-5D-3L, HUI3, SG, and TTO estimates relating to standard treatment (receiving ≤ 4 ARTs) or intensified treatment (receiving ≥ 5 ARTs) [40]. HUI3 estimates (Canada, UK, US populations/Canada value set) were the lowest (0.58–0.61 across health states). EQ-5D-3L values (Canada, UK, US populations/US value set), SG (US population), and TTO (US population) were 0.76, 0.79, and 0.73 in the standard group versus 0.77, 0.79, and 0.81 in the intensified group [40]. It is likely that these findings are due to comparable valuations of health states by the relevant populations. When ART treatment was interrupted (stopped for ≥ 12 weeks), PWH reported a mean (SD) EQ-5D-3L of 0.79 (0.17) versus 0.76 (0.19) for no treatment interruption [40]. Conversely, in a South African study conducted in 2022, mean (SD) EQ-5D-3L HSUV following ART interruption was 0.87 (0.18) versus 0.83 (0.21) for no ART interruption [72].

For PWH receiving ART for ≤ 1 year, mean (SD) EQ-5D-3L estimates ranged from 0.50 (0.35) (Pakistan population/UK value set [24]) to 0.80 (SD, not reported) (Brazil population/value set) [30]; mean (SD) EQ-5D-5L estimates were 0.58 (SD, not reported) (Vietnam population/Thailand crosswalk value set [10]) to 0.925 (0.124) (China population/value set [73]). In a convenience sample of PWH, mean (SD) EQ-5D-5L estimates were higher than SF-6D for those on treatment for ≤ 1 year: 0.89 (0.15) versus 0.77 (0.14). Although SF-6D values appeared unchanged in relation to duration of ART, EQ-5D-3L and EQ-5D-5L displayed mixed trends across treatment durations (Supplementary File 2). This demonstrates little influence of the interruption of ART or ongoing treatment on various measures of HSUVs.

When assessing the impact of prior ARTs on HRQoL, median EQ-5D-5L estimate (Ethiopia population/value set) relating to a health state of receiving one intervention was 0.96 [29]. This reduced by each increase in interventions to 0.89 with ≥ 4 interventions [29]. Additionally, a small but statistically significant decrease in median HSUVs was observed in the health state of experiencing treatment failure (0.92) versus not (0.96) ($p < 0.001$) [29]. Regarding adherence to ART regimens, there were no statistically significant differences in EQ-5D-5L estimates (Romania or Spain populations with country-specific value sets [41] and Vietnam population with Thailand value set [10]) between adherent and non-adherent subgroups of PWH (Table 3).

HIV clinical stage

Overall, a wide variation in HSUV measures regarding HIV clinical stage categories (suppressed, viraemic, and AIDS) were available. (Fig. 3A; Supplementary File 2). Mean TTO estimates were relatively higher versus other HSUV measures across all clinical stages of HIV. EQ-5D-3L data (Pakistan population/UK value set) were the lowest across clinical categories. A possible explanation for this may be a lack of cultural similarity between the population studied and value set used. HSUVs from the remaining valuation methods displayed a mixed trend across clinical stages (Fig. 3A; Supplementary File 2).

Viral load

Overall, six studies [24, 29, 54, 57, 69, 72] reported mean EQ-5D-3L estimates for health states of undetectable VL. Mean (SD) estimates ranged from 0.55 (0.41) (at baseline; Pakistan population/UK value set) [24] to 0.91 (0.15) (Week 48; German population/value set) [57, 72] (Supplementary File 2). One study reported data at both baseline and Week 48 demonstrating an increase from 0.82 (0.18) to 0.90 (0.16) (Spain population/value set) [57]. Six studies [24, 29, 30, 34, 56, 72] reported EQ-5D-3L, EQ-5D-5L, and SF-6D HSUVs across ≥ 2 VL thresholds. Generally, reported values demonstrated an inverse relationship between VL and HSUVs irrespective of the measure used, population source, or preference weight. Mean (SD) EQ-5D-3L estimates for VL health states of 51 < VL ≥ 1000 and > 1000 in a South Africa population (Zimbabwe value set, 0.85 [0.19] and 0.86 [0.19], respectively [72]) and an Ethiopia population

Table 2 Health utility estimates: health states—treatment-naïve and ART regimens (not specified)

Study ID	Measure	Population source	Preference source	Health state n (%) of relevant PWH population	Estimate, mean, median	SD (95% CI) [IQR]
Health state: Treatment-naïve						
Louwagie (2007) [45]	EQ-5D-3L	Afrikaans, Xhosa, Zulu and Sotho*	UK	103 (27.8)	0.690	0.400
Tran 2011 [68]	EQ-5D-3L	Vietnam	UK	175 (43.8)	0.900	(0.88–0.93)
Wang (2022a) [72]	EQ-5D-3L	South Africa	Zimbabwe	178 (13.1)	0.842	0.195
Castro (2019) [30]	EQ-5D-5L	Brazil	Brazil	62 (4.2)	0.801	NR
Kall (2021) [41]	EQ-5D-5L	Romania	Romania	2 (1.2)	0.830	(0.81–0.85)
Kall (2021) [41]	EQ-5D-5L	Spain	Spain	3 (0.8)	0.860	(0.59–1)
Wang (2022b) [74]	EQ-5D-5L	China	China	25 (1.3)	0.896	0.152
Health state: Receiving standard ART						
Louwagie (2007) [45]	EQ-5D-3L	Afrikaans, Xhosa, Zulu and Sotho*	UK	268 (72.2)	0.80	0.29
Louwagie (2007) [45]	EQ-5D-3L	Afrikaans, Xhosa, Zulu and Sotho*	UK	268 (72.2)	0.87	NR [0.73–1.00]
Tran (2011) [68]	EQ-5D-3L	Vietnam	UK	225 (56.3)	0.88	(0.85–0.91)
Tran (2011) [68]	EQ-5D-3L	Vietnam	UK	107 (26.8) (Non-IDU subgroup)	0.88	(0.84–0.91)
Tran (2011) [68]	EQ-5D-3L	Vietnam	UK	118 (29.5) (IDU subgroup)	0.89	(0.85–0.92)
Joyce (2012) [40]	EQ-5D-3L	Canada, UK, US	US	192 (52.2)	0.76	0.19
Joyce (2012) [40]	HUI3	Canada, UK, US	Canada	192 (52.2)	0.58	0.32
Joyce (2012) [40]	SG	US	NA	NR	0.73	0.31
Joyce (2012) [40]	TTO	US	NA	NR	0.79	0.32
Health state: Ongoing ART, no interruption						
Joyce (2012) [40]	EQ-5D-3L	Canada, UK, US	US	175 (51.6)	0.76	0.20
Wang (2022a) [72]	EQ-5D-3L	South Africa	Zimbabwe	880 (64.6)	0.87	0.18
Joyce (2012) [40]	HUI3	Canada, UK, US	Canada	175 (51.6)	0.57	0.32
Joyce (2012) [40]	SG	US	NA	NR	0.74	0.31
Joyce (2012) [40]	TTO	US	NA	NR	0.81	0.29
Health state: Intensified ART						
Joyce (2012) [40]	EQ-5D-3L	Canada, UK, US	US	176 (47.8)	0.79	0.18
Joyce (2012) [40]	HUI3	Canada, UK, US	Canada	176 (47.8)	0.61	0.32
Joyce (2012) [40]	SG	US	NA	NR	0.77	0.27
Joyce (2012) [40]	TTO	US	NA	NR	0.81	0.30
Health state: On ART, with treatment interruption						
Joyce (2012) [40]	EQ-5D-3L	Canada, UK, US	US	164 (48.4)	0.79	0.17
Joyce (2012) [40]	HUI3	Canada, UK, US	Canada	164 (48.4)	0.61	0.30
Joyce (2012) [40]	SG	US	NA	unclear	0.76	0.27
Joyce (2012) [40]	TTO	US	NA	unclear	0.78	0.30
Wang (2022a) [72]	EQ-5D-3L	South Africa	Zimbabwe	303 (22.2)	0.83	0.21

*Language versions of measure administered

ART antiretroviral treatment, *CI* confidence interval, *EQ-5D-3L* EuroQol-5 Dimensions-3 Levels, *EQ-5D-5L* EuroQol-5 Dimensions-5 Levels, *HIV* Human Immunodeficiency Virus, *HUI3* Health Utilities Index Mark 3, *IDU* injection drug use, *IQR* interquartile range, *N* number, *NA* not applicable, *NR* not reported, *PWH* people with HIV, *SD* standard deviation, *SG* standard gamble, *TTO* time trade-off

(Ethiopia value set, 0.94 and 0.88 [29]) were generally similar, especially for the higher VL category.

CD4 cell count

Overall, estimates for EQ-5D-3L [24, 34, 37, 39, 63, 74], EQ-5D-5L [10, 74], SF-6D [63, 72], HUI3 [39], 15D [63],

Table 3 Health utility estimates: health states—number of ARTs received, treatment failure history and adherence

Study ID	Measure	Population source	Preference source	Health state	Health state, N (%), relevant population	Mean median	95% CI	p-value
Health state valued: Number of ARTs								
Belay (2021) [29]	EQ-5D-5L	Ethiopia	Ethiopia	1	208 (40.7)	0.960	NR	< 0.001
Belay (2021) [29]	EQ-5D-5L	Ethiopia	Ethiopia	2	150 (29.4)	0.940	NR	
Belay (2021) [29]	EQ-5D-5L	Ethiopia	Ethiopia	3	91 (17.8)	0.940	NR	
Belay (2021) [29]	EQ-5D-5L	Ethiopia	Ethiopia	4	43 (8.4)	0.910	NR	
Belay (2021) [29]	EQ-5D-5L	Ethiopia	Ethiopia	> 4	19 (3.7)	0.890	NR NR	
Health state valued: History of treatment failure								
Belay (2021) [29]	EQ-5D-5L	Ethiopia	Ethiopia	Yes	94 (18.4)	0.920	NR NR	0.001
Belay (2021) [29]	EQ-5D-5L	Ethiopia	Ethiopia	No	417 (81.6)	0.960	NR NR	
Health state valued: Adherence to ART								
Kall (2021) [41]	EQ-5D-5L	Romania	Romania	Entirely adherent	143 (83.9)	0.860	0.83–0.89	0.301
Kall (2021) [41]	EQ-5D-5L	Romania	Romania	Not entirely adherent	27 (16.1)	0.820	0.75–0.89	
Kall (2021) [41]	EQ-5D-5L	Spain	Spain	Entirely adherent	397 (99.2)	0.890	0.87–0.90	0.435
Kall (2021) [41]	EQ-5D-5L	Spain	Spain	Not entirely adherent	4 (0.9)	0.830	0.65–1.00	
Tran (2012) [10]	EQ-5D-5L	Vietnam	Thailand	Entirely adherent	217 (24.7)	0.650	0.62–0.69	0.91
Tran (2012) [10]	EQ-5D-5L	Vietnam	Thailand	Not entirely adherent	660 (75.3)	0.650	0.63–0.67	

ART antiretroviral treatment, *CI* confidence interval, *EQ-5D-3L* EuroQol-5 Dimensions-3 Levels, *EQ-5D-5L* EuroQol-5 Dimensions-5 Levels, *N* number, *NR* not reported

TTO [39], and SG [39] measures relating to CD4 count (cells/μL) health states showed an improving trend as cell count increased. However, extensive variations for specific cut-off values and ranges were noted for available data (Fig. 3B and C; Supplementary File 2).

Comorbidities and opportunistic infections

Median EQ-5D-5L estimates (Ethiopia population/value set) for PWH with and without opportunistic infections were 0.92 and 0.96, respectively (p = 0.001) (Supplementary File 2) [29]. Another study demonstrated that PWH without comorbidities had higher mean (SD) EQ-5D-5L (Spain population/value set) estimates (0.896 [0.187]) versus those with comorbidities (0.836 [0.224]) (Supplementary File 2) [70].

Longitudinal HSUV data

Overall, ten studies [25, 26, 31–33, 48, 57, 63, 69, 71] provided HSUV estimates with follow-up durations ranging from 6 months to ~ 4 years. Populations, methodologies, and ART history varied across studies (Supplementary File 2).

Treatment-naïve

Two identical RCTs (GEMINI-1, -2) provided HSUVs, comparing two-drug and three-drug regimens across 18 countries [32, 33, 76, 77]. Aggregated mean (SD) EQ-5D-5L (unspecified value set) estimates at baseline and Week 96 were 0.95 (0.08) and 0.96 (0.08) for a two-drug regimen (DTC + 3TC) and 0.94 (0.11) and 0.96 (0.09) for a three-drug regimen (DTC + TDF/FTC) [32, 33, 76, 77].

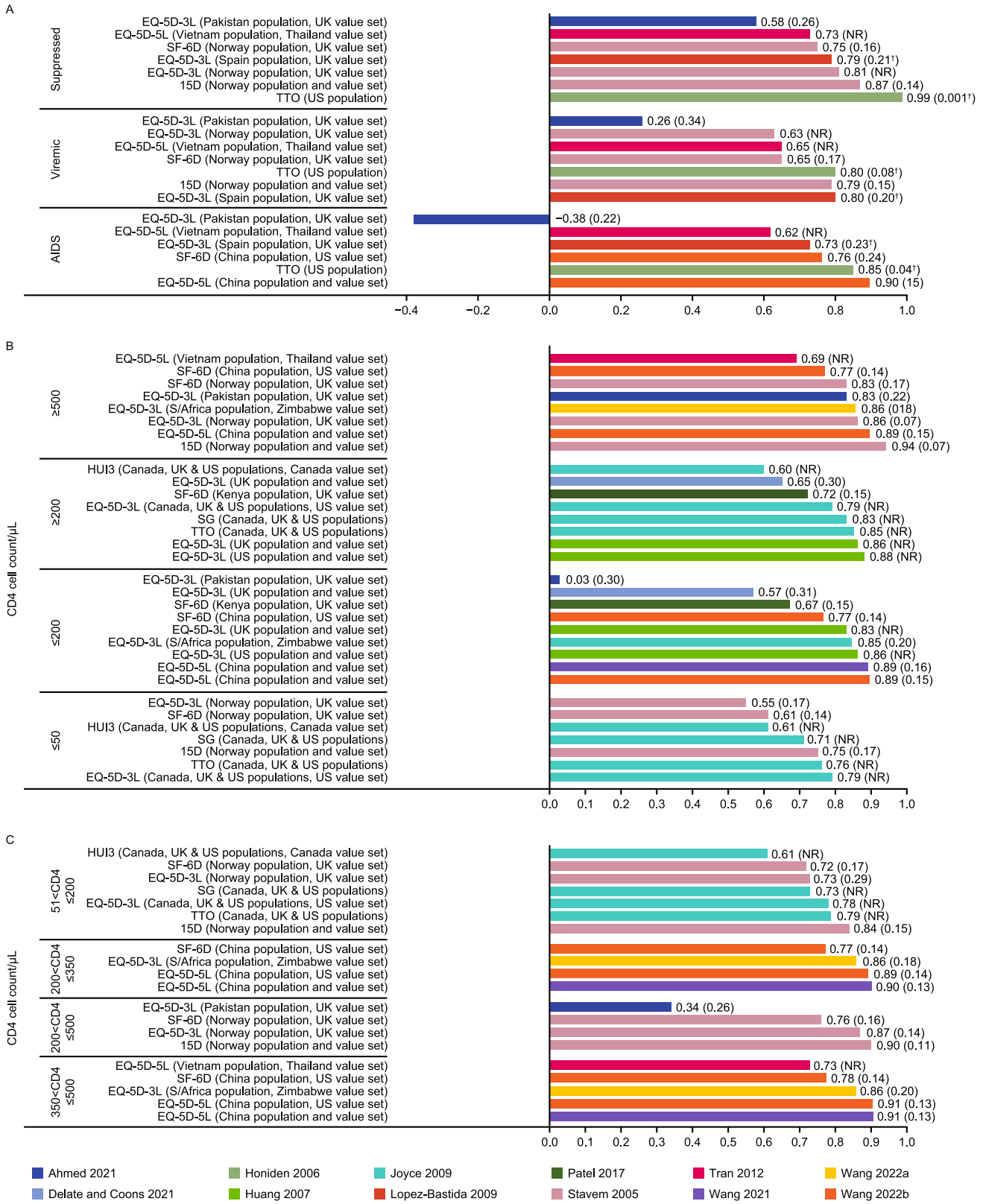

Fig. 3 Mean health utility estimates: health states – stage of infection (**A**); CD4 cells/μL (cut-offs) (**B**); CD4 cells/μL (ranges) (**C**). Data reported are mean (SD). †SE reported instead of SD. *NR* not reported, *SD* standard deviation, *SE* standard error

Treatment-experienced

Overall, treatment-experienced PWH had lower baseline HSUV estimates than treatment-naïve counterparts; however, diverse EQ-5D measures were used across the studies [25, 26, 31, 69, 71]. Treatment-experienced subgroups receiving active treatment demonstrated an improved HRQoL trend over time versus subgroups receiving placebo. One study that investigated the effect of ADEs and non-AIDS SAEs on HRQoL in PWH experiencing treatment failure with ≥ 2 ARTs suggested a relationship between time of onset of the ADE or SAE and the assessment timepoint [26].

Other ART management strategies

In PWH who switched ART following Grade 2–4 AEs, mean (SD) EQ-5D-3L estimates (Spanish population/value set) increased from 0.82 (0.18) at baseline to 0.90 (0.16) at Week 48 [57]. An improved HRQoL trend over time was also seen in a Norwegian population using EQ-5D-3L, SF-6D, and 15D (Norway population/UK value set) [63]. Greater improvements in HRQoL were also seen in a study in Malawi assessing HRQoL 1 year after ART initiation in PWH receiving either facility-based HIV testing and counselling (HTC) or HIV self-testing (HIVST). Baseline estimates using the EQ-5D-3L (UK value set) (0.793 [HTC] and 0.785 [HIVST]) were lower than those obtained using the EQ-5D-3L (Zimbabwe value set) (0.836 in both subgroups). After 1 year, estimates were similar regardless of value set (0.973–0.975) [48].

Discussion

This systematic literature review highlights that there is an extensive catalogue of HSUVs derived from studies in PWH. Identified studies had a wide geographic scope and included cross-sectional and longitudinal data. The most frequently reported estimates were from the EQ-5D-3L and EQ-5D-5L, compared with direct measures, which aligns with HTA agency recommendations who frequently prefer indirect measures [11]. The suitability of HSUV estimates for use in any given decision-analytic economic model depends on a range of factors, depending on what the model is intended to represent and to whom the evidence is intended to inform for any given decision problem [16]. For example, considerations include the intended population/study sample, specific health conditions and states across a pre-specified disease and care pathway, and the extent to which any given modeller and decision-making body is willing to trade off bias and validity for more information/evidence to inform the decision problem. Although most included studies were regarded as high-quality based on ISPOR Task Force guidance [16], the NICE-based grading criteria suggested most did not meet the criteria as being suitable for NICE [20]. In many cases this was because the HSUV did not represent the UK population as the predominant jurisdiction of NICE; however, the same HSUVs could be appropriate for other HTA agencies. It was not possible to provide such grading for all HTA agencies internationally given their relative different jurisdictions, scopes, and preferences [22, 23].

As the outputs from any decision-analytic model are dependent on the inputs and imposed model structure, it is not possible to suggest a one-size-fits-all conclusion that any identified HSUV is suitable for every decision-analytic model. The range of HSUVs and complementary information provided within this compendium is intended to enable a well-informed decision about choosing a HSUV based on its origins, strengths, and limitations.

A predominance of cross-sectional studies was evident. This may present challenges as cross-sectional data only provide a snapshot of an individual's HRQoL at a specific timepoint and thus a static perspective. This can limit any inferences made regarding the dynamics or causality of HSUVs. Comparatively higher HSUVs were reported across most measures for PWH subgroups who were suppressed rather than in the viraemic or AIDS health states. This finding supports that of an earlier meta-analysis that demonstrated that PWH who are viraemic or have AIDS reported a decrease of 0.017 and 0.173 versus PWH with suppressed VL load when adjusting for differences in study characteristics [14]. Additionally, we found that PWH who received fewer ART lines, had no comorbidities, and had higher CD4 counts or lower VL reported higher HSUV estimates across all measures. However, there was variation in HSUV estimates across studies reporting on PWH with similar health states, which may be explained by differences in the participants enrolled and/or cultural and societal settings, among other measured (and unmeasured) factors reported and explored within the relevant study.

Overall, the longitudinal analyses indicated an improving trend in HRQoL over time for PWH who received ART regardless of whether PWH were ART-naïve or -experienced, although PWH who were ART-experienced reported lower baseline HSUV estimates. Notably, heavily treatment-experienced individuals who received active treatment demonstrated significant improvement in HRQoL versus placebo-treated individuals, and comparable findings were seen in both primary studies and secondary analyses from randomised and non-randomised studies. However, although RCTs may be a good source of causal evidence, this is specifically related to differences between randomised treatment arms and assumes that other biases (e.g. information bias due to missing data) have been controlled appropriately. Also, any causal estimates from non-randomised

studies are dependent on the hypothesised causal pathways (e.g. as depicted within directed acyclic graphs) and appropriate analyses to account for pertinent forms of bias (e.g. confounding and selection bias) aligned with the data-generating mechanism (e.g. study design/data collection). Therefore, the causality of such estimates should be judged on the nature, conduct, and analysis of the study, which is not fully explored nor reported in this systematic review. In other disease areas the use of registries that are linked with electronic health records is a good source for longitudinal studies. However, owing to greater caution in handling electronic health records of PWH because of potential concerns around confidentiality of patients' HIV status [78], it may not be suitable to use this approach with HIV registries. As the majority of identified studies were cross-sectional, future research should look at further longitudinal analyses to help elucidate the impact of ART and HIV on individuals' quality of life and the nature of how HSUVs in PWH change over time.

As already stated, one major reason for the finding that few studies provided HSUVs in line with NICE's recommendations for informing cost-effectiveness models [16] was that the study populations of PWH in this review were largely unrepresentative of the UK population. A considerable number of studies were conducted in countries that could be considered as culturally and possibly economically diverse from the UK. It has been shown that regional cultural and economic considerations potentially influence country-specific value sets [79]. This highlights why HTA agencies have a preference for their own country-specific value set. This also explains why many utility values were Grade 3 in this analysis as the NICE preferred value set was not used, emphasising the need for appropriate selection of value sets for specific HTA agencies. The extent to which regional and cultural factors are fully represented within country-specific value sets, and their influence on estimated HSUVs, due to either preference-based measure internal or external factors, should be areas for future research.

Additionally, utility measures and/or preference weights were not always those endorsed by NICE [20]. In some instances, binary ratings were assigned for study quality and appropriateness of HSUV data. Using this approach provides transparency and demonstrates rigour in the assessment process compared with a method of upgrading or downgrading decisions. Analysts can undertake subsequent grading using adapted criteria relevant to a chosen reimbursement agency to identify the most appropriate for their purposes.

Extensive heterogeneity was noted in cross-sectional data. Likely sources of clearly recognisable heterogeneity in the available evidence could be explained by the choice of measure and value set used [80]. It has been shown that the utilities of health states have considerable variation between countries, with an analysis of six EQ-5D-5L value sets demonstrating a median difference of 0.315 in health states between the countries with the highest and lowest index [81]. Differences were also seen when analysing changes from one health state to another, with some countries valuing the change in different directions. For example, a change from a health state of 4 (severe problems) in all five dimensions of the EQ-5D-5L to 5 (extreme problems) in three dimensions and 1 (no problems) in two dimensions was seen as an improvement in the Netherlands and as worsening in Uruguay [81]. This represents approximately one-third variation in values. Therefore, potentially different interpretation of health state changes highlights the importance of choosing an appropriate value set to avoid any inappropriate HTA decisions. Less recognisable heterogeneity may have been due to participant selection and confounding biases. As a result, reported estimates, which are primarily descriptive in nature, may have limited comparability. It also remains unclear whether a calibration of available estimates to approximate improvements or decrements in HRQoL would be a viable approach.

Managing heterogeneity in economic models can be challenging. Accounting for heterogeneity in standard cohort Markov models is difficult to achieve other than through stratification. By comparison, patient-level models are better able to account for heterogeneity; however, for patient-level models, integration of predictive functions to predict HSUs dependent on baseline patient characteristics are better suited than average HSUVs across a sample as identified by our review. Development of such predictive functions, for example, as associated with 'utility mapping functions', and integration within cost-effectiveness models has occurred but is still an area for further research.

It should also be noted that current evidence suggests that women, aging populations and those with comorbidities are frequently under-represented in clinical trials of ARTs in PWH [82, 83]. This is also likely to be the case for studies of newer ARTs and, therefore, capturing the quality of life experiences in these subgroups needs to be carefully considered in CEAs to address equity concerns. The development of standardised datasets for these population groups would be of benefit for future research.

As indicated by our findings, the landscape for available estimates is broad, diverse, and provides a spectrum of HSUVs for potential utilisation. Researchers and decision makers could benefit from more clarity on treatment regimens, preference-weighting methods, and the clinical stage of HIV in future studies to help interpret and select the best HSUVs for cost-effectiveness models. Future research should also focus on how HSUVs may be adapted/adjusted to fit any given HTA agency's criteria to ensure studies can provide relevant information even if the most appropriate PBM or value set has not been used.

Limitations

While the scope of this review was extensive, allowing a broad range of evidence to be assessed, the substantial heterogeneity identified meant that a meta-analysis of the data, even using a random-effects model, was not appropriate, which restricted further analysis of reported HSUVs. Furthermore, the best value set in the absence of country-specific preferences was not explored. The use of vignettes and proxy studies, which could represent different or alternative HSUV estimations, were not included in the search terms meaning that some studies may have been overlooked. However, as vignette and proxy approaches are generally not preferred by HTA agencies internationally who require these HSUVs for use in cost-effectiveness models [20, 23], it is unlikely that this exclusion had a substantial impact on our results. Findings indicated variations in methodologies and populations; therefore, caution should be exercised when using these findings for decision-analytic economic modelling. Many studies had limited and unclear reporting on health states, such as treatment-naïve or HIV stage, meaning that authors' descriptions were accepted. Therefore, more objective classification evidence should be provided in studies reporting HSUVs to ensure that reported utilities reflect the relevant health state. Additionally, owing to a limited number of studies reporting on specific HIV populations, we did not conduct any subgroup analyses by these PWH populations. The date limit for searching, applied to retrieve newer ARTs and see the change in HRQoL and mortality outcomes over time, may have missed studies with relevant health states not related to a specific treatment regimen; additionally, included papers may not have captured all available evidence, especially for new treatments that may not be widely used in clinical settings. Caution should be used when interpreting results from studies published nearer the start of the search period owing to the potential for these datasets to no longer represent the current state of HIV management. Lastly, the extent and intent of publication bias remains unknown as a formal assessment of this type of bias was not feasible.

Conclusions

This systematic literature review demonstrates that there is a large volume of HSUVs reported from 'moderate'- to 'high'-quality studies across a wide geographic range and health states. However, such HSUVs are not necessarily appropriate for every decision-analytic model dependent on the intention of the model and associated required evidence to inform a given decision problem. Therefore, HSUVs must be carefully selected and interpreted for use in economic evaluations of ARTs and other relevant interventions. Considering the impact of reporting and methodological approaches in utility estimations, greater clarity is required in future studies to help interpret and select the best HSUVs for cost-effectiveness models, and researchers should be encouraged to adhere to relevant guidelines when conducting studies reporting HSUVs in PWH. Despite this, our compendium and taxonomy of HSUVs provides a range of detailed information to inform an appropriate choice of HSUVs that can subsequently be used to inform ART economic modelling within relevant populations and different jurisdictions.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s11136-025-03966-3.

Acknowledgements The review team would like to thank Dr Katy Cooper and Professor John Brazier for their advice during the development of the review proposal. Editorial support (in the form of writing assistance, including development of the initial draft based on author direction, assembling tables and figures, collating authors' comments, draft revisions based on author feedback, grammatical editing, and referencing) was provided by Rachel West of Fishawack Indicia Ltd, part of Avalere Health, and was funded by ViiV Healthcare.

Author contributions The authors meet criteria for authorship as recommended by the International Committee of Medical Journal Editors and contributed to the writing and reviewing of the manuscript and have given final approval for the version to be published. All authors had full access to the data in this study and take complete responsibility for the integrity of the data and accuracy of the data analysis.

Funding The systemic literature review (SLR) informing this submission was commissioned by ViiV Healthcare (ScHARR Project ID: 1533). ViiV Healthcare provided guidance and input to the design and conduct of the SLR and reviewed, commented on, and edited the drafts and final version of the manuscript.

Data availability All data are available in the manuscript and supplementary material.

Declarations

Competing interests Ian Jacob and Christina Donatti are employees of ViiV Healthcare and hold financial equities in GSK. Edith Poku, Matthew Franklin, Emma Simpson, and Louise Falzon have no conflicts of interest to declare.

Ethical approval As this was a systematic literature review no ethics approval was required.

Consent for participation Not applicable.

Consent for publication Not applicable.

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