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

<table>
<thead>
<tr>
<th>HIV-specific PROMs (n=6)</th>
<th>W&amp;C domains</th>
<th>Number of articles</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV Treatment Satisfaction Questionnaire (HIV-TSQ)</td>
<td>FS, GHP</td>
<td>18/36</td>
</tr>
<tr>
<td>Medical Outcomes Study-HIV Questionnaire (MOS-HIV)</td>
<td>FS, GHP, QOL</td>
<td>6/36</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Generic PROMs (n=12)</th>
<th>W&amp;C domains</th>
<th>Number of articles</th>
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<tbody>
<tr>
<td>Short Form Survey (SF)</td>
<td>FS, GHP</td>
<td>12/36</td>
</tr>
<tr>
<td>European Quality of Life-5 dimensions (EQ-5D)</td>
<td>FS, GHP</td>
<td>7/36</td>
</tr>
<tr>
<td>Depression Anxiety Stress Scale 21-item (DASS-21)</td>
<td>FS, QOL</td>
<td>3/36</td>
</tr>
<tr>
<td>Center for Epidemiological Studies-Depression (CES-D)</td>
<td>FS, QOL</td>
<td>2/36</td>
</tr>
</tbody>
</table>

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

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.

REFERENCES


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