THE VETERANS RAND 12 ITEM HEALTH SURVEY (VR-12): WHAT IT IS AND HOW IT IS USED

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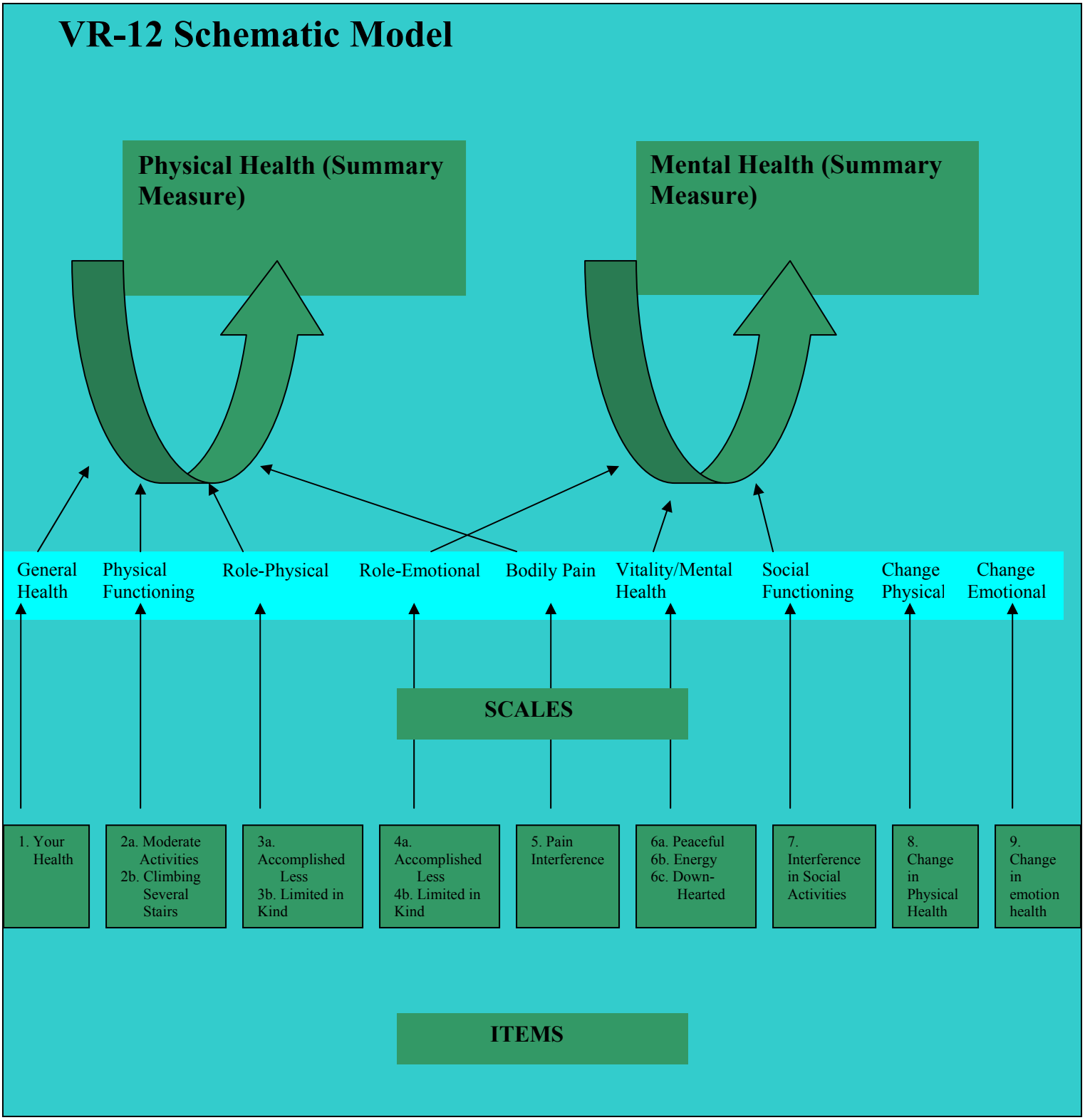
Overview

The Veterans RAND 12 Item Health Survey (VR-12) is a brief, generic, multi-use, self-administered health survey comprised of 12 items. The instrument is primarily used to measure health related quality of life, to estimate disease burden and to evaluate disease-specific benchmarks with other populations. The 12 items in the questionnaire correspond to eight principal physical and mental health domains including *general health perceptions; physical functioning; role limitations due to physical and emotional problems; bodily pain; energy-fatigue, social functioning and mental health.*. The 12 items are summarized into two scores, a "Physical Health Summary Measure {PCS-physical component score}" and a "Mental Health Summary Measure {MCS-mental component score}". These provide an important contrast between physical and psychological health status.



*Change Physical and Change Emotional scales are not used in the calculation of the PCS and MCS summary measures

** Arrows to the summary measures reflect the greater disposition to the appropriate physical or mental health summary measures

Development

The VR-12 was derived from the Veterans RAND 36 Item Health Survey (VR-36), historically called the Veterans SF-36 (Kazis et al 2006 [1,2]). The VR-36 was adapted from the RAND SF-36 Version 1.0 questionnaire, and spans the range of health domains from physical to psychological health status. In comparison with the RAND SF-36, there are two modifications made in the VR-36. The first modification is an increase in the number of response choices for the role physical (RP) and role emotional (RE) items from a two point yes/no choice to a five-point likert scale (no, none of the time, yes, a little of the time, yes, some of the time, yes, most of the time, yes, all of the time).The second modification is the use of two items to assess health change, one focusing on physical health and one on emotional problems, in contrast to the one general change item in the RAND SF-36 (Kazis et al 2004 [3,4]). The VR-36 has been widely used, distributed and documented in the Veterans Health Administration (VHA) with close to 2 million questionnaires administered nationally in six national surveys since 1996. The changes to the survey have increased the overall precision of the instrument and the discriminant validity of the physical and mental component summary scales (Kazis et al 2006 [5]). The VA has adopted the VR-36 as a primary measure of health related quality of life and functional status measures, and a secondary measure of disease burden and for risk adjustment purposes for comparisons made among veterans. The VR-12 was developed using extensive research and normative data from the VR-36 in the VHA. It consists of the 12 most important items from the VR-36 for construction of the physical and mental component summary scales. The 12 items in the VR-12 explain a great deal of the variability in the VR-36. The scoring of PCS and MCS is based on weights derived from the VR-36 administered to 1.4 million veteran enrollees with 877,775 respondents in the 1999 Large Health Survey of Veteran Enrollees (Veterans Health Study), the largest federal survey ever conducted in the VA. The weights were obtained from the large sample in the VA survey to create PCS and MCS scores. That is, dummy indicators were defined for response choices for each of the 12 items in the VR-12 and these were then entered into multiple regressions to predict PCS and MCS scores based on the VR-36. The resulting weights, and the constant term, can be used to compute PCS and MCS scores from the VR-12. The two summary component scales derived from the VR-12 explained over 90% of the variance in PCS and MCS scales of the VR-36 used in the 1999 Large Health Survey of Veterans Enrollees (Jones et al 2001 [6]).

Applications and Usability

Applications of the VR-12

The VR-12 has been administered in national VA surveys in 1997 and 1998 to over 60,000 patients. Since 2002, the VA has administered the VR-12 to approximately 432,000 patients annually as part of its quality management program (Survey of Health Experiences of Patients, SHEP). As of spring 2006, the US Centers for Medicare and Medicaid Studies (CMS) has been administering the VR-12 to Medicare enrollees as part of the Medicare Health Outcomes Survey (Medicare HOS 2.0), designed to monitor the quality of care in Medicare Advantage Plans (MAP) (Kazis et al 2004 [4]). The VR-12 has been included in HEDIS 2007 (Health Plan Employer Data and Information Set), as part of the performance measurement data set most widely used and disseminated in the managed care industry.

When administered to a patient population in time, the VR-12 provides a reliable and valid measure of health status and case mix adjustment. It has been an important source, for the office of Quality and Performance at the VHA, to monitor the process and outcomes of care at the program and system levels. Similarly, CMS uses the VR-12 to assess the physical and mental health functioning of its enrollees and to generate information for payment adjustments.

The effectiveness of the VR-12 in estimating health status and disease burden along with providing a rubric for risk adjustments has been demonstrated in several publications spanning multiple disease systems (Kazis et al 2006 [5]). Subsequently, it has provided applications in the VA for conducting medication effectiveness studies based upon non-randomized prospective quasi-experimental designs that approximate real world clinical conditions. Such applications using the VR-12 have been widely published for medication studies in those diagnosed with hypertension, osteoarthritis, low back pain, depression, and schizophrenia.

Chronic Disease Burden

The most traditional application of health status measures is the evaluation of change in relation to the presence of different comorbid conditions. VR-12 is used to gauge the incremental effect of case mix on health status and make meaningful comparisons about populations with different chronic diseases, thus providing a proxy for disease burden. The Medical Outcomes study (MOS) reported an overall mean (age and sex adjusted) of 43.6 and 52.3 for SF- 36 PCS and MCS scores, respectively. This was in contrast to the means of 36.91 (PCS) and 45.08 (MCS) for VR-36 in the Veterans Administration health care system, thus reflecting a greater disease burden among veterans (Rogers et al 2004 [7]). With respect to the specific effect of comorbid conditions on health status, the use of VR-36 PCS and MCS measures has been instrumental in gauging the incremental impact of case mix across several chronic disease conditions (Kazis et al 2004 [8]). For example the Veterans Health Study showed that having angina resulted in a PCS score that is 2.53 points lower (0.25 of 1 standard deviation) than the score of those veterans without angina. Similarly, the presence of depression led to an 8-point reduction in MCS among veterans while controlling for other comorbidities and demographics.

Average Impact of PCS and MCS Scores Observed in Veterans Health Study

Condition	Impact on PCS┼	Impact on MCS┼
Hypertension	-0.60	-0.50
Angina	-2.53	-0.64
Diabetes	-3.05	-0.08
Osteoarthritis	-4.78	-2.05
Chronic low back pain	-5.51	-2.83
Chronic Lung Disease	-3.57	-
Depression	-	-8.00
Alcohol Disorders	-	-6.59

┼ *Impact of disease on PCS/MCS controlling for sociodemographic and comorbid conditions*

Another study (Gage et al 2003 [9]) calculated the PCS and MCS scores for Veterans with Parkinson disease and compared them with those with eight other neurological or chronic conditions. Veterans with Parkinson's disease had PCS and MCS scores lower than scores of veterans with angina/coronary heart disease, arthritis, chronic low back pain, congestive heart failure, diabetes, and stroke. The incremental or unique effect of Parkinson's disease on Health Related Quality of Life (HRQoL) was found to lower PCS and MCS by 4.10 and 3.42 points, respectively.

Risk Adjustment

Risk adjustment is a methodology used to control for patient characteristics that may affect health care outcomes, and mortality is one key variable of interest in measuring patient-related outcomes. VR-12 PCS and MCS summary measures have been used extensively as integral elements of risk adjustment models that were developed to reliably predict mortality in VA patients receiving ambulatory care. In one longitudinal study (Selim et al 2002 [10]) involving 31, 823 VA patients followed for 18 months, patients with higher VR-12 PCS and MCS scores showed a lower likelihood of dying, as indicated by odds ratios in the logistic regression models. The highly significant associations of VR-12 PCS and MCS summary measures with mortality resulted in their inclusion as important predictor variables in the final risk adjustment model. In another study (Selim et al [11]) comprising a representative sample of 324,865 VHA ambulatory patients, a risk adjustment model for mortality was developed using a prospective monitoring system of outcomes of patients receiving ambulatory care in the Veterans Health Administration (VHA) integrated service networks (VISNs). The baseline VR-12 PCS and MCS measures were significantly associated with mortality and were included as predictor variables in the final risk adjustment model.

Performance Indicator/Outcomes Assessment

Another core application of the VR-36 is its established use in assessing health outcomes and systems' performances in large health care systems. The first application of this kind employed the RAND SF-36 PCS and MCS change scores as performance indicators to compare health outcomes among chronically ill Medicare enrollees in health maintenance organizations (HMO) with the health outcomes of those in the fee for service (FFS) systems (Ware et al 1996 [12]). This approach of using health status measures to measure systems' performance was then validated for the VR-36 in a representative sample of 31, 823 VA patients across 22 integrated service networks (Selim et al 2006 [13]). The change in VR-36 PCS and MCS measures, included as part of a multidimensional risk adjusted model, served as the basis for calculating and comparing expected versus actual PCS and MCS rates at the individual patient level for each integrated network. The adjusted rate for a network was its observed rate divided by its expected rate, multiplied by the mean of the rates observed for all networks. The comparison of expected versus actual rates at the VA regional level (Vertically Integrated Service Networks – VISNs) provided a framework to assess network performance after case mix adjustments and to identify processes of care or management practices that may serve as models for best practices. Conversely, greater-than-expected rates of decline in health status measures served as a basis to assess gaps in quality of care and disease management. Recently, the use of VR-12 health status measures as outcome and performance indicators has been validated in cross-system comparisons between the MAP enrollees and VHS cohorts (Selim et al 2006 [14]).

Interpretation Guidelines of the VR-12: Issues around Clinical Relevance

The clinical relevance of any change observed in PCS and MCS scores in response to an intervention should be an important consideration in understanding the chronic disease conditions. A result may be statistically significant but may not be clinically meaningful.

Therefore one essential characteristic of an instrument is its ability to detect clinically important and meaningful changes in patient's function as a result of an intervention (Kirshner et al 1985 [15], Guyatt et al 1987 [16]). There are several techniques that can be employed to quantify this responsiveness of an instrument towards a clinically important change (Lydick et al 1993 [17]). Anchor-based methodology measures a patient change score against a clinically relevant or outside change, while distribution-based methods rely on effect sizes (Lydick et al 1993 [17]). Effect size is the mean change of the individual divided by the variability of the whole group or the subset of stable subjects. An effect size of 0.2 is considered small, 0.5 is moderate, while 0.8 or greater is considered large (Cohen et al 1977 [18]).

There are at least three published approaches for calculating effect size, where the numerator for each approach is the pre-treatment score minus the post-treatment score. The denominator however differs among these approaches, the first is the standard deviation of score changes for the group (Cohen et al 1977 [18]), the second is the standard deviation of score changes for a stable or a control group (Guyatt et al 1987 [16]), and the third suggested is the standard deviation of the pretreatment group (Kazis et al 1989 [19]).

The VR-36 (and VR-12) has been employed in relation to both anchor based and distribution based techniques to gauge the clinical significance of a change following an intervention. One of the profound applications of VR-36 (and VR-12) is its consistent ability to show the relevant clinical impact of an intervention (or no intervention) as an associated difference in the PCS and/or MCS scores. One randomized double blind placebo controlled trial (Donta et al 2004 [20]), designed to evaluate the benefits and harms of doxycycline treatment among Gulf War veterans, used the change in VR-36 PCS scores as the primary outcome of the study. Following treatment (doxycyline or placebo), the proportion of patients showing more than seven units of improvement on the PCS scores of VR-36 were termed as improved. The change of 7 units or greater was selected because it is outside the 95% confidence interval for an individual participant score (standard error of the measurement) and differences of this magnitude have also been shown to be clinically relevant. Pain, fatigue and cognitive function, measured through VR-36 items, were taken as secondary outcomes. The study showed no significant differences in primary and secondary outcomes as a function of change in VR-36 health status measures between the two groups, and concluded that long term treatment with doxycycline did not improve outcomes of Gulf war veterans at one year.

In another multi-center trial of Gulf War veterans (Donta et al 2003 [21]), VR-36 health status measures were employed to evaluate the effectiveness of cognitive behavioral therapy (CBT), exercise, and a combination of the two at improving physical functioning and decreasing symptoms of Gulf War Veterans' Illness (GWVI). Based on previous validation studies of clinically meaningful change, a metric of seven-units of improvement in VR-36 PCS score and any standardized change in the VR-36 items for pain, fatigue, cognitive functioning, distress and mental health functioning symptoms was taken as primary and secondary end points, respectively. The study showed that CBT significantly improved the physical functioning of veterans as reflected by the PCS summary scores, while exercise led to modest improvements in nearly all symptoms (VR-36 item scales) except pain. Both treatments enhanced cognitive and mental health functioning.

One longitudinal study compared the responsiveness of four generic instrument measures (Quality of Well-Being Scale {QWB}, SF-36 Visual Analog Scale {VAS}, VR-36 MCS, World Health Organization Disablement Assessment Schedule {WHO-DAS}) in detecting clinically meaningful improvement in schizophrenia symptoms among 134 newly diagnosed veterans (Pyne et al 2003 [22]). The VR-36 MCS measure

along with other generic measures showed significant correlations with changes in side effects, depression symptoms, as well as with PANSS (Positive and Negative Syndrome Scale) scores as a function of an effect size variable.

The VR-36 MCS measure was also employed in one longitudinal VA study of 2,427 male veterans to examine the association of sexual assault and religious inclinations with mental health (Chang et al 2003 [23]). The subjects with reported sexual assault showed poorer mental health status as shown by lower MCS scores. Furthermore, the decrement in mental health (MCS score) status was in lesser degrees for patients with religious inclinations.

A widely emerging application of VR-36 (VR-12) PCS and MCS measures is their use in assessing health outcomes for medication effectiveness studies with quasi-experimental designs, employing VA administrative databases. In one retrospective cohort study (Hamed et al 2001 [24]) combined the patient reported data from the 1999 Large Health Survey of Veteran Enrollees with the VA administrative claims and pharmacy data at the individual patient level, and examined the differential effect of various antidepressants on PCS and MCS scores. Results showed that patients on a single anti-depressant medication tended to have higher scores for PCS and MCS (denoting better health) than patients on two or more medications. Among single drug group patients using a serotonin specific reuptake inhibitor (SSRI) or a tricyclic antidepressant (TCA), results were higher for MCS, and lower for PCS, than patients on a serotonin-norepinephrine reuptake inhibitor (SNRI), venlafaxine. Risk adjustments included demographics (age, gender) and medical and psychiatric co-morbidities using ICD-9 codes.

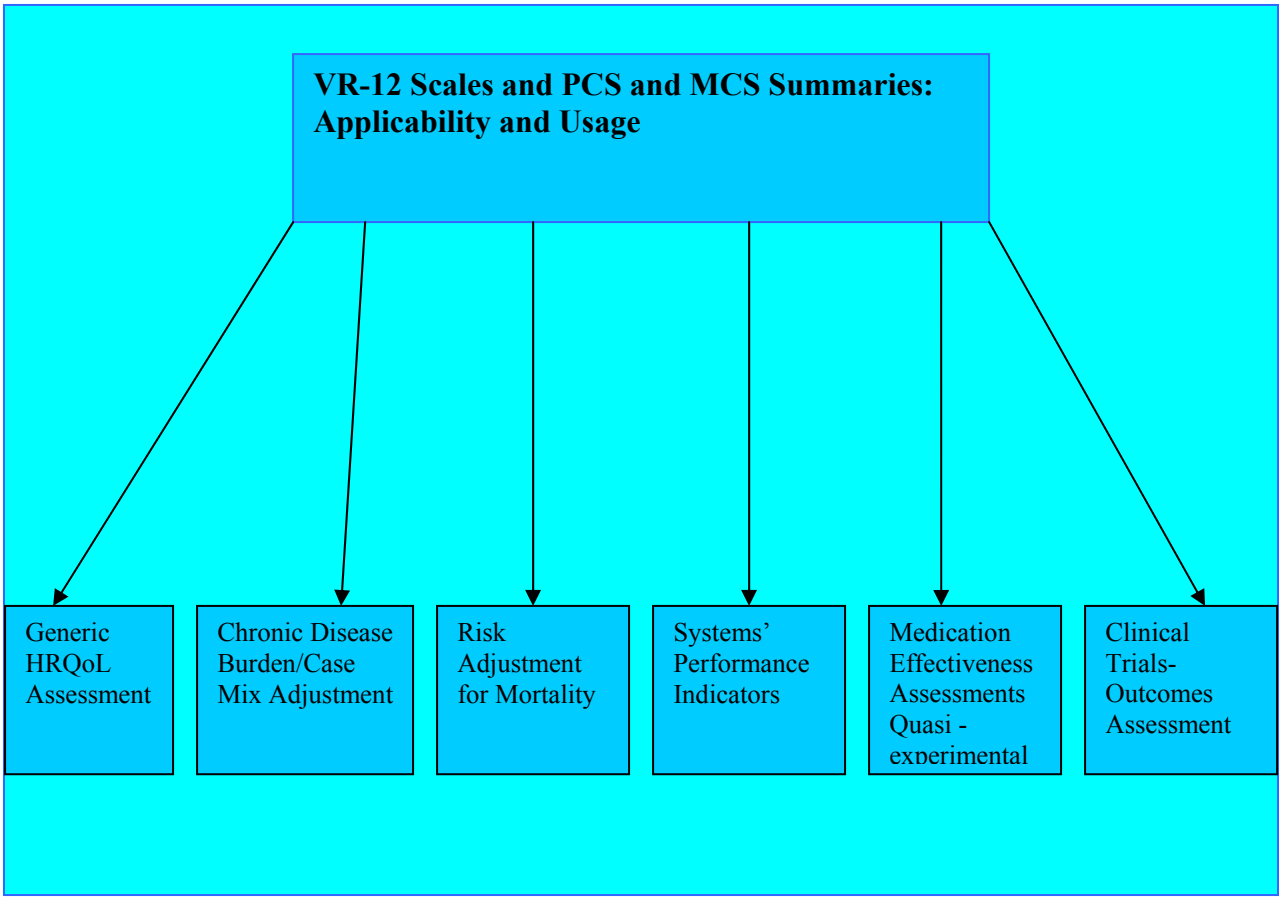
In a separate study related to patient perception of pain in those diagnosed with chronic low back pain (CLB) and/or osteoarthritis (OA), Hamed et al. 2004[25] examined the effect of duration of therapy of an opioid analgesic- transdermal fentanyl (TDF)- on patient-reported change in physical and emotional health using the VR-36. This 3 year, retrospective cohort study merged the patient-reported outcomes data from the 1999 Large Health Survey of Veteran Enrollees with the VA claims and pharmacy data to yield a sample size of 441 veterans who were on therapy with the target medications during the time of the survey. Using the merged data for each patient record, three therapeutic groups were identified based on the pattern of prescription: (1) those prescribed TDF only and no short-acting opioids; (2) switchers-to-TDF who were prescribed a short-acting opioid, then switched to TDF; and (3) concomitant users who were prescribed TDF with a short-acting opioid simultaneously during the period of observation. Multivariate models with risk adjustments showed that TDF was associated with a significant improvement in physical and emotional change per month, reaching a one-half standard deviation improvement (moderate effect size) in 5 months for physical change, and 10 months for emotional change. Results suggested that patients receiving TDF report patient-perceived improvement in their physical and emotional status compared to a year ago, despite their compromised health.

The VR-36 PCS and MCS measures have also been reliable and effective in documenting a perceived change in health-related quality of life and health resource utilization in response to poor health behaviors and lifestyle factors. Several large investigations (Kazis et al 2004 [8], Borzecki et al 2005 [26]) of patient-reported outcomes using VR-36 have shown significant negative associations between smoking and VR-36 PCS and MCS measures, and between alcohol use and VR-36 PCS and MCS scores. Exercise and body mass index (BMI) were also shown to be significant predictors of PCS scores in these studies, after adjusting for sociodemographics and comorbid conditions.

The significant associations of VR-36/VR-12 PCS and MCS summary measures with clinically recognizable and meaningful changes in randomized clinical trials and observational naturalistic prospective studies strongly suggest that these measures can be applied to other empirical inquiries designed to quantify a clinical benefit. However, clinically important differences may differ across different groups of patients with distinct diseases, levels of severity, demographics and socioeconomic status. Repeated, well-designed, and clinically oriented standard HRQoL assessments applied as endpoints across different population groups will help clinicians to

make more reliable and meaningful clinical interpretations of summary scales. They also provide a multidimensional framework to evaluate chronic disease conditions and associated clinical interventions.

Figure 2 shows the schematic application and usage of VR-12



Information for Obtaining the VR-36, VR-12 Questionnaires and Scoring Algorithms

The package available to users includes documentation for the questionnaire, 'scoring guide' and 'algorithms for scoring' including imputation of missing values.

The VR-12 and VR-36 are in the public domain and there is no cost for their use. Details involving the VR-36 and VR-12 questionnaires, scoring algorithms for PCS and MCS summary measures, and imputation programs for missing values can be obtained on request by agreeing to the stipulations given by the RAND Corporation website (See http://www.rand.org/health/surveys_tools/mos/mos_core_36item_terms.html) in a letter to Dr. Lewis Kazis on institutional letter head. The letter should state that the user wishes to obtain permission for the use of the VR-36 and VR-12 (formerly called the Veterans SF-36 and SF-12) from the developer (Dr. Kazis) and adhere to the stipulations given in the RAND Web site. The letter also should indicate that the user plans to give the appropriate acknowledgements for the VR-12 and/or the VR-36 (see below). This should be accompanied with an abstract of the project.

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Acknowledgements

For Users of the VR-36 state: *"The Veterans RAND 36 Item Health Survey (VR-36) was developed from the MOS RAND SF-36 Version 1.0."*
For Users of the VR-12 state: *"The Veterans RAND 12 Item Health Survey (VR-12) was developed from the Veterans RAND 36 Item Health Survey (VR-36) which was developed from the MOS RAND SF-36 Version 1.0."*
If you use the "SF-36" or "SF-12" anywhere in the questionnaire or paper or presentations state: *The SF-36® and SF-12® are registered trademarks of the Medical Outcomes Trust.*

The wording for the acknowledgements can appear as a footnote in any questionnaires, presentations or papers for publication. The acknowledgement and the following citations can be given in papers submitted for publication.[1-6.] In addition, if the scoring and imputation approaches reflected in these algorithms are used proper credit needs to be given by citing the respective documents on scoring and imputation contained in this package.[5-6]

Suggested Citations for Acknowledgements:

1. Kazis LE, Miller DR, Skinner KM, Lee A, Ren XS, Clark JA, Rogers WH, Spiro III A, Selim A, Linzer M, Payne SM, Mansell D, Fincke BG. Applications of Methodologies of the Veterans Health Study in the VA Health Care System: Conclusions and Summary. J Ambulatory Care Management 2006a 29:2 182-188.

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