Title of the project: *Senior PharmAssist: Co-Design and Evaluation of a Toolkit to Promote Scalable Implementation*

Name and affiliation of the principal and co-investigators

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Research Strategy:

a. Study Aims. Community dwelling older adults are at risk for loss of function and reduced quality of life due to challenges they face managing multiple comorbid conditions, including accessing necessary medications, and preventing medication-related problems. An estimated 20% of community-dwelling adults experience inappropriate medication use and this is known to impair physical function,[1] and a wide variety of other adverse outcomes, including excess healthcare utilization and mortality. [2-4] Older adults with limited incomes and those who belong to historically marginalized communities are at particularly high risk for medication-related problems.[5-7] Concurrently, they face challenges navigating a complex web of social and community-based supports to help them remain vital and in their homes.[8] The nonprofit Senior PharmAssist (SPA) was established in 1994 in Durham, North Carolina (NC) to address these concerns.[9] SPA offers a multi-component intervention that addresses both social and clinical drivers of health. The ultimate goal of SPA is to recognize and build upon the strengths of older adults with limited incomes and the organizations designed to support them, so that they can be as highly functional, active and engaged as possible in the community for as long as possible. SPA achieves this goal through supporting older adults' access to and management of medications, navigating and leveraging additional programs and services, and helping them identify the best medical and prescription insurance coverage based on their ability to pay.

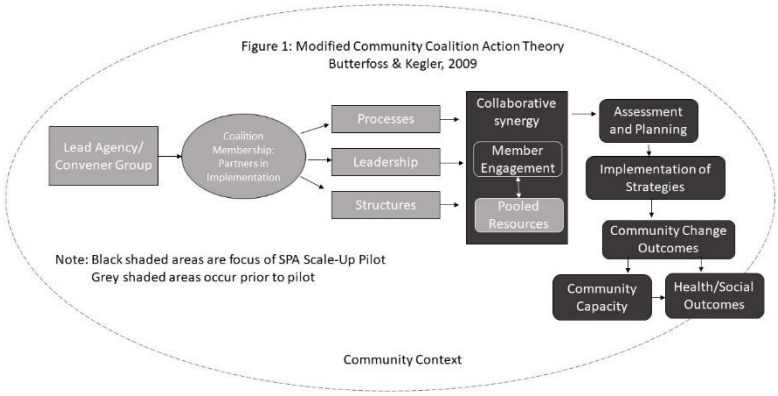
Core components of the SPA program directed toward older adults are: 1) Medication Therapy Management (MTM); 2) medication copayment assistance; 3) tailored community referrals; and 4) Medicare insurance counseling.[6,10] When delivered within a community that embraces the goals of these services, by staff employing a racial equity framework, who engage with participants using motivational interviewing tools while emphasizing continuity of care, these core components have been associated with the maintenance of physical functioning necessary to remain in their homes, improved self-rated health, and a reduction in emergency department visits and hospital admissions. [6,11] Recognizing the program's sustained impact in Durham, NC, and related evidence for improving physical function and well-being, we propose to refine existing SPA replication materials and processes based on community stakeholder feedback, and then support new implementation in three other diverse North Carolina communities, to evaluate the scalability of this program for state-level implementation. Consistent with the goals of NIH-stage V studies we aim to:

(1) Co-develop a SPA implementation toolkit with participants from three diverse NC communities interested in adopting the SPA program. Using existing SPA protocols and guides, the toolkit will be co-developed using the Precede-Proceed Model for Program Planning and Evaluation.[12]

(2) Implement the SPA intervention using multiple small tests of the toolkit's tools and processes and examine the organizational-level barriers and facilitators to implementation. We will create a learning collaborative in partnership with the three NC communities implementing SPA and use the Institute for Healthcare Improvement (IHI) Scale-up Framework[13] to establish a multi-site community-based model that addresses equitable access to medications, medication management, and community supports that promote physical function and healthy aging in place. (Stage V: Implementation).

The research team has a long history of collaboration and brings expertise in community pharmacy, public health, geriatrics, implementation science, and inter-professional care, and has a track record of fostering inclusion of pertinent stakeholders as a means of accelerating implementation of evidence-based programs to improve physical function among vulnerable older adults in an equitable manner. The proposed SPA implementation study aligns with the Duke Roybal Center themes of aging and healthy longevity.

b. Significance. Health and behavior are affected by multiple levels of the environment surrounding both older adults with limited incomes and the agencies designed to serve them. The Community Coalition Action Theory (CCAT) is a change theory that is used to examine how changes such as those needed to implement multi-component community-level interventions such as the SPA program occur across organizations[14]. (See Figure 1). We will integrate this theory with the Precede-Proceed model[12] which was used to develop SPA, along with the Institute for Healthcare Improvement's (IHI)



Scale-up Framework[13] to examine and address barriers to SPA implementation at the community, provider, and participant levels, so that the model can be subsequently scaled to more sites. Although SPA has had some prior success in spreading the model beyond Durham, communities have struggled to implement all components of the intervention. The multi-component intervention requires the development of appropriate implementation tools to support the content that currently exists in the SPA replication guide. Successful, scalable implementation will entail working with local champion(s) to identify a dedicated coalition within the adopting communities that can effectively and efficiently collaborate across local health and social service agencies and work closely with the SPA team to refine the implementation tools. A state-wide readiness survey conducted by SPA in collaboration with the NC Department of Adult and Aging Services and the Office of Rural Health in 2021 indicates a high level of readiness for broader implementation.

Given the long and active history of years of disadvantage to communities of color,[15] this approach to scaling SPA moves beyond a focus on SPA core components alone, to describe how and who should be engaged in program adoption in diverse settings. The implementation process will help all collaborators understand the importance of incorporating a racial equity framework, motivational interviewing techniques, and a continuity of care practice, thus addressing both racial inequities and the challenges presented by complex systems of healthcare and social care delivery. Findings from this study will generate new insights regarding implementation of models that link current medical and social systems of care to promote health equity.

c. Innovation. This proposal is innovative in that it uses a community-centered co-design approach with diverse types of communities to implement the multi-pronged SPA program. The program includes social service and clinical interventions and each of the three communities will have its own unique assets and challenges with implementation.

d. Approach (Study Design, Methods, Analysis Plan)

Study Design. We propose a convergent mixed-methods case study design[16] to evaluate the scalability of the SPA implementation package. The implementation research questions are:

i. How does the use of SPA implementation tools support community-level champions and other stakeholders to implement SPA core components successfully in diverse communities?
ii. What implementation challenges are identified by community-level stakeholders and what modifications do they suggest to ensure that the tools and methods of transfer are easier to use?
iii. What level of support and expertise (capacity) is needed at SPA to scale the program in additional communities after developing the necessary tools?
iv. What level of improvement in measures of self-reported physical function and health care utilization is observed among participants in the pilot projects within each community adopting the SPA program?

Sample. We will purposively select three communities in NC of the 56 that have demonstrated interest and readiness to implement SPA and that have local champions. These communities will differ with respect to characteristics of the lead community agency and will also be diverse with respect to community size, rurality, racial and ethnic diversity, complexity of the community's health and social care networks, and socio-economic position. Older adult participants will be those who meet SPA criteria of being $\geq$ 60 years old and live at or below 200% of the poverty line. At the time of application, we have expressions of interest from 56 communities within NC and determined readiness of state leaders to explore SPA's implementation statewide.

Methods. Co-design phase. We will conduct community-centered design workshops using techniques we have used previously from the IBM-Design Thinking Field Guide.[17] Workshops will engage end-users in refining tools from the existing SPA Replication Guide. Tools already available include how to provide: 1) direct financial assistance at retail pharmacies to lower Part D copayments; 2) Medication Therapy Management (MTM) and related health education; 3) Medicare Insurance counseling; and 4) connections between older participants and other programs and supports. The team will leverage SPA's experience and existing curricula on topics such as MTM, motivational interviewing and racial equity to ensure that program delivery: includes all four intervention core components; is consistent with principles of racial equity and continuity of care; makes use of motivational interviewing techniques to facilitate person-centeredness; embeds measurement and data collection with SPA implementation; and incorporates evaluation and quality improvement as essential components in adopting communities. Together with an already established stakeholder advisory team we will refine tools based on feedback from the adopting communities regarding anticipated implementation

challenges. The Roybal Center interventionist Jennie Riley and design thinking expert Heather Mountz will facilitate tool modification incorporating end-user input. In addition to organizational partner leads from each community, we will work individually or in small groups to obtain additional feedback for refinement from state policy leaders interested in scalable implementation (see letters of support from NC Office of Rural Health and NC Department of Aging and Adult Services). Stakeholder feedback from these co-design sessions will be subjected to rapid qualitative analysis,[18] and insights will guide finalizing an implementation toolkit for adopting communities to use during the learning collaborative.

Toolkit Implementation and Evaluation Phase. Once the tools are refined, we will engage implementing partner community organizations in a monthly learning collaborative to help them modify their existing processes to incorporate the SPA intervention core components. The model our team has used successfully elsewhere includes hour-long sessions that, over time, are more implementer-led in order to facilitate shared lessons and approaches to problem solving. Initially these will be led by our SPA Durham-Duke team as follows. *Session 1*: Strengthening relationships with community champions and sharing in the overall SPA program implementation by asking for feedback about the co-designed intervention tools. *Session 2*: Measuring and monitoring equity of reach, implementation and effectiveness. *Sessions 3-6*: Detailed focus on how each of the SPA core components is delivered through a racial equity framework, emphasizing continuity of relationship and motivational interviewing to respect participants' goals. Each session will include specific 'take home' assignments to ensure that community representatives have clear guidance on next-steps local implementation. Individual consultation from SPA-Durham staff between sessions will occur from SPA staff Upchurch, Brush, Omozokpea, and contracted staff who will provide personalized support to community implementers. SPA staff will maintain logs of contact that capture the amount of time spent in consultation and maintain field notes regarding the specific challenges that the three adopting communities encounter as they implement the SPA core components. Fidelity checklists completed by implementers will be analyzed by project staff to note progress toward implementation of core components. Adopting communities will collect participant level data and share with Duke-SPA project staff. Data will include participant socio-demographics (age, race, education, ethnicity and income), health services utilization (self-reported ED and hospitalizations), and self-reported ADLs/IADLs, and perceived health according to previously published SPA protocols[6,10,11].

Analysis. A case study for each community will be constructed based on a combination of publicly available descriptive statistics about the communities selected for implementation, information gathered in the 2021 statewide survey, quantitative data from sites regarding the number, and demographic characteristics of participants served during SPA implementation. These quantitative data will be integrated with qualitative data from staff field notes regarding implementer responses to the co-design workshops, the learning collaborative sessions, the SPA staff contact logs and field notes, and key informant interviews from each implementing community. Qualitative data will be analyzed using directed content analysis to examine similarities and differences among barriers and facilitators identified by implementers in different communities in accordance with key CCAT theory constructs, and how implementation tools facilitated implementation. Themes regarding barriers and facilitators integrated with aggregate data provided by individual sites on participant response to implementation of SPA core elements will form the foundation of a cross-case comparison of communities using configural design logic[19] to isolate community-level factors that are associated with different levels of fidelity and strength of implementation of the SPA program. In addition, staff logs will be used to quantify the level of technical assistance associated with the implementation experience in each community.

Timetable.

Key Activity	Q1	Q2	Q3	Q4
Finalize site recruitment and obtain IRB approval	X			
Conduct co-design sessions to refine toolkits	X			
Conduct Learning collaborative sessions and collect data re: stakeholder responses		X	X	
Analyze stakeholder feedback				
Analyze de-identified participant-level evaluation data from sites			X	X
Conduct cross-case analysis		X	X	X
Host wrap up collaborative session with state-level leaders				X
Meetings with Royal core staff	X	X	X	X
Abstracts and manuscript preparation			X	X