

## Use of the SF-8 to assess health-related quality of life for a chronically ill, low-income population participating in the Central Louisiana Medication Access Program (CMAP)

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### Abstract

**Objectives:** The utility of the SF-8 for assessing health-related quality of life (HRQL) is demonstrated. Race and gender differences in physical component (PCS) and mental component (MCS) summary scores among participants in the CENLA Medication Access Program (CMAP), along with comparisons to the United States population are made. **Methods:** Age-adjusted multiple linear regression analyses were used to compare 1687 CMAP participants to the US population. Internal race and gender comparisons, adjusting for age and the number of self reported diagnoses, were also obtained. The paired *t*-test was used to assess 6-month change in PCS and MCS scores for a subset of 342 participants. **Results:** CMAP participants have PCS and MCS scores that are significantly 10–12 points lower than the US population, indicating lower self-reported HRQL. Females have significantly higher PCS and significantly lower MCS than males. African-Americans have significantly higher MCS than Caucasians. Significant increases in both PCS and MCS were observed for the subset of participants after 6 months of intervention. **Conclusions:** The expected lower baseline PCS and MCS measures and the expected associations with age and number of diagnoses indicate that the SF-8 survey is an effective tool for measuring the HRQL of participants in this program. Preliminary results indicate significant increases in both PCS and MCS 6 months after intervention.

**Key words:** HRQL, Medication access, SF-8

**Abbreviations:** BP – bodily pain; CMAP – Central Louisiana Medication Access Program; GH – general health; HRQL – health-related quality of life; MCS – mental component score; MH – mental health; PCS – physical component score; PF – physical functioning; QMI – QualityMetrics Incorporated; RE – role emotional; RP – role physical; SF – social functioning; SF-8 – Short Form 8 Health Survey; VT – vitality

### Introduction

Access to affordable medications is a major problem facing the millions of uninsured in the United States [1]. This is especially true for individuals living in poor rural areas, such as the central part of Louisiana where at least 40% of the population has no prescription benefits [G. Becker, unpublished observation]. To help alleviate this need, the Central Louisiana Medication Access Program

(CMAP) was created by The Rapides Foundation in Alexandria, LA to provide prescription medications for low income individuals with chronic illnesses. A description of the CMAP program has been previously published [2]. Adult residents of central Louisiana whose income is at or below 200% of the federal poverty guidelines are eligible for CMAP. All participants for this report are patients at Huey P. Long Medical Center, a regional state hospital that is a member of the

Louisiana State University Health Sciences Center – Health Care Services Division (LSUHSC-HCSD). This public health facility, the oldest structure in the state system, provides care to the medically indigent population of Central Louisiana.

An important outcome of the CMAP program is to measure change in a patient's health-related quality of life (HRQL). HRQL refers to an individual or group's perception of their overall health, and how it affects their daily life [3]. Part of the ongoing evaluation of CMAP is to collect HRQL data using the Short Form 8 (SF-8) Health Survey, developed by QualityMetric, Incorporated (QMI). The SF-8 generates a health profile of eight discrete scores describing HRQL, which are summarized into physical component (PCS) and mental component (MCS) continuous summary scores [4].

The SF-8 questionnaire is self-administered by patients at initial enrollment and at each 6-month re-enrollment period. This paper will discuss the results from baseline data including race and gender differences. In addition, a comparison between this study population and standards for the general United States population, as reported by QMI are discussed. Preliminary results on changes in SF-8 scores from initial to 6-month enrollment in CMAP are also reported.

## Methods

### *SF-8 Health Survey*

The SF-8 Health Survey is an 8-item short form designed to provide a HRQL profile [4]. It is the most recent version of the (Short Form) health surveys, which are the most widely used patient-based health surveys in the world [4]. Several of the SF scales, especially the SF-36, based on 36 questions, and the SF-12, based on 12 questions, have been used extensively in outcomes research, case-control and cross-sectional studies, and clinical trials to monitor health outcomes and to assess HRQL in a variety of studies [5–13]. The SF surveys are often used in chronically ill populations to measure overall HRQL [5–13]. The SF-8 4-week recall is being used in this evaluation.

All three SF surveys can be summarized into an 8-scale profile that can be compared across the

surveys. They also can be scored to report an overall measure of physical and mental functioning that is comparable among the surveys [4]. These summary scales, PCS and MCS, have been normalized in the United States population [4]. These norms are useful for comparing the health of participants in a program or research study to the general US population. Use of the scale to assess programmatic success is common, measuring physical and mental health both before and after the implementation of a program, with higher scores indicating better self-reported HRQL. Test-retest reliability of the SF-8 survey has previously been investigated and proven to be strong, indicating that the survey is sensitive to change, and can therefore be used to assess change in HRQL over time [4].

Although designed for use in primarily large surveys of general populations, the SF-8 questionnaire has proven useful in outcomes research applications [14]. The questionnaire has the practical advantage of being brief (only 8 questions, rather than 12 or 36), while yielding scores that are directly comparable to the eight scores produced by the standard SF-36 and SF-12 questionnaires [11]. The SF-8 survey achieved adjusted multiple correlations of 0.881 and 0.825 in the prediction of MCS-36 and PCS-36, respectively [4]. In a recent study, Turner-Bowker et al. found that the SF-8 could be used to assess HRQL in a group of people suffering from migraines and other chronic conditions [15]. The choice of using the SF-8 for the evaluation in this population came after an unsuccessful pilot test of the SF-36 showed that the patients were not completing the survey, often requiring substantial assistance, which in turn slowed the intake process considerably.

In order to calculate these comparable scores, the SF-8 survey first measures the following eight ordinal items: general health (SF8GH), physical functioning (SF8PF), role physical (SF8RP), bodily pain (SF8BP), vitality (SF8VT), social functioning (SF8SF), mental health (SF8MH), emotional roles (SF8RE). Scale means based on the same standard metrics as the SF-36 are assigned to each ordinal response, creating a continuous outcome for each of the eight items. Regression coefficient weights are assigned to each item to produce a physical component score (PCS-8) and a mental component score (MCS-8)

for each patient [4]. Both PCS and MCS are continuous variables.

In 2000, QMI selected a random sample of 7472 individuals from the general United States population and contacted them via telephone or internet to administer the SF-8 survey [4]. PCS-8 and MCS-8 normative scores, calculated and summarized (means and standard deviations) by QMI, are used in this paper to compare CMAP results to the general population.

### *Population*

This paper reports on a sample of 1687 CMAP participants who self-administered the SF-8 questionnaire at their initial interview. All participants completed the questionnaire between January 12, 2002 and March 20, 2003. Of these 1687, 1222 are women (72.44%), 768 are African-American (45.52%), with an average age ( $\pm$  standard deviation) of  $48.53 \pm 11.93$ . Only 1.6% of the sample reported race/ethnicity other than African-American or Caucasian and were not included in these analyses. Some 186 (11%) of the 1687 have less than an eighth grade education, 393 (23%) have some high school education, 598 (36%) have completed high school, and 222 (13%) have some education beyond high school. Education level was not available for 288 (17%) of the individuals. The average monthly income ( $\pm$  standard deviation) of 1611 that reported income was  $\$839.79 \pm \$507.87$ . Self reported diagnoses were available for 1566 and missing for 121 of the 1687 individuals. Patients were allowed to report multiple diagnoses, with a total of 2531 diagnoses reported. The most frequently reported diagnoses were 837 with hypertension, 371 with diabetes, 143 with high cholesterol, 141 with gastroesophageal reflux disease, and 114 with arthritis. Only one diagnosis was reported by 55% of the 1566, with 32% reporting two, 10% reporting three, and 3% reporting four or five diagnoses. CMAP patients are being followed longitudinally to look for changes in health outcomes. At this time, follow-up data on SF-8 questionnaires are only available for 342 patients.

The distribution and range of scores for each of the eight items (SF8GH, SF8PF, SF8RP, SF8BP, SF8VT, SF8SF, SF8MH, SF8RE) were investigated for any possible limitations in their ability to

measure differences in the 1687 subjects. Scores covered the entire range of outcomes for each measure. No significant ceiling effects were present with only one measure (SF8RE) having 20.33% of the responses at the maximum possible score. All other measures produced between 1.07 and 15.17% responses at the maximum values. Similarly, no significant floor effects were present, with all measures producing between 5.51 and 10.49% responses at the minimum possible values. All measures produced relatively symmetric distributions.

### *Statistical methods*

Weighted multiple regression analyses was used to compare mean SF-8 measures for the 1687 individuals to the mean SF-8 normative values for the US population that are provided by QMI. Age, gender and study (CMAP vs. US) and there interactions were considered as independent variables. Age was considered as a continuous variable, using the midpoint of each interval as the age data point. Gender and study were considered as dummy variables. Since only means and standard errors were available for the QMI data, the reciprocal of the standard error of each mean SF-8 measure was used as the regression weight, to adjust for any differences in mean estimation precision due to varying standard deviations and sample sizes. Prior to performing weighted regression, variance ratio F tests were used to compare variances for CMAP and US SF-8 normative values within age groups. A sensitivity analysis was also performed using un-weighted regression. In addition, residual analyses were performed to verify that differences in variability were not due to the presence of statistically significant outliers [16].

Multiple linear regression was used to assess race and gender differences in initial SF-8 measures (PCS-8, MCS-8, and each of the eight items) for the baseline sample of 1566 CMAP participants who reported diagnoses. Age and the number of diagnoses were included as covariates. In order to investigate the possibility of a selection bias, the sample of 1566 participants was compared to the 121 participants that had missing diagnoses. Average age and SF-8 measures for these two groups were compared using *t*-tests.

Race and gender differences across these groups were investigated using Chi-square analyses.

Paired *t*-tests were used to test for significant change in SF-8 scores for individuals enrolled in the CMAP program for 6 months. All analyses were performed in SAS version 8e.

## Results

### *CMAP and 2000 United States normative values*

Figure 1 presents plots of mean PCS and MCS values by age groups for both the CMAP sample and the 2000 QMI Survey of the general United States population. The age groups presented here were chosen to match published results on these US norms. The US comparison group is slightly younger (US:  $45.65 \pm 16.51$  years, CMAP:  $48.52 \pm 11.93$  years), and less than 3% of the normative population is African-American. Considerably fewer females were sampled in the normative group (53%) compared to the CMAP sample (72%). Overall PCS-8 and MCS-8 CMAP scores are 10–12 points lower than the national averages, as could be expected in a chronically ill population. Similar CMAP/US comparisons for PCS-8 and MCS-8 are observed by race and gender. For both males and females, PCS-8 measures tend to decrease with age, while MCS-8 measures tend to increase with age.

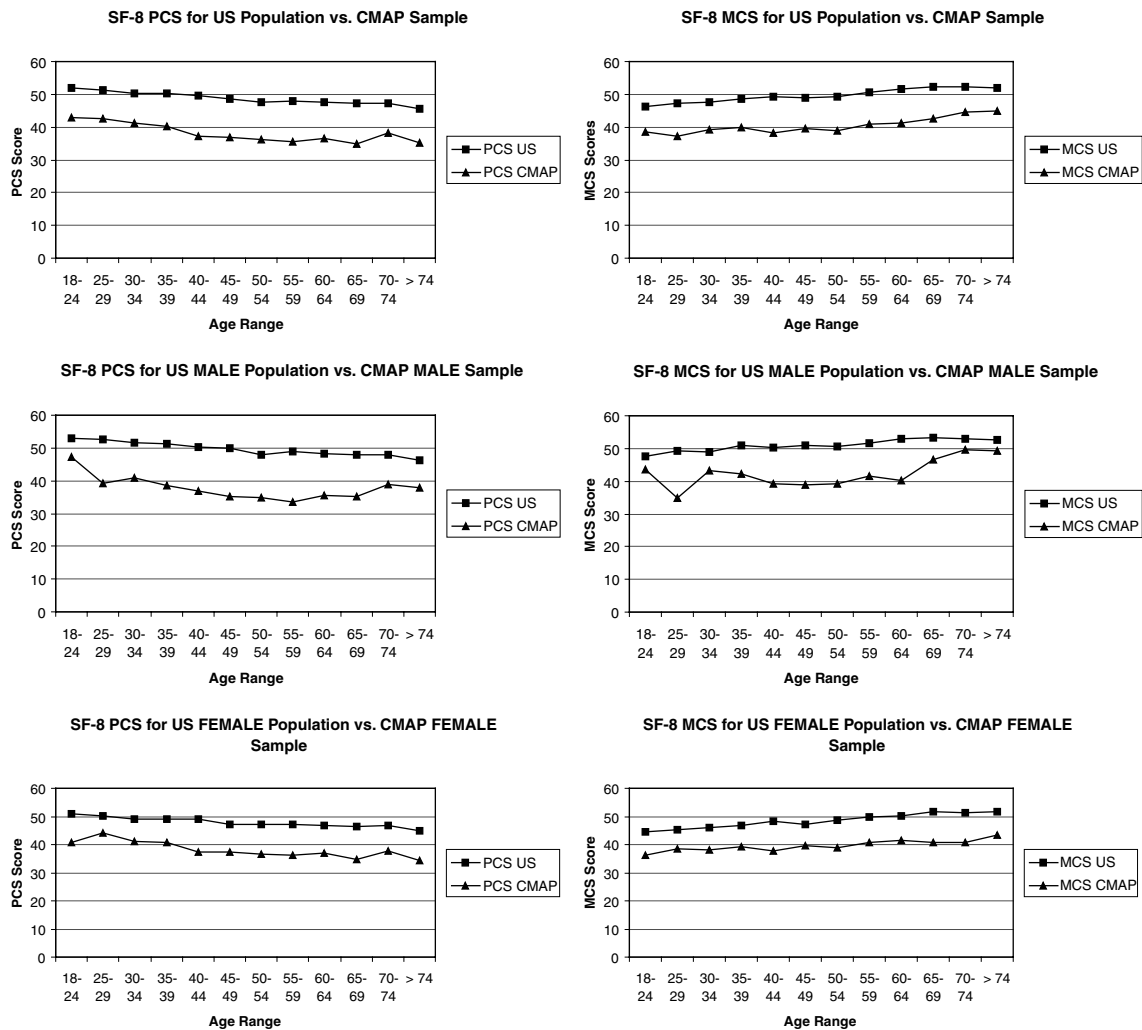
Variance ratio *F* tests detected significantly different variances for CMAP and US PCS-8 measures in 4 out of 12 age groups for females and 7 out of 12 age groups for males. Likewise, significantly different variances for CMAP and US MCS-8 measures were detected in 9 out of 12 age groups for females and 6 out of 12 age groups for men. An analysis of studentized residuals failed to detect any significant outliers that may contribute to differences in variances. Since they are functions of both variance and sample size, the standard errors of each mean SF-8 measure were used as inverse regression weights in multiple regressions. Interactions between age, gender, and study (CMAP vs. US) were considered, with significant interactions detected between gender and study only. Males showed larger study differences than females. Therefore weighted regressions were performed separately for males and females (Table 1).

As noted in the plots, PCS-8 significantly decreases with age and MCS-8 significantly increases with age for both males and females. Females in the CMAP group score 10.00 units lower on the PCS-8 and 8.88 units lower on the MCS-8 than the US population. Larger effects are observed for males, with differences of 12.56 and 9.06 for PCS-8 and MCS-8 respectively.

Un-weighted regressions were also performed, with similar and also statistically significant PCS-8 and MCS-8 differences. These analyses concluded that females in the CMAP group score 9.76 units lower on the PCS-8 and 8.83 units lower on the MCS-8 than the US population. For males, the un-weighted analyses produced differences of 11.79 and 8.66 for PCS-8 and MCS-8 respectively.

### *Race/ethnicity and gender differences within the study population*

Table 2 presents average PCS-8 and MCS-8 measures, average age, and the distribution of number of diagnoses for the CMAP sample, by gender and race. Caucasians report significantly ( $p = 0.0002$ ) more diagnoses than African-Americans, (Caucasian: 51% one diagnosis: 33% two diagnoses, 16% three or more diagnoses; African-Americans: 60% one diagnosis, 31% two diagnoses, 9% three or more diagnoses). On the average, CMAP females have higher PCS-8 measures, with males scoring higher on the MCS-8 measures. CMAP African-Americans score higher than Caucasians on both PCS-8 and MCS-8 measures. Table 2 also presents the results of multiple regression analyses for the 1566 CMAP participants who reported number of diagnoses, where PCS-8 and MCS-8 are regressed on age, race, gender, and the number of diagnoses reported. Initial analyses comparing the 121 individuals without reported diagnoses to the 1566 analyzed here resulted in no significant differences in any SF-8 survey measures, race or gender. There appears to be no selection bias in eliminating these 121 cases from this analysis. No interactions between age, race, gender, and number of diagnoses exist. The number of diagnoses was statistically significant for PCS-8, MCS-8 and all eight SF-8 measures. The average PCS-8 measure decreases by 1.98 and average MCS-8 decreases by 1.73 for each increase of one diagnosis. Again, a significant age effect is detected with PCS-8 decreasing with age



**Figure 1.** PCS and MCS summary scores for the CMAP sample compared to the United States population standard: overall and by gender.

**Table 1.** Comparison of CMAP sample to the 2000 US population by gender

		PCS-8 Coefficient ± SE <sup>a</sup> ( <i>p</i> -value)	MCS-8 Coefficient ± SE ( <i>p</i> -value)
Female	Intercept	52.97 ± 0.62 (<0.001)	42.42 ± 0.48 (<0.001)
	Age	-0.10 ± 0.01 (<0.001)	0.12 ± 0.01 (<0.001)
	CMAP vs. US	-10.00 ± 0.43 (<0.001)	-8.88 ± 0.33 (<0.001)
Male	Intercept	55.37 ± 0.81 (<0.001)	46.06 ± 1.08 (<0.001)
	Age	-0.12 ± 0.02 (<0.001)	0.10 ± 0.02 (<0.001)
	CMAP vs. US	-12.56 ± 0.69 (<0.001)	-9.06 ± 0.86 (<0.001)

and MCS-8 increasing with age. The observed gender effects are also significant after adjusting for

age, race and differences in the number of diagnoses. The gender effect on PCS-8 is also reflected in

**Table 2.** CMAP SF-8 summary scores, age and number of diagnoses by gender, race/ethnicity

Summary statistics	PCS-8	MCS-8	Age	Number of diagnoses		
	Mean $\pm$ SD <sup>a</sup>	Mean $\pm$ SD	Mean $\pm$ SD	1 (%)	2 (%)	$\geq 3$ (%)
Female (n = 1135)	37.78 $\pm$ 10.28	39.45 $\pm$ 11.55	48.73 $\pm$ 11.55	53.83	32.33	13.83
Male (n = 431)	36.66 $\pm$ 10.55	40.76 $\pm$ 11.38	48.56 $\pm$ 12.37	57.54	31.32	11.14
African-American (n = 714)	38.18 $\pm$ 10.37	40.90 $\pm$ 11.40	47.79 $\pm$ 11.73	59.94	30.81	9.24
Caucasian (n = 852)	36.88 $\pm$ 10.32	38.90 $\pm$ 11.53	49.43 $\pm$ 11.78	50.59	33.10	16.32
Total (n = 1566)	37.47 $\pm$ 10.36	39.81 $\pm$ 11.51	48.68 $\pm$ 11.78	54.85	32.06	13.09
Multiple regression analyses	Coefficient $\pm$ SE <sup>b</sup> ( <i>p</i> -value)					
Intercept	46.77 $\pm$ 1.20 (<0.001)	35.08 $\pm$ 1.34 (<0.001)				
Age	-0.12 $\pm$ 0.02 (<0.001)	0.13 $\pm$ 0.02 (<0.001)				
Race	0.69 $\pm$ 0.52 (0.1796)	1.93 $\pm$ 0.58 (<0.001)				
Gender	-1.27 $\pm$ 0.57 (0.0264)	1.27 $\pm$ 0.64 (0.0475)				
Number of diagnoses	-1.98 $\pm$ 0.33 (<0.001)	-1.73 $\pm$ 0.37 (<0.001)				

Coding for multiple regression analyses: Race = 1 if African-American, 0 = Caucasian; Gender = 1 if male, 0 = female; SF-8 scores (PCS-8 and MCS-8) are the outcome variables.

<sup>a</sup> SD: standard deviation.

<sup>b</sup> SE: standard error.

the regression of the original SF-8 measures on age, race, gender, and number of diagnoses. Males have significantly lower role physical (SF8RP) measures than females, indicating a greater difficulty performing daily activities because of physical health, which contributes to a lower overall physical ability score (PCS-8). Females score significantly lower on mental health (SF8MH) than males, indicating a greater degree of being bothered by emotional problems, which contributes to a lower overall mental ability score. Gender differences exist at the extremes of the mental health measure, with 12% of women and 7% of men reporting that they are extremely bothered by emotional problems, with 14% of women and 17% of men reporting that they are not bothered at all by emotional problems. While statistically significant, the magnitude of the gender effect for both PCS-8 and MCS-8 is 1.27, resulting in very little practical difference in adjusted mean scores for men and women. Using the regression equations in Table 2, the adjusted mean PCS-8 and MCS-8 measures are 36.77 for men and 38.04 for women, and 40.76 for men and 39.49 for women respectively.

African-Americans score significantly higher than Caucasians on MCS-8 after adjusting for age, gender, and number of diagnoses. This effect is significant in five of the eight SF-8 measures, with

non-significant similar trends for general health (SF8GH), bodily pain (SF8BP) and emotional roles (SF8RE). Again, adjusted mean MCS-8 measures for African-Americans (40.89) and Caucasians (38.96) show little practical differences.

#### *Change in SF-8 after 6 month on CMAP*

Table 3 presents changes in PCS and MCS from baseline to 6-month follow-up for the 342 patients that have follow up data at this time. PCS increased by 3.02 ( $p < 0.001$ ) and MCS increases by 3.73 ( $p < 0.001$ ). PCS change was significant for females (3.42,  $p < 0.001$ ), but not males. Males had a slightly larger MCS change (4.95,  $p < 0.001$ ) than females (3.95,  $p < 0.001$ ). Both African-Americans and Caucasians demonstrated significant PCS effects, with increases of 3.09 ( $p < 0.001$ ) and 2.96 ( $p < 0.001$ ) respectively. Similar MCS effects were observed in these two groups with increases of 3.89 ( $p < 0.001$ ) for African-Americans, and 3.60 ( $p < 0.001$ ) for Caucasians.

#### **Discussion**

The SF-8 Health Survey is useful as a comparison tool, especially when looking at the differences

**Table 3.** Change in SF-8 measures from baseline to 6-month follow-up on CMAP by gender, race/ethnicity, overall

	N	Age at initial enrollment			PCS			MCS		
		Mean $\pm$ SD	Initial enrollment Mean $\pm$ SD	6-Month follow-up Mean $\pm$ SD	Change <sup>a</sup> Mean $\pm$ SE ( <i>p</i> -value)	Initial enrollment Mean $\pm$ SD	6-month follow-up Mean $\pm$ SD	Change <sup>a</sup> Mean $\pm$ SE ( <i>p</i> -value)		
Female	260	51.20 $\pm$ 11.21	37.09 $\pm$ 10.08	40.51 $\pm$ 9.77	3.42 $\pm$ 0.59 (<0.001)	40.76 $\pm$ 11.66	44.11 $\pm$ 11.56	3.35 $\pm$ 0.74 (<0.001)		
Male	82	50.55 $\pm$ 12.33	38.17 $\pm$ 11.19	39.95 $\pm$ 11.66	1.78 $\pm$ 1.27 (0.164)	42.53 $\pm$ 10.23	47.48 $\pm$ 10.87	4.95 $\pm$ 1.20 (<0.001)		
African-American	155	49.59 $\pm$ 11.83	38.31 $\pm$ 10.91	41.40 $\pm$ 10.62	3.09 $\pm$ 0.84 (<0.001)	41.87 $\pm$ 11.58	45.76 $\pm$ 11.74	3.89 $\pm$ 0.99 (<0.001)		
Caucasian	187	52.26 $\pm$ 11.05	36.55 $\pm$ 9.82	39.52 $\pm$ 9.86	2.96 $\pm$ 0.70 (<0.001)	40.61 $\pm$ 11.14	44.21 $\pm$ 11.23	3.60 $\pm$ 0.89 (<0.001)		
Total	342	51.05 $\pm$ 11.47	37.35 $\pm$ 10.35	40.37 $\pm$ 10.24	3.02 $\pm$ 0.54 (<0.001)	41.18 $\pm$ 11.34	44.92 $\pm$ 11.47	3.73 $\pm$ 0.63 (<0.001)		

<sup>a</sup> Change in SF-8 measure from initial interview to 6-month follow-up.

between a population with chronic illness and comparing it to a standard. It has been shown that single item scales, such as the SF-8, are precise when applied to large samples [17]. The SF-8's sensitivity to change makes it a valuable tool when looking for a shift in overall health due to an intervention. Expected associations with age and number of diagnoses were observed in this application and support the use of the SF-8 survey for health research studies. In addition, when plotted against age, the parallel pattern of PCS and MCS compared to the US survey results further supports its use.

The CMAP population appears to be suffering from an overall downward shift in health when compared to a randomly selected sample of the United States population. Overall physical and mental functioning scores are between 10 and 12 points lower than the national averages, as would be expected in a chronically ill population. While both men and women in the CMAP group have lower physical and mental functioning than their respective gender groups in the United States population, men in the CMAP group have the greatest decline in physical functioning when compared to the United States population.

After adjusting for age, race, and the number of diagnoses in the CMAP group, men have significantly lower physical function scores than women. Women in the CMAP group have significantly lower mental functioning scores than corresponding men, due to reporting that they are bothered by emotional problems to a greater degree. Caucasians in the CMAP group report significantly more diagnoses than African-Americans in the CMAP group, accounting for observed differences in physical functioning. Adjusting for age, gender, and number of diagnoses still results in African-Americans having significantly higher mental functioning than Caucasians in the CMAP group. While statistically significant, gender and race differences in physical and mental functioning scores are of little practical significance.

Limitations of this study include potential bias issues related to the use of self-reported SF-8 measures. This however is the nature of most applications of short form surveys. Another potential limitation is the use of a non-random sample. Individuals elect to participate in the

CMAP program to benefit from acquiring needed medications at reduced costs. An evaluation of the health benefits of such a program is restricted to looking at change in health and hospital use for those who choose to participate. However, demographics and income status observed in this study are similar to those observed in other studies of indigent rural populations [18, 19]. There is no true external control group for this study, as participants will serve as their own controls and change from initial SF-8 measures will be investigated.

Future analyses for this study will include correlations of SF-8 measures with self reported activities of daily living. Potential relationship with individual disease conditions will also be considered.

There are very few published studies that report the use of the SF-8 in large clinic populations, indicating that much more research using the SF-8 is needed in order to further validate its use in both large and small samples.

## Conclusion

These initial results describe the baseline status of the CMAP group. The success of the CMAP program hinges on its ability to improve the health of its participants. If a noticeable shift toward better health can be seen on the SF-8, and as this population approaches the US population, it can be inferred that access to free or low-cost prescription medications improve overall HRQL. Preliminary longitudinal results are promising, with significant increases in both physical and mental functioning being observed 6-months into the CMAP program. Individuals having access to the medications that are necessary to help them function can explain this shift toward better physical and mental health. Also, the effect of being under regular clinic care, as required by the CMAP program, helps individuals make an investment in their healthcare and well-being. The SF-8 Health Survey is an effective tool for measuring the HRQL of participants in the CMAP program.

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