MEASURING OUTCOMES OF LOW VISION REHABILITATION DELIVERED BY A MOBILE CLINIC

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ABSTRACT

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Purpose

Geographic barriers to low vision rehabilitation (LVR) may prevent service utilization. Circumventing these barriers can promote access to and utilization of LVR. In the state of Massachusetts, a mobile clinic was used to deliver LVR in areas with an inadequate supply of providers to meet patient demand for services. In this novel mobile clinic LVR delivery model, it was imperative to determine whether clinically meaningful LVR outcomes were achieved, and if so, how they compared to other delivery models. In order to rigorously evaluate these questions, this study was designed to explore functional outcomes and device abandonment for patients receiving LVR on the mobile clinic.

Methods

Participants enrolled in this study had previously been registered as legally blind per U.S. Social Security definition and scheduled for mobile clinic LVR. The Massof Activity Inventory (AI), a validated adaptive visual function questionnaire, was administered before LVR, three months post-LVR, and one year post-LVR to assess functional outcomes for each participant. AI data underwent Rasch analysis after item filtering. Person measures, change

scores, and measures of clinical effect (i.e. Cohen's effect size, Minimum Clinically Important Difference [MCID]) were calculated and were the primary outcome measures of this study. These measures were compared for different time points, and effect size was used to compare effectiveness with previous measures from other LVR delivery models.

Device abandonment was an additional outcome measure in this study. It was assessed using a questionnaire which has previously been found to give repeatable results. Participants who received one or more device recommendation during mobile clinic LVR were included in this analysis. They were asked whether they still had each device, how frequently each device was used, and which task each device was used to accomplish at 3 months and 1 year post-LVR. Data were compiled to quantify the type, goal, and frequency of use for all device recommendations. The odds of abandonment were calculated in comparison to a previous study which made use of the same questionnaire.

Secondary outcome measures included personal and clinical participant characteristics. These were: incoming systemic and ocular diagnoses, age, self-reported history of prior LVR examination, best corrected visual acuity, binocular Mars contrast sensitivity, device recommendations, and additional examination or training recommendations.

Results

Participants in this study (n=66) had a mean best corrected visual acuity of 0.93 logMAR (20/170 Snellen equivalent), a mean binocular Mars contrast sensitivity of 0.87 logCS, and a mean age of 72.5 years. On average, participants had 2.4 systemic comorbidities each, and

47% of participants received their first ever LVR examination on the mobile clinic after enrolling in this study.

AI results produced person measures which were significantly larger at both 3 months and 1 year post-LVR compared to baseline ($p<0.0001$), and there was no significant difference in person measure at 3 months versus 1 year. Change scores were positive and effect sizes were moderate to large, with a large effect size ($d=1.12$) in visual ability (overall goals). A majority of participants achieved MCID in goals (56% at 3 months, 71% at 1 year) and in each AI domain. Subjective report of worsening vision was a significant predictor of LVR outcome.

Sixty-five participants received device recommendations on the mobile clinic. Device use data were collected on 151 devices at 3 months post-LVR and 99 devices at 1 year post-LVR. There was no significant difference in abandonment 3 months post-LVR versus 1 year post-LVR. Abandonment occurred for 14 % of recommended devices at 3 months and 15% of recommended devices at 1 year. Filters and telescopes were more likely to be abandoned, while devices recommended for reading were most frequently used and least often abandoned. No patient characteristics, including AI functional outcome, were predictive of abandonment. Additionally, many participants benefitted from an updated spectacle prescription (n=29, 45%) provided by the mobile clinic. Spectacles were most often in use or never obtained by the participant. Abandonment of spectacles was rare. There was no significant difference in the odds of device abandonment on the mobile clinic compared to a previous study in academic outpatient LVR clinics

Conclusions

Mobile clinic LVR is effective at expanding access to care. Functional outcomes, as assessed by AI, improved at both time points, and effect sizes were comparable to those measured in other private outpatient LVR delivery models. Only 17% of device recommendations were abandoned at 3 months, and 18% of devices were abandoned at 1 year. This is similar to academic outpatient LVR clinics.

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CHAPTER 1: LITERATURE REVIEW AND GENERAL INTRODUCTION

1.1 Scope of the problem

With the increasing prevalence of age-related eye disease, visual impairment poses a growing public health concern. Several large cross-sectional studies (i.e. The Framingham Eye Study, The Beaver Dam Eye Study, The Baltimore Eye Survey, The Mud Creek Valley Study, and The Salisbury Eye Evaluation Study) have examined the prevalence of eye disease and visual impairment in various geographic regions (Massof 2002). Generally, these studies screened populations for eye disease and measured visual acuity, performing a refraction or pinhole acuity to obtain best corrected visual acuity (BCVA) only if presenting visual acuity was worse than a certain threshold. These studies differ in what that acuity cutoff was (i.e. 20/40 versus 20/60), how acuity was measured (i.e. ETDRS versus Snellen or Landolt C), and the ranges of acuities reported (Massof, 2002). Studies also differed demographically, with different racial distributions and ages represented in each study population. For example, the Mud Creek Valley Study (Dana et al., 1990) recruited from a poor, rural, underserved region in Kentucky and all participants were Caucasian. Conversely, the Salisbury Eye Evaluation Study (Klein, Klein, Linton, & De Mets, 1991), conducted in a middle-income city in Maryland, evaluated people 65 to 85 years old who were Caucasian or African American (Massof, 2002). Findings from these studies may not agree with one another, and generalizability to the U.S. population as a whole is limited. A meta-analysis of these studies, however, has been used to reasonably estimate the number of people who have low vision (Massof, 2002; Chan, Friedman, Bradley, & Massof, 2018). Based on the application of a multiple logistic regression model of low vision prevalence and incidence to 2010 United

States census data, over 3 million Americans were estimated to have low vision (BCVA ≤20/40) in 2017, with nearly 500,000 incident cases that year (Chan et al., 2018).

In high income regions, low vision is a problem that predominantly affects the elderly, although causes of visual impairment vary in different populations (Taylor & Keeffe, 2001). Age-related macular degeneration (AMD) is the leading cause of blindness in Caucasian populations, while open angle glaucoma is the primary cause in Hispanic populations (Scholl, Massof, & West, 2013). In the African American population, causes of blindness are more evenly distributed, with cataract and open angle glaucoma being more prevalent. In the Caucasian population, females are more likely to be blind or visually impaired than males, while the opposite is true of the African American population. There is no significant difference in likelihood of blindness between sexes in the Hispanic population (Scholl et al., 2013). Similarly, leading causes of visual impairment in the population presenting for outpatient LVR include: macular disease, glaucoma, and diabetic retinopathy. The majority of the population presenting for outpatient LVR, at 66%, is female (Goldstein, Massof, Deremeik, et al., 2012). The mean age is 77 years, and the distribution is left skewed with 73% of patients presenting for outpatient LVR in the U.S. being at least 65 years old (Goldstein et al., 2012).

While a large and increasing proportion of the U.S. population has low vision, LVR plays an important role in preventing the development of visual disability or handicap. A patient is considered visually impaired when everyday tasks, such as reading recipes or finding food items, cannot be accomplished due to poor vision. Visual disability occurs when an inability

to perform tasks prevents the patient from achieving larger goals, such as preparing daily meals. Handicap occurs when inability to accomplish goals prevents the patient from meeting societal objectives, such as independently achieving daily living activities (Massof et al., 2005a). By reducing visual disability and handicap, patient quality of life is improved through increased independence. Additionally, visual disability is associated with increased risk of cognitive impairment and depression, which negatively impact quality of life (Scholl et al., 2013). LVR is effective at reducing disability and improving quality of life through the provision of devices and training that make challenging tasks less difficult or unnecessary so that the patient can achieve important goals despite reduced vision (Massof, 1998; Massof et al., 2005a, 2005b).

1.2 Clinically Meaningful LVR Outcomes

Evaluating and developing consistent methods to measure LVR outcomes is essential in assessing clinical effectiveness and comparing among different LVR clinical delivery models. Varied delivery models have been used to provide LVR, including intensive interdisciplinary Veteran's Affairs (VA) hospital programs (Stelmack, Szlyk, et al., 2006b; J.A. Stelmack, Tang, & Reda, 2008; J. A. Stelmack, Tang, Wei, & et al., 2016) and more diverse non-VA hospital and private clinic settings (Goldstein et al., 2012; Goldstein, Chun, Fletcher, Deremeik, & Massof, 2014; Goldstein, Jackson, Fox, Deremeik, & Massof, 2015). Different services are provided in each delivery model, with hospital settings more likely to provide additional non-optometric services than private optometric practices. Given the breadth of possible approaches and different LVR interventions, alternative methods of measurement are warranted to evaluate outcomes. Both objective and self-report measures

have a role in low vision outcomes research. Objective measures, such as reading speed and acuity (Subramanian & Pardhan, 2009) or navigation of an obstacle course (Hassan, Lovie-Kitchin, & Woods, 2002), may be useful when assessing interventions which target a specific, narrowly defined, goal. However, these measures do not allow a holistic understanding of change due to LVR, and therefore are less appropriate in a diverse patient population. Self-report better assesses the impact of LVR on overall quality of life, as it measures patients' perceived experiences (Scholl et al., 2013). Self-report methods involve use of a questionnaire that can be generic or vision specific. Generic questionnaires are useful in measuring impact on quality of life in a way that can be compared to other non-ocular conditions. In contrast, visual function questionnaires (VFQs) do not allow comparison with other non-ocular diseases, but are less subject to bias by comorbidities than general questionnaires. VFQs are important in measuring the impact of a visual intervention on quality of life (Scholl et al., 2013).

1.2.1. Visual Function Questionnaires

In recent years, a myriad of VFQs have been developed to serve a range of purposes. VFQs may be disease-specific (e.g. Macular Degeneration Quality of Life Instrument [MacDQoL] (Mitchell, Wolfson, Woodcock, Anderson, et al., 2008)), target a specific aspect of quality of life (e.g. Independent Mobility Questionnaire (Turano, Geruschat, Stahl, & Massof, 1999)), or be appropriate for a certain demographic (e.g. Cardiff Visual Ability Questionnaire for Children (Khadka, Ryan, Margrain, Court, & Woodhouse, 2010)). Even in the general adult low vision population, multiple visual function questionnaires are available for use (Massof et al., 2007; Stelmack et al., 2006b). However, questionnaire psychometric properties are not

equivalent across instruments. While methods such Rasch analysis (see section 1.2.3 for further detail) have become standard, differences between questionnaires persist despite use of rigorous analysis techniques.

Review studies have sought to establish standard methods of assessing VFQ quality (Massof & Rubin, 2001; Pesudovs, Burr, Harley, & Elliott, 2007; Khadka, McAlinden, & Pesudovs, 2013), with one group going so far as to develop a checklist (COSMIN) (Mokkink, Terwee, Knol, Stratford, et al., 2010). Standard methods allow the identification of important criteria to assess VFQ quality. Previously established criteria included: content development, psychometric properties (i.e. response categories, dimensionality, measurement precision, item fit statistics, differential item functioning, targeting), validity (i.e. concurrent, convergent, discriminant, known group), and reliability (test-retest, responsiveness)(Pesudovs et al., 2007; Khadka et al., 2013). Based on these criteria, a 2013 review article (Khadka et al 2013) identified five visual function questionnaires with adequate interval measurement properties, only two of which had published information on validity: the VA LV VFQ-48 and Massof Activity Inventory (AI) (Khadka et al., 2013).

1.2.2 The Activity Inventory

The AI is an adaptive, well-calibrated VFQ developed through a retrospective review of the charts of 3200 low vision patients (Massof et al., 2005a, Massof et al., 2005b; Massof et al., 2007; Goldstein et al., 2014). Goals and tasks that are frequently reported as difficult in the population seeking LVR were identified and organized into this VFQ. The AI has been validated and provides a reliable measure of the same visual ability variable measured by

other VFQs (Massof et al., 2007). According to Khadka et al (2013), the AI is inferior in response categories, item fit, and dimensionality to the VA LV VFQ-48. However, these apparent deficits are offset by both the large number of items that compose the AI and findings which established that multidimensionality of the AI visual ability variable does not distort measurements (Massof et al., 2007). In a diverse outpatient LVR population, the numerous and broadly targeted items in the AI may indicate the use of this psychometrically robust questionnaire over others. The AI is a powerful tool to measure LVR outcomes, and is well-targeted for most patients presenting for LVR.

The AI consists of 3 objectives, 50 goals, and 460 tasks, all of which are organized into a hierarchical activity breakdown structure (Massof et al., 2007). Each task, such as "avoid cutting yourself" must be performed in order to achieve a certain goal, such as "daily meal preparation." Each goal falls under an objective, such as "daily living," which defines the social context of achieving goals (Massof et al., 2007). Participants first report how important a goal is, and then how difficult it is to complete that goal without help. If the goal is unimportant or not difficult, subsequent tasks which are part of that goal do not affect the participant's ability, and therefore do not receive a difficulty rating. During follow up questionnaires, items that were rated unimportant or not difficult at baseline are not inquired about, since these items would not have been targeted by LVR and no change will have occurred (Goldstein et al., 2012). The AI is adaptive in that only tasks that affect participants' abilities to perform important goals affect ability measures (Massof et al., 2007). The AI can provide information about overall visual ability, but can also generate ability scores in the specific functional domains of reading, mobility, visual information, visual motor, activities

of daily living (ADL), inside the home, and outside the home. This is accomplished when only goals that contribute to the specific functional domain are included in an analysis, and is possible due to Rasch analysis of many AI items.

1.2.3 Rasch Analysis

Prior to application of Rasch theory to low vision VFQ outcomes, classic test theory (CTT) was commonly used. In the CTT paradigm, difficulty ratings of each item were added together to yield a total score. CTT is limited in its measurement abilities because it does not account for differing item difficulty (Mallinson, 2007; Massof, 2011). Additionally, it is unable to adjust for missing data, which would therefore inappropriately impact measurements. The subsequent application of Item Response Theory (IRT) and Rasch theory to questionnaire data lends power to VFQ outcomes by enabling measurement on an interval scale (Massof, 2011; Pesudovs, 2006). Unlike CTT, these methods account for varied item difficulty, enabling difference in value to have meaning. Missing data can also be appropriately accounted for assuming that the VFQ has an adequate distribution of remaining item measures to target participants completing the VFQ. Rasch and IRT analysis differ primarily in how they account for measurement error and in the model's assumptions about response category thresholds (Massof, 2011). Consequently, Rasch analysis has become the gold standard in measuring LVR VFQ outcomes.

When completing the AI questionnaire, Rasch analysis is especially important because missing data is nearly guaranteed. Goals included in the AI range from using a public restroom to working with leather or performing outdoor recreational activities (Appendix 1).

Since non-important items are scored as missing data, it is highly unlikely that any participant will rate every AI item. Importantly, this also means that the majority of participants' goals are represented, enabling uncommon goals to impact person measures for participants who consider them important without skewing results for those who do not. Rasch analysis of the AI enables person measures to be more reflective of each individual participant's unique rehabilitation goals, while still allowing inter-participant comparison of outcomes.

According to the Rasch method, each AI item has an intrinsic level of difficulty for a population of low vision patients. This numerical value is known as an item measure, and has been set for each item through the calibration of the AI to approximately 3,000 low vision participants (Massof, 1998; Massof et al., 2005a; Massof et al., 2005b; Goldstein et al., 2014). Participants' task difficulty ratings depend not only on the inherent difficulty of a task, but also on how able the participant is to complete the task. Person measure is a variable estimated by the AI which indicates how capable a participant is to perform tasks included in the AI, with a positive value being more able and a negative value being less able (Massof, 2011). Functional reserve is defined as the difference between a participant's person measure and the item measure for a given task. Each time a study participant answers a question about the difficulty of performing a specific task, the participant is comparing his or her ability (i.e. person measure) to task difficulty (i.e. item measure), thereby providing a measure of functional reserve (Massof et al., 2007).

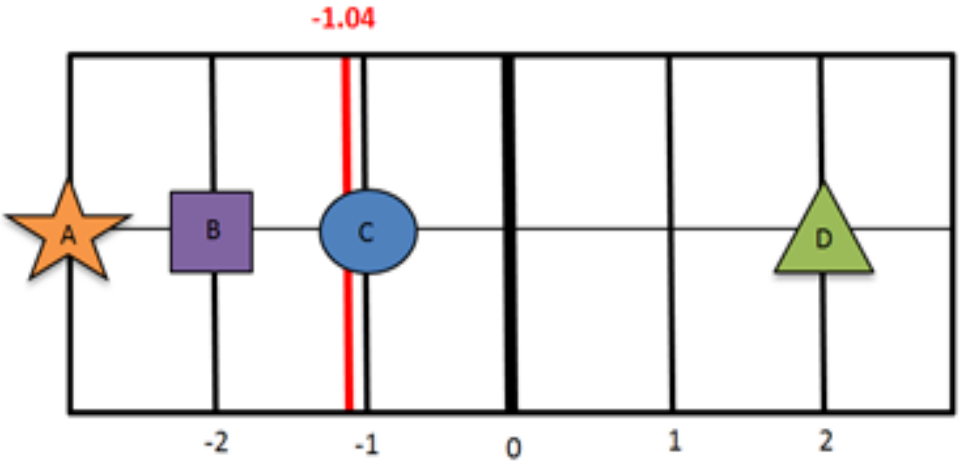

Figure 1.1: Person and Item* Measures *for the "Finding Food Items" Task
Adapted from Massof 2013
Item measure is represented by the red vertical line with a value of -1.04 logits. Person measures are shown for four theoretical participants: D (2 logits), C (-1 logits), B (-2 logits) and A (-3 logits). As participant D's person measure is much greater than the item measure, functional reserve will be positive and the task will be rated as not difficult. As participant A's person measure is much more negative than the person measure, functional reserve is negative and large so the task will be rated as impossible to do without help. Participant B has a person measure lower than the item measure but not as negative as participant A, and will rate the task as moderately difficult. Participant C's person measure is very close to the item measure, so the item will be rated as slightly difficult. (Massof & Stelmack, 2013)

For example, in the AI's daily living objective under the daily meal preparation goal, the task "finding food items" has an item measure of -1.04 (Massof et al., 2005b) (Figure 1.1). As a result, participants with person measures much greater than -1.04 will rate this task as not difficult. Participants with person measures much less than -1.04 will rate the task as impossible to do without help. Participants whose person measures are close to -1.04 will say that finding food items is slightly, moderately, or very difficult. Which rating is selected depends on how much larger or smaller the person measure is in comparison to the item measure – that is, the participant's functional reserve (Figure 1.1). Threshold functional reserve measures have been set for each difficulty rating for each item of the AI (Massof et al., 2007). By rating the difficulty of many tasks, many measures of functional reserve are

used to estimate an overall person measure (i.e. visual ability) (Massof et al., 2007). The AI provides 510 different data points to measure functional reserve each time it is administered, although it is highly unlikely that any one patient will complete all 510 data points due to the AI's adaptive format.

1.2.4 Outcome Measurements

Numerous studies have used VFQs to evaluate the effectiveness of LVR at improving visual function in varied clinical settings (Stelmack et al., 2006a; Stelmack et al., 2008; Goldstein et al., 2015;Stelmack et al., 2016; Deemer, Massof, Rovner, Casten, & Piersol, 2017). Outcome measures differ with delivery model and measurement instrument (Binns et al., 2017). Overall, VA hospital-based programs have produced large effect sizes and clinically meaningful outcomes in a majority of participants. The Veteran's Affairs Low Vision Intervention Trial (LOVIT)(J.A. Stelmack et al., 2008) yielded tremendous improvements in visual ability through an intensive, multidisciplinary outpatient intervention in a sample of veterans with legal blindness secondary to macular disease. Outcomes were measured using the VA LV VFQ-48 (Stelmack et al., 2008). LOVIT II followed up on these findings in a sample with better baseline visual acuities (20/50-20/200), showing comparatively smaller outcomes in participants receiving basic low vision or low vision rehabilitation (Stelmack et al., 2016). The VA's Blind Rehabilitation Center (BRC) programs, which are intensive inpatient programs for legally blind veterans, have also shown large effect sizes via VA LV VFQ-48, similar to what was seen in LOVIT I (Stelmack et al., 2006a).

Effect sizes measured in VA hospital-based programs are substantially larger than those reported in private low vision services. One study reported that private low vision outcomes were one fifth the size of what has been observed in the BRC (Massof & Stelmack, 2013; Stelmack et al., 2006a). Outpatient private low vision services typically produce small to moderate clinical effect sizes (Massof & Stelmack, 2013). The Low Vision Rehabilitation Outcome Study (LVROS) (Goldstein et al., 2012; Goldstein et al., 2014; Goldstein et al., 2015) was a large multicenter study which used the AI to measure a moderate but clinically significant treatment effect when surveying 779 low vision patients at 28 private outpatient clinical centers across the country. Standard care varied by clinic site, and participants of all

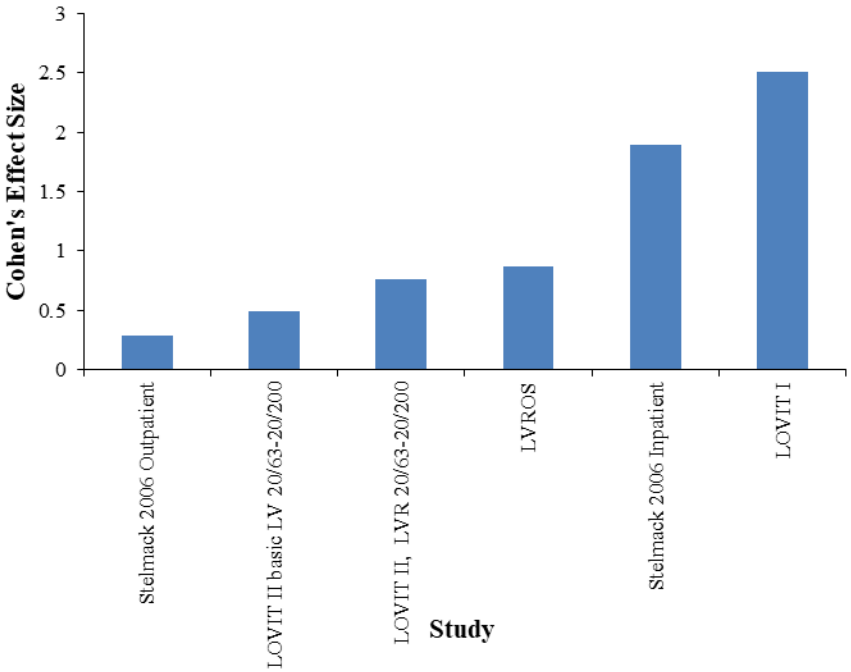

Figure 1.2: Outcome Measures from Previous Studies
Cohen's effect sizes reported in LOVIT I (Stelmack et al., 2008), LOVIT II (Stelmack et al., 2016), the Blind Rehabilitation Center inpatient program (Stelmack 2006 Inpatient) (Stelmack et al., 2006a), Low Vision Rehabilitation Outcome Study (LVROS) (Goldstein et al., 2015), and Blind Rehabilitation Center outpatient program (Stelmack 2006 Outpatient) (Stelmack et al., 2006a).

visual acuities and causes of impairment were eligible for study enrollment (Goldstein et al., 2015).

Patient individual characteristics may impact self-perceived abilities, which affect responses to VFQs, thereby influencing results. The LVROS sample, which was designed to be representative of those presenting for LVR across the U.S., was largely elderly and female, with a majority of participants self-reporting additional co-morbidities (Goldstein et al., 2012). Physical disabilities that reduced capability to perform daily tasks were reported by 60% of LVROS participants. Psychosocial difficulties were also highly prevalent among LVROS participants including anxiety, depression, frustration and occasional periods of forgetfulness (Goldstein et al., 2012). Change in overall AI visual ability was predicted by age. Changes in the visual information AI domain were predicted by visual acuity.

LVROS also explored interactions between self-reported physical and psychosocial comorbidities and self-reported AI visual ability measures (Goldstein et al., 2015). While these comorbidities were found to influence visual ability AI scores, they did not impact the overall change scores of LVR intervention (Goldstein et al., 2014; Goldstein et al., 2015). More recently, the VITAL study (Rovner et al., 2014; Deemer et al., 2017) has investigated the impact of behavior activation therapy to reduce depression incidence in patients at risk when presenting for LVR (Rovner et al., 2014; Deemer et al., 2017). Participants who received behavior activation therapy showed less depression severity and greater functional improvement as assessed by AI in comparison to an attention-control group (Deemer et al.,

2017). While psychosocial comorbidity does appear to influence self-reported visual ability, it importantly does not appear to impact assessments of change due to LVR.

Multiple studies have identified best-corrected visual acuity as a predictor of functional outcome. In LVROS, participants with moderate visual impairment, who had a visual acuity ranging from 0.48 to 1.00 logMAR (reported as worse than 20/60 and better than 20/200), showed the least improvement in change score due to LVR (Goldstein et al., 2015). Conversely, in a VA hospital setting, inpatient participants who had worse visual acuity showed larger clinical outcomes than outpatients with better acuities. Difference in acuity was cited as a likely reason for the seven-fold difference in outcome measures seen in outpatient and inpatient LVR (Stelmack et al., 2006a). In LOVIT II, the interaction between intervention, acuity, and clinical outcome was further clarified. This study enrolled participants with macular degeneration and acuities ranging from 20/50 – 20/200 in the better eye. Participants were randomized to receive basic low vision services, consisting of a low vision exam and device prescription, or comprehensive low vision rehabilitation. The comprehensive low vision rehabilitation group included basic low vision as well as an average of 1.9 training sessions and 9.8 hours of homework (Stelmack et al., 2016). Improvements in overall visual ability as well as all visual ability domains except visual information processing (i.e. reading, visual motor, and mobility) were predicted by lower baseline visual ability and with assignment to the low vision rehabilitation group (Stelmack et al., 2016). Patients who had mild visual impairment (20/50-20/63) saw no significant difference in outcome based on group assignment. Patients with moderately impaired acuity (20/63-20/200) showed significantly better outcomes if assigned to the low vision

rehabilitation group instead of the basic low vision group (Stelmack et al., 2016). This was true of overall visual ability, as well as the reading and visual motor domains. The impact of visual acuity on patient-reported visual function appears to differ based on level of services provided.

Baseline visual acuity's impact on visual function is further complicated by visual field defect. Research has shown that central scotoma location differentially impacts AI domain ability measures (Ross, Goldstein, & Massof, 2013). Driving difficulty was associated with scotomas coinciding with instrument panel and rearview mirror locations. Scotomas 7.5° left and 12.5° right of fixation and below and to the lower right of fixation were associated with decreased reading ability, interrupting text preview and moving to the next line of text. Mobility scores were worse with scotomas below and to the upper right of fixation (Ross et al., 2013). While these findings elaborate on the impact of certain types of field loss, the impact of peripheral visual field constriction on overall visual ability remains largely unexamined. Rasch analysis has been used to examine functional outcomes in patients with retinitis pigmentosa, but it is unclear how these results compare with others (Latham, Baranian, Timmis, Fisher, & Pardhan, 2016). Consequently, they do not inform our understanding of the interaction between visual field and visual function.

1.3 Cost effectiveness

1.3.1 Methods to Assess Cost Effectiveness

While low vision has an important impact on quality of life, it also can have an economic impact. Economic implications of a disease state typically are assessed through health utility

in units of quality-adjusted life year (QALY), where a year lived with perfect health is worth 1 QALY, and a year with imperfect health is worth between 0 and 1 QALY (Torrance, Furlong, & Feeny, 2002). To determine the QALY value of a year with imperfect health, several different methods are used including: time trade off (TTO), standard gamble (SG), or through instruments which approximate health utility such as the Euroqual 5 Dimensions (EQ-5D) (Malkin, Goldstein, & Massof, 2012; Malkin, Goldstein, Perlmutter, Massof, & Group, 2013). The TTO method asks participants how many years of life they would trade for perfect health for the remainder of their years, while SG asks participants what percent risk of instant death they are willing to accept in order to undergo a procedure that could provide perfect health. Work has shown that inquiring about total blindness rather than death yields results with the same units, enabling TTO and SG methods to be used related to vision (Malkin et al., 2012). The EQ-5D takes a somewhat gentler approach by asking participants to rate whether they have problems in five categories: mobility, self-care, usual activities (e.g. work, study, housework, leisure activities), and pain/discomfort (https://euroqol.org/). While the pain/discomfort category is unlikely to be relevant for visual impairment, the usual activities category may be too general for participants with visual impairment.

1.3.2 Cost Effectiveness in LVR

The economic implications of visual impairment have been quantified. One analysis examining health care costs has shown higher medical care expenditures, a greater number of informal care days, and a decrease in health utility in people who are blind or visually impaired (Frick, Gower, Kempen, & Wolff, 2007). Nationally, this amounts to an additional $5.5 billion per year for medical and informal care. It also amounts to a loss of 209,000

quality-adjusted life years (QALYs) as measured through the EQ-5D health utility (Frick et al., 2007). This does not account for any decrease in productivity that may occur due to vision loss.

Cost effectiveness of LVR intervention is a topic that has otherwise largely gone unexplored, likely related to the difficulty of measurement in this population. Patient characteristics other than visual impairment status haven been found to heavily impact TTO and SG measures, rendering them ineffective due to high inter-participant variability caused by differing participant response criteria (Malkin et al., 2012). Additionally, when the EQ-5D was administered to LVROS participants, it only weakly correlated with functional outcomes, and was unresponsive to change due to LVR intervention (Malkin et al., 2013). Standard methods have thus far proved ineffective in assessing cost effectiveness of LVR intervention.

An economic analysis using alternative methods has successfully been conducted in a VA hospital. This study examined the costs and consequences of inpatient BRC LVR versus outpatient LOVIT protocol LVR. In this analysis, VA LV VFQ-48 outcomes were compared, as were direct and indirect costs for each protocol. The analysis identified significantly lower costs through LOVIT protocol. Clinical outcomes were similar between the two protocols in domains of reading and visual information but better in BRC LVR for overall visual ability, mobility, and visual motor domains. Depending on individual rehabilitative needs, LOVIT protocol LVR can be a cost effective intervention (Stroupe et al., 2008). While this analysis was unable to yield results in units of QALYs and therefore has limited comparability with other healthcare fields, it does successfully examine cost versus benefit in an LVR setting.

1.4 Access to LVR

Despite the significant quality of life improvements produced by LVR, many barriers preclude patients from accessing these beneficial services. One deterrent to service utilization is a lack of awareness about the availability and potential impact of LVR (Pollard, Simpson, Lamoureux, & Keeffe, 2003; Matti, Pesudovs, Daly, Brown, & Chen, 2011; Fraser, Johnson, Wittich, & Overbury, 2014). Patients who do not access care due to a lack of information are more likely to have great difficulty achieving certain tasks (i.e. reading signs and doing fine handiwork), and likely need additional education before electing to seek LVR (Fraser et al., 2014). Additionally, the physical disability and chronic illness that are highly prevalent in this population can prevent LVR utilization, as patients or their family members may believe that care utilization is implausible due to patients' frailty or busy appointment schedules (Matti et al., 2011). Patients may also choose not to access care due to concern about being perceived by others as "disabled." This is reflected in the finding that patients who live independently are less likely to choose to access LVR (Overbury & Wittich, 2011).

Major studies have failed to determine whether lack of geographical proximity to a low vision provider creates a barrier to LVR utilization (Pollard et al., 2003; Matti et al., 2011; Fraser et al., 2014). This factor is often underestimated due to participant selection methods. Access to LVR has been explored largely in urban hospitals where participants were recruited from ophthalmologists' waiting rooms. LVR was available close to, if not within, these hospitals, and participants lived within 17 miles of the site (Overbury et al., 2011; Fraser et al., 2014). Consequently, these studies fail to account for the historically reported difficulty patients experience in accessing care that is not conveniently located, as well as in

complying with potentially beneficial LVR follow-up visits. One Australian study did identify transport as a barrier to care, with focus group participants reporting anxiety about public transportation or taxis to distant locations (Pollard et al., 2003).

Geographic barriers impact care utilization in rural environments where specialists, such as LVR providers, are scarce (Iezzoni, Killeen, & O'Day, 2006). Based on 2016 U.S. census data, Massachusetts' Hampden County was estimated to have 2,229 people 18 year of age or older with low vision (defined as BCVA of 20/60 or worse in the better eye) in 2016, but only two optometrists in the area that provide LVR (Massof, 2002; Malkin & Massof, 2017; Chan et al., 2018). Based on 2016 U.S. census data, an estimated 33,006 Massachusetts residents 18 years of age or older had low vision (BCVA 20/60 or better), 11,670 of which met the visual acuity definition of legal blindness (BCVA $\leq$ 20/200), with 39 low vision providers available to care for this population (Chan et al., 2018). The average county based patient-to-provider ratio is 1,007, ranging from 361 in Suffolk county to 2,378 in Plymouth county (Figure 1.3).

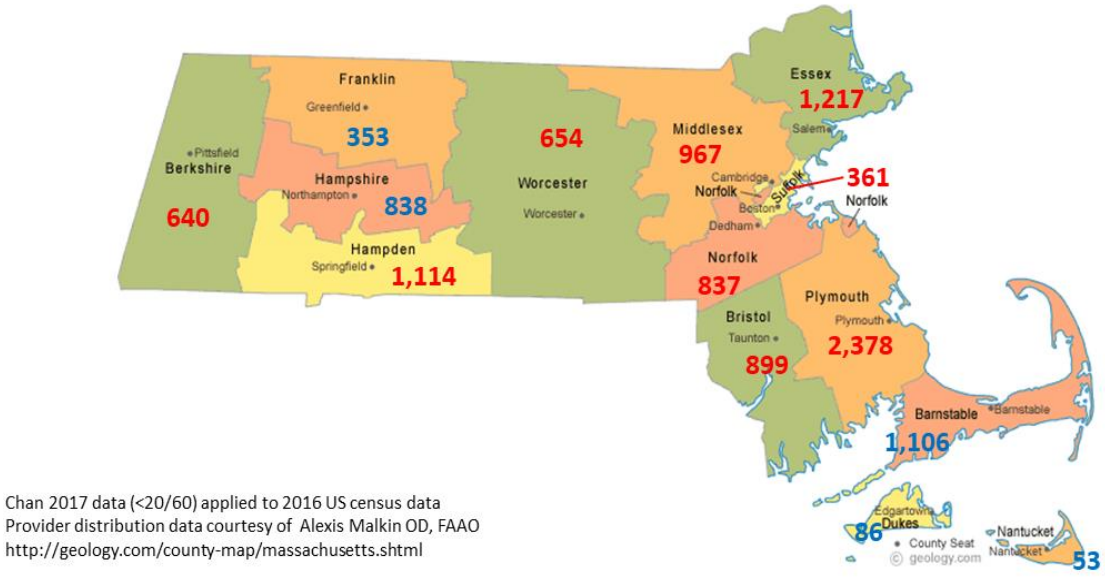

Figure 1.3: Distribution of Low Vision Patients and Providers in Massachusetts Counties
Red numbers indicate the ratio of people with visual impairment (VA 20/60 or worse) to low vision optometrists in that county, while blue numbers represent people with visual impairment in counties that lack low vision providers.

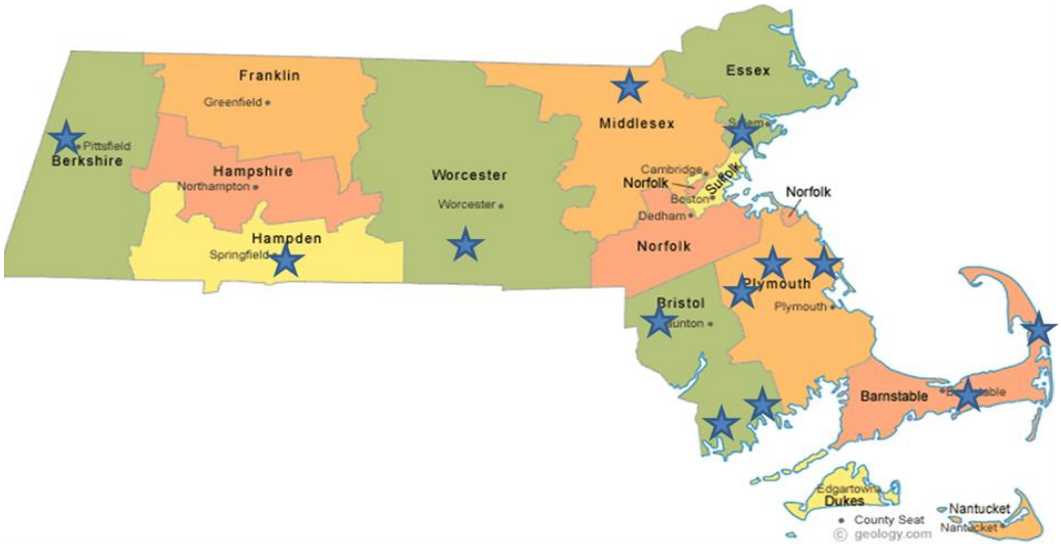

Figure 1.4: Mobile Clinic On Site Locations
Blue stars represent sites visited by the mobile clinic to provide LVR intervention

Five additional counties lack optometric LVR providers. While patients who have low vision can cross state and county lines to obtain needed care, this may be challenging in a population which often relies on others for transportation needs.

1.5 Outcomes of Mobile Clinic LVR

In the state of Massachusetts, a mobile clinic was used to provide LVR within communities, aiming to minimize geographic barriers to care. It traveled to numerous sites where inadequate LVR providers were available to meet patient demand (Figure 1.4). This project measures outcomes from this pre-existing mobile clinic using several different approaches. We first investigate whether AI outcomes from mobile clinic LVR are clinically meaningful and comparable to LVR delivered in in other clinical settings (Chapter 2). We then evaluate low vision device utilization and abandonment in patients who received mobile clinic LVR (Chapter 3). Additional sub analyses include the impact of time on outcome measure (Supplement 1) and a cost versus benefit analysis (Supplement 2). Finally, we discuss our results and future directions (Chapter 4).

CHAPTER 2: CLINICAL OUTCOMES OF LOW VISION REHABILITATION DELIVERED BY A MOBILE CLINIC

This chapter is the peer reviewed version of the following article:

***Gobeille M**, Malkin A, Jamara R & Ross NC. Clinical outcomes of low vision rehabilitation delivered by a mobile clinic. Ophthalmic Physiol Opt 2018;38: 193-202.*

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2.1. Abstract

PURPOSE: This prospective cohort study examined clinical outcomes of low vision rehabilitation (LVR) delivered by mobile clinic.

METHODS: Participants were recruited from those scheduled for mobile clinic LVR and met the United States definition of legal blindness. They completed the Massof Activity Inventory (AI) before LVR, 3 months post-LVR, and 1 year post-LVR. Change scores and measures of clinical effect (i.e. Cohen's effect size and Minimum Clinically Important Difference (MCID)) were calculated for each time point and compared. Additional participant characteristics (i.e. age, acuity, contrast sensitivity, cause of visual impairment, training recommendations, and prior LVR experience) were also explored with respect to outcome measures.

RESULTS: Of the 66 participants enrolled in this study, 47% had no prior LVR experience. Significant differences were noted between baseline and 3-month person measures, and between baseline and one-year person measures. There was no significant difference between 3-month and one-year person measures, nor was there a significant difference in change score between these two time points. At 1 year post-LVR the overall visual ability effect size was 0.74. A clinically meaningful outcome was achieved in 56% of participants at 3 months and 71% at 1 year for overall visual ability. There was no significant difference in the proportion of participants achieving a MCID at 3 months versus 1 year. Of participants who completed the 1 year post-LVR AI, 59% reported a subjective worsening of vision during the study period. This subgroup also tended to have smaller 1 year change scores.

CONCLUSIONS: Mobile clinic LVR is effective at expanding access to care and produces clinically meaningful outcomes comparable to those seen in other outpatient LVR delivery models.

2.2 Introduction

Visual impairment is a highly prevalent problem, affecting approximately 3 million Americans and increasing in incidence as the population ages (Massof, 2002). With this expanding population, effective and accessible low vision rehabilitation (LVR) provision becomes a pressing concern. Randomized clinical trials conducted in Veteran's Affairs (VA) hospital-based programs have evaluated effectiveness of intensive rehabilitation service delivery models (Stelmack et al., 2006a; Stelmack et al., 2008; Stelmack et al., 2016). Private outpatient LVR has also been shown to produce clinically meaningful outcomes in the United States (Goldstein et al., 2014; Goldstein et al., 2015). Additionally, a primary care based low vision service has been shown to improve outcomes and expand access to LVR in Wales (Ryan, White, Wild, Court, & Margrain, 2010). However, no prior study has evaluated the effectiveness of mobile clinic LVR.

Outcome studies have relied on various visual function questionnaires to evaluate a clinical intervention's impact on quality of life. These questionnaires ask patients to self-report the difficulty of a number of visually mediated tasks or goals. Utilizing Rasch analysis, a measurement of a person's visual ability is obtained by comparing self-reported difficulty for each item with the inherent level of difficulty of that item (i.e. item measure). The Massof Activity Inventory (AI) is one such validated questionnaire which has been implemented, measured, and calibrated with nearly 3,000 low vision patients (Massof, 2011; Massof et al., 2007). The AI makes use of a hierarchical activity breakdown structure, with 460 tasks serving one of 50 larger goals (Massof et al., 2007).

When completing the AI, a person first rates the importance of a visually mediated goal. He/she then rates his/her difficulty (i.e. slightly difficult, moderately difficult, very difficult, impossible to do without help from another person, not applicable) accomplishing each task that is related to that goal, if the goal was rated as important. Due to this adaptive format coupled with Rasch analysis, a visual ability variable is approximated in such a way that it is impacted only by goals and tasks rated as important and difficult at baseline. Additionally, the AI's many items span a broad range of item measures, limiting the likelihood that floor and ceiling effects will impact outcomes. This allows accurate and precise measurement, making the AI a powerful tool to measure LVR outcomes.

This prospective cohort study uses the AI to examine outcomes from LVR provided by a mobile clinic, which travelled to areas with an identified scarcity of low vision providers. Outcomes are explored in comparison to previous work completed in other delivery models. Additional factors such as participant characteristics and training recommendations are also examined in relation to outcome measures.

2.3. Methods

2.3.1. Participants:

Participants were recruited between May 2015 and October 2016. All patients scheduled for mobile clinic LVR were contacted by telephone prior to their examination to determine eligibility and interest in study participation. Patients who elected to enrol as participants were required to be legally blind according to 2014 United States Social Security standards ("Social Security Blue Book Section 2.00 Special Senses And Speech - Adult,") (i.e. better

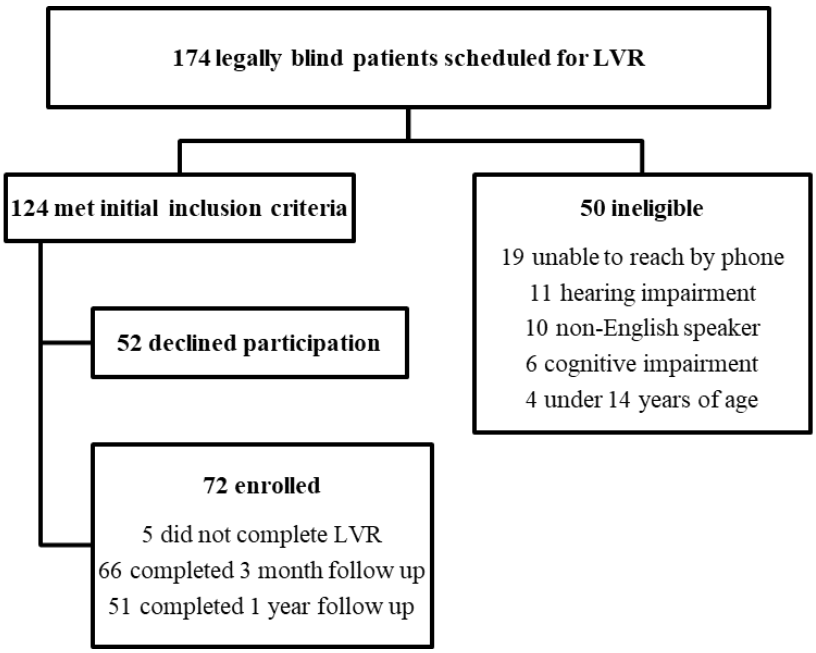

Figure 2.1: Enrollment Flow Chart

seeing eye worse than 0.70 logMAR (20/100 Snellen Equivalent) and/or visual field subtending less than 20 degrees in the largest diameter) at time of enrolment. Participants were at least 14 years of age and able to complete the AI in English by telephone on three separate occasions as dictated by study protocol. Use of a telephone questionnaire excluded those with inadequate English fluency and/or telephone access to comply with data collection procedures. Participants with a medical or self-reported history of cognitive impairment were also excluded. The study protocol was approved by the New England College of Optometry Institutional Review Board and followed the tenets of the Declaration of Helsinki. All participants provided both oral and written informed consent.

Table 2.1: Devices Available for Participants

Hand Magnifiers	10 to 50 D, LED illumination available in white or yellow light
Pocket Magnifiers	2.5 to 10x
Stand Magnifiers	LED illuminated with white or yellow light 3 to15x, § Dome magnifier, Eschenbach Makrolux (2.2x, 3.6x), Eschenbach Scribolux magnifier
Prism half eyes	$+4D/6^{\Delta}$ base out to $+14D/16^{\Delta}$ base out
Microscope fit set	2x (8 Diopter) to 8x (32 Diopter)
Loupes	All available Eschenbach loupes, Donegan optivisor
Telemicroscope	2.2X Max Detail spectacle or clip
Electronic magnification	Portable (Ruby, Smartlux, Pebble, Optelec) and desktop models (Topaz and Magnilink Zip)
Optical Character Recognition	AbiSee OCR, KNFB reader application on iPad
Filters	Fitover filters in all available NoIR and Eschenbach tints
Telescopes	2.2X Max TV (spectacles and clip), monocular telescopes (2x20, 3.15x25, 4x12, 6x16, 8x21; Keplerian and Galilean designs), bioptic telescope fitting sets (Complete designs for vision telescope fitting set, Ocutech Sight Scope fitting set, Ocutech VES telescope fitting set, Ocutech instamount 2.2x telescope)
Field expansion	Ocutech image minifier (0.5x), Peli peripheral prisms
Other	Mattingly smart reading light clip, Verilux floor and stand daylight lamps, clip-boards and writing stands, Zoomtext software trial, Fresnel prism, Bangerter occlusion foils, conventional spectacle frames with optical services coordinated offsite

2.3.2. Clinical Examination and Study Setting

Mobile clinic examinations were delivered to provide usual LVR. The mobile clinic consists of two 10 foot fully-equipped optometric examination lanes with trial lenses for trial frame

refraction, visual acuity charts (e.g. Feinbloom and ETDRS), Mars contrast sensitivity charts, MNRead near charts, slit lamp microscope, retinoscope, binocular indirect ophthalmoscope, diagnostic lenses, optical coherence tomography imaging, and an assortment of visual assistive equipment (Table 2.1). Examinations were conducted by final-year optometry doctoral interns under the direct supervision and in concert with licensed mobile clinic LVR optometrists. The LVR examination included visual acuity, contrast sensitivity, confrontation visual field assessment, Amsler grid central field assessment, retinoscopy, trial frame refraction, visual assistive equipment (VAE) assessment, and ocular health evaluation.

During VAE assessment, equivalent dioptric power required for reading 1.0M print was determined using the inverse of the critical print size as assessed by MNRead continuous text chart (Subramanian & Pardhan, 2009) while participants wore their best reading correction. Distance magnification starting points were determined based on distant goal text size and visual acuity while wearing optimal distance correction (Dickinson, 1998). A broad range of VAE were available for evaluation (Table 2.1). Evaluated VAE were then titrated to meet the individual's needs and preferences. If improvement was demonstrated (e.g. increased reading fluency, smaller threshold, subjective improvement, attainment of goal), VAE was recommended. Recommended VAE were provided at no charge to the patient through a grant administered by the state commission for the blind. VAE were dispensed on site or ordered and delivered at a later date, most often within 3 months.

While literature has demonstrated that electronic devices are preferred for leisure reading (Taylor et al., 2017), optical magnifiers were preferentially provided in this study due to the

grant structure and coverage regulations in place. As such, for this study population electronic magnification was recommended whenever optical magnification strategies proved insufficient to meet participant goals (i.e. due to severely reduced contrast sensitivity or functionally significant scotoma and visual field loss).

Recommendations and referrals for orientation and mobility training, device use training, technology assessment, activity of daily living (ADL) skills training, follow up LVR, or follow up ocular health examination were provided when indicated. Training recommendations were made based on clinical examination and subjective report of difficulty elicited by directly questioning participants. Orientation and mobility training was recommended for participants who reported concerns regarding safe navigation of their environment, had a significant fall history, or reported a fear of falling. Those who reported difficulty achieving daily living tasks were referred for ADL training. Participants who identified adaptive computer access (i.e. screen magnification and/or reader) as a rehabilitation goal were referred for technology assessment. Those who were not able to demonstrate efficient use of recommended VAE by the end of their mobile clinic examination were referred for further device use training by a local rehabilitation therapist. Follow up LVR or ocular health examinations were recommended for any participant whose functional or ocular health needs were not entirely met by mobile clinic LVR (e.g. need for follow up care prior to next mobile clinic visit or outside the scope of practice available on the mobile clinic). Training recommendations were facilitated through the local state rehabilitation agency (i.e. regional offices of the Massachusetts Commission for the Blind) and follow up care was coordinated by the mobile clinic LVR optometrist. The number of

rehabilitation therapy and/or training visits was determined independently by local rehabilitation therapists based on a participant's needs.

2.3.3. Data Collection

Participants completed the AI prior to receiving mobile clinic LVR, 3 months (±14 days) after LVR, and 1 year (± 60 days) after LVR. One research assistant administered all phone questionnaires pertaining to this study. Participants who did not complete LVR were contacted in an attempt to obtain follow up data, but were unable to be reached by telephone. Thus outcomes could not be assessed from these participants.

Demographic and clinical examination data were recorded during LVR. Demographic variables included age, incoming self-reported systemic and ocular diagnoses, and self-reported prior LVR examination experience. Clinical examination data included best corrected visual acuity measured by electronic log MAR chart or, if necessary (i.e. visual acuity worse than 1.60 log MAR (20/800 Snellen Equivalent)) a Feinbloom number chart (Feinbloom, 1935). Also included were: Mars Contrast Sensitivity (if visual acuity was 1.48 log MAR (20/600 Snellen Equivalent) or better) (Arditi, 2005), VAE recommendations, training recommendations, and follow up recommendations.

2.3.4. Outcome Measures:

Similar to previous studies (Goldstein et al., 2015), the primary outcome measure was change in overall visual ability, estimated from participants' difficulty ratings of AI goals at baseline, at 3 months, and at one-year after the initial LVR evaluation. Secondary outcome measures were estimated from difficulty ratings of specific subsets of AI tasks which included:

reading, mobility, visual information, visual motor functioning, instrumental activities of daily living function (IADL), inside the home functional ability, and outside the home functional ability. Item measures and response thresholds for each difficulty rating category were calibrated from the responses of over 3000 low vision patients, as described by Massof et al.(Massof, 2011; Massof et al., 2007).

Effect size of AI change scores, and percentage of participants achieving a meaningful clinically important difference (MCID) post LVR were also explored and compared to other LVR models of care.

2.3.5. Sample size

A Cohen's effect size of 0.42 was the smallest determined in the Low Vision Rehabilitation Outcomes Study (LVROS) (Goldstein et al., 2015). Results of the power analysis to detect a Cohen's d of 0.42 with alpha set at $p < 0.05$ and power of 0.80 indicated a sample of $N = 49$. A mobile clinic delivery model may create unique challenges to participant retention, so estimating a 20% drop-out rate, our target sample size was increased to $N = 63$.

2.3.6. Data analysis

Data collected by AI were filtered so that items rated as not difficult at baseline were scored as missing throughout all analyses (Goldstein et al., 2012). Filtered AI data underwent Rasch analysis (http://www.winsteps.com/index.htm) to estimate person measures for overall visual ability as well as for seven functional domains: reading, visual information, visual motor, mobility, IADL, inside the home activities, and outside the home activities.

A three (time: baseline, 3 months, one-year) by eight (AI domains: overall visual ability, seven AI sub-score domains) within subject analysis of variance was conducted to explore significant improvements in person measures at each of these time points (https://www.ibm.com/products/spss-statistics). This was then followed with a principle component and a principle axis factoring analyses of baseline AI person measures.

Change scores (e.g. differences between baseline and 3 month post LVR person measures and baseline and one year post LVR person measures) were computed. Student t-tests were conducted to explore statistically significant differences at the 95% confidence level.

Cohen's effect sizes (d coefficients) and minimum clinically important differences (MCID) were then calculated using Excel (https://office.microsoft.com/excel/) to measure clinical effect in each domain as well as overall goals. Cohen's effect size was calculated as mean change score across participants divided by change score standard deviation. MCID was calculated for each participant by dividing change score by 1.96 (derived from the 95% confidence interval) times the standard error. Proportion of participants who achieved MCID (i.e. calculation greater than 1) was reported. As such, MCID is informative in terms of the proportion experiencing a clinically meaningful outcome, while d coefficients provide information regarding overall clinical effect magnitude. Participants who completed all follow up questionnaires (3 months and one year) were included in the analyses, as no trends or biases were observed in those who withdrew from the study. To determine significant changes in proportions between 3 months and 1 year a McNamar test was conducted.

To explore possible predictors between AI person measures and clinical examination measures (i.e. binocular logMAR visual acuity, binocular log contrast sensitivity, and age) a series of correlations were conducted. A follow up one-way ANOVA with Bonferroni technique to control for inflated type I error was performed, allowing further investigation of AI change score predictors. This was followed by a multi-linear regression. All statistical analysis was performed with SPSS (https://www.ibm.com/products/spss-statistics).

To assess the relationships of additional referrals (e.g. orientation and mobility training, rehabilitation therapy, technology assessment, follow up clinical LVR evaluation) on one-year change scores, a series of bi-serial correlations were conducted between each type of referral with one-year change scores for each AI domain result.

2.4. Results

2.4.1. Participants

Among participants (n=66), the most common ocular diagnosis was age-related macular degeneration, although visual conditions which primarily affect peripheral vision (e.g. glaucoma, retinitis pigmentosa) were also present at high levels (Figure 2.2). Many participants had multiple ocular diagnoses (n=44), and the mean number of systemic comorbidities was 2.45 (self-report). Psychosocial problems (e.g. anxiety, depression), heart disease, and neurological disorders were highly prevalent.

Mean baseline visual acuity was moderately reduced (Goldstein et al., 2012) at 0.93 log MAR (SD=0.45, 20/170 Snellen equivalent). Average log contrast sensitivity was severely

reduced(Goldstein et al., 2012) at 0.87 log CS (SD=0.40) (Table 2.2). Of participants enrolled in the study, 60 had severe visual impairment – 49 based on acuity (i.e. VA 1.00 logMAR (20/200 Snellen equivalent) or worse) and 11 based exclusively on visual field (i.e. incoming visual field findings subtending less than 20 degrees in largest field diameter in the better seeing eye). Only 6 participants had mild to moderate visual impairment.

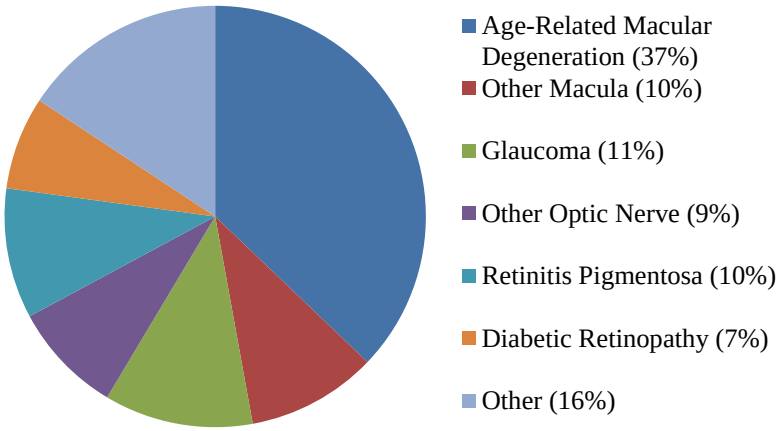

Figure 2.2: Primary Cause of Visual Impairment
Other conditions included: congenital cataract (n=2), retinopathy of prematurity (n=2), neurological visual field loss (n=2), chronic uveitis (n=2), other unspecified congenital vision loss (n=2), and cytomegalovirus retinitis (n=1).

Table2.2: Baseline Participant Characteristics

Characteristic or Measure	Mean (SD)
Visual Acuity (better eye Log MAR)	0.93 (0.45)
Binocular MARS Contrast Sensitivity (log CS)	0.87 (0.40)
Age (years)	72.5 (21.0)
Gender	64% female, 36% male
Percent Experiencing First LVR Examination	47%

Most participants were female (64%), and ages ranged from 17 to 92 years, with a mean of 72.5 years and a median of 65.6 years (Table 2.2). Forty-seven percent

had never previously had an LVR examination. Mean baseline overall goal visual ability was -0.33 logits, which is well within the range targeted by the AI (Massof et al., 2007). As such, the AI is unlikely to yield results limited by floor or ceiling effects in this sample.

2.4.2. Outcome Measures

Figure 2.3 illustrates the person measures for overall goals and for each of the seven AI domains at baseline, three months and 1 year. At three months person measures were

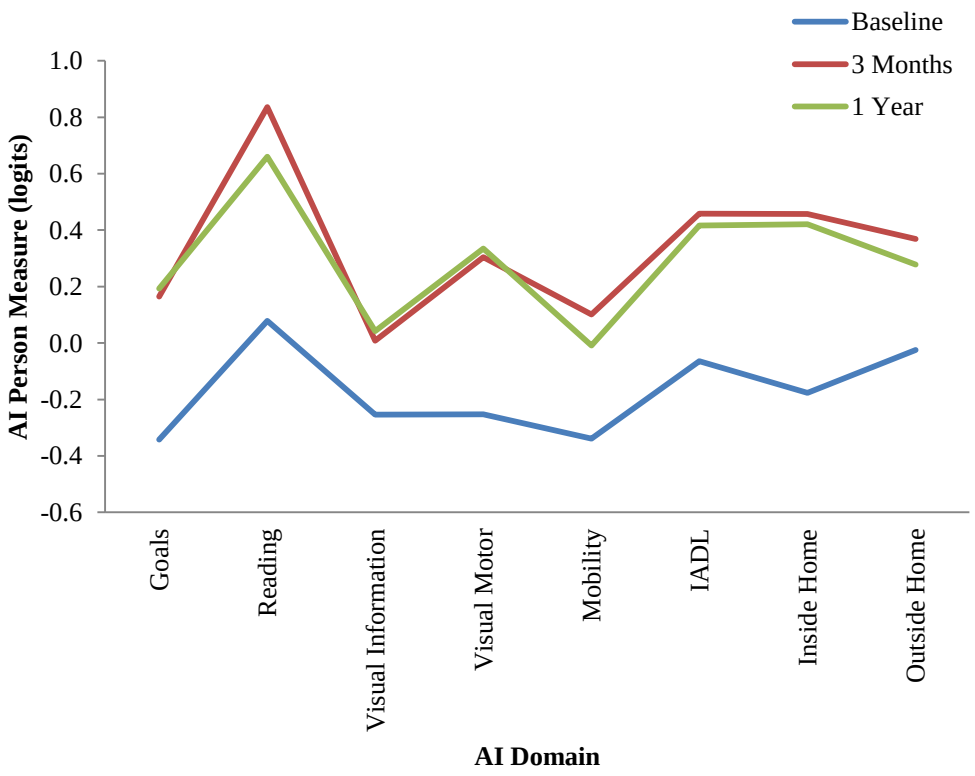

Figure 2.3: Person Measures at Baseline, 3-Month and One-Year Time Points.
A three (time: baseline, 3 months, one year) by eight (overall goals and seven AI domains,) within subject analysis of variance demonstrated significant improvements in person measures at each time point. Significant differences were identified between baseline and 3 month person measures (logits) for all AI domains ($p<0.0001$). No significant differences were found between 3 month and one-year person measures.

significantly larger than at baseline after Bonferroni correction ($p<0.0001$), with a positive mean change score in each domain (Table 2.3). Outcomes seen at 3 months were retained 1-year post-LVR; no significant differences were noted between 3-month and one-year person measures for each AI domain.

A principle axis factoring analysis was performed on baseline person measures of goals, reading, mobility, visual information and visual motor. IADL, inside the home and outside the home were not included as these domains contain many of the same tasks already included in the other domains. In this sample, the first principle component accounted for 72% of the variance. Given that previous reports by Massof et al. support that visual ability

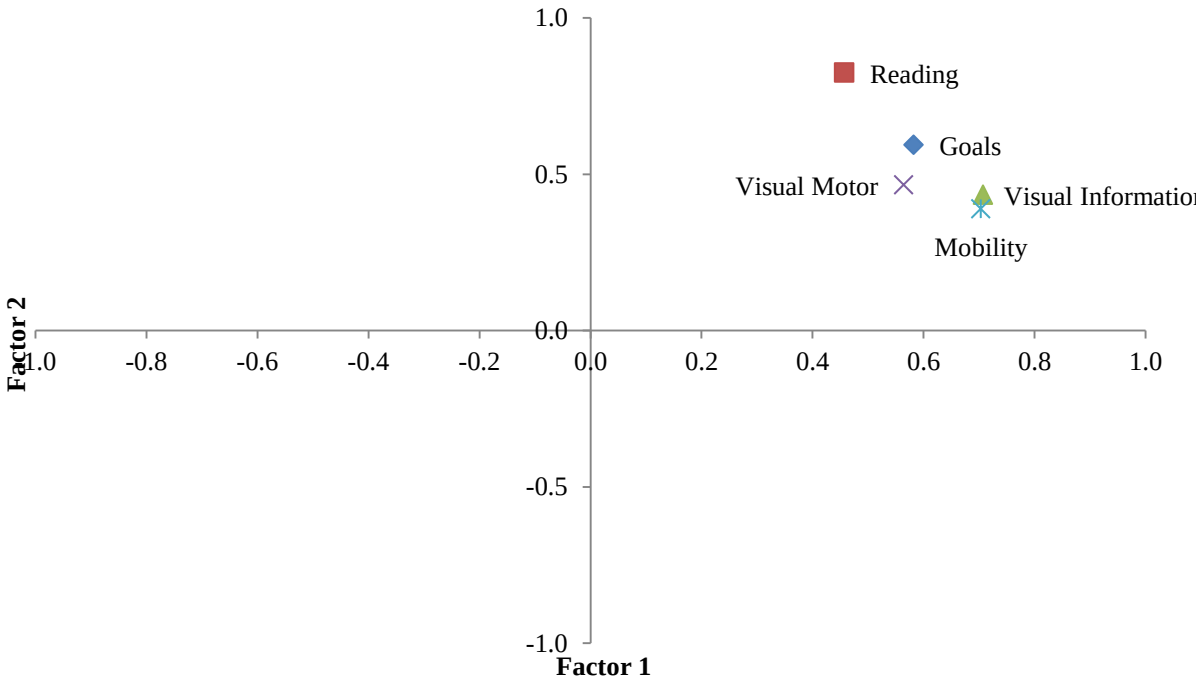

Figure 2.4. Factor Analysis Plot of Five Sets of Person Measures.
These findings support previous reports, reading loads most heavily onto one factor and mobility loads most heavily on the other.

Table 2.3: AI Change Scores at each Time Point

	Mean Change Score	Standard Deviation	Cohen's d Coefficient	95% Confidence
Goals, 3 Months	**0.51**	**0.45**	**1.12**	**1.00 - 1.25**
Reading, 3 Months	0.76	0.99	0.76	0.49 - 1.04
Visual Information, 3 Months	0.26	0.45	0.59	0.46 - 0.71
Visual Motor, 3 Months	0.56	0.60	0.93	0.77 - 1.10
Mobility, 3 Months	0.44	0.80	0.55	0.33 - 0.77
IADL, 3 Months	0.52	0.54	0.97	0.82 - 1.12
Inside Home, 3 Months	0.63	0.79	0.80	0.58 - 1.02
Outside Home, 3 Months	0.39	0.57	0.69	0.54 - 0.85
Goals, 1 Year	**0.53**	**0.71**	**0.74**	**0.54 - 0.93**
Reading, 1 Year	0.56	1.13	0.50	0.19 - 0.81
Visual Information, 1 Year	0.29	0.66	0.43	0.25 - 0.62
Visual Motor, 1 Year	0.58	0.97	0.60	0.34 - 0.87
Mobility, 1 Year	0.31	0.79	0.39	0.17 - 0.61
IADL, 1 Year	0.47	0.82	0.58	0.35-0.80
Inside Home, 1 Year	0.59	0.83	0.71	0.49-0.94
Outside Home, 1 Year	0.27	0.81	0.33	0.11-0.56

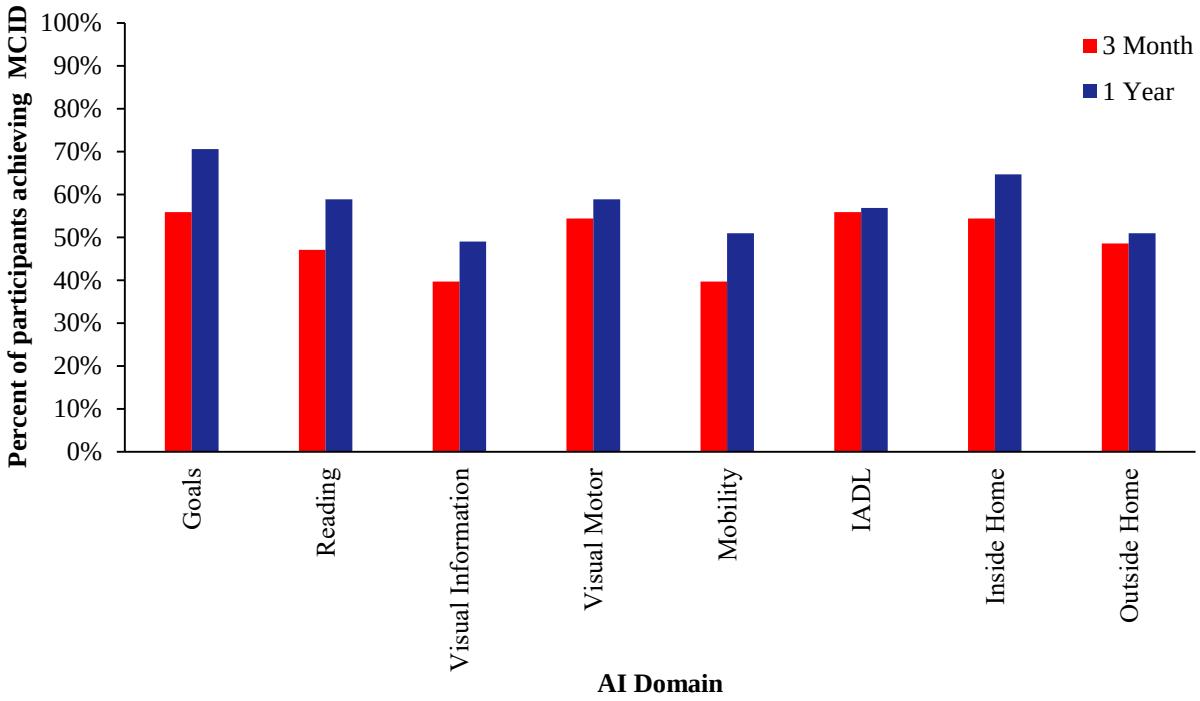

Figure 2.5: Minimum Clinically Important Difference (MCID) at 3 Months and 1 Year
Percentages of participants who achieved the Minimum Clinically Important Difference (MCID) based on Activity Inventory (AI) outcomes at 3 months (red bars) and 1 year (blue bars) are shown for overall visual ability (goals) as well as each AI domain (i.e. reading, visual information, visual motor, mobility, instrumental activities of daily living (IADL), inside the home, and outside the home). MCID was less frequently achieved at 3 months than at 1 year for all domains. In overall visual ability (goals), MCID was achieved in 56% of participants at 3 months and 71% of participants at 1 year.

is a composite variable with at least two dimensions, a two-dimensional factor analysis using principle axis factoring was performed on the five sets of person measures with varimax rotation. Figure 2.4 shows the factor plot, which illustrates that while reading loads most heavily on one factor, mobility loads on the other.

Cohen's effect size for overall visual ability was 1.12 at 3 months and 0.74 at 1 year. Across domains, 1 year effect sizes ranged from 0.43 in visual information to 0.71 in inside the home activities (Table 2.3). A majority of participants achieved clinically meaningful outcomes in overall visual ability and in all domains (change in person measure >1.96

standard errors of baseline person measure estimate). Seventy-one percent of participants achieved MCID in overall visual ability at one-year. This was most frequently achieved inside the home (65%) and least frequently achieved in visual information (49%) (Figure 2.5).

At one-year, MCID was achieved for 71% of participants in overall goals. Across domains, MCID was most frequently achieved inside the home (67%) and least frequently achieved in visual information (49%) (Figure 2.5). There was no statistically significant difference in the percentage of participants who achieved MCID at 3 months versus 1 year across the seven AI domains.

2.4.3. Predictors of LVR Outcome

A series of correlations were conducted between age, binocular logMAR visual acuity, binocular log contrast sensitivity and baseline person measures for overall goals and each AI domain. LogMAR visual acuity was negatively correlated with baseline overall goals ($r=-0.37$, $p<0.001$). Log contrast sensitivity was positively correlated with baseline overall goals ($r=0.43$, $p<0.001$). Effects of age were negatively correlated with baseline person measures, but were not significant

A series of multiple regressions were conducted where age, binocular logMAR visual acuity, binocular log contrast sensitivity, subjective report of worsening vision during the study period, and previous exposure to LVR prior to the study period were regressed on each AI domain change score at one year. Of participants who completed 1-year follow up (n=51), 30 self-reported a significant worsening of vision over the past year. Those who reported

worsening vision during the study period were advised to follow up with the mobile clinic or their local eye-care provider. Part correlations are shown in Table 2.4. Subjective report of worsening vision emerged as a significant predictor when controlled by the other variables for the AI domains of visual information, IADL and outside the home activities.

A series of one way ANOVAs were conducted with peripheral vision loss, central vision loss or combined visual loss as a fixed factor with the one year change score for each of the eight AI domains as the dependent variable. Results failed to achieve statistical significance on each of these analyses.

Table 2.4: Part correlations for 1 year change score for each domain and age, binocular logMAR visual acuity (VA), binocular log Contrast Sensitivity, subjective reported worsening vision, and previous exposure to LVR. *p<0.05

	R^2	Age	LogMAR VA	LogCS	Subjective Worsening of VA	Previous Exposure to LVR
All Goals	0.14	-0.05	-0.16	-0.02	-0.29 *	-0.12
Reading	0.12	-0.12	-0.02	0.03	-0.22	-0.2
Visual Information	0.22*	-0.02	-0.16	-0.05	-0.40*	-0.15
Visual Motor	0.04	0.05	0.06	0.07	-0.16	0.02
IADL	0.15	-0.08	-0.06	0.02	-0.30*	-0.19
Inside the Home	0.9	-0.05	0.03	0.08	-0.18	-0.21
Outside the Home	0.17	-0.09	-0.19	-0.03	-0.32*	-0.09

2.4.4..Referral patterns

Of the 66 participants, 22 were referred for orientation and mobility training while 16 were referred for rehabilitation therapy (i.e. ADL and/or device use training) (Table 2.5). A series of bi-serial correlations were conducted between each type of referral with one-year change scores for each AI domain, and results failed to reveal any significant relationships.

Table 2.5: Referrals Provided to Participants

Referral Type	Count
Orientation and Mobility Training	28
Rehabilitation Therapy	16
Technology Assessment	23
Follow Up Examination	26

One-year follow up on the mobile clinic with the optometrist was routinely recommended unless otherwise indicated. A follow up mobile clinic examination within the one-year study period was recommended for 26 participants, of which 14 participants complied. Of the participants who had multiple visits on the mobile clinic, 8 participants had two visits, 5 participants had 3 visits and one participant had 4 visits within the study period. Due to small cell size further analysis was not possible.

2.5. Discussion

Mobile clinic LVR produced moderate to large clinical outcomes at 3 months (d=1.12) and 1 year (d=0.74). There was a clinically significant effect in a majority of participants (56% and 71% respectively). These findings are, overall, similar to what has previously been reported in other delivery models (Figure 6). The mobile clinic outcomes are most similar to those seen in LVROS (Goldstein et al., 2015) and VITAL (Deemer et al., 2017; Rovner et al.,

2014), and are larger than some other outpatient LVR delivery models (Stelmack et al., 2006a; Lamoureux et al., 2007).

A Welsh primary care based low vision service measured a change score of 0.79 logits using the 7-item NEI-VFQ (Ryan et al., 2010). While this is larger than the change score observed in this study, the apparent discrepancy may be explained by differences in both the analysis technique (e.g.. Cohen's effect size and MCID not reported) and the survey questionnaire employed (e.g. the NEI-VFQ has been shown in other publications to be less robust(Massof

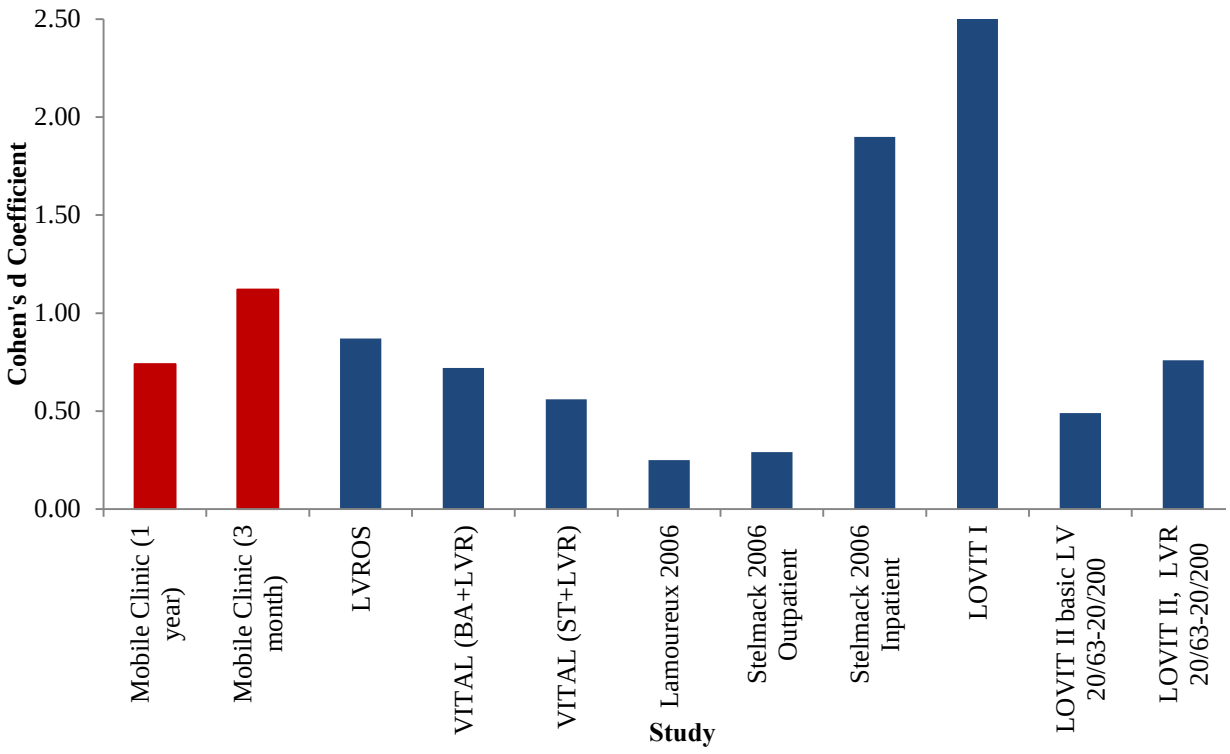

Figure 2.6: Cohen's Effect Size Comparison Across Prior Studies
Cohen's effect sizes measured in previous studies using visual function questionnaire data after Rasch analysis are shown above. Reported effect sizes range from 2.51 seen in LOVIT to 0.25 measured in Lamoureux 2006. The mobile clinic outcomes from this study were 0.86 at 3 months and 0.74 at 1 year.

et al., 2007)).

Participant demographics from the mobile clinic are different from those seen in VA hospital outcome studies in terms of age, gender distribution, and underlying etiology of visual impairment. Additionally, many VA hospital-based studies have been able to measure outcomes via randomized clinical trial, which is less likely than cohort studies to inflate results due to placebo and Hawthorne effects. These differences may qualify comparison between the mobile clinic and VA hospital LVR outcomes. Two VA hospital-based studies included in this analysis made use of a waiting list control (Stelmack et al., 2006b; Stelmack et al., 2008).

Outcomes seen in the VA Blind Rehabilitation Centre are substantially larger than those from the mobile clinic (Stelmack et al., 2006a). The LOVIT studies measured outcomes 4 months post-LVR and only enroled participants who had macular disease (Stelmack et al., 2008; Stelmack et al., 2016). Outcomes from the mobile clinic are smaller than those reported in LOVIT I (Stelmack et al., 2008), and similar to those from LOVIT II (Stelmack et al., 2016). Participants in LOVIT I were more severely impaired (visual acuity 0.7 – 1.4 log MAR; Snellen equivalent 20/100 – 20/500) than those enroled in LOVIT II (Stelmack et al., 2016) (visual acuity 0.4 – 1.0 log MAR, Snellen equivalent 20/50 – 20/200). With a mean acuity of 0.93 log MAR (20/170 Snellen equivalent) observed in the mobile clinic participants, degree of visual impairment is intermediate to the two LOVIT studies.

Mobile clinic LVR change scores at 3 months were retained 1-year post-LVR. Additionally, 59% of participants reported a subjective worsening of vision at 1 year, which was shown to

significantly affect outcomes in the domains of visual information, IADL, and outside the home. Device abandonment and clinical follow up schedules should be explored in consideration of these findings. Follow up LVR may be particularly important in patients whose ocular disease is progressive and likely to cause further decrease in visual function. The impact of follow up schedule has not yet been thoroughly explored, although a growing body of literature begins to show enhanced outcomes with additional non-optometric vision rehabilitation services (Acton, Molik, Court, & Margrain, 2016; Stelmack et al., 2016).

The high prevalence of glaucoma and retinitis pigmentosa in this sample led to analysis of LVR outcomes with respect to cause of visual impairment (i.e. central vision loss, peripheral vision loss, or a combination). However type of visual loss was not found to be a significant predictor of outcomes. This analysis has some limitations. Participants were assigned to groups based on etiology of visual impairment and presenting better eye visual acuity. Consequently, there is potential for error due to misclassification. Additionally, as Goldmann or automated visual field assessment is not possible on the mobile clinic, these data are not available for all participants. As such, the extent of visual field loss cannot be correlated with subjective outcome measures. This warrants further analysis and investigation.

In addition to the clinical outcomes produced, the mobile clinic was also successful at expanding access to LVR. The large proportion of participants who had no LVR experience prior to mobile clinic examination (47%) suggests that these patients would otherwise be unable to access LVR.

Strengths of this study include the use of the AI and Rasch analysis, as well as an adequate sample size and excellent participant retention 3 months post-LVR. Limitations include lower retention 1 year post-LVR. Also, participants enrolled in this study had severe visual impairment, and as such results in a sample with mild to moderate visual impairment may differ. Finally, randomization to a control group could not ethically be used in this study's design.

This work shows that mobile clinic LVR can produce outcomes comparable to those seen in other delivery models. Further research will explore device abandonment in patients receiving mobile clinic LVR.

CHAPTER 3: UTILIZATION AND ABANDONMENT OF LOW VISION DEVICES PRESCRIBED ON A MOBILE CLINIC

3.1. Abstract

Significance: Device utilization and abandonment for patients seen on a mobile clinic are explored. Findings are informative for resource allocation in a novel low vision rehabilitation (LVR) delivery model. This study also explores the relationships between device abandonment and LVR patient reported functional outcomes.

Purpose: This prospective cohort study investigates low vision device utilization and abandonment in a novel mobile clinic delivery model.

Methods: A device abandonment questionnaire was administered by telephone 3 months and 1 year post mobile clinic low vision rehabilitation (LVR). Participants (n=65) had previously met the U.S. definition of legal blindness, and were prescribed a total of 154 devices at their low vision consultative visits. Trends in device utilization and correlations with clinical and demographic participant characteristics, as well as functional outcomes as assessed by Massof Activity Inventory (AI), are explored.

Results: An average of 2.6 device recommendations were made per participant. Digital magnification, optical magnifiers, and filters were most frequently recommended. At 3 months 29% of participants abandoned at least 1 device, although only 14% of all device recommendations were abandoned. There was no significant difference in the number of devices used, abandoned, or not received at 3 months versus 1 year post-LVR. Devices prescribed for reading goals were most frequently used and least often abandoned, while

glare control and distance magnification devices were more frequently abandoned. Neither patient characteristics nor AI change score were predictive of device abandonment. There was no significant difference in the odds of device abandonment in comparison to a previous study, which assessed academic outpatient LVR clinics using the same questionnaire. Conclusions: While more device recommendations are given per patient on the mobile clinic, there is no significant difference in device abandonment for patients seen on the mobile clinic versus other outpatient LVR delivery models

3.2 Introduction

With the growing prevalence of age-related eye disease, demand for low vision rehabilitation has expanded(Chan et al., 2018). Studies have demonstrated meaningful low vision rehabilitation patient outcomes in multiple clinical settings (Goldstein et al., 2015; Stelmack et al., 2008; Stelmack et al., 2016). However, device utilization is not always considered when evaluating low vision rehabilitation intervention effectiveness. Recommendation of devices to help patients achieve visually mediated goals is a critical component of low vision rehabilitation, and device nonuse may preclude patients from experiencing the full benefits of low vision rehabilitation.

Few studies have assessed post-rehabilitation utilization of devices in an outpatient population. One study explored abandonment of near devices approximately 1 year post low vision rehabilitation optometric exam. Hand magnifiers were most frequently recommended, and 19% of all devices were abandoned (Dougherty et al., 2011). Another study examined perceived usefulness and frequency of use for optical devices prescribed to first-time low vision rehabilitation patients who had age-related macular degeneration. Devices were reported to be frequently used and beneficial, with few abandoned 1 week, 1 month, and 3 months after low vision rehabilitation (DeCarlo et al., 2012).

Visual function questionnaire data has more commonly been used to assess low vision rehabilitation outcomes. Studies have demonstrated clinical effectiveness using these questionnaires in Veteran's Affairs hospital-based programs(Stelmack et al., 2008; Stelmack et al., 2016) and private outpatient low vision rehabilitation clinics (Goldstein et al., 2015). However, visual function questionnaires do not evaluate device utilization, and functional

outcome studies have not examined whether device recommendations made during low vision rehabilitation were obtained, utilized, or abandoned. Consequently, the relationship between functional outcome and device use is largely unknown.

Recently, a novel mobile clinic delivery model has been used to provide low vision rehabilitation in areas with a scarcity of low vision providers. This mobile clinic traveled to central locations in different communities to provide low vision rehabilitation for patients who would otherwise lack access. Mobile clinic low vision rehabilitation has been shown to expand access to care while producing clinically meaningful outcomes, comparable to other outpatient low vision rehabilitation clinic delivery models (Gobeille, Malkin, Jamara, & Ross, 2018). However, device abandonment has not yet been examined in this sample. Since the mobile clinic travelled to many communities, this delivery model may pose unique challenges in implementation of rehabilitation plans, especially with respect to low vision device receipt and training with prescribed devices. Here, outcomes of device recommendations for mobile clinic low vision rehabilitation patients are investigated, exploring prescribing patterns, receipt, utilization, and abandonment.

3.3 Methods

3.3.1 Participant Enrollment

Enrollment took place between May 2015 and October 2016. Participants recruited for this study had previously been registered as legally blind according to 2014 U.S. Social Security standards (i.e. better eye visual acuity of worse than 0.70 log MAR (20/100 Snellen Equivalent) or visual field subtending less than 20 degrees in the widest diameter) and

scheduled for mobile clinic LVR when recruited. Participants had adequate hearing, English fluency, and cognitive function to provide consent and conduct telephone questionnaires. They also were at least 14 years of age. All patients scheduled for mobile clinic low vision rehabilitation during the study period (n=174) were contacted by telephone to determine interest in study participation. Interested participants were enrolled in the study if inclusion criteria were met and at least one device recommendation was provided during initial mobile clinic low vision rehabilitation examination (n=65). Written informed consent was obtained from all participants at the time of mobile clinic LVR. Further detail on enrollment is available in a previous publication (Gobeille et al., 2018). This study was approved by the New England College of Optometry Institutional Review Board and followed the tenets of the Declaration of Helsinki.

3.3.2 Mobile Clinic LVR Intervention

Mobile clinic low vision rehabilitation was delivered to provide usual low vision optometric care, consisting of low vision entrance testing (distance visual acuity, Mars contrast sensitivity, finger counting visual field assessment, Amsler grid), trial frame refraction, reading assessment, device evaluation, and ocular health assessment. Care was provided by final year optometry students in collaboration with one of the study authors (NCR, AGM, or RJ). Near magnification starting points were determined with participants wearing appropriate near correction using the inverse of the MNRead critical print size, identified by ear as the last line the patient read at maximum speed. Goal text size and distance acuity were used to determine distance magnification requirements. Final device recommendations were

determined based on patient goals, magnification requirements, and patient performance with devices evaluated during the mobile clinic examination.

Mobile clinic low vision rehabilitation examinations culminated in provision of recommendations for devices, spectacles, training, and follow-up examination. Devices were acquired through a grant administered by the state commission for the blind, and as such, were obtained by participants at no personal cost. A number of common optical devices were kept in stock on the mobile clinic (e.g. hand magnifiers, stand magnifiers, certain telescopes), and could be dispensed at the conclusion of the low vision rehabilitation examination. Due to state coverage policies and the grant structure in place, devices that cost more than $300.00 or were not in stock were requested through the usual approval process with the state commission for the blind. These devices, pending authorization, were delivered to participants at a later date.

3.3.3 Data Collection

Data were collected using a device abandonment questionnaire, which was previously found to be repeatable in low vision patients presenting to academic outpatient low vision rehabilitation clinics in the United States (Dougherty et al., 2011). The questionnaire was administered by telephone regarding a participant's use of a single device, and was thus administered multiple times to the same participant if he/she received multiple device recommendations. This questionnaire asked participants to report whether they had the device, how frequently it was used, what the device was used to do, and (if applicable) why they did not use the device. Demographic and clinical examination data (i.e. visual acuity,

Mars contrast sensitivity, age, and incoming diagnosis) were also collected during mobile clinic low vision rehabilitation examination.

Additional data were acquired through administration of a validated, psychometrically robust visual function questionnaire: the Massof Activity Inventory. The Activity Inventory was administered by telephone prior to low vision rehabilitation, 3 months post-rehabilitation, and 1 year post-rehabilitation. Data underwent Rasch analysis to generate measures of visual ability at each time point, allowing calculation of a change score (i.e. final visual ability minus baseline visual ability) (Massof et al., 2007). While further details regarding Activity Inventory outcome measurements and results in the mobile clinic population have been reported elsewhere (Gobeille et al., 2018), Activity Inventory results are examined here with respect to device use.

3.3.4 Data Analysis

The primary outcome measure in this study was device abandonment 3 months and 1 year post-rehabilitation. Secondary outcome measures included: device non-receipt, device utilization, and frequency of device use. Additional outcomes included the proportion of participants who benefitted from a spectacle prescription (i.e. subjective and/or objective improvement in vision after refraction) issued on the mobile clinic, spectacle abandonment, spectacle utilization, or spectacle non-receipt. The same statistical methods were used to assess outcome measures at 3 months and 1 year post-rehabilitation.

Summary statistics (e.g. totals, means) regarding the number of device recommendations, abandonment, use, or non-receipt were computed using Excel (https://office.microsoft.com/excel/). A two-tailed paired t-test at a 95% confidence level was

used to explore differences in the number of devices reported as abandoned at 3 months and 1 year.

A multiple linear regression was performed using R statistical software (https://www.r-project.org/) to explore predictors of device abandonment. Possible predictors included in this analysis were patient characteristics of age, visual acuity, contrast sensitivity, number of systemic comorbidities, and overall Activity Inventory change score. Pearson correlation coefficients were calculated for device abandonment in participants with central versus peripheral vision loss, and for device abandonment and prior low vision rehabilitation experience.

Odds ratios were calculated using Excel (https://office.microsoft.com/excel/) to determine the odds of a participant abandoning one or more device, as well as the odds of any mobile clinic device recommendation being abandoned. Odds were calculated in comparison with data extracted from Dougherty et al (2011). Confidence intervals at a 95% level were constructed to determine whether odds ratios were significant (i.e. confidence interval did not include 1).

3.4 Results

3.4.1 Participants and Recommendations

Participants (n=65) enrolled in this study had a mean better eye visual acuity of 0.93 log MAR (20/170 Snellen equivalent, median = 0.90 log MAR, interquartile range 0.49 – 1.09 log MAR) and a binocular Mars contrast sensitivity of 0.87 log CS ($\pm$0.40). Of those who enrolled, 11 qualified as legally blind based exclusively on visual field, 48 qualified based on

visual acuity, and 6 did not meet the definition of legal blindness upon presentation to the mobile clinic. These participants were allowed to continue in the study, but were also advised to follow up with their local eye care provider to ensure appropriate service eligibility.

Mean age was 72.5 years and 47% of participants received their first low vision rehabilitation examination on the mobile clinic. Participants in this analysis had an average of 2.4 systemic comorbidities, most often including heart disease, neurological disorder, or psychosocial disorder. Further detail of sample demographics has previously been reported[7].

Table 3.1: Number and Type of Devices Utilized at 3 Months and 1 Year

	3 Months				1 Year			
	Recommended	Abandoned	In Use	Never Received	Recommended	Abandoned	In Use	Never Received
Digital magnification	32	0	15	17	25	3	17	5
Filters	36	7	27	2	18	3	13	2
Hand magnifier	39	1	37	0	28	1	26	1
Optical Character Recognition technology	3	0	0	3	1	0	0	1
Smartphone app	2	1	1	0	1	1	0	0
Spectacle-based magnification	11	3	6	2	6	0	4	2
Stand magnifier	4	0	2	2	4	1	2	1
Telemicroscope/loupe	5	2	2	1	5	1	2	2
Telescope	19	7	9	3	11	6	2	3

Of those enrolled, 45% (n=29) benefited from a spectacle prescription. While most of these recommendations were provided to optimize distance vision (n=22), many participants (n=18) also benefitted from an age-appropriate add which provided minimal appreciable magnification but was useful for daily living tasks (e.g. seeing food on a plate, maintaining focus of computer or electronic magnifier screen). There was no significant association between lack of prior low vision rehabilitation and benefit from spectacle prescription *(P=.29, t=.77, df=62)*.

Recommendations for devices were provided to all participants, averaging 2.6 (median = 2, range 1-6) recommendations per participant. This is larger than the 1.4 device recommendations per participant seen in previous work (Dougherty et al., 2011). A total of 154 devices were recommended. Digital magnification, optical magnifiers, and filters were

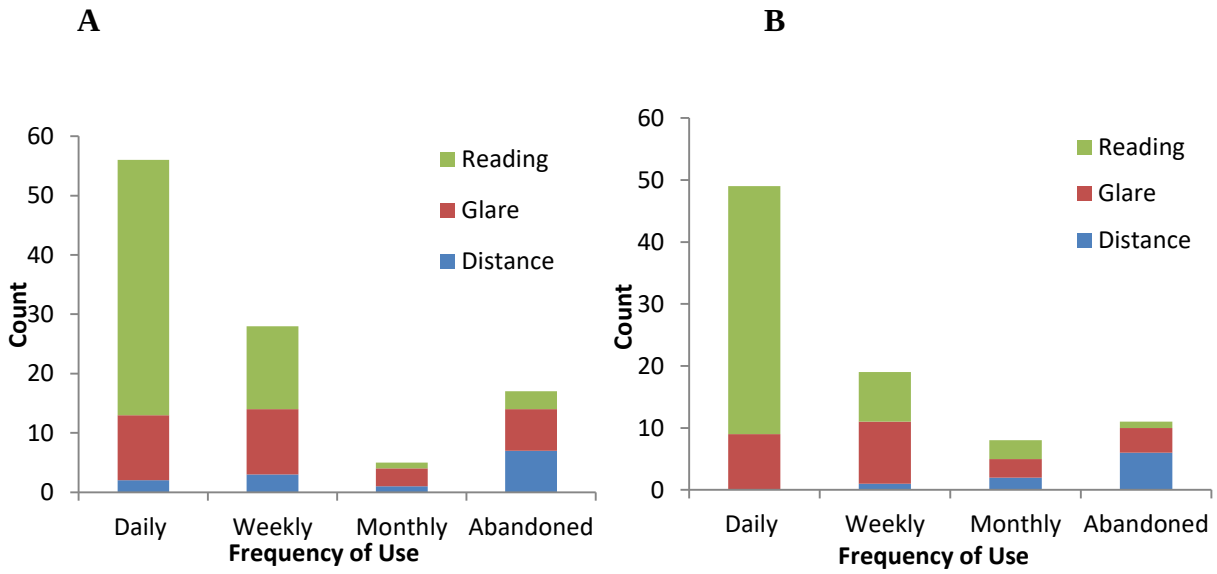

Figure 3.1: Frequency of Device Use
The number of devices used to achieve reading (green bar), glare control (red bar), and distance magnification (blue bar) goals are shown based on frequency of use at 3 months (panel A) and 1 year (panel B). At both time points, reading devices were used most frequently, most on a daily basis. Glare control and distance magnification devices were most frequently abandoned.

most frequently recommended, while optical character recognition technology and use of a smartphone app were less common (Table 3.1).

3.4.2 Utilization 3 Months After Low Vision Rehabilitation

At 3 months, 65 participants provided data about 151 devices. Most devices were actively in use (n=100, 66% of all recommendations) while some had not yet been received (n=30, 20% of all recommendations) and fewer devices had been abandoned (n=21, 14% of all recommendations). Of device recipients, 29% had abandoned 1 or more device. Overall, 17% of devices that were received by 3 months were also abandoned. Most devices that were prescribed for reading tasks (e.g. electronic or optical magnifiers) were used on a daily basis, and devices recommended for glare control or distance magnification accounted for most instances of abandonment (Figure 3.1).

No digital magnification devices were abandoned, with all either in use (n=15) or not yet received (n=17). All hand magnifiers had been received, with 37 actively in use and 1 abandoned. Of received devices, most spectacle-based magnification (n=6) and all stand magnifiers (n=2) were actively used. No optical character recognition technology had been obtained. While the majority of telescopes were in use at 3 months, they were also the most likely device to have been abandoned (Table 3.1).

Of the 29 spectacle prescriptions issued, 4 had been abandoned, while 13 (45%) were actively in use and 12 (41%) had not been obtained.

3.4.3 Utilization 1 Year After Low Vision Rehabilitation

One year post-rehabilitation device utilization was assessed across 51 participants regarding 99 devices. At one year, 68 devices were actively in use, while 15 had been abandoned and 16 were not yet received. Participants lost to follow up at 1 year tended to have more systemic comorbidities and poorer contrast sensitivity than the rest of the sample, but these differences did not achieve statistical significance. Devices recommended for reading were most commonly used daily, with infrequent abandonment. Distance magnification devices were most often abandoned, while devices providing glare control were most often used on a daily to weekly basis (Figure 3.2).

Digital magnification and hand magnifiers continued to be most frequently used 1 year post-low vision rehabilitation, with infrequent abandonment (3 digital devices abandoned and 1 hand magnifier abandoned). Stand magnifiers and spectacle-based magnification continued to be in use by most participants for whom they were recommended, while telescopes were more often abandoned than used or not received (Table 3.1). There was no significant difference at 3 months versus 1 year in the proportion of devices abandoned (P=.23, t=.82, df=16), used (P=.89, t=.38, df=16), or not received (P=.53, t=.60, df=16).

Of those who completed 1 year post-rehabilitation data collection, 14 had received spectacle prescriptions at their initial low vision rehabilitation examination. Abandonment occurred in 3 participants, while most actively used their new spectacles (n=7, 50%) or had never received or pursued them (n=6, 43%).

3.4.4 Predicting Abandonment

A multiple linear regression was used to determine if device abandonment could be predicted by age, visual acuity, contrast sensitivity, number of systemic comorbidities, or overall Activity Inventory change score. None of these variables were significantly predictive of device abandonment at 3 months or 1 year. Additionally, Pearson correlation coefficient testing showed that there was no significant difference in device abandonment for patients with central versus peripheral vision loss. A similar number of recommendations per patient was seen for patients with central (mean = 2.2, median = 2 recommendations per patient) versus peripheral (mean = 2.5, median =2 recommendations per patient) vision loss. A lack of prior low vision rehabilitation experience also was not predictive of device abandonment. Within the study period, 26 participants were advised to return for a follow up mobile clinic low vision rehabilitation examination. Of participants who were noncompliant with recommended follow up schedule (n=11), 36% abandoned one or more device at 3 months, while 55% abandoned at least one device 1 year post-rehabilitation. For those who complied with follow up recommendations (n=13), 38% abandoned at least one device at 3 months while 31% abandoned at least one device at 1 year. Additional devices were prescribed during follow up mobile clinic low vision rehabilitation for 2 participants due to changes in visual function or visual demands. One of these two participants was subsequently lost to follow up, while the remaining participant had received only one new device recommendation. Consequently, devices recommended at follow up were excluded from this analysis. A number of participants were also referred for additional training (i.e. 28 participants referred for orientation and mobility training, 16 referred for rehabilitation

therapy). The number of therapy sessions each participant received varied and was determined by the therapist who provided services.

3.4.5 Evaluation in Comparison to Previous Work

In comparing the likelihood of participants abandoning one or more device, those seen on the mobile clinic had greater odds of abandoning at least one device than participants enrolled in Dougherty et al (2011), although the difference was not statistically significant. This was true at both 3 months (odds ratio = 1.5, 95% CI: .72 – 3.14) and one year (odds ratio = 1.37, 95% CI: .62 – 3.05).

The odds of any device being abandoned during the mobile clinic study period versus in Dougherty et al's study (2011) were also determined. Similar odds were seen at 3 months (odds ratio=.93, 95% CI: .48 – 1.79) and 1 year (odds ratio=.97, 95% CI: .47 – 2.01) in comparison to Dougherty et al. There was no significant difference in overall device abandonment.

3.5 Discussion

This study found that abandonment occurred for 17% of received mobile clinic device recommendations at 3 months and 18% of received mobile clinic device recommendations at 1 year. Additionally, 29% of the mobile clinic study participants abandoned at least 1 recommended device. No significant difference in the odds of abandoning at least 1 device or of overall device abandonment was found in participants in the mobile clinic study versus participants in a study conducted in U.S. academic outpatient low vision rehabilitation clinics (Dougherty et al., 2011).

The similar abandonment found in these studies is surprising in consideration of differing patient characteristics and care accessibility in the two samples. While participant demographics were similar in age and primary cause of visual impairment, those enrolled in the mobile clinic study had more severe visual impairment and therefore may have greater need for devices. Additionally, limited access to low vision rehabilitation care was the hallmark of participants enrolled in the mobile clinic study, as patients were seen on the mobile clinic due to a severe lack of low vision providers in their communities. This is reflected in the 47% of participants who experienced their first ever low vision rehabilitation examination on the mobile clinic despite their moderate to severe visual impairment (Goldstein et al., 2012).

While inability to obtain low vision rehabilitation care and devices elsewhere would be expected to decrease the likelihood of abandonment, it also makes follow up low vision rehabilitation and training particularly challenging to implement, which could ultimately prevent successful device utilization. Providers may alter typical prescribing patterns and follow up protocol to best meet patient goals in a timely fashion, as the mobile clinic may not return to a given community for several weeks. This is reflected in the increased number of device recommendations per patient given on the mobile clinic versus in academic outpatient low vision rehabilitation clinics (Dougherty et al., 2011). The similarity in abandonment for patients seen on the mobile clinic versus other delivery models indicates that a modified management strategy may not have impacted successful device utilization. The lack of significant difference between abandonment and utilization of devices 3 months and 1 year

post-rehabilitation also suggests that follow up examination was appropriate, and sufficient training was provided to allow consistent device use over time.

Overall, the majority of recommended devices were received during the course of this study, with only 20% of devices at 3 months and 16% of devices at 1 year having never been received. Electronic magnifiers were the most likely device not to be received, despite the rarity of abandonment and the common report of daily use by participants who had received their device. In the U.K., research has found portable electronic magnifiers to be the device of choice for leisure reading in experienced optical magnifier users, and a cost-effective supplement to optical devices (Bray et al., 2017; Taylor et al., 2017). Together, these findings support the importance of electronic magnifier provision, even in a setting with limited financing.

Devices such as filters and telescopes, which were more often abandoned, may have been less successful due to certain limitations. Filters, while frequently used, were also frequently abandoned. Abandonment may be related to limited ability to evaluate filters in patients' natural environments. Often, local rehabilitation therapists or case workers from the commission for the blind adjusted filter recommendations as needed when providing care in patients' homes. This led to abandonment of the mobile clinic device despite replacing that device with one better suited to the patient's specific needs.

Telescopes were most often abandoned in this sample. However, telescopes were less commonly recommended than many other devices, with the majority of recommendations being for a full-field spectacle Galilean telescope that provides approximately 2x magnification and is designed for television viewing. While all subjects reported subjective

improvement with this approach during the clinical session, based on a mean visual acuity of 0.93 log MAR (Snellen equivalent: 20/170), this would only be expected to improve patients' visual acuity to 0.63 log MAR (Snellen equivalent: 20/85)(Faye, 2011). Thus there was perhaps inadequate reserve to achieve television viewing goals. Other telescope types (e.g. bioptic, monocular) were recommended too infrequently to enable sub-analysis in this sample. Further exploration of abandonment of devices which provide distance magnification would be informative.

In addition to low vision devices, spectacle prescriptions were issued on the mobile clinic. Improvement with refractive correction was common, with 45% of participants found to benefit from some form of distance and/or near correction. In this study, spectacles were considered beneficial if participants reported a subjective improvement, with or without a measurable improvement in visual acuity. Previous studies have used change in visual acuity to determine benefit from spectacle correction. However, the percent of participants experiencing a benefit from spectacle correction in this study was substantially larger than what has previously been reported(Sunness & El Annan, 2010), likely in part due to limited accessibility of low vision rehabilitation. Since the mobile clinic serves patients in areas with a scarcity of low vision rehabilitation providers, many participants may have not had a thorough refraction for some time.

While this study's strengths include its prospective design, use of a questionnaire previously found to give repeatable results (Dougherty et al., 2011), and good 3 month post-rehabilitation retention, it does have several limitations. There was a sizable decrease in the number of devices reported about at 1 year as some participants were lost to follow up.

Additionally, the questionnaire used in this study does not provide information about intensity and duration of use. The self-report data collected in this study is not objective, and is thus subject to recall bias. The small proportion of devices that were abandoned limits our ability to determine patient characteristics predictive of abandonment.

Another qualification that must be made regarding results involves financing of recommended devices. In the United States, low vision devices are not covered by major medical insurances, including Medicare. Participants in this study received devices through a grant administered by the state commission for the blind. Abandonment, therefore, may differ in populations which must pay out of pocket. However, our results' agreement with Dougherty et al (2011), in which participants likely purchased their own devices, suggest that this may not be the case.

This study shows that device abandonment in a mobile clinic population is similar to that previously assessed for outpatient low vision rehabilitation. Findings of this study contribute to our understanding of device recommendation effectiveness, which may be an important consideration for policy decisions regarding resource allocation in providing devices to low vision rehabilitation patients. In general, there was strong acceptance and utilization of devices, particularly those recommended for near tasks.

CHAPTER 4: GENERAL DISCUSSION, CONCLUSION, AND FUTURE DIRECTIONS

In this project, several different approaches were used to assess outcomes of low vision rehabilitation (LVR) delivered by mobile clinic. Collectively, these findings show that mobile clinic LVR is an effective means to expand access to LVR, and produces comparable functional outcomes and device abandonment to other outpatient LVR delivery models.

4.1. Clinical Outcomes

In our first study (Chapter 2, (Gobeille et al., 2018)) the Massof Activity Inventory (AI) was used to assess functional LVR outcomes. Person measures were significantly larger 3 months and 1 year post-LVR than at baseline across all AI domains and overall goals. Change scores were positive, and effect sizes were moderate to large. The majority of participants achieved a clinically meaningful outcome. There was no significant difference in these findings at 3 months versus one year, indicating retention of clinical outcome. Subjective report of worsening vision was a significant predictor for worse outcome measures post-LVR. Clinical effect size was found to be similar to other private outpatient LVR outcome studies, indicating that mobile clinic LVR is likely a clinically effective intervention.

Participants enrolled in this study were registered as legally blind with a mean visual acuity of 0.93 logMAR (20/170). Only six participants had mild to moderate visual impairment. Participants in this study with worse baseline visual ability had larger clinical outcomes, as they had more room for growth. This finding has also been observed in other study samples

(Stelmack et al., 2006a; Stelmack et al., 2016). It is possible that mobile clinic effect size would differ if more participants had mild to moderate visual impairment.

While our study enrolled a large number of participants with visual impairment due to constricted visual field, little is known about how constricted visual field interacts with visual ability. In our sample, early data analysis suggested that those with peripheral vision loss may have worse outcomes, but after controlling for baseline visual ability this finding was insignificant. Additionally, visual field was only able to be assessed by confrontation in this study. Further research could assess the impact of visual field constriction, ensuring that automated or manual visual field assessment is incorporated into the research protocol.

The impact of additional referrals also warrants further investigation. A study has shown clinical improvement through an occupational therapy based intervention (Acton et al., 2016). Additionally, LOVIT II shows enhanced outcomes with additional rehabilitative training only for those with severe vision loss (Stelmack et al., 2016). In the mobile clinic sample, it is likely that some of the observed clinical benefit could be attributed to additional training and therapy recommendations facilitated by the mobile clinic. However, the amount and type (e.g. orientation and mobility, rehabilitative therapy, technology assessment) of training provided varied according to usual care practices, and therefore the extent to which additional training contributed to outcomes cannot be discerned.

Research has not yet illustrated the ideal follow up schedule for LVR (Binns et al., 2017), and decisions of when patients should return for follow up LVR depends on provider preferences and individual patient characteristics. Many mobile clinic participants had

follow up mobile clinic LVR in the course of the study period. While these participants' outcomes did not significantly differ from those seen by participants who deferred follow-up care, it is unknown whether these participants would have better or worse outcomes with a different follow up schedule. Further research on this topic is needed.

Lastly, in our pilot project (Supplement 1), a rehabilitation halo was observed in which effect sizes were inflated when assessed 2 weeks post-LVR. This finding was previously seen in a Veterans' Affairs Hospital Blind Rehabilitation Center when outcomes were assessed prior to patients' return to the community. This is an interesting finding in a private outpatient LVR setting such as the mobile clinic. Optimal time frame to assess LVR intervention has yet to be determined. Studies have shown that attrition of rehabilitation effect starts about 2 months post-LVR and is worse 1 year post-LVR due to further decline in vision (Binns et al., 2017). In this project, the retention of clinical outcome from 3 months to 1 year suggests that sampling time was appropriate. Additionally, data collection timing was consistent with other major studies (Goldstein et al., 2015; Stelmack et al., 2008; Stelmack et al., 2016). However, further research could elucidate best practices.

4.2. Device abandonment

Device abandonment was also explored in this project. Mobile clinic participants abandoned devices at similar rates to participants in another study which investigated device abandonment in academic LVR clinics (Dougherty et al., 2011). However, more device recommendations were given per patient on the mobile clinic. Since the mobile clinic may not return to a community for several months, these additional recommendations allowed

participants' rehabilitative goals to be achieved more expediently without exacerbating abandonment rate.

The most successful device recommendations were for devices used for reading, such as hand and electronic magnifiers and spectacle-based magnification. Telescopes were most frequently abandoned. The great success of devices used for reading is unsurprising in a population whose most frequent presenting complaint is reading difficulty (Brown et al., 2014). The limited effectiveness of telescope recommendations may also relate to this. Since most participants had reading related goals, fewer telescopes were prescribed. Most prescribed telescopes targeted the goal of television viewing. Magnification prescribed for this goal often did not provide sufficient reserve to meet patients' expectations, although they reported a subjective improvement when evaluating television viewing telescopic glasses on the mobile clinic. Other telescope options (e.g. monocular, bioptic) were underrepresented in this sample. Telescope abandonment has not been well studied, but would be an interesting investigation. Often when telescopes are prescribed, additional training, especially orientation and mobility training, is helpful in promoting proficient use. Consideration of training recommendations would be important in further investigation.

Spectacle recommendations were also issued more often on the mobile clinic than is typically seen in LVR clinics (Sunness & El Annan, 2010). This is largely due to the limited care accessibility seen in the mobile clinic sample. While spectacle abandonment was uncommon, the number of participants who actively used their spectacles or deferred filling their prescription was similar. Perhaps prescriptions given on the mobile clinic were misplaced

before they could be filled. Alternatively, participants receiving spectacle prescriptions may have realized after further reflection that new glasses did not improve vision enough to warrant the cost of purchasing them. A better understanding of why participants did not fill their prescriptions would provide more useful information on the effectiveness of mobile clinic spectacle prescriptions in the low vision population.

While no participant factors were found to be predictive of device abandonment, abandonment was uncommon, with only 21 devices abandoned at 3 months and 15 devices abandoned at 1 year. It is plausible that if more devices were abandoned, trends would emerge. A larger sample size would be useful in determining if this is the case. While it could be hypothesized that those with worse outcomes would be more likely to abandon devices, functional outcome as assessed by AI was not predictive of abandonment in this sample.

4.3. Access to Care

Mobile clinic LVR expanded access to care, enabling many with no prior LVR experience to utilize beneficial services. During the course of this study, 174 legally blind patients were seen on the mobile clinic, and 47% of the 66 study participants had their first LVR examination on the mobile clinic. Additionally, receiving care on the mobile clinic saved participants approximately three hours of round trip travel time, in comparison to traveling to Boston for LVR (Supplement 2). In a population with travel limitations in which many depend on caregivers to provide transportation to appointments, this likely has an important impact in lessening geographical barriers to care.

Further analysis should look at ways to continue providing care in these communities without the mobile clinic. Additional options which warrant consideration include establishing satellite clinics within communities to be staffed by previous mobile clinic providers or local providers. During mobile clinic operations, doctors in the community received post-professional training and mentorship from mobile clinic providers. While training providers in the community to provide LVR would be an obvious and sustainable solution, feasibility and local provider interest are not guaranteed.

4.4. Discussion

Overall, further research is warranted about mobile clinic LVR as well as functional LVR outcomes and device abandonment as a whole. Since outcome measures have been shown to differ in patients with different levels of visual impairment, it would be useful to determine how mobile clinic outcomes compare in a mildly to moderately impaired sample.

Further outcomes studies could assess the impact of visual field constriction and LVR follow up protocol on LVR outcomes. Additionally, further work could determine optimal data collection timing. Device abandonment should be assessed in a larger sample so that enough devices will be abandoned to enable analysis of patient factors predictive of abandonment. Methods to objectively measure device use would also be useful to avoid bias inherent in self-reported data. Telescope utilization and abandonment, and how these interact with additional training, would also be an interesting area of focus.

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SUPPLEMENT 1: PILOT PHASE

S1.1. Introduction

Assessing outcomes of low vision rehabilitation (LVR) delivered by a mobile clinic poses logistical challenges. As participants live distantly from LVR providers, data must be collected remotely, making in-person recruitment implausible. As such, a pilot project was designed to ensure successful enrollment and data collection. Outcomes were assessed soon after LVR to more expediently inform study design.

Research detailing the impact of timing on patient reported outcome measures is limited to one study which assessed outcomes upon discharge from a VA Blind Rehabilitation Center (BRC). A “rehabilitation halo” was detected: participants were questioned too soon after LVR and overestimated their abilities due to a lack of experience using new tools and techniques in a natural home environment (Stelmack, Babcock-Parziale, et al., 2006). This finding has not been observed elsewhere, although most studies do not assess outcomes so soon after LVR.

As pilot phase data from the mobile clinic became available, trends in patient outcomes related to time of assessment became apparent. As such, this pilot project analysis explores trends in clinical outcome measures related to timing of Activity Inventory (AI) administration from participants who enrolled in the early pilot phase.

S1.2. Methods

The early pilot phase of this study enrolled participants between May 29th and July 31st of 2015. Participants enrolled in the study met all inclusion and exclusion criteria for other components of this project (as outlined in Chapter 2 (Gobeille et al., 2018)), but consented to complete AIs prior to LVR, 2 weeks after LVR, and 3 months after LVR. Participants involved in the pilot project later agreed to transition to the final study protocol, completing a fourth AI 1 year after LVR.

Rasch analysis was used to estimate visual ability. Change scores and measures of clinical effect (i.e. MCID, Cohen's "d" effect size) were calculated. Further details regarding these methods are provided in Chapter 2.

Data analysis was conducted using non-parametric statistical testing, as data from our small sample (n=12) was not normally distributed. Consequently, a two-tailed Wilcoxon Rank Sum test was used when indicated. Statistical testing was conducted with a 0.05 significance level.

S1.3. Results

Of the 12 participants enrolled in the early pilot phase, 1 was lost to follow up. Consequently 11 participants are included in this analysis. Participants had a median age of 69, ranging from 21 to 92 years. Median binocular visual acuity was 1.10 logMAR, and ranged from 0.50 to 2.30 logMAR. Contrast sensitivity ranged from being worse than 0.04

Table S1.1: Baseline Participant Characteristics

	Median (Range)
Age	69 (21-92)
Visual Acuity (logMAR)	1.1 (0.50-2.30)
Contrast Sensitivity(log CS)	0.84 (<0.04-1.36)
First Exam on Mobile Clinic	50%

logCS (profound CS loss, per Mars Contrast Sensitivity Test User Manual) to 1.36 logCS (moderate CS loss), with a median value of 0.84 logCS (severe CS loss). First low vision exams were experienced on the mobile clinic for 50% of participants (Table S1.1). Participants' primary ocular diagnoses were varied, but included retinitis pigmentosa (n=4), glaucoma (n=3), age related macular degeneration (n=3), and ischemic disorders affecting the eye or brain (n=2). Systemic comorbidities reported in this population included type two diabetes, hypertension, atrial fibrillation, fibromyalgia, depression, osteoarthritis, osteoporosis, asthma, anxiety, and post-traumatic stress disorder.

The median baseline goal person measure was -0.58 logits, with an interquartile range from -0.51 to -1.11 logits. The AI has a mean goal item measure of -0.17 logits with a standard deviation of 0.66 logits (Massof et al., 2007). Since the median baseline person score is within 1 standard deviation of the mean item measure, the AI is an accurate measurement tool for this population, and results should not be impacted by floor or ceiling effects due to poor targeting..

Table S1.2: Cohen's d Coefficient

AI Domain	2 week	3 month	1 year
Goals	2.64	0.89	0.96
IADL	1.10	0.77	0.38
Inside the home	1.18	0.84	0.43
Mobility	0.95	0.53	0.10
Outside the home	0.57	0.68	0.14
Reading	0.78	0.66	0.32
Visual information	1.00	0.29	0.32
Visual motor	1.25	1.18	0.53

Table S1.3: Percent Achieving MCID

AI Domain	2 week	3 month	1 year
Goals	100%	92%	55%
IADL	75%	58%	27%
Inside the home	75%	75%	27%
Mobility	58%	25%	18%
Outside the home	25%	50%	27%
Reading	58%	42%	36%
Visual information	67%	33%	27%
Visual motor	75%	67%	36%

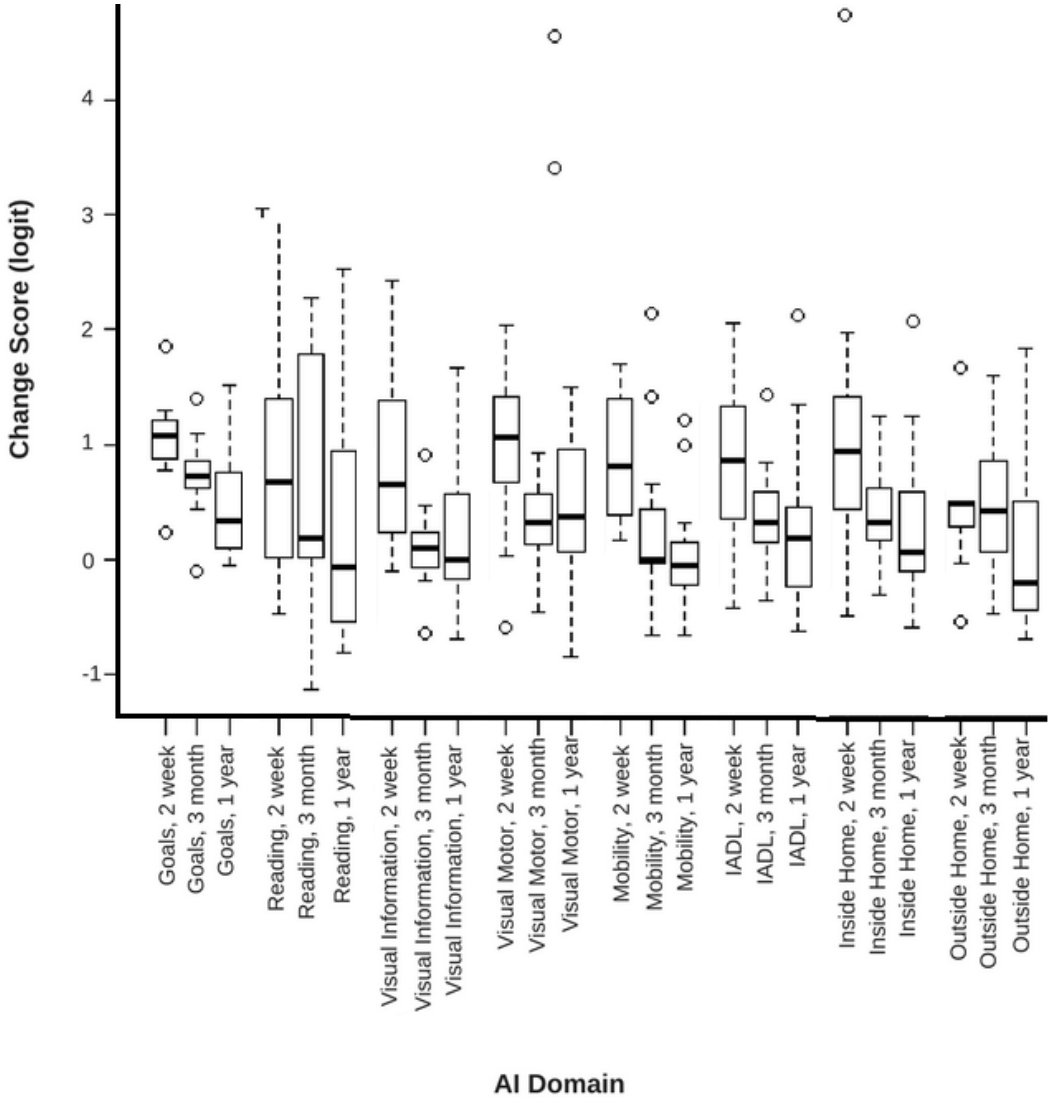

Figure S1.1: Change Scores at Each Time Point
Box plot of change scores at 2 weeks, 3 months, and 1 year post-LVR. Change scores at 2 weeks have larger median values than those seen at 3 months and 1 year. Interquartile range tends to be smallest at 3 months across most domains (i.e. overall goals, visual information, IADL, inside home)

Two week outcomes yielded high results for both MCID and Cohen's effect size despite the limited proportion of participants (36%, n=4) who had received all VAE at 2 week follow up. At 2 weeks all participants (n=11) experienced MCID in overall goals (Table S1.3). The smallest number (n=2) experienced MCID outside the home, while the most common domains to experience MCID were IADL, inside the home, and mobility (n=8). Change score was largest for overall goals (1.08 logit median) and smallest for the outside the home domain (0.48 logit median) (Figure S1.2). Similarly, Cohen's effect size (Table S1.2) showed the largest magnitude of clinical effect for overall goals (d=2.64) and the smallest for outside the home (d=0.57). Cohen's d coefficient revealed a moderate to large clinical effect at 2 week follow up.

MCID and Cohen's effect size revealed moderate to large outcomes from LVR at 3 months, when 63% (n=7) had received all VAE. As seen in Table S1.3, MCID was most often achieved in overall goals (n=10). Of domains examined, mobility showed the least frequent MCID (n=3), while inside the home was the most common (n=8). Change scores were largest in overall goals (0.45 logit median) and smallest in mobility (0 logit median) (Figure S1.2). Cohen's d measures (Table S1.2) were more moderate, with a maximum for overall goals (d=0.89). Of domains, d coefficients were smallest for visual information (d=0.29) and largest for visual motor (d=1.18).

At one year, measures of clinical effect continued to be smaller than at 2 weeks. At this time, 82% (n=9) of participants had received all VAE. MCID was most often achieved in overall goals and visual information (n=6), and least frequently achieved in mobility (n=3) (Table

S1.3). Change scores were largest in visual motor (0.53 logit median) and smallest in outside the home (0.14 logit median) (Figure S1.2).The largest clinical effect was seen in overall goals (d=0.96) followed by visual motor (d=0.53). The smallest occurred in the outside the home domain (d=0.13) (Table S1.2).

In comparing outcomes from different follow up time points, measures were notably larger at 2 weeks versus 3 months and 1 year, with no data set being normally distributed (Figure S1.3). Despite this lack of normalcy, overall change scores appear to be more narrowly distributed at 3 months than at 2 weeks or 1 year (Figure S1.2, Figure S1.3). Wilcoxon signed

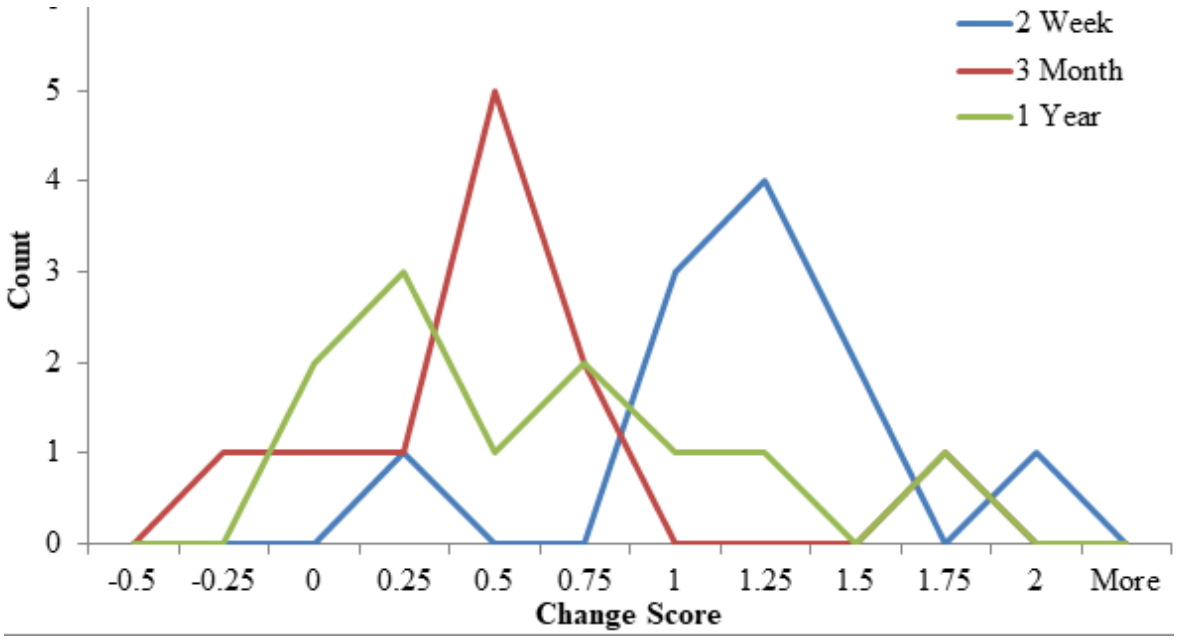

Figure S1.2. Histogram of Overall Visual Ability Change Score
The distribution of change scores at 2 weeks (blue line), 3 months (red line), and 1 year (green line) are shown. At two weeks, a median change score of 1.08 logit (IQR 0.87 – 1.21 logit) was observed, while at 3 months a median change score of 0.45 logit (IQR 0.29-0.50 logit) was observed, and at one year a median change score of 0.27 logit (IQR 0.10 – 0.76 logit). The distribution of change scores appears to be most narrowly distributed at 3 months. Based on Wilcoxon signed rank analysis, change scores were significantly different (p=0.028) at 2 weeks versus 3 months, but there was no significant difference between 3 months and 1 year (p=0.59).

rank hypothesis testing revealed a significant difference in overall visual ability change scores at 2 weeks versus 3 months (p=0.028), and no significant difference was observed between 3 month and one year change scores (p=0.59). Mean MCID and Cohen's d coefficient for each AI domain were also analyzed and compared between follow up time points. At two weeks we noted a trend towards higher MCID in several domains (visual information, mobility, IADL), visible in Table S1.3. A difference was noted between Cohen's effect size at 2 weeks versus 3 months, with 3 month data showing a smaller clinical effect than 2 week data (Table S1.2). Interestingly, the outside the home domain did not follow this trend, and measured slightly higher at 3 months than 2 weeks (d=0.57 versus d=0.68) (Table S1.2). Cohen's d coefficient was substantially smaller at 1 year in comparison to 2 weeks in all domains, as well as for overall goals.

S1.4. Discussion

Based on analysis of pilot study data, LVR delivered via mobile clinic produces a moderate to large clinical effect, yielding clinically meaningful outcomes in a large majority of participants. A greater change in visual ability is observed at 2 weeks than at 3 months, and clinical effect is considerably smaller at 1 year. The comparison of 2 week versus 3 month outcomes suggests that 2 week follow up produces artificially high measures of clinical effect. Factors that likely impacted these measurements include a delay in device receipt and a rehabilitation halo effect.

A rehabilitation halo effect in overall visual ability was reported by Stelmack et al in a population being discharged from an intensive VA BRC program (Stelmack, Babcock-

Parziale, et al., 2006). Measurements were taken at discharge, and participants significantly overestimated their own abilities. A similar trend of overestimated abilities was seen in our 2 week data. While our sample is similar to the population recruited by Stelmack et al in being legally blind and having expenses from LVR covered by a government agency (Veteran's Affairs and Massachusetts Commission for the Blind respectively), it also differs in the barriers to care experienced, the care delivery model (inpatient versus mobile clinic), and follow up timeframe (upon discharge versus 2 weeks post-LVR). Regardless of the exact cause of our rehabilitation halo finding, it is interesting to note that rehabilitation halos are not a finding that is unique to the VA BRC. This finding was also important in our study design, prompting us to modify the follow up timeframe to involve AIs 3 months and 1 year after LVR, eliminating the 2 week time point.

While changes in overall visual ability were greater at the two week time point, this was not true for all functional domains. As it often takes longer than 2 weeks for participants to obtain recommended VAE or training, we expect that some measures of clinical effect may be low 2 weeks after LVR, when participants have not yet received the full benefit of LVR. This may explain outside the home domain data, which showed more frequent clinical effectiveness at 3 months, and a trend of a slightly larger, if not significantly different, clinical effect at 3 months. This theory is supported in that the outside the home domain includes many tasks which emphasize orientation and mobility. Since orientation and mobility training with an instructor takes some time to impact outcomes, changes from such an intervention would more likely be seen at 3 month and 1 year than 2 week follow-up.

Since overall visual ability and most domains do not show greater effect at 3 months, another factor must overcome this trend.

Overall, this pilot study showed that using the AI to assess LVR functional outcomes from a mobile clinic is feasible. Inflated measures of clinical effect were observed 2 weeks post-LVR, suggesting modifications in follow-up protocol to better assess outcomes.

SUPPLEMENT 2: ECONOMIC FEASIBILITY ANALYSIS

S2.1. Introduction

Visual impairment and blindness have severe economic consequences, annually leading to expenditures of approximately $5.5 billion on medical and informal care as well as a loss of 209,000 quality-adjusted life years (QALYs) (Frick et al., 2007). While the clinical effectiveness of low vision rehabilitation (LVR) is well established (Stelmack et al., 2006a; Stelmack et al., 2008; Goldstein et al., 2015), numerous studies have been unable to measure change following LVR via health utility (Malkin et al., 2012; Malkin et al., 2013). This complicates analysis of LVR cost effectiveness. One successful Veteran's Affairs (VA) hospital-based economic analysis noted greater clinical outcomes and lower cost in Low Vision Intervention Trial (LOVIT) protocol LVR versus Blind Rehabilitation Center (BRC) LVR (Stroupe et al., 2008). However, cost effectiveness in other LVR delivery models has yet to be determined.

Many people with visual impairment have transportation limitations which may impact their abilities to access care (DeCarlo, Scilley, Wells, & Owsley, 2003; Iezzoni et al., 2006; Chan, Fujiyama, & Rubin, 2015). In the state of Massachusetts, LVR providers are most densely distributed in metropolitan areas, leaving those who live more distantly with significant barriers to care. Thus, a mobile clinic was implemented to deliver LVR state-wide. This two lane optometry clinic traveled to central locations in various counties, allowing decreased travel time for patients and their caregivers. We have found this delivery model to produce clinically meaningful outcomes (Chapter 2 (Gobeille et al., 2018)). However, the costs and

benefits of mobile clinic LVR must be further explored to determine whether bringing care to patients' communities via mobile clinic is a practical and economically feasible solution.

S2.2. Methods

S2.2.1. Economic Costs

Direct and indirect clinic costs were calculated per day based on fiscal year 2016 expenses. It was assumed that the clinic was operating at full capacity (10 new exams per day). Travel time, support staff, and overhead contributed to overall cost. Further breakdown of these costs is detailed in Table S2.1.

Table S2.1: Mobile Clinic Costs

Travel Time • Patient and caregiver • Practitioner
Support Staff • Driver • Patient Care Coordinator
Overhead • Insurance • Maintenance • Fuel
Cost of Care • Medical insurance • Goods sold

Participants enrolled in this study were registered as legally blind, and therefore qualified for visual assistive equipment through a grant administered by the state commission for the blind. Therefore, direct and indirect patient costs were limited to cost for service delivery and travel. Mobile clinic LVR exams are billed to medical insurance. Insurance copay information is unavailable, but this would be consistent for any LVR delivery model and therefore is not specific to mobile clinic economic feasibility.

Participant travel time was calculated using google maps. The 2016 federal mileage rate of $0.54 per mile was applied to the number of miles traveled for each participant. Many

patients who utilized mobile clinic LVR required advanced management strategies or had activity of daily living limitations which necessitated advanced LVR management. Since most Massachusetts clinics providing specialty LVR are located in or around Boston, travel time to the New England College of Optometry Center for Eye Care was used to compare travel time and expense.

S2.2.2. Economic Benefit

Estimates of daily reimbursement per exam were calculated from account review. Reimbursement for refraction is highly variable and not specific to mobile clinic LVR. As such, it was excluded from this analysis. Additionally, due to the structure of the mobile clinic support grant, device sales did not generate revenue in this setting, which is unique to our clinic but not to mobile clinic LVR.

S2.2.3. Analysis of Clinical Benefit

Clinical benefit was assessed in the subset of mobile clinic patients who enrolled in our mobile clinic outcome study (Gobeille et al., 2018) between May 2015 and October 2016. Measurement of LVR outcome was completed through administration of the Massof Activity Inventory (AI) and calculation of measures of clinical effect (e.g. Cohen's d coefficient) based on AI change scores from baseline versus 3 months and 1 year post-LVR. Further details on these research methods are provided in Chapter 2

S2.3. Results

S2.3.1. Travel time

When a mobile clinic was used to deliver LVR, the provider traveled an average of 181.5 miles roundtrip, or 206.7 minutes (Table S2.2). Patients' average travel distance to the central mobile clinic location was 11.4 miles. Average roundtrip travel time was 39.2 minutes. Consequently, the patient and his or her caregiver spent 129.2 minutes traveling to and attending the mobile clinic examination.

Table S2.2: Provider Versus Participant Round Trip Travel Time Costs

	Provider	**Participant**
Miles	**181.5**	**22.8**
Minutes	**206.7**	**39.2**
Cost		**$12.36**

In contrast, roundtrip travel to a clinic in Boston would take an average of 210 minutes. When the time spent attending the examination is accounted for, this would amount to 300 total minutes. This is significantly longer than the travel time to the mobile clinic ($p>>0.001$).

S2.3.2. Assessment of Cost

Overall, it would cost $1,832.00 to operate the two exam lane mobile clinic for one day. Provider travel costs are implicitly included in this amount, accounting for $98.00 of the total. Additional roundtrip travel costs were incurred by patients, averaging $12.36 per patient per day (i.e. $123.60 total per day).

If a patient needed to travel to Boston for LVR, total patient travel expenses would be $744.40 (i.e. for 10 patients to travel) and provider travel costs would be negligible. This makes travel costs $522.80 more expensive than the mobile clinic LVR delivery model.

S2.3.3. Economic and Clinical Benefit

Average revenue generated per LVR examination at NECO Center for Eye Care locations including the mobile clinic was $107.00. As a full day of mobile clinic operation included time slots for 10 low vision examinations, $1,070.00 would be generated per day.

Clinical outcomes three months post-LVR revealed an overall Cohen's effect size of 1.12. One year Cohen's effect size was 0.74. These outcomes reveal a large clinical effect, and are similar to the 0.87 overall effect size reported in the Low Vision Rehabilitation Outcome Study (Goldstein et al., 2015).

S2.3.4. Benefit of Coverage

During fiscal year 2016, the mobile clinic provided LVR on 24 days, serving 174 different patients. The mobile clinic traveled to one of 9 different locations which had been identified as having a high prevalence of visual impairment with few local LVR providers available (See Chapter 1, Figure 1.4). Of patients who enrolled in the study, 47% experienced their first LVR examination on the mobile clinic.

Mobile clinic LVR also expanded access to care through educational endeavors, growing human resources to meet demand for services. The mobile clinic was involved in the training of 54 senior optometric student interns. An additional 36 post-graduate education events provided training for optometrists, occupational therapists, certified rehabilitation therapists, and orientation and mobility instructors. An additional optometrist who is based in Western Massachusetts (approximately 150 minute drive from Boston) received extensive LVR

training on the mobile clinic, and now provides 6 low vision examinations per month in his community.

S2.4. Discussion

In a mobile clinic LVR delivery model, the burden of travel time and expense is largely shifted from patient to provider. Each patient spends approximately 3 fewer hours traveling to and receiving LVR. With a significant decrease in travel time, the patient and caregiver have less need to alter their daily activities to attend an appointment. They may therefore be able to miss fewer work hours to attend LVR, resulting in a decrease in lost wages and productivity.

Financial analysis of mobile clinic LVR shows that per day cost ($1,832.00) is greater than the average daily amount of revenue generated from exams ($1,070.00). However, income is not limited to exam reimbursement in most clinical models. Reimbursement for refraction would also generate revenue, although the amount would vary widely across patients depending on insurance status. While the NECO mobile clinic did not sell devices, goods sold could also be a reliable source of income. Overall, our calculations underestimate possible mobile clinic revenue. This financial analysis also does not incorporate the substantial overall savings associated with travel time for mobile clinic LVR.

In addition to the clear positive clinical outcomes that have been demonstrated in our mobile clinic outcomes analysis (Chapter 2,(Gobeille et al., 2018)), the mobile clinic is beneficial in delivering otherwise inaccessible services. With nearly half of participants reporting no prior LVR experience, it is evident that the mobile clinic reaches patients who would otherwise be

unable to utilize LVR care. Additionally, the mobile clinic's role in educating students and post-graduate providers works to expand access to care by developing the human resources needed to deliver LVR in distant communities.

This analysis has several limitations. First, no comparison group could be used, as variability in cost per square foot would skew results. As such, the cost effectiveness of mobile clinic LVR may differ by geographic location. Additionally, start-up costs are not considered here. Finally, the NECO mobile clinic served Massachusetts, a relatively small state with high population density. In areas where people's homes are more sparsely distributed, mobile clinic LVR may be less feasible. As such, conclusions regarding mobile clinic economic feasibility may not generalize to all areas of the country.

This analysis demonstrates that mobile clinic LVR produced clinical outcomes comparable to the general outpatient LVR population and was economically feasible in the state of Massachusetts. Further work could evaluate how mobile clinic cost effectiveness compares to other care delivery models designed to reduce geographical barriers to care, such as satellite clinics or telerehabilitation.

APPENDIX 1: MASSOF ACTIVITY INVENTORY

Massof, R. W., Ahmadian, L., Grover, L. L., Deremeik, J. T., Goldstein, J. E., Rainey, C., Barnett, G. D. (2007). The Activity Inventory: an adaptive visual function questionaire. *Optometry and Vision Science, 84*(8), 763-774.

How important is it for you to use the restroom in a public place without anyone else's assistance?

How difficult is it for you to use a restroom in a public place without anyone else's assistance?

How difficult is it for you to find a restroom in a public place?

How difficult is it for you to find the toilet or urinal in a public place?

How difficult is it for you to find the toilet paper?

How difficult is it for you to use the sink in a public restroom?

How difficult is it for you to find the soap or soap dispenser?

How difficult is it for you to find the paper towel dispenser or hand dryer?

How important is it for you to groom yourself; shave, trim nails, apply makeup, etc., without anyone else's assistance?

How difficult is it for you to groom yourself; shave, trim nails, apply makeup, etc., without anyone else's assistance?

How difficult is it for you to safely get in and out of the tub?

How difficult is it for you to fill the tub?

How difficult is it for you to find the soap?

How difficult is it for you to avoid falling in the tub or shower?

How difficult is it for you to find towels or washcloth?

How difficult is it for you to brush and floss your teeth?

How difficult is it for you to clean your dentures?

How difficult is it for you to care for your skin?

How difficult is it for you to shave?

How difficult is it for you to trim your nails, manicure, pedicure?

How difficult is it for you to apply makeup?

How difficult is it for you to comb, brush or style your hair?

How difficult is it for you to find or match jewelry or accessories without the assistance of another person?

How difficult is it for you to find the bathroom at night?

How important is it for you to choose your clothes and dress yourself without anyone else's assistance?

How difficult is it for you to choose your clothes and dress yourself without anyone else's assistance?

How difficult is it for you to find clothes in the closet?

How difficult is it for you to button clothes?

How difficult is it for you to tie shoes?

How difficult is it for you to find clothes in drawers?

How difficult is it for you to knot ties or scarves?

How difficult is it for you to choose matching clothes?

How difficult is it for you to fasten zippers, clasps, or hooks?

How important is it for you to take care of your health without anyone else's assistance?

How difficult is it for you to take care of your health without anyone else's assistance?

How difficult is it for you to identify medications?

How difficult is it for you to read medication labels?

How difficult is it for you to read medication instructions?

How difficult is it for you measure liquid medications?

How difficult is it for you to use eye drops?

How difficult is it for you to use sprays?

How difficult is it for you to take pills?

How difficult is it for you to see pills or capsules?

How difficult is it for you to fill a syringe?

How difficult is it for you to give yourself injections?

How difficult is it for you to read a bathroom scale?

How difficult is it for you to measure your blood pressure?

How difficult is it for you to measure your glucose levels?

How difficult is it for you to inspect your skin for sore?

How difficult is it for you to read nutritional information on food packaging?

How difficult is it for you to exercise?

How difficult is it for you to measure your blood sugar level?

How difficult is it for you to read a thermometer?

How difficult is it for you to take care of your contact lenses?

How difficult is it for you to check wounds?

How difficult is it for you to care for toileting needs that involve catheters?

How difficult is it for you to perform home dialysis?

How difficult is it for you to care for your prosthesis?

How important is it for you to eat your meals without anyone else's assistance?

How difficult is it for you to eat your meals without anyone else's assistance?

How difficult is it for you to see food on the plate?

How difficult is it for you to drink without spilling?

How difficult is it for you to see the food on your utensils?

How difficult is it for you to eat without dropping food?

How difficult is it for you to locate items on the dinner table?

How important is it for you to prepare your daily meals without anyone else's assistance?

How difficult is it for you to prepare your daily meals without anyone else's assistance?

How difficult is it for you to read recipes?

How difficult is it for you to transfer liquids without spilling?

How difficult is it for you to read timers or clocks?

How difficult is it for you to read settings on kitchen appliances without the assistance of another person?

How difficult is it for you to find utensils?

How difficult is it for you to measure ingredients?

How difficult is it for you to read labels on packages, cans, or bottles?

How difficult is it for you to read stove or oven dials?

How difficult is it for you to avoid cutting yourself?

How difficult is it for you to find food items?

How difficult for you is it to pour or mix without spilling?

How difficult is it for you to read a thermometer?

How difficult is it for you to avoid burning yourself?

How difficult is it for you to judge browning or doneness of food?

How difficult is it for you to cut, chop, or dice food?

How important is it for you to perform everyday household tasks such as cleaning, laundry, or setting a thermostat without anyone else's assistance?

How difficult is it for you to perform everyday household tasks such as cleaning, laundry, or setting a thermostat without anyone else's assistance?

How difficult is it for you to read the controls on a washer or dryer?

How difficult is it for you to sort clothes?

How difficult is it for you to detect stains or soils on clothes?

How difficult is it for you to read laundry or cleaning product labels?

How difficult is it for you to read washing instruction labels on clothing?

How difficult is it for you to measure powders or other laundry or cleaning products?

How difficult is it for you to iron clothes?

How difficult is it for you to mend clothes?

How difficult is it for you to thread a needle?

How difficult is it for you to sew a hem?

How difficult is it for you to sew on a button?

How difficult is it for you to wash dishes?

How difficult is it for you to clean floors?

How difficult is it for you to clean counter surface?

How difficult is it for you to vacuum?

How difficult is it for you to make or change beds?

How difficult is it for you to dust or polish furniture?

How difficult is it for you to hammer a nail?

How difficult is it for you to turn a screw?

How difficult is it for you to change a fuse or reset a circuit breaker?

How difficult is it for you to set and clear the table?

How difficult is it for you to read and set the thermostat?

How difficult is it for you to set your alarm clock?

How difficult is it for you to find the correct key?

How difficult is it for you to insert the key in the lock?

How difficult is it for you to read a tape measure or ruler?

How difficult is it for you to see diagrams or blueprints?

How difficult is it for you to identify screw, nails, bolts, or nuts?

How difficult is it for you to read manuals and directions?

How difficult is it for you to repair appliances or engines?

How difficult is it for you to perform general household tasks (painting, washing windows, etc.) without the assistance of another person?

How important is it for you to recognize people, see expressions, and make eye contact during personal communications?

How difficult is it for you to recognize people, see expressions, and make eye contact during personal communications?

How difficult is it for you to see facial expressions during personal communications?

How difficult is it for you to see gestures during personal communications?

How difficult is it for you to see body language during personal communications?

How difficult is it for you to recognize people during personal communications?

How difficult is it for you to understand people during personal communications?

How important is it for you to read mail and write letters without the assistance of another person?

How difficult is it for you to read mail and write letters without the assistance of another person?

How difficult is it for you to write letters?

How difficult is it for you to sign your name?

How difficult is it for you to read handwritten mail?

How difficult is it for you to read typed or printed mail?

How difficult is it for you to see photographs?

How difficult is it for you to read email messages?

How difficult is it for you to write email messages?

How important is it for you to follow the news and keep up with current events?

How difficult is it for you to follow the news and keep up with current events?

How difficult is it for you to read a magazine table of contents?

How difficult is it for you to read a syndicated newspaper column?

How difficult is it for you to read TV listings?

How difficult is it for you to read obituaries?

How difficult is it for you to read magazine articles without the assistance of another person?

How difficult is it for you to read sports statistics?

How difficult is it for you to read stock pages?

How difficult is it for you to read classified ads?

How difficult is it for you to read the comics?

How difficult is it for you to read newspaper articles?

How difficult is it for you to read newspaper weather information?

How difficult is it for you to watch TV?

How difficult is it for you to listen to the radio?

How important is it for you to read the time and follow a schedule?

How difficult is it for you to read the time and follow a schedule?

How difficult is it for you to read a clock?

How difficult is it for you to read handwritten notes?

How difficult is it for you to read a watch?

How difficult is it for you to read calendars?

How important is it for you to pay bills, balance accounts, or manage personal or household finances?

How difficult is it for you to pay bills, balance accounts, or manage personal or household finances?

How difficult is it for you to read bills?

How difficult is it for you to balance a checkbook?

How difficult is it for you to write checks?

How difficult is it for you to use a calculator?

How difficult is it for you to file tax forms?

How difficult is it for you to read bank statements?

How difficult is it for you to read financial statements and reports?

How difficult is it for you to use a computer?

How difficult is it for you to read stock pages?

How important is it for you to go shopping for food, clothes, or other necessities?

How difficult is it for you to go shopping for food, clothes, or other necessities?

How difficult is it for you to arrange transportation?

How difficult is it for you to read product labels?

How difficult is it for you to use credit cards without the assistance of another person?

How difficult is it for you to read receipts?

How difficult is it for you to read signs?

How difficult is it for you to read nutritional information on food packaging?

How difficult is it for you to identify or count currency?

How difficult is it for you to locate products in the store?

How difficult is it for you to read price tags?

How difficult is it for you to write checks?

How difficult is it for you to use public transportation?

How difficult is it for you to find your way through an outdoor shopping district?

How difficult is it for you to find your way and walk around in an indoor shopping mall?

How difficult is it for you to find your way and walk around in a store?

How difficult is it for you to read classified ads?

How difficult is it for you to read printed ads?

How difficult is it for you to identify coupons?

How difficult is it for you to read catalogues?

How difficult is it for you to do home shopping with the TV?

How difficult is it for you to do home shopping with the computer?

How difficult is it for you to make sure you receive the correct change?

How important is it for you to care for young children?

How difficult is it for you to care for young children?

How difficult is it for you to supervise children?

How difficult is it for you to feed children?

How difficult is it for you to change diapers?

How difficult is it for you to clean children?

How difficult is it for you to dress children?

How difficult is it for you to read to children?

How difficult is it for you to play with children?

How important is it for you to be able to drive?

How difficult is it for you to be able to drive?

How difficult is it for you to read road signs; i.e. stop signs, speed limit signs?

How difficult is it for you to identify traffic signals?

How difficult is it for you to stop at the right place at an intersection?

How difficult is it for you to change lanes?

How difficult is it for you to merge into traffic?

How difficult is it for you to see merging cars?

How difficult is it for you to see pedestrians?

How difficult is it for you to see traffic on the interstate?

How difficult is it for you to see traffic on rural roads?

How difficult is it for you to see traffic on city streets?

How difficult is it for you to read road maps?

How difficult is it for you to read the instrument panel without the assistance of another person?

How difficult is it for you to read the speedometer?

How difficult is it for you to see lane markings?

How difficult is it for you to navigate in parking lots with ramps?

How difficult is it for you to drive at night?

How difficult is it for you to stay in the lane?

How difficult is it for you to distinguish when a car is stopped on the shoulder of the highway or interstate without the assistance of another person?

How difficult is it for you to maintain appropriate distance from the car in front of you?

How difficult is it for you to read the gas gauge?

How difficult is it for you to park in the appropriate parking space?

How difficult is it for you to park curb-side-parallel parking?

How important is it for you to provide home care for an adult?

How difficult is it for you to provide home care for an adult?

How difficult is it for you to dress the person for whom you provide care?

How difficult is it for you to prepare food for the person for whom you provide care?

How difficult is it for you to feed the person for whom you provide care?

How difficult is it for you to supervise the person for whom you provide care?

How difficult is it for you to provide a safe, accident-free environment for the person for whom you provide care?

How difficult is it for you to arrange transportation for medical appointments for the person for whom you provide care?

How difficult is it for you to tend to the hygiene needs of the person for whom you provide care?

How difficult is it for you to move the person for whom you provide care (i.e. from bed to wheelchair; from bed to toilet, etc.)?

How difficult is it for you to take care of the grooming needs of the person for whom you provide care?

How difficult is it for you to inspect the skin (for bed sores, bruising, or other sores) of the person for whom you provide care?

How difficult is it for you to administer medications to the person for whom you provide care?

How difficult is it for you to take care of the toileting needs of the person for whom you provide care?

How difficult is it for you to provide leisure entertainment for the person for whom you provide care?

How difficult is it for you to bathe the person for whom you provide care?

How difficult is it for you to tend to the mobility needs (walking etc.) of the person for whom you provide care?

How difficult is it for you to do the shopping for the person for whom you provide care?

How difficult is it for you to handle business and financial transactions of the person for whom you provide care?

How difficult is it for you to do housework for the person for whom you provide care?

How difficult is it for you to do the laundry of the person for whom you provide care?

How important is it for you to provide care for a pet?

How difficult is it for you to provide care for a pet?

How difficult is it for you to feed the pet?

How difficult is it for you to clean up after the pet?

How difficult is it for you to check for ticks and fleas?

How difficult is it for you to groom the pet?

How difficult is it for you to walk or exercise the pet?

How difficult is it for you to administer medications to the pet?

How important is it for you to be able to use the telephone?

How difficult is it for you to be able to use the telephone?

How difficult is it for you to dial the phone number?

How difficult is it for you to look up telephone numbers?

How important is it for you to attend parties or other functions without anyone else's assistance?

How difficult is it for you to attend parties or other functions without anyone else's assistance?

How difficult is it for you to recognize people?

How difficult is it for you to see gestures, expressions, and body language?

How difficult is it for you to navigate in low light levels?

How difficult is it for you to arrange and use transportation to social functions?

How difficult is it for you to find your way and walk around at social functions?

How difficult is it for you to identify food and drinks?

How difficult is it for you to drink without spilling?

How difficult is it for you to eat without dropping food?

How important is it for you to entertain guests?

How difficult is it for you to entertain guests?

How difficult is it for you to recognize people?

How difficult is it for you to decorate?

How difficult is it for you to serve food?

How difficult is it for you to set the table?

How difficult is it for you to see gestures, expressions, and body language?

How difficult is it for you to identify food?

How difficult is it for you to drink without spilling?

How difficult is it for you to eat without dropping food?

How important is it for you to cook or bake for social functions; i.e. Thanksgiving and holidays?

How difficult is it for you to cook or bake for social functions; i.e. Thanksgiving and holidays?

How difficult is it for you to read recipes?

How difficult is it for you to pour or mix without spilling?

How difficult is it for you to measure ingredients?

How difficult is it for you to transfer liquids?

How difficult is it for you to read a cooking thermometer?

How difficult is it for you to read a timer or clock?

How difficult is it for you to read stove or oven dials?

How difficult is it for you to avoid burning yourself?

How difficult is it for you to avoid cutting yourself?

How difficult is it for you to check browning or doneness of food?

How difficult is it for you to find utensils?

How difficult is it for you to find food items?

How difficult is it for you to cut, chop, or dice food?

How difficult is it for you to read labels on packages, cans or bottle?

How difficult is it for you to read settings on kitchen appliances?

How important is it for you to dine out?

How difficult is it for you to dine out?

How difficult is it for you to read handheld menus?

How difficult is it for you to use a credit card?

How difficult is it for you to read receipts?

How difficult is it for you to read overhead menus?

How difficult is it for you to identify and count currency?

How difficult is it for you to read the bill?

How difficult is it for you to write a check?

How difficult is it for you to see food on the plate?

How difficult is it for you to drink without spilling?

How difficult is it for you to eat without dropping food?

How difficult is it for you to see food on the utensil?

How difficult is it for you to see expressions, gestures, and body language of people you are dining with?

How difficult is it for you to navigate in low light levels?

How difficult is it for you to find your way and walk around in the restaurant without the assistance of another person?

How difficult is it for you to get the server's attention?

How difficult is it for you to arrange and use transportation to restaurant?

How important is it for you to attend plays, concerts, movies, sporting events, etc.?

How difficult is it for you to attend plays, concerts, movies, sporting events, etc.?

How difficult is it for you to read a program?

How difficult is it for you to see the activity?

How difficult is it for you to navigate in low light levels?

How difficult is it for you to arrange and use transportation to an event?

How difficult is it for you to find your way and walk around at an event?

How important is it for you to attend meetings of a club, church, civic group, etc?

How difficult is it for you to attend meetings of a club, church, civic group, etc?

How difficult is it for you to read the agenda or minutes?

How difficult is it for you to see charts, blackboards, or projection screens?

How difficult is it for you to read presentation notes?

How difficult is it for you to recognize people?

How difficult is it for you to record minutes or notes?

How difficult is it for you to see expressions, gestures, or body language of people at meetings?

How difficult is it for you to navigate in low light levels?

How difficult is it for you to arrange and use transportation to meetings?

How difficult is it for you to identify food and drinks?

How difficult is it for you to drink without spilling?

How difficult is it for you to eat without dropping food?

How difficult is it for you to find your way and walk around at the meeting?

How important is it for you to play cards, board games, Bingo, or other games?

How difficult is it for you to play cards, board games, Bingo, or other games?

How difficult is it for you to read the cards in your hand?

How difficult is it for you to read cards on the table?

How difficult is it for you to read Bingo cards?

How difficult is it for you to see board games?

How difficult is it for you to see your partner's signals?

How difficult is it for you to read instructions?

How important is it for you to sing in a choir or play an instrument publicly, perform in plays, speak publicly or perform before a group?

How difficult is it for you to sing in a choir or play an instrument publicly, perform in plays, speak publicly or perform before a group?

How difficult is it for you to read sheet music?

How difficult is it for you to see the instrument?

How difficult is it for you to see the conductor?

How difficult is it for you to see the director?

How difficult is it for you to see the actor's expressions and gestures?

How difficult is it for you to see cues?

How difficult is it for you to navigate on the set or stage?

How important is it for you to attend church or house of worship services?

How difficult is it for you to attend church or house of worship services?

How difficult is it for you to read a bulletin?

How difficult is it for you to read hymnal without the assistance of another person?

How difficult is it for you to read prayer books without the assistance of another person?

How difficult is it for you to see pulpit without the assistance of another person?

How difficult is it for you to recognize people without the assistance of another person?

How difficult is it for you to read Bible, Torah, Koran, or other Holy Book without the assistance of another person?

How difficult is it for you to read missal without the assistance of another person?

How difficult is it for you to navigate in low illumination without the assistance of another person?

How difficult is it for you to find your way and walk around in your place of worship without the assistance of another person?

How difficult is it for you to arrange and use transportation to place of worship without the assistance of another person?

How important is it for you to dance socially?

How difficult is it for you to dance socially?

How difficult is it for you to find a dance partner at the dance hall or club?

How difficult is it for you to lead or follow your dance partner around the dance floor without bumping into anything or anyone else?

How difficult is it for you to recognize acquaintances at the dance hall or club?

How important is it for you to provide yourself with leisure entertainment without anyone else's assistance?

How difficult is it for you to provide yourself with leisure entertainment without anyone else's assistance?

How difficult is it for you to watch TV?

How difficult is it for you to read books for pleasure?

How difficult is it for you to read short stories?

How difficult is it for you to read poetry?

How difficult is it for you to see video games?

How difficult is it for you to play arcade games?

How difficult is it for you to see playing cards?

How difficult is it for you to read word puzzles?

How difficult is it for you to assemble jigsaw or other puzzles?

How difficult is it for you to read magazines?

How difficult is it for you to read numbers on TV?

How difficult is it for you to recognize objects or people in pictures or photographs?

How difficult is it for you to view scenery; such as wildlife, children playing, or other neighborhood activities?

How difficult is it for you to view flowers, plants, or vegetables?

How difficult is it for you to use a camera?

How difficult is it for you to operate a VCR?

How difficult is it for you to read a newspaper?

How important is it for you to exercise?

How difficult is it for you to exercise?

How difficult is it for you to see an exercise video?

How difficult is it for you to exercise without bumping into other objects or people?

How difficult is it for you to see an exercise instructor and follow the instructor's movements?

How difficult is it for you to mount and dismount exercise equipment?

How difficult is it for you to set controls on exercise equipment?

How important is it for you to sew or do needlework?

How difficult is it for you to sew or do needlework?

How difficult is it for you to select thread or fabric?

How difficult is it for you to thread a needle?

How difficult is it for you to cut material?

How difficult is it for you to do stitching?

How difficult is it for you to operate a sewing machine?

How difficult is it for you to sew on buttons, patches, etc?

How difficult is it for you to read a tape measure?

How difficult is it for you to follow a pattern?

How important is it for you to knit or crochet?

How difficult is it for you to knit or crochet?

How difficult is it for you to select hooks or needles?

How difficult is it for you to knit, crochet, or tie?

How difficult is it for you to select yarns or thread?

How important is it for you to do woodworking?

How difficult is it for you to do woodworking?

How difficult is it for you to use power tools?

How difficult is it for you to drill, saw or sand?

How difficult is it for you to do painting, staining or finishing of woodwork?

How difficult is it for you to see wood surface and grain?

How difficult is it for you to use hand tools?

How difficult is it for you to glue, nail, or screw parts without the assistance of another person?

How difficult is it for you to follow a pattern?

How important is it for you to do metalwork?

How difficult is it for you to do metalwork?

How difficult is it for you to use power tools?

How difficult is it for you to use hand tools?

How difficult is it for you to weld metal?

How difficult is it for you to paint or finish metal?

How difficult is it for you to install or tighten screws?

How difficult is it for you to cut, mill, drill or bend metal?

How difficult is it for you to follow a pattern?

How important is it for you to paint or draw?

How difficult is it for you to paint or draw?

How difficult is it for you to see colors?

How difficult is it for you to read labels?

How difficult is it for you to see a subject or model?

How difficult is it for you to select brushes or pencils?

How difficult is it for you to see he artwork you are making?

How important is it for you to cook or bake for recreation?

How difficult is it for you to cook or bake for recreation?

How difficult is it for you to read recipes?

How difficult is it for you to pour or mix without spilling?

How difficult is it for you to measure ingredients?

How difficult is it for you to transfer liquids?

How difficult is it for you to read a cooking thermometer?

How difficult is it for you to read a timer or clock?

How difficult is it for you to read stove or oven dials?

How difficult is it for you to avoid burning yourself?

How difficult is it for you to avoid cutting yourself?

How difficult is it for you to check doneness of food?

How difficult is it for you to find utensils?

How difficult is it for you to find food items?

How difficult is it for you to cut, chop, or dice food?

How difficult is it for you to read labels on packages, cans or bottles?

How difficult is it for you to read settings on kitchen appliances?

How important is it for you to do electrical work?

How difficult is it for you to do electrical work?

How difficult is it for you to see wire colors?

How difficult is it for you to see resistor or capacitor codes?

How difficult is it for you to follow circuit schematics?

How difficult is it for you to identify components?

How difficult is it for you to place components?

How difficult is it for you to solder, crimp or fasten components?

How important is it for you to build models?

How difficult is it for you to build models?

How difficult is it for you to read and follow instructions?

How difficult is it for you to paint small parts?

How difficult is it for you to glue model parts?

How difficult is it for you to attach decals?

How important is it for you to play a musical instrument?

How difficult is it for you to play a musical instrument?

How difficult is it for you to read sheet music?

How difficult is it for you to see the instrument?

How important is it for you to travel?

How difficult is it for you to travel?

How difficult is it for you to read signs?

How difficult is it for you to read maps?

How difficult is it for you to read brochures?

How difficult is it for you to see the sights?

How difficult is it for you to arrange and use transportation?

How difficult is it for you to find your way and walk around?

How difficult is it for you to see displays at a museum or exhibition?

How difficult is it for you to read exhibit descriptions on signs?

How difficult is it for you to use a camera?

How difficult is it for you to make sure you receive the correct change?

How important is it for you to fish?

How difficult is it for you to fish?

How difficult is it for you to prepare fishing tackle?

How difficult is it for you to bait a hook?

How difficult is it for you to tie flies?

How difficult is it for you to pilot a boat?

How difficult is it for you to remove a caught fish from a hook?

How difficult is it for you to cast a rod?

How important is it for you to go hunting or shooting?

How difficult is it for you to go hunting or shooting?

How difficult is it for you to find your way around outside?

How difficult is it for you to sight a weapon?

How difficult is it for you to see the target?

How difficult is it for you to identify game?

How difficult is it for you to navigate in low light levels?

How important is it for you to perform outdoor recreational activities; i.e., boating, hiking, fishing, etc?

How difficult is it for you to perform outdoor recreational activities; i.e., boating, hiking, fishing, etc?

How difficult is it for you to go boating?

How difficult is it for you to go biking?

How difficult is it for you to go hiking?

How difficult is it for you to go skiing?

How difficult is it for you to go swimming?

How important is it for you to garden for pleasure or work in the yard?

How difficult is it for you to garden for pleasure or work in the yard?

How difficult is it for you to plant trees or pot houseplants?

How difficult is it for you to plant flowers or vegetables?

How difficult is it for you to inspect plants?

How difficult is it for you to prune plants?

How difficult is it for you to mow the lawn?

How difficult is it for you to identify plants and weeds?

How difficult is it for you to read lawn and gardening magazines?

How difficult is it for you to read lawn and gardening books?

How difficult is it for you to read product labels?

How difficult is it for you to measure lawn or garden products?

How difficult is it for you to trim shrubs?

How important is it for you to play sports such as golf, bowling, tennis, etc.?

How difficult is it for you to play sports such as golf, bowling, tennis, etc.?

How difficult is it for you to play golf?

How difficult is it for you to play tennis or other racquet sports?

How difficult is it for you to go bowling?

How difficult is it for you to play croquet, horseshoes, or shuffleboard?

How difficult is it for you to play softball without the assistance of another person?

How important is it for you to work with leather?

How difficult is it for you to work with leather?

How difficult is it for you to see leather grain?

How difficult is it for you to cut leather?

How difficult is it for you to use an awl or hole punch?

How difficult is it for you to stitch leather?

How difficult is it for you to emboss leather?

How difficult is it for you to see embossing?

How important is it for you to use a computer?

How difficult is it for you to use a computer?

How difficult is it for you to use a word processor?

How difficult is it for you to read a computer keyboard?

How difficult is it for you to fill out forms or work with spreadsheets?

How difficult is it for you to use the Internet?

How difficult is it for you to use e-mail?

How difficult is it for you to use a mouse to control the functions of the computer?

How difficult is it for you to use programs that allow you to work with pictures; such as photo shop and paint?

How difficult is it for you to play computer games?

How difficult is it for you to read help statements or manuals on the computer?

How important is it for you to collect things; i.e. antiques, stamps, coins, cards, dolls, etc.?

How difficult is it for you to collect things; i.e. antiques, stamps, coins, cards, dolls, etc.?

How difficult is it for you to find new pieces or collectibles?

How difficult is it for you to organize and display your collection?

How difficult is it for you to maintain and clean your collection?

How difficult is it for you to catalog your collection?

How important is it for you to read the newspaper?

How difficult is it for you to read the newspaper?

How difficult is it for you to read the headlines?

How difficult is it for you to read the newspaper column?

How difficult is it for you to read the TV listings?

How difficult is it for you to read the obituaries?

How difficult is it for you to read the sports statistics?

How difficult is it for you to read the stock pages?

How difficult is it for you to read the classified ads?

How difficult is it for you to read the comics?

How difficult is it for you to read the newspaper weather information?

How important is it for you to do photography?

How difficult is it for you to do photography?

How difficult is it for you to load film in the camera?

How difficult is it for you to develop the film?

How difficult is it for you to frame and mount your photographs?

How difficult is it for you to focus the camera?

How difficult is it for you to maintain and take care of the camera?

How difficult is it for you to see people and objects you are photographing?

APPENDIX 2: DEVICE ABANDONMENT QUESTIONNAIRE

Dougherty, B. E., Kehler, K. B., Jamara, R., Patterson, N., Valenti, D., & Vera-Diaz, F. A. (2011). Abandonment of low-vision devices in an outpatient population. *Optometry and Vision Science, 88*(11), 1283-1287.

1. **Do you have the device? (if yes, go to question 2)**

   □ YES □NO

   Why?

   □ Lost/ Stolen

   □ Never received it

   □ Was unsure how to obtain

2. **When did you last use the device**

   □ Record Time: _____

   How often do you use the device?

   □ Everyday

   □ At least once a week

   □ At least once a month

   □ Within 3 months

   □ Greater than 3 months ago, since you last used the device (go to question 3)

   □ Not sure

3. **Why have you not used the device (or never used)**

   □ Record answer: _____

   Categorize Answer?

   □ Vision change

   □ Physical reason

   □ Device Issue

   □ Too complex to use

   □ limited field of view

   □ letters too small

   □ light burned out

   □ too cumbersome to use

□ it takes too long to do what I want to do

□ Cognitive Issue

□ I forgot how to use it

□ I get frustrated using it

□ I don't have the patience to use it

□ Adaptive Issue

□ I no longer need the device

□ I no longer do the task I used the device for

□ I found a different way to do the task

4. **What did you use the device for**
   - **□ Record answer: _____**

Closing steps:

1. **Thank the subject for their time**
2. **Remind the subject we may call again**
3. **Transcribe any notes or comments**
4. **Save the data**