Mrs. A and Mr. B

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PCORI RESEARCH PLAN

Applicants are encouraged to refer to the contents of the PCORI draft Methodology Report in developing their Research Plan.

RESEARCH STRATEGY

(Use continuation pages as needed to provide the required information in the format shown below. Limit 15 pages for this section. Refer to the PCORI Application Guidelines for additional guidance.)

RESEARCH STRATEGY

Part A: Background and Significance

Overall guiding philosophy: During the principal investigator's (MGS) clinical experiences as a physician caring for people with spinal cord injury and other catastrophically disabling injuries or diagnoses, she found that patients (typically out of shame, denial, or fear) rarely disclose their true feelings about their functional loss. Consequently, she developed and applied the "Recovery Preference Exploration (RPE) procedure" where patients imagine disabilities more severe than their own and are guided through an imagined recovery process. Her team found that discussions within the RPE imagined life space were contextually rich which enlightened and led to valuable insights that commonly inspired changes in patients' therapeutic goals. Through these insights, the PI recognized the potential of "virtual worlds" where identities are masked and the expert versus subject distinctions can be wiped away as a mechanism to stimulate deeper and more in-depth discourse about potentially sensitive topics. Various experiences of "world" have confirmed the power of communication as protected through masked identity. Consequently, we will situate our primary inquiry in an existing virtual world (Second Life®, www.secondlife.com) which includes an established community of hundreds of people with a wide range of physical and mental disabilities. We will parallel it in a non-virtual urban setting. Together, these will provide context-rich information to inform quantitative evidence-based results and will enrich and inform the value, interpretation, and implications of such results to the understanding and empowerment of populations of people with disabilities (PWD).

Impact of the Condition on the Health of Individuals and Populations (Criterion 1)

The burden imposed by disability on working age and elderly Medicare beneficiaries and on the population at large will be extreme in the coming decades. Medicare insures about 43 million elderly and working-aged disabled people.[1] The Medicare fund is projected to increase from 3.6 in 2010 to 5.5 percent of the Gross Domestic Product by 2035.[2] Projected expenditure needs are expected to be higher than revenues. Consequently, the fund is expected to fail long-range tests of actuarial balance leading to concerns that necessary cuts may erode access to services for Medicare beneficiaries.[3] Erosions in access may impact at-risk populations disproportionately, heightening the critical nature of this study.

Disabling injuries and illnesses are imposing increasingly significant burdens on individuals, families, and the US population as the 65 years and older population is increasing at an unprecedented rate. There will be from 99-108 million persons 65 years and older in the US by 2050 compared to 38.7 million in 2008.[4] In 2005, approximately 18% had 1-2, 5% had 3-4, and 3% had 5-6 activities of daily living (ADL) limitations.[5] Median yearly healthcare costs increase with the number of ADL limitations.[6] Elderly people with ADL or instrumental ADL (IADL) limitations tend to have multiple chronic conditions. Although the younger working age population represented only about 13% of total Medicare enrollment in 1995, their enrollment is increasing. Among those with ADL or IADL limitations, more than half reported having more than one chronic health condition and 35% reported 4 or more.[7] Compared to the elderly,

younger Medicare beneficiaries typically have greater healthcare needs and costs,[1,8] experience more barriers to access,[9] and enter Medicare because they are expected to be disabled or seriously ill for the rest of their lives.[10] Chronic health conditions and disability clearly place great burden on the US population with respect to prevalence, mortality, morbidity, suffering, and loss of productivity across the life span.

Innovation and Potential for Improvement through Research (Criterion 2)

A. *This research addresses a critical gap in current knowledge as noted in the literature and by multiple government agencies and non-government organizations.* The Centers for Disease Control and Prevention (CDC) has monitored the nation's health for six decades with particular interest in reducing gaps between the most and least vulnerable groups of people.[11] Major disparities and inequities based on urban/rural setting,[12] physician supply,[13] race,[14,15] income,[16,17] and education[16,17] are well documented. Higher proportions of PWD are ethnic minorities. PWD often experience low educational achievement and low literacy barriers and have poorer health status, lower incomes, and less social and less emotional support than people without disabilities (PWOD).[18] Above and beyond these socioeconomic characteristics that enhance vulnerability, PWD face accessibility barriers particular to their conditions.[19,20] PWD increasingly are recognized as vulnerable. Healthy People (HP)-2020 documents common difficulties or delays in getting needed healthcare among PWD.[18] For the first time, the CDC in its 2011 Health Disparities and Inequalities report recognized the presence of disability as an "at risk" demographic, asserting that disability be treated as a descriptor in all ongoing population surveillance.[11] The Agency for Healthcare Research and Quality (AHRQ) designated PWD as a priority population[21] calling for efforts to understand and "close the quality gap." The Patient Protection and Affordable Health Care Act of 2010 acknowledged the need for standard data aggregation techniques to identify inequities in healthcare and health disparities among PWD,[22,23] as did the National Institutes of Health (NIH).[24]

B. *Wide variations in disparity highlight uncertainty.* Careful literature review documents that disparities in health services related to disability are complex and sometimes not consistent.[25-30] Although PWD consistently receive fewer preventive services such as dental care, mammograms, or fecal occult blood tests compared to PWOD with the same chronic conditions,[11,18,31-33] practice patterns vary.[34] Our preliminary studies found that people with mild disabilities were more likely to receive influenza vaccines than PWOD, while those with the most severe disabilities experiencing the greatest need and the greatest access barriers were less likely vaccinated. These inconsistencies may relate to greater medical needs interacting with hampered abilities to obtain services.

C. *Policy change can benefit populations.* Potentially preventable hospitalizations for certain conditions are declining in the general population[35] suggesting improvements in ambulatory care. Greater access to community health centers, rural health clinics, Medicaid Managed Care, Health Maintenance Organizations, and implementation of Medicare Part D[36] with increased drug coverage have been linked to reduced hospitalizations.[37-39] Having a regular place of care[40] is associated with receipt of better prevention. This suggests that policies supporting greater access to ambulatory care may be improving population health. If access disparities are severe among PWD, that sub-population may be excluded from these benefits.

D. *Importance to patients or caregivers:* The Institute of Medicine's (IOM) September 2012 report, "Best Care at Lower Cost,"[41] calls for improving "capacity to capture clinical, care delivery processes" and achieving "better care, system improvement and the generation of new knowledge." PWD, family members, and healthcare providers partnering with researchers who will analyze a decade of records from the ongoing Medicare Current Beneficiary Survey (MCBS) about clinical and care delivery processes will be partnering to develop the ecologically valid **Patient-Informed Surveillance Tool**. This Tool will have the potential to improve the

fundamental capacity for meaningful surveillance. It will help sub-groups of people most vulnerable to functional decline, institutionalization, and death and will link these transition outcomes with lapses in healthcare/primary care provider (PCP) access and quality. It could inform targeted interventions to reduce disparities in populations of PWD, benefiting individual patients and caregivers.

E. *Innovations in the populations being studied and methods:* The proposal applies innovative methods that look through the lenses of individual peoples' experiences to guide statistical derivation of the "**Patient-Informed Surveillance Tool**." The resulting population risk stratification measure could ultimately enhance the quality of care provided to the communities of those individuals who helped inform its development. The PI and stakeholder consultants are PWD. Among them they experience deafness, low vision, respiratory insufficiency, neurologic (multiple sclerosis), and congenital orthopedic deformities which give them a first-hand perspective. Reflecting elements of the medical and social disability models (see Choice of Study Design), we combine emerging cyber anthropology (observation in a virtual world)[42] with classic cultural anthropology (observation in the physical world) giving voice to PWD and those in severe poverty who otherwise would be silent. We will develop the **Patient-Informed Surveillance Tool** according to participants' experiences of health disparities and the impact magnitude of those disparities on transition outcomes as determined through rigorous statistical multivariable analyses in population-level data.

Impact on Health Care Performance (Criterion 3)

In 2001, Kaiser Permanente was sued over issues of disability access.[43] A creative landmark settlement led to Kaiser's implementation of a comprehensive approach to enhancing accessibility and the quality of services provided to PWD. The Kaiser program is generally acknowledged to be a model as it demonstrates the feasibility and benefits of broad enhancement of access and quality. If poor quality, restricted access, and less confidence in PCP skills are shown to increase vulnerability to adverse outcome transitions, the proposed research could inspire similar enhancements at the level of the entire US Medicare population. The quality comparators (shown below) will form the backbone of the **Patient-Informed Surveillance Tool.** By documenting variations in access and quality of care and the clinical consequences of those variations to population wellbeing, the tool will be capable of guiding ongoing healthcare policy change. Ultimately, study findings will provide policy makers and managers of healthcare systems quantified evidence of healthcare disparities, thus accelerating the reach of this research into community practice focusing on high impact problems.[44] Also, dissemination of findings to healthcare provider organizations and individual providers about disparities in access and quality as well as problems in quality of PCP care provided to PWD compared to PWOD could stimulate direct change in local practice patterns.

Part B: Relevance to Patients (Criterion 4)

ADL, IADL, avoiding institutionalization, and survival are all relevant to patients. Stages built to reflect the International Classification of Functioning, Disability and Health (ICF) are patient-centered outcomes (PCO) derived from patient- or proxy-reported answers to simple questions about difficulties performing basic activities (Table 1).[45,46] For each of the 12 activities, respondents are asked, "Because of a health condition, do you (or does the person you are answering for) have difficulty with…?"[47,48] The MCBS and most population-level surveys typically express severity of disability as counts of ADL or IADL limitations but do not specify which activities are limited.[5,49,50] Stages specify the activities people must be able to do without disability according to the same hierarchy of item-level difficulty that underlies item-response theory (IRT)-based Patient Reported Outcomes Measurement information System (PROMIS) measures.[51].By distinguishing activities people are still able to do without difficulty from those

that they find difficult, we believe stages will better enhance opportunities for discourse among stakeholders about strategies for reducing disparities.

The vignettes of Mrs. A and Mr. B illustrate enhanced transparency engendered by applying stages rather than traditional counts of activity limitation. Mrs. A had difficulty with 1 ADL and 1 IADL. In contrast, Mr. B had difficulty with 5 ADLs and 6 IADLs. Clearly, both the counts and the stages indicate Mr. B is far more disabled. The stage assignments provide additional information about the qualitative nature of their disabilities within the setting of healthcare provision.

Table 1. Activity of Daily Living (ADL) and Instrumental ADL (IADL) Stages

STAGING Instructions: Starting at stage 0, ask the questions associated with each domain. The stage is the point when the answers are all true.	**ADL thresholds of retained functioning: "SELF-CARE"** The following activities are included: eating, using the toilet, dressing, bathing or showering, transferring (getting in and out of bed or chairs), and walking.	**IADL thresholds of retained functioning: "DOMESTIC LIFE"** The following activities are included: using the telephone, managing money (keeping track of expenses or paying bills), preparing own meals, performing light housework (straightening up or light cleaning, washing dishes), shopping for personal items (such as toilet items or medications), and doing heavy housework.
0: No difficulty	Can you perform all ADLs without difficulty? Are you able to eat, use the toilet, dress, bathe or shower, transfer, and walk without difficulty?	Are you able to do all IADLs without difficulty? Can you use the telephone, manage money, prepare your own meals, do light housework, shop for personal items, and do heavy housework without difficulty?
I: Mild difficulty	Are you able to eat, toilet, dress, and bathe or shower without difficulty?	Are you able to telephone, manage money, prepare meals, and do light housework without difficulty?
II: Moderate difficulty	Are you able to eat and toilet without difficulty?	Are you able to telephone and manage money without difficulty?
III: Severe difficulty	Do you have difficulty eating and/or toileting but are still able to do at least 1 ADL without difficulty?	Are you experiencing difficulty using the telephone and/or managing money but still able to do at least 1 IADL without difficulty?
IV: Complete difficulty	Do you have difficulty with all ADLs?	Do you have difficulty with all IADLs?

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Mrs. A and Mr. B

Mrs. A is a 73-year-old woman with arthritis and type II diabetes. She has no difficulty eating, using the toilet, dressing, bathing, or getting in and out of bed or chairs. She states she has difficulty walking. She is unable to do heavy housework but has no other IADL difficulties. Mrs. A has mild self-care limitations and domestic life limitations staged at ADL-I and IADL-I (See Table 1). As expected from her stage and the physical configuration of her PCP's clinic, she finds seeing her PCP difficult. Even if dropped off at the clinic, she has a long painful walk to the patient waiting area and another to the laboratory for blood draws. Will she be risking further functional decline by not obtaining recommended levels of care?

Mr. B is a 33-year-old man with intellectual disabilities. Living with his parents, he is able to get in and out of bed without difficulty and walk but has difficulty with all other ADLs. He is unable to perform any IADLs. Mr. B is at ADL-III; IADL-IV. His mother, Mrs. B, takes him to a primary care clinic close to home. With his stages at ADL-III and IADL-IV, the clinicians and office staff are challenged by his needing assistance with disrobing and using the toilet during

his visit and by his inability to understand basic concepts. The clinicians always seem in a hurry to Mrs. B; they avoid discussing important issues. Everyone in the office is condescending. Mrs. B often leaves appointments feeling that she has not received sufficient information to provide adequate care. Would Mr. B be at less risk of further decline in ADL or even possibly be able to improve functionally if his mother were to change to a clinic that was more engaged?

Part C: Approach (Rigorous Research Methods) (Criterion 5)

Study Design

Research Question

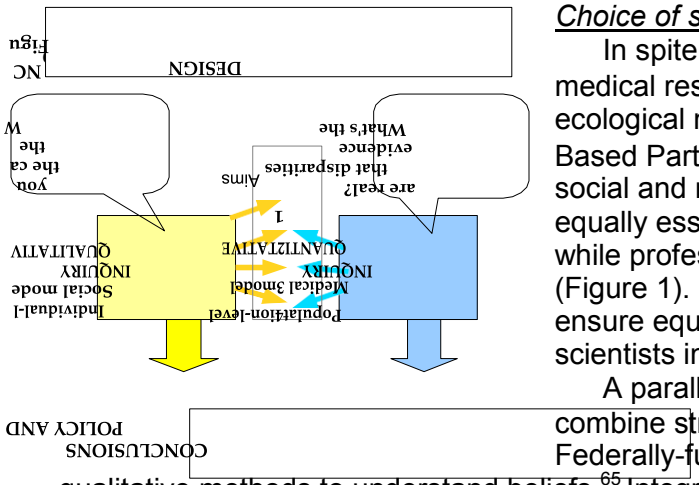
What access- and quality-related elements of the healthcare system and of PCP management most appear to impact progressive loss of independence? The project will yield patient-informed surveillance measures for use within the existing structure of the MCBS and within administrative evaluation databases of large healthcare systems for monitoring and addressing disability-related healthcare disparities and the impact of ongoing policy changes on associated 1, 2, and 3 year transition outcomes.

Choice of comparators for analyses- Aims 3 and 4

Choice of the 5 quality comparators (Table 2) was based on evidence that PWD experience more barriers to healthcare access and quality and believe that PCP lack fundamental knowledge about disability.[52-59] Even physicians acknowledge need for more training about PWD and admit to financial disadvantages in caring for PWD within contexts of volume-driven practices.[60] The comparators are patient-centered and perception-based. Each includes several questions about modifiable aspects of access and quality. The particular question sets compiling each individual comparator were also selected because they are patient reported.

Table 2. Comparators and Example Related Decision Point Issues

QUALITY COMPARATOR	ISSUES AND DECISION POINTS RELEVENT TO EACH COMPARATOR
Care coordination and quality	I feel the overall quality of my healthcare is poor and there is lack of coordination. If I seek a different provider, will I be at less risk of greater disabilities?
Access barriers	I have problems accessing my PCP. Will my medical conditions become more disabling because of this if I do not find a way to resolve the problem?
Technical skills of PCP	How important are the technical skills of my PCP to help me maintain my ability to care for myself and live independently? Should I seek a PCP with better skills?
Interpersonal skills of PCP	I feel my PCP is not interacting well with me. Will this affect my functioning? Should I look for better strategies for engaging my PCP?
Quality of information provided by PCP	I feel unable to care for myself because my PCP is not giving me the information I need. If I go to a different provider, will I do better?



Choice of study design

In spite of spectacular advances, medicine and medical research at times exploit PWD.[61] The biopsycho-ecological model informs this mixed methods Community-Based Participatory Research (CBPR) study[62,63] where social and medical models of disablement are considered equally essential. Stakeholders input to the social model, while professional researchers input to the medical model (Figure 1). Consequently, we selected CBPR methods to ensure equal participation of stakeholders and clinician scientists in this work.

A parallel mixed methods design was chosen to combine strengths of qualitative and quantitative inquiry.[64] Federally-funded investigators increasingly apply qualitative methods to understand beliefs.[65] Integration of qualitative and quantitative methods

will link subjective (transformative) with objective (measurable) knowledge in ways that findings can be generalized to larger populations yet informed through the lens of diverse stakeholders.

Reflecting National Quality Forum (NQF) 3-step healthcare quality enhancement processes,[66] stakeholders will explore how quality lapses (as measured by the 5 comparators) might change outcomes. The magnitude of actual quality lapses and the degree to which those lapses are associated with transition outcomes will be quantified. Stakeholders' interpretations of findings will inform policy simulations estimating maximum benefits to reducing gaps in quality according to each of the 5 comparators. The final deliverable will be a **Patient-Informed Surveillance Tool** through which the effects of healthcare system change on disparities and the wellbeing of PWD can be tested. All questions in the tool will be from the publicly available MCBS ensuring availability for immediate wide-spread implementation by health systems at project conclusion. Implementation of this tool by Medicare could have huge impact on the quality of care provided to millions of PWD. CBPR, in combination with broad dissemination efforts, is intended to engage patient, family, and clinician stakeholders to cause healthcare plans and PCPs to improve systems of care and services to PWD at the grass roots.

Choice of the Stakeholder Study Population

We chose to recruit PWD, family members, and PWOD from two populations. The Virtual Ability Island community (VAI) was selected because it is a well-established world-wide online virtual community designed by and for people with a wide range of physical, mental, sensory, and intellectual disabilities. VAI operates within several virtual worlds, including a long-established (2003) commercial, publicly available, free 3D graphic environment called Second Life (SL) with millions of users. SL "residents" are avatars, controlled by people from all walks of life who live, work, and play within the virtual world.[67] VAI empowers and helps PWD move beyond the barriers separating them from the larger society.[68] People come from many diverse cultures across the age spectrum, and frequently share innovative grassroots solutions to living autonomously, making VAI ideal for community-engaged research. Groups formed within VAI will be referred to as the **"VAI groups."**[69] Yet, access to VAI requires the ability to use computers which are not accessible to all PWD.[70] Concerned that VAI might not be representative of the larger population of PWD, we will also recruit from a low income integrated supportive urban community housing project run by Jewish Family Services (JFS) Housing, Inc. This population of adults is located in two buildings, Bradley Crossing and Deerwood Crossing, in Milwaukee, WI. This second cohort will include a high proportion of ethnic minorities with educational challenges and low computer literacy. Groups of these individuals will be referred to as the **"Urban groups."** Additionally, clinician stakeholders will be recruited from Second Life and referred to as the **"Clinician groups."** VAI and Clinician groups together compose the "**SL groups**" since they will both be convened within Second Life.

***Selection Criteria* for CBPR and Qualitative Study**

Each VAI and Urban group will include 4 to 6 PWD, 1 or 2 PWOD, and 1 or 2 caregivers. Clinician groups will be separate and will also consist of about 6 to 8 individuals per group. PWD will be defined as being at ADL- and/or IADL-I, II, III, or IV, and PWOD as being at ADL- and IADL-0. Clinicians must be clinically active health professionals (nurse, physician, physical therapist, and others). Inclusion criteria are: 1) Age 21 years old or older and living in a US community; and 2) The ability to communicate and participate in small group dialogue online (VAI groups) or in-person (Urban groups) with or without an Americans with Disability Act (ADA) accommodation.

Sampling will be purposive to ensure enrollment of people from diverse socioeconomic circumstances and across the broad spectrum of disability type and severity. Participants for the VAI groups will be recruited through the VAI membership of over 700 PWD and 175 caregivers of PWD, building on protocols established and applied extensively in Second Life by our

consultant Tom Boellstorff.[71-75] Participants in the Urban groups will be recruited from JFS Housing, Inc. (with about 135 PWD) through community newsletters and community meetings. Clinicians will be recruited through Second Life. The stakeholder consultant (Alice Krueger) personally has about 100 medical professional contacts within Second Life including nurses, paramedics, physicians, midwives, occupational therapists, and mental health counselors belonging to over 60 Second Life health professional groups.

Choice of outcomes

The 5 patient-centered comparators will be the outcomes for Aim 2. The comparators were selected because quality of health and PCP care received might impact patients' long-term outcomes. They then become the "exposure" for the remaining Aims. For Aims 3 and 4, the transition outcome was selected because the ability to perform functional activities, avoidance of institutionalization, and death are meaningful and important to people.

Analytic Methods (General)

Approach to Community-Based Participatory Research:[69] PWD have already contributed substantially to this proposal, forging strong partnerships between stakeholders and scientists. PWD helped establish Aims and Hypotheses, started building necessary research infrastructures within VAI's extensive and well-established volunteer network, drafted questions for use in focus groups, tested focus group procedures within VAI, evaluated and interpreted preliminary findings, contributed to the management plan, and advised on human subject protection issues. Stakeholders will participate in all aspects of CBPR design. In total, there will be 8 VAI groups, 3 Urban (in-person) groups, and 4 Clinician groups recruited for these tasks whose participation will address all 4 Aims. CBPR methods will thus secure knowledge from "inside experts" living with a variety of disabilities.

"Medicalized" disabilities tend to be defined negatively as personal deviation from "the normal or ideal." Stakeholders with disabilities will be engaged to move inferences about disability beyond "medicalization" thus embracing the social model of disability. Stakeholder involvement offers the "most authentic voices" about external barriers to healthcare and articulates factors PWD, their families, and clinicians believe threaten their abilities to maintain independence and autonomy. Aim 1 (fully qualitative) is preparatory for all other Aims. Aims 2, 3, and 4 each begin with quantitative inquiry followed by clarifying and continued qualitative stakeholder input.

Reducing low literacy barriers: About 14% of the population cannot do simple reading tasks such as locating an expiration date on a driver's license or signing their name.[76] To reach our stakeholders, prior to beginning the Aims, one VAI and one Urban group will help staff rewrite focus group questions to enhance readability for low literacy participants. The optimal readability goal will be set between the 4th and 6th grades as measured by a Flesch-Kincaid readability score.[77] This score interprets comprehension difficulty of text according to US educational reading grade level by determining average sentence length and number of syllables and the degree to which proper nouns and structurally complex sentences are included.[78]

Preliminary findings:

Our preliminary work established strong partnerships between stakeholders and scientists. The stakeholder and scientist teams contributed equally to this proposal, generating ideas, creating and finalizing the specific Aims, establishing the initial protocol, interpreting preliminary findings, running groups in Second Life, and establishing a shared timeline.

Qualitative and CPBR: The stakeholder and scientific teams had multiple group meetings in Second Life where they worked on protocol design, interpretation of the preliminary results, and all other project preparations. The PI and stakeholder consultant (Dr. Stineman and Alice Krueger) ran 4 pilot peer support groups in VAI on the inaccessibility of medical equipment and

services (see example of de-identified "chat" in Appendix C). The "public abstract" was written iteratively partnering between the stakeholder and quantitative analytic teams. We reached our readability goal at or below the 6th grade level. Readability was estimated by the Flesch-Kincaid Grade Level score, which was approximately at grade 5.5 based on the USA educational system.[78]

Quantitative: Using MCBS data from 3 panels active at the time of the Fall interview in 2005 (N=10,399) and with complete information, we applied a multinomial logistic regression model studying 1-year transition outcomes (2006 on the 4-level transition outcome with no change in function being reference). The global quality comparator was most consistently associated with outcome transition. Poorer perceived healthcare was significantly associated with 1-year, functional deterioration, institutionalization, and mortality (all p-values ≤0.03). Poorer perceived healthcare quality was strongly associated with functional improvement (p=.0001). Both functional improvement and deterioration were strongly associated with poorer access (both p<.0001). Perceptions of poorer access were also associated with death at 1 year (p=.02).

The PCP quality comparators were less strongly related to 1-year transitions. Poorer PCP interpersonal skills were associated with functional deterioration (p=.01) and 1-year mortality (p=.003). Patients' perceptions of poorer PCP interpersonal skills were marginally associated to institutionalization (p=.07). Poorer quality of information provision was related to institutionalization (p=.04). These findings provide powerful support for this study.

Stakeholder interpretation: Stakeholders found all findings logical except linkage between poorer perceived healthcare access and quality and functional improvement. They had the following thoughts and questions: Being angry with poor access and low quality healthcare might motivate functional improvement. Those who improved functionally might be more motivated to fight for better care. Will these findings persist after statistical adjustment and analyses across a decade and timeframe of 3 years? What other factors, potentially discoverable through stakeholder engagement, might explain this startling finding?

AIM 1: *Where do we see the problems?* Aim 1 seeks to uncover themes related to the 5 comparators and stakeholders' perceptions on whether or not they experience healthcare and PCP quality problems and if those problems impact transition outcomes. PWD, PWOD, and families, in VAI and Urban groups, will address the following kinds of questions in a focus group format: *How does access and quality of healthcare received differ for PWD and PWOD? How does poorer quality healthcare impact risks of functional decline, institutionalization, or death?* The Clinician groups will address identical questions but relative to their clinical practices.

Six focus groups (3 VAI, 1 Urban, and 2 Clinician) will participate. Participants from Second Life (VAI and Clinicians) will be assured that their off-screen identities will remain confidential. Once people provide informed consent, they will be given entry into a private chat room on VAI property at a specific date and time. All of the focus groups will be led by a stakeholder co-investigator with personal knowledge about living with disability. The group leader's role will be to pose questions in a standardized manner, moderate the discussion, move the discussion along, and keep the discussion safe for all participants. (See draft instructions for stakeholder focus groups in Appendix A). Prior to participation, each participant will be asked to complete a survey about disability(s) and life circumstance (See draft Appendix B). For groups in the virtual world, true identities will be masked behind created avatars (personas that individuals choose to represent themselves); in face-to-face Urban groups, members and their disabilities are known to each other. Text-to-speech software will be available to those who have low literacy.

Participation in the SL focus groups will generate "chat" in the form of typed dialogue (see Appendix C for an example). Participants' characteristics (derived from the pre-group questionnaire) will be linked to their screen or avatar name (but not their actual identity). The

dialogue will be downloaded into document form and entered into QSR NVivo 10.0 for coding and analysis. The Urban group will use the same discussion guide as in the SL groups. Groups will be conducted in a private room. Because in-person focus groups are, by nature, only semi-private, we cannot assure confidentiality, but we will ask all group members to respect the confidentiality of group participants. Individual identities will not be revealed outside the group. All focus group results will be reported in the aggregate and we will not link an individual's name with anything s/he said. In-person focus group proceedings will involve a captionist as an ADA accommodation for deafness. This automatically generates a verbatim transcript which will be entered into NVivo 10.0 software along with chat from the SL groups for coding and analysis.

Data analysis: We will use a modified grounded theory approach in the analysis.[79] The investigators will develop a coding structure and a coding dictionary based upon a close reading of the transcripts. All transcripts will be double-coded by project staff from the Mixed Methods Research Lab (MMRL) and from VAI. Once the data are coded, the software will allow us to generate queries to identify the context in which key ideas emerge. The software will also enable us to conduct inter-rater reliability analyses (described below). Areas of content divergence between thematic and quantitative findings will be hypothesis generated. Based upon our experience, these focus groups should be adequate to achieve saturation (where no new themes are emerging from the data). Once we have formed a preliminary theory about the data we have collected, we will use the technique of "member checking" where we will return to a subset of the original group of respondents to obtain feedback on our analysis. Procedures are detailed in the protocol (project plan and timeline).

Stakeholder input to Aims 2, 3, and 4: discuss emerging "quantitative" findings

Stakeholder groups will join researchers in interpreting findings during Aims 2 and 3. Tables and figures illustrating results will be presented to 3 VAI, 1 Urban, and 1 Clinician stakeholder groups. First, we will determine whether stakeholders understand the presentation by asking, "How would you explain these findings to a friend or family member?" Then we will ask questions such as, "What do you think explains these results?" "Tell us how to show these findings more clearly?" "What makes sense to you, and why?" "What does not make sense, and why?" Information will be applied to enhance clarity of findings for dissemination. Stakeholder concepts (particularly the "Do these findings make sense?" questions) will be combined with quantitative findings and the literature in formulating the **Patient-Informed Surveillance Tool.**

Stakeholder group member checking - did the researchers get it right?

The growing bank of stakeholder knowledge will help determine if we have asked the right questions and if answers make sense. We may suppress or choose not to include certain predictive associations between comparators and outcomes that appear counter-intuitive, unexplainable, or we believe might encourage adverse quality incentives when building the **Patient-Informed Surveillance Tool**. The association of perceptions of poorer quality with functional improvement is an example from preliminary work that might be presented but not included in the final surveillance tools.

Stakeholder groups will inform the simulations and final conclusions helping researchers interpret all findings. We will ask 2 VAI, 1 Urban, and 1 Clinician group to discuss strategies to encourage changes in the healthcare system targeted to enhancing the wellbeing of PWD. We will present scenarios illustrating findings from the statistical simulations. The following example illustrates the types of questions to be asked using preliminary findings.

"*Our research shows that when people with disabilities receive coordinated and high quality healthcare, their disabilities are less likely to get worse. How should healthcare be improved? How could your doctor implement these improvements?"* Materials from these groups will be analyzed as described in Aim 1 with quotes extracted to enhance clarity of findings.

What is the evidence? Our goal for the quantitative component of Aims 2-4 is to provide evidence for existence or non-existence of disability-related disparities in healthcare and, if present, to quantify their outcome implications among PWD compared to PWOD. Gaps as perceived by stakeholders (according to the 5 comparators) will be quantified using the MCBS. Results will be presented to groups of PWD in simplified illustrative scenarios and to clinicians in scientific presentation format.

Choice of data for quantitative analyses and Description of Data Sources

The MCBS is conducted by the Centers for Medicare and Medicaid Services (CMS) through in-person beneficiary or proxy interviews.[80-82] Respondents are sampled from the Medicare enrollment file to be representative of the Medicare population as a whole. Sample persons are interviewed three times a year for a maximum of four years forming a continuous profile of each individual's personal health care experience. Aims 2, 3, and 4 will apply a decade of data from the MCBS. The MCBS sample was selected for the qualitative aspects of Aims 2, 3, and 4 because these data provide the means to quantify the prevalence of disparities within the Medicare population and any associated outcome burden at the societal level. Also, derivation of the **Patient-Informed Surveillance Tool** within MCBS data will facilitate its potential implementation within Medicare as a means to monitor disparities and outcomes. The oldest old (80 and over) and the young disabled (between the ages of 21 and 64) are oversampled to permit more detailed analyses of these sub-populations.[83] The MCBS applies a rotating panel survey design. A rotating panel will be followed for 12 interviews. There are four panels active at any one time. Each has approximately 4,000 sample persons. New panels introduced each year in the fall round will replace the oldest panel retired the following summer. This project will use the Access to Care files from the MCBS which include all variables needed in the analyses.

The Study Sample: An Access to Care file is released within 2 years of the survey. We plan to request 10 panels entering at the time of their fall interview in 2000-2009. Access to Care files in the following 3 fall interviews (2010-2012) will serve to track 1, 2, and 3 year transition outcomes. The sample will include all fee for service and Health Maintenance Organization (HMO) Medicare beneficiaries 21 years of age and older. Those living in institutions at the time of their initial interviews will not be included since institutionalization is an outcome state.

1. **Variable Definition and Measurement** (Quantitative). All variables are available in the MCBS Access to Care files.

Outcomes:

Aim 2: Comparators (see description below and in Table 2)

Aims 3 and 4: "no change" (individual remains at the same ADL/IADL stage), "functional improvement" (recovery to stage of less functional limitation), "functional deterioration" (reflected in higher ADL/IADL staging), "institutionalization" (long-term institutionalization), or "death."

2. Quality Comparators (Outcomes for Aim 2 and exposures for Aims 3 and 4)

Each quality comparator is made up of patient or proxy answers to several questions rated either as: "very satisfied, satisfied, dissatisfied, or very dissatisfied" or as: "strongly agree, agree, disagree, or strongly disagree" during the patient's baseline interview. Higher values will be coded to represent negative connotations. The comparators and component questions address: **Comparator 1: Care Coordination and Quality:** 5 questions on overall quality of care, information given, follow-up care, concern for overall health, and needs met at same location. **Comparator 2: Access Barriers:** 3 questions on availability of night/weekend, ease/convenience, and out-of-pocket costs. **Comparator 3: Technical Skills of PCP:** 3 questions about checking "everything", understanding medical history, and understanding what is wrong. **Comparator 4: Interpersonal Skills of PCP:** 4 questions about whether or not the PCP is in a hurry, does not explain, does not discuss, and acts like doing a favor. **Comparator 5: Quality of Information provided by PCP:** 4 questions about whether the PCP "tells all I

want to know," "answers all my questions," "has my confidence," and dependence on doctor(s) to "feel better both physically and emotionally." Combination of these questions into 5 comparator measures is supported[84] by factor analyses with factor loadings of items on the 5 scores of 0.55 or greater. Cronbach's coefficient alpha was 0.82 for global quality, 0.54 for access barriers, 0.89 for PCP technical skills, 0.79 for interpersonal manner, and 0.84 for Information giving. Average item-level responses will be determined for each variable. Comparators 1 and 2 will be available for all patients, but PCP comparators only for the approximately 90% of patients who have regular PCPs. Comparators will be presented trichotomously, addressing high and low quality extremes. For the access and quality comparators, the best and worse access and quality will be compared to the middle quartiles. For the PCP comparators, no PCP and quality in the highest quartile will be compared to the 3 lower quartiles similar to the approach taken by Lee and Casper.[85]

Activity Limitation Stages determined during the baseline fall interview will be the key independent variable (see Table 1 for definitions). ADL stages (0-IV) will be primary and IADL stages (0-IV) analyzed secondarily. IADLs such as meal preparation are not always relevant when someone else is available to perform those tasks, yet IADL enables exploration of the effects of milder disabilities.

Other covariates: *Working age* 21 to 64 and 65 and over; *gender; race* (African American or Black, Hispanic, White, and other); e*ducation* (high school graduation Y/N); *marital status (married/unmarried)*; *income* (Medicare categories of annual household income from all sources); *insurance type* (Medicare only, Medicare and Medicaid-dual enrollee, private-supplemental, other (i.e., Champus, VA)); *living arrangement* (i.e., lives alone or with spouse only, with children, with other relatives or non-relatives, or in a retirement community); and the *presence or absence of accessibility features in the home* (home accessibility features). Health status will be captured by physician-reported *chronic conditions and impairments (*hypertension, asthma, diabetes, COPD, coronary artery disease, and congestive heart failure, intellectual and/or developmental disability, dementia or Alzheimer's disease, neurological disorders, mental illness, no usable vision, and deaf). Building on our previous work,[86,87] we know that the nature and severity of disabilities resulting from these conditions can be expected to vary. As example, neuropsychiatric conditions, particularly those causing intellectual disabilities, are often extremely disabling, while people who are blind or deaf often find ways to accommodate and perform basic activities.[87-91] Analyses will control for residence based on Census regions.

Data Analysis

Complex survey design: The MCBS uses a multi-stage clustering sample with unequal sampling probabilities. We will take into account the complex design by using appropriate survey commands in Stata to calculate the correct point estimates and their variances.[92] Specifically, the set of longitudinal weights (RIC X2) allowing analysis of data trends over a two year period and a second set of longitudinal weights (RIC X3) will be applied to two- and three-year outcomes.[93]

Proxies: Proxy responses will be included in all models. About 9.8% of MCBS baseline interviews were conducted by proxies and our previous work indicates that exclusion of proxy responses results in underestimates of disability prevalence.[94] Recognizing this may explain proxy differences we will explore replacing proxy status with reason for proxy use.

Missing data and attrition: See Avoidance of Bias below.

General approach to analysis: Each Aim will describe the sample of Medicare beneficiaries with weighted uni-variable summary statistics appropriate to the distributional characteristics of the variables of interest and bi-variable associations with outcomes. Because of concerns that some variables may be intermediate on causal pathways, to understand associations, we will build etiological models hierarchically. All will control for baseline age, gender, race, ADL or

IADL stage, and proxy status. Health conditions and living circumstances[95,96] will be added sequentially, selected according to associations with functional change, institutionalization, or mortality[12,14-17,49,97-100] or according to emergent themes from stakeholder groups. The Goodness-of-Fit (GOF), Deviance and Pearson GOF Statistic, ROC curve, and r-square values as appropriate to each regression will be reported to document model fit of the multinomial regressions. Stata 11.0 (Stata Corp, College Station, Texas) will be used for all analyses (except for multiple imputation as noted below). A 2-sided $p<.05$ will be used for all final tests of significance.

Aim 2 will address the degree to which people with disabilities experience healthcare disparities. The comparators will be the outcome here and ADL/IADL stages will be the main exposure. We will model each trichotomously expressed comparator through multinomial logistic regression. We will report adjusted relative risk ratios (RRRs) and their 95% confidence intervals (CIs) for the ADL and IADL stages (stage I as reference). For each continuously expressed comparator, we will report sample weighted estimates for the ADL and IADL stages (stage I as reference) obtained through linear regression.

Aim 3 will determine if people who experience better access and higher quality healthcare and who rate their PCPs highly on technical skills, inter-personal manner, and the provision of sufficient information to understand their health condition(s) will be less likely to experience a negative transition outcome. The 5-state transition outcome will be modeled by multinomial logistic regression models with no change in function as reference. We will report RRRs and their 95% CIs. In the multinomial logistic regression, the relative risk of improvement in function, decline in function, institutionalization, or death will be defined as the probability of improvement in function, decline in function, institutionalization, or death divided by the probability of remaining at the same ADL stage.

Each of the 5 comparators will be modeled individually after considering other covariates. They will also be entered into one model to determine the relative independent effects of each after considering the other exposures.

Aim 4 While models for aims 2 and 3 will be etiological and explanatory, the policy simulations will be predictive. We will simulate the maximum benefit of healthcare programs or policies aimed at improving each comparator, i.e., coordination and quality of care, increasing access, PCP technical skills, PCP interpersonal skills, and the quality of information provided by PCPs on likelihood of functional improvement, functional decline, institutionalization, or death over 1, 2, and 3 years. Taking the scenario of increased access as example, the simulation will: estimate the effect of poor access to care according to the transition outcome using β-coefficients from a multinomial regression similar to those proposed in Aims 2 and 3, i.e., we will use coefficients to predict status according to the multiple outcome states of “improved in function,” “deteriorated in function,” “institutionalized,” and “died” by 1-, 2- and 3-year follow-up compared to “remained at the same ADL stage,” given the new optimized access comparator, while holding baseline ADL stage and all other variables constant at the individual-levels. This will allow creation of new population prevalence estimates for each of the outcome states assuming optimal access. Comparison of these predicted/adjusted values and their associated confidence intervals will show the relative potential of policies targeted to improve the access comparator (when compared to any other policy change scenario) included in the simulation. Simulations will be performed for the 1-, 2- and 3-year time frames and for ADL and IADL stage transitions. This will produce a table showing the regression-based, predicted effects of optimizing alternative comparators on population status. These simulations will help frame the results of our study according to the “comparative effectiveness” of alternative policy instruments targeted to the 5 quality comparators. These findings will be triangulated with thematic materials extracted from the stakeholder groups (see above).

The **Patient-Informed Surveillance Tool** will be developed in three steps using an approach we applied recently:[101] (1) assess the quality of candidate predictors through the combined input of stakeholder and researcher recommendations with demonstrated bi-variable associations p<.20; (2) beginning with a regression containing all candidate covariates, estimate a parsimonious model by using backward selection to remove all candidate variables at p>.05; (3) develop a simply applied point-scoring system from the estimates associated with each variable in the final model by dividing each significant β-coefficient by the lowest significant β-coefficient and rounding to the nearest integer. A value of "0" will be assigned to non-significant β-coefficients.[102,103] Depending on demonstrated affect modification, working-aged and elderly beneficiaries might be included in separate Tools. The final set of **Patient-Informed Surveillance Tools** will group sub-populations by outcome expectation as determined by perceptions according to each comparator adjusted for ADL or IADL stage, living circumstances (i.e., family members who might provide care, home accessibility, etc.), diagnoses, socioeconomic status (i.e., income, education, etc.), comparator status, and other covariates. The final selection of variables in the Tools will be informed by stakeholder input (see above) as well as statistical findings.

Avoidance of bias:

Qualitative analyses: Qualitative research by its nature is context-rich but not generalizable. Our qualitative sampling strategies including both VAI and Urban groups were designed to include a broad range of PWD and PWOD with diverse experiences. We will use the inter-rater reliability function within NVivo to ensure consistency in coding establishing trustworthiness of the data. Virtual worlds are acknowledged as having a yet to be tapped potential for social, human-centered ethnographic research and represent the emerging field of "cyber anthropology".[42,104] Second Life is a 'virtual world' that mimics complex physical spaces where people represented as avatars can interact with each other, learn, and express their self identities. Self is defined in reaction to mental perceptions and how we want to be perceived by people in the dominant or alternative social and political culture(s) to which we choose to relate[105] with disabilities existing in the contexts of the normal or an ideal construct. Second Life is a particularly useful vehicle for connection among PWD with limited options to socialize in the natural world[26,106,107] where group identification and work for social change is protective and can be empowering to oneself and to ones' larger group.[107] Virtual worlds have been applied successfully in a variety of anthropological studies.[27-29,71-75,107-112] Still, some might ask are virtual worlds real? We argue that virtual worlds are not just representations, but are places with "worldness" cohabited and alterable by people interacting and engaging while embodied as avatars. All human culture is virtual[74] as it is superimposed on the natural world. Second Life is a relatively complete "world," and by its graphic interface more analogous to the experienced world outside media, than are telephones, books, and computer games.[74]

Quantitative: ADL and IADL are fundamental. Yet, other activities such as driving and additional unobservable cofounders could bias interpretations. We minimized unobservable confounders by selecting a content-rich data source. Recall bias which in surveys can be problematic[113] is minimized in the MCBS by having people keep records. Around 18% of Medicare beneficiaries refuse to participate in the MCBS which could potentially reduce generalizability. Studies of the MCBS data indicate that bias caused by differences between non-responders and responders was small and substantially reduced by the non-response procedures employed.[114] MCBS cumulative response rates by the fourth year range between 63-68%.[81] Recognizing that lost to follow-up may be more common among those with substantial disabilities, we will include post-stratification weights to minimize potential effects of differential non-response, and adjust the weight further by considering propensity to drop out.

We will also impute missing data using SAS callable IVEware software 0.2 through multiple imputation.[115] After generating 5 multiple imputation datasets, we will conduct all analyses allowing inclusion of all subjects. We will compare findings across the different analytical approaches. Also, we acknowledge that this observational design is not causal; however, the mixed methods design and use of large broadly representative populations enhance validity. Finally, it is essential to recognize the essential patient centeredness of this project. We will be addressing patients' perceptions of and beliefs about healthcare quality and physician competence. Conclusions that might be drawn from patient perceptions and professional measures may differ.

Study population: See description in study sample section.

Sample size

We did power calculation for Aims 2 and 3. Here, we focus on the association between ADL stage and the first comparator, care coordination and quality, in Aim 2, and that between the first comparator and transition in Aim 3.

First, we show the detectable RRRs for associations between ADL stages and the first comparator. Using our preliminary data in Table 2 which included three panels, we assume the distribution of the ADL stages will be similar across 10 years for which we will request the data for the project. After trichotomizing the first comparator, we obtained the proportion for the three categories (1, 2, and 3 from dissatisfied to satisfied) for stage I. They are 13.32%, 60.19%, and 26.49%.

Relative risk of being dissatisfied is defined as the probability of being dissatisfied divided by the probability of being neither dissatisfied nor satisfied. The detectable RRRs comparing other stages to stage I are shown in Table 3. With 10 years of data, we will be able to detect RRRs of 0.91 and 1.07 when comparing stages 0 to I. The RRRs we observed using 1 year data are actually much bigger than these, which indicate that we have adequate power.

Table 3. Detectable RRRs comparing other Stages to Stage I (assuming 80% power and 5% significance level)

	Category 1 versus Category 2	Category 3 versus Category 2
Stage 0 versus I	0.91	1.07
Stage II versus I	1.15	0.89
Stage III versus I	1.16	0.88
Stage IV versus I	1.29	0.80

We then calculate the detectable RRRs when we compare the transition outcome across the three groups for the first comparator. We again assume the distribution of the first comparator will be similar across 10 years and the transition probability for the reference category, "neither dissatisfied nor satisfied," was estimated from the 1 year transition in ADL stages for the three panels that were active in both 2005 and 2006. Relative risk of functional improvement is defined as the probability of ADL functional improvement divided by the probability of being stable in ADL stage. All the detectable risk ratios (Table 4) are smaller than 2 except for one RRR for institutionalization, which indicate ample power for our analysis.

Table 4. Detectable RRRs of transition (functional stable is the reference) for the three categories of the first comparator (assuming 80% power and 5% significance level)

	Death	Institutionalization	Functional deterioration	Functional improvement
Dissatisfied vs. neither dissatisfied nor satisfied	1.71	2.71	1.50	1.49
Satisfied vs. neither dissatisfied nor satisfied	1.24	1.63	1.16	0.90

Qualitative: The SL group analyses will include geographically diverse stakeholders with a variety of socioeconomic circumstances, disabilities, comorbidities, and life circumstances. The SL groups will be computer literate. The addition of Urban groups further enriches the sample

by obtaining PWD from a predominantly minority low literacy population. The SL and Urban recruitment strategies enable the inclusion of hard-to-reach people, including those who face numerous disability-related, economic, educational, social class, ethnicity, and cultural barriers.

By design, the MCBS samples are weighted to be representative of the entire elderly and working age Medicare population, and thus by its nature will include a diverse study population. The sample will also have a wide range of medical comorbidities. Preliminary results (Table 5) show diversity with respect to ADL and IADL stage as well as transition outcome status (above). Finally, the sampling frame is designed to be geographically diverse. Table 5 provides sample size estimates from 3 active panels of respondents at the fall 2006 Access to Care interview (about 3/10ths the study sample size). Over 4 and 5 million people had mild ADL or IADL limitations, respectively, with another 4.6 and 7.0 million people having more serious ADL and IADL limitations. Between-group differences across the 5 comparators will be addressed quantitatively according to the transition outcomes with independent effects of ADL and IADL stage determined.

Table 5. Sample size shown for 3 panels; expected size for 10 panels will be 40,000

	Difficulties in ADL			**Difficulties in IADL**		
Stage	Raw N	Expected N in population (million)	Weighted percent (SE on weighted %)	Raw N	Expected n in population (million)	Weighted percent (SE on weighted %)
0	8208	21.1	69.25 (0.86)	6924	18.2	59.65 (0.97)
I	1942	4.8	15.73 (0.50)	2094	5.3	17.5 (0.59)
II	995	2.4	7.72 (0.37)	1141	2.9	9.45 (0.37)
II	728	1.8	5.97 (0.36)	1558	3.4	11.1 (0.41)
IV	185	0.4	1.33 (0.14)	341	0.7	2.3 (0.15)
Total	12058	30.5	100	12058	30.5	100

Part D: Inclusiveness of Different Populations (Criterion 6)

The VAI and Urban groups clearly represent diverse populations of PWD as described above. Moreover the MCBS is by its nature diverse with respect to geographic location, age, gender, race/ethnicity, disabilities and comorbidities as sampled to reflect the Medicare population. These populations include many different sub-populations of people within them.

REPLICATION AND REPRODUCIBILITY OF RESEARCH AND DATA SHARING PLAN

(Use continuation pages as needed to provide the required information in the format shown below. Limit 2 pages for this section. Mouse over each underlined subheading for a short description of each. Refer to the PCORI Application Guidelines for additional information.)

Provision of a complete, final study protocol, describing the study population; primary and secondary hypotheses to be tested; sources and methods of measuring exposures, outcomes, and all covariates used in analyses, including data definitions, coding instructions, discussion guides for qualitative research, and the analysis plan. The protocol will usually be expected to be delivered along with the first 12-month progress report, and always within three months of the end of the funding period. PCORI will reserve the right to share these materials with appropriate researchers, in consultation with the principal investigator of the study.

- Proposed clinical trials or observational outcomes studies must be registered at www.clinicaltrials.gov.
- Proposed evidence synthesis studies must be registered at http://www.crd.york.ac.uk/prospero/
- Descriptions of study datasets, including code books, meta-data related to the datasets, and documented programming code used for creating the final study population, for creating variables, and for conducting all outcomes analyses. These must be provided within three months of the end of the final funding year.

The project will encourage other research groups to replicate findings from this study in the MCBS and in other populations, such as veterans, as well as in other data sets. Work plans, variable definitions, methods applied, and findings will be downloadable from the project website. The initial study protocol (which will include a description of the study population, initial hypotheses to be tested, definitions of all data and covariates, discussion guides (for qualitative analyses), coding instructions for qualitative data, the survey, IRB approved informed consent documents, and the analysis plans) will be delivered in Month 9 to the PCORI organization and website. Because of the nature of CBPR, there may be changes in the protocol year 1 or even early in the second year. The complete final study protocol (which will additionally include full population and dataset descriptions, all hypotheses tested, definitions, and codebooks) will be delivered within 3 months of the end of the funding period to PCORI and made available on the project website at the same time. Thematic codes including code label and frequency of appearance in the data along with tabular materials from the quantitative analyses of the MCBS, hypotheses tested, variable definitions, statistical code instructions, and work plans will be provided to facilitate the research of other groups. A full set of these materials will be provided with the project report. The project will be registered as required by PCORI to encourage replication.

We hope policy makers and health systems will implement the Patient-Informed Surveillance Tool. Statistical analysis code with instructions will be made available facilitating policy stakeholders use of the Tool in performing population surveillance according to the National Quality Forum (NQF) 3-step healthcare quality enhancement processes.[66] Researchers wanting to replicate or build on our quantitative findings based on the MCBS would need to obtain permission to use those data from CMS through Research Data Assistance Center (ResDAC). Contacts for doing that will be placed on the website, along with information on how to obtain our SAS code. Statistical analysis code (in SAS and/or STATA) will be linked to analysis plans.

Reproduction of Research Findings (Data Sharing Plan)

Note: The requirement for a data-sharing plan applies only to studies that are requesting funding at a level greater than $500,000 in direct costs in any project year. The data sharing plan must:

- *State that a complete, cleaned, de-identified copy of the final dataset used in conducting the final analyses will be made available within nine months of the end of the final year of funding.*
- *Propose a method by which investigators will make this dataset available if requested.*
- *Propose a budget that would cover costs of data sharing if requested.*

2 pages

Although a data-sharing plan is not required for a project of this size, we provide a plan because full transparency is an important objective of our work. We will include explicit descriptions of qualitative protocols and also methods for formulating, developing, and analyzing the data elements we use.

Moreover, all measures used, algorithms developed, and other results will be in the public domain. This means that individual healthcare providers or health systems will be able to apply stages to track characteristics of their treatment population and use the same sets of comparator questions to address quality and coordination, access, and PCP quality. Complete, cleaned, de-identified copies of the qualitative data used in the final analyses will be made available to other researchers within nine months of the final funding year. Outside researchers will be asked to acknowledge PCORI and publications from the project as the primary funder and source of scientific materials, respectively.

Qualitative: All focus group probes applied in the Second Life® (VAI and Clinician) and Urban focus groups will be downloadable from the project website. All coded thematic data will be freely available including the themes and the number of times each was identified.

Quantitative: Use of MCBS data requires permission from CMS and execution of a Data Use Agreement (DUA) through the CMS contractor ResDAC.

http://www.resdac.org/cms-data/search?f%5B0%5D=im_field_privacy_level%3A42

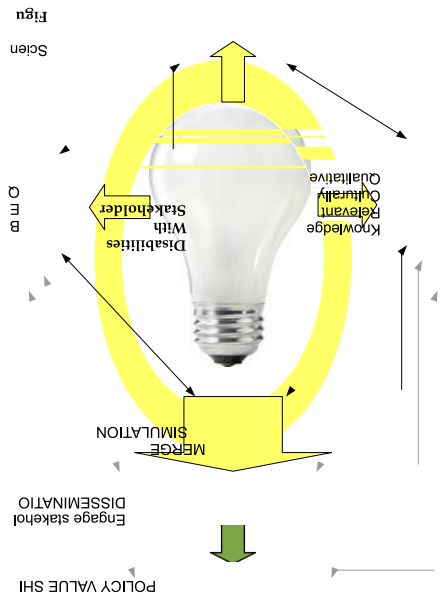
Researchers requesting quantitative data sets will be provided a set of instructions and referred to ResDAC for the completion of a formal DUA as required by Medicare for use of MCBS materials. Once a DUA is established for use of MCBS data, we will make our codebooks and analytic instructions available, facilitating full replication. Detailed variable descriptions, analytic work plans, statistician notes, and findings will be downloadable from the “Mrs. A and Mr. B” website.

DISSEMINATION AND IMPLEMENTATION ASSESSMENT

(Use continuation pages as needed to provide the required information in the format shown below. Limit 2 pages for this section. Mouse over each underlined subheading for a short description of each. Refer to the PCORI Application Guidelines for additional information.)

Governance Plan

Dr. Stineman (the PI) in partnership with the PCORI organization will serve to direct governance and linkages between all scientific, stakeholder, and administrative aspects of the project. Detailed procedures of governance and decision-making will be established the first month of the grant. General principles fallow. Governance and project direction will be equally shared between the stakeholder and scientific leadership. Scheduled governance meetings will involve the 2 stakeholder consultants (Krueger and Colletti), the primary scientific PI (Stineman) and the project manager (Jibby Kurichi). Meetings will occur in VAI so as to be able to communicate using typed chat. Sister Colletti is deaf. Jibby Kurichi will review and reformat the chat so as to be appropriate for formal minutes, distribution and as a record of project quality monitoring and milestone achievements. Key study personnel including the project investigators (Bogner, Xie, and Barg) and the project data analyst will attend as needed, as will other scientific or stakeholders assigned specific tasks during the project. The first part of the meetings will be open to the public as they will involve project overview and the gathering of information from stakeholders based on their experience of participation and reactions to findings.



The second, closed part of the meetings will be reactive to all stakeholder input gathered including that from focus groups, informal discussions among the co-PIs and PIs with participants and information from the blog post. The meeting we will also focus on technical issues, and how work plans should be altered based on stakeholder input. Detailed findings both quantitative and qualitative will be shared and cross implications discussed. Each meeting will also include assessment and review of both the quality of the effort and project achievements related to milestones. Decision-making will be by consensus. Any conflicts that need resolution and other aspects of the project will be discussed. We see the project as a partnership with PCORI. Consequently, all PCORI personnel will have an open invitation to attend any and all parts of the meetings (or have copies of the resulting minutes). We will seek guidance with respect to what results should be disseminated when and how. Governance meetings will be bi-weekly and closely linked to project tasks as shown in the Figure 2. We abandoned our attempt to create a typical organizational chart when we recognized that flow from top to bottom suggests a hierarchical power structure and thus violates the principles of partnership and linkages that are fundamental to our goals. Brief structural roles are indicated below and articulated in greater detail within the budget justification document.

The Second Life® team: A. Krueger will serve to govern and direct administration of qualitative procedures and data collection within Second Life.

The Urban team: Sister P. Colletti, SDS, will provide direct administration and project implementation of the work at JFS Housing, Inc. She will also oversee and manage website design.

Methodology team: Dr. Barg will manage the overall scientific approach and analysis of the qualitative data as collected by the SL and Urban teams. The statistician, Dr. Dawei Xie will manage the overall scientific approach to multivariable modeling and simulation studies in the MCBS data.

Quantitative analyses Dr. Stineman (PI) will serve in the governance of the overall clinician scientific leader of this project. She will direct quantitative analyses and guide the final quantitative qualitative merge in partnership with all participants.

Stakeholder teams: The stakeholder consultant and stakeholder focus groups are the content leaders of this project. It is towards enhancing their wellbeing and better access to high quality healthcare that we are all working. The individual stake holder focus groups are seen as teams. We anticipate that some individuals who participate will chose to stay active and engaged in the project through all years. They may review project updates through the blog, join and provide input at the public component of governance meetings or contribute ideas informally through second life or JFS-Housing Inc.

Resource Sharing

Funds for consultation, supplies, travel, salary, and equipment will be shared with and flow to each individual from the PIs institution. In developing this proposal the Co-PI, consultants, collaborators and PI worked extensively together to develop procedures and allocate resources fairly, adequately and carefully so as to support anticipated work flow over the 3 years as detailed by the budget justifications. Recognizing the preciousness of resources and the importance of public trust, we also attempted to build in cost saving to the PCORI organization. Many stakeholder partners and participants are on SSI or SSD because of their disabilities and thus cannot receive salary or consultation fees.

The Co-PI, under the VAI subcontract, once he receives their subcontract will be responsible for allocating funds for their programs while the PI will allocate funds to the analytic staff working at the University of Pennsylvania.

Stakeholder participants of the focus groups from Second Life will be offered Linden dollars (which can be spent for clothing, concerts, rent for property or other virtual goods within Second Life), and those from JFS-housing will receive gift cards to purchase groceries worth about $5 as a token of our appreciation.

REFERENCES CITED

(Use continuation pages as needed to provide the required information. Do not exceed 10 pages.)

Provide a list of references cited in the Research Plan. Each reference must include names of all authors (in the same sequence in which they appear in the publication); the article title; and journal or book title, volume number, page numbers, and year of publication. Include only bibliographic citations. Follow scholarly practices in providing citations for source materials relied on in preparing any section of the application. Refer to the PCORI Application Guidelines for additional information.

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PROTECTION OF HUMAN SUBJECTS

(Use continuation pages as needed to provide the required information. For detailed instruction, refer to the Supplemental Instructions for Preparing the Protection of Human Subjects Section of the Research Plan in Part II of the Instructions for the PHS 398 Form, as found on the National Institutes of Health (NIH) website. Do not exceed 5 pages.)

QUALITATIVE SUBJECT CHARACTERISTICS: All group participants, whether recruited through VAI, JFS Housing, Inc., the project website, or by participant referral, will be 21 years of age or older. Participants will be recruited purposively to include gender, age, and racial/ethnic minority distributions approximating proportions in the Medicare population (see targeted enrollment information in Table 6) and a broad range of disabilities.

ADEQUACY AND PROTECTION AGAINST RISKS

Recruitment and informed consent

Study objectives will be described. Group announcements and invitations will be posted within Second Life to the VAI membership, at the project website, and thorough a variety of methods to residents at the JFS Housing, Inc. facilities. Individuals wishing to participate will be instructed to contact the group facilitator within Second Life, to submit a message at the project website, or to contact the office of the Inclusion Coordinator (P. Colletti) within JFS Housing, Inc. Project staff will seek informed consent through the use of an online or hard copy form. Consent information will explain that this is a research project in which participation is fully voluntary, people can withdraw at any time, and their online chat or transcribed conversation in a focus group might be quoted, but that no identifying material will be published and details of text chat will be altered so it could not be searched via an online database and thus attributable to them. The researchers will not publish personally identifying information, including not just physical world names, but also avatar names, since these are important identities to many informants.

The consent form will be returned by the potential participant to the facilitator or by completing it on the website. Within Second Life, the participant will receive the consent form through a process called “gifting,” where the participation must first agree to accept a written “note card” which will then be placed into a specific area of the recipient’s inventory. Inadvertent consent will be guarded against based on this being a multi-step procedure. Consent, linked to the participant’s avatar (removed from the individual’s true identity) will be provided by their typing the following statement in chat, “I have read and understand your consent form and agree to participate in the Mrs. A and Mr. B research study.” Consents will be maintained linked to the avatar name but not to the real name. They will be stored outside Second Life in an encrypted file separated from the de-identified chat. At JFS Housing, Inc., the Inclusion Coordinator will meet with each participant to assist him or her in understanding the informed consent. He or she will give consent through his/her signature or, if appropriate, that of a proxy (guardian or caregiver with such authority).

Research procedures

After giving consent, participants will be asked to complete a survey which will determine eligibility for inclusion. Prior to attending a focus group, participants will be asked: 1) their age (decade), 2) marital status, 3) gender, 4) whether they have disabilities or are caring for someone with disabilities (family member, paid caregiver, health professional). Focus group participants will be asked to indicate the broad type(s) of disabilities they (or the person they care for) has. Finally, they will be asked if their disability (or the disability of the individual for whom they are providing care) is obvious (can be seen) or is hidden. The participant can complete the survey with or without ADA accommodations, depending on need.

Once the survey has been completed, the participant will receive information about the time, date, and location of a focus group. Each participant who completes a focus group in Second Life will be gifted 1000 Linden dollars (currency used in Second Life, valued at about $4.85) and each participant in a face-to-face focus group will receive a gift card to Target or Walmart worth $5.00 to compensate for participation.

Risk of loss of subject confidentiality is minimal to nonexistent. Neither real names nor any information that might be used to track individuals will be sought or included in the study records. The only contact between focus group participants and study personnel will be through confidential focus group discussions using masked-identity avatars in SL and appropriate confidentiality procedures at JFS Housing, Inc.

Participants will be reminded that answering any questions and information sharing is voluntary. They may pass on a particular question (chat is entered voluntarily) or exit easily from the focus group at any time should they feel uncomfortable. With respect to minimizing any discomfort PWD may experience talking about their health care, group moderators will be selected on the basis of their personal attributes and interpersonal skills as well as their substantive knowledge. They will be further trained and periodically observed to ensure that they are respectful and sensitive to the needs and feelings of the participants. Participants will receive the PI's office phone number and will be asked to contact the PI with any concerns about the study. Also, moderators will be instructed to call the PI (Dr. Stineman) if there is serious concern about a participant's safety or involvement.

De-identification and storage of resulting "chat streams"

De-identification of text: In the virtual environment of SL, discussions held in a focus group are rendered into text (called the "chat stream"). In the face-to-face environment, captioning will be available to include deaf/hard of hearing participants. It will also provide a verbatim transcription of the conversations held. As a special safeguard of anonymity, VAI staff will de-identify all text, removing any elements (inadvertently provided by participants) that could be seen as representing Protected Health Information. Once de-identified, the chat will be checked by a second VAI reader. Finally, readers at the Mixed Methods Research Laboratory (at the University of Pennsylvania) will do a final check to make sure that de-identification is complete. Formal procedures and rules for de-identification will be developed. Examples of rules include the following: 1) All avatar and personal names (even nicknames) from the focus groups will be replaced with a unique identifier. (The name with its code will be kept in a separate encrypted file in a computer directory location separate from the text that will be accessible only through a password protected desktop.); 2) Information provided by non-consented speakers will be deleted; 3) Exact ages will be replaced with the decade; 4) Specific locations or references (including locations within Second Life) will be replaced by region or state and Second Life locations deleted; 5) Specific diagnoses will be replaced by broader categories (see categories in data collection forms in Appendix B). Data (de-identified chat) will be stored on an encrypted and separate hard disk or USB stick. They will be opened only when needed.

All data will be reported at a thematic level with no theme attributed to an individual. If an individual's quote is used to illustrate a theme, the individual will be contacted (through the avatar within SL or personally for the Urban groups) to seek consent through a separate form.

QUANTITATIVE: PROTECTION OF HUMAN SUBJECTS: RISKS TO THE SUBJECTS: Human Subjects Involvement and Characteristics This research involves the study of existing "limited" data and diagnostic records in a series of databases available from the Centers for Medicare and Medicaid Services (CMS). Data will be merged from the Medicare Current Beneficiary Survey (MCBS) Access to Care files which will be obtained from the Research Data Assistance Center (ResDAC). ResDAC is a CMS contractor (Contract Number

HHSM-500-2005-00027I) that provides free assistance to academic, government, and non-profit researchers interested in using Medicare and/or Medicaid data for research.

Based on analysis of the 2006 MCBS data, there are no children involved in this study. The subjects range in age from 22 to over 85 years of age. Disabled persons under the age of 65 and very old persons of the age of 80 and over are oversampled. Age-wise, 82.63% of the Medicare beneficiaries are at least 65 years of age and older and 17.37% are people younger than 65 years of age who either have disabilities or severe chronic illnesses. Among the 82.63% of Medicare beneficiaries who are 65 years and older sub-group, 40.52% are between 65 and 74 years old, 40.55% are between 75 and 84 years old, and 18.93% are 85 years and older. Among the 17.37% disabled Medicare beneficiaries sub-group, 50.57% are 22 to 44 years old and 49.43% are 45-64 years old. Gender-wise, 44.30% of Medicare beneficiaries are male and 55.70% are female. In terms of ethnicity, 84.43% of Medicare beneficiaries are White non-Hispanic, 10.30% are Black non-Hispanic, 2.33% are Hispanic or Latino, and 2.94% are classified as other.

Potential Risks

We will be using the Limited Data Set (LDS) Files which have been stripped of data elements that might permit identification of beneficiaries. Even though we will be obtaining LDS files, our group has carefully designed a series of protocols which will be applied to protect and ensure beneficiary's privacy (see Protection Against Risk, below).

ADEQUACY OF PROTECTION AGAINST RISKS

Recruitment and Informed Consent

The subjects will not be identified and informed consent for the quantitative Aims 2, 3, and 4 will not be obtained (see below).

Protection Against Risk

We have spoken extensively with ResDAC[116] and will be following the instructions listed on the ResDAC website for submitting a LDS new use request. Specifically, we will not analyze nor report any cell sizes less than 11 or the percentages that would result from such a small sample.

Any publication or public dissemination of statistics arising from our work which highlight beneficiary- or facility-level data will receive prior authorization from CMS to ensure that beneficiary confidentiality is properly maintained. Any statistics developed using CMS data will be made available to the entire public. Publication will be in aggregate form. We are familiar with the use of identifiable data and have multiple safeguards in place.

Center for Clinical Epidemiology and Biostatistics (CCEB) Data Security

Research data is maintained on file servers, located in a physically secured Data Center, under the control of designated CCEB system administrators. This gives a measure of physical security to the logical controls also in place. A highly-available central Storage Area Network (SAN) serves dedicated, isolated disk space to file servers. The servers, in turn, provide data confidentiality, enforce permissions, and restrict data access based on individually assigned user IDs and permission groups. Membership in a permission group is approved by the project's Principal Investigator or designee. A private network then provides secure access to authorized users who are authenticated by means of user ID and password.

Security within the CCEB Network

The CCEB research computing environment has built in security measures in order to meet the requirements of HIPAA and other federal, state, and sponsoring agency compliance protocols. Utilizing Virtual Local Area Network (VLAN) technology, the CCEB secures its logical

network using Virtual Private Network (VPN) and Network Address Translation (NAT) protocols, layered on top of the single logical VLAN. The VPN protocols provide encrypted "data in motion" protections and "fire-walled" connections between each of the physical network segments of the logical network. Applying encrypted VPN connections over the VLAN allows all internal CCEB data to "tunnel through" and traverse the University's physical networks as needed, while maintaining security at the logical CCEB network level, thus ensuring the privacy of the CCEB data and the availability of the data to only CCEB managed resources and users.

In addition to the VLAN and VPN technologies, the CCEB network utilizes the NAT protocols to provide private network addressing within the logical CCEB network. This additional precaution ensures that all network protocols running into or out of the logical CCEB network are essentially "proxy" connections that are only passed through one of several CCEB firewall devices. Providing a proxy service allows the CCEB to monitor, log, and control the flow of data. This precaution also allows the internal network to remain effective regardless of external connectivity issues, sometimes outside the control of the CCEB network administrators. Because the NAT protocols use non-routable IP addresses, an additional level of control is provided within the network, as private IP addresses can only exist within the CCEB logical network. These addresses are managed locally within the CCEB, also ensuring that only appropriate connections are identified and permitted within the CCEB data network.

Dr. Stineman and her staff will treat the MCBS data as containing privileged information. This team has completed many projects requiring the careful protection of human subjects' information, and has developed a strict protocol for the use of such data. The server is dedicated to patient research data, and will be maintained by the safeguards described above. Access is limited to research personnel by username and password protection. All data are encrypted. Incremental backups are automated. The data remains encrypted during the backup procedure. Raw data is maintained behind the University of Pennsylvania firewall. All study data will be presented or published for the purposes of research only in aggregate form such that no individuals can be identified. With regard to the CMS MCBS data, no raw data transfer via portable media such as thumb drives or any other devices is allowed.

The following types of Protected Health Information (PHI) will be used in the study, with reasons for use highlighted:

Birth dates, sex, ethnic code, functional status, diagnoses, dates of hospitalizations, and dates of death will be used in the project analyses. The project requires functional status information to define the Activity Limitation Stages. The project requires diagnoses to define disabling impairments as covariates. Admission dates to functional status, nursing home, and death dates are required for the outcomes.These data are fundamental to the aims. Ages will be grouped in categories. Eighty-five years of age and above is the oldest category. Data will be presented only in aggregated form. Socioeconomic information will be necessary to adjust outcomes for the effects of these differences.

Potential benefits of the proposed research to the subjects and others:

The proposed research could benefit subjects or caregivers if they gain a deeper understanding of their healthcare experiences and of the potential deleterious impacts of quality lapses, and if they learn about additional resources and strategies from one another. Results could yield information beneficial to future Americans with disabilities in the following ways: (1) The identification of difficulties experienced by people with particular types of disabling impairments or at particular ADL and IADL stages when attempting to access ambulatory care services could facilitate programs targeted to ensuring better services.; (2) The characterization of particular profiles of disability that place people at risk for outcome transitions may provide insights (through analysis of the comparators) that might be used to reduce those risks; and (3)

The US population potentially benefits should the Patient-Informed Surveillance Tool be applied in policy determination. Such surveillance could enable disability management that reduces risks of adverse outcomes and improves the quality of life among persons with disabilities of all ages within the Medicare population. Although the project does not include formal economic analyses, there may be cost savings to society if institutionalization can be reduced at the population-level.

Importance of knowledge to be gained:

This study will identify thresholds of ADL and IADL function (stages) associated with healthcare disparities making it possible to identify groups of PWD within the Medicare population who are at risk for experiencing lower quality PCP care, healthcare overall, and restricted access as they perceive it. It will further link perceptions of healthcare inadequacy to quantifiable outcomes (ADL stage transitions, nursing home use, and death). Ultimately, we hope to produce new knowledge that can be used by all stakeholders (patients, families, healthcare professionals, and policy makers) to help improve the quality of healthcare and the quality of life of PWD.

Exempt Human Subjects Research:

This study is anticipated to be Exempt 4, and is pending approval by the University of Pennsylvania IRB.

Table 6: TARGETED/PLANNED ENROLLMENT: Anticipated Percentage Distribution

Ethnic Category	Sex/Gender		
	Females	Males	Total
Hispanic or Latino	4.1	3.5	7.6
Not Hispanic or Latino	51.8	40.6	92.4
Ethnic Category: Total of All Subjects *	55.9	44.1	100
Racial Categories			
Black or African American	5.6	4.0	9.6
White	46.9	37.5	84.3
Others (American Indian/Alaska Native, Asian, Native Hawaiian or Other Pacific Islander, Unknown/refused/other race/more than one)	3.4	2.7	6.1
Racial Categories: Total of All Subjects *	55.9	44.2	100

* The “Ethnic Category: Total of All Subjects” must be equal to the “Racial Categories: Total of All Subjects.”

CONSORTIUM/CONTRACTUAL ARRANGEMENTS

(Use continuation pages as needed to provide the required information. Do not exceed 5 pages.)

Use this section to further describe the research projects of the subcontracts and explain the strengths that the partners bring to the overall project.

The project has a consortium/contract to Virtual Ability Inc.. Virtual Ability inc. is a 501(c)(3) non-profit corporation that runs a cross-disability support community in Second Life®. Most contributors to this sub-contract are consultants as described in the budget justification. The subcontract has a principal investigator, two primary stakeholder consultant roles and additional consultants. This description focuses on the PI and the two primary stakeholder consultants who are recognized as the content leaders of this partnership.

David F. Ludwig, Principal Investigator sub-contract

Mr. Ludwig will serve as principal investigator of this sub-contract. He brings more than 20 years experience in business through diverse industries including software engineering, Information technologies and project management he brings unusual administrative skills to this position. Mr. Ludwig is a volunteer with the Virtual Ability peer support community for persons with a wide range of disabilities within the virtual world of Second Life, and is Vice President and a member of the Board of its sponsoring 501(c)(3) non-profit corporation, Virtual Ability, Inc. (www.VirtualAbility.org). He has experience in the **coordination and administration of grants, contracts, and projects** that sustain companies financially. For the Virtual Ability community, he manages the website and social media accounts, oversees donation processing and reporting, assists with policy development, mentors new members, participates in peer support and community events, and makes presentations to that community. He will help guide overall project direction, establish the project infrastructure and contribute to dissemination efforts.

Primary Stakeholder Consult Alice Krueger

Alice Krueger is the first primary stakeholder consultant. She is an advocate and innovator who established Virtual Ability, Inc. as a peer-based supportive community for PWD. Through its existing infrastructure, and extensive network of volunteers the community within virtual ability island has the potential to serve as a groundbreaking platform for CBPR. Virtual Ability, Inc. is a non-profit corporation based in Colorado. Its mission is to enable people with a wide range of disabilities by providing a supporting environment for them to enter and thrive in online virtual worlds like Second Life®. Virtual Ability hosts numerous events of relevance to people with disabilities. For example, the International Disability Rights Affirmation Conference, August 3-4, 2012, was an international conference exploring the concept of embedded communities (http://blog.virtualability.org/search/label/IDRAC-2012). The Virtual Ability community hosts an art gallery and a library, both of which feature works by PWD. This project will benefit from the large population of PWDs within Virtual Ability (VAI) and Second Life® (SL), including the extensive voluntary organization of self-help groups within SL. A number of these individuals are disability advocates who seek to improve services (including health care) for PWD.

Alice Krueger (stakeholder consultant), President of Virtual Ability, Inc., and Dr. Stineman (PI) introduced the University of Pennsylvania scientific partners to VAI, who through their avatars attended multiple project planning meetings at Dr. Stineman's "virtual home" located on Cape Serenity within SL. The partners worked within and outside Second Life with all project personnel to design this project. Ms. Krueger and Dr. Stineman also ran 4 focus groups to

collect ideas for enhancing the accessibility of medical equipment from a roundtable of people with a variety of disabilities. These ideas were presented by invitation on July 29, 2010 at a Public Meeting of the federal Access Board: "Accessibility Standards to be Developed for Medical Diagnostic Equipment: Approach to Rulemaking," Washington, DC. Dr. Stineman also gave an invited lecture within Second Life for the American Congress of Rehabilitation Medicine on challenges faced by researchers with disabilities. Image of the virtual conference room was projected onto the screen of a real conference room. Many of the speakers were to disabled to travel. Thus both the stakeholder and scientific teams are familiar with second life.

The Virtual Ability community supports a wide variety of disability-related research which has resulted in several findings of significance to PWD. One of the most important projects through Loyola Marymount University has shown statistically significant social-emotional outcomes for persons with disabilities who participate in activities in virtual worlds.[108]

In addition to supporting qualitative studies in Second Life®, Virtual Ability, and other organizations within that virtual world will be a vehicle for dissemination of findings of relevance to PWD and their caregivers. Virtual Ability staff have identified over 120 different peer support groups for persons with various disabling conditions or chronic illnesses that meet in Second Life each of which will be a target for dissemination.

Focus groups will be held within a virtual meeting room provided by VAI, facilitating communication with, accessibility to, and attendance by PWD and chronic health conditions many of whom would be unable to leave their homes to travel to meetings. Thus, through this mechanism, we give voice to those who have little opportunity to make their thoughts known.

Figure 3 shows Dr. Stineman's avatar in Second Life in a virtual conference room. Alice Krueger and Sister Patrice M. Colletti (both primary stakeholder consultants) , are interacting through their avatars (seated) while discussing access to and operations of the site during the project. A portion of the typed conversational chat appears to the left of the image. The discussion occurred simultaneously in typed chat and in voice enhancing accessibility to Dr. Stineman who has low vision and Sister Colletti who is deaf. As the team thought about procedures for the focus groups and semi-structured probes, the PI and consultants shared many challenges they experienced when seeking healthcare in light of their disabilities. The discussions were eye opening and shed light on the importance of stakeholder input at all stages of proposed research. By interpreting findings through the lens of the stakeholders who could be impacted by our findings, the value of the work will be enhanced and expectations of researchers may be altered. See letter of support from David F. Ludwig, Vice President, on behalf of the Board of Directors of Virtual Ability, Inc.

Figure 3. Screenshot of virtual meeting in Second Life. Avatars of the PI and the two primary stakeholder consultants are shown.

As founder of the innovative VAI virtual peer support community and its numerous programs for PWD, Mrs. Krueger will have a major role in implementing the qualitative aspects of this study. Her efforts will be supported by the consultant Carla Broek (project manager) who will be responsible for the day to day operations of the project within VAI as directed by Ms. Krueger. As primary stakeholder consultant and director of the Second Life

team and CBPR, Ms. Krueger brings her skills as a special education professional, researcher, virtual world visionary and community leader to bear on these tasks:

Primary Stakeholder Consultant Sister Patrice M Colletti, SDS, Inclusion Coordinator at Jewish Family Services (JFS) Housing, Inc.,

As the second primary consultant of this project, Sister Patrice Colletti, SDS will direct both our Urban Team and our Dissemination Teams, bringing skills and experiences as an educator, nonprofit leader, educational technology user with expert level skills, and long-time disability rights advocate to the project. In her role with JFS Housing, Inc., she will work directly with and oversee inclusion of PWD residing at Bradley Crossing, a supportive living community serving low income people in Milwaukee County, Wisconsin. For this project, she will also work directly with PWD residing at nearby Deerwood Crossing, another JFS Housing, Inc. facility. Deerwood Crossing is an assisted living facility serving adults over age 55. Recruitment of participants from JFS-housing inc. is intended to balance the VAI recruitment by including people who likely would have difficulty with accessing VAI due to limited computer skills.

S. Patrice's consulting will also include ongoing moderator roles for VAI (backing up Mrs. Krueger, and oversight of the work of website design. She will be the primary author of low-literacy materials and work to ensure ADA accessibility for the website and other materials by incorporation of recommendations by PWD on literacy accessibility. She will work with a web design professional (Sister Nelda Hernandez, a consultant) to develop, implement, maintain, and monitor a publically available website and blog, for the Mrs. A and Mr, B Project. This website will have multiple linkages to and from other sites including the virtual ability website. In building this site she will seek feedback from Mr. Ludwig experienced with social media within industry, Mrs. Krueger, as well as Drs. Stineman, Bogner, and Barg (qualitative methodology investigator) and their staff. This tool will incorporate the use of social media (likely Twitter, RSS, and/or Facebook exposures) to disseminate information about the project, facilitate stakeholder enrollment, and collect feedback from the general public that can be used to enhance project operations.

Sub-contract responsibilities for CBPR and stakeholder participation

1. In collaboration with project partners, design and pilot a process for informed consent and recruitment for virtual and face-to-face focus groups.
2. Ask a few participants from the VAI and/or Urban sites to help rewrite proposed focus group questions and questions for the focus group collection form so as to maximize their readability by people who have low literacy.
3. Design, implement, and oversee a small training program to train a cohort of PWD and caregivers of PWD who are residing in urban, low income integrated housing to use the internet, use common blog or internet-based communications, and use assistive technologies (if needed) to access online communications related to the project, so that members of focus groups conducted face-to-face have the same information available as members of focus groups conducted in Second Life. The training program will also assist participants to learn the basic "how to's" of focus groups if they have never had that type of experience before. These individuals will then be equipped to participate as stakeholders in the focus group process.
4. In collaboration with project partners, design and pilot a process for conducting both virtual and face-to-face focus groups. Train VAI facilitators and mediators for virtual focus groups. Set up and run virtual focus groups in Second Life for the VAI groups, and at the JFS-sites for the urban groups including recruitment, and obtaining inform. Arrange for ADA accommodations, as needed for full participation

5. In collaboration with project partners, design and pilot a process for de-identifying text transcripts from focus groups. Design and pilot a process for coding text transcripts from focus groups. Work closely with the Mixed Methods Research Laboratory (at the University of Pennsylvania) to develop the codebook and validate coding procedures. Oversee the de-identification of focus group chat and transmission to the Mixed Methods Research Laboratory at the University of Pennsylvania.

Subcontract responsibilities for Web-site development and dissemination:

1. In collaboration with project partners, translate findings for various audiences. Work with project staff to disseminate procedures, interim findings, related content information, and results via website, social media, in-person presentations, and in world presentations using methods that are accessible to individuals with disabilities as well as to adults with lower literacy levels, as they form a significant portion of the consumer base for healthcare. Use the experience and expertise of JFS Housing, Inc. and VAI participants for insights and recommendations for successfully reaching low literacy audiences.
2. Work with project partners to design and implement recruitment and informed consent processes, and pilot methodologies for focus groups in both virtual and non-virtual settings.
3. Work with all partners to disseminate procedures, interim findings, related content information, and results via website, social media, in-person presentations, and in world presentations using methods that are accessible to individuals with disabilities as well as to adults with lower literacy levels.
4. Collaborate in the preparation and dissemination of papers and professional articles to professional audiences via publications and presentations.

MRS A and MR B WEBSITE: The website will be designed as a vehicle for making the project methods, operation, and findings fully transparent to the public, which is important to governance. **S. Nelda Hernandez, SDS,** a graphics design professional, will co-create the website with S. Patrice Colletti. The easy-to-use site will establish an interactive web presence early in Year One and grow as various project milestones are achieved. The website's audience is diverse: PWD, PWD's caregivers, clinicians, health educators, policy makers, nonprofits serving people with disabilities, researchers, students in higher education, and the general public. It will include tabs for PWD/families, clinicians/educators, researchers, and policy makers. All tabs will be freely accessible.

Phase 1: Introduction to the scope of the project and its stakeholder groups (in general, not including personally identifiable information); collection and organization of pertinent healthcare and healthcare disparity-related information relevant to collaborators, researchers, focus group members, and the general public; creation of an online interactive forum focusing on discussion of related topics; and linkages to other entities with interest in the topic.

Phase 2: Recruitment information relative to focus groups, downloadable consent forms, consent explanations, general information about Virtual Ability, Second Life, and JFS Housing, Inc. communities, materials for trainers and trainees or researchers wanting to replicate the focus groups, preliminary information aggregated data from population-based quantitative studies, linkages to quality low-literacy and English as a second language resources related to the ADA, access to healthcare for persons with disabilities, and related topics.

Phase 3: Presentation of preliminary findings, dialogue with geographically dispersed individuals

on pertinent topics via forum discussions, launch of social media channels, and dissemination of materials produced by or for PWD through this project.

Phase 4: Presentation and dissemination of professional articles to professional audiences, linkages to associated research sources, and presentations and Power Points made available to the general public for download.

Post-Project Continuance: The website will be designed to allow low-cost continuation beyond the project's funded completion. No project funds will be used to support continuation of the site.

Tom Boellstorff, Professor, University of California, Irvine: Consultant to the University of Pennsylvania (Prime)

As a world authority on ethnography within virtual worlds and the use of ethnographic methods to study highly sensitive issues (sexuality and gay culture) internationally, Dr. Boellstorff will advise on human subject issues and philosophical issues with regard to interpretation and reduction of narrative resulting from focus groups and chat. In the spirit of full transparency, Dr. Boellstorff has been invited (and will be funded) to follow the process of this project as an anthropologist observer. This is consistent with the ethnographic techniques Dr. Boellstorff typically employs. He will be provided summaries of the project and will be invited to all focus groups and oversight meetings. He will perform his own analyses based on his findings and critical analysis. An experienced SL user, Dr. Boellstorff will receive invitations to observe focus groups and other sessions which he can attend at his own will. He will be provided access to de-identified chat and meeting summaries. An important role of Dr. Boellstorff will be to begin the process of data sharing which we hope to encourage.

Dr. Boellstorff's project roles are as follows:

1. Assist Alice Krueger, Sister Patrice, and Dr. Stineman on setting up Community-Based Participatory Research Partnership methods and stakeholder groups within Second Life.
2. Guide Dr. Stineman regarding the University of Pennsylvania IRB with human subject issues based on experiences with his institution.
3. Independently evaluate and study our research project, stakeholder responses, and implication of its findings applying the same observational anthropological methods that he developed for his earlier Second Life studies. Write a report on findings independent of the project teams and submit for publication freely.

PROJECT PLAN AND TIMELINE

(Use continuation pages as needed to provide the required information. Do not exceed 5 pages.)

Provide a project plan with accompanying timeline for completion of the research project within the project duration being requested. There is no required format for this plan, but a timeline or Gantt chart is appropriate. Required components include a list of major activities, milestones, and deliverables (including interim deliverables) and estimated dates for each. The project plan must include at least one deliverable or interim deliverable to be submitted to PCORI during each 12-month period of the project. Refer to the PCORI Application Guidelines for additional information.

QUALITATIVE: Plan for recruitment: THE SECOND LIFE® TEAM: VAI supports PWD in Second Life through a remarkable existing network of peer volunteers dedicated to helping people maximize opportunities to participate and thrive. That network of volunteers will be drawn upon as stakeholder researchers to help plan and operate all aspects of the project. Although recruitment will be limited to US participants non-English speaking participants can be accommodated within second life through chat which has an automatic translator that operates for numerous languages.

THE URBAN TEAM: Recognizing that PWD who use SL may differ from the general population, concurrent participation by stakeholders representing low income, culturally diverse PWD residing in an urban apartment complex (Bradley Crossing) and assisted living facility (Deerwood Crossing) will establish comparisons, deepening access to stakeholder voices. VAI and URBAN team participants will participate in stakeholder groups, and also assist directly with developing and modifying materials for accessibility by PWD who also experience low literacy.

In addition to the blog, all social media venues will include invitations for formal involvement with instructions on how to set up an avatar and enter Second Life to join VAI (see draft in Appendix A and D). Once an individual enters SL, VAI volunteers will orient him or her to the virtual world. If he or she expresses continuing interest in participating in the study formally and meets entry criteria, the volunteers will connect him or her to a study facilitator. This mechanism is intended to enrich and diversify the stakeholder sample by reaching beyond the extant VAI community.

Group procedures: All stakeholder participants will complete a short demographic survey describing their (de-identified) personal characteristics (Appendix B) and will provide informed consent prior to participation (See Protection of Human Subjects and Appendix A).

Translating forms for low literacy people: VAI and Urban team staff will each work with one group (about 10 people) to translate the data collection forms and qualitative comparator questions so as to be more culturally appropriate and accessible. This will be done using techniques where PWD will be asked to describe what they believe the text is saying. Text will be modified until the meanings as perceived by the staff and stakeholders merge.

Hypothesis generation Aim 1: About 6 groups will be formed including PWD and PWOD and/or family/caregivers and clinicians separately (6 to 8 people per group). During groups in Second Life, the moderator will communicate through an avatar after disclosing his or her real name, professional identity, qualifications, and contact information. Participants can choose to participate by typed chat or voice. The Second Life user interface can be adapted to maximize inclusion of people with all types of disabilities and assistive technology usage. A facilitator will type spoken dialog for people who are deaf and with voice text for people with visual limitations. The use of assistants to aid those with the most severe disabilities will be encouraged. All of these access options are currently being applied within VAI, have already been used by the collaborative team, and will be applied during the groups.[70] The protocol applied within VAI will follow that established by Boellstorff and colleagues (2012).[109]

Data analysis: Chat transcripts and field notes resulting from the groups, once cleared of any potentially identifying or inadvertently provided personal health information, will be read by two members of the VAI community, by one investigator and by one research assistant at the Mixed Methods Research Laboratory (MMRL) at the University of Pennsylvania to develop a coding structure. Although there will be a few codes that we will establish upfront based on the qualitative comparators, we will allow most codes to emerge from the data. Establishing the codes from the participants' words will maximize their opportunity to present themes we have not thought of. Once codes have been identified, a formal codebook will be developed and the transcripts coded by two members of the VAI community (including the moderator) and Masters level research assistants at the MMRL at the University of Pennsylvania. As reading continues and additional themes are identified, codes representative of these themes will be added to the codebook and updated, and codebooks will be distributed to all readers. Any computer files needing to be transmitted will be sent as password protected digitally encrypted files.

Ongoing stakeholder involvement: Once a stakeholder has entered the study, he or she will be considered part of the stakeholder research team and encouraged to contribute further to tasks in the study (as appropriate) including dissemination and advocacy. Although groups will officially last one hour, the process is intended to stimulate engagement. Participating individuals will be encouraged to remain after the formal session to continue interactions. They will also be invited to interact through the blog and website and to monitor and evaluate emerging findings along with the formal groups that will be convened to do so.

Pilot: During a pilot (of 1 or more groups), the group interaction procedures will be formulated and tested. The stakeholder consultants will recruit a group of 5 members from VAI who will read the transcripts from this initial session as well as 2 or 3 of the subsequent groups that follow. The members from VAI will be asked to read the text transcripts and to mark and label themes that they see within them. They will be asked to be particularly cognizant to identify themes that relate to the 5 qualitative comparators, but also themes outside those comparators that might further inform our understanding of the healthcare quality issues experienced. The codebook will be updated through Aim 1 and earlier transcripts may be re-read to check for themes found later in the process.

Interpretations and recommendations: About 4 groups will be convened to help interpret the quantitative findings established for Aims 2, 3, and 4. Researchers will present tabular findings to stakeholders and through an iterative process using "think aloud" techniques they will refine finding presentations until they are more fully understandable to PWD and clinicians. In addition to seeking ways to frame and explain findings, stakeholders will be asked to discuss implications and make policy recommendations to enhance access, improve function, and ameliorate disparities. Formal thematic analysis will not be undertaken on these transcripts. Information from them will be applied when reporting on findings of their implications and to enhance clarity of dissemination.

Stakeholder engagement: Consistent with Community-Based Participatory Research (CBPR) principles, a "train the trainer" protocol will be employed involving full and equal engagement of PWD from the communities with the professional researchers and clinicians in all operations of the qualitative study and its integration with the quantitative findings. Tasks will be fully integrated among the stakeholder research groups, the MMRL laboratory, and all other researchers.

Quantitative: Overview and General Approach to Multivariable Estimation: Our specific aims focus on empirically quantifying disparities in the quality of health and PCP care as perceived by PWD compared to PWOD and the impact of any disparities identified on transition outcomes. Taking advantage of the large nationally representative contemporary cohort of Medicare beneficiaries enrolled over a decade in the MCBS, quantitative methods will begin by

exploring the associations of all covariates to ADL and IADL stage transitions over 1, 2- and 3-year periods. A series of multivariable regressions will be implemented in Aims 2, 3, and 4 to provide a comprehensive perspective on disparities and the factors influencing transitions. After quantifying the net contribution (if any) of each comparator to outcome transitions, we will then use parameter estimates generated by these analyses in the Aim 4 simulation study. The goal will be to simulate the maximum effect of alternative programs intended to improve access to care, quality of care, and the technical and other qualities of PCPs on the wellbeing of the US Medicare population.

The quantitative analytic team under the direction of Dr. Stineman is highly experienced in population-level analyses of PWD as well as in the use of qualitative and quantitative merge designs. The analytic protocol will include weekly meetings of Dr. Stineman and all team members, with consultants and subcontractors joining at key times in formulating linkages between the qualitative findings and its use in informing the evidence-based findings. Formal agendas will be disseminated by email, followed by minutes which are jointly produced by Dr. Stineman and Ms. Kurichi (project manager). Our extensive preliminary work with MCBS data highlights the time and careful analyses required to prepare the data. Because final analyses require merging across multiple years, and not all that data will be available the first study year, analyses for all Aims will continue cyclically. We will program for table shell development, building in additional data as it becomes available over the years (see project timeline). No cell size of less than 11 persons will be analyzed or reported. Since each of the 10 entry cohorts will be formulated the same way, we will be able to use the early data waves to form analytic files which will be appended over the study years. Thus, Aims 2, 3, and 4 have both early and late phases.

Project time lines for each 12-month period

Table 7. Numbers and Types of Stakeholder Groups and Tasks by Year (6-8 people per group)

	PWD-VAI	PWD-Urban	Health professionals-VAI
Year 1	3 groups (discuss 5 comparators)	1 group (discuss 5 comparators)	2 groups (discuss 5 comparators)
Year 2	3 groups (discuss emerging quantitative data)	1 group (discuss emerging quantitative data)	1 group (discuss emerging quantitative data)
Year 3	2 groups (member checking—did we get it right?)	1 group (member checking-did we get it right?)	1 group (member checking-did we get it right?)

Table 8. Stakeholder Groups and Tasks

TASKS OF STAKEHOLDER GROUP PARTICIPANTS (VAI, Rural and Clinician)	NUMBER OF GROUPS
DESIGN: Help translate questions and forms (for use in groups) enhancing clarity, cultural appropriateness, and accessibility to low literacy participants.	1 VAI 1 Urban (not included in above focus group chart)
HYPOTHESIS GENERATION: *Discuss comparators:* Themes related to 5 comparators and perceived impact on status transitions (Aim 1).	3 VAI, 1 Urban, 2 Clinician
INTERPRETATIONS: *Discuss emerging quantitative data*: React to and help interpret quantitative findings in MCBS relative to evidence of comparator effects on transitions outcomes in populations of people at different stages of disability (reactions to Aims 2 and 3).	3 VAI, 1 Clinician
RECOMMENDATIONS: *Did we get it right?* As supported by simulations and summary of all findings, discuss strategies to encourage appropriate changes in the structure of the healthcare system targeted to enhancing the wellbeing of people with disabilities (reactions to Aim 4).	2 VAI, 1 Urban, 1 Clinician

This project brings together a strong interdisciplinary team of physician researchers (rehabilitation and family medicine/prevention), a statistician, and a qualitative researcher along

with stakeholder researchers experienced in program development, education, service of at-risk populations, advocacy, and CBPR methods. All these individuals have contributed extensively to this proposal and will continue to be part of its implementation

As Tables 7 and 8 and Figure 4 show, the qualitative analyses are fully integrated with the quantitative and continue throughout the project. The green blocks correspond to the qualitative while the gray show the quantitative components of the study. The dark shaded areas indicate the time when the task will be most active and the gray blocks indicate when times when the tasks continue but are expected to be less heavy. As example, the first dark gray box corresponds to early initiation of governance and final protocol development, yet governance and the protocol will be active through all years (the light shaded area).

Figure 4. Project Timeline

Funding Year	**Year 1**				**Year 2**				**Year 3**			
Quarters	**1**	**2**	**3**	**4**	**1**	**2**	**3**	**4**	**1**	**2**	**3**	**4**
Finalize and managed governance plan and protocol (U, V, A)												
Data uploads and merges/formation of analytic data sets (A)												
Recruitment: Plan (U, V)												
Recruitment implement (U, V)												
Obtain informed consent (U, V, A)												
Launch computer training/support (U)												
Scientific aims												
Prepare forms and questions for low literacy participants (U, V)												
De-identification and coding process design low literacy (U, V)												
De-identification and coding of transcripts plan (U, V, Q)												
De-identification and coding of transcripts implement (U, V, Q)												
Aim 1: Stakeholder groups inform hypotheses (U, V)												
Aim 2: Impact of healthcare quality on transition outcomes (A)												
Early analyses (A)												
Late analyses (A)												
Stakeholder groups address finding implications (U, V, Q)												
Aim 3: Determine impact of PCP quality on adverse transitions												
Early analyses (A)												
Late analyses (A)												
Stakeholder groups: inform findings early and late (U, V, Q)												
Aim 4: Simulation (A)												
Stakeholder groups to inform simulation and final conclusions (U, V, Q)												
Dissemination efforts												
Manuscript development (U, V, A, Q)												
Design Website and blogs (U)												
Website maintenance and updates (U, V, Q, A)												
Dissemination via web/other written public forums												
Dissemination via presentations (scientific and stakeholder) (U, V, A, Q)												
Implement assessment and reporting												

U= Urban team, V=VAI team, Q=Qualitative methods team, A=Analytic methods team; Green=qualitative efforts; Gray=quantitative efforts. Dark shading indicates heavier effort and light shading indicates lighter effort.

There are two times of MCBS data procurement which drive the early and late component of Aims 2, 3, and 4 as well as the heavy times of focus group work which are tied to those Aims. Analytic data set formation (light gray boxes) is complex and will continue throughout the entire project in series of steps that cycle through 1) variable specification, 2) variable formation, and 3) variable checking, as well as 1) file specification, 2) file formation, and 3) file verification. Missing values and attrition will need to be carefully tracked and documented. Analytic code for Aims 2 and 3 will be generated at early (with the subset of data available) and at late periods (when all data are available). Aim 4 at the end of the study culminates, merges, and capitalizes

on all qualitative and quantitative findings. It will generate final products for dissemination and implementation assessment. Governance, dissemination of interim findings, website formation and maintenance, and manuscript and presentation formulation will occur throughout as detailed above.

Table 9. Deliverables by year and month

Year 1	1) Formation of operational website with announcement of project through website, blog, and other venues. A basic website will be operational at the end of 3 months with descriptions of project Aims and Objectives. The site will be modified throughout the project as findings become available. 2) Produce set of questions for use in focus groups that have been re-written for low literacy comprehension (available by month 5). 3) Order data through ResDAC with early formation of datasets (anticipate arrival by month 3). 4) Report themes emerging from first 5 groups with possible presentation (by month 11). 5) Revise Hypotheses for Aims 2-3 based on themes (month 11). 6) Presentation of final protocol, variable specifications, and descriptive analyses of the MCBS data baseline years (2000-2009). This will include prevalence of ADL and IADL according to stages in the population and according to each comparator as well as essential demographic and diagnostic characteristics. 7) Reframe comparative effectiveness (CES) aspects based on patient and clinician input. 8) All above will be presented in the first year report to PCORI.
Year 2	1) Definitive qualitative paper written and submitted based on first 6 stakeholder groups (month 5). 2) Early report on age- and gender-adjusted ADL and IADL stages at baseline by state transition outcomes.(month 8). 3) Identify factors that predict state transitions and the independent effects of initial stage on those transitions (month 9). 4) Dissemination of above through website, blog, and other venues, early papers written and submitted with presentations made (month 12). 5) All above will be provided in second year PCORI report.
Year 3	1) Year 1 and year 2 papers may begin appearing in literature (month 1). 2) Establish the independent effects of each comparator on state transition outcomes (Aims 2 and 3 completed) (month 6). 3) Report and submit papers on models estimating the independent effects of all 5 comparators on state transition outcomes (month 7). 4) Perform simulations applying population-level statistical models triangulated with qualitative findings in order to discover optimal health system solutions. Specifically show how improvements across each of the 5 quality dimensions may benefit those without disabilities. In comparison, show how improvements in each of the 5 quality dimensions may benefit those at each stage of greater disability (month 8 begin writing up). 5) Report and submit papers on comparators effects and simulations. 6) Show how implementation of developed patient-informed surveillance (prognostic stratification) might be applied to cyclically study the results of policies to reduce the adverse impacts of the various comparators analyzed (month 9 begin writing up). 7) Final dissemination through website, blog, and other venues (by month 12) as guided by the governance committee and PCORI organization. 8) All above will be provided in a final report to PCORI along with all final protocol information and statistical analytic code.

Addendum:

The comparators as used in this proposal address the magnitude of gaps across 5 healthcare quality dimensions as experienced by people at each of 4 stages of disability in comparison to those without disabilities, and the implications of those quality gaps to risks of functional deterioration. The health care quality dimensions as assessed by the patient include 1) Care coordination and quality, 2) Access barriers, 3) Technical skills of the PCP, 4) Interpersonal skills of the PCP, 5) Quality of information provided by the PCP.

APPENDIX

(Use continuation pages as needed to provide the required information. Note that the Appendix is optional.)

Appendix A: Draft instructions to the stakeholder focus groups

Appendix B: Draft demographic survey

Appendix C: Example de-identified typed chat from pilot focus group in Second Life®

Appendix D: Draft instructions for participation in the Mrs. A and Mr. B Research Project (website version)

Appendix E: Draft stakeholder group guide with example questions and probes

Appendix A: Draft instructions to the stakeholder focus groups

INVITATION TO PARTICIPATE IN RESEARCH: Note: A first task of the proposal will be the revision of these materials to be accessible to lower literacy people.

This project will include people with all kinds of disabilities, their families, and others who care for them. This is an opportunity for your voice to be heard. If findings from this study generate large changes in healthcare policy and the way that medicine is practiced, as we hope, your ideas could affect the quality of medical care provided to millions of people with disabilities in the US.

Health professionals know a great deal about populations but not a lot about you. For example, they know that people who have less education, lower incomes, and who are ethnic minorities tend to receive lower quality care and have poorer outcomes. In contrast, they do not know a lot about you as an individual with disabilities. As people with disabilities, we face MANY challenges to getting healthcare. The qualities of those challenges depend on the types of disabilities we have.

How do these challenges make it difficult to access healthcare? How do you think your disabilities affect the quality of healthcare you receive? Do physicians treat you the same way they treat everyone else? Do health professionals understand your special needs? If you have sub-optimal healthcare, how does that affect you?

This project is about you. By sharing your stories, both good and bad, about healthcare, you will help us see research findings through your eyes. Together, we may contribute to changes in the healthcare system that could benefit all of us. You are being invited to participate in this important project as a person who either has a disability or cares for someone with disability. You will receive 1000 Linden dollars for participation in a Second Life® group or a Walmart or Target gift card worth $5.00 for participation in a face-to-face group as appreciation and reimbursement for time spent.

We hope that this experience will benefit you by encouraging you to advocate for yourself and connect with other group members who also have disabilities. With strong research findings and your ideas, we hope to help create a healthcare system that provides high quality equitable care.

WHO IS ELIGIBLE?

1. You are eligible if you have any kind of disability or a health condition that makes it difficult to care for yourself or live independently OR you are eligible if you are a family member, other individual (Including a health professional or personal care attendant) caring for a person or PWD or health conditions that makes it difficult for them to care for themselves.
2. You must be 21 years old or older.
3. You need to be able to communicate and participate in small group dialogue with or without an ADA accommodation. The accommodation could include one-to-one dialogue.
4. You are not eligible if you are a "devotee" (disability fetishist) or "medical pretender/role player" (person who pretends to have a disability that they do not have in real life).

WHAT WILL I BE ASKED?
Example questions are:

1. *How does the quality of healthcare you receive (if at all) differ from those without disabilities?*
2. *What gets in the way (if anything) of your receiving and accessing high quality coordinated care?*

3. *What issues or problems (if any) do you experience with your PCP's i) technical skills, ii) interpersonal manner, or iii) quality of information provided?*
4. *How has access to and quality of care affected your health or disability?*
5. *How do you think poorer access to care or lower quality healthcare might increase your risk of functional decline or institutionalization or reduce your survival?*

WHAT SHOULD I SAY?

1. Say whatever is in your heart and mind and that you are comfortable sharing.
2. Share ideas and things you have learned relevant to your own life experiences.

CODE OF CONDUCT for STAKEHOLDER GROUP PARTICIPATION: Second Life (similar code will be written for in-person group participation).

The following policies are intended to guide interactions among focus group participants, facilitators, and moderators. They apply to everyone involved in this research, whether research staff or community participants. If you have concerns about these policies or their implementation, please send a message to the study Facilitator or Moderator. If concerns involve a research staff member, please contact one of the project Principal Investigator or Consultants listed below.

RESPECT FOR OTHERS:

1. Treat other members with respect and dignity. Show consideration for their opinions and experiences.
2. Give everyone time to speak and finish their thought before offering a response or your own ideas.
3. Remember that people with some types of disabilities may not be able to respond as quickly as others. Be patient.

CONFIDENTIALITY AND INFORMED CONSENT:

1. Make sure you provide informed consent prior to or during the focus group session. No input, ideas, or chat can be included in this project until explicit written permission from you is provided.
2. No personal information provided in the group should be shared outside the focus group.
3. Please share your own experiences and how you were able to deal with the situations that were difficult in attempting to get the medical care you needed.

YOUR PARTICIPATION IS VOLUNTARY:

1. If you do not feel comfortable or safe enough to openly talk about yourself or a particular topic, it is okay to just listen.
2. Your contribution and participation is totally voluntary.
3. You can leave any time you might not feel comfortable and you are also welcome to return.

MISCONDUCT:

1. Behavior that could be hurtful, disrespectful, or threatening will not be tolerated.
2. If you have concerns about someone's behavior, please discretely notify the moderator or facilitator of your group.
3. After the person being disruptive receives a discrete warning, he or she will be removed from the group if the objectionable behavior continues.

4. "Devotees" (disability fetishists) and "medical pretenders/role players" (people who pretend to have a disability that they do not have in real life) are not to be included in this research. If you believe someone is a devotee or medical pretender, do not confront the individual. Please discretely communicate your concern to the moderator after the meeting.

HOW ARE MY IDEAS TO BE USED?

1. The general information about you will be combined with the information from all other participants and used to describe the characteristics of the people that participated in the Mrs. A and Mr. B study. All typed chat will be logged and all voice communication will be transcribed to text for the purpose of the research.
2. This material is maintained for research purposes and will help us understand healthcare in ways that can lead to better service for people with disabilities.
3. Information that could identify you, such as your age, name, location, or specific diagnoses, will be carefully removed from the research documents before use.
4. Quotes may be published from chat to illustrate ideas. These quotes will not include any personal information that could be used to identify you.

WHAT IF I AM UPSET ABOUT WHAT I FEEL OR EXPERIENCE?

1. If a topic upsets you, you may leave the discussion at any time.
2. We would also encourage and welcome you to contact research staff or the (Dr. Margaret Stineman - See contact information below). Anything discussed with research staff in confidence will not be shared outside the research staff team.

PRINCIPAL INVESTIGATOR CONTACT INFORMATION
Professional Contact.
Dr. Margaret Grace Stineman
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Professor of Epidemiology
Center for Clinical Epidemiology and Biostatistics
Perelman School of Medicine, University of Pennsylvania
904 Blockey Hall, 423 Guardian Drive
Philadelphia, PA 19104-6021
Mstinema@exchange.upenn.edu;
Second life contact: “MargaretGrace Sapphire”
215-898-6272

CONSULTANT CONTACT INFORMATION
Sister Patrice Colletti, SDS
Inclusion Coordinator
Bradley Crossing/ Deerwood Crossing
JFS Housing, Inc.
Room 317
414-502-7797

Alice Krueger
Second Life contact: “Gentle Heron”

Appendix B: Draft demographic survey

DRAFT SURVEY FOR PWD and family members. May be completed with the help of a proxy

(guardian, family caregiver, non-family caregiver, interpreter, etc., as an ADA accommodation). Note: Versions will be developed for family and non-family caregivers and clinicians with similar content. The clinician version will be designed to focus on describing the population they treat.

1- Do you have any difficulty with any of the following self-care activities (check all that apply)?
   - ○ Eating
   - ○ Using the toilet
   - ○ Dressing
   - ○ Bathing or showering
   - ○ Transferring (getting in and out of bed or chairs)
   - ○ Walking
   - ○ Other problem (Describe_____)

2- Do you have difficulty with any of the following independent living activities (check all that apply)?
   - ○ Managing money (keeping track of expenses or paying bills)
   - ○ Preparing own meals
   - ○ Doing light housework (straightening up, light cleaning or dishes)
   - ○ Shopping for personal items (such as toilet items or medications)
   - ○ Using the telephone
   - ○ Doing heavy housework
   - ○ Other problem (Describe_____)

3- Do you see yourself as a
   - ○ Person with disability?
   - ○ Family member caregiver? Request form for family member caregiver.
   - ○ Non-family caregiver? Request form for non-family caregiver.
   - ○ Health professional? Request dates for health professional stakeholder group.
   - ○ None of these? You are not eligible to participate in this study.

4- Gender (Check all that apply)
   - ○ Male
   - ○ Female
   - ○ LGBT (Lesbian/Gay/Bisexual/Transgender)
   - ○ Chose not to disclose

5- How old are you?
   - ○ 21- 30
   - ○ 31-40
   - ○ 41-50
   - ○ 51-60
   - ○ 61-70
   - ○ 70-80
   - ○ 81 or older
   - ○ Choose not to disclose

6- Partnership or marital status
   - ○ Married or currently partnered
   - ○ Single or currently alone
   - ○ Widow, widower, divorced, or previously partnered
   - ○ Choose not to disclose

7- Do you live alone?
- Yes
- No

8- Because of your disabilities, do you have problems with the following? Select all that apply to you:
- Cognition (Intellectual functions such as memory, knowing time and place)
- Mental health (Emotional, social functioning)
- Hearing (Deaf)
- Seeing (Blind)
- Chronic fatigue
- Pain
- Communication (Voice, speech, expression and understanding)
- Cardiovascular or respiratory
- Digestive (problems with bowels or stomach)
- Genitourinary/kidney (problems with urination, renal dialysis)
- Sexual function
- Movement related (Joints or bones including back)
- Movement related (muscle power/paralysis)
- Other (please specify) _____
- Choose not to disclose

9- Is your disability visible (Will people notice it when looking at you or talking with you?)
- Yes
- No
- Choose not to disclose

10- Was your disability present at birth?
- Yes
- No
- Chose not to disclose

Appendix C: Example de-identified typed chat from pilot focus group in Second Life®

This shows the potential richness of content. The discussions were focused on quality of healthcare and PCP communication.

Gentle Heron (Alice Krueger) served as moderator. Margaret Stineman (MargaretGrace Sapphire) served as facilitator. The Chat has been de-identified through the removal and replacement of all avatar names and potentially identifiable information. The goal was to determine barriers associated with medical equipment and procedures that reduced the quality of healthcare provided to people with disabilities. The groups combined PWD, family members, health educators, and clinicians. Time appears at the left in square brackets.

Introduction and general instructions
[17:09] Gentle Heron: It is absolutely essential that your personal identity be protected. Thus please do not provide anything that would identify you.
[17:09] Gentle Heron: Specifically, do not give out such information as your real name, address, age or particular unusual diagnoses that might identify you.
[17:10] Gentle Heron: We will need to know your types of RL disabilities in order to sort the input.
[17:10] Gentle Heron: Very general statements will be fine, such as, I am unable (or have difficulty) standing, transferring, walking, with balance, seeing, hearing, speaking etc. You can mention more than one type of challenge that relates to you.
[17:10] Gentle Heron: No names (SL or RL) or personally identifying information (such as age or gender) will be associated with your input.
[17:10] Gentle Heron: The results will be organized into broad themes and thoughts that many of us share.
[17:10] Gentle Heron: So that we can organize the information into broad themes when you speak or type, please address the following:
[17:11] Gentle Heron: or just talk to us!
[17:11] Gentle Heron: 1. Type of diagnostic equipment commented on:
2. Comments on current level of accessibility of equipment:
3. Suggestions for improvement:
[17:11] Gentle Heron: 4. Story of personal success or problem using this equipment:
5. RL disability (or role- parent/caregiver; medical professional).
[17:11] Gentle Heron: Again, no specifics please. Broad descriptions are fine. Just describe the types of problems you have.
[17:11] Gentle Heron: We're open for discussion.
[17:12] Gentle Heron: If you would rather not share your ideas publicly, you are welcome to send your thoughts on a notecard to Healthinfo Ordinary, who will collect the notes and add them into the other materials.
The group turns to pain as a barrier to people with disabilities seeking healthcare, discussing difficulties reducing and managing it, inadequate clinical training and high degrees of variability in clinician response. Participants offer some valuable solutions and share frightening stories.
[17:17] PARTICIPANT B: I am transitioning from dental to having blood drawn
[17:17] PARTICIPANT C: why don't you get a prescription from your doctor
[17:18] PARTICIPANT B: the doctor says they are not allowed to
[17:18] PARTICIPANT C: to use a topical anesthetic at home
[17:18] PARTICIPANT B: insurance won't cover it
[17:18] PARTICIPANT C: you can't appeal it?

[17:18] PARTICIPANT C: based on his disability
[17:18] Gentle Heron: Rub his arm with Numzit (teething gel) prior to the blood draw
[17:18] PARTICIPANT B: it ought to be allowed in cases where it is psychologically or physically traumatic
[17:18] PARTICIPANT B: I know, Gentle - if I have warning
[17:19] PARTICIPANT C: emla cream is used a lot for things like iv starts and dialysis patients
[17:19] MargaretGrace Sapphire: This is SUCH an important idea for children as well as people with disabilities or anyone
[17:19] PARTICIPANT B: but this is something the system is not handling correctly
[17:19] Gentle Heron: What if the procedure is known to cause pain? Sometimes there's no way around it.
[17:19] MargaretGrace Sapphire: That is true
[17:19] PARTICIPANT B: I agree sometimes pain is unavoidable
[17:19] PARTICIPANT B: but when it can be avoided, why not?
[17:19] PARTICIPANT C: i agree
[17:19] MargaretGrace Sapphire: sometimes attempts to relieve it are just as painful
[17:20] PARTICIPANT B: it is inhumane to cause unnecessary trauma
[17:20] MargaretGrace Sapphire: There needs to be a priority in medicine to relieve pain
[17:20] PARTICIPANT C: its just a cream
[17:20] PARTICIPANT B: exactly,
[17:20] PARTICIPANT C: emla cream can be applied 15 minutes prior and it isn't painful
[17:20] Gentle Heron: how do you prepare your son for procedures?
[17:20] PARTICIPANT B: usually, we end up with three of us holding him down by force
[17:20] Gentle Heron: now that's horrible for you also!
[17:21] PARTICIPANT B: yes
[17:21] PARTICIPANT C: there is also hurricane spray
[17:21] PARTICIPANT C: its just a cooling spray that numbs the skin
[17:21] PARTICIPANT B: that one is new to me, - thanks!
[17:21] PARTICIPANT C: it doesn't hurt and its great!
[17:21] MargaretGrace Sapphire: Does it ever help to role play what is going to happen to him? Sometimes that can help a little
[17:21] PARTICIPANT B: I stockpile and hoard drugs from other treatments specifically to self-medicate when the system won't for things like this
[17:21] PARTICIPANT C: Can't tell you how many nerve blocks and steroid shots that got me through
[17:22] MargaretGrace Sapphire: WOW
[17:22] Gentle Heron: steroid shots.... awful things
[17:22] PARTICIPANT B: steroid shots are so dangerous
[17:22] PARTICIPANT B: and the prophylaxis is under used
[17:22] MargaretGrace Sapphire: This should be part of training
[17:22] MargaretGrace Sapphire: of doctors
[17:23] PARTICIPANT B: they say there isn't enough evidence yet
[17:23] PARTICIPANT C: i have tarsal tunnel in both feet and had to have steroid shots in both for several years
[17:23] Gentle Heron: pain relief should be part of training.... you mean it isn't already?
[17:23] PARTICIPANT B: it is common practice in some parts of the country, but totally not used in others

Ideas for enhancing the quality and safety of healthcare emerged as it is provided to people with disabilities

"A small screen placed in MRI tubes through which typed information can be provided to deaf patients"
"Develop more non-invasive testing options such as salivary diagnostics"
"Create lighter portable oxygen tanks or concentrators"
"Replace open gynecological stirrups with stirrups that support patient's legs"
"Have professional patient advocates for those who cannot advocate for themselves and have no family."
"Train expert volunteers to help patients navigate the healthcare system"
"Move more towards mobile diagnostics and healthcare systems that treat people in their own homes"
"Mandate training and certification in safe patient transfers, use of transfer board and Hoyer lifts for all clinical staff."
"Allow use of topical and local numbing agents consistently for all procedures".

Other themes and important quotes and themes emerged providing strong stakeholder support for the proposed project.

"A culture of service"
"Empower local connections"
"Small groups on line"
"Patients need to advocate politically for their own needs"
"Push support and education out into the broader community"
"Make the patient and care giver part of the team"
"Transparency and openness of care"
"It all comes down to ensuring connections and community."
"If you have many eyes watching at attention, then many minds looking for solutions….everyone trusts the system to do it, no one is watching."
"If people have the right attitudes, the equipment (and procedures) will be changed by default."
"Education of providers in a situation where all of us become some level of provider."
"Some of the old ways were better"
"Listening to heart and lungs rather than imaging them"
"Take the old ways, but embroidering them with new tech and solutions"
"people are more important than machines"
"Your insights will be valuable in my classroom"
"Thank you for doing this"

Appendix D: Draft instructions for participation in the Mrs. A and Mr. B research project

(To be placed on website)

You can participate in the Mrs. A and Mr. B study in two different ways. The first way is simply follow the study and its findings and contribute your responses and questions to the formally involved researchers and stakeholders through the blog on the website. The second way is to more formally participate by coming into Second Life® and participating in an interactive stakeholder group.

> To come into Second Life (SL) through the Virtual Ability (VAI) website, go to www.virtualability.org. Just follow the directions and you will be guided through the steps.
>
> You can set up your avatar (your clothes, your hairdo and its color, and your gender. You CANNOT change the avatar (account) name you choose once you set up your avatar and account (note setting up an account is free).

When you create an account on the VAI website, you will then be prompted to download the Second Life viewer (user interface) software. Unlike other online games where everything takes place in the game designers' computer system, SL works through software on your desktop.

Once you have an account and have downloaded the software, you are ready to see your avatar in the Second Life world for the first time. If you entered through our website, your avatar should begin on VIRTUAL ABILITY ISLAND.

Our main public island contains a new resident orientation path. New avatars begin right at the start of the training path. There you will learn all the basic skills. It's kind of like Drivers Ed for your avatar. We designed it to be self-teaching, but we can also have a mentor work through it with you and answer your questions as you go along. Mentors are also useful when you get to the end of the path and have an opportunity to customize the appearance of your avatar. We all have tons of hairdos, body shapes, skins, clothing, etc., to outfit new community members. At the end of the path, you will see a sign stating, “Sign up to participate in the “Mrs. A and Mr. B” study.” Right click on that sign and instructions will appear on your screen.

Appendix E: Draft stakeholder group guide with example questions and probes

Thank you for agreeing to participate in our study. We are very interested in knowing, based on your experience, ideas, and opinions, what you think about the qualities of the healthcare system and physicians in the US, particularly as related to those of us with disabilities. Once you participate in this group, you are considered a stakeholder participant and we hope that you will continue to be involved in the project. Follow findings on the website. Contribute further ideas to the blog. Tell your friends, family, and healthcare providers about what we are learning about the quality of healthcare provided to people with disabilities. But please remember you must not discuss the specific stories you hear outside of this focus group. We hope you enjoy the process.

Note: All groups will end with the following question:
How well did this process work for you?

Example questions for stakeholders:

DESIGN PHASE: Help translate questions and forms (for use in groups) enhancing clarity, cultural appropriateness, and accessibility to low literacy participants: (about 6 VAI and 6 Urban participants).

- What are your views about this question?
- What do you see this question as asking?
- With this question, what sorts of things go through your mind?
- How would you make this question easier to understand?
- How important is this question?
- Are there other important questions?

HYPOTHESIS GENERATION: Themes related to the 5 comparators and perceived impact on status transitions (3 VAI, 1 Urban, 2 Clinician groups).

- How would poor quality healthcare, access, or coordination affect your chance of continuing to care for yourself and live independently? Please give examples.
- How would the skill and inter-personal manner of your primary healthcare provider influence your chance of continuing to care for yourself and live independently? Please give examples.
- Please describe how your physician's ability to provide important information for your health is essential to your ability to care for yourself and live independently. Please give examples.

INTERPRETATIONS: React to and help interpret quantitative findings as discovered through analysis of the MCBS relative to evidence of comparator effects on actual status transitions in populations of people at different stages of disability (reactions to Aims 2 and 3 findings). This will include 3 VAI, 1 Urban, and 1Clinician Group

- How would you explain these findings to a friend or family member (tests participants' understanding)?
- What do you think of these findings?
- What makes sense to you?
- What surprises you?
- How would you present these findings more clearly?

RECOMMENDATIONS: As supported by simulations and summary of all findings, discuss strategies to encourage appropriate changes in the structure of the healthcare system targeted to enhancing the wellbeing of people with disabilities (reactions to Aim 4). The following example scenario reflects our preliminary findings (2 VAI, 1 Urban, and 1 Clinician group).

"*Our research shows that when people who have disabilities receive high quality healthcare that this may reduce the chance of their disabilities getting worse, reduce chances of their needing to go to a nursing home, and increase how long they live.*"

- Why do you think this is?
- What ideas do you have about improving healthcare quality for people with disabilities?
- What healthcare programs are most essential to helping people live independently and maintain their autonomy?
- If you could change one thing about the health services you receive, what would it be?
- People during earlier groups shared the following views and ideas about quality and access issues: (Key illustrative quotes from dominant themes will be provided.) What healthcare improvements would be most compatible with these ideas about quality issues?
- How could your doctor implement these improvements?
- What are the most important findings that we need to share with communities of people with disabilities, family members, clinicians, and policy makers?
- How would you describe these findings in your own words?
- How are these findings important?