

## 1 Appendix

Studies applying PRO instruments in TB	Study Type	Country
Adeyeye et al 2014 (Adeyeye et al., 2014)	cross-sectional	Nigeria
Aggarwal et al 2013 (Aggarwal et al., 2013)	longitudinal	India
Atif et al 2014 (Atif et al., 2014b)	cross-sectional	Malaysia
Atif et al 2014 (Atif et al., 2014a)	longitudinal	Malaysia
Atif et al 2013 (Atif et al., 2013)	cross-sectional	Malaysia
Awaisu et al 2012 (Awaisu et al., 2012)	cross-sectional	Malaysia
Babikako et al 2010 (Babikako et al., 2010)	cross-sectional	Uganda
Balgude et al 2012 (Balgude and Sontakke, 2012)	longitudinal	India
Bauer et al 2013 (Bauer et al., 2013)	systematic Review	NA
Chamla 2004 (Chamla, 2004)	longitudinal	China
Chung et al 2012 (Chung et al., 2012)	longitudinal	Taiwan

<b>Corless et al 2009 (Corless et al., 2009)</b>	<b>cross-sectional</b>	<b>South Africa</b>
<b>Dhingra and Rajpal 2005 (Dhingra and Rajpal, 2005)</b>	<b>longitudinal</b>	<b>India</b>
<b>Dhuria et al 2009 (Dhuria et al., 2009)</b>	<b>longitudinal</b>	<b>India</b>
<b>Dion et al 2004 (Dion et al., 2004)</b>	<b>cross-sectional</b>	<b>Canada</b>
<b>Dujaili et al 2015 (Dujaili et al., 2015)</b>	<b>longitudinal</b>	<b>Iraq</b>
<b>Guo et al 2009 (Guo et al., 2009)</b>	<b>systematic review</b>	<b>NA</b>
<b>Guo et al 2008 (Guo N, 2008)</b>	<b>cross-sectional</b>	<b>Canada</b>
<b>Husain et al 2008 (Husain MO, 2008)</b>	<b>cross-sectional</b>	<b>Pakistan</b>
<b>Issa et al 2009 (Bauer et al., 2013)</b>	<b>cross-sectional</b>	<b>Nigeria</b>
<b>Kittikraisak et al 2012 (Kittikraisak et al., 2012)</b>	<b>cross-sectional</b>	<b>Thailand</b>
<b>Kruijshaar et al 2010 (Kruijshaar et al., 2010)</b>	<b>longitudinal</b>	<b>UK</b>
<b>Louw et al 2012 (Louw et al., 2012)</b>	<b>cross-sectional</b>	<b>South Africa</b>
<b>Maguire et al 2009 (Maguire et al., 2009)</b>	<b>longitudinal</b>	<b>Indonesia</b>

<b>Mamani et al 2014 (Mamani et al., 2014)</b>	<b>longitudinal</b>	<b>Western Iran</b>
<b>Marra et al 2008 (Marra et al., 2008)</b>	<b>longitudinal</b>	<b>Canada</b>
<b>Masumoto et al 2014 (Masumoto et al., 2014)</b>	<b>cross-sectional</b>	<b>Philippines</b>
<b>McInerney et al 2007 (McInerney et al., 2007)</b>	<b>cross-sectional</b>	<b>South Africa</b>
<b>Muniyandi et al 2007 (Muniyandi et al., 2007)</b>	<b>cross-sectional</b>	<b>India</b>
<b>Naidoo and Mwaba 2010 (Naidoo and Mwaba, 2010)</b>	<b>qualitative</b>	<b>South Africa</b>
<b>Othman et al 2011 (Othman, 2011)</b>	<b>cross-sectional</b>	<b>Yemen</b>
<b>Pasipanodya et al 2007 (Pasipanodya et al., 2007a)</b>	<b>cross-sectional</b>	<b>USA</b>
<b>Pasipanodya et al 2007 B (Pasipanodya et al., 2007b)</b>	<b>cross-sectional</b>	<b>USA</b>
<b>Peltzer et al 2013 (Peltzer et al., 2013)</b>	<b>cross-sectional</b>	<b>South Africa</b>
<b>Peltzer et al 2012 (Peltzer K, 2012)</b>	<b>cross-sectional</b>	<b>South Africa</b>
<b>Rajeswari et al 2005 (Rajeswari et al., 2005)</b>	<b>longitudinal</b>	<b>India</b>

Ralph et al 2013 (Ralph et al., 2013)	longitudinal	Indonesia
Yin et al 2012 (Yin et al., 2012)	cross-sectional	China

2 Table 1 lists all studies included in the development of study design.

PRO measures applied in assessment of HRQOL	Number of single studies identified	Countries
Short-Form-36 (SF-36)	18	Uganda, Canada, China, South Africa, UK, India, Western Iran, Malaysia, USA, India
World Health Organization's Quality of Life - BREF (WHOQOL-BREF)	5	India, Taiwan, Nigeria
EuroQoL (EQ-5D)	4	Canada, UK, Thailand, Malaysia
Beck Depression Inventory (BDI)	4	South Africa, Turkey, Canada
Kessler-10	4	South Africa, Ethiopia
St. George's Respiratory Questionnaire (SGRQ)	4	USA, Indonesia
Standard Gamble (SG)	3	Canada, UK, Turkey
Visual Analogue Scale (VAS)	3	Canada, Thailand
General Health Questionnaire 12 (GHQ-12)	2	Turkey, Nigeria
Mood Adjective Check List Short Form (MACL)	2	Sweden
Severe Respiratory Insufficiency Questionnaire (SRI)	2	Spain, Germany
SF-6D utility score	2	Canada

<b>Sickness Impact Profile (SIP)</b>	2	Sweden
<b>State-Trait Anxiety Inventory</b> <b>Short Form (STAI-6)</b>	2	UK, Turkey
<b>Center for Epidemiologic Studies</b> <b>Depression Scale (CES-D)</b>	2	UK, USA
<b>Duke Health Profile (DUKE)</b>	2	Colombia, Philippines
<b>DR-12</b>	2	India, Yemen
<b>Hospital Anxiety and Depression</b> <b>Scale (HADS)</b>	1	Pakistan
<b>Short-Form 12 (SF-12)</b>	1	South Africa
<b>Beck Depression Inventory (BDI)</b> <b>Short Form</b>	1	South Africa
<b>Brief Disability Questionnaire</b> <b>(BDQ)</b>	1	Turkey
<b>Dysfunctional Analysis</b> <b>Questionnaire (DAQ)</b>	1	India
<b>Health Utilities Index 2 (HUI 2)</b>	1	Canada
<b>Health Utilities Index 3 (HUI 3)</b>	1	Canada
<b>Life Satisfaction Index Z</b>	1	China
<b>Mental Health Index (MHI-5)</b>	1	USA
<b>Modified Version of SF-36</b>	1	India
<b>Modified St. Georges</b> <b>Respiratory Questionnaire</b>	1	Indonesia
<b>Present State Examination (PSE)</b>	1	Nigeria
<b>Rosenberg Self-Esteem Scale</b> <b>(RSE)</b>	1	South Africa
<b>Self-Rating Anxiety Scale (SAS)</b>	1	China
<b>Sheehan Disability Scale (SDS)</b>	1	China

<b>Social Support Rating Scale (SSRS)</b>	1	China
<b>Symptoms Check List (SCL-90)</b>	1	China
<b>Voice Handicap Index-10 (VHI-10)</b>	1	Turkey
<b>Quality of Life Questionnaire (QLQ)</b>	1	Turkey
<b>Short-Form 8 (SF-8)</b>	1	Philippines
<b>Medical Research Council (MRC) dyspnea scale</b>	1	Philippines
<b>Primary Care PTSD screen</b>	1	South Africa
<b>World Health Organization's Quality of Life - HIV (WHOQOL-HIV)</b>	1	Ethiopia
<b>The Functional Assessment of Chronic Illness Therapy-Tuberculosis (FACIT-TB)</b>	1	Iraq
<b>Illness Perception Questionnaire (IPQ)</b>	1	Pakistan
<b>Patient Health Questionnaire (PHQ-9)</b>	1	Nigeria

3 Table 2 lists all HRQOL measures identified and extracted from studies included

<b>PRO measures applied in adherence assessment</b>	<b>Number of studies</b>	<b>Country</b>
<b>Morisky Medication Adherence Scale (MMAS)</b>	2	South Africa
<b>Perceived Nonadherence Scale (ACTG)</b>	1	South Africa

<b>TB medication adherence scale (TBMAS)</b>	<b>1</b>	<b>China</b>
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4 Table 3 lists all adherence measures identified and extracted from published studies included.

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<b>PRO HRQOL measures</b>	<b>Pathology/Disease</b>
<b>Baseline and Transition Dyspnea Indexes (BDI-TDI)</b>	Pulmonary Disease, Chronic Obstructive ,Respiratory Tract Diseases
<b>Clinical COPD Questionnaire (CCQ)</b>	Pulmonary Disease, Chronic Obstructive ,Respiratory Tract Diseases
<b>Chronic Respiratory Disease Questionnaire Self-Administered Standardized (CRQ-SAS)</b>	Pulmonary Disease, Chronic Obstructive ,Respiratory Tract Diseases
<b>Inhaled Corticosteroid Questionnaire (ICQ)</b>	Pulmonary Disease, Chronic Obstructive ,Respiratory Tract Diseases
<b>St George's Respiratory Questionnaire (SGRQ)</b>	Pulmonary Disease, Chronic Obstructive ,Respiratory Tract Diseases
<b>Asthma Control Diary (ACD)</b>	Respiratory Tract Diseases
<b>Asthma Control Questionnaire (ACQ)</b>	Respiratory Tract Diseases
<b>Asthma Control Test (ACT)</b>	Respiratory Tract Diseases
<b>Asthma Quality of Life Questionnaire (AQLQ)</b>	Respiratory Tract Diseases
<b>Community-Acquired Pneumonia Symptom questionnaire (CAP-Sym)</b>	Respiratory Tract Diseases
<b>EORTC Quality of Life Questionnaire - Lung Cancer Module (EORTC-QLQ LC13)</b>	Respiratory Tract Diseases
<b>Geriatric Depression Scale (GDS)</b>	Psychiatry/Psychology
<b>Hospital Anxiety and Depression scale (HADS)</b>	Psychiatry/Psychology
<b>Inventory of Depressive Symptomatology (IDS-SR and IDS-C)</b>	Psychiatry/Psychology
<b>Montgomery-Asberg Depression Rating Scale</b>	Psychiatry/Psychology

(MADRS)	
Quick Inventory of Depressive Symptomatology	Psychiatry/Psychology
(QIDS-SR and QIDS-C)	
Quality of Life in Depression Scale (QLDS)	Psychiatry/Psychology

Table 4 presents 17 instruments for HRQOL assessment in the indications pulmonary, respiratory and psychological diseases and linguistically validated for English in South Africa, accessed from PROQOLID database.

### **Description of Selected HRQOL and Adherence PROMs**

The following section provides a description of the PROMs applied to evaluate HRQOL and medication adherence in TB. Information was derived from PROQOLID database (PROQOLID) for EQ-5D, SF-12v2, SGRQ and HADS and from the developer of MMAS Prof Morisky for the MMAS instrument.

#### ***EQ-5D-5L (provided through EuroQol)***

EQ-5D (Euroqol) assesses health outcomes and is widely used as a utility index for estimating QALYs in cost-effectiveness studies. EQ-5D comprises 5 domains/items

- Mobility
- Self-care
- Usual activities
- Pain/discomfort
- Anxiety/depression

and one vertical visual analogue scale (VAS 20 cm). Each item allows five levels of severity of response ranging from 'no problems' to 'extreme problems'. Higher scores indicate better HRQOL. The VAS records the respondent's self-rated health on a 20 cm vertical, visual analogue scale with endpoints labelled 'the best health you can imagine' and 'the worst health you can imagine'. This information is used as quantitative measure of health as judged by the individual respondents. Index-based values (utilities) are calculated from EQ-5D-5L by deriving values from country-specific value sets. Such value-sets for EQ-5D-5L are currently under development. A crosswalk between the 5L and 3L of EQ-5D is available for 10 countries, including Zimbabwe as only African country. Value sets for South Africa are not available for any version of EQ-5D. The completion time for EQ-5D takes a few minutes. Reliability, validity and ability to detect change are approved (PROQOLID) A minimal important difference (MID) for EQ-5D-3L is approved with Mean MID = 0.074 (range - 0.011 - 0.140) and MID = 7 for VAS scores (Walters, 2005).

#### ***Short-Form 12 (SF-12) (Author Ware John E, provided through Quality Metrics)***

SF-12 is an abbreviated version of SF-36 containing 12 items over 8 domains:

- Physical functioning (PF) with 2 items
- Role physical (RP) with 2 items
- Bodily pain (BP) with 1 item



- General health (GH) with 1 item
- Vitality (VT) with 1 item
- Social functioning (SF) with 1 item
- Role emotional (RE) with 2 items
- Mental health (MH) with 2 items

Domains can be aggregated into composite summary scores for physical and mental state, referred to as Physical Component Score (PCS-12) and Mental Component Score (MCS-12). PCS-12 includes PF, RP, BP, and GH domains, MCS-12 include VT, SF, RE and MH domains. Scoring ranges from 0 to 100; greater scores represent better HRQOL. The completion time for SF-12v2 is 2 minutes. Reliability, validity and ability to detect change are approved (PROQOLID). A minimal important difference for SF-12v2 is not defined; however a minimum meaningful difference for SF-36 is mentioned as > 3 point change (Maruish, 2009). SF-36 and SF-12v2 are comparable in their outcomes and a minimum meaningful difference of > 3 points can be considered for SF-12v2 (Maruish ME, 2009).

***St. George's Respiratory Questionnaire (SGRQ) (Author Jones Paul W, provided through The St. George's University of London Medical School)***

A disease-specific instrument designed to assess patients with respiratory tract diseases and immune system diseases, especially asthma, pulmonary diseases, and chronic obstructive disease. SGRQ comprises 50 items over 3 domains (symptoms, activity, and impacts on daily life) over two parts. Part I covers symptoms (several scales) and Part II covers activity and impacts on daily life (dichotomous true/false) except the last question (4-point Likert scale). The Symptom Component Score is calculated from questions 1-8, the Activity Component Score is calculated from questions 11 and 15, and the Impacts Component Score is calculated from questions 9-10, 12-14, and 16-17. Scores are scaled from 0 to 100, with higher scores indicating worse HRQOL. The completion time for SGRQ is 10 minutes. Reliability, validity and ability to detect change are approved (PROQOLID). A minimal important difference (MID) for SGRQ is defined as improvement of 4 points on the separate domains and the total score (Jones, 2005).

***Hospital Anxiety and Depression Scale (HADS) (Authors Snaith RP and Zigmond AS, provided through GL Assessment)***

HADS is an instrument applied in psychology/psychiatry to detect states of anxiety and depression. HADS comprises 14 items over 2 dimensions

- Anxiety with 7 items
- Depression with 7 items

Scores for each item range from 0 to 3, with higher scores indicating worse HRQOL (i.e. more anxiety and depression). The anxiety subscale scoring ranges from 0-21 (8-10 mild anxiety, 11-14 moderate anxiety, 15-21 severe anxiety). The completion time for HADS is 2-5 minutes. Reliability, validity and ability to detect change are approved (PROQOLID). A minimal important difference (MID) for HADS has not been evaluated. A MID was observed for COPD with a value of 1.5 points corresponding to a change from baseline of 20% and informed by both anchor- and distribution-based methods (Puhan et al., 2008).

### ***Morisky Medication Adherence Scale (MMAS-8) (Author Morisky DE)***

MMAS-8 is being used in the assessment of self reported medication taking behaviour (Morisky, 2008a; Krousel-Wood, 2009; Morisky and DiMatteo, 2011). The scale is a generic measure assessing long-term chronic and infectious medical regimens, such as high blood pressure, diabetes, tuberculosis, HIV, elevated serum lipids, osteoporosis, immunosuppressant medication. It is a reliable and valid indicator to assess self reported medication-taking behaviour, including several levels of criterion related validity (blood pressure control, HgA1c) discriminant validity (social desirability) and persistence using pharmacy fills as a criterion. MMAS has a high sensitivity of 93% to identify low adherence and is a simple scale to identify and monitor adherence (Morisky, 2008b). The MMAS-8 scale ranges from 0 to 8.0; total scores are interpreted in the following way:

- Low adherence <6.0
- Medium adherence 6.0 – 8.0
- High adherence =8.0

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