

SYSTEMATIC REVIEW OF PATIENT-REPORTED OUTCOME MEASURES USED IN CLINICAL TRIALS OF HIV-INFECTED ADULTS ON COMBINATION ANTIRETROVIRAL THERAPY

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BACKGROUND

- New combined antiretroviral therapy (cART) regimens are highly effective in achieving viral suppression and reducing HIV-related morbidity and mortality.¹
- Given similar drug efficacy, patient factors are increasingly considered when selecting cART.
- Patient-reported outcome measures (PROMs) are a growing focus in recent HIV clinical trials.²

Objective: To identify PROMs reported in clinical trials on cART, and the health domains that are captured.

MATERIALS AND METHODS

Databases: PubMed, Embase, PsycInfo, and CINAHL.

Date limits: January 2015 to January 2020.

Inclusion criteria: Clinical trials testing cART in adults living with HIV, reporting results of at least one PROM at any timepoint.

PROM mapping: Items from each PROM were individually mapped to the Wilson & Cleary (W&C) health-related quality of life (HRQOL)³ framework.



RESULTS

- 36 trials were included from a total of 3,774 records
- 18 PROMs identified, 17 mapped to W&C*
- 15/36 (42%) trials had PROMs as primary outcome

Frequently reported PROMs

HIV-specific PROMs (n=6)	W&C domains	Number of articles
HIV Treatment Satisfaction Questionnaire (HIV-TSQ)	FS, GHP	18/36
Medical Outcomes Study-HIV Questionnaire (MOS-HIV)	FS, GHP, QOL	6/36
Generic PROMs (n=12)		
Short Form Survey (SF)	FS, GHP	12/36
European Quality of Life-5 dimensions (EQ-5D)	FS, GHP	7/36
Depression Anxiety Stress Scale 21-item (DASS-21)	FS, QOL	3/36
Center for Epidemiological Studies-Depression (CES-D)	FS, QOL	2/36

*The PROQOL-HIV questionnaire is not in the public domain and could not be included in the synthesis

Domains and subdomains captured by 18 PROMs

Functional status (n=15)

- Physical function
- Work productivity
- Cognitive function
- Psychological function

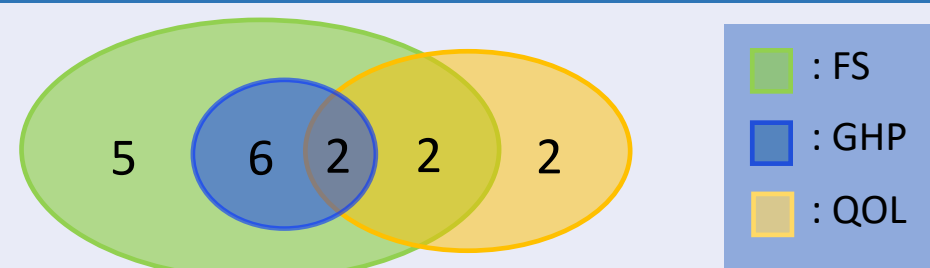
General health perceptions (n=8)

- Perceived health status
- Perceived efficacy of HIV treatment on health
- Overall treatment satisfaction

Quality of life (n=6)

- Perceived value of life
- Enjoyment of life

Number of PROMs mapped to each W&C domain



CONCLUSIONS

- PROMs measuring quality of life are fewer compared to those measuring functional status and general health perceptions in HIV clinical trials.
- Consensus on single most appropriate PROMs for different HRQOL domains and subdomains in HIV clinical trials is needed.
- PROMs covering all domains of HRQOL are rare but highly valuable when making patient-centered clinical decisions about cART.

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