PRINCIPAL INVESTIGATOR (LAST, FIRST, MIDDLE): Kraschnewski, Jennifer L.

PCORI RESEARCH PLAN TEMPLATE: COVID-19 TARGETED PFA

RESEARCH STRATEGY

A. Research Question. Nursing homes have been ground zero for the COVID-19 pandemic. Over 1,300,000 US residents currently live in 15,600 nursing homes.[1] Since March 2020, nursing home residents with COVID-19 are the largest population coming to hospitals, requiring ventilators, and dying from the virus.[2] More than 182,000 nursing home residents and staff have died from COVID-19, with cases in every state.[3,4] Nationally, nursing homes have been devastated with 1,363,000 cases.[5] The COVID-19 pandemic shines a spotlight on the infection control principles for some of America's frailest, most vulnerable patients.[6-9] However, infectious disease outbreaks in nursing homes is not a new challenge. CDC estimates that the burden of influenza (flu) during the 2018–2019 season included an estimated 35.5 million people getting sick with influenza, 16.5 million people going to a health care provider for their illness, 490,600 hospitalizations, and 34,200 deaths. The majority (57%) of hospitalizations and 75% of influenza-associated deaths occurred in older adults aged ≥65, highlighting that this population is particularly vulnerable to severe outcomes resulting from an influenza virus infection, despite high rates of vaccination (greater than 70%). Unfortunately, vaccination alone is not enough to prevent flu outbreaks in the nursing home setting.

Since our original proposal, the COVID-19 vaccine became available to healthcare workers and nursing home residents beginning in December 2020. As of May 12, 71.9% of older adults (≥65 years) have been fully vaccinated; however, nursing home staff rates lag far behind that of healthcare workers, at less than 50%. There are many reasons for this disparity, pointing toward the need for a multi-pronged approach to infection control in nursing homes beyond vaccination alone. Unfortunately, infection control within the nursing home setting is a major challenge. Though facilities are required to have designated infection control staff, only 3% have taken a basic infection control course.[10-12] A cross-sectional survey of 2514 randomly selected US nursing homes was to assess CMS' final rule requiring nursing homes develop an infection control program, employing a trained infection preventionist (IP). Surveys were received from 990 nursing homes and one-third of the sample reported receiving an infection control deficiency citation. Other challenges to infection control include caregivers moving frequently between rooms and inconsistent hand washing.[11]

Evidence-based infection control strategies are not effectively implemented in nursing homes (RQ-1). The Centers for Disease Control and Prevention (CDC) outlines several strategies to assist nursing homes in addressing the pandemic.[12] Unfortunately, these evidence-based infection control measures have failed to translate into effective implementation.[13] Although guidelines may appear relatively straightforward, implementation requires organizational capacity, staff engagement and problem solving that can task organizations lacking appropriate training, resources and support. We conducted a needs assessment in April 2020 with nursing home administrators and staff (n=71) that indicated several challenges to implementing infection control strategies, including lack of infection control training, managing resident transfers, preventing transmissions, information overload, and staff wellbeing. Our study seeks to answer the critical research question of how evidence-based infection control guidelines can be implemented effectively in nursing homes (RQ-1).

Identifying effective implementation for evidence-based strategies is of critical importance to decision makers to address infection control in nursing homes and requires studying innovative approaches. Although significant research has focused on infection control in the acute care setting, little is known about the implementation of practices and effective interventions in long-term care facilities.[11,14] Currently, Centers for Medicare & Medicaid Services (CMS), CDC, and Occupational Safety and Health Administration (OSHA) provide nursing homes with written guidance for

infection control and prevention of COVID-19.[15-17] We propose evaluating an intervention utilizing Project ECHO, an evidence-based telehealth model, to connect Penn State University (PSU) experts with remote nursing home staff and administrators to proactively support evidence-based infection control guideline implementation. Founded at the University of New Mexico (UNM) by Dr. Arora (Co-I), Project ECHO utilizes case-based, collaborative learning to support discussion of learners' challenges and barriers to guideline implementation.[18] This differentiates ECHO from traditional learning and facilitates rapid dissemination of medical knowledge and increased capacity to deliver best-practice care. The model's explosive growth to 240 institutions nationally positions ECHO for outstanding responsiveness in a pandemic.[19] Led by Dr. Kraschnewski (PI), PSU has two years' experience with delivering ECHO interventions for 12 different diseases. Following our original research proposal, the University of New Mexico successfully proposed a national ECHO to address COVID-19 in nursing homes, supported by the federal Agency for Healthcare Research and Quality (AHRQ) and offered in collaboration with the Institute for Healthcare Improvement (IHI). We have made several serial modifications to our original proposal to accommodate this broader, evolving funded project. Specifically, we have adjusted our research plan to evaluate the AHRQ COVID-19 ECHO (ECHO) as compared to a modified AHRQ COVID-19 ECHO (ECHO plus).

- November 2020: Comparators were adjusted from the original proposal to include the National AHRQ ECHO intervention. We proposed comparing the 16-week AHRQ COVID-19 ECHO (ECHO) to the 16-week COVID-19 ECHO plus 9 additional sessions in infection control (ECHO plus).
- May 2021: Comparators were adjusted to account for a phase 2 of the AHRQ Nursing Home intervention, which included additional "Community of Learning" sessions: we are comparing the 16-week AHRQ-funded COVID-19 ECHO followed by 9 weekly optional office hour sessions (ECHO), to the AHRQ-funded COVID-19 ECHO plus 17 weekly 60 minute sessions (ECHO plus). In addition, we added an additional secondary outcome, flu-like illness.

Our research and stakeholder team are expertly positioned to produce actionable findings towards our long-term objective to effectively improve infection control implementation in nursing homes through the following aims:
Primary Aim: To compare the effectiveness of 16-week AHRQ phase 1 COVID-19 Project ECHO intervention (ECHO) followed by 9 weekly optional 60-minute office hour sessions (AHRQ phase 2) to the ECHO plus 17 additional 60 minute sessions (including an 8-week flu-focused refresher series for fall 2021) focused on infection control (ECHO plus) in reducing the number of nursing home residents with COVID-19. *We hypothesize that nursing homes engaged in the AHRQ ECHO plus intervention will have had 20% fewer COVID-19 infections than those in the AHRQ ECHO arm after 6 months.*

Secondary Aims:

1. To compare the effectiveness of ECHO versus ECHO plus on other patient-centered outcomes, including quality of life (QOL), flu-like symptoms, hospitalizations, and deaths. *We hypothesize that nursing home participation in the COVID-19 ECHO will significantly improve QOL and decrease hospitalizations and deaths.*

2. To evaluate the impact of the COVID-19 ECHO on key implementation outcomes in nursing home settings using the RE-AIM framework. *We hypothesize that nursing homes in both intervention conditions will report similar levels of adoption, implementation, and maintenance at the end of phase 1. We also hypothesize that, after completion of phase 2, nursing homes receiving the ECHO plus intervention will have higher levels of adoption, implementation, and maintenance of COVID-19 infection control guidelines than nursing homes in the ECHO arm.*

If effective, the COVID-19 ECHO, combined with the national ECHO infrastructure, will provide a real-world solution for stakeholders to address infection control guideline implementation in nursing homes.

B. Significance. Our research and stakeholder team are expertly positioned to produce actionable findings to inform stakeholders on how to address COVID-19 and other infectious outbreaks in nursing homes. At the start of the pandemic, we competitively obtained internal funding to develop and test the feasibility of a pilot COVID-19 ECHO intervention for health care providers, which provides a critical foundation to this proposal. We launched the intervention within a week of funding and had engaged 16 nursing homes in the pilot. Briefly, the intervention consisted of weekly sessions which included case-based discussions and didactics adapted from the CDC's evidence-based infection prevention training combined with technical assistance from our real-world experts in providing COVID-19 infection control.[20] This pilot study demonstrates our team's existing infrastructure and ability to rapidly recruit and engage nursing home staff in the COVID-19 ECHO and will guide the proposed study. ECHO participants included infection control staff and clinical leadership (e.g., medical director, director of nursing, administrators) who reported multiple training needs, including infection control, communicating with residents and families, and supporting their staff. These needs create an outstanding ECHO training opportunity for sharing of best practices across facilities. The ECHO model has significant strengths when compared to traditional training in that it allows for remote learning and utilizes case discussions that match the context and capacity of nursing homes. Learners have the ability to make real-time changes in practice, as participation equips them to make timely and informed health decisions and leverage expertise of specialists during this rapidly evolving pandemic. Given little is known about effective implementation of infection control guidelines in nursing homes,[11,14] we propose a randomized controlled study to evaluate the impact of this AHRQ-funded COVID-19 ECHO intervention.[19] Identifying effective approaches to successfully engage nursing homes has the potential to save countless lives.

Patient-Centeredness (RQ-6): There is perhaps no greater patient-centered outcome for nursing home residents or their loved ones than knowing how to keep them safe from contracting COVID-19 as proposed by our research question. "Those that are in most need, suffering the most, don't have a voice. I can be that voice." [Patient/Family Stakeholder]. QOL is another critical patient-centered outcome for nursing homes, particularly in this pandemic where residents are socially distanced from each other and their loved ones. Implementation of strategies that include resident input, such as we propose, has demonstrated higher satisfaction with overall QOL in nursing homes.[21] The ECHO plus curriculum will be expanded, with the input of stakeholders, to foster person-centered care. If successful, our study findings will be novel, given there are no current effective methods of guideline implementation in nursing homes to prevent COVID-19 infection and its consequences. Our team is well-equipped to rapidly conduct and evaluate the proposed AHRQ-funded COVID-19 ECHO. We have significant connections with UNM (Co-Is Drs. Arora and Clewett) and the national Impact Collaborative that our team leads (62 ECHO hubs that meet monthly to discuss ECHO impact) to ensure dissemination of our findings. Study of the nationally disseminated AHRQ-funded ECHO presents a valuable opportunity to investigate the impact of the ECHO model in the nursing home setting.

C. Study Design Overview: A stratified cluster randomized design will be used. Using a 1:1 ratio, we randomly assigned 136 nursing homes (with approximately 16,700 residents) to: 1) AHRQ-funded COVID-19 ECHO that includes 16 weekly telehealth sessions addressing COVID-19 guidelines and best practices plus 9 weekly optional 60-minute office hour sessions or 2) AHRQ-funded COVID-19 ECHO plus 17 sessions with a focus on stakeholder identified needs and CDC infection control training. Randomization was stratified by geographic location (rural vs. urban), current COVID-19 infection rate (some vs. none), and facility capacity (<60 beds vs. ≥60 beds). Patient-centered outcomes (nursing home residents with COVID-19 infections, flu-like illness, hospitalizations, deaths, and QOL) will be assessed at baseline (intervention start date), 4, 6, 12, and 18 months. Our study is guided by the RE-AIM framework to critically evaluate both effectiveness and implementation outcomes of the proposed intervention.[22] The RE-AIM framework is frequently utilized to improve sustainable adoption and implementation of effective, generalizable, evidence-based interventions

like Project ECHO. A formal study protocol will be developed upon funding (RQ-2). This protocol will further outline a data management plan that addresses data collection, organization, handling, description, preservation and sharing (IR-7).

Study Population and Setting (RQ-3; PC-2): We recruited 136 nursing homes from national nursing home lists, focusing primarily in Pennsylvania (PA), but including other sites within the northeast and Midwest from states that are demographically and geographically similar, including Connecticut, New Jersey, New York, Wisconsin, New Hampshire, Illinois, Vermont, Indiana, Virginia, Maryland, and Ohio. (CI-2). Given the differences in nursing home types and how they impact effective programming, our project focused on skilled nursing facilities eligible for the AHRQ-funded ECHO program. Nursing homes were recruited through collaborations with our stakeholders, including multiple state agencies (Department of Health-DOH, Department of Human Services-DHS, Department of Aging-DA) and state nursing home organizations (PA Healthcare Association, Leading Age PA) through phone calls and emails. COVID-19 ECHO participants include two nursing home staff members as required by the AHRQ program, and we encouraged participation by infection control staff and other facility leadership (e.g., medical director, nursing, administrators). Participants in our pilot study (n=16) and those who may have participated in any COVID-19 focused Project ECHO series will be excluded. These 112 nursing homes have already been offered the opportunity to participate in either Penn State's pilot AHRQ-funded ECHO cohort or by our colleagues at Wellspan Health. We were confident in the willingness of nursing home staff to participate in weekly, 90-minute ECHO sessions (the last 30 minutes are optional) over the proposed study period, as we have already piloted this weekly program early in the pandemic, resulting in 80% of participants (27 of 34) attending every week over the 6-week timeframe. Further, we have partnered with multiple state and local nursing home stakeholders who have shared with us in our conversations the critical nature of this intervention and the eagerness for nursing homes to be engaged to access this information. Although many stakeholders mentioned this, the feedback was particularly strong from Chris Fisher, Director of Quality Initiatives for the Pennsylvania Healthcare Association, whose organization engages 200 nursing homes and 400 members and has a national umbrella organization through which to reach nursing homes in additional states. We are confident that through our conversations with our 16 stakeholders who provided letters of support for our proposal, including nursing home staff and administrators, three state agencies, three state professional organizations, and healthcare systems, we have a finger on the pulse of participant willingness to engage. Willingness to engage in ECHO is also strengthened by our overwhelmingly positive response to our pilot series. Half of these participants reported never participating in an ECHO series previously yet rated the experience highly as more powerful than traditional learning. These responses highlight the belief in the intervention and will strengthen willingness to participate regularly.

Comparators (RQ-5): Our proposed study intervention is to evaluate the 16-week AHRQ-funded COVID-19 ECHO (Phase 1) followed by 9 weekly optional office hour sessions (Phase 2), an evidence-based model designed for guideline implementation, to nursing home staff with a focus on addressing COVID-19 and quality improvement, as compared to the AHRQ-funded COVID-19 ECHO plus, consisting of the 16-week AHRQ-funded Phase 1 plus 17 weekly 60 minute sessions (Phase 2) with a focus on general stakeholder identified needs and CDC-recommended infection control training.

Table 1. Summary of Comparators

Phase 1	**ECHO**	**ECHO Plus**
16-week infection control ECHO	x	x
Quality Improvement component	x	x

Number of experts	3	3
Phase 2		
9-week office hours	optional	Not optional
9-week ECHO		x
Number of experts	1	2
8-week refresher series (Fall 2021)		x

Our preliminary data positions us for success: **(1) We have extensive success with Project ECHO.** Our PSU research team has engaged in both the implementation and evaluation of this platform for 12 different diseases over the past two years. Our team also partnered with the PA DOH (see letter) to deliver an ECHO intervention to the eight PA health systems, with 94 clinics, located across the state. We have provided over 1,075 continuing medical education credits delivered to 280 participants. **(2) Our team has firsthand experience overseeing nursing home operations in the COVID-19 pandemic**. Our team includes experts who have assisted the PA DOH with COVID-19 efforts in nursing homes in addition to the targeted Project ECHO pilot for their consumption, providing significant preliminary data. Specifically, our COVID-19 ECHO pilot has resulted in 96% of participants reporting increased knowledge, 88% reporting improved ability to care for patients, 83% making changes in their practice and importantly, during a time of high provider burnout and concern for mental health, 81% reporting decreased professional isolation. **(3) We are ready to launch the COVID-19 ECHO intervention.** We have run 4 ECHO series specific to COVID-19 in three different languages and have registered 700 participants since March 2020. We launched the first pilot on March 20, targeting physicians in hospital and clinical settings. We offered several sessions each week on a range of COVID-19 topics, including setting up drive-up testing, managing an inpatient plan, starting a COVID-19 clinic, and mental health considerations for providers. Overall, we had 40 topics presented. Of note, these did not engage nursing home participants, but rather physicians, nurses, community members and administrators from various health care systems and clinical settings. The sessions and goals were very different. These were designed to widely broadcast much-needed information and did not follow the ECHO model's goal of 15-20 participants to allow for networking and case presentation. We launched a second, smaller pilot specifically for nursing homes when we realized that their needs were very different. We recruited 16 nursing homes in just three days for the pilot study and have partnered with multiple state-level stakeholders who can facilitate study recruitment. These sessions met weekly, covering topics of interest to these participants. This second pilot provided us with experience to prepare us for the proposed PCORI. Further, Penn State Project ECHO has multiple different disease topics that are being addressed, resulting in efficiencies that have been passed along to the current proposal. Specifically, we have a template for REDCap surveys that will be utilized for development and distribution, as well as for providing continuing education credit. Further, we have developed PowerPoint templates for brief lectures, fillable pdf case forms, facilitation scripts, agendas, and standard operating procedures for start-up and clinic coordination. Additionally, we have developed template recruitment materials that can be tailored to specific audiences. This includes information on the structure of an ECHO and what to expect with participation. Although these will require adaptation to the current proposal, we will not need to begin these efforts from scratch. We also have regularly scheduled, twice monthly, ECHO team meetings during which the current proposed project will be discussed by all ECHO team members in addition to those funded on the current proposal. Combined, these experiences expertly position our team to facilitate the generation of actionable findings.

The study arms each include two phases (Phase 1 and Phase 2) of the AHRQ intervention ECHO sessions and will have the following components:

1) AHRQ-funded COVID-19 ECHO. Nursing homes in this arm will ideally receive the intervention via real-time, interactive videoconferencing using Zoom at no cost to participants; however, session recordings are available for those who are unable to participate live. Phase 1 sessions will be 90 minutes in duration (the last 30 minutes are optional) and held weekly for 4 months (16 sessions total) at regularly scheduled times. Sessions will follow the AHRQ-funded program format:

- Introductions (5 minutes) – Introductions provide an inviting atmosphere. Participants will include nursing home staff to the intervention who are frontline in caring for patients and overseeing infection control policies and operations. Specifically, we are interested in enrolling each facility's infection preventionist, who has primary professional training in nursing, medical technology, microbiology, or other related field and is employed at least part-time per CMS requirement. However, our stakeholders have assured us that the level of daily involvement and knowledge of the nursing facility administrators is very different from those of acute care. Unlike hospitals, long-term care administrators are licensed and fully accountable for outcomes, therefore are very involved in operations. It is likely that nursing homes will encourage the administrator, director of nursing, infection control officer, and other department heads to be involved in training and education generally, so would be likely to take part in the proposed study. We will engage the required two participants per nursing home to meet AHRQ requirements.

Based on other successful models of knowledge dissemination in these settings, we will encourage facilities to designate 1-2 certified nursing assistants and unit managers to lead the efforts for the facility. Daily huddles can be used in these settings for transmission of knowledge. The ECHO sessions can be a train-the-trainer approach and ideas for continual process improvement through brief huddles, frequent mandatory in-service, and even built into new employee orientation to enhance communication and observation/feedback techniques.

- Didactic presentations (Two presentations x 10-15 minutes each) – Experts will deliver two short PowerPoint presentations on the week's topic (Table 2). Participants will have electronic access to all presentations and materials, including recordings of sessions.

Table 2. AHRQ-funded ECHO Topics

Preventing and Limiting the Spread of COVID-19 in Nursing Homes
Infection Prevention and Management: Guidance and Practical Approaches for Use of Personal Protective Equipment (PPE) during COVID-19
Infection Prevention and Management: Approaches to Cohorting during COVID-19
Infection Prevention and Management: Promoting Solutions for Making the Built Environment Safer During COVID-19
Infection Prevention and Management: Guidance for Cleaning & Disinfecting During COVID-19
COVID-19 Testing for Nursing Homes
COVID-19 Community Transmission and Nursing Home Screening Strategies
Staff Returning to Work Safely during COVID-19
Interprofessional Team Management of Mild cases of COVID-19
Advance Care Planning in the time of COVID-19
Promoting Safe Care Transitions during COVID-19 –Admissions, Discharges and Transfers
Promoting Safe Visitation and Nursing Home Re-opening during COVID-19
The Role of certified nursing assistants (CNAs) in managing and Supporting Residents and Families during COVID-19

Managing Social Isolation during COVID 19: Perspectives on Staff and Residents
Supporting the Emotional Well-being of Staff Caring for Residents during COVID-19
Effective Leadership and Communication during COVID

- Case presentations (30 minutes) – Each session includes case-based discussions (1-2 cases/session) to ensure mastery of the content and skills. Each participant will present at least one case during the program. Other participants are encouraged to ask clarifying questions and weigh in on recommendations, then the ECHO experts provide advice on addressing each case using best practices (recommendations are summarized verbally and by email). To protect patient confidentiality, cases are presented without protected health information using a standard REDCap case form.
- Question and Answer period (up to 30 minutes, optional) – Nursing homes will be invited to stay however are not required per AHRQ to attend this period.
- Close and debrief (5 minutes) – All sessions conclude with a reminder to complete the session evaluation, and the hub team encourages providers to put into practice what they have learned, which is later assessed.

At the end of 16 weeks, this group will be offered an opportunity to participate in phase 2 of the AHRQ-funded intervention. For the ECHO group, this will consist of weekly optional 60-minute office hours in which participants may ask specific questions and receive guidance from our experts on a variety of topics. We will also ensure that all AHRQ resources, including PowerPoint slides and recorded lectures, are made available to them in a shared online folder.

2) AHRQ-Funded COVID-19 ECHO Plus. Nursing homes in this arm will receive the Phase 1 intervention as described above. Phase 2 of the intervention will include several modifications as described below. We have carefully identified modifications, in collaboration with our COVID-19 experts and stakeholders that may enhance nursing home engagement and potentially strengthen the proposed intervention. Specifically, phase 2 sessions will consist of nine weeks of live 60-minute ECHO sessions, following the format described for phase 1 and covering the COVID-19 topics listed in Table 3, as identified by our stakeholders and experts. If nursing home staff are unable to attend the session live, they will be offered an opportunity to view the recording of that session. Attendance is expected as these sessions are not optional. In addition, phase 2 will include an additional 8-session refresher series in the Fall of 2021, providing an opportunity to cover additional topics identified by stakeholders and within the CDC infection control training. Rationale for refresher series: Unfortunately, nursing home staff across organizations have undergone tremendous turnover throughout the pandemic. Further, the AHRQ project requirements have provided limited opportunity for effective comparators. Lastly, there is grave concern flu season will be a challenge this year. To address these concerns, we propose offering an additional infection prevention control refresher series with a focus of flu. This will also allow us to demonstrate potential impact of Project ECHO on another infectious disease of significant importance to nursing homes. Topics for the flu refresher series will include: addressing vaccine hesitancy in staff and residents; reinforcing hand washing best practices; addressing outbreaks; COVID updates; other topics as deemed important for consideration by stakeholders.

Table 3. Stakeholder and Expert Identified ECHO Plus Additional Topics.

COVID Variants and Vaccine Hesitancy
Crisis Management and Communication

Resident Quality of Life/Social Isolation
Grief and Loss (for staff, residents, and resident families)
Role of the Medical Director
Other staff roles (activities, facilities management, dining/food services)
COVID updates (info on boosters, new data, new guidance)
Sustainability of best practices
What's next? Ongoing QI

Outcomes: Guided by the RE-AIM framework, we will simultaneously evaluate the study effectiveness and implementation outcomes (Table 4. We will evaluate different aspects of implementation practices in nursing homes. These outcomes will be assessed at baseline (intervention start date), 4, 6, 12, and 18 months. We have added the 4-month timepoint to reflect the evaluation of phase 1 of the AHRQ-funded program, which includes 4 months (16 weeks) of sessions. These data will be collected using publicly available datasets maintained by federal and state health agencies (Effectiveness; see below) and validated tools adapted to this project and interviews with nursing home stakeholders. Effectiveness: The *primary outcome* is COVID-19 infection rate reduction in nursing homes. This de-identified patient data will be obtained using The Nursing Home COVID-19 Public File[5] along with three *secondary outcomes*: flu-like illness, COVID-19 hospitalizations, and deaths. Secondary outcomes will be collected through the National COVID-19 Nursing Home data file that is publicly available (https://data.cms.gov/stories/s/COVID-19-Nursing-Home-Data/bkwz-xpvg). Specifically, the variables that will be assessed include: Residents Weekly and Total Admissions, Residents Weekly and Total COVID-19 Deaths, Number of Residents with New Influenza, and Number of Residents with Acute Respiratory Illness Symptoms Excluding COVID-19 and/or Influenza. This data is also available for staff. Nursing home resident QOL (*secondary outcome; PC-3*) will be measured using CMS' Minimum Data Set,[23] including emotional, symptom and functional statuses, behavioral disturbances, social support, patient engagement, and shared decision making. CMS data will be linked to residents at participating nursing homes (IR-3). We will collect several measures to assess how much COVID-19 ECHO is utilized in nursing homes (see attached Excel spreadsheet). Our Aim 2 proposed using the RE-AIM framework to critically evaluate the utilization of interventions in both trial arms. To accomplish this, for example, we will record and categorize participation in each session (e.g., number of staff per nursing home site, role of participants in nursing homes, engagement in sessions). At the beginning of each ECHO session, we ask that all participants place their name, email address, and affiliation in the chat box. In addition, we can pull zoom reports to identify participants and the length of time they joined each session (to ensure full participation). We will also offer continuing education credits, which is a second opportunity to record engagement and assess quality dimensions that explain participation (e.g., satisfaction, acceptability). Surveys at the end of the cohort will also provide feedback as to the utilization of best practices taught throughout ECHO sessions. Lastly, as described in the interviews, we will have questions specifically identifying how engagement in ECHO changed practice. Equally important, all data collection is guided by the RE-AIM framework in order to provide a complete picture of how ECHO facilitates practice change and supports adoption of best practices. Implementation outcomes: We will measure Reach by assessing the characteristics of nursing homes and staff who participate in the study and those who do not. We will then compare these data to the overall characteristics of PA nursing homes to assess representativeness. We will evaluate Adoption by assessing the characteristics of early adopters

as well as barriers and facilitators (i.e., inner and outer contexts,[24] Organizational Readiness for Implementing Change scale [ORIC],[25] Practice Adaptive Reserve scale [PAR],[26] Change Process Capacity Questionnaire [CPCQ]).[27]

Table 4. Proposed Study Outcomes

Study Outcomes	Description	Data Source (Timing of Assessment)
Reach	Absolute number, proportion, and representativeness of nursing homes and staff who *agree to participate*	Study recruitment logs and staff survey (baseline)
Effectiveness	*Primary outcome:* COVID-19 infection rate reduction; *Secondary outcomes:* flu-like illness, hospitalizations, deaths, QOL	National COVID-19 Nursing Home data file and CMS Minimum Data Set (baseline, 4, 6, 12, 18 months)
Adoption	Absolute number, proportion, and representativeness of nursing homes and staff who *initiate* and *complete* the ECHO series; and barriers and facilitators for adoption	Study participation logs; staff survey (baseline, 6 months) with validated measures including ORIC, PAR, and CPCQ; and key informant interviews (6 months post intervention)
Implementation	Nursing home staff knowledge and attitudes towards the various intervention functions and components, their level of implementation, and barriers and facilitators for implementation	Selected items from CDC's Preparedness Checklist; staff surveys (baseline, 6, 12 months) wkith validated measures; and key informant interview (6 months)
Maintenance	Extent to which implemented guidelines for emergency preparedness in an infectious disease outbreak become part of nursing home policies post-intervention	Key informant interview (12 months)

Implementation will be assessed in nursing homes (enactment fidelity) using CDC's COVID-19 Preparedness Checklist[16] for nursing homes as well as barriers and facilitators (i.e., Implementation Climate questionnaire, Key Driver Implementation scale).[28] For Maintenance, we will assess policies nursing homes utilize to incorporate best-practice guidelines on addressing COVID-19, quality improvement, and infection control into routine practice. All staff survey data will be collected through REDCap, HIPAA compliant survey software. Our implementation evaluation will finalize with key informant interviews with a subsample of nursing home administrators/staff (n=40) following an explanatory-sequential design. With this design, our team will use interview discussions to further explain the effectiveness results of the RCT (infection rates, hospitalizations, and deaths) in the own words of the implementers, as well as strategies being implemented to support maintenance. These interviews will also help the study team understand additional contextual factors that were not present in the original submission (e.g., vaccine rollout in nursing home facilities). Main guiding questions (probing questions will be added as needed) are organized under 3 major themes corresponding to our RE-AIM evaluation plan and are listed below:

Theme 1) Factors associated with differential study outcomes

Q1. How did the infrastructure of your organization (size, networks, or physical layout) affect the study outcomes?

Q2. Did you have sufficient resources to implement and administer the strategies presented in ECHO sessions?

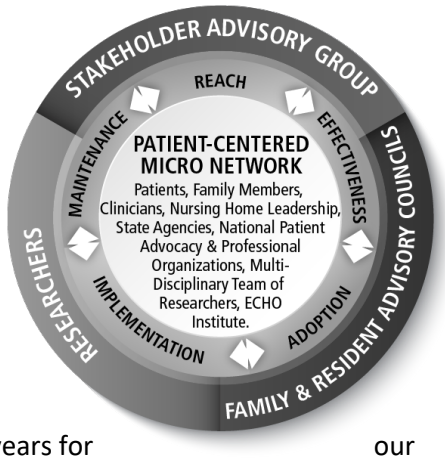
Q3. Do you consider that the participation of your nursing home facility in the study was a success or a burden? Why?
Theme 2) General implementation processes
Q4. How does the intervention compare to other alternatives that may have been considered or that you know about?
Q5. What is your perception of the quality of the ECHO sessions and supporting materials? Did they meet your expectations?
Q6. Tell me a new strategy that your facility implemented in the past 6 month as a result of participating in this study.
Theme 3) Experiences with Covid-19 vaccine rollout
Q7. Describe your facility's experience with the Covid-19 vaccine rollout. What are you doing to ensure that new residents get vaccinated?
Q8. What is your facility doing to increase vaccine confidence and uptake among staff?

Sample Size, Power, and Analytic Plan (IR-1): The proposed study is a cluster randomization trial (stratified; RC-5). The intervention will be given at the cluster level (nursing homes). Study objectives and primary outcomes will be considered at both the cluster and individual levels (RC-1). There are several reasons why a cluster randomization was preferred over a traditional randomized controlled trial. First, the cluster randomization was preferred because the target of the intervention is a collective (i.e., a nursing home) rather than a particular patient. Second, cluster randomization was preferred due to potential contamination. Third, cluster randomization is compelling for practical reasons, when patient-specific level protocols would be nearly impossible like in the nursing home care (RC-2). The potential confounders will be balanced out by the randomization design. We will compare the observed confounders between two study arms and adjust them in the analysis if they are not balanced by design. Further, we will measure potential confounders before the start of exposure and report data on potential confounders with study results (CI-1; CI-4). We will monitor data collection for the RE-AIM metrics (surveys and interviews), routinely checking and following up with study sites to recover missing data (MD-1). We will use multilevel models such as mixed effects models or marginal models based on generalized estimating equation (GEE) method to estimate the intervention effect". Both methods are valid if the outcome data are missing completely at random. For data missing at random (i.e., depends on observed data only), mixed models can still provide valid inference and the weighted GEE methods will be considered to account for this type of missing data. We will also conduct sensitivity analyses to examine the robustness of results to missing data. Multiple imputation methods will be used to address the missing data in the covariates (MD-2, MD-4). Further, we plan to record and report all reasons for dropout and missing data and account for patients. Specifically, we will record reasons for missing data and perform analysis based on intention-to-treat principle as described below (MD-3). We have 126 nursing homes (62 in ECHO and 64 in ECHO plus) continuing to the phase 2 of the study. According to the CMS weekly data as of April 2021, the average weekly COVID-19 infection rate was 0.1%, average number of residents in nursing homes (cluster size) was around 75-80 and the coefficient of variation of cluster size was at about 0.76. Assuming 1% infection rate in the ECHO arm over the 9 weeks when additional topic sessions are provided in the ECHO plus arm, our study will have 80% power to detect a significant intervention effect if the infection rate is reduced to below 0.3% in ECHO plus arm. This calculation was based on a two-sided statistical test of difference between Poisson rates at alpha=0.05 and intracluster correlation coefficient (ICC) ≤0.01. Our power will be below 80% if ICC is 0.05 or higher even if the infection rate is nearly zero in the ECHO plus arm. We will test the effectiveness of ECHO plus group by performing both individual-level analyses (primary) and cluster-level analyses (secondary) following the intention-to-treat principle. To account for intracluster correlations within nursing homes, we will use multilevel models such as mixed effects models or marginal models based on generalized estimating equation (GEE) method to estimate the intervention effect. The outcomes after 6-months of intervention will be analyzed using generalized linear models, with an appropriate link function depending on outcome type. Intervention effect on infection risk will be estimated as odds ratio or incidence

rate ratio based on logistic, Poisson or negative binomial regressions. State and cohort variations will be examined and accounted for using fixed or random effects in the models. Characteristics of residents (e.g., age, gender, cognitive function/dementia) and nursing homes (e.g., size, quality, baseline infection rate) will be adjusted. We hypothesize that the ECHO plus effect is heterogeneous and expect stronger intervention effects in subgroups without cognitive dysfunction/dementia as well as those who are younger (HT-1). Subgroup analysis with regard to key participant factors will be performed similarly to examine potential heterogeneity of intervention effects, further tested by interaction analysis (HT-2). If data are sufficient, we plan to explore the heterogeneity of intervention effect on infection rate based on the key participant factors such as age group, gender, dementia, insurance status, and race/ethnicity (HT-3). Outcomes will be assessed after the intervention is initiated (CI-3). Using all measures at 4, 6, 12 and 18 months, we will perform longitudinal analysis to evaluate if the intervention effect changes over time using the same modeling approach but add additional variables for time and time by intervention interaction. Correlations of repeated measures for the same resident will be taken into account in model estimation. Subgroup analysis with regard to key participant factors will be performed similarly to examine potential heterogeneity of intervention effects, further tested by interaction analysis. For cluster-level analyses, the aggregated outcomes (infection, hospitalization) are rates or proportions between 0 and 1 instead of being binary or count variables, we will use Beta regression to model them with a logit link function so that the coefficient can be interpreted as log odds ratio. We will also perform longitudinal analysis for aggregated outcomes based on Beta regression. All statistical tests will be two-sided, with p-values<0.05 considered statistically significant.

D. Engagement Approach (PC-1): Our investigative team has extensive experience with engaged research and has ensured incorporation of stakeholder engagement on multiple levels in the proposed study's planning and design (see appendix).[30-36] Our pilot COVID-19 ECHO has received overwhelmingly positive feedback: "Penn State Project ECHO is one of the best eLearning communities I've participated in. It's an excellent way to learn from each other, discuss challenges and best practices." We assembled a robust stakeholder Advisory Board (AB; see letters, biosketches), with both new and established(*) team partners, including: nursing home patients and their families (Edwards, Evans), nursing home staff/administration (Guardian Eldercare, Pleasant Acres, Presbyterian Senior Living, Spruce Manor Rehabilitation, Windy Hill Village), state and federal policy makers (PA's DOH*, DHS*, DA), payers (Highmark*, Horst Group, Optum Health*) and state professional organizations (PA Healthcare Association*, Leading Age PA, PA Association of Community Health Centers*). These synergistic partnerships across all facets of nursing home care will ensure our research continually focuses on what matters to stakeholders. To further enhance engagement, we will partner with existing nursing home resident and family advisory councils to bring additional voices to the research ensuring patient-centeredness. We have engaged each of our 16 stakeholders in this proposal's development and their input has shaped the study design. Our AB has convened twice in virtual meetings in the two months of this award. We have used virtual stakeholder meetings for the past four years for our current PCORI award and have developed effective, engaging best practices.[31] The goals for this meeting include: review study aims and objectives, collaboratively discuss stakeholder roles and establish engagement guidelines (PCORI engagement principles),[37,38] seek intervention feedback on curriculum design, and outline dissemination mechanisms for early results. Subsequent AB meetings will occur every other month, allowing for continuous feedback through an iterative process. Targeted agendas distributed before meetings with specific requests for stakeholder input will bolster

Fig 1. Patient-Centered Micro Network



discussions. To facilitate rapid feedback between meetings, we will use electronic surveys through REDCap. Stakeholders will also be offered Just-In-Time trainings to maximize engagement by providing a foundational research knowledge-base.[39] A critical strength of the proposed research is to serve as a state-level demonstration project, ultimately leveraging our AB's national connections for widespread dissemination.

E. Research Team and Environment: This multidisciplinary research team brings together experienced faculty at PSU as well as collaborators and stakeholders from partnering institutions (UNM) and organizations. Specifically, our research team has expertise in patient-centered engaged research (Kraschnewski, Calo, Leslie), nursing home infection control education and COVID-19 outbreaks (MacGregor-Skinner, Osevala, Ahmad), infectious disease and infection control expertise (Paules), public health research (Kraschnewski, Calo, Leslie), nursing home operations (King), effectiveness trial design and analysis (Calo, Kong), geriatric QOL (Osevala, Ahmad, Whitaker), mental health (Joshi) and ECHO evaluation and dissemination (Kraschnewski, Calo, Arora, Clewett). **Dr. Kraschnewski** is expertly positioned to lead the team as a clinician-investigator with a focus on patient-centered research (PCORI contracts: NEN-1509-32304, PCS-1406-18325, CDRN-1306-04912, AD-2017C3-8752, CDR-1310-07055) and director of PSU Project ECHO and the national ECHO Impact Collaborative. A major strength is our established PSU ECHO staff (Francis, Hogentogler, Sabol, Bowers, Poger) with >80 years of combined experience who will facilitate the day-to-day operations. PSU is an excellent environment, given our land-grant connections across the Commonwealth, stakeholder engagement with multiple state agencies and organizations, and commitment to serving our community. In response to PIR #1101, Dr. Paules has been added as a co-investigator at 10% effort. Dr. Paules is Assistant Professor of Medicine and an infectious disease physician-scientist with expertise in both treating and researching COVID-19 during the pandemic. She will assist with the Project ECHO intervention providing additional infection control expertise to complement that of Mr. MacGregor-Skinner. She will be an active research team member, participating in regular investigator meetings and assisting with study design refinement, ensuring the highest impact topics are covered early in the curriculum. She will also assist with data collection instruments, data analysis and interpretation, and results presentation through abstracts and manuscripts throughout the proposed study period.

DISSEMINATION AND IMPLEMENTATION POTENTIAL (PC-4)

We believe this work has great potential for dissemination and implementation for the following reasons: **First, we are partnering with the leading institution (UNM) of the ECHO movement to widely disseminate our project findings across the 240 U.S. institutions offering ECHO.** We strongly believe that a nursing home-focused ECHO on infection control can be disseminated by the explosive network of ECHO programs. Further, study results can drive policy change given the significant need our intervention addresses and we have assembled stakeholders, including state departments and organizations, with this expertise. **Second, Project ECHO interventions have strong potential for future federal funding and intervention sustainability.** Each year, Project ECHO hosts a policy day, bringing faculty and staff from across the country to Washington, DC to share their ECHO experiences. These policy connections happen regularly outside of these designated policy days through well-established connections that have led to two different federal ECHO legislations. In 2016, the US Senate passed the Expanding Capacity for Health Outcomes (ECHO) Act, legislation aimed to increase access to healthcare in rural areas by authorizing the US Department of Health and Human Services (HHS) to study the Project ECHO model.[42] In 2018, Congress passed the SUPPORT for Patients and Communities Act, which aims to help expand tools available to Medicare and Medicaid in combating the nation's opioid crisis allowing HHS to give preference to groups using the ECHO model.[43] Taken together, these federal laws create a path towards future funding opportunities for Project ECHO models, laying the groundwork for infrastructure sustainability. University of New Mexico maintains these relationships and has agreed to assist us in broad policy dissemination of study findings. This creates an opportunity for potential policy decisions, which is perhaps the greatest form of dissemination.

Third, this study is disseminable because it was designed using RE-AIM principles. We are experienced working with these principles.[35,42-44] To assess the dissemination potential, during the study we will measure previously validated aspects of the RE-AIM framework.[46] Understanding the Reach, Effectiveness, Adoption, Implementation and Maintenance will assist in our understanding of how amenable the intervention is for wide-scale dissemination. Equally important, by using the RE-AIM framework we will collect and disseminate data that are easy to understand and apply in real-world community and clinical settings where research and evaluation resources are limited. Thus, the RE-AIM framework will greatly strengthen our dissemination capability by providing simplified, pragmatic, user-centered, and theory-driven information to increase the adoption of the COVID-19 ECHO project in additional nursing home settings across the US. **Fourth, two of our stakeholder organizations represent state-level organizations with national umbrellas – Leading Age PA (nonprofit facilities) and Pennsylvania Healthcare Association (PHCA**). Both of these organizations have agreed to assist with connections to their national organizations to share the findings of our study across their membership. These organizations are professional homes to facilities across the United States, channeling these communications to the decision makers for next steps. Specifically, Chris Fisher from PHCA serves as the team leader for the American Health Care Association (national organization) and as a senior level quality award examiner, supporting these opportunities for national dissemination. Implementing newly disseminated successful programs remains a challenge. To overcome this barrier, we have designed a randomized controlled trial to provide the highest level of evidence to help convince policy makers and other stakeholders to support the program. Overall, our proposed COVID-19 ECHO intervention uses resources efficiently (i.e., virtual training, minimum time commitment) and addresses critical patient-centered outcomes, including COVID-19 infection, hospitalizations, deaths and QOL. We have further designed the intervention to broadly cover training in infection control that can provide benefit to prevent all seasonal outbreaks which face nursing homes every year. Further, it is difficult to raise awareness about effective programs. In order to overcome this barrier, we will utilize our national connections through UNM to share results with all ECHO sites across the country.

RETURN OF AGGREGATE STUDY RESULTS

Disseminating study results is important and we believe in the timely and appropriate translation of results to the participants who assisted in making it happen. Our team has experience disseminating lay public results, include lay briefs of manuscripts and other resources to study partners using multiple outlets to maximize reach (see Appendix).[30,31,33] By leveraging broad-reaching stakeholder connections, we will deliver regular communications electronically via media alerts, newsletters, social media, and website updates providing results to professional and community-based listservs. Stakeholders will actively contribute to dissemination efforts by presenting at conferences, co-authoring manuscripts, developing lay abstracts and dissemination briefs of study papers, and disseminating study resources at community events. We propose creating and disseminating educational, patient-facing multimedia distributed through our partnerships. We plan to employ all of these best practices in the proposed study, providing opportunities for our stakeholders to play an active role in the dissemination of results to participants and beyond.

PRINCIPAL INVESTIGATOR (LAST, FIRST, MIDDLE): Kraschnewski, Jennifer L.

PROJECT PLAN AND TIMELINE

Upon funding approval, the research team will begin meeting weekly to rapidly prepare the study protocol for stakeholder feedback at the kickoff Advisory Board (AB) meeting. During this meeting, we anticipate receiving feedback and guidance on recruitment strategy, curriculum development, curriculum content, and data collection. Our ECHO infrastructure is set up for rapid launch, with registration, session evaluations, and pre/post-test surveys programmed into REDCap and ready for customization within days for new project launches. We have received promise for an expedited Institutional Review Board (IRB) approval given our institution's prioritization for COVID-19 studies, and the minimum risk proposed. Following IRB approval, recruitment of 200 nursing homes will be completed in collaboration with our state stakeholders. During the next 6 months, we will run weekly ECHO sessions with nursing homes randomized to the intervention. We will continue to meet every other month with stakeholders to guide important study decisions at each research phase. Primary outcomes including COVID-19 infection rate reduction, hospitalizations, and deaths will be collected at 4, 6, 12, and 18 months. Early 6-month outcomes will be discussed with our stakeholders to guide dissemination to both policy and public audiences. At the end of year 1 we will hold an annual in person AB meeting (if allowed) to discuss study updates, challenges, dissemination, and ideas for secondary outcome assessments utilizing the CMS Minimum Data Set. During year 2, the project team will analyze data and implement suggested stakeholder activities for results dissemination and prepare the manuscript of final results.

STEPS AND MILESTONES	**Year 1 (Q)**				**Year 2 (Q)**			
Every other month meetings with Stakeholder Advisory Board	X	X	X	X	X	X	X	X
Annual in-person meeting of Investigative Team/Advisory Board				X				X
Subcontract execution	X							
Finalization of study protocol with key stakeholders	X							
IRB Submission and Approval	X							
Study Registration at ClinicalTrials.gov	X							
Begin recruitment of nursing homes	X							
Completion of recruitment of 136 nursing homes		X						
COVID-19 ECHO implementation and delivery		X	X	X	X	X		
Primary outcome assessment: COVID-19 infection rate reduction (4, 6, 12, and 18 months)			X	X	X	X	X	
Secondary outcomes assessment: Flu-like illness, COVID-19 hospitalizations, deaths (4, 6, 12, and 18 months)			X	X	X	X	X	
Secondary outcome assessment: QOL (CMS Minimum Data Set, delayed 15 months)							X	
Secondary RE-AIM outcomes assessment: (baseline, 6, 12 months)	X	X	X	X	X	X	X	
Manuscript accepted for publication: Baseline paper				X				
Early post-intervention results (based on 6 month outcomes)				X				
Early results dissemination (scientific and lay public, including to nursing home residents and families; deliverable)				X				
Secondary outcomes analyses and reporting (deliverable)						X	X	
Final report (deliverable)								X
Toolkit for national ECHO dissemination, including marketing and recruitment materials, curriculum design, and evaluation (deliverable)			X	X	X	X	X	X

PRINCIPAL INVESTIGATOR (LAST, FIRST, MIDDLE): Kraschnewski, Jennifer L.

Manuscript preparation of final results (deliverable)							X	X

PRINCIPAL INVESTIGATOR (LAST, FIRST, MIDDLE): Kraschnewski, Jennifer L.

PROTECTION OF HUMAN SUBJECTS

Education in the protection of human research subjects through the Collaborative Institutional Training Initiative (CITI Program) at the University of Miami, as required by PSU, has been met by all relevant Key Personnel. Similar human subjects research training has been completed by all co-investigators at collaborating institutions. The proposed project will be submitted to and approved by the PSU Institutional Review Board. COVID-19 applications are currently being prioritized for review, which will ensure timely approval and start date as proposed in the timeline.

I. Risks to Human Subjects

a. *Involvement of Human Subjects:* The proposed study includes human subjects in its research but poses no more than minimal risk. We will recruit a total of 200 nursing homes to participate in the proposed randomized controlled trial. We anticipate enrolling at least one representative from each nursing home, which may include administration, director of nursing, or infection control staff to participate in ECHO sessions if the nursing home is randomized to the intervention group. We anticipate including de-identified data to assess our primary outcome (COVID-19 infection rate reduction) from the publicly available PA COVID-19 Nursing Home Reporting System. *Sources of Materials:* This study's primary outcome will rely on de-identified data from a publicly available source
(The Nursing Home COVID-19 Public File), in aggregate, describing de-identified nursing home resident cases of COVID-19, hospitalizations and death. Additionally, we will obtain identifiable nursing home resident data through PSU's secure access to Medicare data through the Administrative Data Accelerator. Data analysis by investigators will occur through secure remote computing. Given our reliance on only secondary data for nursing home residents' outcomes, they will not be required to consent to participation. However, we will create and share messaging to make them aware of the study for dissemination at the nursing home level. The data will be used for research purposes only.

b. *Potential Risks:* The minimal risks to human subjects in the proposed project include loss of confidentiality.

II. Adequacy of Protection Against Risks

a. *Recruitment and Informed Consent:* This project involves randomizing nursing home facilities to weekly ECHO educational sessions. Nursing homes will be recruited by recommendations from our stakeholder connections. Given enrollment and proposed nursing home surveys do not require release of protected health information (PHI), an implied summary explanation of research document will be administered to all enrolled nursing home facilities explaining study procedures and randomization. Attendance at ECHO sessions implies consent to participate, as ECHO itself has been deemed exempt by the Penn State IRB. Information routinely collected for CME credit hours will be obtained from nursing home staff who participate in the weekly ECHO sessions.

b. Protection Against Risks: The minimal risks to human subjects in the proposed project include loss of confidentiality. Because we propose to use only existing data, our project poses no health risk. However, as in any data analysis, there are risks posed to confidentiality. These risks are minimal, since we will not use data on diseases (e.g. HIV) or health behaviors (e.g. sexual practices) that are associated with high social stigma. To minimize the likelihood of a breach in confidentiality, we will follow standard PSU procedures with regards to data management. Aggregate health data will be obtained through secure remote access and data analysis will occur through secure, password-protected remote computing. There is no need for a Data and Safety Monitoring Plan for the proposed study given that patient-level data analyzed will only include existing data.

III. Potential Benefits of the Proposed Research to Human Subjects and Others. If the ECHO plus intervention is effective, COVID-19 infection rate may be improved. This may result in decreased hospitalizations and deaths as well as improved QOL. Other benefits will be to add to the evidence of the ECHO model for infection control in nursing homes. These benefits appear to outweigh any minimal risk.

IV. Importance of the Knowledge to be Gained. The study results will provide an understanding of the impact of COVID-19 ECHO intervention on nursing home infection rate and patient-centered outcomes and may inform policy decisions to support future ECHO programs targeting nursing home infection control programs.

PRINCIPAL INVESTIGATOR (LAST, FIRST, MIDDLE): Kraschnewski, Jennifer L.

CONSORTIUM CONTRACTUAL ARRANGEMENTS

The Pennsylvania State University College of Medicine will enter into a consortium agreement with the University of New Mexico (UNM) in order to undertake the proposed study. Penn State will oversee all fiscal arrangements. The grant will be administered at Penn State with a sub-award to the University of New Mexico.

The University of New Mexico (UNM) is pleased to collaborate with the Penn State University (PSU) on their proposal to the Patient-Centered Outcomes Research Institute entitled, "COVID-19 Project ECHO for Nursing Homes: A Patient-centered, Randomized-controlled Trial to Implement Infection Control and Quality of Life Best Practices." Through the preparation of this proposal, and over the past two years, we have assisted your team in developing an evaluative infrastructure for Project ECHO. We founded Project ECHO and currently oversee the network, which includes 249 institutions in 32 countries addressing more than 100 health conditions and public health topics. We also engage policymakers to further disseminate Project ECHO. In 2016, the US Senate passed the Expanding Capacity for Health Outcomes (ECHO) Act, legislation aimed to increase access to healthcare in rural areas by authorizing the US Department of Health and Human Services (HHS) to study the Project ECHO model. This bill required the Secretary of HHS to study the model and examine the impact on addressing mental and substance use disorders and chronic diseases, the impact on provider capacity and workforce issues and the delivery or healthcare services in rural areas and medically underserved areas.

We have been delighted to work very closely with your PSU ECHO team, having been partners since your launch in 2018. We also join forces with your team in the evaluation of the movement, including your leadership of the national ECHO movement's Impact Collaborative to help us build the evidence base for the model. This proposal plans to test the ECHO model at a critical time, the COVID-19 pandemic, in our most vulnerable of populations. This innovative use of the ECHO model to provide infection control as well as to improve resident quality of life is important for our nursing homes, both during the pandemic and beyond. Our New Mexico ECHO team is excited to collaborate on this proposal and further evaluation of the ECHO model. We will attend research team meetings and bimonthly stakeholder meetings in order to share the national ECHO perspective. Specifically, we can assist with connecting your research team with institutions across the country and beyond and commit to disseminating your study findings through our extensive network. In this way, your effective program has the opportunity for national impact.

We propose the following work as part of a sub-award to University of New Mexico to ensure successful submission of your contract deliverables in accordance with the milestone schedule. The sub-award will include the following tasks:

1. Study design, planning and conduct
    a. Dr. Clewett (Co-I) will assist with protocol development and attend regular team meetings
    b. Dr. Arora (Co-I) will provide expert consultation
2. Content expertise: To provide content expertise on the Project ECHO network and policy
3. Assist with dissemination of study results and the COVID-19 ECHO toolkit for nursing homes
    a. To provide connections across the national ECHO network through e-communications
    b. To facilitate dissemination through ECHO's connections with federal policymakers

Proposed Personnel

Sanjeev Arora, MD, is Founder and Director of Project ECHO and will serve as a co-investigator for the proposed study. In this role, he will provide content expertise in the Project ECHO model and network as well as translating ECHO into policy. Dr. Arora's national connections through the ECHO network will facilitate dissemination of study results as well as the COVID-19 ECHO toolkit proposed.

Elizabeth Clewett, PhD, Dr. Clewett is Chief of Staff at the University of New Mexico Project ECHO Institute and will serve as a co-investigator on the proposed project. In this role, Dr. Clewett will assist with the development of the study protocol, design, and conduct. She will attend regular research team meetings, providing insight into the ECHO network and expertise on dissemination for both the early study results and the proposed ECHO toolkit.

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