# DEPRESSION AND ITS ASSOCIATION WITH DISEASE ACTIVITY AND QUALITY OF LIFE IN PATIENTS WITH RHEUMATOID ARTHRITIS AT THE KENYATTA NATIONAL HOSPITAL.

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A dissertation submitted in part fulfillment of the degree of Master of Medicine, Internal Medicine.

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## DECLARATION

This research dissertation is my original work and has been presented as a prerequisite for a Master's degree to the Department of Clinical Medicine and Therapeutics, University of Nairobi, Kenya. It has not been presented for any other degree to any other University.

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# LIST OF ACRONYMS AND ABBREVIATIONS

ACR: American College of Rheumatology

BMI: Body Mass Index

CDAI: Clinical Disease Activity Index

CI: Confidence Interval

CORRONA: Consortium of Rheumatology Researchers of North America

CRP: C-Reactive Protein

DAS28: Disease activity score in 28 joints

DMARDs: Disease Modifying Anti-Rheumatic Drugs

EGA: Evaluator (or Physician) Global assessment of disease activity

ESR: Erythrocyte Sedimentation Rate

HAQ: Health Assessment Questionnaire

HR: Hazard Ratio

mHAQ: Modified Health Assessment Questionnaire

IPW: Inverse Probability Weight

KNH- Kenyatta National Hospital

LDA: Low Disease Activity

MDD: Major Depressive Disorder

MTX: Methotrexate

OR: Odds Ratio

PI- Principal Investigator

PGA: Patient Global Assessment of Disease Activity

PS: Propensity Score

RA: Rheumatoid Arthritis

SJC: Swollen Joint Count

TJC: Tender Joint Count

VAS: Visual Analogue Scale

QC- Quality Control

UoN- University of Nairobi

# ABSTRACT


## Background

Rheumatoid arthritis severity can range from self-limiting disease to severe destruction and systemic complications. RA affects patients physically, psychologically and socially. Patients experience pain, joint swelling, stiffness, functional limitations and fatigue and overall poor quality of life. In addition, they report anxiety and depressive symptoms and concerns about increased physical limitations. Experiencing psychological distress may inflate the subjective severity of patient-reported symptoms such as pain and tenderness. Furthermore, patients experience a loss of independence and restrictions in participation, i.e. a decrease in socializing which may in turn propagate symptoms of depression. An accurate description of the

relationship between depression, disease severity and quality of life is necessary for our setting. If an interaction exists then there is a group of vulnerable patients who could benefit from earlier identification of depression and the impact their disease has on Health Related Quality of Life (HRQoL) and appropriate management provided.

## Objective

To determine the prevalence of depression and the relationship between depression, disease activity and quality of life in ambulatory patients with Rheumatoid Arthritis at the Kenyatta National Hospital.

## Methods

A descriptive-cross sectional study carried out at The Rheumatology clinic at The Kenyatta National Hospital. The study population included ambulatory patients with a diagnosis of rheumatoid arthritis who are above the age of 14 years. The Physical Health Questionnaire-9 (PHQ-9), Short Form-36 (SF-36) and Clinical Disease Activity Index form (CDAI) were used to asses for depression and quality of life and severity of disease respectively. Statistical associations of patients' characteristics, co-morbid depression and HRQoL scores were analyzed using Chi-square test. Factors associated with HRQoL and CDAI were analyzed using Pearson correlation or Spearman rank correlation.

## Results

A total of 74 patients with rheumatoid arthritis were studied. The prevalence of comorbid depression in patients with Rheumatoid Arthritis at the outpatient clinic in KNH using the PHQ-9 was 28.4%, of which 13.5% had mild depression, 9.5% had moderate depression and 5.4% had severe depression. The bulk of the patients had moderate to high disease activity (71.6%). The PHC and MHC summary scores were categorized as fair (49.1 and 57.2 respectively). The mean CDAI score for depressed group was 23.5(SD

14.3) compared to a lower mean score of 19.5 (SD 16.9) for those not depressed. Patients with poorer physical health quality of life scores were more likely to be depressed (p=0.041). Patients who had poorer energy scores, poorer emotional well-being scores and poorer social functioning scores were significantly more likely to be depressed.

**Conclusion**

In our study population of rheumatoid arthritis, the prevalence of depression is much higher than the prevalence of depression in global estimates. The bulk of the patients had moderate to high disease activity. Generally fair QoL scores were noted. Poorer disease severity scores were noted in the clinically depressed recruits than those not depressed. Poor QoL scores in the sub-types- emotional well being, social functioning and energy scores showed significant correlation to the presence of depression. Poor physical health scores were also found to be correlated to the presence of depression. Depression is a treatable disease and regular screening for undiagnosed depression may improve disease activity, symptoms of arthritis and quality of life in these patients.

# CHAPTER 1: INTRODUCTION

Rheumatoid arthritis (RA) is a chronic debilitating disease that affects approximately 0.5-1% of the world's population (1)and causes joint swelling and joint deformities which require chronic medical care. Depression in the general population causes significant distress and impairment in a person's social, occupational or educational functioning. It has been shown to affect 21.3% of women and 12.7% of men(2)(3). Depression is common in patients with chronic diseases, occurring in 13-42% of patients with rheumatoid arthritis and is associated with worse outcomes(4). Patients with rheumatoid arthritis and depression have increased health service utilization(5) and are less likely to be adherent to their medications(6). Co -morbid depression in rheumatoid arthritis has been found to be an independent risk factor for myocardial infarction(7), suicidal ideation and death (8)(9).

While functional limitation is a known contributor to depression in RA, it is also well known that demographic and socioeconomic factors such as sex, age, income, education, and health access are powerful determinants of health (10-12).

Studies done in our setting on rheumatoid arthritis(13,14) have provided significant data on demographics of the disease and disease activity measurement but none so far on co-relation with depression.

An accurate description of the relationship between depression, functional limitation and demographic factors for our setting is necessary.

# CHAPTER 2: REVIEW OF LITERATURE.

## Rheumatoid Arthritis and Depression.

Rheumatoid arthritis (RA) is a chronic autoimmune disorder that primarily affects joints with many patients developing progressive functional limitation and physical disability(15). Psychiatric comorbidity, particularly depression, is a significant problem in this population and is two to three times more common among RA patients when compared to the general population(16-18). The ramifications of depression in RA patients are numerous and far reaching and the effects of this condition on quality of life and indirect societal costs are immense. Depression exacerbates the unfavorable health outcomes of RA and is associated with higher mortality, an increased risk for myocardial infarction (MI), greater work disability, and elevated healthcare expenditures(19-21).

When occurring in the context of chronic physical illness, depression may lead to poorer outcomes when compared to the occurrence of either condition alone, and evidence suggests medical management frequently becomes difficult(22,23). The impact of depression is further compounded because depression is not adequately recognized in RA patients and up to 50% of all people do not receive the appropriate treatment for it(24-27).

The mechanisms and interactions of depression and RA disease progression are still relatively unclear. A study by Maes et al (28) posited that depression is an inflammatory condition, and thus may be pathologically linked to the etiological mechanisms in RA disease activity through pro-inflammatory cytokine pathways i.e. IL-6 and TNF-a (29). Evidence has demonstrated that major depression is accompanied by the activation of cell-mediated immunity. Meta-analyses of cross-sectional studies have consistently demonstrated positive correlations between various cytokines and the presence and severity of depression(30,31)

## Conceptual Framework

Researchers have posited the relationship between RA disease activity and depression to be bidirectional. This implies that RA disease activity has a temporal influence on longitudinal changes in depression, and vice versa, that depression has an effect on the prospective manifestation or perception of RA disease activity.

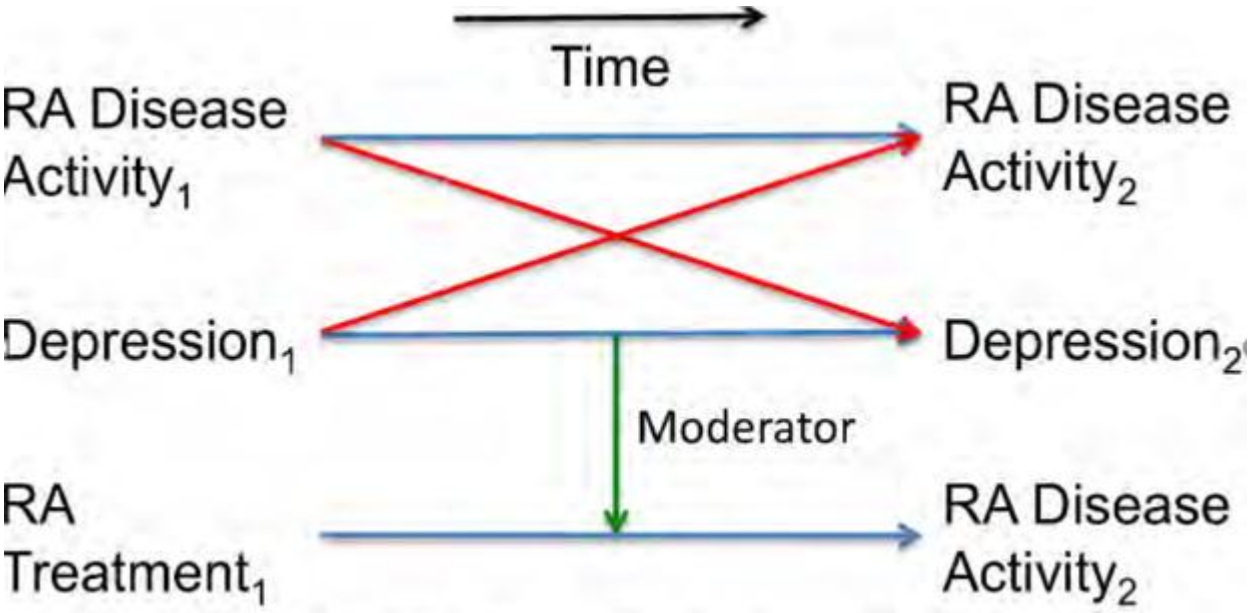



Figure 1: Conceptual framework for depression and its impact on RA disease activity and treatment.

Several studies have been done to show the prevalence of depression in patients with rheumatoid arthritis. A study by Katz(5) done in the USA in 1993 showed a prevalence of depression of 14 percent. Depressed individuals were less likely to be married and had longer duration of RA and other comorbidities. Depressive symptoms were consistently associated with negative health and functional outcomes, and, in most cases, with increased health services utilization.

A study by Margeretten(32) done in California, US in the year 2011 showed prevalence of comorbid depression in RA of 37% meeting criteria for moderate to severe depressive symptoms. Increased functional limitation remained significantly associated with increased depression scores. Also noted

was that a vulnerable population with functional limitations is at higher risk of developing depressive symptoms.

Nas, in 2011 studied 421 patients with RA recruited from a joint database of five tertiary centers in Turkey. Prevalence of depression was at 75 percent. Patients with higher risk for depression or anxiety had poorer quality of life compared to the patients without risk for depression. Depression and anxiety scores correlated with quality of life questionnaires with worsening in both disease specific and generic health related quality of life.

In a study by Mella(33) in 2010 in Brazil, the prevalence of depressive symptoms was of 53.2% in rheumatoid arthritis and 28.3% in osteoarthritis ($p = 0.005$). The prevalence of anxiety symptoms was of 48.4% in rheumatoid arthritis and 50.0% in osteoarthritis. Rheumatoid arthritis patients with depressive symptoms had lower education and higher disease activity and functional disability. Although these two rheumatic diseases are similar in terms of the pain and functional disability that they cause, a significantly higher prevalence of depressive symptoms was found in rheumatoid arthritis patients. This difference might be explained by the hypothesis of a neuroimmunobiological mechanism related to cytokines in inflammatory diseases, which has been considered as a candidate to the development of depressive symptoms.

## TABLE 1 – PREVALENCE OF DEPRESSION IN RHEUMATOID ARTHRITIS

| Study ID | Country | Criteria | Nature | Sample | Mean | Women | Prevalence |
|---|---|---|---|---|---|---|---|

| | | for detection of depression | of study | size | age (SD) years | (%) | of depression |
|---|---|---|---|---|---|---|---|
| Abdel-Nasser 1998 | Egypt | DSM III-R | Cross-sectional | 60 | 39.7 (10.9) | 80 | 23.3 |
| Katz 1994 | US | S-GDS | Cross-sectional | 726 | 60.4 | 77 | 14 |
| Margeretten 2011 | US | PHQ-9 | Cross-sectional | 466 | 54 (14) | 85 | 37 |
| Mella 2010 | Brazil | HADS | Cross-sectional | 62 | 51 (12.8) | 83.9 | 53.2 |
| Nas 2011 | Turkey | HADS | Cross-sectional | 421 | 50.1 | 82.9 | 75 |

## Detection of depression.

There are multiple methods available to detect depression. The gold standard method is psychiatric interview and diagnosis according to the Diagnostic and Statistical Manual (DSM) or International Classification of Diseases (ICD) criteria. Such interviews are however, time consuming and therefore often not ideal for examining patients in a busy hospital environment. Alternatively, self-report screening questionnaires, such as the Patient Health Questionnaire (PHQ) and the Hospital Anxiety and Depression Scale (HADS), may be used. These self-report tools are quick and easy to complete. They are often preferred by researchers attempting to collect a large amount of data from a large sample.

The PHQ-9 is a 9-question instrument used in patients in hospital settings to screen for the presence and severity of depression. The results of the PHQ-9 may be used to make a depression diagnosis according to DSM-IV criteria and ask about the patient's experience in the last 2 weeks. The PHQ-9 questionnaire is completed by the patient in minutes and help the clinician in rapid scoring. Scores range from 0 to 27. In general, a total of 10 or above is suggestive of the presence of depression. Full questionnaire available in Appendix- Table 9 and 10.

# TABLE 2 – DIAGNOSIS OF DEPRESSION WITH PHQ-9 SCORE

| PHQ-9 Score | Depression severity | Suggested intervention |
|---|---|---|
| 0-4 | None- minimal symptoms | None |
| 5-9 | Mild symptoms | Repeat PHQ-9 at follow-up |
| ≥10 | MAJOR DEPRESSION | |
| 10-14 | Depression- Mild | Make treatment plan, counselling, follow up +/- medical treatment |
| 15-19 | Depression- Moderate | Prescription drugs and counselling |
| 20-27 | Depression- Severe | Prescription drugs and counselling and refer to psychiatric specialist if no improvement. |

## Validity of PHQ-9 questionnaire

The diagnostic validity of PHQ-9 questionnaire was established in studies involving eight primary care and seven obstetrical clinics(34). Cronbach's alpha reliability of 0.89 and 0.86 among 3,000 primary care patients. The test-retest reliability was assessed by the correlation between PHQ-9 scores obtained from in-person and phone interviews with the same patients. The value of correlation obtained was 0.84.

In an assessment of construct validity, the correlation coefficient between the SF-20 mental health scale and the PHQ-9 was 0.73. PHQ-9 scores of ≥10 had a sensitivity of 88% and a specificity of 88% for major depressive disorder.(34)

The Behavioral Risk Factor Surveillance Survey (BRFSS), the National Health and Nutrition Examination Survey, the Medical Expenditure Panel Survey, the National Epidemiologic Survey on Alcohol and Related Conditions, and the Millennium Cohort Study used the PHQ-9 or a shortened form of it. The PHQ-9 is also the most commonly used depression measure in the United Kingdom's National Health Service, which requires providers to use a depression screening instrument when treating depression(35).

Studies have found that the PHQ-9 is also useful for screening for depression in psychiatric clinics(36). Studies have used the PHQ-9 to study patients with diabetes(37), chronic pain, arthritis, fibromyalgia, epilepsy, and substance abuse(38). The PHQ-9 questionnaire has been validated for use in our setting in a cohort of patients in Western Kenya with HIV)(39). It also is used in studies involving patients with physical disabilities as well as older adults, students, and adolescents(38). The PHQ-9 is available in over 30 languages(40) and it has been

validated for use in different ethnicities(38). Currently Pfizer owns the copyright of the PHQ-9, but allows it to be accessed for free(41).

## Disease activity and functional status assessment in rheumatoid arthritis patients.

Routine assessments of disease activity and functional status are a key part of high quality rheumatology care. Many tools can be used to monitor disease activity in rheumatoid arthritis.

For many years, the measurement of disease activity in RA has been done by Disease Activity Score-28 (i.e., DAS-28). DAS-28 is measured by assessing 28-tender-joint count (range 0–28), 28-swollen-joint count (range 0–28), Erythrocyte Sedimentation Rate (ESR) and general health on VAS scale (0–100 mm). DAS-28 is a continuous index ranging from 0 to 9.4, in which low disease activity as is defined as ≤3.2; moderate disease activity is defined as >3.2 to ≤5.1; high disease activity is defined as >5.1. A commonly used cutoff point for remission in DAS-28 is <2.6(42). A newer tool for evaluation of disease activity is Clinical Disease Activity Index (CDAI). Its disease activity index does not require an acute-phase reactant (40).

Clinical Disease Activity Index (CDAI) is a composite index for assessing disease activity. CDAI is based on the simple summation of the count of swollen/tender joint count of 28 joints along with patient and physician global assessment on VAS (0–10 cm) Scale for estimating disease activity [4]. The CDAI has range from 0 to 76. Clinical Disease Activity Index (CDAI) of the patients is performed by the following formula:

$$CDAI = TJC + SJC + PDGA + EDGA$$

where TJC is the Tender Joint Count, SJC is the Swollen Joint Count, PDGA is the Patient's Disease Global Assessment (VAS 0–10 cm), and EDGA is the Evaluator/Assessor's Disease Global Assessment (VAS 0–10 cm).

Validity of CDAI was determined by Aletaha et al(43) by studying its correlation with DAS28 and ACR response criteria. They also determined validity by correlation with HAQDI scores and outcomes of the disease, e.g. radiological progression [9]. The greater advantage associated with CDAI is its employment in evaluation of patients with RA independently of any calculating device and can be used repeatedly through the disease course. It can therefore be used everywhere and anytime for disease activity assessment in RA patients. Therefore, target for CDAI-categorized remission should be more beneficial to the patients in the terms of symptom control and disease morbidity. The merit of CDAI is obvious given its sheer simplicity for usage in clinical practice [4]. It was shown that the CDAI, a simple composite index obtained by numerical summation of four solely clinical variables, has a moderate-to-good correlation ($\kappa = 0.533$; $P < 0.0001$) with DAS-28 for disease activity assessment in RA patients(43).

A study was done by Ndirangu KM(14) at KNH to compare the congruence of the Disease Activity Score with 28-joint count (DAS-28) with the Simplified Disease Activity Index (SDAI) and the Clinical Disease Activity Index (CDAI) in measuring disease activity in Rheumatoid Arthritis (RA). It showed DAS28, SDAI and CDAI were significantly correlated with each other on a group level ($p < 0.001$). Internal consistency was highest for CDAI (alpha = 0.705) and lowest for DAS28 (alpha = 0.67). Kappa statistics revealed substantial degree of agreement with respect to controlled, active, moderate and high disease activity categories according to the three scores. It was concluded that both SDAI and CDAI proved to be in congruence with DAS28 in daily clinical routine. SDAI and CDAI were found to be more stringent in defining remission.

It is suggested that CDAI has good concordance with DAS-28 for disease activity assessment in Rheumatoid Arthritis patients. Also, CDAI is easy to use in day-to-day clinical practice without the need of any lab value or any calculator/computer device. Therefore, CDAI is a very useful disease activity assessment tool in daily clinical practice for RA patients(43).

## Rheumatoid Arthritis and Health Related Quality of Life.

The medical and economic consequences of arthritis are of great concern to researchers and clinicians. This disease also affects an individual's capacity to live a full and active life. It has increasingly become clear that the problems associated with arthritis are not simply medical ones but that the disease appears to have a substantial impact on a person's functional capacity and quality of life.(44)

There have been very few trials that collect quality of life related data. It has become clear that the perspective of the patient is a very critical variable. As a result, emphasis has shifted gradually toward evaluations of medical/health-related outcomes from the patient's perspective(45).

Such assessments potentially are of use to researchers, clinicians, administrators, and policy makers as they offer a profile of an individual's current state who is experiencing a particular illness or chronic disease. This provides additional information beyond that offered by traditional medical and clinical measures. It is valuable in helping to understand the wide variability in individual responses to similar conditions. HRQL measures are also valuable in evaluating the effects of treatment, and the cost effectiveness of treatments(45).

Because of the chronic debilitating nature of this disease, it seems particularly appropriate to measure HRQoL as it likely takes a considerable toll on HRQL. This makes the assessment of HRQL in

arthritis patients critical. This is because this chronic disease does not typically cause death, but has a substantial effect on fitness, health, and physical, emotional, and social functioning. Therefore, HRQL is likely to be a good indicator of both the global effects of arthritis on a patient's life, as well as the effects of treatment(46).

A study was done by Ozcetin et al(47) in West Indies to measure the effect of Depression and Anxiety on Quality of Life of Patients with Rheumatoid Arthritis, Knee Osteoarthritis (OA) and Fibromyalgia Syndrome (FMS). In all diagnostic groups, the scores of SF-36 subscales were significantly low in patients who scored above the threshold value of depression scale ($p < 0.001$). A strong negative correlation was detected between scores of anxiety scale and the scores of all SF-36 subscales in patients with RA. Quality of life is significantly low in patients with RA, knee OA and FMS, whose depression and/or anxiety scores are high. Therefore, these patients should be managed using a multidisciplinary approach including psychiatric support.

A study by Owino et al(13) in Ambulatory patients at KNH to determine Health Related Quality Of Life (HRQOL) profiles of patients with Rheumatoid Arthritis showed both physical and mental health HRQOL summary scores showed significant negative correlations with disease activity (DAS-28) scores ($p< 0.001$ for both) among the study patients. Physical component HRQOL ranged from poor to fair, while mental component HRQOL ranged from good to very good in the majority of patients. Severity of disease showed a strong negative association with HRQOL among the study patients, while DMARD therapy and adherence to drug treatment showed a positive association with HRQOL.

In a study by Esam et al(48) in Egypt found strong correlation between depression and anxiety on one hand and PCS and MCS on the other hand. They also found that patients with lower level of education had much higher level of depression than highly educated patients.

In a study by Mikuls(49) in 2003 whereby they examined the association of elderly onset rheumatoid arthritis (RA) with health related quality of life in a population based cohort of older women. The study showed that elderly onset RA was associated with a 6-fold risk (OR 6.0, 95% CI 3.6-10.1) of significant functional disability. Similarly, elderly onset RA was significantly associated with lower physical component scores of the Medical Outcome Study Short Form-12.

The SF-36 is the most widely used generic measure of health status(50). It defines HRQoL as the extent to which physical health impacts an individual's functional ability and perceived well-being in mental, social and physical aspects of life. The SF-36 can be self-administered or with the use of an interviewer. It can be completed in 5-10 minutes and has been applied to large populations in a number of countries and to patients with a variety of illnesses of all age groups. There are 36 questions in the SF-36, these items are grouped into 8 scales; physical functioning (PF), role-physical (RP), bodily pain (BP), general health (GH), vitality (VT), social functioning (SF), role emotional (RE) and mental health (MH). There are 2 summary measures which aggregate the 8 scales; Physical Health (PF, RP, BP, GH) and Mental Health (VT, SF, RE, MH). All but one of the 36 items are used to score the 8 SF-36 scales. Each item is used in scoring only one scale. These 8 scales were selected from the 40 used in the Medical Outcomes Study, those chosen were felt to represent the most frequently measured concepts in widely-used health surveys and those most affected by disease and treatment. The SF-36 scores are weighted sums of the questions in each section. Scores range from 0 - 100 Lower scores = more disability, higher scores = less disability. HRQOL scores are categorized as: 0-40 (poor), 41-60 (fair), 61-80 (good), 81-100 (very good). PC= Physical component; MC= Mental Component(50).

The SF-36 has been found to be a reliable and valid measure in RA(50)(51) and most widely used(52).

# STUDY JUSTIFICATION.

Depression affects 350 million people worldwide and the incidence is on the rise. It has been suggested that depression in RA is nearly three times that of the general population. Depression is a common comorbidity in rheumatoid arthritis (RA), yet it may not be adequately recognized during routine clinical care. Rheumatoid arthritis symptoms may confer a risk for depression, and vice versa; depression may affect RA disease activity and response to treatment. Treating depression can improve the patients' quality of life and even ease joint pain and inflammation. Also noted was that if depression in rheumatoid arthritis is not treated then the treatment of RA itself can be less effective.

Evidence suggests that functional capacity, and therefore QOL, in RA patients is influenced by disease activity, joint destruction, and psychosocial characteristics of each individual patient. Assessing patient-centered outcomes in RA has become a high priority for patients and providers, particularly in the light of newer and more effective treatment options aimed at maintaining good functional capacity. Assessment of HRQL provides a reliable way for rheumatologists and arthritis researchers to better understand the effect of rheumatoid arthritis on overall functioning and well-being. Such an understanding promises to influence the quality of care provided to arthritis patients.

We currently do not have local data on depression and quality of life in RA and such a study will provide such data.

# RESEARCH QUESTION

Is there any relationship between depression, disease activity and quality of life in patients with Rheumatoid arthritis?

# OBJECTIVE

## BROAD

To determine the prevalence of depression and the relationship between depression, disease activity and health related quality of life in ambulatory patients with Rheumatoid Arthritis at the Kenyatta National Hospital.

## PRIMARY OBJECTIVES

a) To determine the prevalence of depression using the PHQ-9 questionnaire, among patients with rheumatoid arthritis.
b) To determine the severity of depression among patients with rheumatoid arthritis.
c) To determine disease activity among patients with Rheumatoid Arthritis using the CDAI questionnaire.
d) To determine Health Related Quality of Life profiles using the SF-36 questionnaire in patients with rheumatoid.

## SECONDARY OBJECTIVE

a) To correlate depression with age, sex, duration of disease, disease activity and health related quality of life scores.

# CHAPTER 3: METHODS

## STUDY DESIGN

This was a hospital based descriptive cross-sectional study.

## STUDY SETTING

Kenyatta National Hospital (KNH) is a national referral and teaching hospital located within an urban environment in Nairobi. KNH does not have a designated ward for rheumatology patients, however there is a rheumatology clinic held once a week on Thursday afternoon which is operated by Rheumatologists and registrars in the department of clinical medicine and therapeutics. The study was carried out at the KNH Rheumatology Clinic.

## STUDY POPULATION

Adult patients who were above the age of 14 years with Rheumatoid arthritis as per The 2010 American College of Rheumatology (Table 11) attending the KNH Rheumatology clinic.

## CASE DEFINITION

**Rheumatoid Arthritis**

A patient with a documented diagnosis of Rheumatoid Arthritis in their medical records.

**Depression.**

A patient with a PHQ 9 score of 10 and above.

## SAMPLE SIZE ESTIMATION

Sample size calculation for finite population.

$$n = \frac{Nz^2pq}{E^2(N-1) + z^2pq}$$

$n$ = Desired sample size

$N$ = population size (number of rheumatoid arthritis patients currently seen at the rheumatology clinic at the Kenyatta National Hospital 125).

$Z$ = value from standard normal distribution corresponding to desired confidence level (Z=1.96 for 95% CI)

$p$ = The prevalence of depression in rheumatoid arthritis ranges from 14 to 42 percent. In a study by Katz done in the USA, the prevalence was calculated as 14%

$q = 1 - p$

$E$ = desired precision (0.05)

$$n = \frac{125\ x\ 1.96^2\ x\ 0.14\ x\ 0.86}{0.05^2(125-1) + (1.96^2\ x\ 0.14\ x\ 0.86)} = 74$$

A sample size of 74 patients was recruited for the study.

## PATIENT SELECTION

All patients who fulfilled the inclusion criteria.

## INCLUSION CRITERIA

- Patients with a file diagnosis of rheumatoid arthritis.

-Age equal to or above 14 years.

## EXCLUSION CRITERIA

Patients who did not consent to be part of the study.

Patients who were not able to speak either English or Kiswahili.

## SAMPLING TECHNIQUE

Consecutive sampling technique was utilized on the scheduled clinic days.

## SCREENING AND RECRUITMENT

The Principal Investigator and Study assistant reviewed the records of patients presenting at the rheumatology clinic.

Those patients with a file diagnosis of rheumatoid arthritis that conformed to the 2010 American college of Rheumatology were recruited.

The patients were identified and rapport established with them and their caretakers. Patients who agreed to participate in the study were asked to sign a written consent and thereafter enrolled in the study.

Specific information about age, duration of disease, employment status was obtained from the patients and their medical records. Patients that fulfilled the inclusion criteria were included in the

study. Each patient recruited in the study was requested to fill in the PHQ-9, SF-36 form with the assistance of the principal investigator or research assistant. The CDAI form was filled by the PI or research assistant after relevant history was taken and a focused physical exam was done.

## DEFINITION OF STUDY VARIABLES.

1) Age- number of years from documented or reported date of birth.
2) Sex- Male or Female.
3) Duration of rheumatoid arthritis- calculated based on date of diagnosis recorded in patient medical records.
4) Marital status- single, married, divorced, separated or widowed.
5) Level of education- No formal education, Primary level, Secondary level, Tertiary level education.
6) Depression- Evaluated using PHQ-9 sore
7) Severity of rheumatoid arthritis- Functional limitation evaluated using the CDAI score.
8) Severity of HRQOL scores- Evaluated using the SF-36 questionnaire.

## QUALITY ASSURANCE

The PHQ-9 and SF-36 are validated tools for the screening, diagnosis and assessing the severity of depression and Quality of life respectively. The CDAI is a validated tool for stratifying the severity of

rheumatoid arthritis. The research assistant was adequately trained to administer the PHQ-9 questionnaire, SF-36 questionnaire and CDAI questionnaires appropriately and in a consistent manner.

## DATA MANAGEMENT AND ANALYSIS

Completed forms were stored under lock and key by the PI in a secure location.

Data was coded, entered and managed in a password protected Microsoft Access 2013 database. A check to ensure the database and manual records was carried out to ensure accuracy.

Data was entered and analysed by the use of Statistical Package for Social Sciences version 21.

Continuous variables such as age were summarised as means and standard deviation while categorical variables such as gender, marital status and level of education were summarised as proportions.

Prevalence of co-morbid depression was calculated and presented as percentage with 95% confidence interval. Severity of depression was presented using percentages. The HRQOL scores and CDAI scores in the study patients were presented as means, standard deviation. Factors associated with depression were analysed using Chi- square tests. The statistical test was tested at 5% level of significance (p- value less than or equal to 0.05 were interpreted as significant). Relationships between two continuous variables, for example HRQOL and age, HRQOL and duration of illness, HRQOL and CDAI, were analyzed by Pearson correlation coefficients (where variables are normally distributed) or by Spearman rank correlation (where variables not normally distributed).

## ETHICAL CONSIDERATION.

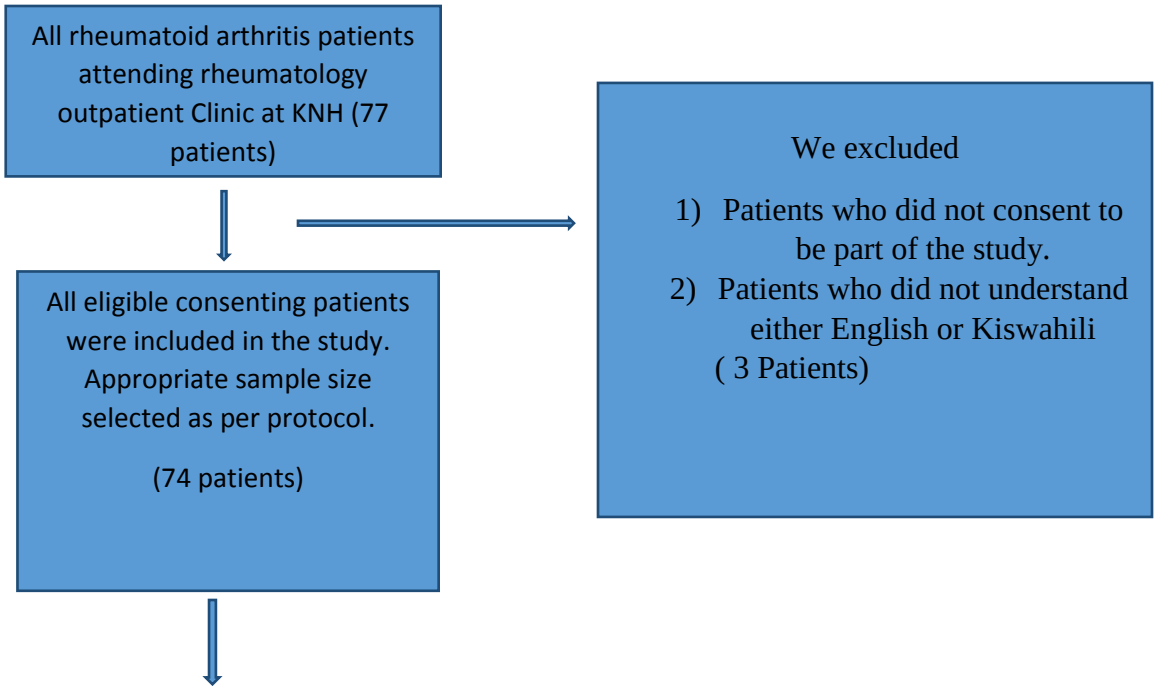
The proposal was presented to the Department of Internal Medicine and Therapeutics and permission to pursue the study was granted. Ethical approval was sought from the University of Nairobi/Kenyatta National Hospital Ethics, and Review Committee, Research approval number P221/03/2019. The study was clearly explained to potential participants in a language they could understand (English, Kiswahili). Strict confidentiality was maintained for all the data. We

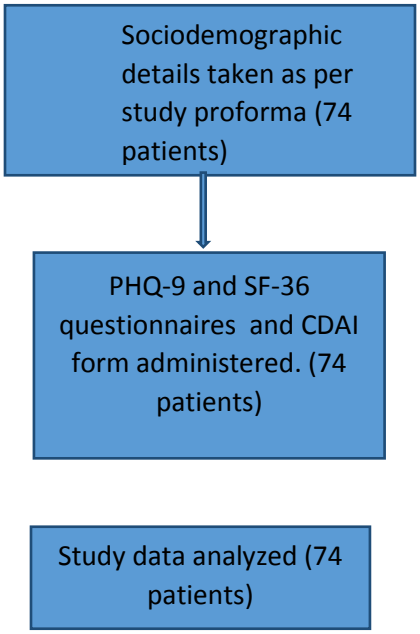
emphasized to the patients that participation was voluntary, and they did not stand to lose anything if they declined to participate in the study. Further, no monetary gains would be forthcoming to participating patients. The patient did not bear any costs for the investigations related to this study. The results were disseminated to the health care providers to aid in patient care. Patients who were found to have co-morbid depression were referred to the Department of Mental Health for appropriate psychiatrist review and treatment.

# CHAPTER 4: RESULTS

STUDY FLOW CHART

FIGURE 2; RECRUITMENT OF STUDY PARTICIPANT






## SOCIODEMOGRAPHIC CHARACTERISTICS OF STUDY PARTICIPANTS.

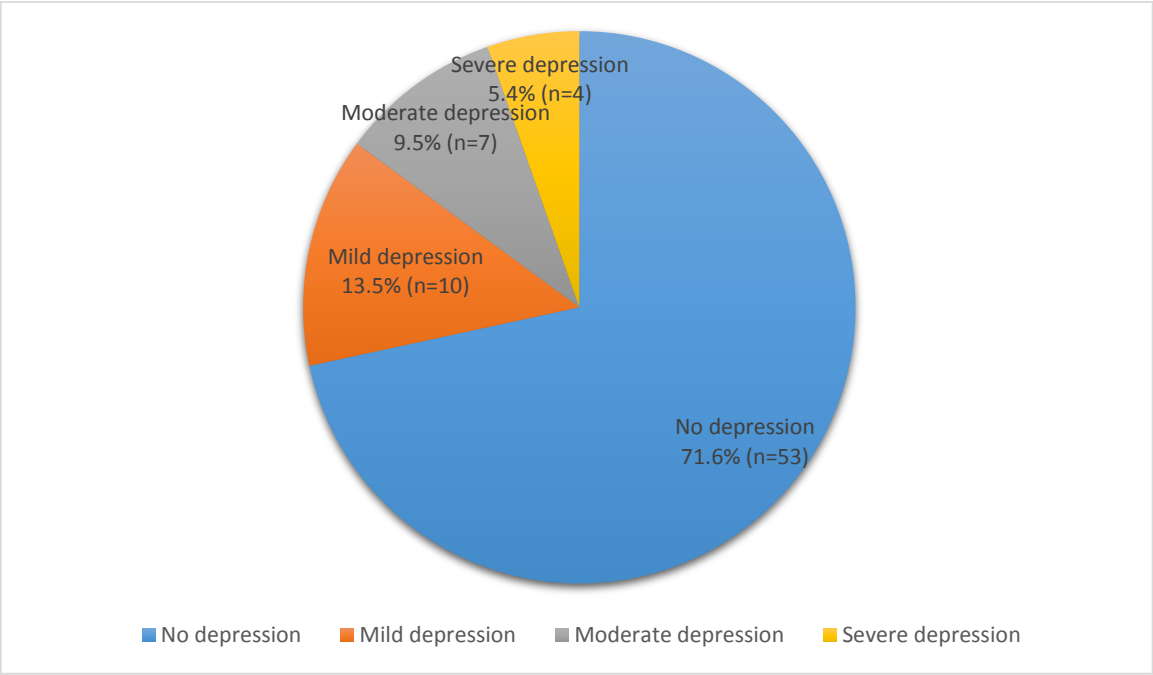
We recruited a total of 74 patients. The study population had a mean (SD) age of 50.6 ± 16.6 years. The ages of the recruits ranged from 19 years to 89 years. Patients less than 65 years formed 52(70.3%) of the study population. The population was predominantly female at 72(97.3%). Of the recruits, 27(36.5%) had received at least primary level education and 12(16.2%) of the participants had received up to tertiary level of education. Patients who did not have any sort of formal education formed 12(16.2%) 0f the recruits. The bulk of the study recruits were married 45(60.8%) while 16(21.6%) were single.

**Table 3: Demographic information of the patients.**

| **Variable** | **Frequency (%)** |
|---|---|
| **Gender** | |
| Male | 2 (2.7) |
| Female | 72 (97.3) |
| Mean age in years (SD) | 50.6 (16.6) |
| Min-Max | 19-89 |

| | |
|---|---|
| 14-30 years | 11 (14.9) |
| 31-45 years | 12 (16.2) |
| 46-55 years | 10 (13.5) |
| 56-65 years | 19 (25.7) |
| >65 years | 22 (29.7) |
| **Duration of illness** | |
| 0-5yrs | 26 (35.1) |
| 5-10yrs | 23 (31.1) |
| >10yrs | 24 (32.4) |
| Missing | 1 (1.4) |
| **Highest level of education** | |
| No formal education | 12 (16.2) |
| Primary level | 27 (36.5) |
| Secondary level | 21 (28.4) |
| Tertiary level | 12 (16.2) |
| Missing | 2 (2.7) |
| **Marital Status** | |
| Single | 16 (21.6) |
| Divorced | 4 (5.4) |
| Married | 45 (60.8) |
| Separated | 5 (6.8) |
| Widowed | 3 (4.1) |
| Missing | 1 (1.4) |

FIGURE 3: PIE CHART SHOWING PREVALENCE OF COMORBID DEPRESSION IN RHEUMATOID ARTHRITIS.




The prevalence of depression in our study population was at 28.4% whereby 21 of the 74 study participants was noted to be clinically depressed. Out of the 74 patients, 10 (13.5%) of the patients had mild depression, this was followed by moderate depression, with 7 (9.5%) being so, while 4 (5.4%) were severely depressed.

Table 4: CDAI mean and median scores.

| **CDAI Scores** | **Frequency (%)** |
|---|---|
| Mean (SD)<br>Median (IQR) | 20.7 (16.2)<br>15.3 (8.8-27.5) |

The patient's severity of Rheumatoid Arthritis is shown in figure 4 below. Only 2 (2.7%) of the population was in remission. The bulk of the patients had moderate to high disease activity. This was presented as 26(35.1%) as having moderate disease activity and 27(36.5%) as having high disease activity. Low disease activity was described in 19(25.7%) of the population. A mean CDAI score of 20.7 (SD 16.2) was noted in this cohort of RA.

FIGURE 4: Pie chart showing proportion of severity of rheumatoid arthritis.

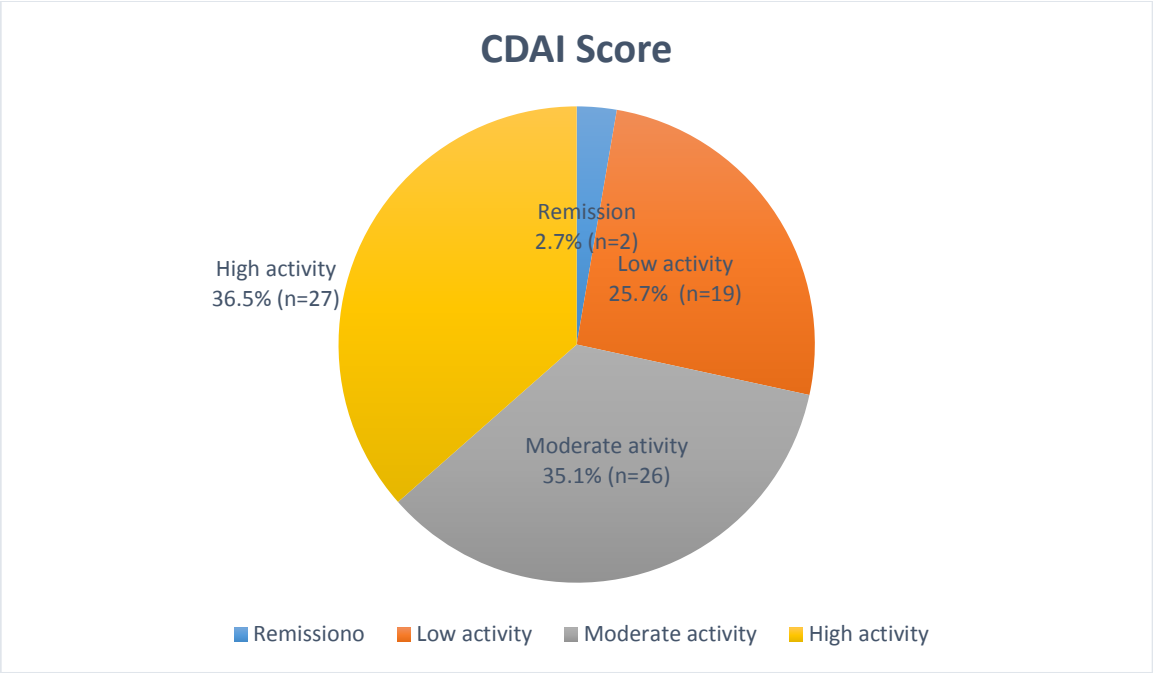



**Table 5: Health related quality of life (HRQoL).**

| **Variable** | **Mean (SD)** | **Score category** | **Median (IQR)** |
|---|---|---|---|
| Physical functioning | 59.2 (26.8) | Fair | 65 (40-80) |
| Role Limitation due to physical health | 33.6 (43.0) | Poor | 0 (0-100) |
| Role Limitation due to emotional problem | 40.2 (46.4) | Fair | 0 (0-100) |
| Energy/Fatigue | 55.1 (16.7) | Fair | 55 (45-65) |
| Emotional well-being | 64.9 (19.3) | Good | 64 (52-80) |
| Social functioning | 68.9 (24.8) | Good | 75 (50-87.5) |
| Pain | 53.1 (25.7) | Fair | 45 (32.5-71.3) |

| | | | |
|---|---|---|---|
| General Health | 49.6 (17.6) | Fair | 50 (35-60) |
| Health change | 60.8 (31.0) | Fair | 75 (25-81.3) |
| Physical Health Component (PHC) | 49.1 (20.7) | Fair | 49.4 (33.3-62.0) |
| Mental Health Component (MHC) | 57. 2(19.9) | Fair | 53.1 (43.0-74.4) |

HRQOL scores were categorized as: 0-40 (poor), 41-60 (fair), 61-80 (good), 81-100 (very good)

Good emotional well-being and social functioning was reported among the patients with mean scores of 64.9 (SD 19.3) and 68.9 (SD 24.8). Role limitation due to physical health had a poor score of 33.6 (SD 43.0). Fair scores were reported in other parameters of the quality of life subscales. The mean Physical Health Component summary scores and Mental Health Component summary scores were categorized as fair at 49.1 (SD 20.7) and 57.2 (SD 19.9) respectively.

FIGURE 5: Bar graph comparing mean scores of HRQoL sub groups.

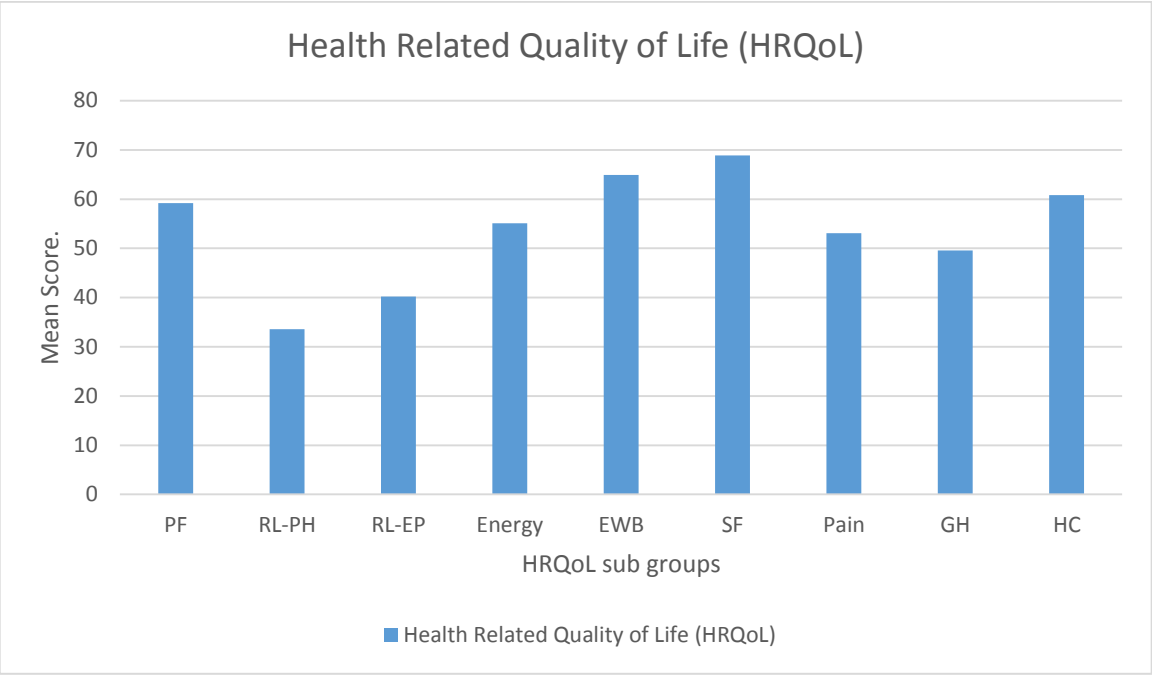



**Table 6: Factors associated with depression in RA patients.**

| Variable | Depressed | Normal | OR (95% CI) | P value |
|---|---|---|---|---|
| Age, mean (SD) | 48.2 (18.3) | 51.5 (16.0) | - | 0.455 |
| 14-35 | 4 (36.4) | 7 (63.6) | 1.0 | |
| 36-45 | 6 (50.0) | 6 (50.0) | 1.8 (0.3-9.3) | 0.510 |
| 46-55 | 2 (20.0) | 8 (80.0) | 0.4 (0.1-3.2) | 0.407 |
| 56-65 | 2 (10.5) | 17 (89.5) | 0.2 (0.0-1.4) | 0.088 |
| >65 | 7 (31.8) | 15 (68.2) | 0.8 (0.2-3.7) | 0.794 |
| **Gender** | | | | |
| Male | 2 (100.0) | 0 (0.0) | - | 0.078 |
| Female | 19 (26.4) | 53 (73.6) | | |
| **Duration of illness** | | | | |
| 0-5yrs | 8 (30.8) | 18 (69.2) | 1.7 (0.5-6.1) | 0.526 |
| 5-10yrs | 7 (30.4) | 16 (69.6) | 1.7 (0.4-6.3) | 0.517 |
| >10yrs | 5 (20.8) | 19 (79.2) | 1.0 | |
| **Highest level of education** | | | | |
| No formal education | 3 (25.0) | 9 (75.0) | 1.0 | |
| Primary level | 9 (33.3) | 18 (66.7) | 1.5 (0.3-6.9) | 0.719 |
| Secondary level | 4 (19.0) | 17 (81.0) | 0.7 (0.1-3.9) | 0.686 |
| Tertiary level | 4 (33.3) | 8 (66.7) | 1.5 (0.3-8.8) | 1.000 |
| **Marital status** | | | | |
| Single | 4 (25.0) | 12 (75.0) | 1.0 | |
| Divorced | 1 (25.0) | 3 (75.0) | 1.0 (0.1-12.6) | 1.000 |
| Married | 13 (28.9) | 32 (71.1) | 1.2 (0.3-4.5) | 1.000 |
| Separated | 1 (20.0) | 4 (80.0) | 0.8 (0.1-8.8) | 1.000 |
| Widowed | 1 (33.3) | 2 (66.7) | 1.5 (0.1-21.3) | 1.000 |
| **CDAI** | | | | |
| Median (IQR) | 21 (15-13) | 12.5 (-26) | - | 0.411 |
| **Category, n (%)** | | | | |
| Remission | 0 (0.0) | 2 (100.0) | | |
| Low Activity | 3 (15.8) | 16 (84.2) | - | 1.000 |
| Moderate Activity | 8 (30.8) | 18 (69.2) | 1.0 | |
| High Activity | 10 (37.0) | 17 (63.0) | 2.4 (0.6-10.5) | 0.309 |
| | | | 3.1 (0.7-13.5) | 0.184 |

**Table 7: Quality of life subset scores and summary scores**.

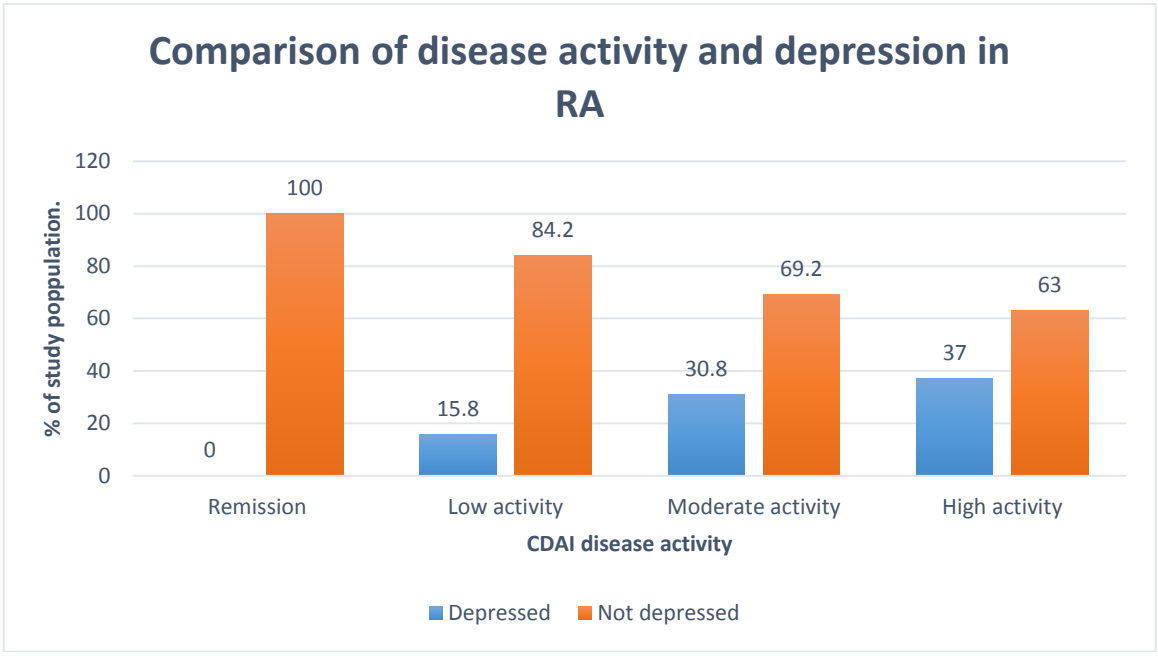
| Variable | Depressed | Normal | OR (95% CI) | P value |
|---|---|---|---|---|

| | | | | |
|---|---|---|---|---|
| Physical functioning | 65 (40-80) | 65 (40-75) | - | 0.942 |
| Role limitation due to physical health | 0 (0-100) | 10 (0-50) | - | 0.787 |
| Role limitation due to emotional problem | 0 (0-100) | 10 (0-100) | - | 0.806 |
| Energy/Fatigue | 50 (40-55) | 55 (50-65) | - | **0.012** |
| Emotional well-being | 52 (44-76) | 68 (60-80) | - | **0.034** |
| Social Functioning | 50 (37.5-75) | 75 (62.5-100) | - | **0.003** |
| Pain | 45 (30-57.5) | 47.5 (35-75) | - | 0.317 |
| General Health | 48 (30-60) | 50 (40-60) | - | 0.444 |
| Health change | 50 (25-100) | 75 (50-75) | - | 0.936 |
| PHC | 48.9 (31.9-55) | 57.4 (34.3-65) | - | **0.041** |
| MHC | 48.5 (33.6-68.8) | 54 (44.6-74.9) | - | 0.109 |

In our study as shown in table 6, when the groups were compared, no statistically significant differences were found with regard to age, gender, marital status, education or duration of disease.

Patients whose rheumatoid activity was in remission did not have detectable depression 0(0%). As the disease activity worsened, the proportion of patients with depression also increased. Those with moderate level activity 8(30.8%) had two times increase proportion of depressed compared with low activity 3(15.8%). Poorly controlled RA with high disease activity had the highest proportion of depression 10(37%). There was no statistically significant difference between the groups in relation to the level of disease activity.

FIGURE 6: Bar graph showing comparison of disease activity and depression in RA




Poorer median score were noted in all quality of life subscales in the patients who were depressed compared to those who were not depressed. From the table 7 poor energy/fatigue, poor emotional wellbeing and poor social functioning scores were significantly related to depression in RA (p value 0.012, 0.034, 0.003 respectively). Physical Health QoL scores showed statistical correlation with depression in RA (p value 0.041). Poorer median Mental health QoL scores were noted in the depressed compared to those not depressed. This however did not show any statistical significant correlation with depression in our study.

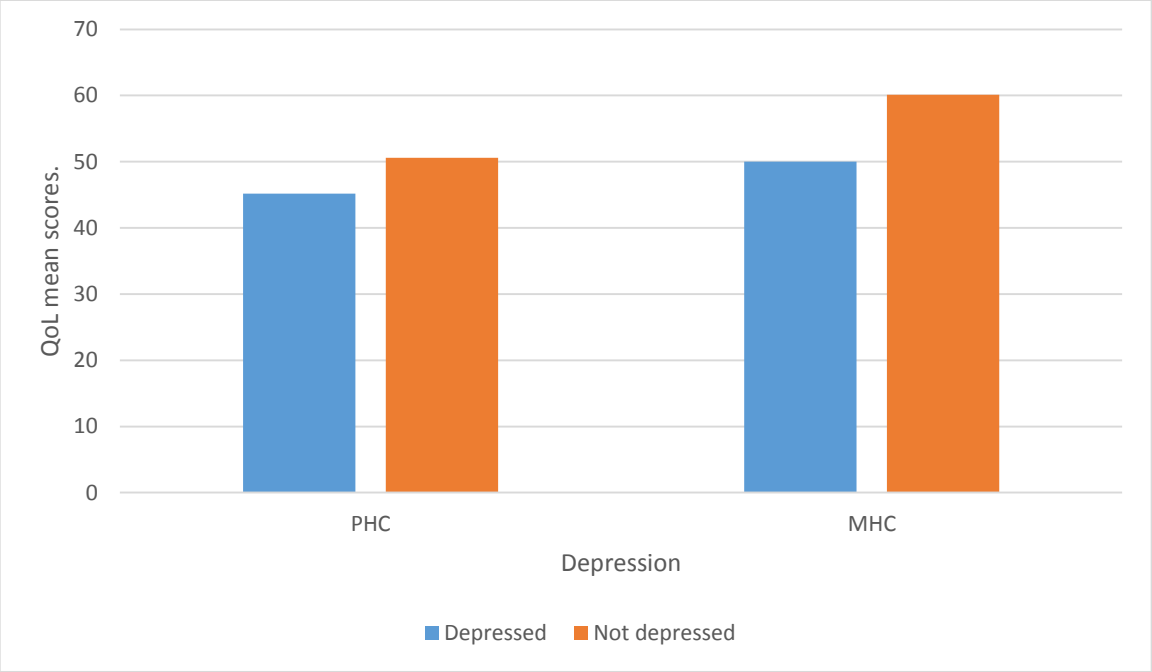
Table 8: Relationship between depression, CDAI and mean QoL summary scores in study population.

| | No depression (n=53) | Depression (n=21) | P-value |
|---|---|---|---|
| | Mean ±SD | | |
| CDAI | 19.5 ±16.9 | 23 ± 14.3 | 0.411 |
| PH Score | 50.6 ±21.6 | 45.2 ±18.4 | 0.041 |
| MH Score | 60.1 ±18.6 | 50.0 ±21.5 | 0.109 |

In regard to the above table 8, the mean CDAI score for patients diagnosed to have depression was 23.5 (SD 14.3) compared to a lower mean score of 19.5 (SD 16.9) in those not depressed. There was no statistical correlation noted between CDAI scores and presence of depression. Lower mean physical health summary score was noted in the depressed group (45.2 SD= 18.4) compared to the

group without depression (50.6 SD= 21.6). There was significant correlation between physical health scores and detection of depression (P=0.041). No statistical significance was noted in the mental health component however, poorer scores (50.0 SD=21.5) in the group with depression compared to (60.1 SD 18.6) in group without depression.

FIGURE 7: Bar graph showing comparison between mean QoL scores (PHC and MHC) in depression.




# DISCUSSION.

## THE PREVALENCE OF DEPRESSION IN RHEUMATOID ARTHRITIS.

Major depressive disorder is a common condition affecting RA patients. In the last 20 years, a lot of research focus has been on the psychological aspect of RA due to the chronic debilitating nature of the disease. This study revealed that the prevalence of comorbid depression in rheumatoid arthritis outpatients in KNH using the PHQ-9 was 28.4%. About half (14.9%) had moderate to severe

depression and this is significant because this group of patients require immediate psychiatry referral with active treatment (pharmacotherapy and/or psychotherapy)(53).

This prevalence of comorbid depression is lower than that reported in a cross-sectional study by Ndetei DM et al in 2005 including 2,770 general medical outpatients across 10 different health facilities in Kenya and they reported that 42.3% of the study patients had clinical depression using BDI. The cohort of patients in Ndetei's study had various diagnosis including cancer, respiratory diseases, cardiovascular diseases, diabetes, HIV etc. and more than half of the patients suffering from cancer (59.6%) and HIV/AIDS (52.2%) had depression. These variations in study subjects as well as study design probably explain the difference in prevalence rate of depression from our study.

The overall prevalence of comorbid depression in our study was comparable to study done in Egypt by Abdel-Nasser looked at depression in RA, whereby the prevalence was at 23.3% (hospital based cross-sectional study in 1998), Kobayashi-Gutlierrez in Mexico (prevalence of 26.6% hospital based cross-sectional study in 2009), Alishiri in Iran with a prevalence rate of 23.4% (HADS questionnaire, cross-sectional study, hospital based done in 2008). A study by Mella et al in Brazil done in 2010 showed a higher prevalence rate of 53.2%. This similarity in the prevalence rates of comorbid depression in RA may be due to shared psycho-social stressors among the developing nations and similar health system challenges which may help explain part of this similarity in prevalence. Relatively lower depression rates were reported in Western studies on patients with RA including Katz et al in USA(Prevalence of 14%,using S-DGS, Cross-sectional design,1994) and Mo et al, UK (PR=2.9%, using HADS, Hospital based survey,2010). The differences in prevalence rates might be due to variation in attributes of study participants, use of different psychometric tool for depression, study design and diversity in psychosocial stressors and health seeking behaviors from one community to another.

In our study, 97.3% of the patients had active disease while only 2.7% were in remission. In a study by Owino et al done in 2009 at the KNH, a large majority of patients (88%) had active disease with 18%

having mild disease, 38% moderate activity and 32% having severe disease. Only 12% of patients had disease in remission. In contrast, remission rates were at 34.8% in a study by Wolfe (54)in the UK in 2009. This may be due to better health seeking behavior, availability of newer disease modifying drugs and biologic agents, which have fewer side effects, and more disease modifying activity.

Among the study participants with comorbid depression, we also analyzed the frequency of depression on the basis of socio-demographic and clinical parameters (including age, gender, marital status, education, and duration of RA and severity of RA. Overall, we found no significant associations in regard to age, gender, , level of education, marital status, duration of illness and severity of disease.

A large portion of patients below the age of 55 years was noted to have depression however, the association between age and risk of depression was not statistically significant (95% CI, p value=0.455). The data is important as it represents a younger population that is likely to have co-morbid depression. This cohort represents a group of patients who are in the peak of their productivity, and this lost productivity is likely to be worse since duration of uncontrolled disease worsens depression. RA with poorly controlled disease are more likely to face the physical challenges of the disease. Attributes like chronic pain and deformity, which may cause challenges of work leading to early retirement and inadequate earning that may come around. All of these factors contribute to major stressors in this age group. A study done by Wright et al in USA (1998)(55),a significant correlation between age and depression was found; younger persons (age ≤45 years) with RA were significantly more depressed, even after controlling for potentially confounding variables such as sex, marital status, antidepressant medication, arthritis medication, functional class, and disease duration

CDAI scores were correlated with depression and were not found to be statistically significant. However, it was noted that, as disease activity worsened, so did the percentage of depression in the study population. Such results are of particular concern because depression is known to increase the risk of mortality in RA patients(19). In addition, patients with long-standing high disease activity are at substantially increased risk of mortality. Effective control of disease decreases mortality(56) and

therapies are available to prevent progression of disease and treatment of depression. In a study by Rakiro in 2019 done at the AKUHN showed a strong positive correlation between RA disease activity measured by CDAI and depression severity ($r= 0.643$, $p<0.001$). This data was availed via personal communication with the principal investigator of the study. In a study by Muhammad Yaser (57)in 2015 in Pakistan also showed the relationship between severity of depression and activity of Rheumatoid Arthritis was linear with a significant p value of <0.0001.

Physical health QOL summary scores showed significant correlations with depression in rheumatoid arthritis, (p value 0.041) among the study patients. This association reflects functional capacity of patients with RA. The presence of depressive symptoms could be conditioned by fear of disability, the severe chronic pain accompanied by progressive joint destruction and disability and disfigurement. On the other hand, mental health summary scores did not show any significant correlation for depression. However, it is important to note that the clinically depressed showed higher mean mental health QoL summary scores than those who were not depressed.

Poor energy scores, poor emotional well being and poor social functioning were significantly associated with clinical depression. These factors are very important as each of them forms a complex integration with the other. In general practice it may be very difficult to determine whether it is rheumatoid arthritis leading to these psychological factors or an isolated depression. Regardless of the causality, it is of clinical significance to detect these aspects and provide adequate intervention for the general wellbeing of the patient. An American study by Margaretten(32) of 172 patients found that disease severity (calculated using the Health Assessment Questionnaire, HAQ) and ethnicity were significantly associated with depression. A similar finding was noted by Esam Mohammed in Egypt in 2014 who studied anxiety and depression and found a strong co-relation with PCS and MCS.

There is documented evidence that functional capacity, and therefore QOL, in RA patients is influenced by multiple variables. The variables most frequently suggested are disease activity, joint destruction, and psycho-social characteristics of each individual patient. Studies have further shown that whereas disease

activity is a strong determinant of functional capacity throughout the course of RA, the contribution from joint destruction becomes increasingly important with time, and is the main determinant of functional capacity later in life.

# CONCLUSION

We found a relatively high prevalence of depression in patients with rheumatoid arthritis. A large cohort of younger patients were noted to be clinically depressed. The bulk of the patients had moderate to high disease activity. The mean PHC and MHC summary scores were categorized as fair. Poorer disease severity scores were noted in the clinically depressed patients. Poor quality of life scores in the sub- types - energy scores, emotional wellbeing and social functioning showed significant correlation to presence of depression. Poor physical health scores were also found to be correlated to presence of depression.

## LIMITATIONS OF THE STUDY.

1) The small sample size increases the likelihood of type2 error and the study lacks the statistical power to make correlations particularly between depression and age, sex, disease severity and quality of life.

2) Assessment of depression in this study was done using questionnaires and thus the findings are prone to reporting bias. The questionnaires were available in English and Kiswahili. This may lead to selection bias as it was necessary to exclude those who could not understand fluently either one of those languages.

3) The diagnosis of rheumatoid arthritis was based on previous documented file diagnosis. The diagnostic criteria may not have been fully considered when arriving at the diagnosis of rheumatoid arthritis.

4) Lastly, KNH is a referral center and therefore those with greater disease activity and poor response to medications may have been the ones referred for follow-up. This may lead to poorer clinical disease activity scores compared to the general population.

## RECOMMENDATIONS.

The following were our recommendations from this study :

1) We recommend that all patients with rheumatoid arthritis should be routinely assessed for depression using a simple screening tool (e.g PHQ-9).
2) We further recommend that larger multi- center studies should be carried out across the country to look at the burden and the risk factors of depression in rheumatoid arthritis and to design effective interventional programs.
3) A multi-disciplinary team including psychiatrists, psychologists and rheumatologists should be involved in the management of patients with rheumatoid arthritis.

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## APPENDIX
## INFORMED PATIENT CONSENT FORM.

INFORMED CONSENT FOR RESEARCH STUDY TO DETERMINE THE PREVALENCE OF DEPRESSION AND QUALITY OF LIFE IN PATIENTS WITH RHEUMATOID ARTHRITIS AT KENYATTA NATIONAL HOSPITAL.

**Institution:**

Department of Clinical Medicine and Therapeutics, College of Health Sciences

University of Nairobi,

P.O BOX 30197-00400, Nairobi.

**Principal Investigator:**

Dr. Doshi Shradha Jayant

P.O.BOX 22838-00-100, Nairobi.

Phone : 0738406492

Lead Supervisors: Prof. Oyoo/ Dr Okech-Helu.

Department of Clinical Medicine and Therapeutics (UoN) /Department of Mental Health (KNH).

**Ethical Approval:**

Kenyatta National Hospital /University of Nairobi Ethics and Research committee,

P.O. BOX 20723-00100, Nairobi.

Tel 2726300/2716450 Ext 44102

**Introduction**

I am Dr. S. Doshi, a postgraduate student pursuing a degree in Master of Medicine in Internal Medicine at The University of Nairobi.

This form will give you information you need to decide if you want to participate in the study. If you have any questions, do not hesitate to ask for clarification.

**Purpose of Study**

I am carrying out a study to look at prevalence of depression in patients with rheumatoid arthritis. I hope this study will help to improve in the management of patients with rheumatoid arthritis in the future.

**Procedures to be followed in the study**

Once you agree to participate in the study, you will sign a consent form. Socio-demographic data will be collected from you. You will then be given a self-administering PHQ-9 questionnaire and SF-36 form to complete. You will also be asked questions about your disease condition and severity. We will also be collecting data from your file on tests already done.

**Risks and costs incurred**

There are minimal risks involved for participation in the study. However you may feel emotional discomfort when answering questions about your personal life. The costs incurred will be covered by the primary investigator.

**Your rights as a participant**

Your participation in this research is voluntary and in the event that you refuse to participate in this study, your treatment will not be affected. If you choose to participate and not answer certain questions, you are free to do so. You are free to terminate the interview and withdraw from the study at any time. You are free to ask questions before signing the consent form.

**Assurance of confidentiality**

All your responses as well as your results will remain confidential. Your individual responses will be stored in a locked place under my control and will only be seen by my statistician and I.

**Benefits to you as a participant**

Your participation in the study bear no cost to you but the findings will be used for your individual benefit. Information obtained will improve knowledge to health care givers at Kenyatta National hospital.

**Contacts**

In case you need to contact me, my academic department or the Kenyatta National Hospital / University of Nairobi Ethics and Research Committee concerning this study, please feel free to use the contacts provided above.

I request you to sign the consent form attached.

**Consent form – patient / next of kin**

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Print Name of Participant/ Next of kin:……..

Signature / Left thumbprint of subject:……...……

Date:……

**Investigator's statement:**

I, the Principal Investigator, have fully informed the research participant on the purpose and implication of this study.

Signed: ..... Date: ……

## FOMU YA MAELEZO YA UTAFITI- WAGONJWA

**Fomu ya maelezo ya utafiti wa kupima kiwango cha ugonjwa wa kushuka moyo kwa Rheumatoid Arthritis katika hospitali ya Taifa ya Kenyatta**

**Taasisi:** Idhaa ya matibabu ya watu wazima, Chuo cha sayansi ya afya, Chuo kikuu cha Nairobi S.L.P. 30197-00400, Nairobi.

**Mtafiti mkuu:** Dkt. Doshi Shradha Jayant, S.L.P. 22838-0000, Nairobi. Simu ya mkononi : 073406492

Idhaa ya matibabu ya watu wazima

**Msimamizi mkuu:** Prof. Oyoo/ Dkt Okech-Helu.

**Ridhaa:**

Kenyatta National Hospital /University of Nairobi Ethics and Research committee, S.L.P. 20723-00100, Nairobi. Tel 2726300/2716450 Ext 44102

**Utangulizi**

Mimi ni Dkt. S. Doshi, mwanafunzi katika chuo kikuu cha Nairobi.

Fomu hii ni ya maelezo yote utakayohitaji ukiamua kama utajiunga na utafiti huu. Unapoisoma na baada ya kusoma fomu hii, uko huru kuuliza maswali yoyote kama kuna sehemu hujaelewa vyema.

**Je,utafiti huu unalenga kutambua nini?**

Ninataraji kufanya utafiti kwa wagonjwa wanaoonekana kwa hospitali ya Taifa ya Kenyatta. Ninataka kupima kiwango ya ugonjwa wa kushuka moyo kwa wagonjwa ambawo wako na Rheumatoid Arthritis.

Natumaini kwa kufanya utafiti huu tutaboresha njia ya kutibu maambukizi.Utafiti huu unahitajika kama sehemu ya masomo yangu lakini matokeo yatakayopatikana yatatumiwa kutoa maelezo, ambayo ikiwa itatumika italeta manufaa katikaa matibabu na hali ya maisha ya wagonjwa

**Utaratibu wa utafiti:**

Mara utakapokubali kuhusika kwenye utafitu huu, utatia sahihi katika fomu ya ridhaa na matakwa ya utafiti. Itabidi ujibu maswali ya kibinafsi utakayoulizwa kisha utachunguzwa kimwili. Mapimo ambazo zimefanywa na ambazo ziko kwenya faili yako zitarekodiwa.

**Hatari na gharama inayohusika**

Kuna hatari ndogo zinazohusika kushiriki katika utafiti. Hata hivyo unaweza kujisikia wasiwasi wakati wa kujibu maswali kuhusu maisha yako binafsi.

**Haki zako**

Kujiunga na utafiti huu ni kwa hiari yako. Hutabaguliwa kimatibabu ukikataa kujiunga na utafiti huu. Ukijiunga na utafiti huu na ushindwe kujibu mojawapo au maswali mengine tutakayouliza, ni sawa. Una uhuru wa kutoka kwenye mahojiano na kujitoa kwa utafiti huu wakati wowote. Una uhuru wa kuuliza maswali yoyote uliyo nayo kabla ya kutia sahihi fomu ya makubaliano. Maelezo yako yote yatawekwa pahali pa siri. Ni mtafiti mkuu na mwanatakwimu wake pekee ambao wataangalia maelezo yako.

**Manufaa ya utafiti huu**

Hakuna pesa utahitajika kulipa kwa kujihusisha kwa utafiti huu. Matokeo ya vipimo vya ini vitakufaidi kibinafsi. Matokeo ya utafiti yatasaidia wauguzi katika hospitali ya Kenyatta.

**Cheti cha ridhaa**

Nimesoma, au nimesomewa maelezo yaliyopewa. Nimepata fursa ya kuuliza maswali kuhusu utafiti na maswali yote niliyouliza yamejibiwa vyema. Ninakubali kuhusika katika utafiti huu.

Jina la Mhusika:……

Sahihi/Alama ya kidole gumba cha kushoto :……....

Tarehe:……

**Kauli ya Mtafiti :**

Mimi, mtafiti mkuu, nimemweleza mhusika vilivyo kuhusu utafiti huu.

Sahihi: ..... Tarehe:……..

## Study Proforma

### Clinical data collection form.

1. Demographic

Patient code …….
Hospital number …….
Date of enrollment ……

Gender : Male ……. Female ……..

Age…….
Date of rheumatoid arthritis diagnosis
……..……..

Duration of illness: 0-5yrs …… 5-10yrs …… > 10years ……..……..

Highest level of education completed: No formal education……..……
Primary level ……..……
Secondary level ……..
Tertiary level ……..…….

Marital status: Single

……..……
.

Divorced……
…….

Married

……..……..

Separated

……...…….

Widowed

……

TABLE 9 - Patient Health Questionnaire (PHQ-9)

## PATIENT HEALTH QUESTIONNAIRE-9 (PHQ-9)

| **Over the last 2 weeks, how often have you been bothered by any of the following problems?** *(Use "✔" to indicate your answer)* | **Not at all** | **Several days** | **More than half the days** | **Nearly every day** |
|---|---|---|---|---|
| **1.** Little interest or pleasure in doing things | 0 | 1 | 2 | 3 |
| **2.** Feeling down, depressed, or hopeless | 0 | 1 | 2 | 3 |
| **3.** Trouble falling or staying asleep, or sleeping too much | 0 | 1 | 2 | 3 |
| **4.** Feeling tired or having little energy | 0 | 1 | 2 | 3 |
| **5.** Poor appetite or overeating | 0 | 1 | 2 | 3 |
| **6.** Feeling bad about yourself — or that you are a failure or have let yourself or your family down | 0 | 1 | 2 | 3 |
| **7.** Trouble concentrating on things, such as reading the newspaper or watching television | 0 | 1 | 2 | 3 |
| **8.** Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual | 0 | 1 | 2 | 3 |
| **9.** Thoughts that you would be better off dead or of hurting yourself in some way | 0 | 1 | 2 | 3 |

FOR OFFICE CODING 0 + _____ + _____ + _____

=Total Score: _____

**If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?**

| **Not difficult at all** | **Somewhat difficult** | **Very difficult** | **Extremely difficult** |
|---|---|---|---|
| ⑤ | ⑤ | ⑤ | ⑤ |

TABLE 10- Patient Health Questionnaire (PHQ-9) – (Kiswahili)

## KIDODOSI JUU YA AFYA YA MGONJWA -9 (PHQ-9)

| Katika kipindi cha wiki mbili zilizopita ni mara ngapi umesumbuliwa na matatizo haya yafuatayo? *(Tumia "✔" ili kuashiria jibu lako)* | Haijatoke zea kabisa | Siku kadhaa | Zaidi ya nusu ya siku hizo | Takriban kila siku |
|---|---|---|---|---|
| 1. Kutokuwa na hamu au raha ya kufanya kitu | 0 | 1 | 2 | 3 |
| 2. Kujisikia tabu sana au kukata tamaa | 0 | 1 | 2 | 3 |
| 3. Matatizo ya kupata usingizi au kuweza kulala au kulala sana | 0 | 1 | 2 | 3 |
| 4. Kujisikia kuchoka au kutokuwa na nguvu | 0 | 1 | 2 | 3 |
| 5. Kutokuwa na hamu ya kula au kula sana | 0 | 1 | 2 | 3 |
| 6. Kujisikia vibaya-au kujiona kuwa umeshindwa kabisa au umejiangusha au kuikatisha tama familia yako | 0 | 1 | 2 | 3 |
| 7. Matatizo ya kuwa makini kwa mfano unaposoma gazeti au kuangalia TV | 0 | 1 | 2 | 3 |
| 8. Kutembea au kuongea taratibu sana mpaka watu wakawa wameona tofauti? Au kinyume chake kwamba hutulizani na unahangaika sana kuliko ilivyo kawaida | 0 | 1 | 2 | 3 |
| 9. Mawazo kuwa ni afadhali zaidi ufe au ujidhuru kwa namna fulani | 0 | 1 | 2 | 3 |

FOR OFFICE CODING 0 + _____ + _____ + _____

=Total Score: _____

Kama ulitia alama matatizo yoyote, matatizo hayo yamefanye iwe vigumu kivipi kwako kufanya kazi yako, kushughulikia vitu nyumbani, au kutangamana na watu wengine?

| Sio ngumu hata kidogo | Ngumu kiasi | Ngumu sana | Ngumu zaidi |
|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ |

TABLE 11 - The ACR 2010 criteria for Rheumatoid Arthritis.

| 2010 ACR/EULAR Criteria | | |
|---|---|---|
| | Criteria | Score |
| Joint Involvement | 1 Large Joint | 0 |
| | 2-10 Large Joints | 1 |
| | 1-3 Small Joints | 3 |
| | >10 Joints (at least 1 small joint) | 4 |
| Serology | Negative RF and anti-CCP | 0 |
| | Low-Positive RF or anti-CCP | 2 |
| | High-Positive RF or anti-CCP | 3 |
| Acute-Phase Reactants | Normal CRP and ESR | 0 |
| | Abnormal CRP or ESR | 1 |
| Duration of Symptoms | <6 weeks | 0 |
| | ≥6 weeks | 1 |
| *Total score of greater than 6 is classified as RA | | |

TABLE 12 - The Clinical Disease Activity Index (CDAI)

**Clinical Disease Activity Index (CDAI)**

| Joint | Left | | Right | |
|---|---|---|---|---|
| | Tender | Swollen | Tender | Swollen |
| Shoulder | | | | |
| Elbow | | | | |
| Wrist | | | | |
| MCP 1 | | | | |
| MCP 2 | | | | |
| MCP 3 | | | | |
| MCP 4 | | | | |
| MCP 5 | | | | |
| PIP 1 | | | | |
| PIP 2 | | | | |
| PIP 3 | | | | |
| PIP 4 | | | | |
| PIP 5 | | | | |
| Knee | | | | |
| Total | Tender: | | Swollen: | |

**Patient Global Assessment ot Disease Activity**

Considering all the ways your arthritis affects you, rate how well you are doing on the following scale:

Very Well O O O O O O O O O O O O O O O O O O O O O Very Poor
0 0.5 1.0 1.5 2.0 2.5 3.0 3.5 4.0 4.5 5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 9.0 9.5 10

**Your Name**_____ **Date of Birth** _____ **Today's Date** _____

**Provider Global Assessment of Disease Activity**

Very Well O O O O O O O O O O O O O O O O O O O O O Very Poor
0 0.5 1.0 1.5 2.0 2.5 3.0 3.5 4.0 4.5 5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 9.0 9.5 10

**How to Score the CDAI**

| Variable | Range | Value |
|---|---|---|
| Tender joint score | (0-28) | |
| Swollen joint score | (0-28) | |
| Patient global score | (0-10) | |
| Provider global score | (0-10) | |
| **Add the above values to calculate the CDAI score** | **(0-76)** | |

| CDAI Score Interpretation | |
|---|---|
| 0.0 – 2.8 | Remission |
| 2.9 – 10.0 | Low Activity |
| 10.1 – 22.0 | Moderate Activity |
| 22.1 – 76.0 | High Activity |

## SF-36 QUESTIONNAIRE

( 1992 -- Medical Outcomes Trust)

**Patient Name: ----------Date: ----------**

In general, would you say your health is: (circle one)

Excellent Very good Good Fair Poor

Compared to one year ago, how would you rate your health in general now? (Tick one)

1. Much better now than one year ago
2. Somewhat better now than one year ago
3. About the same as one year ago
4. Somewhat worse than one year ago.
5. Much worse than one year ago.

The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much? (Mark each answer with an **X**)

| **ACTIVITIES** | **Yes, Limited A Lot** | **Yes, Limited A Little** | **No, Not Limited At All** |
|---|---|---|---|
| a. **Vigorous activities,** such as running, lifting heavy objects, participating in strenuous sports | | | |
| b. **Moderate activities,** such as moving a table, pushing a vacuum cleaner, bowling, or playing golf | | | |
| c. Lifting or carrying groceries | | | |
| d. Climbing **several** flights of stairs | | | |
| e. Climbing **one** flight of stairs | | | |
| f. Bending, kneeling or stooping | | | |
| g. Walking **more than a mile** | | | |
| h. Walking **several blocks** | | | |
| i. Walking **one block** | | | |
| j. Bathing or dressing yourself | | | |

1. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? (Mark each answer with an **X**)

| | **YES** | **NO** |
|---|---|---|
| a. Cut down on the **amount of time** you spent on work or other activities | | |
| b. **Accomplished less** than you would like | | |
| c. Were limited in the **kind** of work or other activities | | |
| d. Had **difficulty** performing the work or other activities (for example, it took extra effort) | | |

2. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)? (Mark each answer with an **X**)

| | **YES** | **NO** |
|---|---|---|
| a. Cut down the **amount of time** you spent on work or other activities | | |
| b. **Accomplished less** than you would like | | |
| c. Didn't do work or other activities as **carefully** as usual | | |

3. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors or groups? (circle one)

Not at all Slightly Moderately Quite a bit Extremely

4. How much bodily pain have you had during the past 4 weeks? (circle one)

None Very mild Mild Moderate Severe Very severe

5. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

Not at all A little bit Moderately Quite a bit Extremely

6. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks - (Mark each answer with an **X**)

| | **All of the Time** | **Most of the Time** | **A Good Bit of the Time** | **Some of the Time** | **A Little of the Time** | **None of the Time** |
|---|---|---|---|---|---|---|
| a. Did you feel full of pep? | | | | | | |
| b. Have you been a very nervous person? | | | | | | |
| c. Have you felt so down in the dumps that nothing could cheer you up? | | | | | | |
| d. Have you felt calm and peaceful? | | | | | | |
| e. Did you have a lot of energy? | | | | | | |
| f. Have you felt downhearted and blue? | | | | | | |
| g. Did you feel worn out? | | | | | | |
| h. Have you been a happy person? | | | | | | |
| i. Did you feel tired? | | | | | | |

7. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)? (circle one)

All of the time Most of the time Some of the time A little of the time None of the time

8. How TRUE or FALSE is each of the following statements for you?

| | **Definitely True** | **Mostly True** | **Don't Know** | **Mostly False** | **Definitely False** |
|---|---|---|---|---|---|
| a. I seem to get sick a little easier than other people | | | | | |
| b. I am as healthy as anybody I know | | | | | |
| c. I expect my health to get worse | | | | | |
| d. My health is excellent | | | | | |