

# Health-Related Quality of Life among Patients with Depression: A Systematic Review of Measure Development and Properties

Nkporbu AK1,2\*, Ogaji DS1,3 and Nduka EC4

<sup>1</sup>Department of Public Health, University of Port Harcourt, Nigeria

<sup>2</sup>Department of Mental Health, University of Port Harcourt, Nigeria

<sup>3</sup>African Centre for Public Health and Toxicological Research, University of Port Harcourt, Nigeria

<sup>4</sup>Department of Mathematics Statistics, University of Port Harcourt, Nigeria

#### Abstract

**Background:** An increasing number of measures are being developed for assessing Health-Related Quality of Life (HRQOL) of patients with depression. The high level of variability of these measures and their suitability for practice settings in developing countries remain a concern.

**Aim:** A systematic review of the development, contents and measurement properties of available measures for HRQOL among patients with depression.

Design: A systematic review.

**Data sources:** Systematic search for worldwide published literature from PubMed, MEDLINE, CINAHL Plus, EMBASE, and PsycINFO databases were conducted.

**Study eligibility criteria:** Studies included in this review reported the development and validation of measures for health-related quality of patients with depression.

**Data extraction:** Data was extracted with a template prepared in accordance with the review objectives. Template had article identifier, setting, context, developmental processes, contents (domains, items, and scales), potential utility, psychometric and measurement properties (reliability, validity, and acceptability) were extracted, and narrative reports were presented.

**Findings:** The review found 20 studies reporting 6 different measures for the evaluation of HRQOL of patients with depression. Three (50%) of these questionnaires were developed in the USA and the remaining from Brazil, Sweden and Norway. No measure had been developed or validated in the continent of Africa. The majority were published after 1990 (83%), contained between 20 to 40 core items (44%) which were developed inductively (85%). The most reported measurement index was the Cronbach's alpha (74%) with only one study reporting positive predictive value and testretest reliability. The domains of 78% of these measures can potentially be used to evaluate major depression.

**Conclusion:** The wholesome transfer and use of measures developed for HRQOL of depressed patients across cultural and practice setting may pose enormous difficulties if not locally validated.

The limited application of some pf the existing measures in the Nigerian practice setting provides a justification for the validation of the most adjudged appropriate measure to affirm its measurement properties in this locality.

Keywords: Health-Related Quality of life; HRQOL; Depression; Measures; Questionnaires; Nigeria

# Introduction

Depression is a common mental disorder with an estimated prevalence of 11% and about 322 million people currently suffering from the disease globally [1]. Depression is recognized as a global public health concern [2], the second leading contributor to the global burden of disease and projected to be first by the year 2030 (Centers for Disease Control and Prevention, 2011) [3].

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#### \*Correspondence:

Nkporbu AK, Department of Public Health, University of Port Harcourt,

Nigeria,

E-mail: nakpigi2008@yahoo.com
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In Nigeria, the prevalence of depression has continued to have a steady rise. Population-based surveys indicate that the lifetime prevalence of depression ranges from 10% to 15% [4]. In a study conducted in western Nigeria more than a decade an ago using an interviewer-administered structured questionnaire, and the General Health Questionnaire (GHQ 12) as a screening tool, the overall prevalence of depression was found to be 5.2% [5]. In another study done in 2009, the lifetime prevalence of major depression was 3.1% while that of 12-month prevalence was 1.1% [6]. Other studies conducted in Nigeria have reported the prevalence of depression among young adults, elderly and IDPs as 25%, 26.2% and 28.6% respectively [6-10]. In another study, 7 million people currently suffer from depression in Nigeria, with a 12-month prevalence rate of 3.9% [11]. In a recent cross-sectional study among students in northern Nigeria, the prevalence of depression was 58.2%, with 37.0%, 15.7%, 3.9%, and 1.6% having mild, moderate, moderately severe, and severe depression, respectively [6].

Major identified risk factors for depression include genetic predisposition, vulnerable personality traits, environmental factors like enduring difficulties, family and marital disharmony, losses, poverty, unemployment, chronic medical conditions and prolonged stress [12-16].

Depression negatively affects the cognition, emotion, behavior, functionality and quality of life of people [17]. It is also associated with poor outcome, increased utilization of health-care resources and ultimately impacts negatively on the health systems of nations [18]. Poor quality of life results in high rates of relapse, inability to perform occupational and social activities, impaired outlook, and increased overall health care related costs [19].

Several programmers', health and strategies have been introduced to tackle the rising prevalence of depression in Nigeria. These include integrating the initial care of depression into the Primary Health Care (PHC) being a signatory to the global mGAP program as well as increased public mental health awareness. In addition, several non-governmental organizations have equally joined in advocacy and creation of awareness for depression and its deadly consequence, suicide. Finally, an effort by the Nigerian federal legislators to get the mental health bill passed is underway. This bill if passed into law will redefine public perception for mental disorders including depression and increase access to mental health treatment facilities among others [20].

People with severe mental illnesses are more vulnerable to have a diminished health-related quality of life, and depression takes a higher proportion [21,22]. Thus, the nature of symptoms (loss of interest, depressed mood, lack of interest for pleasurable activities, low self-esteem, psychomotor retardation and others) and its comorbid illnesses together with the social, occupational and cognitive impairments significantly affect the quality of life of people with depression [23]. Due to their high vulnerability, perceived quality of life of patients with depression may be significantly low on all eight dimensions of health-related quality of life. Depression impairs an individual's functioning ability in several ways [19,24]. It has a significant effect not only on mental well-being but also on perceived physical functioning and bodily pain, and even on general health perceptions.

Health-Related Quality of Life (HRQOL) is defined as "individuals' perceptions of their position in the context of the culture and value systems they live and in relation to their goals, expectations,

standards and concerns" [25]. It is a broad ranging concept incorporating the persons' physical health, psychological state, and level of independence, social relationships, and their relationships to silent features of the environment.

Current evidence shows that the quality of life of people with depression is highly impaired in both the developed and developing nations [26,27]. Age of patients, age of onset of depression, medication non-adherence, comorbid illness, poor social support, perceived stigma of their depressive status and family history of depression have been observed to have a statistically significant association with health-related quality of life of people with depression [28-31].

The poor health-related quality of life among people with depression again can increase the vulnerability for medical complications such as chronic heart disease, diabetes mellitus and hypertension due to the immunity compromisation effects of stress related to poor quality of life [32,33]. Perhaps, for this reason some studies have looked at the quality of life among patients with different medical conditions such as hypertension, diabetes, HIV, arthritis, cancer, tuberculosis with comorbid depression. Here again, the focus of these research is usually on the role depression plays in the quality of life of the sufferers. The outcome of this is a further introduction of variability with the various measures as it may be difficult to clearly isolate the impact of the depression alone on HRQOL from the other medical conditions. Hence, the need to adapt and validate a depression-specific health related quality of life study instrument.

Several measures have been developed in different clinical settings to measure the health-related quality of life of people with depression. Some were developed through inductive method, deductive method, while others utilized mixed methods. However, such tools have not been comprehensive enough as many only assess areas that qualify as components of health-related quality of life [34]. They include the Oslo Social Support Scale used to measure the social support level, Morrisky Green Levine Medication Adherence Scale used to evaluate psychotropic medication adherence level of people with depression, the Jacoby Stigma Scale to assess perceived stigma [25,35-38]. These could be incorporated into a single health-related quality of life measure.

With the current emphasis on patient-centered health care and the increasing demand for accountability in health care delivery, research measures for health-related quality of life must take into cognizance and make attempt to address the basic concerns of the patients (Skevington et al, 2001). This has become important especially as patients' evaluation of health care quality now focuses more on their health status (Staniszewska, 1999).

It is further believed that measures of health status need to take both the concept of disease as well as the patients feeling of illness into consideration [39]. The patient's rather than the professionals' feeling is of greater importance in contemporary assessment of health status. This is particularly so in chronic medical conditions like depression, where symptom response or survival rates are no longer enough, rather emphasis is now on health status and whether it is more or less likely to lead to an outcome of a life worth living in social, psychological as well as physical terms [40].

Patients Reported Outcome Measures (PROMs) differ from patients reported experience measures [41]. While the latter deals with the patience view of the quality of healthcare and efficiency of delivery, the former is concern with the actual reported health status

of patients. According to US-FDA (2009) [42], a Patient Reported Outcome (PRO) is any report of the status of a patient's health condition that comes directly from the patient, without any form of interpretation of the patient's response by a clinician or anyone else. PROs typically include information about Health-Related Quality of Life (HRQOL), symptoms, function, satisfaction with care or symptoms, adherence to prescribed medications or other therapy, and perceived value of treatment [43]. PRO data are used to inform and guide patient-centered care, clinical decision-making, and health policy decisions and are an important component in learning healthcare systems [44].

The emergence and use of different measures with varied psychometric properties may explain the wide variation in HRQOL outcomes of patients with depression from both developed and developing nations [45,46]. This worrisome trend provides a justification for the determination of the psychometric properties and standardization of measures of HRQOL used in different cultural practice and setting.

Despite the severe and incapacitating consequences of depression, no measurement tool for assessing HRQOL of people from the disease had been validated for use in Nigeria. This has made the implementation of patients reported outcome measures in routine clinical practice most challenging. Closing this gap will require the determination of the dimensionality, acceptability, validity and reliability of measures currently used to assess HRQOL of people with depression. The purpose of this study therefore is to systematically review available measures of HRQOL of depressed patients as part of an overall goal of validating the most appropriate measure for the Nigerian practice setting.

The review attempted to answer questions about the available measures for assessing HRQOL of patients with depression, their development, content and measurement properties as well as their appropriateness in the Nigerian practice setting?

# **Methods**

This study is a systematic review and a systematic search for worldwide published literature from PubMed, Medline, CINAHL Plus, EMBASE, and PsycINFO databases were conducted. This was supplemented by a manual search of retrieved references. Data extracted with the template prepared in accordance with the review objectives included. Article identifier, setting, context, developmental processes, contents (domains, items and scales), potential utility, psychometric and measurement properties (reliability, validity, and acceptability).

## Study eligibility criteria

Studies included in this review reported the development and validation of measures for health-related quality of life among patients with depression, all study designs among adults aged between 15 years and 60 years who have been diagnosed with major depression were included. While there was no time restriction, only studies published in English language were included. Item generations were categorized as induction, deductive or mix, while the setting of development was either primary or secondary or tertiary healthcare facilities.

A short score-base evaluation protocol was used to determine appropriateness of the measures to the Nigerian practice setting base on established recommendations (Van Campen et al, 1995; Terwee et al, 2007). The psychometric properties were rated as 3 (= good)

if it was within acceptable values, or 2 (= intermediate) where good number of the criteria were satisfied or rated as 1 (= poor) where values varied substantially from the normal values and do not satisfy good number of the criteria, or?? Was used where = no information on the psychometric property of the measure was available in any of the published article.

# Additional criteria that were considered included

- a. If the contents of the questionnaire were patient based. Here the key approaches for generating items were reviewed to ascertain if patients were involved in the process. Essentially, questionnaires considered as truly patient-based derived the majority of their contents from patients.
- b. If use of the questionnaire constitutes a high burden to the patients and administrators in a survey. Here the length of the questionnaire and the response pattern were considered. Shorter and closed ended questionnaires are often less burdensome to patients. This review used an arbitrary cut-off of more than 40 items in a questionnaire as being long and also examined the response patterns of ease for patients' use.
- c. If the questionnaire had been validated in Nigeria. Searches were done for published reports on their validation in the Nigerian PHC setting.
- d. If the questionnaire has been validated in sub-Saharan Africa. A similar approach like (c) above was done in the context of sub-Saharan Africa.

#### Search strategy

A Systematic search for worldwide published literature from PubMed, Medline, CINAHL Plus, EMBASE, and PsycINFO databases were conducted.

The following strategies were used to search:

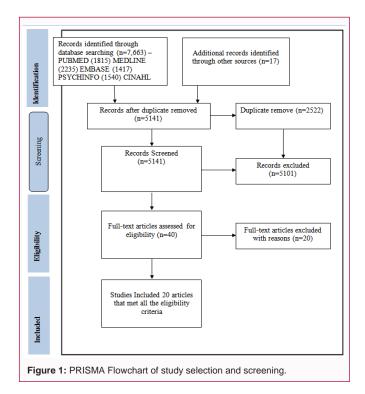
- 1. MeSH descriptor health related quality of life, this term only
- 2. MeSH descriptor patients with major depression, this term only
  - 3. MeSH descriptor tools, this term only
  - 4. MeSH descriptor questionnaire, this term only
  - 5. Quality of life
  - 6. Depression
  - 7. (#1 OR #2 OR #3 OR #4 OR #5 OR 6)
  - 8. MeSH descriptor methods, this term only
  - 9. MeSH descriptor measures, this term only
  - 10. (#7 OR #8)
  - 11. (#6 AND #9)

Language restrictions were applied to retrieve only studies published in English language.

The reference lists and citations of all included studies were reviewed. Where possible, authors of included studies were contacted and consulted about additional published and unpublished studies.

# Data collection and analysis

Firstly, the titles and abstracts of studies identified from the



search were independently reviewed by two authors. Secondly, the full text of each study deemed possibly relevant was retrieved and independently reviewed by two authors.

# Data extraction and management

Two reviewers independently extracted data using the developed data extraction forms. Information was collected on participants (age, sex, instrument used, psychometric properties, outcome measures (description of measures used, timing of administration, continuous/dichotomous nature, references provided), and results (point estimates and measures of variability, frequency counts for dichotomous variables, number of patients).

# Assessment of risk of bias in included studies

Two review authors independently assessed the risk of bias of each included study against key criteria: Incomplete outcome data; selective outcome reporting; and other sources of bias, in accordance with methods recommended by the PRISMA checklist [47]. The following judgments were used: low risk, moderate risk, high risk, or unclear (either lack of information or uncertainty over the potential for bias). Reviewers resolved disagreements by consensus, and a third reviewer was consulted to resolve disagreements where necessary.

# Results

A total of 7,663 titles were identified during the systematic search: PubMed-1815, MEDLINE-2235, EMBASE-1417, PSYCHINFO-1540, CINAH-639 and Other Sources-17 making a total of 7,663 articles identified from the search (Figure 1). After the initial rapid screening, 5141 abstracts were retrieved for more screening but only 40 full studies were retrieved for detailed assessment. Majority were later excluded because they did not describe the development of a questionnaire for HRQOL among patients with depression or they described the development and/or validation of a questionnaire for patient evaluation of HRQOL but not specifically among patients with depression.

There were 20 studies that met all the criteria for inclusion. Table 1 presents data on the development and key findings from the empirical studies (Table 2, 3).

#### **Discussion**

The review followed the PRISMA statement [48] and essentially adopted a narrative approach to provide answers to the following review questions: (a) which settings and contexts were HRQOL measures for depressed patients developed? (b) What processes were involved in the development of these measures? (c) What are the contents of these measures? (d) What are the reported measurement properties of these questionnaires?

This review was equally important as a valid and reliable measurement of health-related quality of life often reflects, not only the health status of the populace but also the quality of healthcare service as well as the functionality of the health system and policy. HRQOL is a multi-domain concept that represents the patient's perception of the effect of illness and treatment on physical, psychological, and social aspects of life. An inadequate conceptual framework therefore can affect the grouping and scoring of items into domains and can also affect the analysis and interpretation of PRO scores [48].

The review found 20 studies using different 6 measures developed for the evaluation of health-related quality of life of patients with depression globally. Three (50%) of these questionnaires were developed in the USA and the remaining in countries of Northern Europe (30%) and South America (20%). None of the measures was developed or validated in the continent of Africa. The publication pattern shows the increasing interest as well as the variability in the development of questionnaire evaluation of health-related quality of life of patients with depression. In most of the publications, the authors show increasing need to involve patients in the evaluation of health care satisfaction.

Measures for evaluation of health-related quality of life of patients with depression were mostly developed in tertiary health care setting and in developed countries. Until recently, most countries are yet to integrate mental health into PHC [49]; hence it could not serve as appropriate setting for developing a measure for mental health. This observation is again not surprising as the legitimacy and interest in patient's views on their health status mirror political developments, and the level of modernization of the society. In many developing countries, periodic self-assessment of health is rarely done. This underscores the desire to actualize study process that influence development of questionnaires to suit specific contexts and the periodic revalidation of existing ones to make them relevant to the current patients and practice requirements.

Many of the questionnaires used extensive processes that involved item generation as against patient's evaluation in their development. Also, most measures from developed countries depended more on theoretical assumptions for item. In this regards, patients' needs, expectations and culture played less prominent roles in the [50] generation of items. There is evidence that items generated through theory-based approach are consistent with professionally defined construct and often supported by conceptual models., the inductive item generation as a paradigm is influenced by current ideology of driving quality improvements more through the actual needs of patients rather than their presumed needs or technically defined criteria. It looks alright to expect truly patient-based measures to field items that are relevant to the needs of the patients and also

Table 1: Overview of included studies.

AUTHORs	TOPIC	METHODOLOGY	MEASURE	FINDINGS	STUDY DESIGN	SAMPLE SIZE	RISK OF BIAS	
Pyne et al. [40]	Assessment of the quality of life of patients with major depression	Medical Centre and surrounding area were compared using a variety of measures, including the Quality of Well -Being (QWB) scale, the Hamilton rating Scale for Depression, and the Beck Depression Inventory	QWB	The severity of depressive symptoms was inversely related to quality of life as measured by the QWB, independent of the variables that were controlled for. The QWB is sensitive to symptoms of depression among patients diagnosed with major depression.	Cross- sectional study	100	High	
Elliot et al. [67]	Chronic Pain, Depression, and Quality of Life: Correlations and Predictive Value of the SF-36	The Medical Outcomes Study short-form general health survey-36, known as SF-36 was the instrument used in measuring the HRQOL of the patients	SF-36	Chronic pain patients with major depressive disorder had a significantly lower Mental Composite Score t-score than those with minor or no depression—34.1 and 47.6, respectively (P < 0.001). The positive predictive value of the SF- 36 for differentiating major depression from minor or no depression was 98% (sensitivity = 84.4%, specificity = 93.9%).	Cross- sectional study	242	Low	
Rapaport et al. [69]	Quality-of-Life Impairment in Depressive and Anxiety Disorders	The short form of the Quality- of-Life Enjoyment and Satisfaction Questionnaire was completed by the subjects before treatment in every study.	SF-36	Subjects with affective or anxiety disorders who enter clinical trials have significant quality-of-life impairment, although the degree of dysfunction varies	Cross- sectional study	307	Low	
Grotmol et al. [70]	Depression - a major contributor to poor quality of life in patients with advanced cancer.	. QoL was measured using the Global Health/ QoL sub-scale from the European Organisation for Research and Treatment of Cancer Quality of Life Core Questionnaire (EORTC-QLQ-C30)	EORTC- QLQ-C30	. Our findings emphasize the importance of managing depression to achieve the best possible QoL for these patients.	Cross- sectional study	563	Low	
Sobocki et al. [71]	Health-Related Quality of Life Measured with EQ- 5D in Patients Treated for Depression in Primary Care	Health-related quality of life (HRQL) with the EQ-5D instrument	EQ-5D	Depression has a substantial impact on HRQL	Think aloud Cross- sectional study	447	Low	
Lima et al. [72]	Quality of life, diagnosis, and treatment of patients with major depression: a prospective cohort study in primary care	Several evaluation instruments were used, including the World Health Organization Quality of Life and the Quality of Life—		In relation to quality of life, there were significant differences especially between baseline and after nine months in almost all measures.	Cross- sectional study	179	Moderate	
Shafipour [73]	A survey of the quality of life in patients undergoing hemodialysis and its association with depression, anxiety and stress	Data collection was performed over three months using three questionnaires of demographic characteristics, DASS-21 and quality of life (SF-36)	SF-36	According to the results of this study, increased depression, anxiety and stress could reduce QOL in hemodialysis patients	Cross- sectional study	160	Unclear	
Hajbaghery et al. [74]	Health Related Quality of Life, Depression, Anxiety and Stress in Patients with Beta-Thalassemia Major	Data collection instrument consisted of three parts including: demographic questions, SF-36 questionnaire and depression, anxiety, and stress scale (DAS-21)	SF-36	This study showed that β-TM patients experienced a considerable decrease both in their overall QoL and in its dimensions	Cross- sectional study	173	Moderate	
Helvik et al. [75]	Health-related quality of life in older depressed psychogeriatric patients	. HQoL was measured using the EuroQol Group's EQ-5D Index and a visual analog scale (EQ-VAS)	EQ-5D	Older hospital patients with depression who experienced remission one year after admission gained HQoL and their HQoL was comparable with the HQoL in a reference group of older adults without depression when adjusting for differences in socio-demographics and health conditions.	Think aloud Cross- sectional study	160	Unclear	
Talukder et al. [76]	Major depressive disorder in different age groups and quality of life	(WHOQOL-BREF)	WHOQOL	The study revealed that young people were mostly depressed, and their quality of life was decreasing	Cross- sectional study	65	High	

Mantovani et al. [77]	DEPRESSION AND QUALITY OF LIFE IN HYPERTENSIVE ADULTS	(SF-36)	SF-36	it can be inferred that depression had a negative impact on the QoL of the patients investigated.	Descriptive Study	387	Low
Vyas et al. [78]	Impact of Depression Treatment on Health- Related Quality of Life among Adults with Cancer and Depression	(SF-12)	SF-12	Despite treatment for depression, HRQoL did not improve during the measurement timeframe	Cross- sectional study	450	Low
Kumar et al. [79]	Depression and its Association with Quality of Life in Female Patients at Different Hormonal Phases of Life – A Cross Sectional Study in Western U.P	(WHOQOL-BREF)	WHOQOL	Depression has shown to significantly influence the quality of life in these subjects.	Descriptive Study	60	High
Shumye et al. [80]	Health related quality of life and its correlates among people with depression attending outpatient department in Ethiopia: a cross sectional study	WHOQOL-BRFE	WHOQOL	This study revealed that nearly half of study participants scored below the mean score in each domain of health-related quality of life	Cross- sectional study	394	Low
Tarhani et al. [81]	Uncertainty, anxiety, depression and the quality of life in patients with cancer	WHOQOL-BREF	WHOQOL	According to the results, patients had a high level of uncertainty in illness and their quality of life was at a medium level	Observational Analytic	163	High
Dantchev et al. [82]	health-related quality of life in depressed patients: 6-month results from the French cohort of finder study	(SF36, EQ-5D)	SF-36	We observed that patients experiencing a moderate/severe pain at baseline had worse outcomes on QoL and depression response than those with mild or not pain at baseline.	Descriptive study	606	Low
Enkoyee et al. [83]	Quality Of Life and Associated Factors among Patients with Major Depression on follow up at Amanuel Mental Specialized Hospital, Addis Ababa, Ethiopia	WHOQOL-BREF	WHOQOL	The mean score QOL in each domain was lower compared to other studies, and nearly half the participants are below the mean score QOL.	Descriptive study	502	Low

better suited for measuring improvements in patient health status. Understandably, the latter approach would require more extensive development process to ensure that the final questionnaire has good measurement properties.

The development of patients' self-report questionnaires most often follows the application of an iterative procedure underpinned by sound scientific methodology. The involvement of the patients during the development process remains critical for a true patient self-report questionnaire [51]. Questionnaire development may adopt extensive processes with greater patient participation or shorter processes that rely more on experts view and literature [52]. Each phase in the development of the questionnaire may require different samples from the population where questionnaire would be used. The iterative development often follows three sequential and coherent stages-item generation (from inductive, deductive or a combination), questionnaire refinement (pilots, content validation, translation) and validation (determination of the acceptability, reliability and validity) [53-55].

The lengths of questionnaires in this review are varied with 80% of them fielding 30 core items or less. It is important that questionnaires are expected to contain adequate sample of items that are relevant [56] and representative of the constructs to be measured. The length of the questionnaire can also be a trade-off between ease of administration and questionnaires' validity because longer questionnaires have higher validity and internal consistency, but patients are more favorably disposed to completing shorter questionnaires without necessarily getting fatigued. Furthermore, survey administrators can easily administer and manage surveys with shorter length of questionnaire [57]. The above considerations notwithstanding,

decisions on the length questionnaire should consider the context and characteristics of potential respondents to assure the validity of questionnaire surveys (Fitzpatric et al, 1998) [41].

The floor and ceiling effects are important measurement properties which were reported in 13% of studies. There are tendencies for extreme response bias in which respondents preferentially endorse the endpoints of a questionnaire. The finding of low floor and ceiling effects is not only indicative of the acceptability and discriminative properties of the questionnaires but is also additional evidence to support the content validity and reliability of the questionnaire [34,58].

The commonest measurement property reported was the internal consistency as 83.3% of studies reported the value of the Cronbach's alpha. The Internal consistency which estimates the overall degree of relatedness of all items in a scale and so is related to the number of items, standard deviation of observed score and the sample size. The Cronbach's alpha is considered an adequate measure for internal consistency and most of the alpha values reported for domains and entire questionnaire were within the recommended ranges of 0.7 to 0.9. It is important to note that the value of the Cronbach's alpha is not fixed but varies with the context and population studied. This means that the internal consistency of the questionnaire should be determined for every defined population and context. Aside internal consistency, the reproducibility of the questionnaire which demonstrates its stability with repeated measurements is another form of reliability assessment. The observation from this review that only one study determined the test-retest reliability index and this reflects the reluctance of researchers to undertake such assessment. One reason for this may be the threat of bias as patient experience or

Table 2: Development and validation of measures.

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Author(s)	Place of	Setting of	Instrument	Method of	Domains of measure	Instrument	Stages of	Cronback	Predictive	Content	Test-retest
	Development	Development Development		Development	Domains of measure	item number	Development	Alpha	validity	Validity	reliability
Pyne et al. [40]	San Diego, California, USA	Tertiary health care	QWB	Inductive	QoL	4	IG, SD, SE	0.86		Poor	
Elliot et al. [69]	North Central USA	Tertiary health care	SF-36	Inductive	General Health, Social activities, Physical health, Emotional Health.	36	IG, SD, SE	0.77- 0.9	Sensitivity = 84.4% Specificity = 9.39%	Good	0.65
Grotmol et al. [70]	Oslo, Norway	Tertiary health care	EORTC- QLQ-C30	Inductive	Physical health, social activities, Emotional health.	30	IG, SD	0.83		Poor	?
Sobocki et al. [71]	Stockholm, Sweden	Tertiary health care	EQ-SD	Inductive	Mobility, Self-care, Usual activities, Pain/Discomfort, Anxiety/depression	26	IG, SD			Good	?
Lima et al. [72]	Porto Alegre, Brazil	Primary health care	WHOQOL	Inductive	Social, physical, psychological, environmental.	34	IG, SD, SE	0.83	Sensitivity=88% Specificity=94% Predictive value=99%	Good	?
Vyas et al. [78]	Kingston, Rhode Island, USA	Tertiary health care	SF-12	Deductive	Social activities, Physical health, Emotional health.	12	IG, SD, SE	0.84		Good	?

Key: IG: Item Generation; SD: Scale Development; SE: Scale Evaluation

Table 3: Evaluation of appropriateness of measures to the Nigerian practice setting.

Questionnaire	Content validity	Internal consistency	Construct validity	Reproducibility		Responsiveness	Floor or ceiling effect	Interpretability	Feasibility in large population	Previous use in Nigeria	Total Score
				Agreement	Reliability						
QWB	2	2	1	2	2	2	1	2	2	3	19
SF - 36	3	2	2	2	2	3	2	3	2	3	20
FORT	2	1	1	1	2	2	1	2	1	??	13
EQ-SD	2	1	1	1	2	2	1	2	1	??	13
WHOQOL	3	3	2	2	3	3	2	3	3	3	27
SF – 12	2	2	2	2	2	3	3	3	3	3	25

Rating: 3: Positive; 2: Intermediate; -1: Poor; ??: No information available

satisfaction changes with time and event.

The finding of excellent performance of the WHOQOL-Bref when evaluated against other measures for their applicability in the Nigerian practice setting was consistent with earlier comparison where the WHOQOL was reported to have good concurrent validity, greater comprehensiveness and good responsiveness to clinical change in comparison with the SF-36 (Skevington et al, 2001).

# **Implication for Global Practices**

HRQOL captures an individual's or a group's perceived mental and physical health over time reflects the patient's report of the way a disease or its treatment affects physical, emotional and social wellbeing [43]. HRQOL is now considered an important prognostic indicator of mental illness progress following intervention. This needs to be integrated in the clinical evaluation, monitoring and intervention measures of people with severe mental illness including depression [25].

Patients with depression and their relatives increasingly expect improvements not only in their symptoms, but beyond that, they also expect improvements of their functioning and quality of life [58,60]. There is also a growing consensus that successful treatment of depression should not only target symptom severity, but also impairment in functioning and QOL which will lead to a better restoration of health [61,62]. The scope of treatment of people with depression, therefore, extends to the patients' subjective feelings of wellbeing, satisfaction, functioning and impairment beyond the traditional symptoms reductions approaches [61,63]. As a result, measurement of health-related quality of life has become a major area of research interest; however, this interest has succeeded in a multiplicity of measures with resultant variable outcomes.

After a conceptual framework is hypothesized, it should be adjusted based on patient input. The instruments measuring the domains within the conceptual framework are then tested for reliability, validity, and ability to detect change. Only after this testing is complete are the instrument content, scoring, procedures, formats and training materials finalized and ready for full use in the research environment. Because the development of an instrument is an iterative process, after data are collected, analyzed, and interpreted, the instrument may be further modified and the cycle repeated (US FDA, 2009) [42]. Therefore, adherence to recommended guideline for questionnaire development is pertinent especially when dealing with latent or subjective psychological constructs like patient experience or satisfaction as evidenced in depression. It is equally important to ensure the use of questionnaires that are reliable (producing consistent results); valid (measuring what it is supposed to) and show transferability (measure the same construct when applied to different patient groups) when measuring such latent constructs.

There had been multiplicity of studies on assessing or examining health related quality of life among depressive patients conducted without the use of valid and reliable measure. Different studies adopt different methods and measures, but the World Health Organization Quality of Life Instrument appear to be most used in many studies assessing health-related quality of life among depressive patients [64]. The poor adoption of a common measurement tool may be indicative of many of the measures being devoid of ease of usability, lack of internal consistency, while some may lack the needed validity.

While a modest body of research has been conducted in a highly selected group, but there is limited research that adopted a common measurement tool for health-related quality of life for patients with depression. With the further plethora of confounding factors that can

affect health related quality of life such as age of patients, onset of depression, medication non-adherence, comorbid illness, and poor social support, perceived stigma of their depressive status and family history of depression [36,65], it is unclear whether most of conducted studies adequately measure all the important aspects of health-related quality of life. Given the degree of functional impairment, level of social devastation and the high economic impact of depression, the hidden burden and the possibly economic impact of workplace productivity, this issue deserves further investigation. The clinical benefits derivable from health-related quality of life for monitoring as an improvement indicator in patients' conditions are not commonly utilized.

This review showed the wide variability of measures used to assess the quality of life of people with depression and thus helped easy integration of a bio-psycho-social view in the holistic treatment approaches of depression [33,66].

# **Implications of the Findings for the Nigerian Practice Setting**

There were two important observations related to the Nigerian practice setting. First was the absence of any questionnaire developed and/or validated for the Nigerian practice setting. Secondly, none of the identified questionnaire as well demonstrated satisfactory results for all stated criteria used to evaluate their appropriateness for the Nigerian context. The questions of whether to jettison existing questionnaires and embark on the development of a new one for the Nigerian setting do not have a straightforward answer. Clearly, the benefits of verifying the applicability and appropriateness of available questionnaires before commencing work on the development of a new questionnaire are obvious as this will save time and resources. The minimum requirements for a success in this regard, could be the assurance of the content validity, construct validity and the reliability of the new measures.

An additional requirement in the Nigerian context would be the forward and backward translation of these measures and the validation of the translated questionnaire. This is so because 38% of women and 21% of men, especially those living in the northern parts of Nigeria and in rural areas have no formal education. Other setbacks which should be considered before the decision for adaptation or validation of questionnaires across socio-cultural and practice settings include the difficulty resolving semantic issues across [67]. The option of validating existing questionnaire for studies in Nigeria appear to be most feasible; this review therefore had provided data on those questionnaires that are most appropriate for the Nigerian practice setting.

## **Limitations of the Review**

There are a number of limitations of the methods and findings of this review. Firstly, only explicitly reported data were extracted from the included articles. While this was done to prevent misrepresentation, it is not an exhausted approach as some procedures would have been done without actual statement credited to them. Also, repositories of institutions like the World Health Organization which may contain English or non-English instrument for patient evaluation were not included in the search for published questionnaires for evaluation of HRQOL for patients with depression. Finally, the assessment of the individual studies did not extend to a critical appraisal of the strength of their methodologies or their performances on measurement indices documented in this review.

## **Conclusion**

This review on the development, content and measurement properties of published questionnaires for evaluating HRQOL for patients with depression showed none of the six existing questionnaires developed or previously validated in Nigeria or Africa. Whilst there are options for the adaptation of an existing or development of an original questionnaire, the limited applications of existing questionnaires in Nigeria presents a justification for the validation of the most appropriate measure for the Nigerian practice setting.

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