Evaluation of the Low Vision Rehabilitation Demonstration

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Design Report

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Attachments

1 Overview of Evaluation Approach

The objective of this study is to evaluate a change in vision rehabilitation services for Medicare beneficiaries, to be demonstrated in six sites beginning in April 2006. The Low Vision Rehabilitation Demonstration (LVRD) will be evaluated for its impact on cost to Medicare and impact on outcomes for Medicare beneficiaries. In addition, a process evaluation will provide information on provider participation and other issues, to provide insight into feasibility of nationwide implementation.

The low vision rehabilitation demonstration includes two major changes in the way services are provided to elders with deteriorating sight. First, the demonstration expands the list of providers who can offer LVR services. The expanded list includes qualified occupational therapists (OT), low vision therapists, orientation and mobility (O&M) specialists and rehabilitation therapists who are certified.1 Second, the demonstration expands the possible locations of care by allowing physicians to bill for LVRT services supplied by these providers in the home as well as in the doctor's office. Prior to the demonstration, only an OT in private practice or a physician could submit a claim for vision rehabilitation services. 2

Virtually simultaneously with the beginning of the low vision rehabilitation demonstration, the "incident to" rules for Medicare have been clarified. As a result, in non-demonstration areas, low vision therapists, O&M specialists and rehabilitation therapists are not considered qualified providers and their services will not be Medicare reimbursable in the physician's office. Under the previous rules, these providers could treat patients under direct physician supervision, with a claim for services submitted to Medicare by the physician. This, in essence, means that the evaluation is considering multiple, simultaneous changes in the way that LVR services are delivered.

Also, the low vision rehabilitation demonstration will not supercede local coverage decisions (LCD). This means that, in some comparison areas, OTs can provide LVR services in the home. Within the demonstration areas, providers can submit claims either under the demonstration or under LCD rules. In non-demonstration areas, these claims can be submitted only under LCD rules.

Demonstration services will be available only to those Medicare beneficiaries with moderate to severe vision impairment that cannot be corrected by glasses or surgery and who are prescribed vision rehabilitation by a qualified physician. To qualify for services paid under the demonstration, the beneficiary must reside in a demonstration area and the provider must practice in the demonstration area. Covered services will include up to 9 hours of rehabilitation over a consecutive 90-day period.

The objective of the design will be to compare Medicare costs and beneficiary outcomes for low-vision beneficiaries within demonstration site areas to comparison sites; and to carry out a process evaluation of demonstration implementation to glean lessons for potential nationwide implementation. The evaluation will focus on the following three questions:

- What is the impact of the Low Vision Rehabilitation Demonstration on Medicare costs?

[1] Certification must come from the Academy for Certification of Vision Rehabilitation Professionals.

[2] http://www.cms.hhs.gov/DemoProjectsEvalRpts/downloads/LowVisDemo_Summary.pdf

- What is the impact of the Low Vision Rehabilitation Demonstration on beneficiary health outcomes and satisfaction?
- What factors appear to impede or facilitate provision of low vision rehabilitation services under the terms of the demonstration?

These questions will be addressed through collection and analysis of three types of data: 1) data from Medicare eligibility and claims files, available for low-vision beneficiaries before and throughout demonstration implementation; 2) a beneficiary survey of service users conducted approximately 12 months after use of demonstration services for the treatment group and after a comparison date for the comparison group ;and 3) data from provider focus groups and key-informant interviews, which will support an understanding of program implementation.

2 Quantitative Analysis of Medicare Utilization and Expenditure Outcomes of Low Vision Services

2.1 Overview and Objectives

Claims analyses will be performed to investigate the impact the Medicare demonstration on who receives low vision rehabilitation services, the location and providers of such services, and their costs. These analyses begin by identifying Medicare beneficiaries with specific low vision diagnoses residing in the demonstration areas and hence eligible for demonstration compliant services. The first component of the analyses will describe receipt of low vision services among such demonstration beneficiaries. We will calculate the number of users of services, their proportion among seemingly eligible beneficiaries and provide estimates of associated costs and utilizations. The second component of our claims study will analyze how the group of low vision users and their use of rehabilitation services may have changed because of the demonstration. These analyses will begin by using demographics, diagnoses, and pre-demonstration medical care information from CMS claims files to match our identified low vision demonstration beneficiaries with similar beneficiaries in comparison regions. The comparison regions used for these analyses will be the same as used for the beneficiary surveys. The matched comparison subjects, once identified, will then be used to provide estimates of the CMS service utilizations and corresponding reimbursed expenditures our demonstration beneficiaries would have had, if the demonstration had not taken place. Differences in utilizations and expenditures between low vision demonstration beneficiaries and similar beneficiaries in comparison regions represent the effect of the demonstration and provide an estimate the increased CMS cost associated with the demonstration.

The analyses for these comparisons will consist of both difference-in-differences comparisons to estimate the unadjusted effect of the demonstration and multivariate regression models to estimate the demonstration effect after adjustment for geographical and beneficiary level factors. For both analyses, low vision demonstration beneficiaries are matched to beneficiaries in comparison regions based on pre-demonstration claims information to lessen the potential for selection bias, which may arise because the expansion in Medicare low vision service coverage might affect not only how low vision service users received treatment, but also who ultimately receives services. If so, comparison between users in the demonstration and users in the comparison areas would be biased and not necessarily reflect the full impact of the demonstration.

2.2 Data Sources

The claims data used for our analyses will come from CMS Data Center using DESY. Preliminary analyses describing utilization and expenditures due to the demonstration's expansion of low vision Medicare coverage will be performed on claims from the physician Part B data files, supplemented by demographic data from CMS' Enrollment Database (EDB). Analyses of demonstration effect on total and within category Medicare expenditures and utilizations will be derived using claims from CMS hospital inpatient, outpatient, skilled nursing facilities, home health, and durable medical equipment data files as well. Data files from 2004 through the end of the demonstration will be needed. Claims and enrollment data for two years prior to the demonstration are necessary to measure the health status and prior medical care utilization of demonstration beneficiaries and properly match them to comparison subjects.

2.3 Identification of Comparison Groups

Both the claims analysis and the beneficiary survey will require the selection of one or more comparison sites for each demonstration site. The goal is to choose comparison areas that have baseline capacity to provide LVR services similar to that of the demonstration sites. If the potential supply of LVR providers is similar between two areas, then it is easier to make the case that observable differences are related to the demonstration. If service capacity is vastly different, then this may explain differences in service use. For the purposes of identifying comparison areas, LVR service capacity is determined by the number of ophthalmologists, optometrists, occupational therapists and low vision rehabilitation professionals in each region (See Table 1 below.) Two other important criteria are geographic proximity and common carrier. As described below, geographic proximity is likely to capture a range of contextual characteristics that are likely to have an impact on the use of low vision rehabilitation services. Carriers are important because local decision rules will have an impact on if and when low vision rehabilitation services are covered.

In addition to these three primary selection criteria, three secondary criteria will also be considered. These are total Medicare payments, low vision service demand and demographic characteristics. These secondary characteristics are useful for making selection decisions when there are a group of states/cities within the same geographic area and Carrier group.

Each selection criteria is described below:

Supply: For the purposes of this analysis, supply or capacity is defined by the number of medical providers who can order low vision rehabilitation and the number of therapists who can offer rehabilitation services. Although some of these supply factors may change over the course of the demonstration (e.g., low vision rehabilitation specialists), matching states and cities on pre-demonstration capacity is important for finding comparison areas that could potentially change ("gear up") in similar ways. Specific supply factors include the following:

- Number of ophthalmologists
- Number of optometrists
- Number of occupational therapists
- Number of low vision rehabilitation professionals

For comparison site selection, ophthalmologists and optometrists were combined. All provider numbers were converted to rates per 1,000 beneficiaries to facilitate comparisons across states and cities.

Geographic proximity: Contiguous states/cities or states/cities in the same region will be given priority over more distal geographic areas. Geographic proximity is likely to capture unobservable differences in low vision practice patterns across the country. In some areas, low vision rehabilitation may be more acceptable or more common, regardless of supply.

This notion is supported by a number of researchers including Gold (2004) who found that less than 50% of the variation in Medicare payments across geographic areas was caused by population mix and health status. The rest reflected "physician supply, provider training, local standards of care, provider preferences, Medicare payment policy, financial incentives, and patient demand for services and propensity to use them." Geographic proximity should help control for these characteristics.

Common carrier: This is an important factor since having a common carrier ensures similar claims adjudication policies. Different carriers may have different local carrier policies regarding low vision claims. Carrier information was obtained from a map made available by CMS to the Medicare Chiropractic Evaluation team.

Medicare payments: Areas with similar Medicare payments per beneficiary may have similar practice patterns.

Realized demand for low vision services: As with the supply factors discussed above, demand for services is another possible driver of service use. For the purposes of selection comparison groups, this will be operationalized in a number of different ways. First, we will consider the rate of low vision services use based on 2004 Medicare fee-for-service beneficiaries with a claim containing a low vision diagnosis. This group represents the largest possible group who could benefit from LVR. Second, we will look at the rate of low vision rehabilitation service use among Medicare fee-for-service (FFS) beneficiaries. The purpose of this information is to match on rehabilitation utilization rates. Realized demand for services is likely to be a good indicator of capacity at baseline for the specialized services.

Demographics: Demographic characteristics of the beneficiaries in a given state/city are another indicator of the potential demand for low vision rehabilitation services. For this analysis, we selected the following three characteristics as relevant predictors of LVR service use:

- percent 65 and older,
- percent urban
- percent of those 65 and older living in poverty

To determine comparison areas, data was collected from two sources: the Medicare 5% SAF and the Area Resource File (ARF). Data for each characteristic listed above was collected for all 50 states and the 20 cities closest in size to New York City and Atlanta. An initial cut was made on the basis of geographic proximity, Carrier group and supply factors. In all cases, this created a small pool of possible comparison areas (See Table 1 below.) These small groups were then further reduced on the basis of secondary characteristics to come up with two comparison areas for each of the 4 states and 2 cities in the demonstration. Since it is difficult to weight the relative importance of any one selection variable, a group of three researchers compared relative values and identified at least two possible comparison areas for each demonstration area. As a validation step, a fourth research reviewed the data and identified possible comparison areas independent from the group process. The two sets of results were then discussed and a small number of differences were reconciled through the group process.

Table 1: Demonstration States and Nominated Comparison Areas (in bold)

State	Common Carrier	Geography	Rate Oph/Opto per 1000	Rate OT per 1000	Rate LVRS per 1000	2002 Medicare payments	Medicare Beneficiaries having a Claim with a Low Vision Dx (per 1000, estimated)*	LV rehab claim users per Medicare FFS beneficiary (per 1000, estimated)	Percent 65+ ^	Percent 65+ Poverty^	1990 percent urban population
Kansas	BCBS KS	---	9.64%	17.68%	0.40%	$5,500	2.99	13.81	0.13	8.1	0.691
Nebraska	BCBS KS	contiguous	8.13%	9.97%	0.46%	$5,189	0.86	0.94	0.14	8	0.661
Colorado	Noridian	contiguous	14.99%	25.29%	1.21%	$5,448	1.61	8.74	0.10	7.4	0.824
Missouri	split	---	9.01%	10.50%	0.53%	$5,826	0.89	0.22	0.14	9.9	0.687
Oklahoma	BCBS AR	---	5.46%	7.12%	0.00%	$6,112	0.55	2.05	0.13	11.1	0.677
Iowa	Noridian	---	6.04%	5.92%	0.41%	$4,931	2.14	0.50	0.15	7.7	0.606
Arkansas	BCBS AR	---	5.77%	10.52%	0.79%	$5,466	0.49	0.63	0.14	13.8	0.535
New Mexico	BCBS AR	---	12.14%	11.81%	0.00%	$4,735	0.47	2.92	0.12	12.8	0.73
New Hampshire	NHIC	---	9.77%	22.44%	1.02%	$5,030	0.30	0.21	0.12	7.2	0.51
California	NHIC	---	16.13%	10.95%	0.40%	$6,942	1.07	1.50	0.11	8.1	0.926
Maine	NHIC	contiguous	6.21%	16.97%	0.80%	$5,037	0.90	1.51	0.14	10.2	0.446
Massachusetts	NHIC	contiguous	12.70%	24.77%	0.89%	$7,065	0.62	0.93	0.14	8.9	0.843
Vermont	NHIC	contiguous	6.18%	7.05%	1.19%	$5,070	0.63	0.41	0.13	8.5	0.322
North Carolina	CIGNA	---	7.71%	9.70%	0.37%	$5,557	0.25	0.44	0.12	13.2	0.504
Idaho	CIGNA	---	9.66%	9.55%	0.70%	$4,867	0.49	2.89	0.11	8.3	0.574
Tennessee	CIGNA	contiguous	8.87%	7.08%	0.40%	$6,152	1.37	0.82	0.12	13.5	0.609
South Carolina	CIGNA	contiguous	8.94%	7.27%	0.46%	$5,900	0.77	3.20	0.12	13.9	0.546
Virginia	Trailblazer	contiguous	7.16%	5.51%	0.38%	$5,296	1.30	2.82	0.11	9.5	0.694
Washington	Noridian	---	11.28%	18.60%	0.35%	$5,280	1.20	1.54	0.11	7.5	0.764
Arizona	Noridian	---	9.17%	11.65%	1.45%	$5,499	1.25	0.83	0.13	8.4	0.875
Colorado	Noridian	contiguous	14.99%	25.29%	1.21%	$5,448	1.61	8.74	0.10	7.4	0.824
Iowa	Noridian	---	6.04%	5.92%	0.41%	$4,931	2.14	0.50	0.15	7.7	0.606
North Dakota	Noridian	---	10.12%	11.35%	1.14%	$4,703	1.32	8.01	0.15	11.1	0.533
Nevada	Noridian	---	3.48%	1.98%	0.32%	$6,070	0.96	7.77	0.11	7.1	0.883
Oregon	Noridian	contiguous	9.42%	10.56%	0.39%	$4,933	1.11	3.54	0.13	7.6	0.705
South Dakota	Noridian	---	3.09%	2.44%	0.89%	$4,498	0.67	0.16	0.14	11.1	0.5
Wyoming	Noridian	---	7.07%	6.62%	0.88%	$4,896	0.29	1.12	0.12	8.9	0.65
Idaho	CIGNA	---	9.66%	9.55%	0.70%	$4,867	0.49	2.89	0.11	8.3	0.574

* 5% Sample, 2004
^ From 2000 Census

For Atlanta, the nominated comparison areas are Dallas, Nashville and Houston. For New York City, the nominated comparison areas are Northern New Jersey (9 counties) and Philadelphia (data not shown.)

Since we have recently downloaded 100 percent data for 2005, the indicators above that are generated from claims will be recalculated and the comparison process will be repeated for all states and cities.

2.4 Claims Analysis Objectives

The objective of the claims analyses is to examine the effects of Medicare's demonstration on beneficiaries with low vision diagnoses appropriate for rehabilitation treatment. Specific tasks include the following:

- Examine the direct effect of the demonstration on the utilizations and expenditures for Medicare covered low vision rehabilitation services within the demonstration regions;

- Examine potentially eligible low vision beneficiaries within demonstration areas to determine which of their characteristics associate with receipt of demonstration services (e.g., those reimbursable only because of the demonstration); and
- Make comparisons of all Medicare covered utilizations and expenditures between potentially eligible low vision beneficiaries within the demonstration regions and matched beneficiaries residing in comparison regions, who are unaffected by the demonstration, and test hypotheses regarding cost savings by determining whether Medicare will experience reductions in reimbursements for other types of medical care partially offsetting their increased expenditures from expanding coverage of low vision rehab services.

The analysis plan that follows is designed to address each of these major areas of inquiry.

2.5 Analyses of Beneficiaries Within Demonstration Region

The first component of the analysis plan focuses on low-vision-diagnosed beneficiaries residing within the demonstration regions. For such beneficiaries we will identify the characteristics predictive of rehabilitation service use. These analyses will distinguish to the extent possible given billing codes between low vision services covered under standard Medicare regulations and services covered only because of the demonstration. We begin with bivariate tables and chi-square analyses to determine the demographic, health related, and prior utilization patterns that predict each category of rehab service use. We will then use multivariate logistic models to see how beneficiary level characteristics work together to predict receipt of rehab services. Additional analyses of receipt of Medicare covered rehab service during the pre-demonstration time period will determine changes in the type of beneficiaries receiving rehabilitation services. In other words, we will conduct pre-demonstration/post-demonstration analysis to see if the characteristics of service users change.

2.6 Comparisons of Beneficiaries in Demonstration and Comparison Regions

The second component of our analyses will match demonstration eligible beneficiaries (identified by specific low vision diagnoses) to similar beneficiaries in other regions and use comparisons of utilizations and expenditures between the two groups to estimate the impacts of the demonstration. To accomplish this task, we will need to select one or more comparison site for each demonstration site as described above in Section 2.3. In addition, we need to develop a method for matching individuals in the demonstration area to individuals in the comparison areas. The matching challenge is to identify a set of individual characteristics that are predictive of using low vision rehabilitation services. Many such characteristics may not be available in claims data (e.g., knowledge of services in the area.) It is also possible that the drivers of service use early in the demonstration are different from the drivers later in the demonstration period. There is little remedy for the first issue above and beyond using proxy variables that are available in claims data. The second issue, however, can be tested empirically by developing models of service use at multiple points during the demonstration. We plan to do this every six months.

To determine the true impact of the demonstration, we must identify and analyze samples of beneficiaries from comparison regions, who are similar to or ‘match’ our identified samples of beneficiaries from the demonstration regions. To match these comparison beneficiaries, we need to determine an efficient set of independent variables, probably no more than 4 or 5 in number, which have high association or predictive relationship with outcomes of interest. Variables

considered for matching purposes include socio-demographic characteristics, case-mix adjustors, and medical care utilization patterns. Our samples of comparison low vision beneficiaries will be chosen through a stratified random selection process with matching distributions based on these predictive independent variables. The purpose of such matching will be to determine comparison region beneficiaries, who can provide an estimate of the utilizations and expenditures that demonstration beneficiaries would have incurred if the demonstration had not taken place. By matching on a set of predictive independent variables, we control for the most obvious alternative explanations for outcome differences and strengthen the conclusion that outcome differences, if found, must be due to the demonstration. Matching provides us with the best possible foundation for obtaining unbiased estimates of the effects of the demonstration.

Candidate variables used for matching will come from the following list:

- Beneficiary demographics – sex, age, race, income
- County characteristics – urbanicity level (e.g., Beale code)
- Low vision-related diagnoses, incidence or ongoing, recent changes in severity
- Comorbidities and HCC conditions
- Past utilization of low vision and/or medical services (e.g., did beneficiary have recent eye surgery?)

If our plan to identify and employ a small set of strongly predictive independent variables proves impractical because no group of highly predictive variables exists, alternative matching approaches that will be tried. These other approaches will involve use of larger set of independent variables to help in creating matches between demonstration and comparison area beneficiaries. Such alternative approaches include:

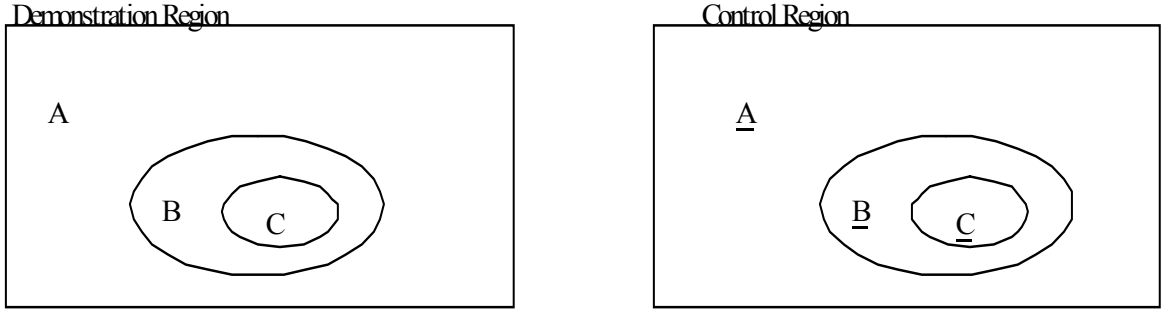
- Use of a metric to determine "distance" among beneficiary characteristics
- Propensity score matching approach (e.g., use a logit model to predict use of demonstration low vision services)
- Combination of exact matching on categorical variables (sex, age group) with closest match on some score (Mahalanobis distance or propensity score)

Our final choice for method of matching will follow preliminary analyses of existing claims data and further discussions with the CMS Project Officer.

2.7 Beneficiary Groups Used in Comparison Analyses

Figure 1 below describes the beneficiary groups used in our comparison analyses and indicates their nested relationship. Our analyses begin by determining the beneficiaries in demonstration and comparison areas with the low vision diagnoses that identify them as potential recipients of low vision rehab services. For all such beneficiaries we will construct utilization and expenditure histories based on claims from the demonstration and pre-demonstration time periods. For background purposes and to judge changes over time, histories of similar beneficiaries from the pre-demonstration time period will also be constructed.

Figure 1: Cohorts used for Medicare Utilization and Expenditure Comparisons



A: beneficiaries with low vision diagnoses B: standard low vision service users C: users of low vision demonstration services

The first set of analyses will concentrate on beneficiaries within the demonstration sites. We will examine the characteristics distinguishing low vision service users from non-users (A-B vs. B), and users of expanded low vision services versus non-users (A-C vs. C). In addition we will examine the beneficiaries in the same diagnosis classes during the pre-demonstration and demonstration time periods and measure how their use and expenditure for low vision rehabilitation services changed.

The second set of analyses uses three sets of beneficiaries within the demonstration regions (A= beneficiaries in specific low vision diagnosis classes, B= users of standard low vision services, C=users of demonstration low vision services), and makes comparisons with matched beneficiaries in the comparison sites (A= comparison beneficiaries matching set A, B = comparison beneficiaries matching set B, C = comparison beneficiaries matching set C). It is important to point out that selection of beneficiaries to be part of our comparison cohorts does not make use of information about actual receipt of low vision services in any way. Increasing likelihood of receiving low vision services and increased amount of such services should be considered outcomes of the demonstration. It would be biasing and undermine our analyses to limit comparison subjects to those who also received low vision services.

Claims data for our three matched samples of demonstration and comparison beneficiaries will be analyzed within a structure of a pre-post, treatment-comparison experimental design. In particular, we will employ bivariate difference in difference and multivariate regression analyses to (1) examine and compare utilization patterns and expenditure for low vision services, (2) examine and compare utilization patterns and expenditures for other Medicare-covered services, and (3) examine recipients of low vision services to determine which characteristics, other than residing within the demonstration area, predict use of demonstration rather than standard services.

2.5.1 Outcome Measures

To estimate the effects of the demonstration and test hypotheses concerning it, Medicare utilization and expenditure outcomes will be compared between beneficiaries from the demonstration and comparison regions. Outcomes of Medicare covered utilizations and expenditures will be compared using each of three cohorts of matched subjects from the demonstration and comparison areas (A vs. A, B vs. B, and C vs. C, as depicted in Figure 1). Analyses of a few specific outcome measures regarding low vision services would not be relevant for some cohorts (e.g., comparison of proportion of beneficiaries receiving low vision

services among users of low vision services) and these analyses are omitted. Table 2 below provides a list of outcomes and the cohorts used in their analysis:

Table 2: Key Outcomes

Beneficiary Cohorts Used	Outcome Measures
Matched pairs of beneficiary cohorts (Cohorts A and A, Cohorts B and B, and Cohorts C and C in Figure 1)	Total Medicare utilization & cost Hospital inpatient utilization & cost Outpatient facility utilization & cost Physician cost Home Health cost Skilled Nursing cost Incidence of burns Incidence of broken bones (e.g., from falls) Entry into nursing home (long term)
Beneficiaries with relevant low vision diagnoses (Cohorts A and A in Figure 1)	Proportion receiving low vision services
Matched Cohorts of beneficiaries receiving low vision services (Cohorts B and B in Figure 1); Matched Cohorts of beneficiaries receiving demonstration low vision services (cohorts C and C in Figure 1)	Amount of utilization of low vision services Expenditure for low vision services
Demonstration beneficiaries with relevant low vision diagnoses (Cohort A in Figure1, divided by outcome into C and A-C)	Use of demonstration low vision services (0/1)
Demonstration beneficiaries who receive low vision services (Cohort B in Figure1, divided into B and B-C)	Utilization of low vision services Expenditure for low vision services

2.5.2 Independent Variables

Theory and the results of previous studies identify certain beneficiary and area level characteristics as potentially affecting many of our outcomes of interest. Such variables, as listed below in Table 3, will be included as covariates in our multivariate regression models to explain as much outcome variation as possible and thereby provide an accurate estimate of the true impact of the demonstration.

Table 3: Independent Variables

Category	Characteristic
Beneficiary level	Age, gender, race Income proxy (e.g., average per capita income for the 65 and over age category within 5-digit zip code) Comorbidities/HCC conditions Specific ICD-9 diagnosis codes Utilization and expenditure during prior year: Hospitalizations Surgeries Physician office visits Emergency department care / urgent care Distance to nearest provider of low vision services
Area level	Number of physicians / PCP physicians per 100K population Number of hospitalizations per 1K population Average Medicare expenditure per beneficiary Number of low vision service providers per 1K population[1]

[1] We will consider including these covariates for low vision service-related outcomes

2.8 Methods of Analyses

Two methods of analyses will be used to estimate the effect of the demonstration on any utilization or expenditure outcome of interest:

A simple 'difference in differences' statistic will provide an unadjusted estimate of demonstration effect:

$$D = (x_{T,0} - x_{T,-1}) - (x_{C,0} - x_{C,-1}).$$

For example, D could represent the statistic of an equivalence test comparing total Medicare low vision expenditures for beneficiaries with incident low vision diagnoses in demonstration and comparison areas. The subscripts T/C distinguishes sample means from demonstration and comparison areas, and the 0/1 subscript distinguishes between sample means for standard and demonstration service use. With 6 demonstration areas, the degrees of freedom for this statistic is 11.

Multivariate regression analyses will provide estimates of demonstration effect after adjustment for beneficiary characteristics such as demographics, diagnoses and comorbidities, and prior

(previous year) medical care utilization. These models may include geographic factors that associate with outcome (e.g., urban versus rural, number of low vision rehab service providers in the region). Because regional factors help explain outcome variation, they may be useful even if demonstration regions are well matched with comparison sites. An example of such a regression model is:

$$Y = \alpha + \tau*\text{time} + \lambda*T + \gamma*\text{inter} + \beta_1*X_1 + \beta_2*X_2 + \ldots\ldots\beta_n*X_n + \varepsilon,$$

where T is the demonstration/comparison indicator, 'inter' is the interaction between time and demonstration indicator T, and X1, X2, …. Xn are beneficiary or region level covariates included in the model as adjustors. With this formulation the estimate of □, the parameter for the interaction between time and T, represents the effect of the demonstration. Other potential model formulations will be explored.

3 Beneficiary Satisfaction: Beneficiary Survey Data and Analysis

3.1 Overview and Objectives

The beneficiary survey has a specialized and important role to play in the context of the claims analysis. Differences in measures of health status, satisfaction, and quality of life that are not easily or reliably available in claims will be estimated through analysis of beneficiary survey data. These data will be used to investigate outcome differences between beneficiaries who receive demonstration services and standard Medicare low-vision services. In addition, the survey will gather information on use of alternative low-vision services not covered by Medicare, and barriers and facilitators of Medicare service use. This additional information, while not strictly necessary for a formal evaluation, will assist policy makers in predicting costs and utilization as they decide whether to extend coverage of the demonstration services beyond the demonstration areas.

The beneficiary survey will thus provide an invaluable adjunct to the information available from claims for the full incident low-vision population in the demonstration and comparison areas.

The comparisons we will make are determined by the nature of the demonstration intervention -- an expansion of the Medicare covered services available to all beneficiaries in the demonstration areas (four states, two cities) whose health status makes them eligible for low-vision rehabilitation services. It is understood that low-vision rehabilitation services are efficacious, and the question for evaluation is whether the expansion of coverage is valuable. Therefore, the ideal comparison is of outcomes for beneficiaries eligible for low-vision rehabilitation services in demonstration areas to outcomes for similarly eligible beneficiaries in comparison areas, regardless of actual service use. To understand whether the services supported by the demonstration are responsible for any observed differences in outcomes, we also wish to compare outcomes for beneficiaries in the demonstration areas receiving standard Medicare services for low vision and services that are covered only under the demonstration. Further, we want to understand whether the expansion of covered services increases access, i.e. if more beneficiaries are likely to use Medicare low vision rehabilitation services in the demonstration areas, and whether alternative services, covered by private or other payers, are being used by eligibles that do not use Medicare-covered services.

These objectives argue for comparisons of:

- beneficiaries in the demonstration areas who are service users, whether they used standard Medicare services or the services available only under demonstration rules, to

similar beneficiaries in comparison areas, who may or may not use low-vision services of any kind; and

- beneficiaries in the demonstration areas with incident low-vision diagnoses, who may or may not use services, to similar beneficiaries in the comparison areas.

Therefore, the groups to be surveyed are:

- demonstration area beneficiaries
    - receiving low vision rehabilitation services that would have been covered without the demonstration, i.e. under current Medicare rules;
    - receiving low vision rehabilitation services only available under demonstration rules; and
    - not receiving low vision rehabilitation services; and
- comparison area beneficiaries, regardless of service use, who would have been likely to receive services available under the demonstration rules if such services had been available.

3.2 Survey Design

The comparison groups for the survey are demonstration service users, standard Medicare low vision service users in demonstration and comparison areas, and low vision service non-users in demonstration and comparison areas. All samples will be restricted to beneficiaries with recent (incident) qualifying diagnoses, which indicate that low vision rehabilitation services may be appropriate. Further, all survey subjects will be community residents (not nursing home residents) and will not be receiving hospice services.

We propose a cross-sectional study design, which will survey both demonstration and comparison area beneficiaries approximately 16 months after their first claims date for a qualifying low vision diagnosis. This follow-up time is proposed to allow sufficient time for the hypothesized impact of demonstration services, particularly on daily function, to occur. Beneficiaries in the survey sample who receive rehabilitation services would be expected to begin receipt of the services within 1 or 2 months of diagnosis and referral and the first round of such services should be completed within 90 days. For such beneficiaries, then, the survey will be conducted approximately one year after treatment is complete. Beneficiaries with qualifying diagnoses who do not receive rehabilitation services will be surveyed after a similar follow-up time from diagnosis.

To standardize the observation time for beneficiaries in both the demonstration and comparison areas, we will survey the selected beneficiaries 16 months following the first claim for a service with a low vision diagnostic code.

3.3 Sample

The beneficiary survey sample will be selected from beneficiaries identified through claims based on qualifying low vision diagnosis. We will include only beneficiaries who have recently experienced vision loss in the second eye (incident cases), who are most appropriate for rehabilitation services. We will develop and document a method to assure that the low vision diagnosis is new within the last year. Two options include creating a claims based definition of incident low vision or implementing a clean period of six month or one year with no observable low vision diagnosis. Relevant diagnosis codes are included in Table 4 below.

Table 4: Diagnoses Identifying Survey-Eligible Beneficiaries

Diagnosis (ICD-9)	Description
368.41	Scotoma Involving Central Area
368.45	Generalized Visual Field Contraction or Constriction
368.46	Homonymous bilateral files defect
368.47	Heteronymous bilateral field defect
369.01	Better eye: total impairment Lesser eye: total impairment
369.03	Better eye: near-total impairment Lesser eye: near-total impairment
369.04	Better eye: profound impairment Lesser eye: total impairment
369.06	Better eye: profound impairment Lesser eye: near-total impairment
369.07	Better eye: profound impairment Lesser eye: profound impairment
369.08	Better eye: severe impairment Lesser eye: total impairment
369.12	Better eye: severe impairment Lesser eye: near-total impairment
369.13	Better eye: severe impairment Lesser eye: profound impairment
369.14	Better eye: moderate impairment Lesser eye: total impairment
369.16	Better eye: moderate impairment Lesser eye: near-total impairment
369.17	Better eye: moderate impairment Lesser eye: profound impairment
369.18	Better eye: severe impairment Lesser eye: severe impairment
369.22	Better eye: moderate impairment Lesser eye: severe impairment

369.24	Better eye: moderate impairment Lesser eye: moderate impairment
369.25	Better eye: total impairment Lesser eye: total impairment

Among such beneficiaries, users of low vision rehabilitation services will be identified as those with specific rehabilitation procedure codes (see Table 5) on the claims with low vision diagnosis codes.

Table 5: Procedures Identifying Low Vision Rehabilitation Users

Procedure (CPT4)	Description
97530	Therapeutic activities
97532	Development of cognitive skills
97533	Sensory integrative techniques
97535	Self care training
97537	Community re-integration
97110	Therapeutic procedures for strength
97112	Therapeutic neuromuscular re-education
97716	Therapeutic gait training

Medicare claims data, specifically Part B physician claims, will be examined on a rolling basis to identify beneficiaries in both demonstration and comparison areas who meet one of the two criteria for being eligibility for survey selection: having a first qualifying diagnosis code appear after the start of the demonstration (the incident low vision cohort) or having procedure codes that indicate low vision rehabilitation services that were initiated after the start of the demonstration (the low vision service users). Low vision service users in the demonstration areas are further classified according to whether their services would have been reimbursed under Medicare's standard conditions (standard low vision service users) or whether the services were only reimbursed because of the demonstration (demonstration low vision service users).

To provide sufficient yield of beneficiaries from these five groups, disproportionate sampling rates are used to select survey subjects. Prior to this sampling, additional stratification is used to assure that the low vision treatment of the survey subjects drawn from the comparison area will represent the experience demonstration area low-vision beneficiaries would have received if the demonstration had not taken place. This condition is achieved by stratifying demonstration area low-vision survey subjects with respect to characteristics known to correlate with likelihood of receiving low vision services, and selecting beneficiaries from in the comparison areas so that the distributions of these characteristics are similar. Disproportionate sampling of this type is done in order to assure sufficient samples of the beneficiaries of most interest in the survey. Many analyses of the resulting sample will require weighting in order to calculate unbiased estimates of the effect of the demonstration on outcomes of interest.

One potential concern is a low number of incident rehabilitation service users. Preliminary analysis with the100 percent file for 2004 shows small numbers of users in several demonstration counties. Low numbers may have an impact on power, so this will be monitored closely during recruiting phase.

3.4 Measures for Outcomes of Interest

Questions will focus on those aspects of daily function and well-being that are affected by low vision and could be improved by LV rehabilitation. Outcomes include daily function, quality of life, depression, and restriction/resumption of physical or social activities due to vision impairment. In addition, because LVR services are likely to increase an individual's perception of their ability to perform specific behaviors successfully (1,2) prior to actual performance, we include a measure of self-efficacy. Based on theoretical and empirical evidence, (1,3) increased self-efficacy is likely to precede behavioral change such as daily function or resumption of restricted activities and might be an early indicator of LVRD effectiveness. Low vision can result in accidents and injuries, such as fall-related injuries and burns or lacerations related to meal preparation or household management. Because an injury might not be serious enough to result in a provider visit (and therefore a claim), the beneficiary will be asked about such events. The respondent will be asked about receipt of low vision rehabilitation services (available through standard Medicare as well as under the demonstration rule), satisfaction with the LVR services received, barriers and facilitators of Medicare service use, and use of alternative low-vision services not covered by Medicare(e.g., through state-funded programs for the blind or private service organizations). Because some devices (e.g. glasses, magnifying glasses, bioptic telescopes, speaking devices) that might be recommended by a LVR provider are not Medicare reimbursable, beneficiaries will be asked what devices, if any, were recommended, if they purchased them and their cost, or reason for not purchasing them (e.g., cost, aversion to use, etc). Any other out-of-pocket expenses for non-covered services will also be collected.

To the greatest extent possible, we will use established measures with reported psychometric properties. To minimize respondent burden, we will use established short-forms of these measures to keep the interview length as short as possible. The measurement of daily function will focus on those instrumental activities of daily living (IADLS) that are most likely affected by vision loss, including home management and repairs, meal preparation, managing finances, managing medications, using the telephone, and mobility (especially outside the home). The respondent will be asked if, because of vision impairment, s/he can do this activity without any help, with use of devices, only with help of another person, or not at all. These questions can be used to examine specific IADL disabilities or to obtain an overall rating of IADL disability and have been used in many national, population-based surveys.

Quality of life will be measured with the 12-item version of the SF-36 4, a widely used measure of overall health-related quality of life. This measure produces an overall score or subscale scores for physical health and emotional health. Depression will be measured with the 5-item version of the CES-D scale 5 that measures frequency of depressive symptoms. This provides a continuous score with a higher score indicating greater risk to depression. Self-efficacy will be measured with the 4-item subscale of perceived ability to perform instrumental activities of daily living used in the Mac Arthur Study on Successful Aging.6 Restriction of physical or social activities will be queried with a single item that asks the degree to which the respondent had stopped doing social or physical activities that s/he used to enjoy doing because of his/her vision

impairment. Accidents and minor injuries will be collected by self-reports (yes/no) of falls, minor burns, and minor cuts the cause of which the respondent attributes to his/her vision loss.

A series of questions will be asked about LVR service use. Respondents will be queried about receipt of a range of LVR services, such as an eye exam, training in the use of magnification and other devices, training in mobility use of a cane, and assessment of home environment and recommended modifications. The respondent will be asked if s/he received the service and where the service was provided (home and/or doctor's office or clinic). Satisfaction with LVR services received will be measured with 2 items that ask about overall satisfaction with and helpfulness of (Likert rating) the services received. The respondent will be asked if they use any special devices or equipment such as magnifiers, speaking devices etc, how the devices were paid for, and how much out-of-pocket money was spent for such devices or equipment.

Finally, for descriptive purposes, the following sociodemographic information will be collected: gender, race, Hispanic origin, marital status, living arrangement (alone/with others) and level of education.

3.5 Data Collection, Management and Analysis

3.5.1 Training and Quality Control Procedures

a. Training and Supervision

NERI retains a stable staff of highly experienced Data Collectors, the majority of whom have many years of interviewing experience as well as graduate degrees in social work or related fields or directly relevant counseling experience. In selecting the part-time Data Collectors, priority is given to available, experienced interviewers among current staff. Ideally several will have already been working together on other projects, and in particular, will have direct experience working with elderly Respondents on prior CMS projects (including the Health of Seniors Survey {HOS}and the Pace Health Survey {PHS}), so that the formation of a cohesive, well-prepared team will take the minimum effort. Our reasons for using part-time interviewers are based on considerable experience. By spreading the telephone work over a greater number of Data Collectors, we can efficiently manage the staff, ensure high-quality data collection, and prevent Interviewer burnout by offering flexible work schedules.

Each new NERI Data Collector is provided with extensive training on the basics of interviewing and non-directive probing. NERI already has manuals for general interviewing techniques as well as evaluation procedures. These are modified and supplemented as needed for new surveys.

We also offer videotapes to supplement our intensive in-house staff training sessions. Practice assignments are a routine part of each training session and a significant amount of time is devoted to role playing and practice interviewing. Before any Data Collector is allowed on the telephone with a Respondent, a practice interview must have been successfully completed with a Data Collection Supervisor. We educate Data Collectors as to the goals and objectives of any research project we undertake unless the scientific aspects of the study require that the Data Collectors remain blinded to the research goals. This enables them to converse intelligently with Respondents to elicit cooperation.

We provide interviewing staff with question by question instructions for each survey instrument. A comprehensive set of interviewer instructions is produced covering such issues as: Respondent eligibility, handling non-response of various types, answering Respondent queries concerning the study and requests for information (for example, concerning additional information about the nature and scope of the research or referral to health services), termination

of interviews, and interruption of interviews. As part of the NERI training and orientation schedule, one team of Data Collectors assists in the final preparation of project protocols and, given their prior experience, reviews drafts of Project-specific Interviewer instructions.

This draft is then thoroughly reviewed with all Data Collectors before finalization. Original instructions are updated as needed through the daily log and debriefing sessions.

Debriefing meetings are held with a new Data Collector on a daily basis for at least one week or until queries and problems decrease to less than one/day. The frequency of such meetings can then be reduced to a minimum of one per week as feasible. Biweekly Interviewer meetings and monthly Project Staff Meetings are held throughout the duration of the Project. Items for discussion at these meetings primarily include entries in the daily log and a review of production statistics. Decisions may be made during these meetings but the Data Collection Supervisor signs off on all such decisions in the project daily log (see below). Another important purpose for these meetings is the maintenance of Interviewer interest and motivation to prevent any possible decline in data quality through boredom.

Perhaps the most important single record of data quality control is the daily log. This file contains queries or suggestions generated by each day's interviewing. All such entries are considered on a daily basis and decisions recorded where necessary by the Data Collection Supervisor. It is the responsibility of each Data Collector to check the log and update instructions as necessary before beginning the next day of interviewing. In this way, one central decision is made concerning any query, which is readily communicated to all staff and which is maintained in a permanent record for full methodological documentation.

Finally, to keep Data Collectors abreast of new developments in the field we provide on-going in-service training seminars covering such topics as: (1) overview of research at NERI; (2) general interviewing skills; (3) refusal conversions; (4) non-directive probing techniques; and (5) ethics and confidentiality issues in the conduct of research. These seminars provide both the opportunity for instruction and improving interviewing techniques and a forum for questions. During the open discussion, Data Collectors share their own experiences and offer suggestions for dealing with particular problems. Often, the Data Collectors themselves provide excellent ideas for resolving the common and unique problems which occur during the interview encounter.

b. Quality Control Procedures

Several procedures are implemented to ensure collection of high quality data:

Instrument Design: Careful design of the screening interview is a subtle way to enhance Respondent cooperation. NERI strives to keep survey instruments to the most feasible minimum in length, detail, and complexity, while ensuring that the research objectives of the Project are met.

Monitoring of Interviewers: NERI's Survey Research Center has individual telephone supervisory stations with a "call monitor" that allows the Supervisor to monitor any telephone line at random without the Interviewer's knowledge. Respondents are informed that a Supervisor may monitor the call for quality assurance. New Data Collectors are monitored more frequently than experienced interviewing staff. Intensive early monitoring not only ensures the quality and consistency of the Data Collector's work, but also may uncover substantive or methodological problems that might otherwise have gone unnoticed until much later in the study. Quality control monitoring is routinely conducted in order to collect consistent, high quality data.

During the monitoring process, the Supervisor views the Respondent's answers on the computer screen and notes any discrepancies on a hard-copy instrument. If problems are uncovered, they are written up and discussed in detail with the Data Collector immediately. At the end of each monitored interview, the Supervisor completes a "Monitoring Checklist" which is reviewed with the Data Collector and kept in the individual's file.

Quality Control Sampling of Final Dispositions: A minimum of 5% of all final dispositions are randomly sampled for re-contact and/or verification each month. Verifications of completed interviews are made by Data Collection Supervisors or Research Associates, who complete a standardized NERI verification form which asks for feedback from the Respondent about the way in which the interview was conducted. Any problems are discussed immediately with the individual Data Collector.

3.5.2 Telephone Survey Procedures

a. Contact Procedures

Up to ten (10) calls will be made to contact the Respondent and to conduct the telephone interview. Our experience suggests that this is a cost-effective breakpoint for a telephone survey.

These calls are made at different times of the day and on different days of the week, in an attempt to maximize contact using assignment procedures already operating smoothly at NERI. The initial call may be made during the daytime hours (9:00 am – 5:00 pm, Respondent's local time) to maximize efficiency by identifying households where individuals are likely to be at home during the daytime. Of the remaining nine call-backs, four calls will be made on different weekday evenings, two will be made on a Saturday between 9:00 a.m. and 7:00 p.m., and two on a Sunday between 12:00 noon and 9:00 p.m., to complete the telephone protocol (Respondent's local time) over a period of not less than 30 days. Alternatively, the Respondent can arrange an appointment or otherwise offer another "best time to call" and/or conduct the telephone interview.

Since many people use the answering machine as a "screening" device, NERI has developed a successful strategy for handling answering machines. On the first telephone call to an answering machine, the Data Collector leaves a project-specific message, with the Interviewer's name, outlining the purpose of the call, and offering a toll-free (1-800) telephone number with the project's extension, saying "we will try you at another time." This message is left up to three times in total. The answering machine script itself is read directly from the computer screen.

b. Introductory Communications

To ensure quality data, it is important to obtain a high response rate. Based on the experience of senior investigators at NERI, the single most important factor in maximizing response rates is the effort contributed by project staff in contacting Respondents and enlisting their cooperation. A crucial factor in obtaining Respondent cooperation is sensitivity to the Respondent's perspective. This is gained if a small amount of extra effort is put forth at the beginning of the survey interview. Interviewer sensitivity to the Respondent's perspective, coupled with sensitivity to the confidentiality of the survey situation, conveys to the Respondent that cooperation in the survey effort is important and that the trust inherent in the situation will not be violated. In addition to general sensitivity, specific procedures to obtain Respondent cooperation are needed. These central elements are part of a standardized protocol which NERI has developed for telephone survey interviewing.

During the introductory telephone call, the Interviewers clearly describe the nature of the proposed research, its sponsorship and the purpose of the study. All Data Collectors are provided with an "interview call script" in a question and answer format that is unique to each project. At the time of the introductory call, the importance of each selected Respondent's participation is explained. This practice consistently increases cooperation rates. The study's importance is specifically spelled out, and the Respondent is told what ultimately may be gained from participation in the survey. Confidentiality guarantees are always offered and oaths of confidentiality must be signed by all NERI staff.

A project-specific toll-free call-in telephone number is provided to Respondents in all communications. NERI staff members are available during specified hours to answer questions.

c. Special Accommodations

NERI will make accommodations in the event that a Respondent cannot hear or speak well enough to conduct a telephone interview, but can see well enough to complete a written questionnaire. NERI will provide the questionnaire in large-print and high contrast for self-administration by individuals with low vision. "Proxy" interviews are considered not suitable for this survey because the outcomes of interest include perceptions and subjective reports. "Proxy" interviews are appropriate for the collection of factual information. While ability to carry out daily function is considered factual in nature, there is consistent evidence that self and proxy responses on these activities differ sufficiently to make them not equivalent.

d. Converting Refusals

A number of Respondents initially refuse to participate in any telephone survey. Special attention is given to refusals, the majority of which are recontacted (98%), either by the Data Collection Supervisor or by an experienced Data Collector for possible conversion. Sometimes the interpersonal "chemistry" between a particular Data Collector and potential Respondent doesn't work, and the introduction of another Data Collector can remedy the situation. In particularly difficult cases, the Data Collection Supervisor will attempt the call. By introducing him/herself as the Supervisor, s/he often is able to complete the interview. NERI closely monitors refusal rates on its telephone surveys so that excessively high refusals for particular Data Collectors can be identified and appropriate corrective action taken. NERI is able to turn around, on average, 30% of initial refusals. In addition, we often find that many of those who initially refuse were not, in fact, eligible for the survey.

e. Report of Dispositions

NERI will provide a complete set of dispositions for the telephone survey. The NERI Survey Center has developed a standard "core" set of dispositions for use across all projects: Eligible and Completed the Interview; Ineligible; Eligible but Refused to complete the survey; No Contact (lost to field or no working or published telephone); and Unavailable to complete the interview during the data collection period. This core set of dispositions ensures that all Interviewers will assign dispositions in a standardized, uniform manner. The dispositions provide a method for handling answering machines; call forwarding; cellular telephones; paging devices; facsimile machines; auto voice mailboxes, etc. Summary Disposition Reports of completed interviews and preliminary response rates (by site) will be sent to CMS in the monthly progress reports.

3.5.3 NERI'S CATI System

a. Survey Implementation

Surveys will be completed using NERI's computer-assisted telephone interviewing (CATI) system. The CATI system uses a state-of-the-art software package featuring the call-scheduler which schedules all calls (adjusted for different time zones). This feature allows for flexible programming to control the days and times for each call-back and virtually eliminates the paperwork associated with large-scale surveys. Each CATI interviewing station is equipped with a stand-alone personal computer and headset. The system is supported by its own local area network and automatic tape backup system.

The CATI system is initialized by creating a file containing an identification number and the telephone numbers for all cases to be contacted. When this file is read into the CATI system, the following information is 'tracked' by the system:

1) the date, time and disposition of every telephone call made;
2) the data file which contains all of the responses to the survey items; and
3) the current interview completion dispositions.

Once a valid final disposition for a case is entered into the CATI system, the case becomes "locked" and further access is automatically denied. This prevents Interviewers from inadvertently working on previously completed cases.

The CATI system schedules each call-back and assigns it to the next available Interviewer. Each case ID# in the system is assigned a priority code automatically, based on the algorithm programmed for the Project. Typically, the CATI programmer (Senior Research Associate) works with the Data Collection Supervisor and other project staff to determine the appropriate algorithm. Confirmed appointments are always assigned the highest priority code for call-backs. The call-scheduler ensures that the Respondent will receive a call-back on the date and time requested.

Responses to survey items are keyed directly into the computer as the screening interview is administered. The responses for close-ended survey items are automatically checked and stored by the system. The CATI system eliminates several intermediate steps in the research process that are particularly error-prone (recording, coding, transcribing, and data entry) and thereby ensures collection of high quality data. For the LVRD evaluation, data can be provided at requested intervals, e.g. at 6 or 12 month intervals.

b. Data Management

As implemented at NERI, the CATI software:

- Checks for invalid or out-of-range response codes and immediately prompts the Interviewer to correct data entry errors (invalid response codes are not accepted by the CATI system)
- Guards against missing data by requiring that Interviewers provide answers to every appropriate question;
- Performs consistency checks among the responses to two or more items (thereby promoting internal consistency of the data);
- Invokes skip patterns automatically (thereby eliminating Interviewer selection error);
- Provides for a greater complexity of data collection, thus allowing for the use of more sophisticated designs than with pencil and paper forms. It can accommodate randomly

assigned ‘modules’ and complex logical structures with questions specifically tailored to the special circumstances of individual cases;

- Incorporates execution-time commands allowing the Interviewer to move backward and forward through the instrument to change answers during the interview if the system finds an internally inconsistent answer or if a Respondent makes an error and wants to review certain questions;
- Prevents any changes or edits to the instrument once the interview has been completed;
- Monitors continuously the interview status of each Respondent ID# and automatically updates this status;
- Compiles summary reports of interview dispositions; and
- Produces formatted data sets for statistical analysis.

c. Data Files

NERI’s CATI system automatically outputs interview responses in a multiple record, fixed-column ASCII format, frequently referred to as a “rectangular” file. Each ASCII record begins with the case identification number and a sequential record number. In addition to the interview responses, NERI routinely adds fields for the final interview disposition, and date and time of the telephone interview, and interview length (time started, time ended).

d. CATI Backup Procedures

An incremental backup of all files in the CATI system is performed each evening after completion of the day's interviewing. Full backups are done weekly. For added security, tape cartridges with full backups are stored off-site in the safety deposit box of a local bank.

3.5.4 Informed Consent and Confidentiality

a. Informed Consent

Verbal consent to participate will be obtained from all Respondents prior to proceeding with the interview. A verbal description of the survey and the nature of the Respondent's participation will be provided by the Data Collector at the time of telephone contact. Confidentiality of all information and the voluntary nature of responses will be emphasized. The standardized consent statement, approved by both the NERI and Brandeis Institutional Review Boards, will be read to Respondents before proceeding with the interview. All Respondents will be given the toll-free telephone number of NERI’s Data Collection Supervisor as well as telephone numbers for the administrator of the Brandeis Institutional Review Board. In addition, the toll-free telephone number for the Principal Investigator at Brandeis (Dr. Bishop) will be provided.

b. Protection of Confidentiality

Confidentiality among research staff will be maintained by using the following system. The project sample will be assigned limited access by password. All subsequent use of the list of telephone numbers will be under the direct supervision of the Project Director or Data Collection Supervisor. (For safety, one duplicate master file will be maintained through the in-house computer back-up system.) Finally, all information about Respondents who have completed the telephone interviews will contain only an identification number. Moreover, all project staff handling data will be required to sign an Oath of Confidentiality, to further emphasize this responsibility. All identifying information is stored in the master data file (password protected and security access required) separately from interview data to protect the confidentiality of data.

c. Benefits and Risk/Benefit Ratio

This is a telephone survey with a series of questions related to the individual's health and in particular, difficulties related to low vision. Respondents who complete the telephone survey will contribute to the knowledge of the research community about the low vision rehabilitation demonstration. There are minimal risks associated with participation in the telephone interview including the fact that certain Respondents may find some of the questions upsetting to them. In such cases, Data Collectors will offer referrals to agencies with toll-free telephone numbers that may be of assistance to Respondents. Methods for protecting confidentiality of the data are described above.

3.5.5 Application for OMB Clearance

Prior to start of the beneficiary survey and site visits, the following supporting materials will be submitted as part of the application: a statement outlining the justification for data collection; discussion of how this project is consistent with CMS's overall goals and responsibilities; all recruitment materials; the telephone survey instrument; a description of the Respondent burden; a statement of justification for the inclusion of any data collection of a "sensitive" nature; methods used to protect the confidentiality of Respondents; and schedule for data collection. The draft application will be submitted to CMS for review and approval by 9 months following the start of the LVRD Program. The final OMB package must be submitted to OMB by 15 months following the start of the LVRD Program. OMB clearance is required within 22 months of the start of the LVRD Program in order to begin the telephone survey component 24 months after the start of the LVRD Program.

3.5.6 Data Analysis

Daily function, self-efficacy, quality of life, and satisfaction outcomes derived from the beneficiary surveys will be analyzed with multivariate regression models much the same as with the claims based analyses. As previously discussed, in all such modeling, we will include a fixed effect for propensity score stratum and a random effect for community in addition to the fixed effect for demonstration or comparison condition.

4 Demonstration Implementation (Process Evaluation): Site Visit Data and Analysis

4.1 Overview and Objectives

The purpose of the process evaluation is to provide contextual information about the implementation of the LVR demonstration program. This information is useful to help interpret the results of the quantitative evaluation data obtained through the claims analysis and the beneficiary survey. In addition, the data collected through the process evaluation can inform plans for a national rollout of this program. The process evaluation will have three specific goals:

- To describe the adoption of the LVRD program among providers and changes in provider practices;
- The understand patient perceptions about changes in services; and
- To describe the facilitators and barriers to change experienced by providers and patients.

4.2 Samples

The process evaluation will draw on data collected with four groups of respondents:

- Rehabilitation Provider Focus Groups (Occupational Therapists (OT), Certified Low Vision Therapists, Low Vision Rehabilitation Specialists (LVRT), and Orientation and Mobility Specialists (OM));
- Physician Interviews (Optometrists and Ophthalmologists);
- Patient Interviews (Elders with low vision problems).

The following outlines the sample identification and sampling for each of the four process evaluation respondent groups.

4.2.1 Low Vision Rehabilitation Provider Focus Groups (OT, LVT, LVRT, OM).

We will complete focus groups with Low Vision Rehabilitation providers for each of the six demonstration and six comparison study sites (See Table 1). This group includes qualified Occupational Therapists and certified Low Vision Rehabilitation Therapists, Orientation and Mobility Specialists and Low Vision Rehabilitation Therapists who work with sighted individuals with moderate to severe visual impairments and who are Medicare eligible (65 years and older or disabled). Only providers who have been in practice in the designated site for at least one year prior to the study will be invited to participate.

The providers will be selected to include: a) those who practice in the LVRD site and are participating in the demonstration program; b) those practicing in the LVRD site but not participating in the program; and c) those practicing in the comparison site. We will construct the recruitment lists for the provider focus groups such that the distribution of provider types recruited for the focus groups reflects the distribution of provider types (OT, Mobility Specialists and LVRT) in the site. .

A multimodal strategy will be used to identify the universe of Low Vision Rehabilitation Providers in each study area, including: 1) web searches of all hospital and clinics providing low vision services; 2) professional society membership and accreditation lists focusing on specialty groups such as the Society for Rehabilitation Specialists, occupational therapy associations and the Academy of Certification of Vision Rehabilitation and Education Professionals (ACVREP) and the National Vision and Rehabilitation Association (NVRA); 3) lists of participants at professional meetings such as the International Low Vision Conference or the Association for Education and Rehabilitation of the Blind and Visually Impaired (AER); and 4) provider referral lists for the state department/ commission for the blind and the Lighthouse National Center for Vision and Aging, a national clearing house on vision and services.

In addition to drawing on existing lists, we will employ a snowball sampling approach. We will ask each provider contacted about the focus group to identify other low vision providers in the practicing in the area. There are a limited number of LVR providers in the country and based on personal communications, they are likely to know each other, especially in a limited geographical area.

Each year for a period of three years, we will conduct 18 focus groups with Rehabilitation Providers. We expect that each focus group will include 8 individuals for a total of 144 participants. The same providers will be invited to the focus group every year. If providers who participated in the first or second focus group are no longer in practice in the 2nd or 3rd year of the study, we will recruit new providers who have been in practice since the beginning of the evaluation to fill the open positions.

4.2.2 Physician Telephone Interviews.

Using a similar approach to that described above for the providers, we will identify respondents for the physician interviews from multiple sources. They will include a combination of the following: 1) web searches of all hospital and clinics providing eye care; 2) use of professional society membership lists focusing on specialty groups such as the American Academy of Ophthalmology, the American Optometric Association, and the state optometry, ophthalmology; 3) lists of participants at professional meetings such as the International Low Vision Conference or the Association for Education and Rehabilitation of the Blind and Visually Impaired (AER); 4) provider referral lists for the state department/ commission for the blind and the Lighthouse National Center for Vision and Aging, a national clearing house on vision and services; and 5) use of procedure codes in the Medicare Beneficiary database indicating an optometrist or an ophthalmologist providing low vision rehabilitation (see codes above). In addition, we will employ a snowball approach by asking physicians to identify their colleagues in their area who are or are not participating in the LVRD program as described above for the Low Vision Rehabilitation Providers.

As for the Low Vision Rehabilitation Providers, we will identify physicians to represent three categories: 1) physicians practicing in the demonstration area and participating in the demonstration program as indicated by their billing codes (billing for rehabilitation services); 2) physicians practicing in the demonstration who have not billed for services using the rehabilitation billing codes; and 3) physicians practicing in the comparison site area. Physicians must have been in practice at least one year prior to the beginning of the study. We will make every effort to ensure that the both optometrists and ophthalmologists are included and that the physicians selected for interview have patient caseloads (types of impairments and racial/ethnic characteristics) typical of patients in the area as reflected in the Medicare Beneficiary database. We will limit these interviews to low vision and retinal specialists whose practice concentrates on individuals who are Medicare eligible (65 years and older and/or disabled) with moderate to severe visual impairments resulting from conditions such as macular degeneration and diabetic retinopathy. The same providers will be interviewed each year over the three- year process evaluation. A total of 36 open-ended telephone interviews with physicians will be completed each year.

4.2.3 Patient Telephone Interviews.

We will ask the low vision rehabilitation providers and physicians who practice in the demonstration site and who participated in the process evaluation focus groups and interviews to identify patients in their practice for interviews. We will conduct telephone interviews with three sets of patients: 1) patients of providers/physicians participating in the LVRD program; and 2) Patients of providers/physicians not participating in the demonstration program and 3) Patients of providers who practice in the comparison sites. We will make every effort to ensure that the patients in the focus groups reflect the caseloads of the providers as defined by the type of visual impairment, gender, and racial/ethnic groups as determined by the claims analysis. We expect to interview 144 patients each year for three years. A new sample of patients will be recruited each year for three years.

4.3 Evaluation Data Collection

4.3.1 Interview Guide Development and Site Visits

Since this portion of the study is based on qualitative data, all of the guides will be open-ended and semi-structured protocols. The data collection procedures, instruments, and data collector trainings will be designed to ensure systematic coverage of the same topics and questions across the sites and over the course of the LVRD.

This section enumerates the research questions that will be used to develop the guides for the focus groups and interviews.

4.3.2 Interview Guides

Low Vision Rehabilitation Provider Focus Groups

The following research questions will guide the development of the discussion guide for the focus groups with the Low Vision Rehabilitation providers.

Practice

How does the composition of the Low Visions Rehabilitation providers' caseloads change over the course of the LVRD program? Do the composition and the changes in composition vary by type of Low Vision Rehabilitation Provider (e.g. Occupational Therapists, Low Vision Rehabilitation Specialists, and Mobility Specialists)?

How do the Low Vision Rehabilitation Providers obtain referrals for care? Do referral sources change over time? Do referral patterns differ between the LVRD and non-LVRD sites? Does participation in the LVRD program affect referral patterns?

What are the usual assessment and treatment regimens employed for a low vision rehabilitation patient? How have they changed since the demonstration has started? Are there differences by type of providers in patient assessments and treatment plans?

How are in-home, treatment services used by providers in the LVRD program? Are there changes in the use of both of these types of services over time? If not, why?

Billing and Reimbursement

Do the services, billings, and contractual arrangements offered by the various types of providers evolve over the course of the LVRD program?

What are the facilitators and barriers to providing and billing for services and how do they evolve over the course of the LVRD program.

Demonstration Program

How do experiences with referrals, treatment patterns and billing vary across the across types of providers who participate in the LVRD program? Are there differences in the experience with the program by LVRT, MS and OTs?

How do the providers (demonstration sites only) understand the LVRD program? To what extent do they understand the coverage of services, expectations or obligations of the providers related to treatment plans and services, and billing codes? Do they need additional information about the LVRD program?

What factors facilitate the adoption of the LVRD program? Why do providers decide to participate or not in the LVRD program? How do the providers learn about the LVRD program?

Are there differences (e.g., case mix, specialty) between providers who participate in the LVRD program and those who do not?

What barriers to participating in the LVRD program do the providers encounter and how do the providers cope with these barriers? Do different types of providers experience different barriers?

Physician Interviews

The following list of research questions will guide the development of the guide for the telephone interviews with the physicians.

Practice

What are the usual assessment and treatment regimens for low vision rehabilitation used by these physicians? How have they changed since the demonstration has started? Are there differences between the LVRD and non-LVRD sites?

How do the optometrists/ophthalmologists provide for low vision rehabilitation treatment for their patients? Do they refer to low vision rehabilitation specialists or orientation/mobility specialists outside of their practice? Do these referral targets change over time during the LVRD? Do referral patterns differ between the LVRD and non-LVRD sites? Does participation in the LVRD program affect referral patterns?

How are in-home treatment services used by the physicians in the demonstration program? Are there changes in the use of both of these types of services over time? If not, why? Are there differences between the LVRD and non-LVRD sites?

Billing and Reimbursement

Do the services, billings, and contractual arrangements used by the optometrists/ophthalmologists evolve over the course of the LVRD program? Are there differences between LVRD and non-LVRD sites?

What do the optometrists/ophthalmologists report to be the facilitators and barriers to providing and billing for services? How do they evolve over the course of the LVRD program? Are there differences between LVRD and non-LVRD sites?

Demonstration Program

What is the range of experiences with the LVRD program among optometrists and ophthalmologists in the LVRD sites?

How do the optometrists and ophthalmologists in the demonstration sites understand the LVRD program? To what extent do they understand the coverage of services, expectations or obligations of the providers related to treatment plans and services, and billing codes? Do they need additional information about the LVRD program?

What factors facilitate the adoption of the LVRD program? Why do optometrists and ophthalmologists decide to participate or not in the LVRD? How do they learn about the LVRD program? Are there differences (e.g., case mix, specialty) between optometrists and ophthalmologists who participate in the LVRD program and those who do not participate?

What do the optometrists/ophthalmologists report to be the facilitators and barriers to participating in the LVRD program? Do different the optometrists and the ophthalmologists experience different barriers?

Patients

The questions outlined in this section specify the research aims for the telephone interviews with low vision patients.

How do patients experience their care from LVR providers and physicians? Do the types of experiences differ by type of provider? Do the experiences differ by type of patient (e.g. racial/ethnic group, severity and type of vision impairment)? Do these experiences change over the period of the LVRD? Do these experiences differ in LVRD and non-LVRD sites? Do these experiences differ by participation or non-participation in the LVRD program?

Do patients receive a full range of LVR services? Are there differences in the types of low vision rehabilitation services offered across types of providers and types of patients?

Is there a difference in the nature of the interaction between patient and provider across types of providers and patients?

Where do patients receive their services? Are there differences in perception of services related to In-home care versus Incident to Service care?

Are their needs for rehabilitation services addressed?

What are the barriers and facilitators for patients in using rehabilitation services? How are barriers addressed?

4.4 Site Visits for Process Evaluation Data Collection

Process evaluation data will include three rounds of data collection components. The data collection ill begin 16 months from the start of the demonstration program. Visits will be conducted in each round with each of the four states and two cities selected by CMS as demonstration sites for a total of 36 site visits. Each site visit will use the following data collection strategies:

4.4.1 Conduct of Focus Groups and Telephone Interviews

The following outlines the basic elements of assembling and conducting the focus groups, recruiting and conducting the interviews.

Focus Groups with LVR Providers (OTs, LVRTs and Mobility Specialists)

Using the sources of information to identify providers described above in Section 4.1.1, we will assemble lists of names and contact information for each type of provider (OT, LVRT and Mobility Specialists) within each of the 12 interview sites. NERI staff will mail a letter to the providers explaining the full study and inviting their participation. The NERI Research Assistant will contact each provider one week after the mailing. The purpose of this call will be to screen the provider for eligibility in the focus group and invite eligible providers to participate. The screening instrument used for the call will be designed to verify or determine the following: Provider's practice specialty (OT, LVRT, Mobility Specialist); practice in the study area in the past year, currently offering low vision rehabilitation services; racial and ethnic composition of the provider's case load; vision impairment status of their case load; LVRD participation status; and plans for participation in LVRD.

Based on the results of the screening, participants will be invited to enroll in a focus group. Providers who are currently participating or expect to participate in the LVRD waiver program prior to the date of a scheduled focus group will be invited to the focus group with "participating" providers of his or her specialty (e.g., OT, LVRT, Mobility Specialists). Those

who are not participating and do not be expect to participate in the near future will be invited to the focus groups with the "non-participating" providers of their specialty. Providers will be invited to participate until the required number of subjects has agreed to participate (overbooking to allow for cancellations or "no-shows"). A confirmation letter will be mailed out one week prior to the group with the date, time and location of the focus group. The Research Associate will call participants the day before the focus group, reminding them of the time and location.

4.4.2 Physician Interviews (Optometrists and Ophthalmologists)

Using a protocol similar to that described above for the LVR providers, a list of optometrists and ophthalmologists will be created. As described above, a letter will be mailed to the physicians and a follow-up phone call will be made. The physicians will be screened to determine eligibility, including specialty (optometry or ophthalmology) as well the remaining criteria outlined above for the other LVR providers. If necessary, physicians who are not available at all during the scheduled site visit can be interviewed by telephone.

4.4.3 Patient Interviews

Participants will be identified through the providers (both participating and non-participating) in each of the six demonstration sites and comparison group areas. In compliance with the HIPAA Privacy Rule, the providers will be asked to distribute a letter of invitation about the study to all of their patients receiving LVR services. The letter will describe the study and the purpose of the interviews with patients. A staff person within each provider's office, or the provider, will place a phone call to the patient one-week after the letter is mailed out. The caller will answer any questions about the study and secure verbal permission from the patient to forward his or her name to NERI staff for screening for an interview. The NERI Research Associate will call all patients who agree to have their name and contact information released. In the event that there are more than 8 patients available to interview for a given site, we propose using a quota system to ensure representation of patients by gender, type and severity of visual impairment, and racial/ethnic group.

The telephone interviewer will begin the interview by explaining the purpose of the study and reading the informed consent. The interviewer will obtain verbal consent before proceeding with the interview. He/she will emphasize that participation is voluntary and remind the respondent that, since the session is being audiotaped, they should not provide identifying information. A check for $40 will be mailed to each respondent completing an interview as an honorarium for their participation. After completing the interview, will be asked to questions to document the characteristics of the participants. The questions will cover: gender, age, racial/ethnic group affiliation; and current health insurance coverage.

4.4.4 Implementation Analysis Report

Data from the focus groups and interviews will be analyzed for an Implementation report. The analysis will proceed as follows. The provider focus groups and the patient and physician interviews will be audiotaped. The audiotapes will be transcribed and imported in Atlas.ti for analysis. Immediately following the focus group, both facilitators (the moderator and the note-taker) will independently record the main themes they heard arising in response to each question and also summarize their observations about the focus group. This ensures more accurate recall while memories are fresh. Facilitator notes and content analysis of the transcripts will be used to describe the implementation of the demonstration services, barriers and successes to adopting and carrying out the program, and changes in implementation over the course of the

demonstration period. Results will also be useful for interpreting the findings of the beneficiary survey and cost analyses as the samples of providers and beneficiaries will be linked.

Table 6. Number of Participants in Process Evaluation

LVRD SITES	PROVIDER FOCUS GROUPS (OT, LVRT, Mobility Specialists)		PROVIDER TELEPHONE INTERVIEWS (Optometrists/ Ophthalmologists)		PATIENT Telephone Interviews	
	Participating	Non-Participating	Participating	Non-Participating	Participating	Non-Participating
NYC	8	8	4/4	4/4	8	8
Atlanta	8	8	4/4	4/4	8	8
Kansas	8	8	4/4	4/4	8	8
New Hampshire	8	8	4/4	4/4	8	10
North Carolina	8	8	4/4	4/4	8	8
Washington	8	8	4/4	4/4	8	8
TOTAL	48	48	48	48	48	48

NON- LVRD SITES (COMPARISON SITES)	PROVIDER FOCUS GROUPS OT, LVRT, Mobility Specialists	PROVIDER Telephone INTERVIEWS Optometrists/ Ophthalmologists	PATIENT Telephone Interviews
City #1	8	4	8
City #2	8	4	8
State #1	8	4	8
State #2	8	4	8
State #3	8	4	8
State #4	8	4	
TOTAL	48	24	48

5 REFERENCES

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Attachment 1: Schedule of Deliverables

Phase I - September 26, 2005 to February 25, 2007 (17 months)

Deliverable No.	Task No.	Description	Quantity	Time after Award Date
1	I.1a.	Monthly conference calls	12	Monthly
2	I.1b.	Written summary of calls	electronic	Monthly
3	I.1c.	Monthly progress reports	4*	Monthly
4	I.2a.	Initial meeting	1	2 months
5	I.3.	Draft evaluation design report	4*	14 months
6	I.3.	Final evaluation design report	4 bound 1 unbound*	16 months
7	I.4a.	Draft beneficiary survey instrument	electronic	6 months
8	I.4a.	Final beneficiary survey instrument	electronic	10 months
9	I.4a.	OMB clearance package--draft	4*	15 months
10	I.4a.	OMB clearance package--final	4	17 months
11	I.4a.	System of records package--draft	4*	10 months
12	I.4a.	System of records package--final	4	12 months
13	I.4a.	Data Use Agreement--final	4	6 months
14	I.4b	Outcomes measurement data collection plan Draft (in design report)	electronic	10 months
15	I.4b	Outcomes measurement data collection plan Final (in design report)	electronic	12 months

16	I.4c	Draft site visit interview guide	electronic	9 months
17	I.4c.	Final site visit interview guide	electronic	11 months
18	I.4c.	First site visit		16 months
20	I.5.	Draft Phase I[3] report	4*	14 months
21	I.2b.	First annual meeting		15 months
22	I.5.	Final Phase I report	4*	16 months
Phase II	**-**	**February 26, 2007 to February 25, 2008 (12 months) [months 18 to 29]**		
23	II.1a.	Monthly conference calls	12	Monthly
24	II.1b.	Written summary of calls	electronic	Monthly
25	II.1c.	Monthly progress reports	12*	Monthly
26	II.3	Draft revisions to evaluation design	electronic	19 months
28	II.4b	Outcomes data collection and analysis continues.		
29	II.4c.	Continue site visits		
30	II.3	Final revisions to evaluation design	electronic	20 months
31	II.5	Draft Phase II report	4*	26 month
32	II.2.	Second annual meeting		27 months
33	II.5.	Final Phase II report	4*	28 months
Phase III	-	February 26, 2008 to February 25, 2009 (12 months) [months 30 to 41]		
34	III.1a.	Monthly conference calls	12	Monthly

[3] At CMS suggestion, the implementation report is renamed Phase I report to reflect its function.

35		III.1b.	Written summary of calls	electronic	Monthly
36		III.1c.	Monthly progress reports	12*	Monthly
37		III.3	Draft revisions to evaluation design	electronic	31 months
38		III.3	Final revisions to evaluation design	electronic	32 months
19[4]		III.4a.	Beneficiary survey implementation		30 months
39					
40		III.4b.	Outcomes data collection and analysis continues		
41		III.4c.	Site visits continue		
42		III.5.	Draft Phase III report	4*	38 months
43		III.2.	Annual meeting		39 months
44		III.5.	Final Phase III report	4*	40 months

Phase IV - February 26, 2009 to February 25, 2010 (12 months) [months 42 to 53]

45	IV.1a.	Monthly conference calls	12	Monthly
46	IV.1b.	Written summary of calls	electronic	Monthly
47	IV.1c.	Monthly progress reports	12*	Monthly
48	IV.4a.	Beneficiary survey collection finishes		48 months
49	IV.4b.	Outcomes data collection and analysis finishes		
50	IV.4c.	Site visits continue		
51	IV.5.	Draft Phase IV report	4*	50 months

[4] The plan for the beneficiary survey was changed from a multi-wave to a single wave survey (see Memo re: survey design). Therefore this activity, originally scheduled for Phases I ,II and II, begins and is completed in Phase III.

52	IV.2.	Annual meeting			51 months
53	IV.5.	Final Phase IV report	4*	5	2 months

LOW VISION
TELEPHONE INTERVIEW

Version 03/24/06

RESPONDENT ID: | | | | | | |

DATE: | | | | | | | | | | | |
MONTH DAY YEAR

INTERVIEWER ID: | | | |

START TIME: | | | : | | | 1. AM 2. PM

ASK RESPONDENT: **Did you receive the introductory letter we sent to you on [DATE]?**

YES ..... ☐1

NO ..... ☐2 **[READ HIGHLIGHTED PORTIONS TO R]**

DON'T KNOW..... ☐d

READ TO ALL RESPONDENTS TO BE INTERVIEWED BY TELEPHONE:
Before we begin, let me assure you that all information is strictly confidential to the extent of the law, and that your name will not be used in any reports. Your answers will be combined with the answers of others and used for statistical purposes only.

Please answer each question as accurately as you can. This interview is completely voluntary and your decision to participate or not will not affect you or services you might receive in any way. The interview will take about 30 minutes. You may decide to stop the interview at any time. If there is a question that you cannot or do not wish to answer, please tell me and I will go on to the next question. The questions deal with your experiences as someone with vision problems and include questions about your health in general, and specifically about how your vision problems may affect other areas of your life, such as your ability to do daily activities, and any health services you may have received for problems with your vision. Your participation will help us to better understand the issues surrounding individuals who have problems with their vision.

[NOTE: READ THIS ONLY IF RESPONDENT STATES THAT THE LETTER WAS NOT RECEIVED OR RESPONDENT DOES NOT RECALL RECEIPT OF THE LETTER]:
If you have any questions or concerns about this survey, you may call NERI's Senior Data Collection Supervisor, Heather Cochran, at (800) 775-6374 extension 606. If you have any questions about your rights as a research subject, you may call Nancy Gee of NERI's Institutional Review Board at (800) 775-6374, extension 249. You may also call the Principal Investigator at Brandeis, Christine E. Bishop, Ph.D., at (XXX) XXX-XXXX, extension XXX. For questions about your rights as a research subject, please call NAME, the TITLE at Brandeis University. The telephone number is (XXX) XXX-XXXX, extension XXX. All of these telephone numbers are ***toll-free***, and there will be absolutely no charge to you for the call.

NOTE: A FEW OF THE INTERVIEWS WILL BE RANDOMLY SELECTED BY THE CATI SYSTEM

FOR TAPING (FOR QUALITY CONTROL PURPOSES)

For quality assurance, my supervisor may monitor this call. In addition, we would like to record your responses in order for us to check your answers in case the supervisor has a question about the interview. Your name will not be used on the tape; only your unique Respondent Identification number will be used. ***And, please do not use any last names on the tape.*** The tape recording will be kept in a locked file, and only project staff will have access to it. At the end of the project, the recording will be destroyed. Do we have your permission to record your responses?

1. NO (That's okay, I understand. Let's begin the interview without it.) [CONTINUE INTERVIEW]
2. YES→ [TURN ON RECORDER:]

Okay, I have just turned on the tape recorder. I need to ask for your permission again, because I need to record your permission. Do we have your permission to record this interview?

1. NO (STOP TAPE RECORDER AND CONTINUE INTERVIEW) (That's okay, I understand. Let's begin the interview without it.)
2. YES

I, THE INTERVIEWER, HAVE READ THIS STATEMENT TO THE RESPONDENT.

INITIALS OF THE INTERVIEWER: _____

Data Entered ❑

Low Vision Telephone Survey

SECTION I

General Health and Daily Activities (including SF-12 items marked with "*")

This interview is designed to collect information from you about your vision problems. Questions will refer to either your "**low vision**" or your "**vision problems**". When we use these terms in the questions, we mean specifically the problems you have with your vision as a result of conditions that have become a problem for you as an adult, such as macular degeneration, diabetic retinopathy, or glaucoma. The questions about vision problems are not meant to include those problems with your vision that you may have had since childhood (such as near-sightedness or far-sightedness, astigmatism, etc). Once again, the terms we will use throughout the interview to describe these conditions are: your "**low vision**" or "**vision problems**".

The first questions ask about your general health and your ability to do certain activities.

*1. In general, would you say your health is:

Excellent	Very good	Good	Fair	Poor
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

*2. The following items are about activities you might do during a typical day. Does **your health now limit you** in these activities? If so, how much?

ACTIVITIES	Yes, limited a lot	Yes, limited a little	No, not limited at all
*a. **Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐ 1	☐ 2	☐ 3
*b. Climbing **several** flights of stairs	☐ 1	☐ 2	☐ 3

*3. During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of your physical health**?

	Yes	No
*a. **Accomplished less** than you would like	☐ 1	☐ 2
*b. Were limited in the **kind** of work or other activities..	☐ 1	☐ 2

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

	Yes	**No**
*a. **Accomplished less** than you would like	☐ 1	☐ 2
*b. Didn't do work or other activities as **carefully** as usual	☐ 1	☐ 2

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

Not at all	**A little bit**	**Moderately**	**Quite a bit**	**Extremely**
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

*6. These questions are about how you feel and how things have been with you during the **past 4 weeks**. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the **past 4 weeks**...	**All of the time**	**Most of the time**	**A good bit of the time**	**Some of the time**	**A little of the time**	**None of the time**
*a. did you feel full of pep?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
*b. have you felt calm and peaceful?....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
*c. did you have a lot of energy?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

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

All of the time	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

8. Have you **stopped doing** some of the things that you used to do, such as playing cards, going to the movies, religious activities, volunteer work, or physical activities such as sports or gardening, because of your vision problems?

Yes	**No**
☐ 1	☐ 2

ALTERNATIVE TO #8 (FOR PRE-TEST):

8a. How many of the social and physical activities, that you used to enjoy doing before your vision loss, such as playing cards, going to the movies, religious activities, volunteer work, or physical activities such as sports or gardening are you still doing now? Would you say…

Most or all	**Some, or**	**A few or None**
☐ 1	☐ 2	☐ 3

These next questions ask about changes that you may have experienced in **the past year**.

9. In the past year, how much have your vision problems interfered with physical and social activities that you enjoy, such as playing cards, going to the movies, religious activities, volunteer work, or physical activities such as sports or gardening? Would you say…

A lot	**Somewhat**	**A little**	**Not at all**
☐ 1	☐ 2	☐ 3	☐ 4

10. In the past year:

	Yes	**No**
10. **Have you had any** injuries such as falls, burns or cuts because of problems with your vision?.....	☐ 1	☐ 2 (Q#11)
10 a. Did you **fall** because of problems with your vision?	☐ 1	☐ 2
10 b. Did you **burn yourself** because of problems with your vision?.....	☐ 1	☐ 2
10 c. Did you **cut yourself** because of problems with your vision?.....	☐ 1	☐ 2

These next questions ask about any special equipment that you may need for your vision problems.

11. Do you currently use any special equipment such as **special** reading glasses, magnifying glasses, a special computer or special computer software, electronic magnifiers and devices such as talking clocks, watches or thermometers?

Yes	**No**	
☐ 1	☐ 2	(Question #12)

11a. How were they paid for? [CHECK ALL THAT APPLY]

Were they paid for by:

Your health insurance? ..... ☐ 1

[**NOTE: IF ONLY "1" IS CHECKED, GO TO SECTION II**]

An organization that provides services for people with low vision (such as the Commission for the Blind)? ..... ☐ 2

You, yourself? ..... ☐ 3

Your family or friends? ..... ☐ 4

Another source? ..... ☐ 5

11.a.1 What source?_____

11.b In the past year, about how much have you (or your family or friends) **altogether**, had to pay for **special** reading glasses, magnifying glasses, a special computer or special computer software, electronic magnifiers and devices such as talking clocks, watches or thermometers?
[Please do not count payments made by your insurance company for these items; just what you and your family or friends paid for you.]

Under $50 in the past year; ..... ☐ 1

$50-$99; ..... ☐ 2

$100-$500, or ..... ☐ 3

Over $500 in the past year ..... ☐ 4

12. Have you been told by a doctor or another health care worker that you are "legally blind"?

Yes	**No**
☐ 1	☐ 2

SECTION II: IADL's

Earlier in the survey we asked you about your daily activities. We are now going to ask a few additional questions in this area.

I will now ask you some questions about daily activities and whether or not you are able to do them or if you need help with them because of **vision problems**. I will read a list of activities. For each activity, please tell me if you are able to do it on your own without help; on your own with special devices used for your vision problems (such as a magnifier); only with help from another person; with the help of another person, but because of another physical problem not related to your vision; or you not do it at all because of another reason (such as someone else always does it for you):

[IF "YES"RESPONSE] → 1.1

1. Are you able to do the Following....	On your own without any help	On your own with the use of devices such as a magnifier, etc.	Only with help from another person,	Do you not do this at all because of problems with your vision, or	Do you not do this at all because of another reason?	FOR "YES" RESPONSE TO CATEGORY 3: Is that because of another physical problem not related to your vision? YES	NO
a. Housework (such as washing dishes, making beds, cleaning floors, or doing laundry)?	☐1	☐2	☐3 → Q#1.1	☐4	☐5	☐1	☐2
b. Home repairs and maintenance, such as fixing a leaky faucet or doing yard work?	☐1	☐2	☐3 → Q#1.1	☐4	☐5	☐1	☐2
c. Preparing Meals (including planning meals, getting ingredients out of the cupboard, measuring and cooking, stove and oven use)?	☐1	☐2	☐3 → Q#1.1	☐4	☐5	☐1	☐2
d. Managing Finances (including handling money, paying bills, writing checks, managing investments and savings, and using a computer for bill payment)?	☐1	☐2	☐3 → Q#1.1	☐4	☐5	☐1	☐2
e. Self-care (including handling medications - reading the medicine labels, taking all of your medications on your own, including giving yourself injections, applying eye drops, applying ointments or bandages; and self-grooming, including shaving, applying make-up and nail care)?	☐1	☐2	☐3 → Q#1.1	☐4	☐5	☐1	☐2

[IF "YES"RESPONSE] → 1.1

1. Are you able to do the Following....	On your own without any help	On your own with the use of devices such as a magnifier, etc.	Only with help from another person,	Do you not do this at all because of problems with your vision, or	Do you not do this at all because of another reason?	FOR "YES" RESPONSE TO CATEGORY 3: Is that because of another physical problem not related to your vision? YES	NO
f. Shopping (including shopping for food, household items, personal items and clothing, but **not** including transportation)?	☐1	☐2	☐3 ➔ Q#1.1	☐4	☐5	☐1	☐2
g. Walking outside of your home including in public places and stores, without tripping or falling; avoiding obstacles and curbs, including street crossing and walking at night?	☐1	☐2	☐3 ➔ Q#1.1	☐4	☐5	☐1	☐2
h. Using stairs, elevators and escalators?	☐1	☐2	☐3 ➔ Q#1.1	☐4	☐5	☐1	☐2
i Transportation, taking a bus or getting a taxi and going places beyond walking distance, **but not including driving yourself**?	☐1	☐2	☐3 ➔ Q#1.1	☐4	☐5	☐1	☐2
j. Communications- Using the telephone (including obtaining telephone numbers, dialing numbers, and handling recorded menu options), and computer use for email?	☐1	☐2	☐3 ➔ Q#1.1	☐4	☐5	☐1	☐2

SECTION III.

SELF-EFFICACY

These next few questions ask for your opinions on a series of statements.

1. Please tell me how strongly you agree or disagree with each of the statements I will read to you:

[READ a-d AND ASK FOR EACH:] Do you "strongly agree", "agree", "disagree", or "strongly disagree":

		Strongly Agree	Agree	Disagree	Strongly Disagree
a.	It's up to me to arrange transportation when I want it	☐1	☐2	☐3	☐4
b.	There are things I could do to make myself feel safer	☐1	☐2	☐3	☐4
c.	I do not have enough control over how good my living arrangements are	☐1	☐2	☐3	☐4
d.	I cannot be as productive as I want to be	☐1	☐2	☐3	☐4

Section IV.

Vision Rehabilitation Services:
Use and Satisfaction with Services

These next questions ask about your use of services specifically for your "low vision" and your satisfaction with these services. These questions do not ask about routine vision services that are not related specifically to your problems with low vision.

1. In the last six months, have you received any of the following services?

	Yes	No	
1a. **Eye Exam**	☐1	☐2	(Q#1b)

↓

How many eye exams have you had in the past six months? ☐

1a.1.

INSTRUCTIONS FOR GRID: [NOTE THIS IS A REPEATING SEGMENT THAT WILL BE PROGRAMMED IN THE CATI SYSTEM] [IF RESPONDENT HAS HAD MORE THAN THREE EYE EXAMS, RECORD INFORMATION FOR THE THREE MOST RECENT.][

1a.1.1. Where did you receive the most recent eye exam?

In your home or current residence, ☐1

In a doctor's office or clinic, or ☐2

Both places (home and doctor's office or clinic)? ☐3

1a.1.2. Where did you receive the second most recent eye exam?

In your home or current residence, ☐1

In a doctor's office or clinic, or ☐2

Both places (home and doctor's office or clinic)? ☐3

1a.1.3. Where did you receive the third most recent eye exam?

In your home or current residence, ☐1

In a doctor's office or clinic, or ☐2

Both places (home and doctor's office or clinic)? ☐3

1. (In the last six months, have you received any of the following services)?

		Yes	No	
1b.	**Magnification devices**	☐1	☐2	(Q#1.c)

↓

1b.1. How many magnification devices (for reading or for distance) did you receive in the past six months? ☐

↓

1.c. In the last six months, did you receive any training in the use of these magnification devices?

Yes	**No**
☐ 1	☐ 2 (Q#1d)

1c.1 How many trainings in the use of magnification devices did you receive in the past six months? ☐

INSTRUCTIONS FOR GRID: [NOTE THIS IS A REPEATING SEGMENT THAT WILL BE PROGRAMMED IN THE CATI SYSTEM] [IF RESPONDENT RECEIVED MORE THAN THREE TRAININGS, RECORD INFORMATION FOR THE THREE MOST RECENT.][

1c.1.1. Where did you receive the most recent training (in the use of magnification devices)?

In your home or current residence, ☐ 1

In a doctor's office or clinic, or ☐ 2

Both places (home and doctor's office or clinic)? ☐ 3

1c.1.2. Where did you receive the second most recent training (in the use of magnification devices)?

In your home or current residence, ☐ 1

In a doctor's office or clinic, or ☐ 2

Both places (home and doctor's office or clinic)? ☐ 3

1c.1.3. Where did you receive the third most recent training (in the use of magnification devices)?

In your home or current residence, ☐ 1

In a doctor's office or clinic, or ☐ 2

Both places (home and doctor's office or clinic)? ☐ 3

1. (In the last six months, have you received any of the following services)?

	Yes	No
1d. **Training in the use of a long cane for walking**	☐1	☐2 (Q#1e)

↓

1d.1. How many trainings in the use of a long cane did you receive in the past six months? ☐

INSTRUCTIONS FOR GRID: [NOTE THIS IS A REPEATING SEGMENT THAT WILL BE PROGRAMMED IN THE CATI SYSTEM] [IF RESPONDENT RECEIVED MORE THAN THREE TRAININGS, RECORD INFORMATION FOR THE THREE MOST RECENT.][

1d.1.1. Where did you receive the most recent training in the use of a long cane?

In your home or current residence, ☐1

In a doctor's office or clinic, or ☐2

Both places (home and doctor's office or clinic)? ☐3

1d.1.2. Where did you receive the second most recent training in the use of a long cane?

In your home or current residence, ☐1

In a doctor's office or clinic, or ☐2

Both places (home and doctor's office or clinic)? ☐3

1d.1.3. Where did you receive the third most recent training in the use of a long cane?

In your home or current residence, ☐1

In a doctor's office or clinic, or ☐2

Both places (home and doctor's office or clinic)? ☐3

1. (In the last six months, have you received any of the following services)?

	Yes	No
1e. Instruction or training in reading techniques or contrast modification or training in the use of special pens or writing aids?	☐ **1**	☐ **2** (Q#1f)

↓

1e.1. How many (instructions or trainings) did you receive in the past six months? ☐

INSTRUCTIONS FOR GRID: [NOTE THIS IS A REPEATING SEGMENT THAT WILL BE PROGRAMMED IN THE CATI SYSTEM] [IF RESPONDENT RECEIVED MORE THAN THREE INSTRUCTIONS/ TRAININGS, RECORD INFORMATION FOR THE THREE MOST RECENT.][

1e.2. What was the most recent service? _____

[**NAME OF SERVICE**]

1e.2.1. Where did you receive the [**ENTER NAME OF SERVICE**]?	
In your home or current residence, ☐1	
In a doctor's office or clinic, or ☐2	
Both places (home and doctor's office or clinic)? ☐3	

1e.2.2. What was the second most recent service?

_____

[**NAME OF SERVICE**]

1e.2.3. Where did you receive the [**ENTER NAME OF SERVICE**]?

In your home or current residence, ☐1

In a doctor's office or clinic, or ☐2

Both places (home and doctor's office or clinic)? ☐3

1e.2.4. What was the third most recent service? _____

[NAME OF SERVICE]

1e.2.5. Where did you receive the [**ENTER NAME OF SERVICE**]?

In your home or current residence, ☐1

In a doctor's office or clinic, or ☐2

Both places (home and doctor's office or clinic)? ☐3

1. (In the last six months, have you received any of the following services)?

	Yes	**No**
1f. An assessment of your home or residence with suggestions for making changes (such as increasing lighting) or training in the use of special equipment or devices (such as filters for glare; talking devices, talking watches, talking books); reading stands, tactile markers on stoves, etc.)?	☐**1**	☐**2** (Q#1g)

⬇

1f.1. How many (assessments or trainings) did you receive in the past six months? ☐

INSTRUCTIONS FOR GRID: [NOTE THIS IS A REPEATING SEGMENT THAT WILL BE PROGRAMMED IN THE CATI SYSTEM] [IF RESPONDENT RECEIVED MORE THAN THREE ASSESSMENTS OR TRAININGS, RECORD INFORMATION FOR THE THREE MOST RECENT.][

1f.2. What was the most recent assessment or training?

_____

[**NAME OF SERVICE**]

1f.2.1. Where did you receive the [**ENTER NAME OF SERVICE**]?	
In your home or current residence, ☐1	
In a doctor's office or clinic, or ☐2	
Both places (home and doctor's office or clinic)? ☐3	

1f.2.2. What was the second most recent assessment or training?

_____

[**NAME OF SERVICE**]

1f.2.3. Where did you receive the [**ENTER NAME OF SERVICE**]?	
In your home or current residence, ☐1	
In a doctor's office or clinic, or ☐2	
Both places (home and doctor's office or clinic)? ☐3	

1f.2.4. What was the third most recent assessment or training?

_____

[**NAME OF SERVICE**]

1f.2.5. Where did you receive the [**ENTER NAME OF SERVICE**]?

In your home or current residence, ☐1

In a doctor's office or clinic, or ☐2

Both places (home and doctor's office or clinic)? ☐3

1. (In the last six months, have you received:)?

	Yes	No
1g. Any other service for your low vision?	☐1	☐2 (Q#2)

↓

1g.1. How many (other services) did you receive in the past six months? ☐

INSTRUCTIONS FOR GRID: [NOTE THIS IS A REPEATING SEGMENT THAT WILL BE PROGRAMMED IN THE CATI SYSTEM] [IF RESPONDENT RECEIVED MORE THAN THREE "OTHER SERVICES", RECORD INFORMATION FOR THE THREE MOST RECENT.][

1g.2. What was the most recent other service? _____

[**NAME OF SERVICE**]

1g.2.1. Where did you receive the [**ENTER NAME OF SERVICE**]?

In your home or current residence, ☐1

In a doctor's office or clinic, or ☐2

Both places (home and doctor's office or clinic)? ☐3

1g.2.2. What was the second most recent other service?

_____

[**NAME OF SERVICE**]

1g.2.3. Where did you receive the [**ENTER NAME OF SERVICE**]?

In your home or current residence, ☐ 1

In a doctor's office or clinic, or ☐ 2

Both places (home and doctor's office or clinic)? ☐ 3

1g.2.4. What was the third most recent other service?

_____

[NAME OF SERVICE]

1g.2.5. Where did you receive the [**ENTER NAME OF SERVICE**]?

In your home or current residence, ☐ 1

In a doctor's office or clinic, or ☐ 2

Both places (home and doctor's office or clinic)? ☐ 3

2. Overall, how **satisfied** were you with all of these services for your vision problems?

Very Satisfied	**Somewhat Satisfied**	**Neither Satisfied nor Dissatisfied**	**Somewhat Dissatisfied**	**Very Dissatisfied**
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

3. Overall, how **helpful** were all of these services in helping you deal with your vision problem(s)?

Very Helpful	**Somewhat Helpful**	**A Little Helpful**	**Not At All Helpful**
☐ 1	☐ 2	☐ 3	☐ 4

SECTION V.

CES-D (5-item scale)

1. Below is a list of ways you may have felt or behaved. Please tell me how you have felt during the past week.

		Rarely or none of the time (less than 1 day)	Some or a little of the time (1-2 days)	Occasionally or moderate amount of time (3-4 days)	Most or all of the time (5-7 days)
a.	I felt depressed	☐0	☐1	☐2	☐3
b.	My sleep was restless	☐0	☐1	☐2	☐3
c.	I felt lonely	☐0	☐1	☐2	☐3
d.	I had crying spells.....	☐0	☐1	☐2	☐3
e.	I could not 'get going'	☐0	☐1	☐2	☐3

SECTION VI.

DEMOGRAPHICS

These last few questions ask for some background information about you, yourself. This is useful so that the information may be reported about **groups** of individuals without identifying them.

[NOTE: VERIFICATION; REQUIRED FOR CATI SYSTEM]

1. Are you male or female?

   Male ..... ☐1

   Female ..... ☐2

2. Are you of Hispanic or Spanish family background?

   Yes..... ☐1

   No ..... ☐2

3. How would you describe your race?

American Indian or Alaskan Native ..... ☐ 1

Asian or Pacific Islander ..... ☐ 2

Black or African American ..... ☐ 3

White, or ..... ☐ 4

Another race or multiracial ..... ☐ 5

4. What is your current marital status?

Married ..... ☐ 1

Divorced ..... ☐ 2

Separated ..... ☐ 3

Widowed, or ..... ☐ 4

Never married ..... ☐ 5

5. With whom do you live? Do you live alone or do you live with others (in the same household)?

LIVES ALONE ..... ☐ 1

LIVES WITH ANOTHER/OTHERS ..... ☐ 2

6. What is the highest grade or level of school that you have completed?

8th grade or less ..... ☐ 1

Some high school, but did not graduate ..... ☐ 2

High school graduate or GED ..... ☐ 3

Some college or 2-year degree ..... ☐ 4

4-year college graduate ..... ☐ 5

More than a 4-year college degree ..... ☐ 6

END TIME: ☐☐ : ☐☐ 1. AM 2. PM

Those are all of the questions I have for you, today. I would like to thank you for completing this telephone interview!

Attachment 3: Site Visit Protocols
LOW VISION REHABILITATION PATIENTS
FOCUS GROUP GUIDE
DRAFT 4 (10.01.06)

II. FOCUS GROUP DISCUSSION GUIDE - LOW VISION REHABILITATION PATIENTS

INTRODUCTION FOR IN-PERSON/TELEPHONE INTERVIEW:

"Thank you for agreeing to take part in this research interview. My name is [NAME].

The Centers for Medicare and Medicaid Services (CMS) is conducting this study. The purpose of the study is to understand the impact of expanded Medicare coverage of low vision rehabilitation services for patients with moderate to severe visual impairments. The study will compare services in six demonstration areas (New Hampshire, New York City, North Carolina, Atlanta GA, Kansas and Washington State) to services in six areas without the demonstration program (TBD).

The interview includes some general questions about your experiences with low vision rehabilitation services you have received in the past 6 months. We expect the interview to take about 30 minutes. Is it a good time now to do the interview?

May I start the tape recorder now?

START TAPE RECORDER

Many different services are available to help someone learn how to live with vision loss. These can include learning how to move around safely, learning how to perform tasks in the home, and learning how to use devices such as a magnifying glass, telescope, or other devices. In the past 6 months, what kinds of services have you received to help you learn how to live with your vision loss?

PROBE IF NOT MENTIONED:

Help with tasks necessary to living at home?

Optical Aids, such as special reading glasses or magnifying glasses?

Adaptive Equipment such as large print clocks or talking watches, bold felt tipped pens? Reading light or task lights

Large print books?

Mobility such as using cane, avoiding slips or tripping?

Patient Education?

Family Education?

Where did you receive these services in the past 6 months?

PROBE: Did you receive any services in your home?

Did you receive any services in your optometrist's or ophthalmologist's office?

In a clinic or hospital?

Community Center, Senior Center, or other organization?

Did you receive any services anywhere else?

Who provided you with the services?

Thinking about these visits, what did the provider do for you that was the most helpful?

Are there any activities, tasks or devices for which you wanted help or training but you did not get this help?

What? Why?

PROBE IF NOT MENTIONED: Were there particular devices you wanted and did not get?

What? Why?

How do you feel about the visits you had with the provider who worked with you in learning how to live with your vision loss?

What did you like most about these visits?

What was missing from these visits? What other services or assistance would you have liked but did not get?

Now I want to ask you about any difficulties you may have experienced in getting the low vision rehabilitation services.

Did you have any difficulties finding a provider to help you with your vision loss?

IF YES: What difficulties? Why?

Do you have any difficulty getting to the location where the low vision services were provided?

IF YES: What difficulties? Why?

Is there anything you would do to improve the services available to people with vision loss?

IF YES: What? Why?

IF NO: Why not?

Is there anything you would do differently to make it easier for people with vision loss to obtain help or services?

IF YES: What? Why?

IF NO: Why not?

DEMOGRAPHIC QUESTIONS

Age

Gender

Race/ ethnicity

Nature of Vision Loss (e,g, ARMD, diabetic retinopathy)

Duration of problems with vision

LOW VISION REHABILITATION PROVIDERS
(Occupational Therapists and Certified Low Vision Therapists,
Orientation and Mobility Specialists, and Low Vision Rehabilitation Therapists)
FOCUS GROUP GUIDE AND DEMOGRAPHIC QUESTIONNAIRE
DRAFT 5 (10.02.06)

II. FOCUS GROUP DISCUSSION GUIDE - LOW VISION REHABILITATION PROVIDERS

COMPLETE CONSENT FORMS

COMPLETE SHORT QUESTIONNAIRE

Hello. My name is _____, and I will be moderating the discussion today. We are here to discuss your experiences as a provider of Low Vision Rehabilitation services. The questions we will cover in the focus group today are about your practices as Low Vision Rehabilitation service providers for patients with moderate to severe visual impairments who are eligible for Medicare (that is 65 years or older and/or disabled). To shorten the questions, I will refer to these specific patients as "low vision patients". I will ask both about your current practice and about any changes in your practice over the past six months specifically as it is related to the types of patients I just described

I would like to go over a few ground rules before we begin:

First, we hope that you will feel comfortable discussing your personal experiences in this group discussion format. However, we realize that it is possible that some of you may feel uncomfortable or uneasy sharing some experiences given the composition of the group. For example, we realize that some of you may know one another. Therefore, if you feel that participation in today's discussion will be awkward, we will fully respect your decision not to participate.

It is important that this evening's/afternoon's/morning's discussion remains confidential. Therefore, I ask you that our conversation does not leave this room. Please use only your first name and please refer to others by first name only. That will allow us to maintain as much anonymity on the tape recording as possible.

I would also like to remind you that today's discussion will be tape recorded. We record all conversations so that we have an accurate and complete report of what was said. You will not be identified on the tape other than by your first name. The tape will be transcribed into a written form (your first name will not be part of the written form). The tapes will not be used for any other purpose and <u>will</u> <u>be</u> <u>destroyed</u> at end of the project.

It is important that only one person speaks at a time, and please speak up so we can capture all of your comments. If there is more than one person speaking at a time, it is very difficult to

transcribe. We need to be able to hear what everyone says so that we can produce an accurate report of the discussion.

Please avoid any side conversations (with your neighbor) during the discussion, since that can interfere with the audiotape transcription, as well.

Interactions between all of the group members are encouraged. Please feel free to share your feelings and opinions, even if you disagree with what has already been said. We would like to hear everyone's viewpoints.

Because this is a group discussion, I will try to make sure that everyone has a chance to speak but that no one dominates the discussion; so please don't be offended if I gently cut you off.

Are there any questions before we begin? We have a lot to discuss, so let's get started.

START TAPE RECORDER

Introduction

I would like to start by having everyone introduce him or herself by first name only and tell us, briefly, your specialty and where you practice.

The next questions are about your practice in general. Thinking back over the past six months, [since month], what are the typical vision problems you treat in your Low Vision Rehabilitation practice? Remember, we are specifically interested in the Medicare eligible patients with moderate to severe visual impairments.

Has the nature of the moderate to severe visual impairment among older or disabled patients that you see through your practice changed in any way over the past six months?

PROBE: Over the past six months, have you noticed a change in the types of vision problems referred to you for treatment?

IF YES: How? Why?

How do the low vision patients (that is those who are older or disabled with moderate to severe visual impairments) typically learn or find out about you? Does someone refer them to you or do they find you some other way?

What types of providers typically refer low vision patients to you?

Has the way in which low vision patients find out about your practice changed in any way over the past six months?

IF YES: How? Why?

When you first see a patient, what do you do in general to assess or identify low vision rehabilitation needs and develop a treatment plan?

In the past six months, have you made any changes in doing these assessments and treatment plans? IF YES: How? Why?

In general, what areas do you typically address in your rehabilitation work with a low vision patient?

PROBE IF NOT MENTIONED:

Home environment such as movement through the home, cooking, cleaning and self-care or toileting?

Optical Aids and other adaptive equipment

Adaptive Equipment?

Mobility?

Patient and Family Education?

Patient or Family Counseling?

Have you made any changes in the approaches you employ with your low vision patients in the past six months?

IF YES: How? Why?

Where do you typically see your low vision rehabilitation patients? Do you usually see your patients in the office / clinic or in the home?

Have there been any changes over the past six months in where you typically see your patients?

IF YES: How? Why?

These next questions are about billing and reimbursement for your practice.

Since April 2006, are you aware of any changes in how low vision rehabilitation services are covered or reimbursed?

IF YES: What are these changes?

What is the reason for these changes?

Since April 2006, are you aware of any changes in the billing codes for low vision rehabilitation services?

IF YES: What are these changes?

What is the reason for these changes?

Is there anything in particular that makes it difficult for you to receive payment or reimbursement for your services?

IF YES: What is it? What is the reason for this problem?

FOR PROVIDERS IN THE DEMONSTRATION SITES ONLY:

These next questions are about a Medicare program to cover low vision rehabilitation services. The program started in April 2006.

Have you ever heard about the Low Vision Rehabilitation Demonstration Program?

IF YES: Please tell me what you know or understand about how this program works.

PROBE: What kinds of services does this program cover?

Which providers can be reimbursed for these services?

How do the billing codes work for this program?

IF NO to 17: Have you heard about a new Medicare demonstration program that will extend coverage to allow low vision rehabilitation by qualified occupational therapists, mobility specialists, or low vision rehabilitation therapists in the home, office or clinic under the general supervision of an ophthalmologist or optometrist?

IF YES: Please tell me what you know or understand about how this program works.

Have you participated in this Medicare demonstration program?

Why or Why not?

What are your experiences, or what have you heard, about this Medicare demonstration program?

How did you hear about this Medicare demonstration program?

IF PARTICIPATED: Has your participation in this demonstration program had an impact in any way on your practice or the treatment of your patients?

PROBE: Your relationship with your patients?

Treatment goals for your patients?

Your patients' outcomes?

Where you provide your services?

How you bill for your services?

Questionnaire Items

Practice type:

OT

LVRT

OMS
LVT

Practice Situation:
In private solo practice
practice within a MD office
practice within a hospital / medical center
other clinical setting
OTHER?

Total number of patient visits completed in an average week.

Of the total number of patients noted in question 3 above, how many are:
4a. Visits with new patients?
4b. Follow-up visits?

What percentage of the visits you complete in a typical week is covered by Medicare?

How are you paid for your low vision rehabilitation services? (Answer Yes/No for each)
Collect out of pocket payment for your services,
Bill Medicare or insurance companies directly [OT's only]
Contract with a physician or hospital group

How does the total number of patient visits you complete in a typical week compare to the total number of visits you completed prior to April 2006?
Increased
Decreased
About the same

Number of years in practice

Gender

10. Race/ ethnicity

OPTOMETRIST / OPHTHALMOLOGIST

TELEPHONE INTERVIEW GUIDE

DRAFT 5 (10.01.06)

II. TELEPHONE INTERVIEW QUESTIONS

INTRODUCTION FOR IN-PERSON/TELEPHONE INTERVIEW:

"Thank you for agreeing to take part in this research interview. The Centers for Medicare and Medicaid Services (CMS) is conducting this study. The purpose of the study is to understand the impact of expanded Medicare coverage of low vision rehabilitation services for patients with moderate to severe visual impairments. The study will compare services in six demonstration areas (New Hampshire, New York City, North Carolina, Atlanta GA, Kansas and Washington State) to services in six areas without the demonstration program (TBD).

The interview includes some general questions about your clinical practice including the types of low vision rehabilitation services you provide, referrals to low vision therapists outside of your office, the types of patients you treat, and how you bill for services. If you are in a demonstration program area, we will also ask you questions about the Medicare demonstration program.

We expect the interview to take about 30 minutes. Is it a good time now to do the interview?

The questions we will cover in the interview are about low vision rehabilitation for your patients. We are specifically interested in patients with moderate to severe visual impairments who are Medicare eligible (that is 65 years or older and/or disabled). To facilitate the questions, I will refer to these specific patients as low vision patients.

The questions will cover both services you may provide yourself as well as services to which you may refer your patients. I will ask both about your current practice and about any changes in your practice since April of 2006.

The first questions are about your practice in general.

Thinking about your practice since April of 2006, what are the typical types of moderate to severe visual impairments among Medicare eligible patients that you see in your practice?

In general, what services do you provide for an older or disabled patient with moderate to severe visual impairments?

How do your patients with moderate to severe visual impairments typically get rehabilitation services?

PROBE: Do you provide all or some of the rehabilitation services yourself? IF YES: What rehabilitation services do you provide?

Do you have a low vision rehabilitation specialist working with you in your practice? IF YES: What does this person do? Where is it done?

Do you refer your patients to providers outside of your office? IF YES: To whom? Where do these providers see your patients?

Again, thinking about older or disabled patients with moderate to severe visual impairments, what kind of assessments do you perform to determine which low vision rehabilitation services such a patient requires?

In the past six months, have there been any changes in the way you conduct these assessments for your older or disabled low vision patients?

IF YES: How? Why?

Has the nature of the low vision conditions for which you offer or refer for low vision rehabilitation services changed in any way since April 2006?

PROBE: Since April 2006, have you noticed a change in the types of low vision problems you refer to someone outside of your office for rehabilitation services?

IF YES: How? Why?

Where do you typically refer your low visions patients for low vision rehabilitation services?

PROBE: What kinds of facilities or what kinds of providers?

Have your referral patterns, or the providers to whom you refer your patients for low vision rehabilitation services, changed in any way over the past six months?

IF YES: How? Why?

These next questions are about billing and reimbursement for your practice.

Are you aware of any changes in how low vision rehabilitation services are covered or reimbursed since April 2006?

IF YES: What are these changes?

What is the reason for these changes?

Are you aware of any changes in the billing codes for low vision rehabilitation services since April of 2006?

IF YES: What are these changes?

What is the reason for these changes?

Is there anything in particular that makes it difficult for you to receive payment or reimbursement for low vision rehabilitation services?

IF YES: What is it? What is the reason for this problem?

FOR OPTOMETRISTS / OPHTHALMOLOGISTS IN THE DEMONSTRATION SITES ONLY:

These next questions are about a relatively new Medicare program to cover low vision rehabilitation services.

Have you ever heard about the Medicare Low Vision Rehabilitation Demonstration?

IF YES: Please tell me what you know or understand about how this program works?

PROBE: What kinds of services does this program cover?

Which providers can be reimbursed for these services?

How do the billing codes work for this program?

IF NO to 17: Have you heard about a new Medicare demonstration program that will extend coverage to allow low vision rehabilitation by qualified occupational therapists, mobility specialists, or low vision rehabilitation therapists in the home, office or clinic under the general supervision of a physician?

IF YES: Please tell me what you know or understand about how this program works?

Have you participated in this Medicare demonstration program?

Why or Why not?

What are your experiences, or what have you heard, about this Medicare demonstration program?

How did you hear about the demonstration program?

IF PARTICIPATED: Has your participation in this demonstration program had an impact in any way on your practice or the treatment of your patients?

PROBE: Your relationship with your patients?

Treatment goals for your patients?

Your patients' outcomes?

Where you provide your services?

How you bill for your services?

Demographic Items

Practice type:
Optometry,
Optometery - Low vision specialty
Ophthalmology general
Ophthalmology – retina specialty
Ophthalmology – low vision specialty
Ophthalmology – other specialty

Practice Situation:
Private solo practice,
Group practice
Hospital or medical center
Other clinical setting,
OTHER?

Number of patients seen per month over past six months

Number of low vision patients in practice seen per month over past six months

Roughly, what percentage of the patients in your practice need low vision rehabilitation services?

Roughly, what percentage of the patients in your practice with a low vision condition receive low vision rehabilitation services:

a. In your office, incident to service treatment?
b. Outside of your office?

Has this number changed in any way over the past six months?
IF YES: How? Why?

Number of years in practice

Gender

Race / ethnicity