Pragmatic Innovations in Post-Acute and Long-Term Care Medicine
Feasible new, practical products or approaches intended to improve outcomes or processes in post-acute or long-term care

The Long-Term Care Data Cooperative: The Next Generation of Data Integration

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A B S T R A C T

Despite important advances in the linkage of residents' Medicare claims and Minimum Data Set (MDS) information, the data infrastructure for long-term care remains inadequate for public health surveillance and clinical research. It is widely known that the evidence base supporting treatment decisions for older nursing home residents is scant as residents are systematically excluded from clinical trials. Electronic health records (EHRs) hold the promise to improve this population's representation in clinical research, especially with the more timely and detailed clinical information available in EHRs that are lacking in claims and MDS. The COVID-19 pandemic shined a spotlight on the data gap in nursing homes. To address this need, the National Institute on Aging funded the Long-Term Care (LTC) Data Cooperative, a collaboration among providers and stakeholders in academia, government, and the private sector. The LTC Data Cooperative assembles residents' EHRs from major specialty vendors and facilitates linkage of these data with Medicare claims to create a comprehensive, longitudinal patient record. These data serve 4 key purposes: (1) health care operations and population health analytics; (2) public health surveillance; (3) observational, comparative effectiveness research; and (4) clinical research studies, including provider and patient recruitment into Phase 3 and Phase 4 randomized trials. Federally funded researchers wanting to conduct pragmatic trials can now enroll their partnering sites in this Cooperative to more easily access the clinical data needed to close the evidence gaps in LTC. Linkage to Medicare data facilitates tracking patients' long-term outcomes after being discharged back to the community. As of August 2022, nearly 1000 nursing homes have joined, feedback reports to facilities are being piloted, algorithms for identifying infections are being tested, and proposals for use of the data have been reviewed and approved. This emerging EHR system is a substantial innovation in the richness and timeliness of the data infrastructure of the nursing home population.
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Keywords: Nursing homes, electronic health records, pragmatic trials, Medicare claims, public health surveillance, dementia

Problem and Significance

The development of the Resident Assessment Instrument, or Minimum Data Set (MDS), in 1990, one of the first nationally standardized digital health records, provided a detailed portrait of nursing home residents that informed state and federal policies, and ultimately became the basis for calculating case-mix reimbursement and quality performance indicators.[1] Since the mid-1990s, researchers

have merged Centers for Medicare & Medicaid Services' (CMS's) MDS with Medicare claims data, giving rise to increasingly sophisticated policy and clinical evaluations.[2] This resource has transformed geriatric pharmacoepidemiology, long-term care policy evaluations, and more recently facilitated large-scale cluster randomized trials of nursing home–based interventions.[3] However, neither the MDS nor Medicare claims contain detailed clinical information. Electronic medical records (EMRs) contain comprehensive clinical data collected at the point of care, and these data—collectively, "electronic health records" (EHRs)[4]—are increasingly needed to improve research on the effectiveness and safety of treatments in this frail population, which is rarely included in clinical trials. Unfortunately, there is no systematic EHR infrastructure for long-term care; the 2009 Health Information Technology for Economic and Clinical Health (HITECH) Act funded hospitals and physicians to adopt EMRs but excluded nursing homes.

The COVID-19 pandemic highlighted the need for an EHR system to quantify infection rates and outcomes rapidly—and to enable studies of vaccines and treatments among residents in long-term care given this population's disproportionate risk of adverse outcomes from infection. In this article, we introduce a novel EHR system developed to support health care operations, public health surveillance, and

Table 1
The Four Key Aims and Example Applications of the LTC Data Cooperative

Aims	Example Applications
Health care operations/ population health analytics	Disseminate nursing home–specific reports summarizing patient risk profiles, indicators of performance, and efficiency; Generate lists of patients with selected risk attributes
Public health surveillance	Report on incidence of select infections (eg, COVID-19, *Clostridium difficile*, methicillin-resistant *Staphylococcus aureus*, etc); Investigate source of infection (eg, transfer from hospital or acquired in the nursing home)
Observational, comparative effectiveness research	Conduct pharmacoepidemiologic studies of benefits and harms of US Food and Drug Administration–approved medical products not tested in this population; Implement comparative effectiveness of treatment programs ranging from group vs individual therapy to music therapy impact on behavior
Clinical research studies, including provider and patient recruitment into Phase 3 and Phase 4 randomized trials*	Conduct multisite, pragmatic cluster-randomized clinical trials (eg, quality improvement interventions, comparative effectiveness); Administer surveys among residents or family members; Collect physiological data from electronic sensors worn by residents; Conduct clinical trials requiring patient-level consent

*May also require facility consent to approach residents or their resident representative.

research in long-term care settings. The National Institute on Aging (NIA) funded the Long-Term Care (LTC) Data Cooperative as a collaboration among government, nursing home providers, academic investigators, commercial EHR vendors, and engineers and data scientists in the private sector. In a process that is compliant with the Health Insurance Portability and Accountability Act (HIPAA), residents' EHR data are taken directly from multiple EMR vendors and compiled within a secure cloud-computing environment. These data serve 4 key purposes: (1) supporting health care operations, such as helping providers monitor or predict residents' needs by generating alerts and lists of residents "at-risk"; (2) supporting public health surveillance, such as quantifying the incidence of infections; (3) enabling observational research on the comparative effectiveness of different treatments and care practices; and (4) serving as a launchpad for recruiting interested facilities and residents to participate in randomized clinical trials of innovative interventions. Once complete, the LTC Data Cooperative will be the largest assembly of EHR data on the nursing home population in the United States and will include geographically and structurally diverse nursing homes. A list of example applications of the LTC Data Cooperative appear in Table 1.

Innovation

The mission of the LTC Data Cooperative is to improve the quality of care within skilled nursing facilities by translating comprehensive EHR data into accessible and actionable insights for providers, public health officials, and researchers. The American Health Care Association (AHCA), the largest national long-term care membership organization, governs the LTC Data Cooperative. An Advisory Committee supports AHCA's governance and is composed of a rotating membership of 7 LTC providers, 3 LTC EMR vendors, 1 academic investigator, and 1 representative of the science and engineering firm that

maintains the data system (Exponent, Inc, Menlo Park, CA). The National Institute on Aging, under a Cooperative Agreement grant with Brown University, helps shape the utility of the LTC Data Cooperative for NIA-funded investigators.

Implementation

Nursing home companies voluntarily participate by authorizing their EMR vendor, in compliance with the 21st Century Cures Act, to transmit their data to the LTC Data Cooperative, which functions as a business associate with the nursing homes.[5] To date, 22 nursing home companies have enrolled all their facilities. Investigators with established nursing home research partners can encourage them to join, further facilitating recruitment, data extraction, and data analysis.

Each LTC Data Cooperative research proposal is reviewed to ensure that the objectives support improvement(s) in long-term care, merit scientific priority, have scientific validity, and are feasible given the available data elements. Additionally, applicants must obtain the requisite external permissions, including from institutional review boards / privacy boards, based on the type of study. The main focus is on research testing the impact of programs, treatments, and other interventions intended to improve the lives of nursing home residents. Public health surveillance, as designated under HIPAA, is similarly prioritized.

The LTC Data Cooperative uses industry best practices for the secure storing, transfer, and analysis of sensitive data. Data are never transferred out of the network to an investigator. Linkage with Medicare claims occurs by an NIA/CMS designated contractor (https://www.medric.info). The data are accessed by researchers via a secure cloud-based environment that is limited to the categories of data approved to conduct the research.

As a business associate of LTC facilities under HIPAA, the LTC Data Cooperative provides health care operations support. Provider-members receive reports that contain information on their resident population to improve care and management. These reports are a combination of resident-level alerts and summary statistics on rates of use of selected treatments or conditions. Using aggregated Medicare claims data on facility residents, reports are generated on hospital transfer rates, 30-day re-hospitalization rates, and mortality rates. A user group made up of volunteer providers will regularly review the content of these reports and will make recommendations for additions and changes.

The COVID-19 pandemic began affecting nursing homes across the country in March 2020, and the Centers for Disease Control and Prevention had limited access to information on the disease's incidence, clinical course, morbidity, or mortality. By the time a preliminary nursing home-based aggregated reporting system was developed in May 2020, the pandemic had spread to thousands of nursing homes, but the aggregated data were of limited value in addressing key clinical questions. Individual-level EHR data enable a richer set of analyses, such as those produced by the Brown University team working with nightly downloads of data from a single nursing home company.[6] Expanding on this work,[7,8] the LTC Data Cooperative will become a nationwide resident-level EHR system enabling detailed public health surveillance. The LTC Data Cooperative will serve as an early-warning system, monitoring new symptoms, treatments, or changes in nursing home residents' cognitive or physical function. We anticipate that as EHRs evolve to include laboratory tests, rapid and explicit identification of emerging pathogens will be possible.

Beyond health care operations and public health surveillance, the LTC Data Cooperative is a unique resource for research, well beyond what is feasible with linked MDS and Medicare claims. The presence of detailed information on patient status, clinical orders, and medication administration provides pharmacoepidemiologists

with information on precisely which drugs are administered to a patient and when. Many nursing facilities use EHRs to record residents' daily cognitive and physical function, as well as behavior, creating more robust measures of such outcomes. In addition, vital signs are present in most EHR systems, and tracking changes in body temperature, respiration rate, and pulse rate were instructive in identifying early indicators of infection with COVID-19.[9] Still more information remains in free-text fields, which over time, the LTC Data Cooperative will structure for use in all applications. These emerging sources of data open a new world of research for investigators in large and highly diverse populations of nursing home residents, all with the goal of informing clinical practice.

The promise of the LTC Data Cooperative for clinical trials deserves special mention. This system will facilitate "passive" data collection and substantially improve the efficiency of recruitment for clinical trials. Particularly well suited are embedded pragmatic clinical trials to evaluate the effectiveness of new treatments, tests, equipment, or care practices that can be done using cluster-random assignment so only a portion of participating facilities implement the novel intervention. For providers already engaged in clinical research, joining the Cooperative will greatly reduce data collection burden by avoiding most primary data collection, relying instead on the existing EHR data. EHR data can be readily used for multisite pragmatic trials or to supplement mandatory case-report forms required for regulated trials of drugs; the LTC Data Cooperative is precisely the solution that Gurwitz and colleagues recently proposed as a network of providers willing to participate in clinical trials.[10]

Evaluation

As of August 2022, nearly 1000 nursing homes have joined the LTC Data Cooperative. A physicially integrated common data model has been developed for data elements found in multiple EHRs, but unique data elements remain accessible. Five research applications have been approved to date: 2 pragmatic trials will assess interventions related to falls and infection management among residents with dementia, and 3 effectiveness studies will examine various outcomes among residents with COVID-19, heart failure, and diabetes mellitus. Data access for researchers is anticipated in late 2022, whereas access to data linked to Medicare claims is expected for 2023.

Comment

The LTC Data Cooperative is a centralized EHR system that represents the next generation of integrated data to improve long-term care. We expect that collaboration among key stakeholders, including providers, researchers, the private sector, and public health officials, will improve and transform care for nursing home residents. Importantly, this initiative is novel in its governance, led by providers first as a means of testing treatments, assessing practices, and disseminating results.

Acknowledgments

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