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Cathy J Bradley
Major professor

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USE OF HEALTH AND ACTIVITIES LIMITATION INDEX (HALEX) FOR UTILITY ASSESSMENT IN PERSONS WITH ASTHMA AND DIABETES

By

Kathleen Oberst

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ABSTRACT

USE OF HEALTH AND ACTIVITIES LIMITATION INDEX (HALEX) FOR UTILITY ASSESSMENT IN PERSONS WITH ASTHMA AND DIABETES

By

Kathleen Oberst

Utility assessment is used to compare the health benefits of different investments. There is no gold standard for utility assessment and researchers are challenged to obtain these values in a methodologically sound yet cost-effective manner.

I compute a HALex score using the algorithm developed by Torrance, et al (1995) for individuals who responded to the 1996 National Health Interview Survey, were 18 years or older at the time of the survey and reported being diagnosed with asthma or diabetes. Using ordinary least squares regression, I show that demographic characteristics may impact HALex scores even when severity of illness is taken into account although to a lesser extent. I also compare the HALex utilities to directly assessed utilities for persons with asthma.

The mean HALex score for asthmatics and diabetics was 0.64 (SD=0.27) and 0.51 (SD=0.26), respectively. HALex scoring was susceptible to influences of demographic characteristics of the involved population and followed trends described in the literature. Even when severity of illness variables were included in regression models, demographic measures continued to achieve statistical significance although to a lesser extent.

I would like to dedicate this thesis and all the work leading up to its' completion to my husband, Dan. Without your support and encouragement throughout this process, it never would have come to completion. Your constant vigilance over the home fires allowed me to focus on the various school and work tasks at hand. I love you very much and the next load of laundry is on me, I mean it this time.

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LIST OF ABBREVIATIONS

Activities of Daily Living ....ADL

Health and Activity Limitation Index ....HALex

Health Utilities Index .... HUI

Instrumental Activities of Daily Living ....IADL

National Health Interview Survey...NHIS

Quality Adjusted Life Year .... QALY

Standardized Mortality Rate ....SMR

Years of Healthy Life...YHL

Chapter 1

INTRODUCTION

Cost-effectiveness analysis of health care compares health benefits and costs that may result from different investments.[7, 21] Due to limited resources, it is necessary to assess interventions and try to determine if the costs are justified compared to alternative treatment strategies. Historically, quantity of life was the focus of judging the worth of interventions. The ability to prolong life or demonstrate increased longevity compared to placebo were the measures of an intervention's effectiveness. Current standards however, require that quality of life or some measure of *utility* for health should also be considered.[1,7]

Many methods are available to evaluate the health status of a population. The most commonly used measures of effectiveness are variations of mortality such as infant mortality or disease-specific mortality.[1] Among the problems associated with these measures is the lack of comparative information about disease states that result in disability and social or mental dysfunction rather than mortality. Additionally, the preferences toward different health states are not taken into account.[7]

There have been many attempts to characterize a preference or utility for specific health states. Unfortunately, no gold standard exists for this type of measurement. The most theoretically sound approach is to directly assess utilities from the societal perspective using the standard gamble. This approach however, is both very costly and time consuming, curtailing its' application.

An important aspect of utility assessment is that utilities should be based upon a pure condition state. That is, the preference for a specific health state should be reflected solely from that particular health state. The preference would not vary whether it was obtained from a white versus non-white individual or whether the individual was more or less educated. Additionally, co-morbidities should not be factored into the utility assessment.

The Health and Activity Limitation Index (HALex) scoring system has been suggested as a means whereby a "catalog" of utilities for various health states may be generated. HALex scoring is based on two domains, activity limitation and perceived health. The benefit of this type of system is that it uses nationally available data, the National Health Interview Survey (NHIS). Therefore, norms for various health states can be generated for the United States in a relatively easy manner. This could ultimately assist priority setting for health care budgets and may also be useful for researchers evaluating cost-effectiveness of interventions targeted at specific diseases.

I will generate HALex scores for individuals with asthma and diabetes. Using ordinary least squares regression in a 2-step process, I will evaluate the potential impact of demographic characteristics on the mean HALex score for each population. Measures of severity of illness will then be added into the regression model to assess their impact on the model. The parameter estimates for the demographic variables will be reviewed for any change in order of magnitude and statistical significance as well.

Other research has indicated that personal, household and lifestyle characteristics have little contribution to health status compared to activity limitation and perceived health.[11, 18] If this is correct, adjustments for demographic variables as recommended by the Panel on Cost-Effectiveness in Health and Medicine would not be necessary.[21] HALex could then be used widely by researchers unable to directly assess utilities. The hypotheses under study are as follows:

- Demographic characteristics including age, gender, race, education, income and marital status will impact HALex scores generated for persons identified with asthma and diabetes in the 1996 NHIS dataset.
- Severity of illness measures including condition onset, time of last visit with physician, restricted activity days in the past two weeks due to condition, bed days in the past two weeks due to condition, bed days in the past twelve months due to condition and report of being hospitalized for condition are correlated with demographic variables. Therefore when these are added to the models, the coefficients on demographic characteristics will diminish in order of magnitude and statistical significance.

Should demographic characteristics have significant impact on HALex scoring, the use of HALex as a readily available "catalog" of utilities would be minimized. In order for HALex to be useful as an "off-the-shelf" utility, a researcher should have confidence that it is applicable to their study population. That is, the HALex scoring system must meet the criteria of generalizability. If the HALex of a particular condition were found to vary by gender, it could not be readily applied to another study population without first ensuring comparability with respect to gender distributions. For example, if the NHIS population used as the reference had a 75% male response and males tend to have a higher preference for the condition of interest; the HALex generated for this group could not be applied to a study group that was 75% female.

HALex is a relatively new tool and its' value is yet to be clearly delineated. Some work has been published evaluating HALex and acute health conditions.[18] Other work has compared HALex for chronic conditions to utility values obtained through other scales such as the Quality of Well Being (QWB) scoring mechanism or Health Utilities Index (HUI) scoring system.[7] This work will add to the body of knowledge by determining if HALex scoring can vary based upon the demographics of the population involved or if some measure of severity of illness/co-morbidity would compensate for any observed relationships.

Chapter 2

LITERATURE REVIEW

HALex scores are a newer method of utility assessment for cost-utility analysis. Their use is intriguing due to the relative ease with which they may be generated. HALex utilities are obtained from a formula developed by Torrance, et al (1995) incorporating age and two health related domains rather than directly assessing values.[1] The two domains are activity limitation and perceived health and the data comes from National Health Interview Survey (NHIS) responses. HALex scores may be combined with life expectancies to form a type of Quality Adjusted Life Year (QALY) known as a Year of Healthy Life (YHL). In fact, the Centers for Disease Control and Prevention are indirectly promoting the HALex scoring system by their reliance on the YHL measure to track progress towards national health objectives.[1,11]

QALYs are useful to researchers in assessing interventions across different disease processes.[15] With all QALYs, time in a less than perfect health state is adjusted downward compared to perfect health. The "utility" is the value of the preference for the alternate health state. Several classification systems that have specified health related domains have been developed to assist researchers in obtaining QALYs. These include the Health Utilities Index based upon the time-trade-off method. Also, the Quality of Well-Being Index and the EuroQol may be used whereby the values assigned to the various domains come in part from direct measurement of community population samples.[7]

It is important to note that different audiences can assign quality weightings. Perspectives may include patients with a condition, health care professionals, family caregivers, or payers. A societal point of view rather than a patient's perspective is preferred for public policy decision-making according to the recommendations of the Panel on Cost-Effectiveness in Health and Medicine.[2,7,21] A random sample of society would include all possible viewpoints towards a specific condition. Those who were afflicted, health care providers, other members of society that had assumed a caretaker role, and those who had no previous knowledge of the condition would all contribute to the weighting. This sort of undertaking would be both resource and time intensive.

In addition to the requirement for a societal perspective, the Panel on Cost-Effectiveness in Health and Medicine has established seventeen recommendations for performing a cost-effectiveness analysis.[21] HALex scoring methodology can satisfy a majority of these.[2] However; there are five recommendations where the method may be questioned. The panel suggests that all health effects are to be included in an effectiveness measure.[21] Since data on comorbidities is not available from NHIS results, it is not able to be determined whether this is accomplished. Also, an analysis should be evaluated with respect to *status quo* treatment.[21] Data on treatments are also not available from the NHIS data. The perspective used to generate the HALex utility can be either patient or family member/co-habitant since only those identified as affected with the particular disease of interest are used to generate the HALex score. Finally, adjustments for age, sex, and race should be made and a correct number of significant digits reported.[21] The wide range in HALex scores indicated by the large standard deviations suggests that a cost-effectiveness analysis may differ depending on the population to be studied.[2]

In the absence of direct assessment, the methods to determine quality adjustment weights for populations has generally involved two steps.[2] First, various dimensions of a health status classification system are quantified and a mathematical formula for combining these is defined and validated. The next phase is to obtain actual assessments of the various dimensions from study subjects and apply the formula from step 1 to generate the weight. It is this method that is applied to generate the HALex.[2]

The two domains of activity limitation and perceived health are combined in a multiplicative model to form a generic index of health-related quality of life. The anchor points of each dimension are then taken from another classification scheme, the Health Utilities Index (HUI). As with many utility scoring systems, HALex scores range from 0.0 (death) to 1.0 (best health state). The premise is similar to that of a standardized mortality rate (SMR).[2] The SMR uses a standard reference population for rate calculation and comparison and this process would be applied to the HALex measure.[2]

The unique feature about the HALex quality weighting system is that an individual is able to compensate for disability. Just because someone may have a physical limitation that would generally result in a lower utility, it can be offset by having a positive perception of his or her health.[1] As an example, an individual who is differently abled yet continues to work and engage in athletic activities might not perceive their health status as diminished. Similarly, that same individual may be able to continue to work at their chosen profession such as a computer programmer and would not consider himself to be limited in their major activity. Bradley, et al (2000) suggest that functional status tools account for only the physical ability portion of a broader scope of functioning; and that ability to perform major activity will ultimately impact the value of a health state.[18]

Proponents of the HALex scoring system suggest that it may be used as an "off-the-shelf" source of quality weighting scores suitable for investigators using secondary data.[7] HALex is simple to use, inexpensive, and the health states it describes are easily understood by investigators.[11] Also, because of the large amount of data obtained during the NHIS, it may be used to assess the effect of various disease states among demographic subsets such as income, age, and gender on utilities.[7] HALex scoring also has the potential to provide national quality of life data for the US population.[11] Since it has the potential to be responsive to health policies and medical intervention, it may be useful to assess the impact of such interventions on utility scoring.[11]

A brief review of the NHIS indicates it is the principal source of information on the health of the population of the United States.[17] These data are used by the Department of Health and Human Services to monitor trends in health and assess compliance with national health objectives such as those specified in Healthy People 2000.[17] The NHIS is a cross-sectional household interview survey conducted annually through personal household interviews of the non-institutionalized population. [17] It consists of a Core Questionnaire that addresses basic health and demographic items along with additional sets of questions on current health topics. Data used for the HALex scoring come from the Core Questionnaire set.

Gold, et al (1998) have been involved with validating the HALex system as a means of promoting consistency in utility analysis.[7] Among the difficulties of the currently available methods is the lack of consistency between values for health conditions and diseases. One study by Fryback, et al (1993) showed some differences between scores for 28 conditions obtained using the Quality of Well-Being Index and the time-trade-off methods.[19] Nease (1995) also reported differences for quality weights on cardiovascular conditions using a rating scale compared to the standard gamble and time-trade-off.[20] A catalog would permit utility data to be obtained for researchers who are unable to obtain primary data. More importantly, it would allow for a common ground to be established to promote comparability across different analyses.

Gold, et al's (1998) analysis reported a range of HALex scores for those with asthma and diabetes for the NHIS datasets of 1987-1992.[7] Those with asthma had a mean age of 32 and had a 25th to 75th percentile range of HALex scores from 0.67-0.92. The mean HALex score was 0.77. Those reporting having diabetes had a mean age of 60 with the HALex scores ranging from 0.38 – 0.84 reflecting the 25th and 75th percentiles respectively. The mean HALex score for diabetic respondents was 0.62. Along with data on individual conditions, average HALex scores were also reported for those who reported having no specific medical conditions. Scores were computed for males and females in varying age groupings. It has been suggested that this may be used as a proxy for the expected health state when a condition is cured or prevented.[7]

Age adjusted HALex scores were compared to those obtained using the Quality of Well Being scale during the Beaver Dam Health Outcome Study. Similarly, weights built upon a Health Utility Index score from the National Health and Nutrition Examination Survey I Epidemiologic Follow-up Survey were compared to age adjusted HALex scores. Table 1 describes the results published by Gold, et al (1998).[7]

The scores for diabetes were similar while the condition asthma experienced greater variation. HALex and HUI had more similar scores than the comparison of HALex to QWB for both disease processes.

Table 1: Condition weights associated with Asthma and Diabetes obtained from HALex scoring, Beaver Dam (BD) Study Quality of Well-Being (QWB) scoring, and the National Health and Nutrition Examination Survey I Epidemiologic Follow-up Survey (NHEFS) Health Utility Index (HUI)

Condition	NHIS HALex Score (1987-1992)	BD QWB Score	BD Adjusted HALex*	NHEFS HUI	NHEFS Adjusted HALex**
Asthma	0.77	0.68	0.64	0.69	0.68
Diabetes	0.62	0.69	0.60	0.63	0.64

*NHIS scores age adjusted to mean age of respondents in Beaver Dam Study (64 years).
**NHIS scores age adjusted to mean age of respondents in NHEFS-HUI Study (55 years).

Gold, et al (1998) acknowledged several limitations of the validation analysis.[7] Only several conditions were common to all three studies and the average age and characteristics of respondents were different.[7] Respondents in the Beaver Dam study were mostly healthy, white individuals while the NHEFS respondents were a nationally representative sample approximately 10 years younger. Despite the differences in respondents and the differences in domains reflected in each scoring system, a surprisingly high correspondence was noted overall for the condition weights.

Gold, et al (1998) acknowledges several limitations to using HALex scores for assessing quality weights.[7] When the number of respondents reporting a specific condition is small, standard errors of the mean HALex scores would be too large to use them with confidence. Also, because of the limitations applied to those who are eligible to participate with the NHIS, condition scores may be biased in either direction.[7] Since those who are institutionalized cannot participate and their health status is likely to be worse, their exclusion may result in an upward bias. Conversely, the health status of those in the military is likely to be higher because of the screening processes in place to enlist as well as the increased physical conditioning of this population. The exclusion of this group could result in a downward bias.[7]

It is important to note that data used to generate the HALex is based upon self-report and proxy report which could also skew results. Proxy reporting is accepted at times when an individual respondent is unavailable because of work or illness. The use of proxies could result in a bias in either direction, depending on the amount of care the proxy provides to the individual with the condition. The perception of a greater degree of dependence could lead to a downward bias.

Another important issue to the validation of HALex scoring is to examine if or how co-morbidities could impact them. Despite the goal to achieve a quality weighting for a pure condition, it is likely that co-morbidities are taken into account by individuals. This might result in a downward bias on the score. If all individuals with diabetes had also suffered an acute myocardial infarction, they would likely apply a different weight towards the diabetes because of their additional cardiovascular compromise. Gold, et al (1998) argues however, that despite this potential bias, scores may be more likely to reflect a truer account of the health states associated with conditions. [7]

Erickson (1998) validated HALex scoring as a generic measure of health. These investigations concentrated on evaluating the construct validity as well as incremental validity.[11] Construct validity determines if HALex scores for specific groups compare to similar domains that have been widely reported in the literature. [11] Since men in the U.S. often report increased health status compared to women, one would expect the HALex scores for males to be higher than that for women as well. Incremental validity examines whether a regression model built around a combination of domains provides more information than either domain independently. [11] The amount of variability provided by a model including multiple domains is greater than that provided by the model(s) containing only a single domain.

Erickson's (1998) work has indicated that perceived health and activity limitation may be combined to form a single measure of health status that follows similar directions of other health status measures published elsewhere. Generally, males have higher HALex scores than females and white respondents have higher HALex scores than those who are non-white. [11] Incremental validity was supported by the absence of perfect correlation between perceived health and activity limitation.[11]

Erickson (1998) has acknowledged another potential limitation of HALex as a scoring method for quality of life. The large majority of those eligible to participate in the NHIS cluster in the top left corner of the HALex matrix (refer to Appendix D). This area of the matrix represents the highest levels of health and suggestions have been made that this could be interpreted as an indication that some domains of health have been left out of the framework.[11] This may be termed a "ceiling effect" of the HALex method. Additional domains include depression, anxiety, or stress and if these are included, may reduce or eliminate the ceiling effect.[11] It is important to note that the observed distribution of HALex scores concentrated in the top left corner does follow the trend that has been reported in other studies of generic health measures.[11] The clustering of individuals might reflect the smaller proportion of those with chronic conditions in the U.S. population at large.

Another way to reduce the potential ceiling effect is to include acute conditions as well as chronic according to Erickson (1998). The activity limitation attribute is based on the presence of a chronic health condition and therefore, dysfunction attributed to more transient states would be underrepresented.[11]

Additional work evaluating the use of HALex scoring in an acute situation is forthcoming. Bradley, et al (2000) have investigated the relationship between acute myocardial infarction and HALex scores.[18] These data supported the credibility of the HALex methodology as it performed similarly to other utility measures for the same disease.

Chapter 3

DATA AND METHODS

Data was obtained from the 1996 NHIS CD available through the US Department of Health and Human Services. The data used to generate the HALex score is a component of the core set of questions that remains consistent from year to year.[1] The question asked to assess perceived health is displayed in Appendix A while those questions asked to assess activity limitation are found in Appendix B. The calculation used to derive the weights assigned to the various health states is displayed in Appendix C. The SETS interface provided by the National Center for Health Statistics was used to export data on respondents contained in the condition dataset who were 18 years of age or older and reported having asthma or diabetes. A total of 897 records were identified for asthma and 1115 records were identified for diabetes. The data was exported to Microsoft Excel 97 worksheets. Disease specific files were then imported into SAS (v 8.0) for analysis.

Descriptive Analysis:

Characteristics of the identified populations are displayed in Table 2. Race was obtained through a recoding of reported race into categories of white, black, or other. Similarly, marital status was recoded into three categories; those being currently married, never married, or widowed/divorced/separated. Income levels were separated by $10,000 increments up to $49,999. If annual income was reported as greater than or equal to $50,000, individuals were collapsed into one category of "high income". Eligible respondents for this analysis were 18 years of age or older at the time of the survey.

Generally, the population with asthma was younger and more educated than the population reporting diabetes. Decreasing age and increasing education have both been associated with higher utilities. The respondents in both conditions were predominantly white females. Race other than white and being female have generally been associated with lower utilities. Just over half of the respondents for each disease process reported being currently married which also has been associated with increased utilities.

Spearman correlation coefficients were estimated using SAS (v8.0) to evaluate the direction of HALex scores with selected demographic and severity of illness variables that were ordinal or continuous. (Refer to Table 4) As education, family income, and time since last doctor visit for condition increased, HALex scores increased. Similarly, those who reported no hospitalization had higher HALex scores than those who did report a hospitalization for condition.

Table 2: Characteristics of Survey Respondents

Characteristic	Asthma (N=897) Mean	Asthma (N=897) Standard Deviation	Diabetes (N=1115) Mean	Diabetes (N=1115) Standard Deviation
Age (years)	44.69	17.74	59.71	14.89
Sex				
Male	29.76%	-	43.05%	-
Female	70.23%	-	56.95%	-
Race				
White	77.93%	-	73.45%	-
Black	17.84%	-	22.51%	-
Other	4.24%	-	4.04%	-
Marital Status				
Married	53.85%	-	58.12%	-
Wid/Div/Sep	23.86%	-	33.09%	-
Never Married	21.96%	-	8.61%	-
Education (years)	12.03	3.41	10.65	4.00
HALex	0.64	0.27	0.51	0.26

HALex Scoring:

HALex scores are computed from responses to the questions on perceived health and activity limitation (refer to Appendix A and B for questions). Perceived health is a straightforward response to a single question with an answer scale ranging from poor to excellent. Activity limitation is more complex and assignment of a level depends on an individual's age.

The NHIS dataset establishes the major activity of individuals based upon age. Those between 18 and 64 years of age may have a major activity of working, keeping house, going to school, or "something else". Their activity limitation may fall into one of the following categories which represent decreasing functional levels: not limited, limited in other activity, limited in major activity, or unable to perform major activity.

Persons who are 65 years of age or older are considered to engage in activities of daily living (ADLs) and instrumental activities of daily living (IADLs) as their primary social role. [1] Their activity limitation may fall into one of the following categories: not limited, limited in other activity, limited in IADLs, limited in ADLs. This prevents older individuals from being able to fall into either of the two categories that reflect limitation in major activity which have higher assigned weights. This process may thus bias HALex scores in a downward manner.

This scoring framework may result in an underestimation of the population's health especially as the respondents reporting the conditions of interest increase in age. (Refer to Appendix C) This would certainly be a pertinent issue especially for diabetes as the prevalence increases with increasing age. Another element of the scoring methodology that can result in a downward bias of scores is the requirement that persons who might be classified into multiple categories of activity limitation are assigned to the category of most dysfunction. [1] Therefore, if an individual less than 65 years of age reports being limited in other activity and limited in IADLs, they would be assigned the IADL weighting factor which would result in a lower HALex score.

Computation of HALex scoring was performed using the algorithm established by Torrance, et al (1986).[1] (Refer to Appendix C) HALex scoring is based on a continuous scale and may range from 0.1 (worst health state) to 1.0 (best health state). The score of 0.0 represents death and since survey respondents are used to generate the HALex score, 0.0 cannot be obtained. Dummy variables were created for categorical variables. Refer to Table 3 for definition of variables and hypothesized relationship to HALex score.

Multivariate Analysis:

Ordinary least squares (OLS) regression was then estimated in a two-step process. OLS was used to predict HALex score from demographic variables alone and then another regression model was estimated using demographic characteristics, plus severity of illness measures as independent variables. The ability of the linear regression equation to predict HALex scores was evaluated by plotting the residuals, i.e. error terms for each disease process. Separate plots were obtained for the demographic, severity of illness, and demographic/severity of illness combined models.

Table 3: Definition of Variables and Expected Direction of HALex

Subset	Variable	Definition	Expected Direction
Demographic	MALE	1 if male, 0 otherwise	+
	AGE	Patient age	-
	BLACK	1 if black, 0 otherwise	-
	OTHER	1 if race other than white, 0 otherwise	-
	WDS	1 if widowed/divorced/separated at time of interview, 0 otherwise	-
	SINGLE	1 if never married at time of interview, 0 otherwise	-
	EDUC	Patient's completed education in years	+
	TEENINC	1 if annual income 11,000-19,999, 0 otherwise	+
	TWENINC	1 if annual income 20,000-29,999, 0 otherwise	+
	THIRINC	1 if annual income 30,000-39,999, 0 otherwise	+
	FORTINC	1 if annual income 40,000-49,999, 0 otherwise	+
	HIINC	1 if annual income 50,000 or greater, 0 otherwise	+
	PROXY	1 if proxy respondent, 0 otherwise	?
Severity of Illness	OVERYR	1 if condition onset over 1 year prior to interview, 0 otherwise	-
	DRINFIV	1 if last doctor visit for condition between 1-5 years prior to interview, 0 otherwise	+
	CRADAY	# restricted activity days due to condition within 14 days prior to interview	-
	CBDDAY	# bed days due to condition within 14 days prior to interview	-
	CBDDAY12	# bed days due to condition within year prior to interview	-
	NOHOSP	1 if never hospitalized for condition, 0 otherwise	+

Omitted Variables: Female, Caucasian, Married, Income <11,000, Self Responder, Onset within 1 year, Doctor visit within 1 year, Hospitalized

Chapter 4

RESULTS

Review of the data for persons who identified themselves as having asthma revealed the following positive correlations with HALex scoring: educational status, family income, time since last doctor visit and never being hospitalized. Conversely, a negative correlation was noted between age, increased time of condition onset, increased restricted activity days in the previous two weeks, bed days within previous two weeks and past year and HALex score.

Table 4: Correlation coefficients (r)

Variable	Asthma	Diabetes
Age	-0.364*	-0.141*
Education	0.396*	0.246*
Family Income (per 10,000)	0.246*	0.285*
Condition Onset	-0.074*	-0.186*
Doctor last seen	0.201*	0.081*
Total restricted activity days in 2 weeks	-0.240*	-0.295*
Bed days in 2 weeks	-0.234*	-0.257*
Bed days in past year	-0.373*	-0.251*
Hospitalization	0.122*	0.233*

*p<.05

Those persons with asthma (N=897) were found to have a mean HALex score of 0.64 with a SD=0.27. (Refer to Table 2) The range of scores was 0.1 (worst health state corresponding to limited in ADLs and poor perceived health) to 1.0 (best health state corresponding to no limitation in major activity and excellent perceived health). These values are slightly lower than the range of utilities for asthma obtained directly using the time trade off (mean=0.89, standard error=0.019) and standard gamble (mean=0.91, standard error=0.018) reported by Blumenschein.[3]

The regression analysis showed all demographic variables except for sex significantly influenced HALex score among persons with asthma. (Refer to Table 5) These variables were found to account for 28% of the variability within the model. The regression analysis including severity of illness measures alone accounted for 18% of the variability in HALex scores and all the variables except hospitalization were statistically significant ($p<0.05$).

When the disease severity measures were included in the regression model along with the demographic variables, the unrestricted model accounted for 37% of the variability. For every one year of education increase, the parameter estimate for HALex score increased by 0.013. As age increased by one year, HALex decreased by 0.003 and those who were not currently married were found to have an estimated HALex score 0.052 less than the mean of their married counterparts. This corresponds to relationships that have been published in the literature showing that demographic variables such as marital status or age have been found to be directly related to health.[11] All severity proxies were found to be significant except bed days in the two weeks prior to the interview date. Persons with asthma who visited a doctor in one to five years had a HALex score 0.065 higher than the mean for those who had visited a doctor within one year of the interview. For every additional day of restricted activity over the previous two weeks, HALex score was reduced by 0.011.

Survey respondents with diabetes (N=1115) had a HALex score of 0.51 with a SD=0.264. (Refer to Table 2) The HALex scores also ranged from 0.1 (worst health state) to 1.0 (best health state). The first regression model including demographic variables alone accounted for 10% of the variability. It was interesting to note however, that responder type (self versus proxy) and sex did not achieve statistical significance ($p<0.05$).

The variables taken as proxy measures for severity of illness were also put into a regression model by themselves. These items accounted for 14% of the variability in the model. Recency of doctor visit and bed days in the 14 days prior to the interview did not achieve statistical significance in the model.

Lastly, a model was estimated including both demographic and disease severity measures. These variables accounted for 21% of the variability in the model. Demographic measures continued to exert some influence on the HALex score in the presence of the severity of illness variables. Age, education and income continued to be highly significant. The parameter estimate of HALex decreased by 0.001 for every one year increase in age and increased by 0.010 for every one year increase in education. Overal, higher income levels were found to have higher parameter estimates of HALex compared to those at the low-income level. (Refer to Table 5) Several of the severity of illness measures were found to consistently influence HALex score. For example, measures that were reflected severity such as having the condition of interest for over a year and increased number of restricted activity days and bed days resulted in lower HALex scores by 0.071, 0.016, and 0.0001 respectively. Those individuals who reported never being hospitalized for their diabetes were found to have higher HALex scores than those hospitalized by 0.071.

The appropriateness of the estimation of a linear relationship between all demographic and severity of illness variables and HALex score was evaluated using plots of the residuals. The graphs indicated a broad downward slope rather than an amorphous shape. Refer to Appendices E and F. Variations of the regression equation were attempted. A log transformation of HALex did not improve the model. Therefore, for ease of interpretation, HALex scores were not changed from their 0-1.0 notation. These equations did produce any more satisfactory error plots. It is suspected that the pattern of residuals is due to some omitted variable such as co-morbidities.

Table 5: Regression Analysis: Parameter estimate (Standard Error)

Variable	Asthma (N=897)		Diabetes (N=1115)	
	Demographic Model	Severity Model	Demographic Model	Severity Model
Age	-0.004 (0.000)**	-0.003 (0.000)**	-0.001 (0.000)**	-0.001 (0.000)**
Male	0.010 (0.018)	0.007 (0.017)	0.009 (0.016)	0.003 (0.015)
Black	-0.074 (0.021)**	-0.047 (0.020)**	-0.044 (0.018)**	-0.034 (0.018)*
Other	-0.065 (0.039)*	-0.036 (0.036)	0.011 (0.038)	0.028 (0.036)
Wid/Div/Sep	-0.056 (0.021)**	-0.052 (0.020)**	-0.038 (0.018)**	-0.031 (0.017)*
Single	-0.007 (0.022)	-0.006 (0.020)	0.033 (0.028)	0.041 (0.027)
Education	0.017 (0.002)**	0.013 (0.002)**	0.012 (0.002)**	0.010 (0.002)**
Teen-range income (11,000-19,999)	-0.027 (0.024)	-0.035 (0.022)	-0.043 (0.021)**	-0.042 (0.020)**
Twenty-range income (20,000-29,999)	0.044 (0.025)*	0.029 (0.023)	-0.032 (0.024)	-0.038 (0.022)*
Thirty-range income (30,000-39,999)	0.075 (0.028)**	0.066 (0.026)**	0.064 (0.028)**	0.038 (0.027)
Forty-range income (40,000-49,999)	0.077 (0.032)**	0.071 (0.030)**	0.028 (0.036)	0.012 (0.034)
High Income (50,000+)	0.125 (0.025)**	0.124 (0.024)**	0.089 (0.028)**	0.056 (0.027)**
Proxy respondent	0.034 (0.020)*	0.018 (0.018)	N/a	N/a
Condition Onset		-0.059 (0.028)**		-0.071 (0.025)**
Doctor last seen in 1-5 years		0.065 (0.019)**		0.013 (0.029)
Total restricted activity days in 2 weeks		-0.011 (0.004)**		-0.016 (0.003)**
Bed days in 2 weeks		-0.010 (0.006)		-0.006 (0.005)
Bed days in past year		-0.000 (0.000)**		-0.000 (0.000)**
Not hospitalized		0.061 (0.026)**		0.071 (0.029)**
Adjusted R-square	0.281	0.374	0.103	0.210

*p<.10 **p<.05

Chapter 5

DISCUSSION

This investigation evaluated the ability of HALex scoring to predict health status of persons with asthma or diabetes and to determine what factors may influence this scoring system. An attempt was made to compare this derived utility score with directly assessed utility scores in the literature. Unfortunately, published scores using a 0.0 to 1.0 scoring system were only found for persons with asthma.[3, 15]

Research is needed to directly assess the value of various health states. Current methods are time consuming and costly. Alternative methods are being explored. However, there remains a need for some attempt at direct assessment. This would allow for the comparison of derived and calculated values, such as the HUI and the HALex to begin to establish the soundness of these methods.

This investigation also assessed the potential impact of demographic variables on HALex scoring. Since the HALex score is computed from data taken from the NHIS, demographic variables such as age, race, and income level are available on a large number of people. It is important to remember however, that although this survey attempts to reach 50,000 households, all data contained within is based on self-report or proxy report. Additionally, although the sample is selected in an effort to obtain a representative sample of the US, certain groups are excluded from participation including those in the military and those who are institutionalized or incarcerated.[1]

A benefit of the HALex scoring algorithm should it be proven to be methodologically sound and generalizable, is that it could be used to track utilities over time. Since the scoring methodology is based upon the answers to several of the core questions contained in the NHIS, comparable data will be available for at least a ten year timeframe (1990-2000).[1] The health status of the US population could be assessed at this level over this decade.

The results indicate utility scores for specified chronic diseases were somewhat dependent on demographic characteristics. When severity variables were added to the regression model along with demographic measures, the demographic variables had a lesser magnitude of effect for both diseases. However, the measures of severity of illness were not strong enough to replace all demographic influences. This would suggest that some adjustments for demographic characteristics would be necessary when applying the HALex scoring methodology. Additionally, some means of assessing severity of disease would be necessary.

Socioeconomic characteristics were retained in the models for each disease process after inclusion of severity proxies. Generally, as educational levels and family income levels increased, so too did the HALex score. It was interesting to note that an annual income in the teens or twenties actually had a negative parameter estimate for HALex compared to those with low income (less than 10,000 annually) in persons with diabetes. One possible explanation for this observation is tied to health care coverage. Perhaps those with slightly higher income levels had no access to health insurance while the individuals at the lowest income level had benefit of health care coverage through public assistance such as Medicaid. HALex scores using responses provided by proxies tended to be higher for persons with asthma. Conversely, race other than white and marital status other than currently married and residing with spouse were correlated with lower HALex scores.

Overall, the regression models incorporating demographic characteristics as well as severity of illness characteristics accounted for more variability in those respondents reporting asthma rather than diabetes. The amount of variability for the asthma and diabetes populations accounted for were 37% and 21% respectively. The mean HALex score for both populations was also higher for asthmatics than for diabetics, 0.64 and 0.51 respectively. This could be attributed to the fact that the diabetes respondents were approximately fifteen years older and had an educational level that was nearly two years less than the respondents in the asthma group. Both increased age and decreased education were associated with lower HALex scores in this analysis and have been associated with lower utilities in other published literature.

Another possible explanation for this observation is that one or more domains of health are not included in the HALex system. Co-morbidities are one such aspect of health that may not be assessed using the HALex scoring methodology. Diabetes is associated with several comorbid states such as cardiovascular and neurological compromise. While asthma may significantly impact the domains of health tracked by HALex, (perceived health and activity limitation) other body systems may not be as strongly affected. Despite the goal of utility assessment to evaluate a single disease individually, comorbidities may be considered by the respondents. Bradley, et al (2000) in fact demonstrated a relationship between comorbidities and utility.

Measures used as proxies for severity of illness were based upon restriction of activities, use of health care resources, and onset of disease. It was hypothesized that an individual who suffered more restricted activity due to their condition could reasonably be expected to have a more severe illness than another person with the same condition does but no restricted activity. Similarly, those who used health care resources such as office visits or requiring hospitalization for their condition to a greater extent would have more severe illness. Onset of disease within the past year was hypothesized to represent a less severe case than one that had been diagnosed for over one year.

Limitations of the severity proxies include the possible confounding of access to health care. Perhaps those that use health care resources more frequently do so simply because they are able to access care by virtue of having insurance. However, if this were the case, one would expect individuals at a higher socioeconomic status (SES) to have greater access to health care and therefore indicators of increased utilization might be associated with a higher rather than lower HALex score. Insurance coverage was not a component of the NHIS core questionnaire during the 1996 survey although revisions to the survey are attempting to track this. Also, onset of disease could be problematic in that a condition might go undiagnosed for a period of time setting the scene for further complications. Recent diagnoses may then reflect individuals who are more compromised in their health state and one would expect lower HALex scores in these individuals.

Chapter 6

CONCLUSIONS

Utility measurement for chronic conditions is an important area for further research. Several methods exist to obtain utility assessment for both acute and chronic conditions via direct or more indirect means. Ideally, direct measurements should be taken in an effort to provide a sound comparison for derived and calculated values. Once such reference values are available, the full capacity of other means of assessing utility scores may be realized. The major obstacle to obtaining direct measurements is the amount of resources required. Because of this, investigators are evaluating secondary methods to obtain utility weights. HALex scoring applied to NHIS survey data is one proposed system to obtain utility weights.

Other research has begun to focus on determining the impact of multiple variables on the HALex scoring system for acute conditions.[18] This investigation evaluated the health scoring of two common chronic conditions of adults. The large standard deviations of the HALex measurements show that it is imprecise for asthma and diabetes.

It was noted that the demographic variable sex was not a significant predictor of HALex scores for persons with either disease. However, age, race, marital status, education and income continued to influence HALex scores for asthma even when severity measures were added. It has been suggested that the measures selected as proxies of severity of illness were not appropriate to asthma. Other measures such as emergency department or urgent care utilization and/or rescue medication use would likely be suitable indicators of severity of illness. Specific items like these are not available from the NHIS.

Race and marital status did not achieve statistical significance in the regression analysis containing the severity of illness measures for diabetes. Generally, increasing age resulted in lower HALex scores and individuals who were no longer married had lower HALex scores than their married counterparts. Education and family income did show a positive correlation with HALex even when severity measures were included.

The severity measures influenced HALex scoring in the anticipated direction. As predicted, individuals who were hypothesized to have more severe illness did in fact experience lower HALex scores. Additionally, the effects of the demographic variables on HALex score diminished in magnitude after inclusion of the severity measures.

The HALex score computed for the asthma population was higher than that obtained for the diabetic population. The mean HALex for asthma was 0.64, SD=0.27. The mean score corresponds with directly obtained rating scale values as reported by Blumenschien.[3] Standard gamble and time-trade-off assessments of the utility for asthma were higher, 0.91 and 0.89 respectively. Among the possible explanations for this observation is the restriction of HALex scoring to only two domains or the possibility that comorbidities were not excluded from consideration when respondents were completing the survey.

Comparison to directly obtained utility scores was limited for diabetes as information on utilities using the 0-1 scale was not found.

The findings for the influence of demographic variables on HALex scoring reflect the patterns reported in published literature such as increasing age being associated with lower utilities. However, Bradley, et al (2000) found demographic variables did not influence HALex score when co-morbidities were taken into account for acute myocardial infarction patients.[18] Further investigation is necessary to determine if the transient nature of acute syndromes permits the use of HALex across populations whereas chronic conditions would have other factors to consider. If an impact is confirmed, it will be necessary for investigators to describe their samples carefully with respect to demographic variables such as age, race, marital status and income when attempting to use HALex utility scores to ensure comparability.

Due to the potential for demographic variables to influence HALex scores, it would not appear to be useful as an off-the-shelf catalog for chronic conditions unless some adjustments were made to ensure comparability of samples. Describing other factors such as co-morbidities that might influence HALex and how they might be controlled is needed. Discrepancy exists between HALex and directly assessed values using the accepted gold standard, the standard gamble. Perhaps more important than demographic influences, a mechanism to adjust for co-morbidities should be established.

The observation that the HALex utilities have some variation with demographic characteristics of the population call into question its' ability to reflect the true preference for that health state. As indicated earlier, the preference should be based solely on the "pure" condition and therefore, the demographic characteristics of and any additional co-morbidities affecting the involved person should not play a role. It may be argued then, that HALex scores may not be suitable for utility assessment. Perhaps one or more significant domains of health are not taken into account and therefore the measure is somehow flawed.

Another observation is that the HALex scores for these conditions were lower than utilities obtained through other methods. The standard gamble has been shown to reflect the highest utility for a condition when several methods are used to assess it. This is thought to occur since people are unwilling to accept significant risks of death.

Also, the anchor points of the HALex system put a significant amount of weight into the perceived health domain as well as the activity limitation domain. If an individual would classify their health state as "good", the highest utility they could obtain would be 0.84. It is conceivable that individuals without a previously diagnosed chronic condition but who smoke and are overweight may select this option to describe their health simply because of their personal habits.

Despite the unanswered questions, one area where the HALex scoring methodology may be useful is when attempting to evaluate different studies that used various means of assessing utilities. After describing the populations involved, appropriately adjusted HALex scores could be computed just to provide a common ground. This methodology may also prove useful for evaluating changes in treatments over time, especially when following an established cohort.

One consumer of the HALex scoring methodology might be found in the managed care arena. Disease management programs attempting to promote the health of individuals diagnosed with chronic diseases struggle to evaluate the cost-effectiveness and cost-utility of programs. Program membership would not likely vary dramatically from year to year. Organizations often survey program enrollees for overall disease specific quality of life issues. However, discrete utilities are not assessed. The addition of 3-5 questions to any survey would not likely impose significant hardship on either the individual completing the survey or those scoring it. Utilities could be computed and the organization could assess if the interventions applied during the past year increased the disease specific utilities. Attempts to address the potential impact of co-morbidities could also occur due to the availability of medical claims information. Ultimately, NHIS HALex scores could also be computed as a reference making adjustments for demographic influences as necessary.

The field of utility assessment has many opportunities for research. The distinction between chronic and acute conditions may be explored as well as the potential impact of co-morbidities on utilities. Additional investigation and attempts to directly assess utilities for various health states would be useful as well. This would allow for comparison of calculated scores to judge the validity of these methodologies.

APPENDICES

APPENDIX A

NHIS QUESTION: PERCEIVED HEALTH

Age Group and Activity	**Perceived Health Question**
All Ages	*Health Indicator* 4. Would you say ____ health in general is excellent, very good, good, fair, or poor?

APPENDIX B

NHIS QUESTIONS: ACTIVITY LIMITATION

Age Group and Activity	Activity Limitation Question
18-64 years Working or keeping house	*Unable to perform major activity* 2a. Does any impairment or health problem NOW keep __ from working at a job or business? 3a. Does any impairment or health problem NOW keep __ from doing any housework at all? *Limited in performing major activity* 2b. Is __ limited in the kind OR amount of work __ can do because of any impairment or health problem? 3b. Is __ limited in the kind OR amount of housework __ can do because of any impairment or health problem?
65 + years independent living	*Limited in activities of daily living (ADL)* 14a. Because of any impairment or health problem, does __ need the help of other persons with __ personal care needs, such as eating, bathing, dressing, or getting around this home? *Limited in instrumental activities of daily living (IADL)* 14b. Because of any impairment or health problem, does __ need the help of other persons in handling __ routine needs, such as everyday household chores, doing necessary business, shopping, or getting around for other purposes?
All ages	*Limited in other activities* 6a. (12a) Is __ limited in ANY WAY in any activities because of an impairment or health problem?

APPENDIX C

SINGLE ATTRIBUTE SCORES ASSIGNED TO ACTIVITY LIMITATION/PERCEIVED HEALTH

		Perceived Health Status (y)					
		Excellent	**Very Good**	**Good**	**Fair**	**Poor**	**Dead**
Activity Limitation (x)	**Attribute Score**	1.00	0.85	0.70	0.30	0.00	
Not limited	1.00	1.00					
Limited – other activity	0.75						
Limited – major activity	0.65			S_{33}			
Unable – major activity	0.40						
Limited – IADL	0.20						
Limited – ADL	0.00	0.47				0.10	
Dead							0.00

Matrix scoring:

$M_{ij} = k_1 * x_i + k_2 * y_j + (1-k_1-k_2) * x_i y_j$ (x = activity limitation, y = perceived health)

$k_1 = k_2 = (S_{61} - a)/(S_{11} - a)$

assumptions: $S_{11} = 1.00$, $S_{65} = 0.10 = a$, $k_1 = k_2$

$k_1 = (0.47 - a)/(1.00 - a)$

When a = 0.10, then

$k_1 = k_2 = 0.41$

$(1 - k_1 - k_2) = 0.18$

HALex scoring:

HALex: $S_{ij} = a + (1-a) * M_{ij}$

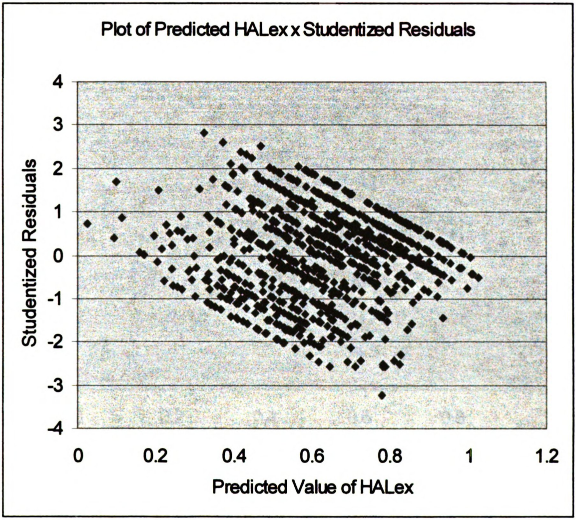
APPENDIX D

TABLE 6: HALEX VALUES FOR ACTIVITY LIMITATION/PERCEIVED HEALTH MATRIX

Activity Limitation	Perceived Health Status				
	Excellent	Very Good	Good	Fair	Poor
Not limited	1.00	0.92	0.84	0.63	0.47
Limited – other activity	0.87	0.79	0.72	0.52	0.38
Limited – major activity	0.81	0.74	0.67	0.48	0.34
Unable – major activity	0.68	0.62	0.55	0.38	0.25
Limited – IADL	0.57	0.51	0.45	0.29	0.17
Limited - ADL	0.47	0.41	0.36	0.21	0.10

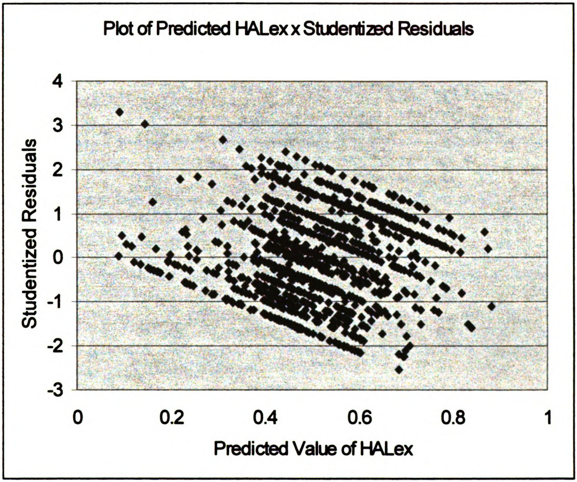
APPENDIX E

FIGURE 1: PLOT OF PREDICTED HALEX x STUDENTIZED RESIDUALS FOR ASTHMA



APPENDIX F

FIGURE 2: PLOT OF PREDICTED HALEX x STUDENTIZED RESIDUALS FOR DIABETES



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