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**Testing Experience and Functional Tools: Functional  
Assessment Standardized Items (FASI) Based on the CARE  
Tool**

**Paperwork Reduction Act Submission  
Part B: Collections of Information  
Employing Statistical Methods**

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**TESTING EXPERIENCE AND FUNCTIONAL TOOLS:**  
**FUNCTIONAL ASSESSMENT STANDARDIZED ITEMS (FASI) BASED ON THE CARE**  
**TOOL**

**PAPERWORK REDUCTION ACT SUBMISSION**  
**PART B: COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS**  
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## **Collections of Information Employing Statistical Methods**

### **1. Sampling**

The primary goal of the FASI project is to promote uptake of interoperable set of data elements, called “items,” (hereafter, the FASI Set) that can be used for standardized functional assessment across community-based long-term services and supports (CB-LTSS) populations. The targeted populations for this project are older adults (individuals aged 65 and over), younger (aged 18 to 64) adults with physical disabilities, and adults of all ages with intellectual /developmental disabilities (I/DD), severe mental illness (SMI), or traumatic brain injury (TBI). The data eventually collected from FASI implementation will be used to test the reliability and validity of these items.

#### **A. Potential Respondent Universe**

Currently, FASI measures are being used in or considered for use in three states; additional outreach by CMS to states is ongoing to promote adoption. More broadly, the FASI is used within the Veterans Health Administration. Though not currently scheduled, data collection is planned anticipated. During data collection, assessors will conduct functional assessments of Medicaid beneficiaries receiving home and community-based services (HCBS) in each of these states. For statistical analysis purposes, the participants will be broken down into the following five subpopulations:

- Older adults (aged 65 and over);
- Younger adults (aged 18 to 64) with physical disabilities; and
- Adults of all ages with:
  - ID/DD
  - SMI
  - TBI.

#### **B. Sampling Method**

The sampling method for at the time of data collection will include people already enrolled in the state programs and expecting to receive an interim or follow-up visit from their case managers in a six-month period. States identify the samples based on these criteria. The samples are then going to be stratified by the five waiver groups to select individuals separately within each of the target population groups. States will be asked for a list of their beneficiaries by population. The sampling information are going to be transferred to the Lewin team through a secure file transfer system.

From the state lists, the Lewin team is going to select a number of individuals three times greater than the desired sample size, to account for refusal or attrition, to assure reaching the desired sample size by subpopulation. The total target for completed assessments is 314 assessments per program population.

### **C. Data on the Universe of Entities in Tabular Form**

***Table 1*** provides the estimated program population numbers by states used for the prior rounds of data collection for an experience of care survey conducted by Truven Health Analytics under contract with CMS.

**Table 1: Estimated program population numbers by state for experience of care survey (figures supplied by each state)**

State	Waiver Program	Aged	Physically Disabled Only	Aged/ Disabled Combined <sup>1</sup>	ID/ DD	TBI	SMI	Total
AZ	Elderly/Physically Disabled (E/PD) 1115 Waiver	.	.	18,525	.	.	.	.
AZ	Division Developmentally Disabled (DDD) 1115 Waiver	.	.	.	23,042	.	.	.
CT	Homecare Program for Elders	10,497	958	.	.	200	200	11,855
GA	Independent Care Waiver Group (ICWP) (Aged/Disabled)	.	.	1,184/ 10,636	.	100	.	100
KY	Aged/Disabled Waiver	.	11,000	.	5,000	200	.	.
MD	Aged Disabled	.	.	4,500	.	60	.	4,560
MN	Elderly Waiver	8,000	.	.	16,000	296	3,044	27,340
Total		18,497	11,958	62,709	58,554	1,041	10,544	105,536
.	Response Rate Needed to obtain 335 respondents	1.8%	2.8%	0.5%	0.6%	32.2%	3.2%	0.3%

<sup>1</sup> Depending on the state, some HCBS programs may serve both aged and working age adults with disabilities. The numbers shown here represent that programmatic structure. However, for purposes of creating our samples, we will treat aged and working age adults with disabilities as two distinct groups.

Based on current knowledge of the subpopulations and the TEFT FASI items, the desired sample size should be between 126 to 335 participants per subpopulation. A sample size of 335 participants per subpopulation is going to enable us to detect a kappa of 0.80—which is significantly different than a kappa of 0.60—with 95% confidence. A 0.60 kappa statistic is commonly interpreted as the lower boundary for “substantial” agreement. A sample size of 126 represents that lower limit. Collecting data on 314 beneficiaries per program will ensure an adequate sample size to measure reliability for each of the FASI Set.

While the plan will be to collect data on 314 participants in each of the five programs, the exact number of participants or types of waiver program enrollments will vary by state. We will work with the six participating states to identify the respective population and sample size from each state that will be targeted. Some states may only collect data on certain populations. Table 2 shows the expected sample size or participants from each program for each state needed to conduct the field test in the prior round of data collection. Table 3 provides the total number of participants that will be approached to participate in the study. A substantially higher number of people will be contacted (Table 3) to ensure we meet the target number of completed assessments noted in *Table 2*.

**Table 2: Target Sample Size of Completed Assessments per State/Program**

State/ Assessment Entity	Aged	PD	ID/DD	BI	SMI	TOTAL
AZ	67	171	.	.	.	238
CO	.	.	189	104	100	393
CT	88	29	.	.	113	230
GA	.	.	.	.	.	104
GA	67	12	.	.	.	79
KY	92	102	.	.	.	194
MN	.	.	125	106	101	332
TOTAL	314	314	314	314	314	1,570

**Table 3: Targeted Sample Size Invitations per State/program**

State/ Assessment Entity	Aged	PD	ID/DD	BI	SMI	# Pop	TOTAL
AZ	164	417	.	.	.	2	581
CO	.	.	600	256	246	3	1102
CT	215	74	.	.	278	3	567
GA	164	28	.	256	.	3	448
KY	227	251	.	.	.	2	478
MN	.	.	400	258	246	3	904
TOTAL	770	770	1,000	<b>770</b>	<b>770</b>	.	4,080

We generally anticipate data collection during a regularly scheduled case management visit, which may or may not include a re-assessment for the participating beneficiaries (i.e., the assessment may be conducted during a regularly scheduled monitoring visit). FASI assessments are only administered to beneficiaries who consent to participate in the study. Assessors use the FASI items to measure four domains: 1) function (mobility, self-care), 2) instrumental activities of daily living (IADL), and 3) caregiver assistance needs.

Individuals are selected based on having an expected annual or interim assessment occurring during a six-month period. All participants falling into these parameters are selected. The individuals are identified by the state or the assessment agency that works with the state to conduct the current Medicaid waiver assessments. A letter is sent to each client describing the study and requesting their participation. We ask states to send the letter on our behalf: a letter coming from a known state agency generally obtains a better response than a letter from an



unknown, out-of-state organization. We also provide information to local assessment organizations to which people may turn with questions.

Following the mailing, assessors schedule an appointment to conduct their regularly scheduled assessment. Participants are asked if they wish to participate during that call. Those not wishing to participate are thanked and those willing are scheduled for their assessment. All participants are given a consent form which is explained by the assessor and signed by the participant or their legal guardian before beginning the assessment. Assessors keep the signed consent forms in their locked offices.

As shown in Table 1 (see last row), with the exception of the subpopulation of people with TBI, a sample of 272 people requires participation from fewer than 4% in any population, and from fewer than 1% in several of the population groups. Thus, with the exception of people with TBI, random selection of more than 272 participants per subpopulation is easily attainable, which helps account for attrition, and obtain the desired 272 participants per subpopulation. Nearly one-third of all participants with TBI is the minimum required for participation, which can be difficult to attain. We work with the states to obtain greater response rates, by reaching out especially to TBI advocacy groups, or recruit other states or organizations that can provide TBI participants for the field test.

## **2. Collecting Information**

Some individuals require interpreters (sign language or non-English spoken language) to be able to participate fully. Others need or prefer that another person (family member, friend, trusted caregiver) be present during the interview. This information is collected at the time of scheduling and helps to assure that scheduled interviews are successfully completed. It also helps to assure the participants that their needs and preferences are respected and, in so doing, help to increase the response rate.

Assessments are conducted by agencies already serving the participants. All assessors are trained by the George Washington University team in the use of the assessment items using the same on-line, mobile training modules developed for the prior data collection. GW uses adult education approaches to create four modules: one on each of the four domains in the FASI set. Assessors are able to access the training modules from their preferred locations (at home, in the agency, wherever they have internet access.) A PowerPoint copy of the four modules is attached here. All other instructions are embedded in the data collection, or FASI tool. Before being authorized to begin data collection, each assessor has to complete and pass each of the on-line training modules.

Data are collected through an assessment interview with the individual participant. Other people, such as knowledgeable family members or caregivers also may provide information during the course of the assessment interview, if requested by the client or if needed in the event the client is unable to provide information without assistance. Information from others will be provided only with the participant's consent.

The assessment data are collected using the assessor's secure, professional laptop or tablet that is used in conducting their regular state assessments. We use an electronic PDF form for the assessors to use in the assessment process. The electronic PDFs are anonymized and contain no

PHI or PII; observation identification numbers are generated as the forms are uploaded to the Lewin team. Each assessor also has a study ID and the combination of the state ID, the assessor ID, and the electronically-generated observation ID provides a study number to each assessment, independent of any personally identifying information on the client. The information collected is submitted electronically at the time of the assessment, or stored on the assessor's secure device and submitted electronically at the end of the day, depending on the availability of a secure wireless signal and the assessors' current methods for submitting their assessment data to the state. The data are submitted to the Lewin team where they are reviewed for completeness and de-identification and then transferred to GWU for review and construction of the analytic files. The Lewin team will be reviewing the data as they are submitted for completeness.

### **3. Maximizing response rate**

FASI assessments are conducted as part of visits to the individual's home or other place of a person's choosing. For example, some individuals prefer to be interviewed at a day program in which they participate in order to minimize disruption to his/her day.

States are asked to send letters to the selected individuals, requesting their participation and informing them of the value of their participation to the state. Having contact with consumers through a known and trusted agency, rather than an unknown and out-of-state organization, increases consumer confidence in the legitimacy of the request and willingness to participate.

Assessors use their usual practices for scheduling assessments. Where an outside agency is conducting the assessment, follow-up calls by the assessors are made with each respondent in advance of the assessment, reminding them of the date, time, and location of the appointment. This reminder helps to ensure that individuals and their caregivers (if expected to be present for the assessment) are present on the scheduled day.

Scheduling of interviews is managed to assure that adequate sample size is attained. Assessors submit weekly counts of the number of participants contacted, scheduled, visited, and assessed to the Qlarant data collection manager. No PHI or PII are transferred in this reporting.

### **4. Analysis of reliability and validity**

We collect FASI Item Set data to examine the validity, reliability, and completeness of responses, as well as the feasibility of implementation and data collection across a variety of Medicaid waiver programs. Data analyses will include examination of the psychometric properties of the FASI Item Set when used for different subpopulations.

The target sample size depends on the prevalence of the characteristics being measured in the population but should be approximately 126 to 335 cases (Sim and Wright, 2005). This range of sample sizes allows us to detect a kappa of 0.80—that is significantly different than a kappa of 0.60—with 95 percent confidence. A 0.60 kappa statistic is commonly interpreted as being the lower bound of what is considered to be “substantial” agreement. Subsample populations will be formed by combining populations across states. **Table 4** is an example approach of how kappas for FASI items are examined overall and stratified by program type. These examples are based

on the approach in the prior CARE item testing under the original OMB authorization and the subsequent 2016 data collection. If an item has more than two levels, we examine both the simple kappa, and a weighted kappa, which allows for the possibility that the “distances” between response levels may not be equal across all levels.

**Table 4: Example Table: IRR testing: Pain and continence at time of HCBS assessment, by population group**

Item	Effective sample size	Kappa	Weighted kappa
<b>Ability to walk 10 feet</b>	.	.	.
ID/DD	.	.	.
Aged ( $\geq 65$ )	.	.	.
Physically Disabled	.	.	.
TBI	.	.	.
Severe Mental Illness	.	.	.
<b>Ability to walk 50 feet and make 2 turns</b>	.	.	.
I/DD	.	.	.
Aged ( $\geq 65$ )	.	.	.
Physically Disabled	.	.	.
TBI	.	.	.
Severe Mental Illness	.	.	.

After analyzing the field test data, we prepare a Field Test Report on the results of reliability, validity, and other testing and its impact on TEFT FASI deliverables (e.g., training materials, the TEFT FASI Item Set) that need to be revised for the second round of data collection. Both the draft and final Field Test Reports are submitted to CMS within a timeframe still to be negotiated.

We perform a variety of statistical tests to assess reliability and validity, as well as:

- Analyze response distribution.
- Compare responses across functional needs and caregiver assistance across each of the five samples (I/DD, Aged, PD, TBI, SMI).
- Examine the distribution of missing data by client characteristic by program type and geography. Uneven distribution of missing responses on an item either by client characteristic, program type, or geography, suggests that bias may be present. **Table 5** shows an example of how we might examine response rates for FASI items by program type.
- Conduct Rasch, confirmatory factor analysis, and other internal consistency analyses to provide information on the construct validity of TEFT FASI items, their proposed scales, and their psychometric properties when used within/across study populations.
- Assess whether there are ceiling effects to be sure that the modified items cover the range of characteristics of participants.

- Evaluate key item-level components of FASI functional assessment, including response scale usage (i.e., the distribution of assistance needs on function items), an examination of the item difficulty hierarchy and how it compares to clinical expectations of item difficulty, and potential disability group differences.
- Perform analyses to assess inter-rater reliability. Inter-rater reliability will be assessed by comparing the information captured by two assessors, recording information independently, but who are both present at the same assessment. This will minimize the burden on respondents, but not requiring each respondent to go through two separate interviews.

**Table 5: Impairments: Percent missing responses by program type**

Item	Item Name	ID/DD (assessments n) percent missing responses	Aged (>=65) (assessments n) percent missing responses	Physically Disabled (assessments n) percent missing responses	Mental Health (assessment: n) Percent missing responses	TBI (assessme nts n) percent missing responses
VA1A	Bladder and Bowel Management A1a. Bladder Incontinence	.	.	.	.	.
VA1B	A1b. Bowel Incontinence	.	.	.	.	.
VA2A	A2a. Bladder	.	.	.	.	.
VA2B	A2b. Bowel	.	.	.	.	.
VA3A	A3a. Bladder	.	.	.	.	.
VA3B	A3b. Bowel	.	.	.	.	.
VB1	Swallowing B1. Swallowing Disorder Signs and symptoms of possible swallowing disorder.	.	.	.	.	.
VB2	B2. Indicate the person's usual ability to swallow.	.	.	.	.	.
VC1	Hearing, Vision, and Communication Comprehension C1. Understandin g verbal content (With hearing aid or device if used)	.	.	.	.	.

Item	Item Name	ID/DD (assessments n) percent missing responses	Aged (>=65) (assessments n) percent missing responses	Physically Disabled (assessments n) percent missing responses	Mental Health (assessment: n) Percent missing responses	TBI (assessme nts n) percent missing responses
VC2	C2. Expression of ideas and wants	.	.	.	.	.
VC3	C3. Ability to see in adequate light (with glasses or other visual appliances):	.	.	.	.	.
VC4	C4. Ability to hear (with hearing aid or hearing appliance if normally used):	.	.	.	.	.

## 5. Contact Information

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