THE SF-36 HEALTH SURVEY: A SUMMARY OF RESPONSIVENESS TO CLINICAL INTERVENTIONS

REPORT PREPARED FOR:

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Background

The Medicare Health Outcomes Survey

As the average age of the US population increases, so does the number of Medicare beneficiaries receiving their health care through managed care organizations. Yet, there is some evidence that seniors treated under managed care fare relatively worse than their counterparts treated in traditional fee-for-service settings. Until recently, there were no systems in place to track patient-reported health outcomes of Medicare beneficiaries treated in managed care settings. The Medicare Health Outcomes Survey (HOS) measure was developed to monitor and evaluate the quality of care provided to these individuals and provide beneficiaries with plan-to-plan comparisons. This new measurement system will be used to help Medicare beneficiaries and various purchasers evaluate the quality of health care plans.

The HOS is based on the Medical Outcomes Study (MOS) SF-36 Health Survey.² The HOS incorporates the latest advances in summarizing outcome results and risk-adjustment, initially developed from the MOS and refined for the Health Outcomes Survey. The measure tracks health outcomes using summary scores computed separately for physical and mental outcomes and collects information for purposes of a standardized plan-to-plan risk adjustment. Additional items include a standardized checklist of comorbid conditions and sociodemographic variables proven useful in the MOS and National Survey of Functional Health Status.^{1,3}

The SF-36 Health Survey

The SF-36 Health Survey, a comprehensive short-form generic measure of health-related quality of life, consists of 36 items; 35 of which are aggregated into eight multi-item scales that measure physical functioning (PF), role limitations due to physical health

problems (RP), bodily pain (BP), general health (GH), vitality (VT), social functioning (SF), role limitations due to emotional problems (RE) and mental health (MH). The 8 scales, in turn, can be aggregated into two summary scales tapping physical and mental health: a physical component summery (PCS) and a mental component summary (MCS).

Tracking of the SF-36 in the published literature reveals more than 1000 articles published to date. These references encompass a multitude of studies investigating different diseases and conditions and different treatments undergone in various study designs. Translations, normative data, and user's manuals have also been published (see Table 1).

Objectives of this Report

This report details the methodology and initial results from an ongoing study of the responsiveness to treatment of the SF-36 Health Survey scales and summary measures. Our goal is to provide benchmarks for interpreting the primary HOS outcome measures: the SF-36 physical and mental health summary scores (PCS and MCS, respectively) to address concerns about whether the SF-36 is responsive enough to detect treatment benefits and to refine interpretation guidelines for documenting the meaning of a change score.

Methods

SF-36

Available evidence to date indicates that the eight SF-36 scales form two distinct higherorder factors, representing physical health and mental health. Empirically, these physical and mental health factors have been shown to account for more than 80-85% of the reliable variance in the eight scale in the general U.S. population⁴, among patients in the Medical Outcomes Study^{4, 5} and in other general populations.⁶

Validity studies have supported the construction of the SF-36 physical and mental component scores by confirming hypothesized relationships between the summary measures and groups of patients defined according to the presence and severity of physical and psychiatric chronic conditions.⁴

The PCS and MCS are scored using all eight SF-36 scales. Three scales (PF, RP and BP) correlate most highly with the physical factor and contribute most to scoring the PCS measure. The GH scale also contributes substantially to the PCS score. The MH, RE, and SF scales correlate most highly with the mental factor, and contribute most to scoring the MCS measure. The VT scale also contributes substantially to the MCS score.

PCS and MCS are scored to have a mean of 50 and standard deviation of 10 in the general U.S. population. Because the majority of published accounts of treatment studies report outcomes only for the eight-scale SF-36 health profile we have, in this report, estimated the PCS and MCS summary scores, using norm-based (standard) scoring.

In addition, we have rescored the eight SF-36 scales using norm based scoring. This standardized (norm-based) scoring is preferred because it allows for comparisons across studies and scales. Norm-based scoring of the SF-36 health profile standardizes each scale to have a mean of 50 and a standard deviation of 10 in the general U.S. population. The advantage of norm-based scoring of the scales and summaries alike is easier interpretation, because the general population mean is built into the scoring

algorithm. All scores above 50 can be interpreted as being above the US population norm and all scores below 50 can be interpreted as being below the US population average. Furthermore, since the standard deviation for each scale is standardized to be at 10, it is easy to see exactly how far above or below a score is from the norm in standard deviation units. Norm-based scoring has another important advantage in that it allows for direct comparisons of scores across the eight scales. The original scoring of SF-36 scales on a continuum from 0 to 100 prohibited such direct comparisons across scales because each scale has a different standard deviation.

Literature search methods

Our goal was to locate all published studies of randomized, controlled treatment studies that reported results on the SF-36 scales or summary measures. We focused only on randomized, controlled trials because that study design is the most defensible in terms of inferring causality from the observed results. Using standard search techniques, an extensive literature search was conducted to identify articles published on or before December 31, 1997. Key words used for searching were: SF, SF-36, short form, shortform 36. A copy of each published article was obtained and was reviewed to identify if it, in fact, contained information about the SF-36. We identified 514 such articles (see Table 1, below)

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¹ Note: The literature search and first version of this report were accomplished during 1999. A manuscript will be prepared later this year that will include all treatment studies published through 12/31/99.

Table 1: Summary of SF-36 Health Survey Publications to Date

| Articles Published to date (March, 2000) | 1,000+ |
|---|--------|
| Articles Published Through 12/31/97 | 514 |
| Number of Diseases/ Conditions with 1 + Articles | 130 |
| Number of Diseases/ Conditions with 5 + Articles | 26 |
| Number of Diseases/ Conditions with 10 + Articles | 15 |
| Diseases with 20+ Articles (Arthritis, Back pain, Depression, | |
| Diabetes, Hypertension | 5 |
| Number of treatment studies | 350 |
| Publications about Translations | 148 |

Those studies identified were further reviewed to assess whether or not they reported data on use of the SF-36 in a study in which a treatment or other intervention was implemented or observed. For the most part, these interventions included: drug treatment; surgical procedures; exercise programs and educational programs. 350 articles met the requirement of describing a treatment intervention.

The final step was to review the study design of the treatment studies. The large majority of these studies had designs that did not include placebo, control or head-to-head treatment comparison groups. Thus, the unique effect of the treatment in question is not possible to assess. For this reason, only studies reporting a direct comparison of treatments, placebo-controlled trials, comparative trials, and cohort studies were retained. This resulted in a final sample of 42 studies, (see Figure 1 and Table 2, below). Finally, out of the 42 treatment studies, those that reported PCS and MCS, (or provided enough data for summaries to be computed post hoc) were compiled in two summary tables, each including 18 studies. The 42 treatment studies are listed in Appendix B. The remaining treatment studies included cross-sectional, pre-post, and other types of designs. They were not further evaluated for the purposes of this report.

Figure 1. Summary of SF-36 Literature Search

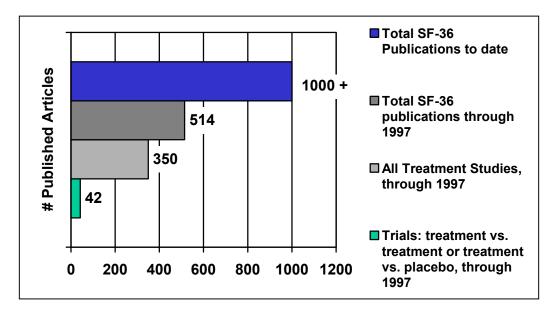


Table 2: Summary of SF-36 Treatment Studies published through 1997

| Randomized, placebo-controlled trials | | 12 | |
|--|-------|----|--|
| Randomized, placebo-controlled cross-over trials | | 1 | |
| Randomized, comparative trial (no placebo) | | 20 | |
| Non-randomized, comparative trial (no placebo) | | 7 | |
| Cohort study | | 2 | |
| | Total | 42 | |

Statistical Analysis

Our focus in this effort has been to compile data summarizing comparisons between treatments groups over time. If provided in the original articles, the statistical significance of the differences between groups is reported in the detailed tables. However, many studies do not report significance levels for relevant statistical tests (for differences or change scores. For example, an article may provide data and significance tests using the 8 SF-36 subscales but not using PCS and MCS. While we are able to compute values for PCS and MCS in this situation, we are not able carry out the significance testing because we lack other critical inputs, such as the standard error of

the mean PCS and MCS scores in that sample. In addition, most studies did not report the study's statistical power, limiting our ability to evaluate the score differences reported.

Additionally, the SF-36 change scores can be examined and manipulated to determine effect sizes. The effect size is calculated by dividing the net change by the standard deviation (in this case, the standard deviation is 10 for all scales). The strength of an effect size has been classified as follows: .2 to .4 as "small", .5 to .7 as "moderate", and equal or greater than .8 as a "large" effect. These standards can easily be applied to the data shown here because all scales are presented with a standard deviation of 10. Thus, if a study reports a net change in PCS score of 6.56, it can be interpreted as an effect size of 0.66 (6.56 / 10), in the "moderate" range.

Results and Interpretation

The detailed tables included in Appendix A of this report classifies studies according to therapeutic area and includes for each reference the year of publication, primary author, the specific condition studied, a description of the study design, and a list of the treatment groups. Tables 3 and 4, following, present a more focused summary of studies for which PCS and MCS could be computed.

Norm-based scores for each of the SF-36 scales and PCS and MCS summaries for relevant time periods are also shown. As discussed earlier, application of the norm-based scoring methods to the SF-36 study data simplifies interpretation, allowing a reader to compare findings between scales as well as between studies. For all scales, a scores of 50 is interpreted as he average score in the US population. Scores of 40

and 60 are interpreted as one standard deviation below and above average, respectively.

Percentile rank: Interpretation can also include examining the meaning of a change in a score for relevance and importance. For example, a change in the PCS score of five points (that is, an effect size of 0.5, in the "moderate" range) has social, clinical, and economic implications, as described in a 1996 publication of patients enrolled in a one-year open-label observation period that followed participation in a randomized, double-blind, placebo-controlled clinical trial. Specifically, the authors examined the five-point improvement in relation patients' PCS scores before and after treatment. In this study, use of the study drug improved average PCS scores from the 17th percentile to the 24th percentile of the general population score distribution. (Similar comparisons can be made using normative data from other reference populations, such as those matched according to demographic characteristics or disease burden.) Tables 3 and 4 present, for each study and treatment group, the percentile rank of the group before and after treatment, to represent not only the improvement or decline in health experienced by patients under study, but also the ultimate health state achieved by those patients, in relation to the US population distribution. ⁴

Effect Size: As described earlier, the size of a treatment effect can be evaluated roughly in terms of magnitude, as "small" (effect size 0.2 to 0.4), "moderate" (effect size 0.5 to 0.7) or "large" (effect size >= 0.8). Table 5 presents a summary of PCS and MCS effects reported here in terms of the effect size category. In general, the "large" effects in physical health are associated with surgery or other therapy for major physical conditions such as hip replacement or heart valve replacement. Effects of drug therapies on PCS scores fell into the effect sizes of "small" or "moderate". For MCS, "large" effects were associated with recovery from clinical depression, and with

treatment for three ostensibly physical conditions. "Moderate" effects were seen for three different treatments for mental health disorders, and "small" effects for 5 drug therapies and two other interventions.

Other interpretations of a five-point improvement in PCS include a substantial reduction in the probability of job loss due to health problems within the next year and a nearly one-third reduction in the probability of being hospitalized within the next six months.⁴ Further, calculations based on published estimates of average health care expenditures indicate that an improvement of five points on the PCS leads to a predicted reduction in expenditures of about 27 percent, from about \$1,500 to \$1,100.⁹

In summary, this report provides evidence that the SF-36 scales and summary measures are sensitive measures that can demonstrate changes in health due to various treatments, including pharmacological, surgical, and educational interventions. Use of a standardized tool like the SF-36 allows clinicians, researchers and patients to evaluate, compare and contrast the outcomes of different treatments, providing a more informed context for everyday clinical decision-making.

Table 3. SF-36 Treatment Studies: Summary of PCS Change Scores

| Therapeutic Area | Condition | Includes Elderly | Study Design | Treatment(s) | PCS Change | | US Pop. Percentile change | Ref |
|--------------------------------|----------------------------|---------------------|---------------------|---|------------|-------------|---------------------------------|-------------------|
| Citations | | | | | Difference | Effect Size | Change | |
| Cardiovascular Disease | | | | | | | | |
| Beniamini, Y | Cardiac patients | Yes | Randomized, | Flexibility Program | 5.49 | | 19 to 31 | pg. 1; table 1 |
| 1997 | | | trial, no placebo | Strength Program | 3.73 | | 24 to 34 | _ |
| | | | | Flexibility vs. Strength Program | 1.76 | 0.18 | | |
| Erickson, SR | Hypertension | Yes | Randomized, | Usual Care | -1.16 | | 11 to 10 | |
| 1997 | <i></i> | | trial, no placebo | Pharmaceutical Care Program | -1.47 | | 13 to 11 | pg. 1; table 1 |
| | | | , , , , | Usual Care vs. Pharmaceutical | 0.31 | 0.03 | | |
| Kusek, JW | Hypertension | NR | Randomized, | Usuai Mean Arterial Blood Pressure (MAP) goal | 3.78 | | 18 to 24 | |
| | пуренензіон | INIX | · | Low MAP goal | -2.78 | | 19 to 17 | pg. 3,4; table 1 |
| 1996 | | | trial, no placebo | Usual MAP goal vs. Low MAP | 6.56 | 0.66 | 1910 17 | |
| | | | | - | | | | |
| Gastrointestinal Disorders (G | • | ., | 5 | Onemanda | 4.56 | | 10 to 20 | |
| Watson, RG | Gastroesophageal | Yes | Randomized, | Omeprazole | | | 19 to 26 | pg. 8; table 3 |
| 1997 | Reflux Disease (GERD) | | cross-over | Placebo | 1.38 | 2.22 | 19 to 20 | |
| | | | | Omeprazole vs. Placebo | 3.18 | 0.32 | | |
| Geriatric Studies | | | | | | | | |
| Clark, F | | Yes | Randomized, | Occupational Therapy | -1.06 | | 28 to 26 | 7 t-bl- 0 |
| 1997 | Independent elderly adults | | trial, no placebo | Nontreatment (control) | -2.47 | | 22 to 18 | pg. 7; table 2 |
| | | | | Occupational Therapy vs Nontreatment | 1.41 | 0.14 | | |
| Genital-Urinary Disorders (GU | <u>n</u> | | | | | | | |
| Cooper, KG | -, | NR | Randomized, | Transcervical resection | 4.66 | | 28 to 26 | |
| 1997 | Heavy Menstrual Loss | | trial, no placebo | Medical Treatment | 2.15 | | 26 to 31 | pg. 9,10; table 4 |
| | , | | ana, no placese | Transcervical resection vs. Medical | 2.51 | 0.25 | 201001 | |
| | | | | | | | | |
| Headache Adelman, JU | | | Unrandomized, | | | | | |
| 1996 | Migraine, Headache | NR | comparative trial, | | | | | pg. 13; table 5 |
| | | | no placebo | Baseline vs post treatment | 2.09 | 0.21 | 28 to 34 | pg. 13; tal |
| Musculoskeletal/Orthopedic (| Conditions | | | | | | | |
| Jarvik, JG | Johannons | Yes | Randomized, | Plain Radiography | 3.59 | | 8 to 12 | , |
| 1997 | Low Back Pain | | trial, no placebo | MR Imaging | 2.99 | | 8 to 11 | pg. 15; table 6 |
| | | | | Plain Radiography vs. MR Imaging | 0.60 | 0.06 | | |
| Psychiatric Disorders | | | | | | | | |
| Heiligenstein, JH | | Yes | Randomized, | Placebo | 0.66 | | 24 to 26 | |
| 1995 | Late Life Depression | | controlled | Fluoxetine | 0.29 | | 28 to 28 | pg. 29; table 8 |
| | | | trial, with placebo | Placebo vs. Fluoxetine | 0.36 | 0.04 | | |
| | | | | | | | | _ |

| Therapeutic Area | Condition | Includes Elderly | Study Design | Troatmont(c) | PCS Change | | US Pop. Percentile | Ref |
|----------------------|-----------------------------------|---------------------|---------------------|---|--------------|-------------|-----------------------|--------------------|
| Citations | Condition | Liderry | Study Design | Treatment(s) | Difference | Effect Size | change | |
| Coulehan, JL | Depression | No | Randomized, trial | Protocol treatment | 1.09 | 2.1000 0.20 | 19 to 20 | |
| | | | no placebo | Usual Care | 0.93 | | 19 to 20 | |
| | | | | Protocol treatment vs Usual Care | 0.16 | 0.02 | | pg. 25; table 8 |
| Brown, C | | No | Randomized, trial | Depression/pharmacotherapy | 0.20 | | 24 to 24 | |
| 1996 | Major Depression, Panic Disorders | | no placebo | Depression/psychotherapy | -1.50 | | 24 to 22 | pg 25,26: table 8 |
| | | | | Depression/pharmaco vs psychotherapy | 1.70 | 0.17 | | pg 25,26. table 8 |
| Jacobs, RJ | | NR | Randomized, | Placebo | -0.39 | | 38 to 38 | |
| 1997 | Panic Disorders | | controlled | Clonazepam | -0.46 | | 41 to 41 | pg. 25,26; table 8 |
| | | | trial, with placebo | Placebo vs Clonazepam | 0.07 | 0.01 | | pg. 23,20, table 0 |
| Respiratory Diseases | | | | Placebo | 0.8 | | 13 to 14 | |
| Jones, PW | | Yes | Randomized, | Salmeterol 50 mcg bid | 2.22 | | 13 to 16 | |
| 1997 | Chronic Obstructive Pulmonary | | controlled | Salmeterol 100 mcg bid | -0.93 | | 12 to 11 | pg. 30,31; table 9 |
| | Disease | | trial, with placebo | Salmeterol 50 mcg vs. 100 mcg bid | 3.15 | 0.32 | | |
| Mahajan, P | Asthma | Yes | | Placebo | -2.37 | | 34 to 28 | |
| 1997 | | | Randomized, | Fluticasone prop. 100 mcg bid | 2.17 | | 38 to 46 | pg. 31,32; table 9 |
| | | | controlled | Fluticasone prop. 250 mcg bid | 1.32 | 0.45 | 34 to 28 | |
| | | | trial, with placebo | Fluticasone prop. 100 mcg bid vs. plcebo | 4.54 | 0.45 | | |
| | | | | Fluticasone prop. 250 mcg bid vs. placebo | 3.69 | 0.37 | | |
| Bousquet, J | Perennial Allergic Rhinitis | NR | Randomized, | Cetirizine | 6.64 | | 24 to 41 | |
| 1996 | | | controlled | Placebo | 0.47 | | 24 to 26 | pg. 33; table 9 |
| | | | trial, with placebo | Cetirizine vs.Placebo | 6.17 | 0.62 | | |
| Other Therapies | | | | | | | | |
| McComb, J | | NR | Unrandomized, | CAPD | 3.04 | | 7 to 10 | |
| 1997 | Peritoneal Dialysis | | comparative trial, | Amp80 | 3.39 | | 12 to 17 | pg. 19; table 7 |
| | | | no placebo | PacXtra | 1.91 0.35 | 0.04 | 7 to 9 | |
| | | | | Amp80 vs CAPD Amp80 vs PacXtra | 1.48 | 0.04 | | |
| | | | | Ampau vs Pacxtra | 1.46 | 0.15 | | |
| Bouchet, C | | No | Randomized, | Vitamin therapy | -0.01 | | 46 to 46 | |
| 1996 | General Population Nutrition | | controlled | Placebo Vitamin vs. Placebo | -0.11 | 0.01 | 46 to 46 | |
| | Program | | trial, with placebo | Vitaliili vs. Placedo | 0.10 | 0.01 | | pg. 20; table 7 |
| Lawrence, K | Inguinal Hernia | No | Randomized, trial | Laparoscpic Surgery | 4.09 | | 26 to 38 | |
| 1995 | | | no placebo | Open Surgery | -0.82 | | 34 to 34 | pg. 23; table 7 |
| | | | | Laparoscopic vs Open Surgery | 4.91 | 0.491 | | |

Table 4. SF-36 Treatment Studies: Summary of MCS Change Scores

| Therapeutic Area | Condition | Includes Elderly | Study Design | Treatment(s) | MCS Change | | US Pop. Percentile | Ref. to detailed |
|---|----------------------------|---------------------|---|---|------------|-------------|-----------------------|-------------------|
| Citations | | , | | | Difference | Effect Size | change | tables |
| Cardiovascular Disease | | | | | | | | |
| Beniamini, Y | 0 5 5 1 | Yes | | Strength Program | 9.62 | | 26 to 59 | |
| 1997 | Cardiac patients | | Randomized trial, no | Flexibility Program | 0.58 | | 28 to 31 | pg. 1; table 1 |
| | | | placebo | Strength vs. Program Flexibility | 9.04 | 0.90 | | |
| Erickson, SR | Hypertension | Yes | | Usual Care | 1.83 | | 28 to 31 | |
| 1997 | ,, | | Randomized trial, no | Pharmaceutical Care Program | -1.61 | | 33 to 28 | pg. 1; table 1 |
| | | | placebo | Usual Care vs. Pharmaceutical | 0.22 | 0.02 | | |
| Kusek, JW | Hypertension | NR | | Usual Mean Arterial Blood Pressure (MAP) goal | 3.31 | | 36 to 48 | |
| 1996 | . Type terior. | | Randomized trial, no | Low MAP goal | 3.05 | | 36 to 48 | pg. 3,4; table 1 |
| 1000 | | | placebo | Usual MAP goal vs. Low MAP | 0.26 | 0.03 | 00 10 10 | |
| Gastrointestinal Disorders | (GI) | | | | | | | |
| Watson, RG | | Yes | | Omeprazole | 6.84 | | 16 to 28 | |
| 1997 | Gastroesopha- geal Reflux | | Randomized, cross-over | Placebo | 3.12 | | 16 to 20 | pg. 8; table 3 |
| | Disease (GERD) | | | Omeprazole vs. Placebo | 3.72 | 0.37 | | |
| | | | | | | | | |
| Genital-Urinary Disorders (Cooper, KG | GU) | NR | | Transcervical resection | 11.8 | | 16 to 44 | |
| 1997 | Heavy Menstrual Loss | | Randomized trial, no | Medical Treatment | 3.39 | | 19 to 24 | pg. 9,10; table 4 |
| | , | | placebo | Transcervical resection vs. Medical | 8.41 | 0.84 | | |
| Geriatric Studies | | | | | | | | |
| Clark, F | | Yes | | Occupational Therapy | -0.42 | | 59 to 59 | |
| 1997 | Independent elderly adults | | Randomized trial, no | Nontreatment (control) | -2.78 | | 49 to 36 | pg. 7; table 2 |
| | , | | placebo | Occupational Therapy vs Nontreatment | 2.36 | 0.24 | | |
| Headache | | | | | | | | |
| Adelman, JU | | NR | Unrandomized, | | | | | |
| 1996 | Migraine / Headache | | comparative trial, no | | | | | pg. 13; table 5 |
| | • | | placebo | Baseline vs post treatment | 2.10 | 0.21 | 48 to 59 | |
| Musculoskeletal/Orthopedi | c Conditions | | | | | | | |
| Jarvik, JG | | Yes | 5 | MR Imaging | 1.84 | | 20 to 22 | na 45 table 0 |
| 1997 | Low Back Pain | | Randomized trial, no | Plain Radiography | -4.81 | | 36 to 24 | pg. 15; table 6 |
| | | | placebo | MR Imaging vs Plain Radiography | 6.65 | 0.67 | | |
| Psychiatric Disorders | | | | | | | | |
| Heiligenstein, JH | | Yes | Dendersiand control 111 | Fluoxetine | 5.92 | | 6 to 12 | pg. 29; table 8 |
| 1995 | Late Life Depression | | Randomized, controlled tria with placebo | ll Placebo | 3.02 | | 7 to 9 | pg. 29; table 8 |
| | | | WILL DISCHOO | Fluoxetine vs Placebo | 2.90 | 0.29 | | |

Table 4. SF-36 Treatment Studies: Summary of MCS Change Scores, continued

| Therapeutic Area | Condition | Includes Elderly | Study Design | Treatment(s) | MCS Change | | US Pop. Percentile | Ref. to detailed |
|----------------------|-----------------------------------|---------------------|--|---|------------|-------------|-----------------------|-------------------|
| Citations | | , | | | Difference | Effect Size | change | tables |
| Coulehan, JL | Depression | No | | Protocol treatment | 16.35 | | 3 to 19 | |
| 997 | | | Randomized trial, no | Usual Care | 9.87 | | 4 to 12 | pg. 25; table 8 |
| | | | placebo | Protocol vs Usual Care | 6.48 | 0.65 | | |
| acobs, RJ | | NR | | Clonazepam | 9.69 | | 5 to 16 | |
| 997 | Panic Disorder | | Randomized, controlled tria | Placebo | 4.69 | | 7 to 12 | pg. 25; table 8 |
| | | | with placbo | Clonazepam vs Placebo | 5.00 | 0.50 | | |
| Brown, C | | No | | Depression/pharmacotherapy | 15.10 | | 5 to 24 | |
| 1996 | Major depression, Anxiety & panic | | Randomized trial, no | Depression/psychotherapy | 14.90 | | 6 to 26 | pg. 26; table 8 |
| 330 | disorders | | placebo | Depression/pharmaco vs psychotherapy | 0.20 | 0.02 | | |
| Respiratory Diseases | | | | | | | | |
| tespiratory Discuses | | | | Placebo | 0.06 | | 31 to 31 | |
| Jones, PW | | Yes | | Salmeterol 50 mcg bid | 0.57 | | 31 to 33 | |
| 1997 | Chronic Obstructive Pulmonary | | Randomized, controlled tria with placbo | Salmeterol 100 mcg bid | -2.49 | | 33 to 26 | pg. 31,32; table |
| | Disease | | with placbo | Salmeterol 50 mcg vs. placebo | 0.51 | 0.05 | | |
| | | | | Salmeterol 100 mcg bid vs. Placebo | -2.55 | 0.26 | | |
| Mahajan, P | Asthma | Yes | | Placebo | -1.5 | | 70 to 59 | |
| 1997 | | | Randomized, controlled tria with placbo | Fluticasone prop. 250 mcg bid | 0.58 | | 78 to 78 | 00 04 4-14 |
| | | | with placbo | Fluticasone prop. 100 mcg bid | -0.08 | | 70 to 70 | pg. 30, 31; table |
| | | | | Fluticasone prop. 100 mcg bid vs. placebo | 1.42 | 0.14 | | |
| | | | | Fluticasone prop. 250 vs. placebo | 2.08 | 0.21 | | |
| Bousquet, J | | NR | Decidencies de controlle d'Arie | Cetirizine | 12.84 | | 22 to 70 | |
| 1996 | Perennial Allergic Rhinitis | | Randomized, controlled tria with placbo | Placebo | -0.26 | | 22 to 20 | pg. 33; table 9 |
| | | | With piaces | Cetirizine vs. Placebo | 13.10 | 1.31 | | pg. 33, table s |
| Other Therapies | | | | CAPD | | | 16 to 12 | |
| AcComb, J | | NR | Unrandomized, | PacXtra | -0.86 | | 40 to 28 | pg. 19; table 7 |
| 997 | Peritoneal Dialysis | | comparative trial, no | Amp80 | -4.16 | | 24 to 22 | pg. 10, table 1 |
| | | | placebo | PacXtra vs Amp80 | 3.3 | 0.33 | | |
| Bouchet, C | | No | | Placebo & 2 questions | 1.59 | | 31 to 33 | |
| 1996 | General Population Nutrition | | Randomized, controlled tria | Vitamin & 2 questions | 1.11 | | 28 to 33 | pg. 20; table 7 |
| | Program | | with placbo | Placebo & 2 ques vs. Vitamin & 2 ques | 0.48 | 0.05 | | |
| _awrence, K | Inguinal Hernia | No | | Laproscopic surgery | -1.90 | | 64 to 53 | |
| | - | | Randomized trial, no | | -2.09 | | 70 to 59 | pg. 23; table 7 |
| 1995 | | | placebo | Open surgery | -2.09 | | 70 10 39 | pg. 23, table 1 |

Table 5. Summary of Treatment Effects by Effect Size Categories

| | Effect Size | ze: Small (0.2 to 0.4) | Effect Size: N | Moderate (0.5 to 0.7) | Effect Size: Larg | ge (0.8 or greater) |
|-----|--------------------------------------|--|---------------------------------------|--|---|--|
| | XS health effects | Change in health | XS health effects | Change in health | XS health effects | Change in health |
| | Impact of back pain/sciatica | Impact of aging 1 year, adults age 65+ | Limitations in use of arm/leg | Effect of treatment for duodenal ulcer | Patients with serious physical morbidity | Total hip replacement surgery |
| | Impact of angina | GERD | Impact of congestive heart failure | Pressure (MAP) goal vs. Low MAP goal for hypertension | congestive heart failure: severe vs. mild | Therapy for low back pain |
| | Impact of type II diabetes | Transcervical resection vs. medical treatment for heavy menstrual loss | Impact of osteoarthritis | Fluticasone prop 100 mcg bid vs. placebo for asthma | Impact of rheumatoid arthritis | Heart valve replacement surgery |
| | Impact of past MI | migraine headaches | Impact of duodenal ulcer | Cetirizine vs. placebo for perennial allergic rhinitis | | |
| | Impact of COPD | Pharmacotherapy vs. psychotherapy for depression | | Laparoscopic vs. open surgery for inguinal hernia | | |
| | Impact of Irritable Bowel Disease | PacXtra vs. Amp80 for peritoneal dialysis | | | | |
| MCS | Impact of chronic | Effect of heart valve replacement | Impact of actions | Effect of treatment for | Impact of clinical | Recovery from |
| | lung disease | surgery | і ппрасі от азіпта | duodenal ulcer | depression | depression |
| | Impact of dermatitis | Effect of hip replacement surgery | | Study therapy vs. usual care for depression | | Strength vs. flex. program for cardiac patients |
| | Impact of vision impairment | Salmeterol 100 mcg bid vs. placebo for COPD | | Rapid MRI vs. plain radiography for low back pain | | Transcervical resection vs. med treatment for heavy menstrual loss |
| | | Omeprazole vs. placebo for GERD | | Clonazepam vs. placebo for panic disorder | | Cetirizine vs. placebo for perennial allergic rhinitis |
| | | PacXtra vs. Amp80 for peritoneal dialysis | | | | |
| | | Occupational therapy vs. control for independent elders | | | | |
| | | Pre/post oral sumatriptan for migraine headaches | | | | |
| | | Fluoxetine vs. placebo for late life depression | | | | |
| | | Fluticasone prop 250 mcg bid vs. placebo for asthma | | | | |

Entries shown in italics are reproduced from SF-36 Physical and Mental Health Summary Scales: A User's Manual. Entries in bold are drawn from articles summarized in this report.

APPENDIX A: SUMMARY TABLES OF TREATMENT STUDIES

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APPENDIX B: CITATIONS FOR SF-36 TREATMENT STUDIES PUBLISHED THROUGH 1997

Experimental, randomized placebo-controlled trials (n=13)

- 1. Bouchet C, Guillemin F, Briancon S. Nonspecific effects in longitudinal studies: impact on quality of life measures. Journal of Clinical Epidemiology 1996; 49(1):15-20.
- 2. Bousquet J, Duchateau J, Pignat JC *et al.* Improvement of quality of life by treatment with cetirizine in patients with perennial allergic rhinitis as determined by a French version of the SF-36 questionnaire. Journal of Allergy and Clinical Immunology 1996; 98:309-16.
- 3. Coleman EA, Buchner DM, Cress ME, Chan BKS, de Lateur BJ. The relationship of joint symptoms with exercise performance in older adults. Journal of the American Geriatrics Society 1996; 1(44):14-21.
- 4. Heiligenstein JH, Ware JE, etal. Acute effects of fluoxetine versus placebo on functional health and well-being in late-life depression. International Psychogeriatrics 1995; 7 suppl: 125-137
- 5. Jacobs RJ, Davidson JRT, Gupta S, Meyerhoff AS. The effects of clonazepam on quality of life and work productivity in panic disorder. American Journal of Managed Care 1997; 3(8):1187-96.
- 6. Jones PW, Bosh TK. Quality of life changes in COPD patients treated with salmeterol. American Journal of Respiratory & Critical Care Medicine 1997; 155(4):1283-9.
- 7. Mahajan P, Okamoto LJ, Schaberg A, Kellerman D, Schoenwetter WF. Impact of fluticasone propionate powder on health-related quality of life in patients with moderate asthma. Journal of Asthma 1997; 34(3):227-34.
- 8. Moseley JB, Wray NP, Kuykendall D, Willis K, Landon G. Arthroscopic treatment of osteoarthritis of the knee: a prospective, randomized, placebo-controlled trial: results of a pilot study. American Journal of Sports Medicine 1996; 1(24):28-34.
- 9. Noonan M, Chervinsky P, Busse WW *et al.* Fluticasone propionate reduces oral prednisone while it improves control of asthma and quality of life. American Journal of Respiratory and Critical Care Medicine 1995; 152:1467-73.
- 10. Okamoto LJ, Noonan M, DeBoisblanc BP, Kellerman DJ. Fluticasone propionate improves quality of life in patients with asthma requiring oral corticosteroids. Annals of Allergy, Asthma, & Immunology 1996; 5(76):455-61.
- 11. Sand PK, Richardson DA, Staskin DR *et al.* Pelvic floor electrical stimulation in the treatment of genuine stress incontinence: a multicenter, placebo-controlled trial. American Journal of Obstetrics and Gynecology 1995; 173(1):72-9.

- 12. Watson RGP, Tham TCK, etal. Double blind cross-over placebo controlled study of omeprazole in the treatment of patients with reflux symptoms and physiological levels of acid reflux the "sensitive oesophagus". Gut 1997; 40: 587-590
- 13. Wu AW, Rubin HR, etal. Functional status and well-being in a placebo-controlled trial of zidovudine in early symptomatic HIV infection. Journal of Acquired Immune Deficiency Syndromes 1993; 6: 452-458

Experimental, randomized comparative trial, no placebo (n =20)

- 14. Beniamini Y, Rubenstein JJ, Zaichkowsky LD, Crim MC. Effects of high-intensity strength training on quality-of-life parameters in cardiac rehabilitation patients. American Journal of Cardiology 1997; 80(7):841-6.
- 15. Boline PD, Kassak K, Bronfort G, Nelson C, Anderson A. Spinal manipulation vs. amitriptyline for the treatment of chronic tension-type headaches: a randomized clinical trial. Journal of Manipulative and Physiological Therapeutics 1995; 18(3):148-54.
- 16. Bozzette SA, Kanouse DE, Berry SH, Duan N. Health status and function with zidovudine or zalcitabine as initial therapy for AIDS: a randomized controlled trial. Journal of the American Medical Association 1995; 273(4):295-301.
- 17. Brown C, Schulberg HC, Madonia MJ, Shear MK, Houck PR. Treatment outcomes for primary care patients with major depression and lifetime anxiety disorders. American Journal of Psychiatry 1996; 153:1293-300.
- 18. Clark F, Azen SP, Zemke R *et al* . Occupational therapy for independent-living older adults: A randomized controlled trial. Journal of the American Medical Association 1997; 278(16):1321-6.
- 19. Coulehan JL, et al. Treating depressed primary care patients improves their physical, mental, and social functioning. Arch Intern Med. 1997 May 26;157(10):1113-20.
- 20. Cooper KG, et al. The impact of using a partially randomised patient preference design when evaluating alternative managements for heavy menstrual bleeding. Br J Obstet Gynaecol. 1997 Dec;104(12):1367-73.
- 21. Cooper KG, et al. A randomised comparison of medical and hysteroscopic management in women consulting a gynaecologist for treatment of heavy menstrual loss. Br J Obstet Gynaecol. 1997 Dec;104(12):1360-6.
- 22. DCCT, Influence of intensive diabetes treatment on quality of life outcomes in the diabetes control and complications trial. Diabetes Care 1996; 19(3): 195-203
- 23. Erickson SR, Slaughter R, Halapy H. Pharmacists' ability to influence outcomes of hypertension therapy. Pharmacotherapy 1997; 17(1):140-7.
- 24. Jarvik JG, et al. Rapid MR imaging versus plain radiography in patients with low back pain: initial results of a randomized study. Radiology. 1997 Aug;204(2):447-54.

- 25. Koopman MW, et al. Treatment of venous thrombosis with intravenous unfractionated heparin administered in the hospital as compared with subcutaneous low-molecular-weight heparin administered at home. The Tasman Study Group. N Engl J Med. 1996 Mar 14;334(11):682-7.
- 26. Kusek JW, et al Effect of blood pressure control and antihypertensive drug regimen on quality of life: the African American Study of Kidney Disease and Hypertension (AASK) Pilot Study. Control Clin Trials. 1996 Aug;17(4 Suppl):40S-46S.
- 27. Lawrence K, et al. Randomised controlled trial of laparoscopic versus open repair of inquinal hernia: early results. BMJ. 1995 Oct 14;311(7011):981-5.
- 28. Lonnqvist J, Shivo S, et al. Moclobemide and fluoxetine in the prevention of relapses following acute treatment of depression. Acta Psychiatrica Scandinavica 1995: 91: 189-194
- 29. Rampal P, Martin C, Marquis P, Ware JE, Bonfils S. A quality of life study in five hundred and eighty-one duodenal ulcer patients. Scandinavian Journal of Gastroenterology 1994; 29(206):44-51.
- Regensteiner JG, Meyer TJ, Krupski WC, Cranford LS, Hiatt WR. Hospital vs homebased exercise rehabilitation for patients with peripheral arterial occlusive disease. Angiology 1997; 48(4):291-300.
- 31. Regensteiner JG . Exercise in the treatment of claudication: assessment and treatment of functional impairment. Vasc Med. 1997;2(3):238-42. Review.
- 32. Shield CF, McGrath MM, Goss TF. Assessment of health-related quality of life in kidney transplant patients receiving tacrolimus (FK506)-based versus cyclosporine-based immunosuppression. Transplantation 1997; 64(12):1738-43.
- 33. Simon GE, VonKorff M, Heiligenstein JH *et al.* Initial antidepressant choice in primary care: effectiveness and cost of Fluoxetine vs tricyclic antidepressants. Journal of the American Medical Association 1996; 275:1897-902.

Experimental, unrandomized, comparative trial, no placebo (n=7)

- 34. Adelman JU, Sharfman M, Johnson R *et al.* Impact of oral sumatriptan on workplace productivity, health-related quality of life, healthcare use, and patient satisfaction with medication in nurses with migraine. American Journal of Managed Care 1996; 2(10):1407-16.
- 35. Coulter A, et al. Quality of life and patient satisfaction following treatment for menorrhagia. Fam Pract. 1994 Dec;11(4):394-401.
- 36. Currie IC, et al. Treatment of intermittent claudication: the impact on quality of life. Eur J Vasc Endovasc Surg. 1995 Oct;10(3):356-61.

- 37. Gross MLP, Dowson AJ, Deavy L, Duthie T. Impact of oral sumatriptan 50 mg on work productivity and quality of life in migraineurs. British Journal of Medical Economics 1996; 10:231-46.
- 38. Mushet GR, Miller D, Clemente B, Pait G, Gutterman DL. Impact of sumatriptan on workplace productivity, nonwork activities, and health-related quality of life among hospital employees with migraine. Headache 1996; 36:137-43.
- 39. McComb J, et al. Impact of portable APD on patient perception of health-related quality of life. Adv Perit Dial. 1997;13:137-40.
- 40. Niemeyer MG, Kleinjans HA, de Ree R, Zwinderman AH, Cleophas TJ, van der Wall EE. Comparison of multiple-dose and once-daily nitrate therapy in 1212 patients with stable angina pectoris: effects on quality of life indices. Angiology 1997; 48(10):855-62.

Non-experimental, Cohort prospective study (n=2)

- 41. Bodner, CH Measuring health-related quality of life outcomes in women with endometriosis results of the gynaeology audit project in Scotland. Health Bulletin 1997; 55(22): 109-17.
- 42. Beard, CJ Complications after treatment with external-beam irradiation in early-stage prostrate cancer patients: a prospective multi-institutional outcomes study. Journal of Clinical Oncology 1997; 15(1): 223-29.

References

- 1. Ware JE, Bayliss MS, Rogers WH, Kosinski M, Tarlov AR. Differences in 4-year health outcomes for elderly and poor, chronically ill patients treated in HMO and feefor-service systems. *JAMA* 1996;276:1039-1047.
- Ware JE Jr, Snow KK, Kosinski M, Gandek B. <u>SF-36 Health Survey Manual and Interpretation Guide</u>. Boston, MA: New England Medical Center, The Health Institute, 1993.
- 3. McHorney CA, Kosinski M, Ware JE. Comparisons of the costs and quality of norms for the SF-36 Health Survey collected by mail versus telephone interview: Results from a national survey. *Medical Care* 1994:32:551-567.
- 4. Ware JE, Kosinski M, & Keller SD. <u>SF-36 Physical and Mental Health Summary</u> Scales: A User's Manual. Boston, MA: Health Assessment Lab, 1994.
- 5. McHorney CA, Ware JE, & Raczek AE. The MOS 36-Item Short-Form Health Survey (SF-36): II. Psychometric and clinical tests of validity in measuring physical and mental health constructs. *Medical Care* 1993; 31: 247-263.
- Ware JE, Kosinski M,Gandek B et al., The factor structure of the SF-36 Health Survey in 10 Countries: Results from the IQOLA Project. *J Clin Epidemiol* 1998;51(11)1159-1165.
- 7. Cohen J. <u>Statistical Power Analysis for the Behavioral Sciences: Second Edition.</u> Hillsdale, NJ: Lawrence Erlbaum Associates, Inc. 1988.
- 8. Okamoto LJ, Noonan M, DeBoisblanc BP, Kellerman DJ. Fluticasone propionate improves quality of life in patients with asthma requiring oral corticosteroids. *Annals of Allergy, Asthma, & Immunology* 1996; 5(76):455-61.
- 9. Hornbrook MC, Goodman MJ. Assessing relative health plan risk with the SF-36 health survey. *Inquiry* 32: 56-74, 1995.