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14. ABSTRACT

Patients with systemic lupus erythematosus (SLE) have reported substantial impairment in physical and cognitive functioning. Despite its importance, specific tools to improve the recognition and facilitate the discussion of functioning are currently lacking in SLE. To address this gap, we leveraged resources from multiple recent studies to address two major objectives: (1) to assess, in a pilot sample of SLE patients, the utility of our physical functioning report in patient-provider encounters and (2) to determine whether and how cognitive assessment data should also be included in a functioning report for SLE patients. For objective 1, individualized reports (including pictorial representations of several domains of physical function: activities of daily living, falls, physical performance, perceived physical functioning, and community mobility) were delivered to 59 lupus patients with existing data on these measures. Of these, 47 (79.7%) completed an online survey about their individualized report. Reported ease of interpretation ranged from 70.2% to 85.1% across the domains of physical function. Most reported that physical functioning domains of the report were useful for treatment or other care planning (range, 70.2-80.5%). For objective 2, patients (2 groups) and providers (2 groups) not only provided specific feedback to improve the report (*e.g.*, refined images and language, de-emphasis on quantitative results), but also provided more general thoughts on comfort with discussing cognitive function in a clinical setting. Our products include a functioning app to produce physical functioning reports for SLE patients and a cognitive functioning report that can be modified based on feedback received. Future studies can help determine how clinical encounters may be improved with real-time functioning reports in SLE and beyond.

15. SUBJECT TERMS
lupus, physical functioning, geriatric assessment, patient-provider communication

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1. **INTRODUCTION:** *Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.*

Even relatively young patients with systemic lupus erythematosus (SLE) have reported substantial impairment in physical and cognitive functioning. In addition to being associated with higher morbidity and mortality, such impairment limits independence and reduces quality of life. Avoiding functional impairment may be as important to patients as the clinical outcomes, such as SLE-related damage and activity, that are emphasized in the traditional disease-based approach to SLE. Despite its importance, functioning is not well-described in most medical charts. Unrecognized functional impairment may lead to care that is not aligned with patients' functional health and, thus, not patient-centered. Specific tools to improve the recognition and facilitate the discussion of functioning are currently lacking in SLE. To address this gap, we leveraged resources from multiple recent studies, including: (1) a pilot study [Approaches to Positive, Patient-Centered Experiences of Aging in Lupus (APPEAL)] in which we performed detailed, in-person multi-domain assessments of physical and cognitive functioning among 60 SLE patients of all ages, recruited from the ongoing population-based Georgians Organized Against Lupus (GOAL) cohort of persons with validated SLE; and (2) another pilot study in which our team developed an individualized app-based report incorporating multiple domains of physical functioning for another chronic disease (end-stage renal disease). We aimed to address two major objectives: (1) to assess, in a pilot sample of SLE patients, the utility of our physical functioning report in patient-provider encounters and (2) to determine whether and how cognitive assessment data should also be included in a functioning report for SLE patients.

2. **KEYWORDS:** *Provide a brief list of keywords (limit to 20 words).*

lupus, physical functioning, geriatric assessment, patient-provider communication

3. **ACCOMPLISHMENTS:** *The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction.*

What were the major goals of the project?

List the major goals of the project as stated in the approved SOW. If the application listed milestones/target dates for important activities or phases of the project, identify these dates and show actual completion dates or the percentage of completion.

Major Task 1: Modification of app

Subtask 1: Determine elements on report that need to be modified (target completion: Month 1; 100% complete)
Subtask 2: Make modifications to app (target completion: Month 3; 100% complete)
Subtask 3: Test modified app (target completion: Month 3; 100% complete)
Subtask 4: Completed app (target completion: Month 4; 100% complete)

Major Task 2: Create & mail reports to pilot study participants

Subtask 1: Use existing data from pilot to create/print reports using app (target completion: Month 4; 100% complete)
Subtask 2: Mail reports to pilot study participants (target completion: Month 4; 100% complete)
Subtask 3: Follow-up recruitment calls (target completion: Month 6; 100% complete)

Major Task 3: Conduct patient surveys

Subtask 1: Design survey (target completion: Month 6; 100% complete)
Subtask 2: Generate/send online survey links (target completion: Month 7; 100% complete)
Subtask 3: Perform telephone surveys if necessary (target completion: Month 9; N/A)
Subtask 4: Analyze results of survey, plan app modifications for future (target completion: Month 11; 75% complete)

Major Task 4: Recruitment for focus groups

Subtask 1: Recruit providers for focus groups (target completion: Month 4; 100% complete)
Subtask 2: Recruit additional SLE patients for focus groups if needed (target completion: Month 7; N/A)

Major Task 5: Conduct focus groups

Subtask 1: Planning (target completion: Month 3; 100% complete)
Subtask 2: Focus groups (target completion: Month 3; 100% complete)
Subtask 3: Analysis of qualitative data (target completion: Month 9; 50% complete)
Subtask 4: Plan future studies (no target completion; 50% complete)

What was accomplished under these goals?

For this reporting period describe: 1) major activities; 2) specific objectives; 3) significant results or key outcomes, including major findings, developments, or conclusions (both positive and negative); and/or 4) other achievements. Include a discussion of stated goals not met. Description shall include pertinent data and graphs in sufficient detail to explain any significant results achieved. A succinct description of the methodology used shall be provided. As the project progresses to completion, the emphasis in reporting in this section should shift from reporting activities to reporting accomplishments.

Major Activities

Major Task 1: Modification of app. The team at Georgia Tech (working with the Emory team) made the necessary modifications to the physical functioning report and the existing code underlying it (*objective 1a*), so that it was compatible with our existing APPEAL pilot data; this was implemented in this study as a command-line tool. The team recently (8/19) completed the app, which can be used on Android devices in real time to both collect physical functioning data and create real-time reports. We are currently thoroughly testing the app's functions, with the intention of using it in an ongoing cohort study of patients with SLE (in which we are measuring physical functioning), as well as for future studies.

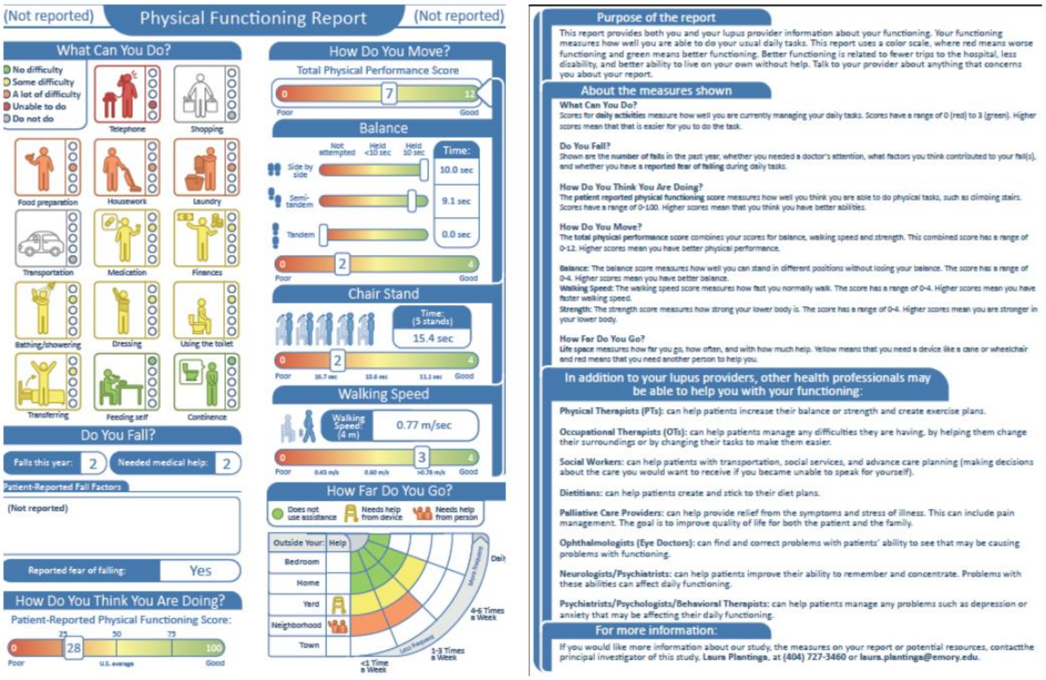
Major Task 2: Create & mail reports to pilot study participants. Using the command-line tool, the Emory team created reports (PDFs) for the 59/60 living original APPEAL participants, using our existing dataset (*objective 1b*; see **Figure 1** for example). Reports were then emailed to the 59 participants (and mailed for participants who did not have an email address on file), with invitations to complete the online surveys (see below).

Major Task 3: Conduct patient surveys. The surveys were designed and administered via REDCap with individualized links (*objective 1c*). A paper version for participants who preferred a paper survey (*n*=5), and these results were manually entered into REDCap by a study coordinator. Participants were instructed to answer the survey with respect to their individualized report. Both versions of the survey oriented the participant to the sections of the report by showing example images. The data have been downloaded and cleaned, and analysis of the results from the survey is underway (see below). We are also considering how these data can inform future projects.

Major Task 4: Recruitment for focus groups. Providers were recruited for focus groups via email and in person. These focus groups were scheduled outside of work hours for the convenience of the providers, according to the best times of those who were interested. The physician focus group included two rheumatologists; a primary care physician and a nephrologist who treat lupus patients in their clinics; and a medical resident. The non-physician focus group included nurses and medical assistants who either currently or formerly worked in lupus or rheumatology clinics. For patients, focus group availability was assessed as part of the survey (see above), and we were able to recruit and schedule enough patients for two focus groups from this effort (no need to recruit additional SLE patients for focus groups).

Major Task 5: Conduct focus groups. Four 90-minute focus groups were facilitated by Co-I Ann Vandenberg using a standardized interview guide and the discussions were recorded, transcribed, and verified. The focus groups each included an initial general discussion of cognitive functioning in lupus, followed by a more specific discussion of a mock cognitive visualization report (**Figure 2**) based on the cognitive data collected in our pilot study. The analyses of these data are underway (see below), along with brainstorming for future studies.

Figure 1. Example modified physical functioning report using APPEAL pilot data, sent to patients along with surveys to elicit feedback on individualized reports.



Purpose of the report

This report provides both you and your lupus provider information about your functioning. Your functioning measures how well you are able to do your usual daily tasks. This report uses a color scale, where red means worse functioning and green means better functioning. Better functioning is related to fewer trips to the hospital, less disability, and better ability to live on your own without help. Talk to your provider about anything that concerns you about your report.

About the measures shown

What Can You Do?
Scores for **daily activities** measure how well you are currently managing your daily tasks. Scores have a range of 0 (red) to 3 (green). Higher scores mean that that is easier for you to do the task.

Do You Fall?
Shown are the **number of falls** in the past year, whether you needed a doctor's attention, what factors you think contributed to your fall(s), and whether you have a **reported fear of falling** during daily tasks.

How Do You Think You Are Doing?
The **patient reported physical functioning** score measures how well you think you are able to do physical tasks, such as climbing stairs. Scores have a range of 0-100. Higher scores mean that you think you have better abilities.

How Do You Move?
The **total physical performance** score combines your scores for balance, walking speed and strength. This combined score has a range of 0-12. Higher scores mean you have better physical performance.

Balance: The balance score measures how well you can stand in different positions without losing your balance. The score has a range of 0-4. Higher scores mean you have better balance.
Walking Speed: The walking speed score measures how fast you normally walk. The score has a range of 0-4. Higher scores mean you have faster walking speed.
Strength: The strength score measures how strong your lower body is. The score has a range of 0-4. Higher scores mean you are stronger in your lower body.

How Far Do You Go?
Life space measures how far you go, how often, and with how much help. Yellow means that you need a device like a cane or wheelchair and red means that you need another person to help you.

In addition to your lupus providers, other health professionals may be able to help you with your functioning:

Physical Therapists (PTs): can help patients increase their balance or strength and create exercise plans.

Occupational Therapists (OTs): can help patients manage any difficulties they are having, by helping them change their surroundings or by changing their tasks to make them easier.

Social Workers: can help patients with transportation, social services, and advance care planning (making decisions about the care you would want to receive if you became unable to speak for yourself).

Dietitians: can help patients create and stick to their diet plans.

Palliative Care Providers: can help provide relief from the symptoms and stress of illness. This can include pain management. The goal is to improve quality of life for both the patient and the family.

Ophthalmologists (Eye Doctors): can find and correct problems with patients' ability to see that may be causing problems with functioning.

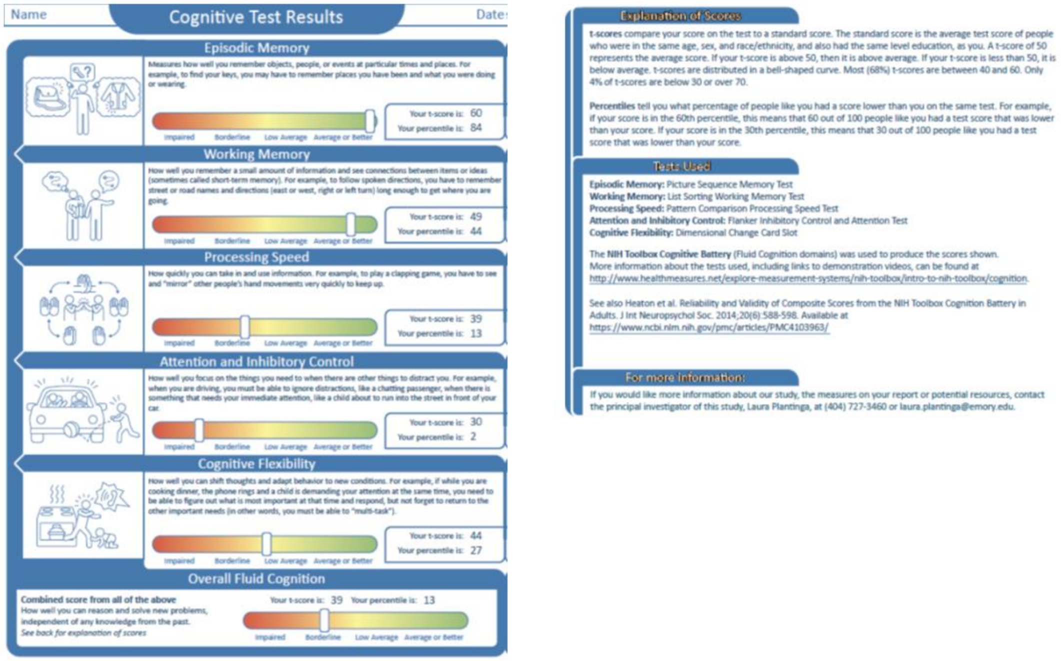
Neurologists/Psychiatrists: can help patients improve their ability to remember and concentrate. Problems with these abilities can affect daily functioning.

Psychiatrists/Psychologists/Behavioral Therapists: can help patients manage any problems such as depression or anxiety that may be affecting their daily functioning.

For more information:

If you would like more information about our study, the measures on your report or potential resources, contactthe principal investigator of this study, **Laura Plantinga**, at **(404) 727-3460** or **laura.plantinga@emory.edu**.

Figure 2. Mock cognitive functioning report based on data collected in the APPEAL pilot, used in focus groups to elicit feedback.



Name
Cognitive Test Results
Date:

Episodic Memory

Measures how well you remember objects, people, or events at particular times and places. For example, to find your keys, you may have to remember places you have been and what you were doing or wearing.

Your t-score is: 60
Your percentile is: 84

Working Memory

How well you remember a small amount of information and see connections between items or ideas (sometimes called short-term memory). For example, to follow spoken directions, you have to remember street or road names and directions (east or west, right or left turn) long enough to get where you are going.

Your t-score is: 49
Your percentile is: 44

Processing Speed

How quickly you can take in and use information. For example, to play a clapping game, you have to see and "mirror" other people's hand movements very quickly to keep up.

Your t-score is: 39
Your percentile is: 13

Attention and Inhibitory Control

How well you focus on the things you need to when there are other things to distract you. For example, when you are driving, you must be able to ignore distractions, like a chatting passenger, when there is something that needs your immediate attention, like a child about to run into the street in front of your car.

Your t-score is: 30
Your percentile is: 2

Cognitive Flexibility

How well you can shift thoughts and adapt behavior to new conditions. For example, if while you are cooking dinner, the phone rings and a child is demanding your attention at the same time, you need to be able to figure out what is most important at that time and respond, but not forget to return to the other important needs (in other words, you must be able to "multi-task").

Your t-score is: 44
Your percentile is: 27

Overall Fluid Cognition

Combined score from all of the above
How well you can reason and solve new problems, independent of any knowledge from the past.
See back for explanation of scores

Your t-score is: 39 Your percentile is: 13

Explanation of Scores

t-scores compare your score on the test to a standard score. The standard score is the average test score of people who were in the same age, sex, and race/ethnicity, and also had the same level education, as you. A t-score of 50 represents the average score. If your t-score is above 50, then it is above average. If your t-score is less than 50, it is below average. t-scores are distributed in a bell-shaped curve. Most (68%) t-scores are between 40 and 60. Only 4% of t-scores are below 30 or over 70.

Percentiles tell you what percentage of people like you had a score lower than you on the same test. For example, if your score is in the 60th percentile, this means that 60 out of 100 people like you had a test score that was lower than your score. If your score is in the 30th percentile, this means that 30 out of 100 people like you had a test score that was lower than your score.

Tests Used

Episodic Memory: Picture Sequence Memory Test
Working Memory: List Sorting Working Memory Test
Processing Speed: Pattern Comparison Processing Speed Test
Attention and Inhibitory Control: Flanker Inhibitory Control and Attention Test
Cognitive Flexibility: Dimensional Change Card Slot

The **NIH Toolbox Cognitive Battery** (Fluid Cognition domains) was used to produce the scores shown. More information about the tests used, including links to demonstration videos, can be found at http://www.healthmeasures.net/explore-measurement-systems/nih-toolbox/intro-to-nih-toolbox/cognition.

See also Heaton et al. Reliability and Validity of Composite Scores from the NIH Toolbox Cognition Battery in Adults. J Int Neuropsychol Soc. 2014;20(6):588-598. Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4103963/

For more Information:

If you would like more information about our study, the measures on your report or potential resources, contact the principal investigator of this study, Laura Plantinga, at (404) 727-3460 or laura.plantinga@emory.edu.

Specific Objectives

Our specific objectives, which did not change over the project period, were:

Objective 1: To assess, in a pilot sample of SLE patients, the utility of our physical functioning report in patient-provider encounters.
1a: We will make necessary modifications to the report and the existing Android app underlying it, to ensure compatibility with existing APPEAL pilot data on multiple domains related to physical functioning.
1b: Using existing APPEAL study data and the app modified in *1a*, we will generate and send individualized physical functioning reports to the 60 APPEAL participants.
1c: We will survey the patients regarding the utility of the report and incorporate this feedback into refinements of the app and report and in future study planning.

Objective 2: To determine whether and how cognitive assessment data should also be included in a functioning report for SLE patients. We will elicit qualitative feedback from patient and SLE provider focus groups on the potential content and visualization of a report using cognitive functioning data; this feedback will be incorporated into refinements of the app and report and in future study planning.

Significant Results

Objective 1 (Major Tasks 1-3). Individualized reports (including pictorial representations of several domains of physical function: activities of daily living, falls, physical performance, perceived physical functioning, and community mobility) were delivered to 59 lupus patients with existing data on these measures. Of these, 47 (79.7%) completed an online survey about their individualized report. See **Table 1** for characteristics of respondents. Ease of interpretation for each domain ("How easy is it to understand your results?") was dichotomized as very easy vs. not; differences by characteristics were assessed by Fisher's exact test. Utility and acceptability were assessed by items relating to usefulness for care planning, comfort with discussing the report, and willingness to undergo assessments and receive reports in real time. Reported ease of interpretation ranged from 70.2% to 85.1% across the domains of physical function (see also **Table 2**). Ease of interpretation was lower among those who were older, black, and female and who had lower cognitive scores; no differences were statistically significant. Most reported that physical functioning domains of the report were useful for treatment or other care planning (range, 70.2-80.5%). Nearly all patients (range, 93.2-100%) reported that they felt comfortable discussing the report with a healthcare provider. Most patients indicated interest in receiving a real-time report (87.2%) and willingness to arrive early to appointments to complete the necessary tests and surveys (89.1%). These results suggest that a report that provides at-a-glance information on physical functioning for lupus patients was associated with high comprehension, utility, and acceptability. Targeted, culturally appropriate efforts may be needed to increase equity in comprehension. Future studies can help determine how clinical encounters may be improved with a real-time functioning report.

Table 1. Characteristics of SLE Patients Participating in Survey Regarding Individualized Physical Functioning Reports

Characteristic	**Overall**
N	47
Age, mean (SD)	49.6 (12.3)
Sex	
Male	4 (8.5%)
Female	43 (91.5%)
Race	
Black	37 (78.7%)
White	7 (14.9%)
Other	3 (6.4%)
Life Space Score, mean (SD)	52.5 (35.0)
Short Physical Performance Battery score, mean (SD)	8.9 (2.45)
Any difficulty in Activities of Daily Living, mean no. (SD)	5.3 (1.1)
Perceived physical functioning score, mean (SD)	40.3 (9.4)
Perceived Stress Scale score, mean (SD)	24.0 (8.0)
Overall Fluid Cognition Score, mean (SD)	40.9 (12.5)

Life Space Score assessed via the University of Alabama at Birmingham (UAB) Study of Aging Life-Space Assessment (LSA). Captures community mobility and social participation; scale 0-120, higher scores = greater life-space mobility. Short Physical Performance Battery includes assessments of balance, lower body strength, and gait speed; scale 0-4, higher scores = higher levels of physical performance; overall score = sum of scores. Activities of daily living (ADLs): basic activities of daily living (*e.g.*, bathing, dressing, transferring) and instrumental activities of daily living (*e.g.*, shopping, managing finances); scores dichotomized as any vs. no difficulty performing the activity independently or with minimal help. Scores represent the mean number of ADLs in which participants had difficulty. Perceived Physical Functioning assessed via the PROMIS physical functioning; 0-100, higher scores = better functioning. Cohen's Perceived Stress Scale measures the degree to which situations in one's life are appraised as stressful; scale 0-56, higher scores = higher stress. Overall fluid cognition score (from the NIH Toolbox) measures the overall capacity to reason and solve novel problems; scale 0-100, higher scores = better functioning, such that 50 = average and 40 = 1 SD below the mean.

Table 2. Summary of feedback on report, by domain of functioning.

	Activities of Daily Living	**Falls Efficacy Score**	**Patient-Perceived Physical Functioning**	**Short Physical Performance Battery**	**Life Space Score**
Recall answering questions on ability to perform tasks	41 (87.2%)	39 (82.3%)	43 (91.5%)	43 (91.5%)	42 (89.4%)
Self-evaluation of performance					
Very well	16 (34.0%)	22 (46.8%)	7 (14.9%)	14 (29.8%)	15 (31.9%)
Well	14 (29.8%)	13 (27.7%)	15 (31.9%)	16 (34.0%)	13 (27.7%)
Fairly	16 (34.0%)	11 (23.4%)	19 (40.4%)	14 (29.8%)	15 (31.9%)
Poorly	1 (2.1%)	1 (2.1%)	6 (12.8%)	3 (6.4%)	4 (8.5%)

Table 2. Summary of feedback on report, by domain of functioning.

	Activities of Daily Living	**Falls Efficacy Score**	**Patient-Perceived Physical Functioning**	**Short Physical Performance Battery**	**Life Space Score**
Ease of interpreting results					
Very easy	33 (70.2%)	40 (85.1%)	35 (74.5%)	35 (74.5%)	36 (76.6%)
Somewhat easy	11 (23.4%)	4 (8.5%)	8 (17.0%)	7 (14.9%)	6 (12.8%)
Neither easy nor difficult	2 (4.3%)	3 (6.4%)	4 (8.5%)	4 (8.5%)	3 (6.4%)
Somewhat difficult	1 (2.1%)	--	--	1 (2.1%)	1 (2.1%)
Very difficult	--	--	--	--	1 (2.1%)
Utility of Report	32 (68.1%)	30 (63.8%)	35 (74.5%)	35 (74.5%)	30 (63.8%)
Coherence of Report					
Scale	43 (91.5%)	--	42 (89.4%)	41 (87.2%)	--
Scoring	44 (93.2%)	--	41 (87.2%)	41 (87.2%)	--
Colors	47 (100%)	--	47 (100%)	47 (100%)	46 (97.9%)
Wording	45 (95.7%)	45 (95.7%)	46 (97.9%)	--	44 (93.2%)
Numbers	--	42 (89.4%)	--	--	--
Picture	--	--	--	47 (100%)	46 (97.9%)
Chart	--	--	--	--	39 (82.3%)
Comfort with Discussion of Report (yes vs. no)	46 (97.9%)	44 (93.2%)	47 (100%)	44 (93.2%)	44 (93.2%)
Comfort with Discussion of Report with:					
Rheumatologist	32 (68.1%)	29 (61.7%)	34 (72.3%)	32 (68.1%)	29 (61.7%)
Primary Care Provider	25 (53.2%)	19 (40.4%)	26 (55.3%)	21 (44.7%)	19 (40.4%)
Social Worker	5 (10.6%)	4 (8.5%)	5 (10.6%)	3 (6.4%)	4 (8.5%)
Physical Therapist	7 (14.9%)	7 (14.9%)	7 (14.9%)	7 (14.9%)	8 (17.0%)
Occupational Therapist	3 (6.4%)	4 (8.5%)	4 (8.5%)	3 (6.4%)	3 (6.4%)
Psychiatrist	4 (8.5%)	2 (4.3%)	1 (2.1%)	2 (4.3%)	3 (6.4%)
Other provider	6 (12.8%)	7 (14.9%)	8 (17.0%)	8 (17.0%)	7 (14.9%)
Spouse	7 (14.9%)	7 (14.9%)	7 (14.9%)	5 (10.6%)	6 (12.8%)
Child	7 (14.9%)	5 (10.6%)	7 (14.9%)	6 (12.8%)	6 (12.8%)
Other relative	8 (17.0%)	9 (19.2%)	9 (19.2%)	6 (12.8%)	7 (14.9%)
Purpose in Discussion					
Improve communication with provider	28 (59.6%)	23 (48.9%)	30 (63.8%)	29 (61.7%)	27 (57.5%)
Obtain needed referrals	9 (19.2%)	11 (23.4%)	13 (27.7%)	10 (21.3%)	11 (23.4%)
Work on improving functioning	30 (63.8%)	15 (31.9%)	22 (46.8%)	22 (46.8%)	19 (40.4%)
Set treatment goals	16 (34.0%)	14 (29.8%)	16 (34.0%)	20 (42.6%)	16 (34.0%)

Coherence of Report: Number of participants who indicated that it was “very easy” or “somewhat easy” in interpreting the overall report. Subsections represent the number of participants who indicated that they had “no difficulty” in interpreting the respective portion of the report. Utility of Report: Number of participants who indicated that they perceived the report to be “useful for treatment or other personal care planning.” Discussion of Report: Number of participants who indicated that they “felt comfortable discussing the report” with healthcare providers or other individuals.

Significant Results, cont.

Objective 2 (Major Tasks 4, 5). The two provider focus groups included 5 physicians (group 1) and 4 nurses/medical assistants (group 2); providers were primarily female (89%) and about half were white (56%). The two patient focus groups had 9 participants each; overall, the average age was 50, the average duration of lupus of 20 years, and most participants were black (83%) and female (83%). In this qualitative study, patients and providers not only provided specific feedback to improve the report (*e.g.*, refined images and language, de-emphasis on quantitative results), but also provided more general thoughts on comfort with discussing cognitive function in a clinical setting. Patients particularly were interested in knowing more about their cognitive issues via testing, understanding risk factors and causes (*e.g.*, "…you find yourself having the same kind of challenges then you wonder okay…am I having something else going on or if it's a lupus fog…"), and learning about supportive resources for continued functioning, suggesting this report could be helpful in the clinical setting. Both patients and providers were interested in having a way to objectively differentiate cognitive impairment from other health issues that may mimic cognitive impairment, such as insomnia, depression, pain, or medication side effects ("It is confusing for the doctors and for themselves to understand what is really disease activity and what is not"). Analyses of the qualitative data regarding whether and why patients and providers would like to see cognitive performance data are underway. We are also using the data to identify consensus on the presentation of cognitive data, to inform modifications to the report and building of an underlying app the create.

Stated goals not yet met. Despite substantial delays in the human subjects approval process, due to significant pre-planning, we were able to begin recruitment immediately upon HRPO approval (received 4/10/19). Thus, our recruitment and data collection steps for both objectives were complete at the end of the project (9/29/19). Although the project has ended, we continue to work on completing analysis of these quantitative (Objective 1) and qualitative (Objective 2) data, which were originally targeted for the last few months of the 1-year pilot. The quantitative analysis of survey results is nearly complete and these results are being incorporated into a thesis by a graduating student (Grace Xu). This work has been submitted in abstract form to the American Geriatrics Society (May 7-9, 2019) and we also plan to submit the thesis to peer-reviewed journal in Spring 2020. The qualitative analysis of the focus group data is also underway, led by Co-I Ann Vandenberg. The plan is to submit this work to a peer-reviewed journal in Spring 2020. We have also begun considering future studies and recently submitted an internal grant to build an app to produce individualized cognitive functioning reports, similar to the app we have to create physical functioning reports (**Figure 1**), based on the feedback we received on the hypothetical cognitive functioning report (**Figure 2**). Having this app available would allow studies of clinical implementation of both reports in real time.

Other Achievements

As mentioned above, our primary non-data-related achievements are: (1) a working app to create physical functioning reports for lupus patients, which may be refined and tested in future studies; and (2) a hypothetical cognitive report (**Figure 2**), which can be refined based on the feedback we received in focus groups and used as a model to build an underlying app, similarly to the physical functioning app-based report.

What opportunities for training and professional development has the project provided?

If the project was not intended to provide training and professional development opportunities or there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe opportunities for training and professional development provided to anyone who worked on the project or anyone who was involved in the activities supported by the project. "Training" activities are those in which individuals with advanced professional skills and experience assist others in attaining greater proficiency. Training activities may include, for example, courses or one-on-one work with a mentor. "Professional development" activities result in increased knowledge or skill in one's area of expertise and may include workshops, conferences, seminars, study groups, and individual study. Include participation in conferences, workshops, and seminars not listed under major activities.

Training: Grace Xu, an undergraduate pre-med student at Emory, is using the data from Objective 1 for a senior honor's thesis. For this work she is working one-on-one with the project PI (Dr. Plantinga) as thesis mentor and with Dr. Drenkard (Co-PI) as a committee member. She has also submitted her work to a national meeting and applied for a student award based on this work. Ms. Xu began working with the data after the end of the project period and thus contributed no effort.

Professional development: nothing to report.

How were the results disseminated to communities of interest?

If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the results were disseminated to communities of interest. Include any outreach activities that were undertaken to reach members of communities who are not usually aware of these project activities, for the purpose of enhancing public understanding and increasing interest in learning and careers in science, technology, and the humanities.

Nothing to report in this project period. However, results from Objective 1 were submitted to a national meeting (see above) and we have plans to disseminate results from both study objectives in peer-reviewed journals, with submissions targeted for spring. The results will also be shared with the lupus patient participants via the parent study (GOAL) newsletter, which provides lay summaries of completed GOAL-related studies for patients.

Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives.

While the project is complete, as noted above, we plan to continue to work on analyses, writing of abstracts and papers, presentations, and follow-up proposals.

4. **IMPACT:** D*escribe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:*

What was the impact on the development of the principal discipline(s) of the project?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how findings, results, techniques that were developed or extended, or other products from the project made an impact or are likely to make an impact on the base of knowledge, theory, and research in the principal disciplinary field(s) of the project. Summarize using language that an intelligent lay audience can understand (Scientific American style).

The findings from objective 1 will be used to refine the individualized app-based report and design studies to implement the reports in the clinical setting. The findings from objective 2 can be used to improve the report of cognitive functioning and facilitate real-time generation of reports via an underlying app. The delivery of either or both of these reports in the clinic has the potential to improve knowledge of functioning, enhance shared decision-making, and help achieve goal-oriented, patient-centered care for lupus.

What was the impact on other disciplines?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the findings, results, or techniques that were developed or improved, or other products from the project made an impact or are likely to make an impact on other disciplines.

The reports being developed could be used in many populations that may be affected by cognitive impairment, including the general older adult population, persons with prodromal Alzheimer's disease and related dementias, and persons with other chronic conditions with associated cognitive symptoms, such as kidney disease.

What was the impact on technology transfer?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe ways in which the project made an impact, or is likely to make an impact, on commercial technology or public use, including:

- *transfer of results to entities in government or industry;*
- *instances where the research has led to the initiation of a start-up company; or*
- *adoption of new practices.*

Although there is nothing to report for this pilot study, our goal is that either or both of the functioning reports that we are developing will eventually be used in the clinical setting, leading to adoption of new practices.

What was the impact on society beyond science and technology?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how results from the project made an impact, or are likely to make an impact, beyond the bounds of science, engineering, and the academic world on areas such as:

- *improving public knowledge, attitudes, skills, and abilities;*
- *changing behavior, practices, decision making, policies (including regulatory policies), or social actions; or*
- *improving social, economic, civic, or environmental conditions.*

As noted above, while the impact in this pilot period was minimal, either or both of these reports could eventually be used in the clinic setting, which could lead to changes in provider behavior as well as patient-provider communication.

5. **CHANGES/PROBLEMS:** *The PD/PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, "Nothing to Report," if applicable:*

Changes in approach and reasons for change
Describe any changes in approach during the reporting period and reasons for these changes. Remember that significant changes in objectives and scope require prior approval of the agency.

Nothing to report.

Actual or anticipated problems or delays and actions or plans to resolve them
Describe problems or delays encountered during the reporting period and actions or plans to resolve them.

Our primary barrier has been the lack of final human subjects approval (until 4/10/19). To mitigate this problem and minimize the delays to the start of recruitment, we responded to every HRPO request immediately. We also used our time while waiting to perform preparatory tasks that did not involve human subjects, including modifying/generating reports, creating a mock visualization of cognitive data, and finalizing our survey and focus group guides. Thus, we were able to complete all proposed subtasks, except those related to analysis and dissemination (currently underway), prior to the end of the project period.

Changes that had a significant impact on expenditures

Describe changes during the reporting period that may have had a significant impact on expenditures, for example, delays in hiring staff or favorable developments that enable meeting objectives at less cost than anticipated.

None.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Describe significant deviations, unexpected outcomes, or changes in approved protocols for the use or care of human subjects, vertebrate animals, biohazards, and/or select agents during the reporting period. If required, were these changes approved by the applicable institution committee (or equivalent) and reported to the agency? Also specify the applicable Institutional Review Board/Institutional Animal Care and Use Committee approval dates.

Significant changes in use or care of human subjects

There were no significant changes to human subjects plans. All amendments to the protocol were approved by the Emory University IRB and approvals were immediately shared with the HRPO.

Significant changes in use or care of vertebrate animals

N/A

Significant changes in use of biohazards and/or select agents

N/A

6. **PRODUCTS:** *List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state "Nothing to Report."*

- **Publications, conference papers, and presentations**

  Report only the major publication(s) resulting from the work under this award.

  Journal publications. *List peer-reviewed articles or papers appearing in scientific, technical, or professional journals. Identify for each publication: Author(s); title; journal; volume: year; page numbers; status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

  Nothing to report.

Books or other non-periodical, one-time publications. *Report any book, monograph, dissertation, abstract, or the like published as or in a separate publication, rather than a periodical or series. Include any significant publication in the proceedings of a one-time conference or in the report of a one-time study, commission, or the like. Identify for each one-time publication: author(s); title; editor; title of collection, if applicable; bibliographic information; year; type of publication (e.g., book, thesis or dissertation); status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Nothing to report.

Other publications, conference papers and presentations. *Identify any other publications, conference papers and/or presentations not reported above. Specify the status of the publication as noted above. List presentations made during the last year (international, national, local societies, military meetings, etc.). Use an asterisk (*) if presentation produced a manuscript.*

Nothing to report.

- **Website(s) or other Internet site(s)**
  List the URL for any Internet site(s) that disseminates the results of the research activities. A short description of each site should be provided. It is not necessary to include the publications already specified above in this section.

  Nothing to report.

- **Technologies or techniques**
  Identify technologies or techniques that resulted from the research activities. Describe the technologies or techniques were shared.

  The technology resulting from our project is the Android app that creates real-time reports (**Figure 1**) for lupus patients. This app is not currently available as we plan to refine it in research studies before making it public.

- **Inventions, patent applications, and/or licenses**
  Identify inventions, patent applications with date, and/or licenses that have resulted from the research. Submission of this information as part of an interim research performance progress report is not a substitute for any other invention reporting required under the terms and conditions of an award.

  Nothing to report.

- **Other Products**

  Identify any other reportable outcomes that were developed under this project. Reportable outcomes are defined as a research result that is or relates to a product, scientific advance, or research tool that makes a meaningful contribution toward the understanding, prevention, diagnosis, prognosis, treatment and /or rehabilitation of a disease, injury or condition, or to improve the quality of life. Examples include:
  - *data or databases;*
  - *physical collections;*
  - *audio or video products;*
  - *software;*
  - *models;*
  - *educational aids or curricula;*
  - *instruments or equipment;*
  - *research material (e.g., Germplasm; cell lines, DNA probes, animal models);*
  - *clinical interventions;*
  - *new business creation; and*
  - *other.*

In addition to the app to create individualized physical functioning reports (described above), we also created a draft cognitive functioning report (**Figure 2**) that we will refine based on feedback obtained in Objective 2.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Provide the following information for: (1) PDs/PIs; and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours of effort). If information is unchanged from a previous submission, provide the name only and indicate "no change".

Name:	*Laura Plantinga*
Project Role:	*Principal Investigator*
ORCID ID:	*0000-0003-0809-8981*
Nearest person month worked:	*12*
Contribution to Project:	*Dr. Plantinga led the project, including continuing project meetings and overseeing the human subjects approval process, as well as co-developed visualizations and surveys.*
Name:	*Charmayne Dunlop-Thomas*
Project Role:	*Project Coordinator*
Nearest person month worked:	*12*
Contribution to Project:	*Ms. Dunlop-Thomas assisted with recruitment plans, IRB amendments, and other human subjects issues, and provided substantial input on visualizations/surveys.*
Name:	*Ann Vandenberg*
Project Role:	*Co-Investigator*
Nearest person month worked:	*12*
Contribution to Project:	*Dr. Vandenberg created the focus group guide and co-developed our survey and facilitated the focus groups.*
Name:	*S. Sam Lim*
Project Role:	*Co-Investigator*
Nearest person month worked:	*12*
Contribution to Project:	*Dr. Lim provided expert clinical and research guidance during monthly team meetings.*
Name:	*Cristina Drenkard*
Project Role:	*Co-Investigator*
ORCID ID:	0000-0002-6832-7291
Nearest person month worked:	*12*
Contribution to Project:	*Dr. Drenkard provided expert clinical and research guidance during monthly team meetings.*

Name:	*Brian Jones*
Project Role:	*Co-Investigator*
Nearest person month worked:	*12*
Contribution to Project:	*Mr. Jones oversaw all Georgia Tech activities on the project.*
Name:	*Jeremy Johnson*
Project Role:	*Co-Investigator*
Nearest person month worked:	*12*
Contribution to Project:	*Mr. Johnson made all modifications to the app and developed a web-based system to generate reports from our existing data, as well as created an Android app for use in future studies.*
Name:	*Amelia Lambeth (no change)*

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

If the active support has changed for the PD/PI(s) or senior/key personnel, then describe what the change has been. Changes may occur, for example, if a previously active grant has closed and/or if a previously pending grant is now active. Annotate this information so it is clear what has changed from the previous submission. Submission of other support information is not necessary for pending changes or for changes in the level of effort for active support reported previously. The awarding agency may require prior written approval if a change in active other support significantly impacts the effort on the project that is the subject of the project report.

Nothing to report.

What other organizations were involved as partners?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe partner organizations – academic institutions, other nonprofits, industrial or commercial firms, state or local governments, schools or school systems, or other organizations (foreign or domestic) – that were involved with the project. Partner organizations may have provided financial or in-kind support, supplied facilities or equipment, collaborated in the research, exchanged personnel, or otherwise contributed.

Organization Name: Georgia Institute of Technology
Location of Organization: (if foreign location list country): Atlanta, GA
Partner's contribution to the project:
In-kind support (app, reports)
Collaboration (Jones, Johnson, Lambeth)

Organization Name: Duke University
Location of Organization: (if foreign location list country): Durham, NC
Partner's contribution to the project:
Collaboration (Dr. Barrett Bowling)

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: *For collaborative awards, independent reports are required from BOTH the Initiating Principal Investigator (PI) and the Collaborating/Partnering PI. A duplicative report is acceptable; however, tasks shall be clearly marked with the responsible PI and research site. A report shall be submitted to* ***https://ers.amedd.army.mil*** *for each unique award.*

QUAD CHARTS: *If applicable, the Quad Chart (available on https://www.usamraa.army.mil) should be updated and submitted with attachments.*

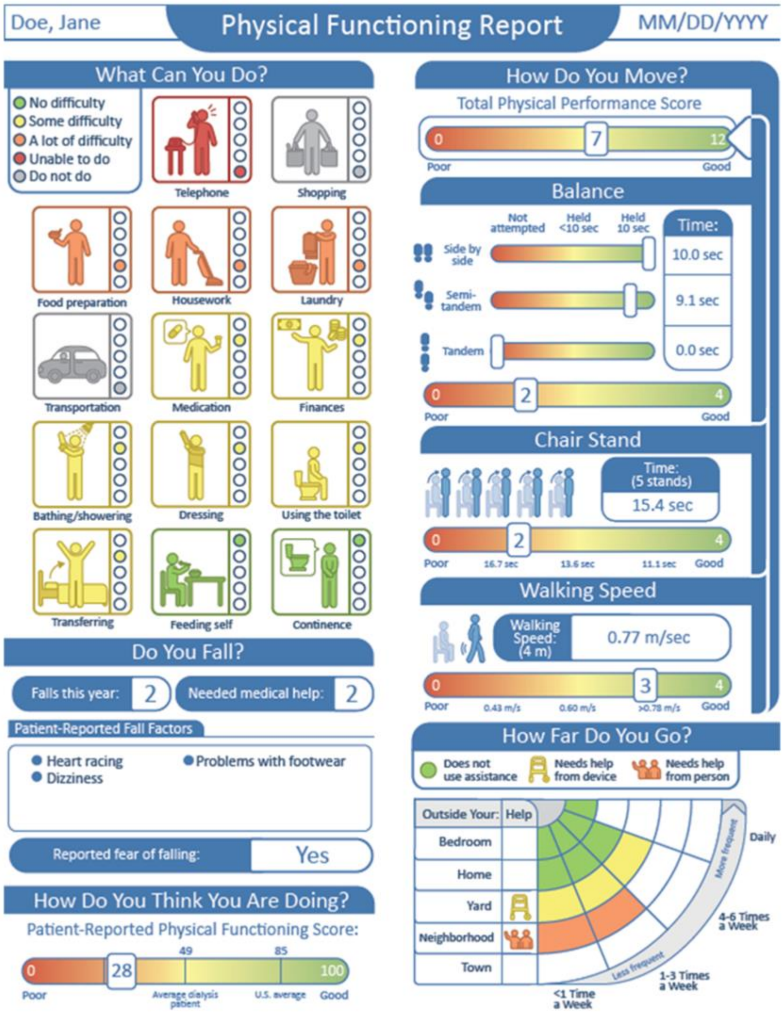
Per our award notice special reporting requirements, an **award chart** is uploaded with this application.

9. **APPENDICES:** *Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.*

Feedback Survey: A Physical Functioning Report for Lupus Patients

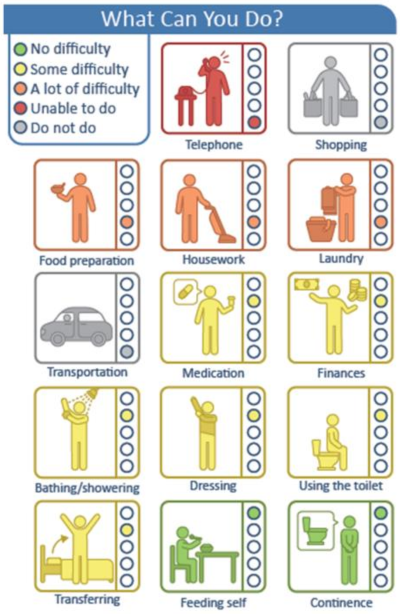
Thank you for agreeing to participate in our study.

We are interested in your thoughts on the physical functioning reports we have developed. Here is an example report.



To complete this survey, you will need your personalized report, which was sent to you by email or mail. This report shows you the results from your visit for the APPEAL pilot study, which took place between October 2016 and April 2017. <u>Looking at the personalized report you received, please answer the questions on the following pages</u>.

To start, please find the part of your report that says "What Can You Do?," which looks like this:



Look at <u>your</u> results in this part of the report to answer the next few questions.

1. Do you remember answering questions during the pilot study about whether you could perform these tasks (circle one)?

Yes No

2. How well do you think you were performing these tasks (check one)?

☐ Very well

☐ Well

☐ Fairly

☐ Poorly

3. How easy is it to understand your results (check one)?

☐ Very easy (skip to question 6)

☐ Somewhat easy

☐ Neither easy nor difficult

☐ Somewhat difficult

☐ Very difficult

4. What part(s) are difficult to understand (check all that apply)?

☐ Pictures
☐ Wording
☐ Colors
☐ Other (list:_________________________________)

5. Please share any ideas you have to make this part of the report easier to understand.

6. Do you think it would be useful for your treatment or other personal care planning to discuss this part of the report with anyone (circle one)?

Yes No (skip to question 9)

7. With whom would you want to discuss this part of your report (check all that apply)?

☐ Rheumatologist/lupus doctor
☐ Primary care provider
☐ Social worker
☐ Physical therapist
☐ Occupational therapist
☐ Psychiatrist/psychologist/therapist
☐ Other healthcare provider (list: _____________________________)
☐ Spouse
☐ Child
☐ Other relative
☐ Friend
☐ Spiritual or religious advisor
☐ Employer
☐ Other (list:________________________________)

8. Why would you discuss this part of the report (check all that apply)?

☐ To have better communication/relationship with providers
☐ To get needed referrals/services
☐ To work on improving my function
☐ To help set treatment goals
☐ Other (list:___________________________________)

9. Would you feel comfortable discussing these tasks with your providers (circle one)?

Yes No

Now please look at the part of your report that says "Do You Fall?," which looks like this:

Do You Fall?

Falls this year: 2

Needed medical help: 2

Patient-Reported Fall Factors

Not measured

Reported fear of falling: Yes

Look at <u>your</u> results in this part of the report to answer the next few questions.

10. Do you remember answering questions during the pilot study about whether you had fallen in the past year, and how confident you were that you would not fall during daily tasks (circle one)?

Yes No

11. How well do you think you were doing in terms of falls (check one)?

☐ Very well
☐ Well
☐ Fairly
☐ Poorly

12. How easy is it to understand your results (check one)?

☐ Very easy (skip to question 15)
☐ Somewhat easy
☐ Neither easy nor difficult
☐ Somewhat difficult
☐ Very difficult

13. What part(s) are difficult to understand (check all that apply)?

☐ Wording
☐ Numbers
☐ Other (list:____________________________________)

14. Please share any ideas you have to make this part of the report easier to understand.

15. Do you think it would be useful for your treatment or other personal care planning to discuss this part of the report with anyone (circle one)?

Yes No (skip to question 18)

16. With whom would you want to discuss this part of your report (check all that apply)?

☐ Rheumatologist/lupus doctor
☐ Primary care provider
☐ Social worker
☐ Physical therapist
☐ Occupational therapist
☐ Psychiatrist/psychologist/therapist
☐ Other healthcare provider (list: ________________________________)
☐ Spouse
☐ Child
☐ Other relative
☐ Friend
☐ Spiritual or religious advisor
☐ Employer
☐ Other (list:___________________________________)

17. Why would you discuss this part of the report (check all that apply)?

☐ To have better communication/relationship with providers
☐ To get needed referrals/services
☐ To work on improving my function
☐ To help set treatment goals
☐ Other (list:___________________________________)

18. Would you feel comfortable discussing your falls or fear of falling with your providers (circle one)?

Yes No

Now please look at the part of your report that says "How Do You Think You Are Doing?," which looks like this:

Look at <u>your</u> results in this part of the report to answer the next few questions.

19. Do you remember answering questions during the pilot study in how much your health limited you in physical activities (circle one)?

Yes No

20. How well did you think you were doing with physical activities (check one)?

☐ Very well
☐ Well
☐ Fairly
☐ Poorly

21. How easy is it to understand your results (check one)?

☐ Very easy (skip to question 24)
☐ Somewhat easy
☐ Neither easy nor difficult
☐ Somewhat difficult
☐ Very difficult

22. What part(s) are difficult to understand (check all that apply)?

☐ Scale (poor to good)
☐ Score
☐ Colors
☐ Wording
☐ Other (list:___________________________________)

23. Please share any ideas you have to make this part of the report easier to understand.

24. Do you think it would be useful for your treatment or other personal care planning to discuss this part of the report with anyone (circle one)?

Yes No (skip to question 27)

25. With whom would you want to discuss this part of your report (check all that apply)?

☐ Rheumatologist/lupus doctor
☐ Primary care provider
☐ Social worker
☐ Physical therapist
☐ Occupational therapist
☐ Psychiatrist/psychologist/therapist
☐ Other healthcare provider (list: ______________________________)
☐ Spouse
☐ Child
☐ Other relative
☐ Friend
☐ Spiritual or religious advisor
☐ Employer
☐ Other (list:_________________________________)

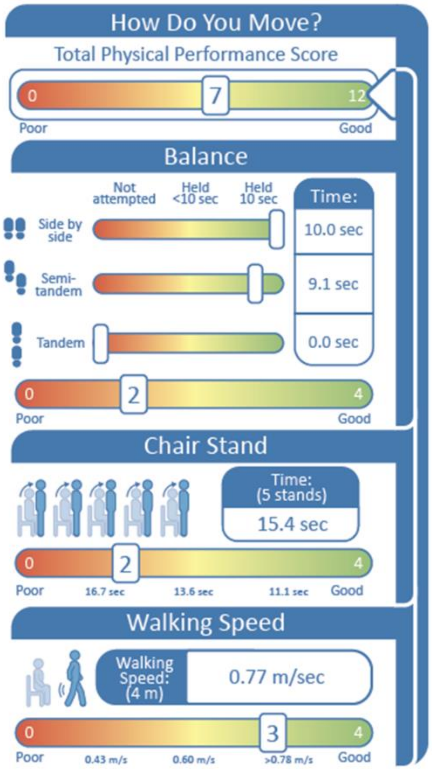
26. Why would you discuss this part of the report (check all that apply)?

☐ To have better communication/relationship with providers
☐ To get needed referrals/services
☐ To work on improving my function
☐ To help set treatment goals
☐ Other (list:_________________________________)

27. Would you feel comfortable discussing how much you feel limited in your physical activities with your providers (circle one)?

Yes No

Now please look at the part of your report that says “How Do You Move?,” which looks like this:



Look at <u>your</u> results in this part of the report to answer the next few questions.

28. Do you remember being asked to perform these tests (balance, walking, standing from a chair) (circle one)?

Yes No

29. How well do you think do you think you did on these tests (check one)?

☐ Very well

☐ Well

☐ Fairly

☐ Poorly

30. How easy is it to understand your results (check one)?

☐ Very easy (skip to question 33)
☐ Somewhat easy
☐ Neither easy nor difficult
☐ Somewhat difficult
☐ Very difficult

31. What part(s) are difficult to understand (check all that apply)?

☐ Scales (poor to good)
☐ Pictures
☐ Scores
☐ Colors
☐ Wording
☐ Other (list:_________________________________)

32. Please share any ideas you have to make this part of the report easier to understand.

33. Do you think it would be useful for your treatment or other personal care planning to discuss this part of the report with anyone (circle one)?

Yes No (skip to question 36)

34. With whom would you want to discuss this part of your report (check all that apply)?

☐ Rheumatologist/lupus doctor
☐ Primary care provider
☐ Social worker
☐ Physical therapist
☐ Occupational therapist
☐ Psychiatrist/psychologist/therapist
☐ Other healthcare provider (list: ________________________________)
☐ Spouse
☐ Child
☐ Other relative
☐ Friend
☐ Spiritual or religious advisor
☐ Employer
☐ Other (list:___________________________________)

35. Why would you discuss this part of the report with providers (check all that apply)?

☐ To have better communication/relationship with providers
☐ To get needed referrals/services
☐ To work on improving my function
☐ To help set treatment goals
☐ Other (list:___________________________________)

36. Would you feel comfortable discussing how you did on these tests with your providers (circle one)?

Yes No

Now please look at the part of your report that says “How Far Do You Go?,” which looks like this:

Look at <u>your</u> results in this part of the report to answer the next few questions.

37. Do you remember being asked questions during the pilot study about how far you go outside your bedroom, how often, and with how much help (circle one)?

Yes No

38. How well do you think you were moving around in your home, neighborhood, and community (check one)?

☐ Very well

☐ Well

☐ Fairly

☐ Poorly

39. How easy is it to understand your results (check one)?

☐ Very easy (skip to question 42)

☐ Somewhat easy

☐ Neither easy nor difficult

☐ Somewhat difficult

☐ Very difficult

40. What part(s) are difficult to understand (check all that apply)?

☐ Chart
☐ Pictures
☐ Colors
☐ Wording
☐ Other (list:_________________________________)

41. Please share any ideas you have to make this part of the report easier to understand.

42. Do you think it would be useful for your treatment or other personal care planning to discuss this part of the report with anyone (circle one)?

Yes No (skip to question 45)

43. With whom would you want to discuss this part of your report (check all that apply)?

☐ Rheumatologist/lupus doctor
☐ Primary care provider
☐ Social worker
☐ Physical therapist
☐ Occupational therapist
☐ Psychiatrist/psychologist/therapist
☐ Other healthcare provider (list: ______________________________)
☐ Spouse
☐ Child
☐ Other relative
☐ Friend
☐ Spiritual or religious advisor
☐ Employer
☐ Other (list:_________________________________)

44. Why would you discuss this part of the report (check all that apply)?

☐ To have better communication/relationship with providers

☐ To get needed referrals/services

☐ To work on improving my function

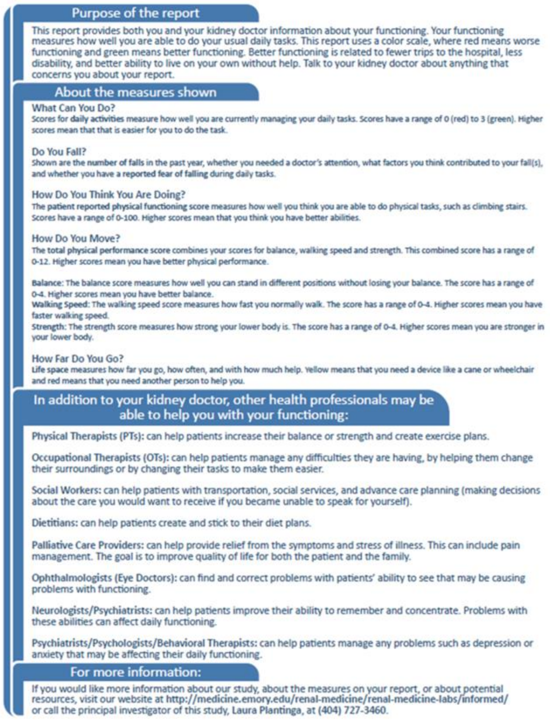
☐ To help set treatment goals

☐ Other (list:__________________________________)

45. Would you feel comfortable discussing how well you are moving around in your community with your providers (circle one)?

Yes No

Now please look at the back of your report, which looks like this:



Purpose of the report

This report provides both you and your kidney doctor information about your functioning. Your functioning measures how well you are able to do your usual daily tasks. This report uses a color scale, where red means worse functioning and green means better functioning. Better functioning is related to fewer trips to the hospital, less disability, and better ability to live on your own without help. Talk to your kidney doctor about anything that concerns you about your report.

About the measures shown

What Can You Do?
Scores for **daily activities** measure how well you are currently managing your daily tasks. Scores have a range of 0 (red) to 3 (green). Higher scores mean that that is easier for you to do the task.

Do You Fall?
Shown are the **number of falls** in the past year, whether you needed a doctor's attention, what factors you think contributed to your fall(s), and whether you have a **reported fear of falling** during daily tasks.

How Do You Think You Are Doing?
The **patient reported physical functioning** score measures how well you think you are able to do physical tasks, such as climbing stairs. Scores have a range of 0-100. Higher scores mean that you think you have better abilities.

How Do You Move?
The **total physical performance** score combines your scores for balance, walking speed and strength. This combined score has a range of 0-12. Higher scores mean you have better physical performance.

Balance: The balance score measures how well you can stand in different positions without losing your balance. The score has a range of 0-4. Higher scores mean you have better balance.
Walking Speed: The walking speed score measures how fast you normally walk. The score has a range of 0-4. Higher scores mean you have faster walking speed.
Strength: The strength score measures how strong your lower body is. The score has a range of 0-4. Higher scores mean you are stronger in your lower body.

How Far Do You Go?
Life space measures how far you go, how often, and with how much help. Yellow means that you need a device like a cane or wheelchair and red means that you need another person to help you.

In addition to your kidney doctor, other health professionals may be able to help you with your functioning:

Physical Therapists (PTs): can help patients increase their balance or strength and create exercise plans.

Occupational Therapists (OTs): can help patients manage any difficulties they are having, by helping them change their surroundings or by changing their tasks to make them easier.

Social Workers: can help patients with transportation, social services, and advance care planning (making decisions about the care you would want to receive if you became unable to speak for yourself).

Dietitians: can help patients create and stick to their diet plans.

Palliative Care Providers: can help provide relief from the symptoms and stress of illness. This can include pain management. The goal is to improve quality of life for both the patient and the family.

Ophthalmologists (Eye Doctors): can find and correct problems with patients' ability to see that may be causing problems with functioning.

Neurologists/Psychiatrists: can help patients improve their ability to remember and concentrate. Problems with these abilities can affect daily functioning.

Psychiatrists/Psychologists/Behavioral Therapists: can help patients manage any problems such as depression or anxiety that may be affecting their daily functioning.

For more information:

If you would like more information about our study, about the measures on your report, or about potential resources, visit our website at http://medicine.emory.edu/renal-medicine/renal-medicine-labs/informed/ or call the principal investigator of this study, Laura Plantinga, at (404) 727-3460.

46. How easy is it to understand this information (check one)?

☐ Very easy

☐ Somewhat easy

☐ Neither easy nor difficult

☐ Somewhat difficult

☐ Very difficult

47. How helpful is this information (check one)?

☐ Very helpful

☐ Somewhat helpful

☐ Neither helpful nor unhelpful

☐ Somewhat unhelpful

☐ Very unhelpful

48. Is there anything that could be included that would make the back of the report easier or more helpful?

Finally, we would like to know your thoughts about the report as a whole, and how useful it might be in your lupus care.

49. Is there anything else *not* included on the report that you would want your provider to know about your functioning?

50. Would you be interested in getting a report like this in real time (in other words, on the same day as it is measured) (circle one)?

Yes No

51. Would you be willing to arrive 20-30 minutes before doctor appointments to perform the physical tests and fill out surveys, so that you and your provider could each have a copy of your report during the appointment (circle one)?

Yes No

52. If this report were offered as part of your usual lupus care, how often would you be willing to do 20-30 minutes of performance tests (for example, walking speed) and surveys to receive this personalized report?

☐ Once a month
☐ Every 3 months
☐ Every 6 months
☐ Once a year
☐ Never
☐ Other (list:_________________________________)

Thank you for sharing your thoughts on this report, which will help us with future research. To show our appreciation, we would like to send you a $25 Walmart gift card. Please provide your preferred email or mailing address below to receive the link to the gift card.

As part of ongoing research in this area, we would also like to know what patients think about their cognitive functioning (thinking ability) and whether and how they discuss it with their providers. For this study, we plan to conduct at least two 90-minute in-person focus groups. Those who complete a focus group will receive a $50 Walmart gift card.

If you are interested in participating in a focus group, please let us know all the days/times you would usually be available for a 90-minute focus group and we will contact you (check all boxes that apply):

Day	Morning	Afternoon	Evening
Monday			
Tuesday			
Wednesday			
Thursday			
Friday			▨
Saturday		▨	▨

Thank you again for your participation in our APPEAL study, which is helping to guide current research in improving lupus care.

If you have any questions about this study or the report, please do not hesitate to contact the study coordinator, Charmayne Dunlop-Thomas (cmdunlo@emory.edu, 404-251-8898), or the principal investigator, Dr. Laura Plantinga (laura.plantinga@emory.edu, 404-727-3460).

APPEAL

GOAL
GEORGIANS ORGANIZED AGAINST LUPUS

APPEAL: A Functioning Report for Lupus Patients

Focus group guide (<u>for clinician groups</u>)

Consent form signing by Charmayne in adjacent room (2 copies each person) (5 min)

Before we begin, we need to have your consent to participate in this project. You should all have received a copy of this consent form in the mail ahead of time. The form provides detailed information about our study, lets you know that your participation is voluntary, tells you that what you say here in this room is confidential, and gives you contact information if you think of any questions later on. Does anyone have any questions about the consent form? There are two copies. Please sign each of them. One is for me and one is for you.

Welcome (5 min)

Welcome - please sign your name and sit at the corresponding number at the table.
We have lunch/dinner on the table. Please help yourself.

Interviewer-recorder introductions (1 min)

Anna and Charmayne from Emory University School of Medicine. I'll be leading the focus group and Charmayne will be observing, keeping us on time, and making sure that we don't forget anything.

Introduction of lupus functioning report project (2 min)

We are working on a project called INFORMED to support better communication and decision making between lupus patients and their clinical team. We are having focus groups with patients, doctors, and nursing staff. We want to ask all of you what you think of discussing lupus patients' cognitive performance in clinic with them. We'll show you an example report that we made to record information on cognition. We want to know what you think of the report, what you like and don't like about it, if you think it's useful or not, and what suggestions you have to make it better. You can help us by being honest and letting us know what you really think. Our goal is to improve the care of your patients.

Ground rules (2 min)

There are three important ground rules:

1. Because we want to make this anonymous, we are trading your name today for a number. Your number is right in front of you. Please say your number before you speak. We are going to be recording our conversation. If you say your number, it will make it a lot easier for us to follow who is saying what when we listen to the recording later on.
2. We ask that what is said in this room stays in this room. That you don't share each other's information with other people. Is that okay with every one?
3. Please turn off unnecessary cell phones for the duration of the focus group.

Are there any questions? Are we ready to begin?

Research questions (75 minutes)

1. To start, can we go around the room and say how long you've been treating lupus and the first thing that comes to mind when you think about lupus? (2 min)

2. To start, I'd like to go around the table and ask each person to quickly say what comes to mind when you hear the phrase "lupus brain fog" or "lupus fog" (3 min)

3. What kinds of cognitive problems do you see with your lupus patients? (Anyone – feel free to say whatever comes to mind.) (8 min)

   Probe for examples:
   - Type of interference: What kinds of things does it interfere with?
   - Where it happens: at work, at home, when socializing
   - Scope: How often does it happen? How big a problem is it?
   - Effect: Feelings, consequences (social, material) How does it make you feel? What happens?

4. How do you find out about these problems? (5 min)

   Probe for:
   - Observations in clinic?
   - Self-reports?
   - Discussions with family/other?
   - Assessment?

5. Is cognitive function something you think patients could benefit from knowing more about? (5 min)

   - Why? Why not?
   - Assessment of your cognition over time
   - Feedback on how you're doing

6. We're interested in developing a report to help and your lupus patients discuss their cognitive function. As part of a research project called APPEAL, patients went through a series of computerized cognitive tests related to the area most vulnerable to change, fluid cognition. We are interested in whether it would be helpful to report these results back to patients and how best to do so. Today we want to ask your opinion about the made-up test results of an example patient.

   [Pass out example Lupus Cognitive Report]

   a. Before we go through each part of the report, does anyone have any quick initial reactions to what you see? Let's go around the table and have each person say something. (3 min)

   Now let's go through each part of the form in more detail.

   b. **Episodic memory**: These are results of a test that measures a person's ability to remember things experienced at particular times and places. In this test patients heard a story and then had to put pictured scenes from the story into the right sequence. (8 min)

  - PICTURE interpretation: This picture tries to show how episodic memory might be relevant in daily life. Can you guess what's going on in the picture? Any ideas? [The person lost her keys and is trying to remember where she left them, thinking back to various places she was in]
  - RELEVANCE: Is this ability important to patients in their daily lives? How so? Why not?
  - SCORE interpretation: What do you think about how the score is indicated? Are there better ways to convey how the patient is doing?
  - PATIENT'S SCORE: What would you do with the score? Would it be useful to discuss with lupus patients?

c. **Working memory**: These are results of a test that measures a person's ability to remember information for a short period of time. In this test patients had to remember all the animals shown on a screen and report them in the order of their size. (8 min)
   a. PICTURE interpretation: This picture tries to show how working memory might be relevant in daily life. Can you guess what's going on in the picture? [The person is getting directions and has to remember the route while they walk or drive down a street]
   b. RELEVANCE: Is this ability important to patients in their daily lives? How so? Why not?
   c. SCORE interpretation: What do you think about how the score is indicated? Are there better ways to convey how the patient is doing?
   d. PATIENT'S SCORE: What would you do with the score? Would it be useful to discuss with lupus patients?

d. **Processing speed**: These are results of a test that measures a person's ability to quickly take in and use information. In this test patients saw pictures of objects on a computer screen had to quickly decide if they were the same or different. (8 min)
   a. PICTURE interpretation: Again, this picture tries to show how this processing speed might be relevant in daily life. Can you guess what's going on in the picture? [The game of patty cake, where you have to quickly mirror your partner's actions]
   b. RELEVANCE: Is this ability important to patients in their daily lives? How so? Why not?
   c. SCORE interpretation: What do you think about how the score is indicated? Are there better ways to convey how the patient is doing?
   d. PATIENT'S SCORE: What would you do with the score? Would it be useful to discuss with lupus patients?

e. **Attention & inhibitory control**: These are results of a test that measures a person's ability to suppress irrelevant information so as to pay attention to what is most important in carrying out a task. In this test patients saw a line of arrows on a screen pointing in different directions and you had to match the direction of the middle arrow and ignore all of the other arrows. (8 min)
   a. PICTURE interpretation: This picture tries to show how attention & inhibitory control might be relevant in daily life. Can you guess what's going on in the picture? [The person is trying to pay attention to driving safely while someone is in the car distracting her]
   b. RELEVANCE: Is this ability important to patients in their daily lives? How so? Why not?
   c. SCORE interpretation: What do you think about how the score is indicated? Are there better ways to convey how the patient is doing?
   d. PATIENT'S SCORE: What would you do with the score? Would it be useful to discuss with lupus patients?

f. **Cognitive flexibility**: These are results of a test that measures a person's ability to adapt to changing conditions. In this test patients had to match pictures on screen first by shape and then by color. (8 min)

   a. PICTURE interpretation: This picture tries to show how cognitive flexibility might be relevant in daily life. Can you guess what's going on in the picture? [The person is trying to multitask in the kitchen]
   b. RELEVANCE: Is this ability important to patients in their daily lives? How so? Why not?
   c. SCORE interpretation: What do you think about how the score is indicated? Are there better ways to convey how the patient is doing?
   d. PATIENT'S SCORE: What would you do with the score? Would it be useful to discuss with lupus patients?

g. **Fluid cognition (total)**: This is the total of all the scores. (5 min)
   a. SCORE interpretation: How well do you think this person is doing overall?
   b. YOUR SCORE: Would you want to know your own score? What would you do with the score? Would you want to discuss it with your doctor or nurse?

7. Concluding question: Thank you very much for your thoughts about our report. It sounds like *[summary statement]*. Is that a fair summary? (5 min)

Probes:

- Do you have any additional thoughts as we conclude?
- Is there anything missing from our conversation?

Concluding remarks

It's been great talking with you. Thank you so much for your time and your ideas. We very much appreciate your help.

APPEAL: A Functioning Report for Lupus Patients

Focus group guide (<u>for lupus patient groups</u>)

Consent form signing by Charmayne in adjacent room (2 copies each person) (5 min)

Before we begin, we need to have your consent to participate in this project. You should all have received a copy of this consent form in the mail ahead of time. The form provides detailed information about our study, lets you know that your participation is voluntary, tells you that what you say here in this room is confidential, and gives you contact information if you think of any questions later on. Does anyone have any questions about the consent form? There are two copies. Please sign each of them. One is for me and one is for you.

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Welcome - please sign your name and sit at the corresponding number at the table.
We have lunch/dinner for anyone who is hungry. Please help yourself.

Interviewer-recorder introductions (1 min)

Anna and Charmayne from Emory University School of Medicine. I'll be leading the focus group and Charmayne will be observing, keeping us on time, and making sure that we don't forget anything.

Introduction of lupus functioning report project (2 min)

We're working on a project to support better communication and decision making between lupus patients and their doctors and nurses. We are having focus groups with both patients, doctors, and nursing staff. We want to ask all of you what you think of discussing **your cognition (or thinking ability)** in connection with lupus. You are all part of the APPEAL study which tested you on your physical and cognitive functioning back in October 2016 to April 2017. The cognitive or thinking part was on an iPad. Do you remember that? Today we'll show you a report that shows that information on cognition (or thinking ability) an example lupus patient that we made up. We want to know what you think of the report, what you like and don't like about it, if you think it's useful or not, and what suggestions you have to make it better. You can help us by being honest and letting us know what you really think. Our goal is to improve patient care.

Ground rules (2 min)

There are three important ground rules:

1. Because we want to make this anonymous, we are trading your name today for a number. Your number is right in front of you. Please say your number before you speak. We are going to be recording our conversation. If you say your number, it will make it a lot easier for us to follow who is saying what when we listen to the recording later on.
2. We ask that what is said in this room stays in this room. That you don't share each other's information with other people. Is that okay with every one?
3. Please turn off unnecessary cell phones for the duration of the focus group.

Are there any questions? Are we ready to begin?

Research questions (75 minutes)

1. To start, can we go around the room and say how long you've had lupus and the first thing that comes to mind when you think about lupus? (2 min)

2. Have you ever heard the phrase "lupus brain fog" or just plain "lupus fog"? Patients sometimes use it when they're frustrated about their cognition or thinking ability. To start, I want to go around the table and ask each person to say what comes to mind when you hear the phrase "lupus fog" (3 min)

3. Can anyone think of an example where "lupus fog" interfered with getting things done? (Anyone – feel free to say whatever comes to mind.) (8 min)

   Probe for examples:
   - Type of interference: What kinds of things does it interfere with?
   - Where it happens: at work, at home, when socializing
   - Scope: How often does it happen? How big a problem is it?
   - Effect: Feelings, consequences (social, material) How does it make you feel? What happened? What did do?

4. Have you ever talked to other people about "lupus fog" or other problems with thinking? (5 min)

   Probe for:
   - Who: Peers, family members, doctors, other clinical staff
   - Initiation: Who initiates conversation?
   - Motivation: Why?
   - Content: What did you talk about?
   - Result: How helpful was it?

5. Is your cognition or thinking ability that something you would like to know more about? (5 min)

   Probe for:
   - Why? Why not?
   - Assessment of your cognition over time
   - Feedback on how you're doing

6. We're interested in developing a report to help you and your doctor talk about your lupus condition. If you think back to 2016-2017, as part of APPEAL you went through a series of physical and cognitive tests. The physical results we put into a physical functioning report that we send to you online or in the mail with a survey to fill out. Did you all receive that? [show picture of the Physical Functioning Report]

   We are interested in adding another page to that report to show the results of the cognitive tests that you did. Today we want to ask your opinion about the test results of an example patient.

   [Pass out example Lupus Cognitive Report]

   This report provides some made-up information about the thinking ability of an example patient who took the same tests that you did. Imagine that the patient did the tests and got this report afterwards showing how they did. Now they can discuss these results with their doctor or nurse. We want to know if you think this sheet is useful or not or how it can be improved. We're going to listen and make changes to the report if we can to make it more useful to you in the future. Don't worry about being critical. We will appreciate all your feedback.

a. Before we go through each part of the report, what are your initial quick reactions to what you see? Let's go around the table and have each person say something. (3 min)

Now let's go through each part of the form in more detail.

b. **Episodic memory**: These are results of a test that measures a person's ability to remember things experienced at particular times and places. This is the test where you heard a story and then had to put pictured scenes from the story into the right sequence. Do you remember doing that? [Observer: note reactions] (8 min)
   - PICTURE interpretation: This picture tries to show you how this ability might be relevant in your daily life. Can you guess what's going on in the picture? Any ideas? [The person lost her keys and is trying to remember where she left them, thinking back to various places she was in]
   - RELEVANCE: Is this ability important to you in your daily life? How so? Why not?
   - SCORE interpretation: How well is this person doing?
   - YOUR SCORE: Would you want to know your own score? What would you do with the score? Would you want to discuss it with your doctor or nurse?

c. **Working memory**: These are results of a test that measures a person's ability to remember information for a short period of time. This was the test where you had to remember all the animals shown on a screen and report them in the order of their size. Do you remember doing that? [Observer: note reactions] (8 min)
   a. PICTURE interpretation: This picture tries to show you how this ability might be relevant in your daily life. Can you guess what's going on in the picture? [The person is getting directions and has to remember the route while they walk or drive down a street]
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d. **Processing speed**: These are results of a test that measures a person's ability to quickly take in and use information. This is the test where you saw pictures of objects on a computer screen had to quickly decide if they were the same or different. Do you remember doing that? [Observer: note reactions] (8 min)
   a. PICTURE interpretation: Again, This picture tries to show you how this ability might be relevant in your daily life. Can you guess what's going on in the picture? [The game of patty cake, where you have to quickly mirror your partner's actions]
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e. **Attention & inhibitory control**: These are results of a test that measures a person's ability to ignore information that is not important and pay attention to what is most important. This is the test where you saw a line of arrows on a screen pointing in different directions and you had to match the direction of the middle arrow and ignore all of the other arrows. Do you remember doing that? [Observer: note reactions] (8 min)
   a. PICTURE interpretation: This picture tries to show you how this ability might be relevant in your daily life. Can you guess what's going on in the picture? [The person is trying to pay attention to driving safely while someone is in the car distracting her]

    b. RELEVANCE: Is this ability important to you in your daily life? How so? Why not?
    c. SCORE interpretation: How well is this person doing?
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f. **Cognitive flexibility**: These are results of a test that measures a person's ability to adapt to changing conditions. This is the test that was a game where you matched pictures on screen first by shape and then by color. Do you remember doing this test? [Observer: note reactions] (8 min)
    a. PICTURE interpretation: This picture tries to show you how this ability might be relevant in your daily life. Can you guess what's going on in the picture? [The person is trying to multitask in the kitchen]
    b. RELEVANCE: Is this ability important to you in your daily life? How so? Why not?
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g. **Fluid cognition (total)**: This is the total of all the scores. (5 min)
    a. SCORE interpretation: How well do you think this person is doing overall?
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7. Concluding question: Thank you very much for your thoughts about our report. It sounds like *[summary statement]*. Is that a fair summary? (5 min)

   Probes:
    - Is there anything else you would like to share?
    - Is there anything missing from our conversation?

Concluding remarks

It's been great talking with you. Thank you so much for your time and your ideas. We very much appreciate your help. Now I'm going to provide each of you with a gift card and will ask you to sign that you have received the card. Then you are free to go.