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Editorial

Pragmatic Trials and Improving Long-Term Care: Recommendations From a National Institutes of Health Conference

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Conducting clinical trials in nursing homes, assisted living, and other long-term settings is attendant with challenges, including but not limited to recruitment and retention of settings, participant attrition, staff time constraints, family resistance, research ethics concerns, burdensome implementation and measurement, cost, and mistrust.[1–7] For these reasons and also because research protocols may dictate exclusionary eligibility criteria, participation rates may be low, data may be incomplete, and results may not be generalizable.[8–15] Recognition of these challenges catalyzed a recent initiative to develop recommendations for a nursing home clinical trials network.[16]

A key limitation of all such trials, however, is the extent to which they ultimately change practice and policy and improve care and outcomes, especially for persons living with dementia; for that purpose, pragmatic trials are recommended. First articulated more than 50 years ago, a pragmatic approach determines an intervention's effectiveness in routine clinical practice.[17] Pragmatism applies to recruitment (extent to which settings and participants are similar to those in usual care, and extent of effort required for recruitment); the intervention itself and its delivery (availability of resources in standard care, flexibility and ease of implementation, encouragement, and monitoring); the nature of follow-up (reasonable intensity); and the nature, determination, and analysis of outcomes (extent to which outcomes are relevant to participants).[18,19]

Pragmatic trials are especially important in long-term care, because limitations in care and resulting outcomes have been long noted. As but a sampling of issues, almost 60% of adverse events among nursing home residents are potentially avoidable, and the majority result in hospitalization.[20] Likewise, in assisted living, the error rate of medication administration exceeds 20%, and more than 40% of residents have unmet care needs.[21–23] Specific to long-term care residents with dementia, unmet needs include care for pain management, visual limitations/sensory issues, activities of daily living, social engagement, support with grief and loss, and end-of-life care.[24–27] Countless interventions have been conducted to address these and other care needs, but few have been implemented in real world settings, hence the need for pragmatic trials of promising practices.

Pragmatic trials are not without their own challenges, however. It may be challenging to recruit organizations that are underperforming, and so eligibility may be restricted and participating organizations may not be generalizable; the proposed intervention may not be consistent with the goals of the organization; requirements to obtain informed consent may be anything but pragmatic; resource needs may exceed capacity; data requirements may not be consistent with standard care; obtaining clinician and staff involvement may be problematic; and maintenance of new care practices may be limited.[28–33]

Recognizing the critical importance of pragmatic trials in long-term care, the National Institute on Aging (NIA) funded a 2021 conference to convene diverse experts to identify priorities and best practices for pragmatic trials in long-term care, with a focus on care for persons with dementia. Experts included international clinical and health service researchers, directors of nursing home and assisted living organizations, and directors and presidents of professional and advocacy organizations (see acknowledgements for a list of experts

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and their affiliations). This editorial presents summative recommendations from that conference; one other article presents *research* challenges and potential solutions, and another presents *implementation and dissemination* challenges and opportunities, all of which inform these recommendations.[34,35]

Importantly, the recommendations aim to not only facilitate the conduct of pragmatic trials in long-term care but also to achieve widespread evidence-based change in long-term care practice and policy.

Recommendations for Pragmatic Trials in Long-Term Care Designed to Achieve Widespread Change

The 12 recommendations emanating from the conference address 4 interrelated areas: *revamp* the academic mindset and enterprise, *respond* to what is known about content and process, *reframe* the partnership paradigm, and *reach* 3 key parties toward 3 key goals when communicating (see Table 1).

1. Revamp the Academic Mindset and Enterprise

Two of the more compelling recommendations from the experts are the need to turn the "evidence-based research" mindset 180 degrees, and advocate for changes in the research enterprise; a third recommendation is to promote and capitalize on nimble funding opportunities.

- *Develop practice-based evidence.* Ultimately, the most pragmatic efforts are those that are already in practice, thereby proving that they meet the sine qua non of pragmatism. As a case in point, developing practice-based evidence is how the evidence for small model Green House nursing homes has been and is being built. The first Green House home opened in 2003 as an alternative to traditional "institutional" care; today there are 362 Green House homes in 32 states, with homes in development in 4 additional states. Research on Green House homes has created evidence of benefits (eg, for hospital readmissions and some quality measures) and also challenges (eg, variability in implementation); this evidence is being used to modify the practice-based model.[36]
- *Change the academic mindset and academic process to one of quality improvement.* The organizational leaders were especially concerned that the academic mindset and related processes interfere with the research they themselves find most useful. Even for a pragmatic trial, institutional review boards (IRBs) may disallow or overly complicate processes that are standard care—such as talking with a family member shortly after the death of a resident or evaluating a new care practice without having to develop intricate clinical trials protocols. Instead, the mindset of *quality improvement* may be more fruitful and more likely to achieve actual practice and policy change and is already incorporated into nursing home care in the context of ongoing quality assurance and performance improvement (QAPI) for which numerous resources are readily available.[37] Research that helps guide and evaluate QAPI initiatives may avoid restrictive academic processes, ensure a focus on topics that are embraced by the organization, and ideally achieve sustainability of new care practices.
- *Maximize nimble funding opportunities.* Long-term care providers are often well aware of their own need for research and evidence, but even with a research partner, a critical challenge is that most funding opportunities entail a lengthy process of proposal development, review, and resubmission, with funding beginning years later. By the time the project is ultimately completed, the provider may no longer be invested in the initial topic. Countless rapid response grant funding opportunities made available during the COVID-19 pandemic prove that more responsive strategies are feasible and can serve as a model for the future. In addition, existing opportunities, such as the NIA Imbedded Pragmatic Alzheimer's Disease and AD-Related Dementias Clinical Trials Collaboratory (NIA IMPACT Collaboratory), allow a shorter timeline and provide support to promote funding success.[38]

2. Respond to What Is Known About Content and Process

Notwithstanding the preceding points about taking the lead from the organization when determining what to study, there is need to be informed by the evidence.

- *Draw from existing knowledge regarding the topic* ***in the context of*** *implementation.* Based on strong efficacy studies, there is an abundance of literature on promising interventions to improve care and outcomes across numerous areas—although specific to persons with dementia, evidence of efficacy for interventions to address agitation and aggression is insufficient.[39–41] At the same time, there is growing literature on challenges related to implementation of pragmatic trials and quality improvement projects, including but not limited to identifying outcome measures that are relevant to residents and their families while being practical to collect, fidelity to the intervention while allowing flexibility in delivery without affecting the "secret sauce" of what is necessary to achieve outcomes, the variable nature of long-term care organizations, and lack of ultimate change in the overall culture of care.[34,42,43] Evidence regarding the "what" and the "how" can and should be better integrated, such that, for example, a trial on advance care planning is informed not only by evidence on advance care planning itself but also by evidence specific to implementation of advance care planning in long-term care. Based on the conference proceedings, the article by Resnick and colleagues summarizes numerous future areas for suggested implementation research on functional care and outcomes, psychosocial care and quality of life, and medical care and outcomes.[34]
- *Think systemically when implementing a new intervention.* Long-term care organizations are complex adaptive systems.[44] As such, care processes and interpersonal interactions are dynamic, and any one component may affect and be affected by another. There is evidence, for example, that relinquishing top-down management may be important to change care,[45] and that different strategies may be important to change practices

Table 1
Recommendations to Improve Pragmatic Trials and Achieve Evidence-Based Change in Long-Term Care Practice and Policy: Revamp, Respond, Reframe, Reach

1. *Revamp* the academic mindset and enterprise
   - Develop practice-based evidence
   - Change the academic mindset and academic process to one of quality improvement
   - Maximize nimble funding opportunities
2. *Respond* to what is known about content and process
   - Draw from existing knowledge regarding the topic *in the context of* implementation
   - Think systemically when implementing a new intervention
   - Build the knowledge base related to the topic in the context of implementation
3. *Reframe* the partnership paradigm
   - Be purposeful in identifying partners
   - Begin the collaboration before the proposal is written
   - Collaborate to change care practices that are not pragmatic
4. *Reach* 3 key parties toward 3 key goals when communicating
   - Communicate to organizations to change care
   - Communicate to the public to drive awareness and create urgency
   - Communicate to academics to promote science

in assisted living vs nursing homes.[46] Thus, it may be necessary to deimplement an established practice so as to implement a new practice and achieve desired outcomes, but the linkage between the two may not be clear. Further, processes to maximize sustainability after the completion of a trial are paramount, because unless the organization has fully incorporated new practices as standard care, there is good chance that care will revert to previous processes after the trial.

- *Build the knowledge base related to the topic in the context of implementation.* Given the need to effect change in long-term care, it is recommended that pragmatic trials themselves further inform implementation. Two models are especially useful toward this end. The Pragmatic-Explanatory Continuum Indicator Summary (PRECIS and PRECIS-2) provides a framework to critically evaluate processes related to recruitment (eg, eligibility, effort, representativeness), the intervention in the context of the organization (eg, available resources, flexibility in delivery and adherence), follow-up (eg, intensity of data collection and monitoring), and outcomes (eg, relevance, intent to treat analyses).[18,19,47] The Readiness Assessment for Pragmatic Trials (RAPT) model reframes these considerations in the context of the extent to which a trial is actually ready for implementation considering how detailed the implementation protocol is, whether evidence supports efficacy, issues regarding risk and safety, feasibility, available measures, cost, acceptability to the organization and the extent to which it aligns with their priorities, and anticipated impact.[48] It is recommended that pragmatic trials not only be informed by the components of these models but also further inform them.

3. Reframe the Partnership Paradigm

The importance of research partnerships has been long-recognized in community-based research/community-based participatory research, including in nursing homes and assisted living.[49–51] However, conference participants noted numerous shortcomings in terms of how truly partnered the long-term care staff, residents, and families are in the research enterprise. As such, 3 recommendations are set forth.

- *Be purposeful in identifying partners.* Perhaps the most important criteria when identifying partners are that the long-term care organization is motivated to change and has the capacity to implement the trial or quality improvement project with fidelity. Such an organization might be willing to redesign jobs and modify performance evaluations and record keeping systems. Unfortunately, these criteria may be at odds with the capacity of poorer performing settings that are most in need of change; if those organizations are excluded, inequity in access may result.[35] One strategy to reconcile this challenge would be to have a sample sufficient enough to achieve likely fidelity while also including organizations less likely to be successful—recognizing that inclusion of the latter may inform pragmatism so as to more successfully involve them going forward. Furthermore, if the research design can stratify such low-resource organizations into intervention and control conditions, it may be reasonable to provide differential implementation support to those providers in acknowledgement of their preexisting disadvantage.
- *Begin the collaboration before the proposal is written.* Although the partners themselves know best what is pragmatic for their organization, what care processes can be conducted with fidelity, and the required timeline for implementation, organizational leaders noted that they are rarely involved when the proposal is at its most formative stage. Consequently, it is critical that the research team reach out to partners while the proposal, and particularly the intervention to be implemented, are still highly formative, and be prepared to pivot. At the same time, it is necessary that a priori, the research team not be naïve to the organization's mission, practices, and challenges; if necessary, it may be advisable to seek consultation before reaching out to potential partners.
- *Collaborate to change care practices that are not pragmatic.* Just as it is recommended to change the academic mindset, so too is there cause to change the organizational mindset. One recommendation that is gaining traction is for research consent to be integrated into clinical consent at the time of admission into a long-term care setting, so that deidentified information from existing records may be used without need to obtain additional time-intense consent.[34] Doing so would also allow for the inclusion of a greater number of residents vs the few who might be approachable and able to consent to a research study. Of note, the National Institutes of Health (NIH) Common Rule allows for waiver of consent for information extracted from medical records without identifiers.[52] Participation in trials in which there is some potential for risk requires individual consent, but interventions such as those that might be introduced as quality improvement projects may allow waiver of consent. An additional area in which care practices may be changed so as to be more pragmatic is to have electronic health records that may be modified/adapted to include select new information, which could benefit medical care as well.[53]

4. Reach 3 Key Parties Toward 3 Key Goals When Communicating

Communication is relevant throughout a pragmatic trial and quality improvement project, but standard communication practices often fail to achieve the desired intent. Toward that end, it is helpful to clarify the intended audience and related purpose and modes of communication.

- *Communicate to organizations to change care*. Messaging matters at all levels of the organization. Related to direct care workers, one organizational leader commented that the term *research*—and by extension, pragmatic or any other type of *trial*—translates to care providers as *more work*; absent motivating factors and reframing, the opportunity to participate in research is not typically met with enthusiasm. At the other end of the spectrum, although C-suite executives—including chief executive, financial, operating, and information officers—are motivated to change practices and engage in data-driven partnerships,[54,55] research results rarely come to their attention, in large part because research findings are published in academic journals. That said, translating materials and providing them passively through conference presentations or unsolicited mailings as an alternate venue for communication is largely ineffective in changing care practices, whereas social influencing interventions and promotion by opinion leaders and social media are more effective.[56,57] If a pragmatic trial is to change care, dissemination must reach the end user; use of dissemination planning tools even before the research begins may be helpful toward this end.[58]
- *Communicate to the public to drive awareness and create urgency.* Setting politics aside, health care practice and policy changed in a heartbeat in response to COVID-19. Although raising awareness does not in and of itself create change, there is little impetus for change absent awareness. Partnering communication efforts with advocacy and provider organizations such as the Alzheimer's Association and the American Health Care Association, and with professional organizations such as the Society for Post-Acute and Long-Term Care Medicine, the American Geriatrics Society, the Gerontological Advanced Practice Nurses Association, and others, can promote

awareness through their own websites and national education campaigns. For example, the Alzheimer's Association's Facts and Figures Report and the American Geriatrics Society website HealthinAging.org share information widely with the public.[59,60] Also, researchers who intend to change practice and policy are advised to share their work with the lay press as a matter of course, lest its importance not come to common knowledge.

- *Communicate to academics to promote science.* The most important messaging to other academics in the context of pragmatic trials are the related successes and failures. If an efficacious practice was widely effective or ineffective, it promotes others' trials to understand what made the trial successful, less successful, or unsuccessful; the PRECIS-2 and RAPT provide useful terminology toward his end.[18,47,48] For example, the Pragmatic Trial of Video Education in Nursing Homes (PROVEN) evidenced low fidelity because the videos were not integrated into work flow, and Mouth Care Without a Battle was successful over 1 year but not over 2 years because sustainability was challenging.[27,42] In sharing information related to implementation, future success is more likely.[61]

Next Steps for Pragmatic Trials in Long-Term Care and Achieving Widespread Change

The 12 recommendations presented herein—in addition to the research, implementation, and dissemination challenges, opportunities, and solutions discussed in the other 2 conference proceeding articles[34,35]—are intended to not only promote the conduct of pragmatic trials in long-term care but also to achieve widespread change in practice and policy. Although pragmatic trials are not a panacea to improve care and outcomes, if the issues related to their successful conduct were fully addressed, there is cause to believe that recommendations related to *revamping* the academic mindset and enterprise, *responding* to what is known about content and process, *reframing* the partnership paradigm, and *reaching* key partners toward key goals when communicating, can go a long way toward that end.

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