Fall Prevention Data Collection 60-Day Federal Register Notice
Comments and ACL Responses

In the Federal Register Notice, Volume 79, No. 124, June 27, 2014, the Administration for Community Living (ACL), Administration on Aging (AoA) announced that the proposed Evidence-Based Falls Prevention Program Standardized Data Collection set had been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act (PRA).

ACL/AoA plans to use the proposed set of data collection tools to monitor grantees receiving cooperative agreements in response to the funding opportunity: ''PPHF–2014—Evidence-Based Falls Prevention Programs Financed Solely by 2014 Prevention and Public Health Funds (PPHF–2014).'' ACL awarded 14 cooperative agreements for a 2-year project period beginning in September, 2014.

ACL received four sets of comments in response to the PRA notice. Representatives of two state units on aging, one state public health department and a falls program developer provided comments.

In addition, ACL received one non-germane comment discussing concerns about government spending. As it is not related to the content of this Paperwork Reduction Act (PRA) notice, we are not able to substantively address the commenter's concerns.

Responses to the other comments follow:

1. **General Comments**

    a. *Comment:* I suggest that each state regardless of funding use similar fields so we can be consistent with collecting and comparing data. If we are not funded, will we be able to use the new forms?

    ACL Response: ACL agrees that it would be desirable for any agency doing evidence-based community falls prevention programs to collect similar data. However, we do not have authority over agencies that we don't fund. Agencies that are not funded by ACL are welcome to use the new forms on a voluntary basis.

    b. *Comment:* While I realize this is not a research study, I would apply the criteria used by our Institutional Review Board that we have an obligation to ensure that all questions asked of participants are useful to the program and that we will use the information they give us. Given the real-world of data collection, there may be little useful data, and an unnecessary burden on participants and programs, to collect paired pre- and post-program survey data for analysis. For example, in our state program, despite the fact that we put staff time into working with our program partners, we had low percentages (less than 50 percent) of data on paired questions to analyze. Unlike a research study, our priority, in order to ensure sustainability,

was to embed the program into the existing structure of the partner organizations and to not provide compensation to program partners. That meant that data collection was often not a priority for the partner, and we allocated the majority of our state staff time to developing relationships leading to more reach. In comparison we were able to achieve 98 percent response on the post-survey during a research study where state staff attended the majority of first and last day classes, and subsidized the classes to ensure partner organizations would comply with data collection procedures. Unless the grantees allocate more time to oversight of data collection, there may be minimal results for paired data (questions 11, 12, 13 on Participant Information Form and questions 3, 4, 5, 6 on Post Survey). Published studies of A Matter of Balance (AMOB) illustrate this concern. For a three-year evaluation of national AMOB data, the analysis was done on 6,922 of the 12,219 data forms (56 percent) "due to missing data for key sociodemograhic variables."[1] For an evaluation of three years of AMOB data in Texas, the sample consisted of 2,054 of the 3,092 participants (66 percent), representing "those older participants who completed both the baseline and post-intervention survey instruments."[2] Both studies acknowledged as limitations the participant attrition for post-intervention data, the level of missing data, and a possible "healthy participant effect", as well as the lack of a control group. For this proposed ACL program, the numbers of participants may be adequate for national data, however the sample size may be too small and limited to provide value at the grantee and program level, where the burden of data collection is the greatest.

ACL Response: The decision to collect both pre and post data was made after extensive consultation with an advisory workgroup consisting of representatives of ACL's Office of Performance and Evaluation, the CDC National Center for Injury Prevention and Control, the Falls Free Coalition; researchers from the University of Georgia and Texas A&M involved in a CDC funded falls prevention outcome study; falls prevention program developers; and staff involved with an existing online falls prevention database. The advisory group selected questions for the data collection tools that will allow for the measurement of short-term impact. The pre/post data is essential for ACL to be able to report program performance outcome measures which are used to monitor program performance and essential in budget justification and other performance reporting. In addition, the data collection is designed to fulfill the requirement that grants financed by the Prevention and Public Health Fund (PPHF) exhibit a high level of transparency, oversight, and accountability. We expect that the grantees will devote adequate resources from their grant budget to data collection efforts.

c. *Comment:* The on-line data collection system is a good idea. However it will probably produce additional burden on state grantees. As stated earlier, for sustainability, state programs may be working with partner organizations that are not funded and they may not have the interest or motivation to do their own data

collection and data entry. This job may fall to the state grantee, meaning the burden will be on them to collect all paper copies and enter the data.

ACL Response: Based on our Chronic Disease Self-Management Education (CDSME) grantee experience, we believe that the benefits of an online data collection system far outweigh any burden. We also expect that the grantees will devote adequate resources from their grant budget to data collection efforts, including centralized data entry if appropriate.

d. *Comment:* Rather than collecting data to continue to provide evidence-based programs that address falls and fear of falling, I would like to see more data collection that will help us address the need for patient-recorded outcomes and patient plans for further action. Health care providers and implementers of evidence-based programs are being asked to focus on patient engagement and patient participation in their health care. [3,4] Providers need to know the direct benefits to their patients of preventive programs using outcomes that people care about and expect such as increased physical function, symptom relief, activity level and quality of life.[5] Program partners who are implementing the programs will be more likely to enter data if they see the value of the data to them and they will receive a feedback report on their data. In our experience, program partners want to know demographic information about participants, participant satisfaction with the classes, some outcome measures to show the value of the program (such as a functional assessment, participants have gained some confidence, and some indications of patient engagement-would recommend to others, plans to make changes). Even if the limitations of sample size, especially for paired data, can be overcome, the utility of telling a state program implementer (senior center or exercise instructor) that participants significantly increase their response from 2.3 to 3.2 on a 4 response Likert scale about "how sure are you that you can find a way to reduce falls" has little practical value. However, tangible and impactful results would include: reporting that X percent of those who scored below normal limits at baseline significantly improved the time take to complete the Timed Up and go test, or that X percent of participant responders noted they are more comfortable talking about their fear of falling, and X percent plan to continue exercising.

ACL Response: The purpose of the Prevention and Public Health falls prevention funding is to provide programs that reduce falls/falls risk. We worked with an advisory group to ensure that the questions on the data collection tools were designed to assess short-term impact for Federal purposes and to assist grantees in documenting short-term program benefits for their partners and other stakeholders. This data collection is not intended for program evaluation or causal enquiries but for program performance reporting and monitoring. Individual grantees might want to pursue other data on their own, such as "patient-recorded outcomes and patient plans for further action." Many of the grantees did propose quality assurance/ data

collection plans outside of what ACL asks for, based on what was deemed useful in their state.

Grantees will have the ability to easily access the online database for local reports that can be shared with partners with minimal burden. We also expect that the database will allow for program partners with a license for the database to access their own data as well as standard reports they can utilize.

e. *Comment:* The length of the two surveys is critical. Our program partners do not want to take significant time away from the intervention, especially when it is an exercise program where participants pay for the class. In some cases, our partners have scheduled participants to come in on an individual basis to fill out forms, or they schedule a Class Zero where participants in Stepping On come in for a paperwork and introduction class. Both of these create a burden on participants and program staff, as well as creating bias toward those who are most interested in completing paperwork. In examining our Tai Chi data, we are noticing a drop in attendance for the last day of class. Instructors tell us some folks are not interested in attending the last class when it is mostly paperwork. This perception limits the dose of intervention a participant receives, a critical element when guidelines call for 50 hours of Tai Chi participation. Therefore a maximum of two pages for the initial survey and one-page for the post-survey would be ideal.

ACL Response: We are proposing one double sided page for both the pre-test and the post-test. Based on previous data collection experience, we do not consider this to be excessive or burdensome. While some missing data is expected, we anticipate the data collection will provide essential performance information for the monitoring and reporting on program results and beneficial data at the state and local levels.

2. **Participant Information Form**

a. *Comment:* The first question about referral source relates to health care providers. We plan on utilizing a number of referral sources. Is it possible to broaden the answer to include EMS, AAA, insurance companies, media etc. or have an "other" box? Also, are physical therapists included under health care provider? We plan on involving rehabs and PTs and I am not sure if people consider them a health care provider.

ACL Response: We have added physical therapists to the list of health care providers. We will not be adding any other response options to this question. We do not need the additional information at the Federal level, and the potential response categories vary greatly from one state and agency to the other. We will give our grantees the option of adding additional referral sources if they wish for local program planning purposes.

b. *Comment:* I reviewed the data forms and have no comments, except for the concern I have for leaders being able to gather this information from frail adults.

ACL Response: Completion of the participant surveys is voluntary and will not affect an individual's ability to participate in the programs. We will be encouraging the use of "Session 0" classes prior to the start of programs to allow more time for the data collection as needed.

c. *Comment:* I also wanted to suggest developing a leader script similar to the one developed for CDSME to help leaders explain why is the information requested and how it will be used.

ACL Response: We have created a new script. See Attachment 7.

d. *Comment:* Regarding questions 7 (What is your race?) and 14 (Has a health care provider ever told you that you have any of the following chronic conditions?), put the instructions "Check all that apply" in bold.

ACL Response: We made these changes. See Attachment 2.

e. *Comment:* There is a question about the usefulness and necessity to ask all the questions on the Participant Information Form. Since programs are evidence-based, it may not be necessary to continue to ask falls and fear of falling questions. Without some of the components of a research study (randomization, control group, vigorous efforts to get complete sample, knowledge of representativeness of the respondents vs. non-respondents) there may be enough limitations that the data analysis will not provide valid and useful conclusions.

ACL Response: The purpose of the data collection is for program monitoring and performance management. The data will provide indications that the program is working as intended and having similar results at the national level as in research settings, as well as provide public accountability and the reporting of accomplishments.

f. *Comment:* Question Four (Do you live alone)-- what is the reason for asking this question and how will it be used in analysis?

ACL Response: We have a commitment to serving vulnerable populations. We have found from past program monitoring efforts that this question is a good indicator of whether we are reaching a high-risk population.

g. *Comment:* It would be useful to have zip code of respondent added to the form. Since zip codes do not always respect county lines, it would be also be useful to ask for city of residence and/or county. Could these fields be added, as an option by grantees, and would the data then be made available to the grantees for data analysis?

ACL Response: We currently do request zip code with our CDSME grantees. However, many public health departments and their partners have had difficulty collecting this information due to privacy concerns. For this reason, we decided not to collect this from the Falls grantees. However, grantees may choose to add this question and the online database will include this as an optional field. The database has the capacity to report county based on zip code data entered into the system.

h. *Comment:* Without having full knowledge of the priorities, I am assuming that Questions One-Three, and Five -Eight on the Participant Information Form are to collect demographic information on participants to verify the program is reaching the high risk population. This seems valid.

   ACL Response: Yes, we are collecting this information to monitor whether the programs are reaching the intended audiences.

i. *Comment:* The wording for Question Nine (about disability) seems very awkward. From a health literacy standpoint this would be a difficult question to comprehend. Has this question been tested with older adult audiences? Why not use the validated question from the CDC Behavioral Risk Factor Surveillance System which is "Are you limited in any way in any activities because of physical, mental, or emotional problems?" The value of Question Nine seems doubtful since many of the evidence-based fall prevention programs have participant exclusions that would make it difficult or impossible for anyone who answers Yes to Question Nine to participate in the program. Exclusions often include using an assistive device full time, inability to communicate in the language of the class, living in a non-independent setting such as assisted living or skilled nursing facility.

   ACL Response: We have changed this question to the CDC Behavioral Risk Factor Surveillance System question. The question is not designed to screen out potential participants, but rather to monitor whether the programs are reaching people who identify as having some type of disability/limitation since that is one of the intended target groups of this funding.

j. *Comment:* On Participant Information Form, Questions 11-13 are about fear of falling. Are all three questions necessary? Will they produce different and usable data? Since we know that evidence-based fall prevention programs lower the fear of falling, are these questions necessary? If fear of falling is a critical element for ACL, could you use a single question, such as Question 11? Has this question be validated in research studies? The question with the most burden for respondents and those doing data entry and analysis is the multi-part Question 12. This set of questions has been used by A Matter of Balance, but is not commonly used by other programs. The most commonly asked question about fear of falling is the Falls Efficacy Scale (FES).[6,7] You may want to consider using the Short FES I [8] which is a series of seven questions and would allow you to compare results (if the limitations problems can be overcome) to other studies.

ACL Response: Our advisory group helped ensure that the questions on the data collection tools were the most appropriate to use, based on their experience with the Matter of Balance (MOB) and other validated sets of tools. We deliberately chose to use questions that were familiar to those already involved with MOB since that is the most widely disseminated falls program and allows for comparison between the federally funded program and other research that has been conducted.

k. *Comment:* From a health literacy standpoint, will older adults understand the responses on question 14, especially "rheumatic disease", glaucoma" and most importantly "chronic?"

   ACL Response: We have successfully used the same question, with a slightly different list of conditions, with our CDSME grantees. We have modified the question to include a definition of chronic condition and to simplify some of the disease names.

l. *Comment:* In our state, we use the Timed Up and Go test with our evidence-based programs. This is a verified test for assessment of functional mobility.[9] This test provides feedback to the participants, and the analysis of this test is well-received by instructors. We also think the results of this test on an individual and/or program/state level will be meaningful and useful to health care providers about the outcomes of our programs. Will the on-line database be able to accommodate the addition of this data field in the data collection, and will grantees be able to get this data back for state and/or program analysis? It would be a burden to both programs and state grantees if this data collection would need to be done separately from the on-line data collection.

   ACL Response: We selected questions that would meet ACL's need for program monitoring and performance management as well as require minimal burden and need for training and so did not include the Timed Up and Go test. However it will be available as an optional data field in the online system for use by grantees who want to collect and report this information.

3. **Participant Post Program Survey**

   a. *Comment:* Regarding questions 6 (Please tell us your thoughts about this program.) and 7 (Since this program began, what have you done to reduce your chance of a fall?), put the instructions "Check one circle for each question" and "Check all that apply" in bold.

   ACL Response: We made these changes. See Attachment 3.

   b. *Comment:* Regarding Question Six, for classes that last for seven or eight weeks, this question pre- to post may not provide useful information. At post test you are asking for information about falls that took place during the last four weeks of the class. You would need to ask this question four weeks post-program to gather information on the value of the class in preventing falls. Given this limitation, it does not seem

this would be a useful question, either as comparison to the falls history question on the Participant Information Form, or as a stand-alone question on the Post Program Survey.

ACL Response: We agree that it would be ideal to ask this question after the program concludes. However, we were trying to reduce the burden on the local agencies and so selected questions that we expect to provide a snapshot of short-term impact. In addition, we wanted to provide a standardized set of questions for use by all of our Falls grantees, many of whom are providing Tai Chi programs with a duration of 12 weeks or more.

c. *Comment:* Questions Seven and Eight are very similar and only one of the questions is needed. I prefer Question Seven which could yield patient engagement information. If Question Eight is used, it should be recognized that it does not apply well to participants of an exercise class such as Tai Chi. Perhaps a response could be add such as "Continue to follow the exercises I learned in class." This question would be more useful asked as a one or six month follow-up to the program. It may be too soon to expect participants to have made those changes while still taking the class.

ACL Response: We believe that we will be able to assess self-efficacy (comfort level and confidence) through question 7 and that question 8 will provide more information about actually taking action. Both types of data on belief and behavior are important indicators of impact. We did modify the question 8 responses to better accommodate those attending a Tai Chi class.

4. Attendance Log

a. *Comment:* Attendance log only has spots for eight weeks of classes. Some evidence-based classes, such as Tai Chi: Moving for Better Balance run 12 weeks or longer.

ACL Response: The Attendance Log has a note at the bottom indicating that it can be adapted to "*include the number of possible sessions. Use additional pages if needed.*"

5. Program Information Cover Sheet

a. *Comment:* I suggest putting #3 the Name of parent/host/sponsoring organization first (as #1) as that is the field I pull up to enter the data. I would also combine the site name and address as it is easier to read on the eye as opposed to filling out the name, city state, looking at question 2, then going back for the street and zip. So, it can be one question, name, address, city, state, zip then type of site.

ACL Response: We have made these changes. See the revised form, Attachment 5, questions 1 and 2.

b. *Comment:* Instead of requiring names and contact info for Leaders/Coaches, it might be best to ask for name and contact information for the best person to contact (or

person submitting the forms) with questions about the forms. A more inclusive designation would be Leaders/Coaches/Instructors.

ACL Response: We have added "Instructors." We use this information to monitor the program delivery workforce. In addition, our CDSME grantees have found it useful to track who is teaching the programs. So we have left the request for the names but have modified the wording to only ask for the "phone number or email of the best person to contact about any questions on the forms." See the revised form, Attachment 5, question 4.

c. *Comment:* Since programs may submit data at any point, a note should be added to Question Eight that states this question needs to be completed only at final data submission. It seems like an unnecessary burden for programs to complete Question Eight, since it can easily be computed from the information on the Attendance Log. This form makes sense when someone is submitting paper copies of data; but the utility of the form is less clear for on-line data submission.

ACL Response: We have added a note to the initial instructions on the form that it should be completed and returned at the end of the program. The completer totals will be calculated by the data system based on the entered attendance data. However, we included Question 8 based on our CDSME experience. Because the paper forms are often sent to a centralized data entry person, the Cover Sheet serves as a quality control mechanism, reminding the local leaders to check the Attendance Log for completeness.

6. **Host Organization Information Form**

   a. *Comment:* The information refers to the license holder, not the actual site where the class is held. Please consider changing the site name to agency name and the type of site to type of agency.

   ACL Response: We have made this change. See the revised form, Attachment 6, question 1 and 2.

7. **Performance Report**

   a. *Comment:* From the perspective of a grantee, I appreciate having the reporting format provided, with templates for reporting, guidelines, and deadlines. This Performance Report will give a good qualitative report on progress. Will the grantees also be asked to report on interim and/or final progress toward meeting the specific Objective and tasks in their required Work Plan? If so, this should be detailed in the Performance report.

   ACL Response: It was our expectation that information about progress towards work plan objectives would be included under the Activities and Accomplishments section, question 1 in the report. We have modified the wording to make that

clearer. There is a separate OMB approved template for ACL final reports which also does request this information (http://www.acl.gov/Funding_Opportunities/Grantee_Info/Reporting.aspx).

b. *Comment:* Appendix A will need some guidelines and possible revision. This format would create a burden on grantee organizations and partners, if they need to either complete on-line reports monthly or need to access the on-line database to complete this report. If you are using an on-line data collection system, the ACL (or designated evaluators) could easily calculate this report.

Under this format, it is unclear how you would report participants and completers for a class. For example, if a class had four sessions during Month 1, with the class scheduled for completion in Month 2, would you report only the number of participants who completed all four sessions that month; the number who attended the four sessions with zero completers and reporting the completer numbers only in Month 2; or some other scheme? You may want to consider having the reporting done by class rather than month. The most important data might be number of participants who attended the program at the first class and the number who completed (according to an agreed upon definition of completer). This can be generated by the on-line data system.

ACL Response: Appendix A is a report that grantees will download from the online national falls database just prior to the due date for the report. Grantees will be expected to enter data on their programs into the online system after each program concludes. We have successfully used the same procedure with our CDSME grantees. To minimize burden on local sites, the CDSME grantees have typically designated a centralized survey coordinator/data entry person.

The reports will reflect data on programs finished by the end of the reporting period. Regarding the participant and completer information, we have added a note with a definition for completers, i.e., the number who complete at least 60% of the available sessions. Because some grantees have proposed multiple programs, the database will generate reports that provide separate data for each program.

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