Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

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Advancing clinical trials in nursing homes: A proposed roadmap to success

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ABSTRACT

An effective clinical research effort in nursing homes to address prevention and treatment of COVID-19 faced overwhelming challenges. Under the Health Care Systems Research Network-Older Americans Independence Centers AGING Initiative, a multidisciplinary Stakeholder Advisory Panel was convened to develop recommendations to improve the capability of the clinical research enterprise in US nursing homes. The Panel considered the nursing home as a setting for clinical trials, reviewed the current state of clinical trials in nursing homes, and ultimately developed recommendations for the establishment of a nursing home clinical trials research network that would be centrally supported and administered. This report summarizes the Panel's recommendations, which were developed in alignment with the following core principles: build on available research infrastructure where appropriate; leverage existing productive partnerships of researchers with groups of nursing homes and nursing home corporations; encompass both efficacy and effectiveness clinical trials; be responsive to a broad range of stakeholders including nursing home residents and their care partners; be relevant to an expansive range of clinical and health care delivery research questions; be able to pivot as necessary to changing research priorities and circumstances; create a pathway for industry-sponsored research as appropriate; invest in strategies to increase diversity in study populations and the research workforce; and foster the development of the next generation of nursing home researchers.

The following authors were members of the AGING Initiative Stakeholder Steering Committee: Rosie Bartel, Alice Bonner, Rebecca Boxer, David Gifford, Bruce Hanson, Susan L. Mitchell, Lona Mody, David Nace, Joseph Ouslander, JoAnne Reifsnyder, Barbara Resnick, and Sheryl Zimmerman.

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Despite the fact that residents of nursing homes were disproportionately and tragically impacted by the COVID-19 pandemic, the US clinical research enterprise largely excluded this population from randomized clinical trials (RCTs) related to the prevention and treatment of COVID-19. Of the 1.3 million residents of US nursing homes, only a few hundred participated in RCTs relating to COVID-19.[1] As with the entire US COVID-19 clinical research enterprise, the problem was not lack of resources.[2] An effective clinical research effort in nursing homes to address prevention and treatment of COVID-19 faced overwhelming challenges, beyond those directly related to the evolving pandemic.[3] These included an underresourced, unstable nursing home industry, complex regulations relating to federal and state oversight of nursing homes, the need for special protections of the vulnerable nursing home population in conducting research, and the absence of clinical research experience and infrastructure in long-term care settings, especially relevant to the conduct of clinical trials.[4]

Recognizing the need to improve the capability of the clinical research enterprise in nursing homes, the National Institute on Aging (NIA) funded the AGING Initiative, a joint endeavor of the Health Care Systems Research Network and the Older Americans Independence Centers, to develop a set of recommendations for creation of a nursing home clinical trials research network to improve efficiency in conducting clinical trials in nursing homes. Toward this end, a multidisciplinary Stakeholder Advisory Panel was convened, which met virtually on 7 occasions over a 9-month period beginning in October 2020. The Panel considered the nursing home as a setting for clinical trials, reviewed the current state of clinical trials in nursing homes, and ultimately developed recommendations and a roadmap for the establishment of a nursing home clinical trials research network.

Challenges to clinical research in the nursing home setting

Many of the practical and contextual considerations relating to clinical research in nursing homes have not changed over decades.[5,6] Nursing homes are settings of care for the most vulnerable of older adults, with a very high prevalence of cognitive impairment. An increasing proportion of nursing home residents require more medicalized, post-acute care. There may be numerous family members involved in decision making. Often, the number of direct care staff may be inadequate, insufficiently trained, and there are high rates of turnover. There can be infrequent and inconsistent involvement of primary care providers. In addition, there is a high degree of regulation and fear of sanctions, as well as an abundance of time-consuming, mandated documentation.[6]

The challenges of conducting research in the nursing home setting have been well described (Table 1).[6] The vulnerability of nursing home residents can create a sense of misgiving among administrators, nursing and medical directors, staff, health care providers, and residents and families about participation in research. Even during nonpandemic times, the presence of outside research staff can create logistical and administrative burdens. Furthermore, there are high levels of turnover of nursing home administrative leadership and staff, complicating the performance of clinical trials that are initiated and carried out over extended periods of time.

Beyond issues of informed consent and surrogate decision makers that may raise ethical concerns, resident assessments for research purposes must accommodate impairment in cognition and function that can make collection of reliable information from study participants challenging. There are also logistical challenges relating to testing requiring specialized equipment (eg, imaging), the handling of research samples and specimens, and management and use of therapeutics.

The inadequacy of nursing home records can hamper and limit research because of unreliable clinical information and documentation, as well as standardized information being collected in time windows not aligned with the specific research question being addressed in the study. For research relying on use of electronic health record (EHR) data across multiple facilities, challenges include different EHR systems and vendors, leading to interoperability and data harmonization difficulties.

In addition, there are complex methodologic issues, including sample size limitations, selective attrition, and missing data, that are more common in this setting than others.

There are also financial considerations and costs that need to be addressed relevant to conducting clinical research in nursing homes. In general, there is a lack of appreciation by researchers and funders as to the costs to facilities in participating in research. And today, more than ever before, there is an imperative to address persistent problems relating to inclusion and diversity in study populations.[7,8]

Table 1
Challenges in conducting research in the nursing home setting.

General apprehension among administration, staff, health care providers, residents, and families about research participation with disruption to usual care activities
Administrative and logistical burdens relating to presence of outside research staff
Informed consent among cognitively impaired residents can be challenging and require substantial time and effort to contact surrogate decision makers
Research assessments (such as the assessment of physical performance) take more time owing to the high prevalence of cognitive and functional impairment
Logistical challenges in performing some testing using specialized equipment (eg, imaging)
Logistical challenges in handling research samples and specimens
Logistical challenges in management and use of therapeutics (especially if non–FDA approved)
Inadequacy of nursing home medical records
Differing electronic health record systems across study nursing homes and challenges with data harmonization
Design and methodologic challenges: Sample size may be limited by difficulties with informed consent, failure to meet screening criteria, and attrition due to illness, death, or discharge. These issues result in:
• the need for multifacility studies to meet sample size requirements
• adjustments in the analyses for differences among facilities participating and selective attrition
Lack of appreciation by investigators and funders of potential costs to facilities of research involvement:
• notifying residents and families of the research and answering questions
• determining capacity to consent and witnessing consent
• preparing and transporting residents to research activities
• staff provision of clinical information (eg, usual functional and mental status)
• staff assistance in administering assessments or interventions
• staff assistance in assessing outcome measures
• preparing and transporting residents to research activities and assessments
• space for outside research staff and research activities

Adapted from Simmons et al.[6]

Recommendations for establishment of a nursing home clinical trials network

The Stakeholder Advisory Panel developed recommendations relating to the establishment of a nursing home clinical trials research network through meetings of the entire panel and domain-based workgroups, each involving 3-4 Stakeholder Advisory Panel members. The workgroups developed an initial set of recommendations across 5 domains: (1) coordination, (2) leadership, (3) stakeholders, (4) regulations, and (5) funding. Initial recommendations were compiled, organized, and distributed to all members of the Stakeholder Panel for individual review and comment, with the opportunity to add additional recommendations and/or to expand on existing ones. These additions were integrated and a final set of

recommendations was reviewed and approved by every member of the Panel.

Overarching recommendations relating to each of the 5 domains are followed by several specific recommendations.

Coordination

Create a centralized research infrastructure that will address essential core functions, including (1) overall coordination, (2) recruitment, (3) training, (4) data management and resources, (5) methods and measures, and (6) communication and dissemination.

Overall coordination

A Coordinating Center will organize and oversee the development of policies related to network membership and processes to facilitate network engagement, access, and collaboration. The Coordinating Center will develop standardized templates and guidance for network engagement, including data use agreements and data security policies. In addition, it will coordinate centralized IRB functions. The Center will establish procedures for tracking trials including notification of any problems encountered during the conduct of research studies, and outcomes of trials (eg publications, patents, drug approvals). The Coordinating Center will additionally oversee the following core activities and functions: recruitment and retention, training, data, methodology, and communications and dissemination. Each of these activities and functions will have designated Cores as described below.

Recruitment and retention

A Recruitment Core will facilitate identification and recruitment of nursing homes by creating profiles of nursing homes (eg, size, location, organization, and resident characteristics) and develop and provide resources to facilitate successful nursing home recruitment and retention. The Core will maintain an accurate registry of nursing homes participating in the Network that will be updated on an ongoing basis and will monitor individual nursing home and resident participation in trials to ensure that facilities and residents are not unduly burdened, and track the inclusion of underrepresented, low-income, and rural populations. The Core will also track leadership changes in participating nursing homes.

Training

A Training Core will coordinate and provide on-line training modules and in-person training services and resources suitable for a variety of audiences, including the provision of Collaborative Institutional Training Initiative (CITI) training, and research training certificate programs for nursing home staff and frontline clinicians as appropriate. Given the intended broad reach of the Network, the Core will work with national organizations (eg, the National Institute on Aging, and professional societies such as AMDA–The Society for Post-Acute and Long-Term Care Medicine, the American Geriatrics Society, and the Gerontological Society of America) to capitalize and expand on existing training resources and opportunities. The Training Core will place a special emphasis on the development and mentorship of the next generation of nursing home researchers. For this purpose, there will be a Research Career Development component with the explicit intent of promoting and enhancing the success of promising junior investigators. The Committee also highlighted knowledge gaps among industry sponsors and clinical research organizations relating to the conduct of clinical trials in nursing homes and felt that the Training Core could help bridge these gaps.

Data management and resources

A Data Core will foster the creation of a common data structure (eg, a widely accessible data acquisition platform) to facilitate the conduct of trials using high-quality data, including common data elements. The Data Core will also address best practices for cost-efficient data collection, data standardization and harmonization (eg, across different electronic health record software products), and optimal data security and sharing practices. In addition, the Core will provide linkages to relevant national databases, including Minimum Data Set (MDS) data.

Methods and measures

A Methods Core will provide support in the design of clinical trials and the analysis of study findings. In designing and conducting trials in nursing home settings, investigators generally employ and/or adapt designs used in other settings of care. However, this "cookie cutter" approach may not account for the unique aspects of this setting and the special characteristics of the nursing home population. The Methods Core will be available for consultation regarding selection of appropriate outcome measures and will create and maintain a research instruments library with relevance to the nursing home setting, with an emphasis on resident-centered outcomes. It will also link to other relevant libraries of outcome measures such as the NIA IMPACT Collaboratory Patient and Caregiver Relevant Outcome Library, which includes information on selected outcome measures for pragmatic trials enrolling people living with Alzheimer disease or related dementias (https://impactcollaboratory.org/pcro-library/) and the Geriatric Research Instrument Library (GRIL) hosted by the OAIC National Coordinating Center, a web-based repository of information and resources about measurement instruments available for use in studies of populations with multiple chronic conditions (https://www.peppercenter.org/public/gril.cfm). In addition to traditional efficacy trials, the Methods Core will promote the design and use of pragmatic clinical trials (effectiveness trials). Pragmatic clinical trials may offer a more efficient and sometimes more cost-effective approach to enrolling larger numbers of participants.[9]

Communication and dissemination

Dissemination of actionable research findings that can lead to improvements in the quality of care provided to nursing home residents will be a driving force behind the network. Working with professional societies and appropriate federal agencies (eg, CMS, CDC, and AHRQ), as well as aging service provider organizations (eg, AHCA and LeadingAge), a robust Communication and Dissemination Core will promote nursing home participation in the network, speed information sharing across the network, and synthesize and disseminate research findings to a wide range of stakeholders to inform nursing home practice and policy. Related efforts will include the publication of briefs on research findings and policy, as well as presentation materials to facilitate broad dissemination.

Leadership

Establish a Nursing Home Clinical Trials Research Network (NHCTRN) Oversight Board that will develop a governance structure for the Network. The Board will be voluntary and representative of all major stakeholder groups as specified below. The Oversight Board will prioritize representation of residents and families.

1. The NHCTRN Oversight Board will develop mission and vision statements for the Network.
2. The NHCTRN Oversight Board will develop a list of initial research priorities.
3. The NHCTRN Oversight Board will select an Executive Director or Chief Operating Officer who will oversee day-to-day network operations.

Stakeholders

Identify and engage a full range of stakeholders (eg, researchers, medical ethicists, residents and care partners, representatives from advocacy organizations, professional organizations, health care professionals, nursing home operators, industry groups, payers, and state and federal regulators) who together will encourage alignment of research priorities, and will guide and inform the essential core functions of the centralized research infrastructure detailed above (recruitment, training, data management and resources, methods and measures, and communication and dissemination). Every stakeholder's voice will be heard and respected equally.

1. Establish clear roles, expectations, and parameters for stakeholder involvement based on core values of bidirectional communication, transparency, mutual respect, and equal partnership.
2. Ensure the involvement of stakeholders and research partners, who have a vested interest in nursing homes and the care provided to residents to identify clinical trial priorities, provide insight into the context in which trials are conducted, inform the development of research protocols that take into consideration the challenges and opportunities of conducting research in these settings, disseminate research findings, and foster the translation of research findings into changes in practice and policy.
3. Align research priorities with priorities of residents and their family members and/or care partners.

Regulations

Federal and state agencies with nursing home oversight should update and coordinate regulations to promote clinical trial research in nursing homes, while balancing the need to protect the privacy and safety of residents. Such regulations should advance, rather than hinder, equitable access to participation in clinical trials.

1. Revise research and clinical trial regulations and policies to include nursing home specific clinical trial regulations. Beyond the importance and necessity of protecting resident safety and privacy as specified in the Nursing Home Resident's "Bill of Rights" (https://downloads.cms.gov/medicare/your_resident_rights_and_protections_section.pdf), regulations should be directed toward ensuring that nursing home residents are allowed access to participation in trials, recognizing that many individuals are admitted to nursing homes with cognitive impairment impairing decision-making capacity and without a named resident representative. Regulations and policies should be directed toward encouraging nursing home participation or designating nursing homes participating in research as "academic" nursing homes, thereby distinguishing them from facilities without this designation.
2. Implement policies to facilitate sharing of deidentified data for use in research. This may involve resident/family opt-outs on admission.
3. Encourage federal-level clinical trial research guidance to avoid inconsistency in state-level requirements and interpretation.
4. Expand clinicaltrials.gov study registration requirements to specifically include clinical trials of not only drug, device, or biological studies but any clinical trials seeking to yield meaningful scientific evidence to impact nursing home care and the health of nursing home residents.

Funding

Establish a sustainable, large-scale collaborative fund for the Nursing Home Clinical Trials Research Network (NHCTRN).

1. Encourage set aside funding by the US Congress, the National Institutes of Health (NIH), and other federal funders for the centralized infrastructure of the network and the conduct of clinical trials in nursing homes.
2. Promote financial partnerships and collaborations with private organizations and foundations, as well as funders like the Patient Centered Outcomes Research Institute (PCORI).
3. Provide direct financial and other incentives to participating nursing homes to facilitate engagement and commitment (eg, participation might be factored into Star Ratings).
4. Prioritize use of civil monetary penalty funds to support clinical trial research in nursing homes.
5. Provide special funding opportunities and preferences particularly directed to the next generation of researchers specially focused on the conduct of clinical trials in nursing homes, including grants for pilot studies that will form the basis for funding of a larger trial.

Discussion

The overall US clinical research enterprise has been described as "a distributed system ... in which investigators are able to pursue studies without much central coordination."[10] In general, this decentralized, uncoordinated process is useful in that it creates a competitive environment for ideas and innovation, but in the context of the pandemic, this uncoordinated approach to clinical research resulted in the most important clinical questions not being addressed in a scientifically rigorous manner or in a timely fashion. This experience has underscored the need for a coordinated national clinical trial infrastructure that can be called on in the context of a public health crisis and used in an ongoing way to more efficiently plan and implement clinical trials designed to improve nursing home care and resident outcomes.

The recommendations outlined in this article are designed to serve as a catalyst to the creation of a coordinated, highly functioning, nursing home clinical trials research network. These recommendations were developed to support a single overarching goal: to establish a nursing home clinical trials research network, involving a diverse group of nursing homes with diverse resident populations, to facilitate the conduct of randomized clinical trials in nursing homes. The envisaged network will be able to respond rapidly to emerging clinical needs of residents and develop, implement, and test new approaches to care (including diagnostics, therapeutics, and services) to optimize outcomes for this vulnerable population.

Several core principles underlie the establishment of this new network, including the following (Table 2): (1) be centrally supported and administered, with the ability to provide financial support to participating nursing homes; (2) integrate, but not duplicate, existing research services and resources, building on available infrastructure where appropriate; (3) leverage established, productive partnerships between researchers, research institutions, groups of nursing homes (affiliated through corporations or industry organizations), as well as governmental organizations like state departments of public health; (4) encompass both efficacy and effectiveness clinical trials; (5) be responsive to a broad range of stakeholders (including residents and care partners), acknowledging that the agenda for research in nursing homes has traditionally been driven by academics and/or industry, and not providers or consumers; (6) be relevant to an expansive range of clinical and health care delivery research questions; (7) be adaptable and nimble to be able to pivot as necessary to changing research priorities; (8) create a clearly defined pathway for the design and conduct of appropriate industry-sponsored clinical trials in the nursing home setting; (9) invest in strategies to increase diversity in study populations and the research workforce; and (10) foster the development of the next generation of researchers who have a full appreciation of the nursing home care context, and who are sensitive

Table 2
Ten core principles underlying the establishment of a nursing home clinical trials network.

1. Be centrally supported and administered, and provide financial support to participating nursing homes.
2. Build on available research infrastructure where appropriate. Integrate, and avoid duplicating existing resources.
3. Leverage existing productive partnerships of researchers and research groups with groups of nursing homes and nursing home corporations.
4. Encompass both efficacy and effectiveness clinical trials.
5. Be responsive to a broad range of stakeholders, including nursing home residents and care partners.
6. Be relevant to an expansive range of clinical and health care delivery research questions.
7. Be able to pivot as necessary to changing research priorities.
8. Create a pathway for appropriate industry-sponsored research.
9. Invest in strategies to increase diversity in study populations and the research workforce.
10. Foster the development of the next generation of nursing home researchers.

to the nursing home culture and the challenges of conducting clinical research in this environment.

Leveraging existing partnerships between researchers, institutions, and groups of nursing homes is an essential first step in establishing a nursing home clinical trials network. The number of investigators performing trials in nursing homes, and with established relationships is relatively modest; building an infrastructure around these individuals and capitalizing on their relationships with one another could serve as an efficient way to initiate the network. A complementary strategy includes building upon existing NIA-funded collaborative efforts such as the Research Centers Collaborative Network (https://www.rccn-aging.org/), the Health Care Systems Research Network-OAICs AGING Initiative (https://theaginginitiative.wordpress.com),[11] and the Imbedded Pragmatic AD/ADRD Clinical Trials (IMPACT) Collaboratory, which fosters pragmatic trials embedded in health systems with a specific focus on the care of older adults living with dementia. Other relevant collaborative research efforts funded by NIA include initiatives focused on deprescribing (https://deprescribingresearch.org/) and geroscience.[12]

The vast majority of members on the Stakeholder Advisory Panel strongly endorsed the need for a nursing home clinical trials network that will take a long-term view focusing especially on nursing home residents' needs and the outcomes of their care, and not driven by the threat of a future public health crisis or limited to a specific research focus. However, it is important to acknowledge that there was not complete unanimity among our multidisciplinary Stakeholder Advisory Panel regarding the conceptualization, feasibility, or even the need for a centrally funded and administered network with an expansive research agenda. Some advocated for having more than 1 network, each with a different focus based on research area (eg, dementia or geroscience[13]) or clinical trial type (eg, a network limited to the conduct of pragmatic clinical trials). Still others suggested that the network should be expanded to other types of settings, such as assisted living communities, senior living residences, and even home health agencies. Finally, the level of exclusivity of the network was left unresolved, with the following questions remaining unanswered. Should the network be limited to trials funded through NIH or foundation grants, or should funding also be sought from pharmaceutical and medical device manufacturers seeking to study their drugs, devices, and technologies in the nursing home setting? Should the network be limited solely to trials led by university-based investigators? And how can collegiality be fostered among investigators working in highly competitive, siloed academic environments to allow the network to come together?

Implications for practice, research, and policy

As long as the nursing home setting continues to be the place of care for large numbers of the most vulnerable among our population, a coordinated approach to clinical trials research is required to answer the most important clinical questions in a rigorous and efficient manner. This important goal will be facilitated through establishment of a nursing home clinical trials network, one that can endure far beyond our current public health crisis.

Declaration of Competing Interest

The authors declare no conflicts of interest.

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