

Implementing a Clinical Research Program in Long Term Care Facilities: Experiences from the University of Louisville Center of Excellence for Research in Infectious Diseases (CERID)

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Abstract

Background: According to the US Census Bureau International Report, in 2015, almost nine percent of the world's population was aged 65 and over. As the worldwide population ages, there is a need to understand how to best care for those individuals. Developing clinical research programs focusing on long term care (LTC) will be critical to defining best practice.

Objectives: The objectives of this manuscript are to: 1) outline the challenges identified in performing clinical research in long term care facilities (LTCF), and 2) offer solutions for future clinical research in the LTC environment based upon our experiences.

Methods: A research feasibility study was performed in 14 LTCFs in Louisville, Kentucky during 2018. Research questions involving identification of LTCF residents experiencing diarrhea were used as the basis for determining challenges and abilities to perform research in the LTC environment.

Results: Challenges to performing clinical research involving an infectious disease were gathered throughout the twenty-week feasibility assessment period and organized into eight distinct yet inter-related areas. These included: 1) facility recruitment; 2) engagement of facility leadership; 3) engagement of facility personnel; 4) identification of research candidates; 5) consenting processes; 6) management of clinical samples; 7) navigating the medical record systems; and 8) study team workflow.

Conclusions: This feasibility assessment found that conducting research in LTCFs was very different in almost every aspect from research conducted in the hospital setting. Results from this feasibility assessment will be used as a basis to determine a more comprehensive population-based incidence of *C. difficile* infection through the City of Louisville Diarrhea (CLOUD) study.

DOI: 10.18297/rgh/vol2/iss2/14

Submitted Date: August 30, 2019

Accepted Date: August 30, 2019

Website: <https://ir.library.louisville.edu/rgh>

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Recommended Citation:

Carrico, Ruth; Balcom, Dawn; Ghosh, Kuldeep; Abaid, Bilal; Salunkhe, Vidyulata; Karki, Bibodh Jung; Kiran, Simra; Furmanek, Stephen; Pena, Senen; and Ramirez, Julio A. (2019) "Implementing a Clinical Research Program in Long Term Care Facilities: Experiences from the University of Louisville Center of Excellence for Research in Infectious Diseases [CERID]." *Journal of Refugee & Global Health*: Vol. 3 : Iss. 2 , Article 14.

Background

The Centers for Medicare and Medicaid Services (CMS) reported in 2016 that more than 3 million individuals in the United States (US) received care in more than 15,600 long term care facilities (LTCF) [1]. According to the US Census Bureau International Report, in 2015, almost nine percent of the world's population was aged 65 and over. This older population of 617 million is projected to increase by an average of 27 million a year reaching 1.6 billion in 2050. By that time, the older population is expected to represent 16.7 percent of the world's total population [2]. Countries without social protective systems will especially need the benefit of clinical research findings to help control healthcare costs and drive efficiencies and evidence-based practice identification and implementation. Therefore, as the worldwide population ages and those receiving care in US LTCFs continues to increase,

there is a need to understand how to best care for those individuals. Developing clinical research programs focusing on long term care will be critical to defining best practice.

For more than thirty years, researchers in the Division of Infectious Diseases at the University of Louisville have been involved in clinical research, primarily in the Louisville area's nine acute care hospitals. The research program has steadily grown and matured and in 2018, elements of the program were aligned into a comprehensive clinical research enterprise. This enterprise provides the framework and support necessary for a robust program focused on population-based clinical research capable of studying health conditions present in patients receiving care in hospitals, long term care facilities, and outpatient settings. This new Center of Excellence for Research in Infectious Diseases (CERID) supports placement

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of research teams in healthcare facilities across the city of Louisville providing abilities to research and describe infection and infection-related, as well as non-infection related, outcomes on a population incidence level.

In 2018, a new CERID clinical research study was proposed for Louisville's LTCFs. This study proposal focused on developing a greater understanding of the incidence of diarrhea, with particular emphasis on *C. difficile*, and its impact on residents receiving care in Louisville area long-term healthcare settings. This represented the first clinical research study by the CERID team in long term care. Although the CERID research infrastructure has significant experience in performing clinical research in the hospital setting, this study would require that the same level of expertise be developed in the long term care setting. A feasibility assessment was crafted in order to determine if a study involving LTCFs across the city of Louisville could be performed, and the operational and financial considerations of such a study. A similar feasibility assessment had been completed in the nine acute care hospitals in the city of Louisville in mid-2018, so performing a similar assessment in long term care was the next phase in understanding the full spectrum of research activity that would be needed for a larger community-wide study.

The objectives of this manuscript are to: 1) outline the challenges identified in performing clinical research in LTCFs, and 2) offer solutions for future clinical research in the long term care environment based upon our experiences.

Methods

A feasibility assessment was conceptualized, developed and implemented in late 2018 with the goal of including fourteen LTCFs as a representative sample in Louisville. The sample of LTCFs included 7/14 (50%) for-profit, 7/14 (50%) non-profit. The feasibility timeline involved research teams spending two weeks in each LTCF.

Steps in the feasibility assessment included: 1) identification of the LTCFs currently in operation in the city of Louisville using information from Health Care Facilities and Regulations-Cabinet for Health and Family Services; 2) develop the feasibility assessment protocol and submit to the University of Louisville Institutional Review Board (IRB) for review and approval; 3) contact administrative teams at each LTCF to discuss the feasibility assessment; 4) identify a sample of fourteen (14) LTCFs willing to participate in the assessment; 5) pilot test steps in the research process including identification of a resident experiencing diarrhea, obtaining a partial waiver to enable pre-screening, obtaining informed consent, specimen collection, specimen storage, specimen transport for testing, collection of resident clinical data, identification of database and informatics capabilities, communication with providers and facility personnel, and communication with family members/legally authorized representatives; and 6) determine personnel and material resources that would be necessary for a larger comprehensive 52 week clinical research study.

Regular meetings of the research staff and the investigators were held to document and clarify challenges and barriers then develop strategies to mitigate or eliminate them. The feasibility assessment was reviewed and approved by the University of Louisville Institutional Review Board (UL IRB# 18.0656), and

further reviewed and approved by participating LTCFs.

Results

Contact was made with the administration of forty-five LTCF through letters, email and telephone calls. Fourteen facilities agreed to participate in the feasibility assessment. Packets were prepared to include a copy of the IRB-approved Study Protocol, IRB-approved Informed Consent, Research Authorization and Permission to Conduct Study forms, and a partial waiver. This information was reviewed with key personnel designated by each of the fourteen participating LTCFs. Developing relationships with these key personnel was an essential step that enabled the research teams to personalize the feasibility assessment processes in their respective facility/facilities. A small team of researchers were assigned to each LTCF so they could become aware of their unique aspects and work directly with designated personnel. The feasibility assessment was completed in that sample of fourteen LTCFs within the desired 20-week timeline.

Challenges to performing clinical research involving an infectious disease were gathered throughout the twenty-week feasibility assessment period and organized into eight distinct yet inter-related areas (**Table 1**). These challenges, and a variety of solutions, are described below.

Table 1 Areas where Research Challenges were Identified

1.	Facility recruitment
2.	Engagement of facility leadership
3.	Engagement of facility personnel
4.	Identification of research candidates
5.	Consenting processes
6.	Management of clinical samples
7.	Navigating the medical record systems
8.	Study team workflow

Facility recruitment

An initial step in the research process involved identification of personnel willing to participate in a clinical research process. As research in long term care is relatively new, most of the facilities approached for the feasibility assessment lacked an existing framework of reference regarding how research is performed and the necessary relationships that must exist between the researchers and the facility personnel. Telephone calls were made to the forty-five LTCFs identified as providing skilled care according to information available from the Health Care Facilities and Regulations-Cabinet for Health and Family Services. Follow-up letters were sent and additional calls were made to identify the contact person appropriate for discussion of the project at each facility. Key contact personnel included the Administrator, Director of Nursing, and the individual responsible for the Infection Prevention and Control program. Personal contact was made with 35/45 (78%) facilities. The first fourteen facilities interested in participation in the feasibility assessment were included, and discussions with additional facilities continued as a means of understanding barriers and challenges to facility engagement. Meetings were held with administrative personnel and often, representatives from legal and risk management departments. Facilities part of for-profit corporate chains required additional negotiations and vetting of the consent form and protocol. Both the for-profit and not-for-profit facilities were attentive to research activities

they felt could interrupt routine operations. Therefore, facility recruitment involved significant time and negotiations to minimize perceived risk to the participating facilities while also addressing foreseeable interruptions or disruptions to routine care practices and operations. Despite lengthy meetings, document development, and document sharing, for-profit facilities were more difficult to engage and more likely to decline involvement despite written agreements and assurances. Reasons for declining participation in the feasibility assessment included: 1) lack of familiarity with the research process; 2) concerns regarding liabilities and resident consenting; 3) lack of familiarity regarding the burden of infectious conditions relevant to the LTC population and the potential benefits of research participation; 4) the need for discussion and clearance with corporate legal and risk management offices; and 5) concerns regarding how residents and families might feel about research participation.

Engagement of Facility Leadership

Long term care facilities have a designated chief medical officer, often a geriatrician practicing locally. These physicians are key in establishing relationships and were found to be champions with the research process. At a collective meeting of the Kentucky Medical Directors Association, local medical directors were provided with an overview of the proposed feasibility assessment study and the background rationale. During the discussion, members of the research team were provided with insight into specific issues of importance to individual facilities including experiences or perceptions about research participation. The medical directors were key links to the facility administrative personnel and other healthcare providers and were included in initial discussions and at their discretion thereafter. For facilities reticent about participation, the medical director acted as a trusted liaison and was key to the negotiations, even if ultimately unsuccessful. Other healthcare providers were open to discussion regarding enrollment of their residents following introduction by the facility medical director and assurances that the research protocol and methods had been appropriately reviewed and vetted. The medical director was also important in identifying key personnel in the individual facilities to begin discussion regarding the operational side of the research project and the baseline education needed for clarity of purpose and process. None of the facility medical directors were opposed to the feasibility assessment or the idea of research in their respective LTCF and each of them facilitated contact with key personnel for initiation of the research discussion. Facility Directors of Nursing were open to the concepts and importance of research and often served as trusted liaisons between administrative teams, the medical director, other providers, and staff. Their primary interest involved the needs of the residents and the needs of the staff. Therefore, their inclusion in the research processes and engagement were also vital. Challenges included: 1) time spent in connecting with the medical director; 2) preparation of individual facility documents addressing concerns regarding research, dispelling research myths, and providing question and answer responses; 3) identification and connection with key healthcare providers at each individual facility; 4) addressing individual provider concerns regarding potential impact on their resident(s) and establishing trusted relationships; and 5) maintaining contact throughout the feasibility assessment study period as a means of strengthening those early relationships and listening to and quickly responding to provider questions and concerns.

Engagement of Facility Personnel

The overwhelming majority of personnel included in the feasibility assessment were open to the concept of engaging in clinical research. Education regarding *C. difficile* and CDI were of particular interest to Directors of Nursing and other facility personnel. Discussions about transmission and identification of *C. difficile* helped provide the necessary context for feasibility assessment study explanation. Employee turnover required ongoing education as new caregivers were introduced to the research team at almost every encounter. The strong interest from facility leadership resulted in identification of ideal methods to engage residents, their family members, and legally authorized representatives (LAR) in the research consent steps. During the initial project discussions, we quickly learned that education regarding HAI in general was strongly desired by the facility leadership and front-line personnel and provided opportune ways to “give back” something of high value to the facilities willing to partner in clinical research activities. Of particular importance was the ability to educate personnel regarding case definitions relevant to the feasibility assessment. For example, the term ‘diarrhea’ was almost universally used to describe any episode of loose stool. Often, documentation noting ‘diarrhea’ would be done once a shift making it difficult to identify whether that episode met the case definition of three loose stools within a 24 hour period or whether it was documentation of a single loose stool event. This point is critical in addressing CDI as part of the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN) reporting [3], as well as reporting the event as part of any HAI-reduction collaborative. Ensuring the entire healthcare team was uniform in recognizing, reporting, and documenting stool events and stool consistency was foundational to the research feasibility assessment. Clarifying the case definition of diarrhea also provided benefit to the facility in terms of their participation with other CDI reporting methods. As an example, use of the Bristol Stool Scale [4] has become increasingly accepted as a means of identifying and documenting stool consistency. Introducing the Bristol Stool Scale is a significant step forward in assisting healthcare personnel consistently characterize stool episodes and provided a valued educational opportunity. In terms of resident safety and benefit, understanding the basic pathophysiology involved in diarrhea also helped facilitate recognition of a true diarrhea event by the healthcare staff. This helped assist them in implementing their facility infection prevention and control procedures, including when to test for CDI and when testing may not be indicated. Challenges to education and engagement included: 1) time to meet with individuals across shifts and work days including weekends; 2) dispelling inaccurate information regarding *C. difficile* transmission and testing; 3) clarifying information relevant to the feasibility assessment such as diarrhea case definitions; and 4) staff turnover rates necessitating ongoing education and relationship building.

Identification of Research Candidates

Recognizing which residents were experiencing diarrhea (3 or more loose stools in a 24-hour period) was critical in identifying residents meeting inclusion criteria for the feasibility assessment. In facilities with high rates of staff turnover, ongoing education and capture of all residents meeting inclusion criteria as part of the pre-screening process remained an ongoing challenge. Researchers would check in with unit nursing personnel and the designated infection preventionist each day to see if any resident met inclusion criteria (pre-screening) based upon their stool history during the prior 24 hours. Facilities with

personnel familiar with the feasibility assessment and with CDI were often prepared to address these questions well before arrival of the research team each day. Other facilities required additional time by the research team to re-educate and explain the feasibility assessment study purpose and protocol to those new staff members. This resulted in wide variation in time spent at each facility with that variation being unknown from day to day. This impacted the planning with respect to multiple facility visits and prescreening of residents for potential inclusion in the assessment and consenting process.

Some facilities had electronic medical record systems (EMRs) that made identification of residents with true diarrhea episodes possible without having to check in with the nursing staff. However, unless the nursing staff were aware of the diarrhea definitions and documentation necessities for the feasibility assessment, the benefit of that electronic record was minimized. Challenges included: 1) staff turnover and its impact in the interruption of a communication process between staff and research team members; 2) variations in documentation and the challenge in pre-screening residents to determine eligibility; 3) variations in documentation and medical record systems impacting the ability to find resident information in the medical records in the event nursing personnel were unavailable or unfamiliar with the research process; and 4) wide variation in time spent with nursing personnel in order to identify residents for pre-screening and that impact on workflow and research time management.

The Consenting Process

Engaging and enrolling the resident as a participant in the feasibility assessment was likely the greatest challenge. Once residents were identified as potential subjects, they were screened to ensure they met criteria (e.g., age 50 years or greater and 3 or more loose stools in a 24 hour period). Once screened and eligibility verified, the resident was approached for enrollment. Experiences during this feasibility assessment found that 70-100% of LTCF residents eligible to participate were unable to participate independently in the informed consent process. This meant that engagement in the research process often began with family members and the legally authorized representative (LAR) with assistance from the facility personnel. Processes for inviting a resident to enroll required frequent discussion with the UL IRB as well as the individual facilities to ensure a valid and ethical consenting process. The consenting process required review with facility legal counsel and risk manager at each LTCF. From a resident protection and abuse prevention perspective, staff from the LTCFs were uniformly concerned about the wellbeing of the resident. Most wished to have an active role in the consenting process where their personnel were included in, or sometime initiated, initial connection with families and LARs. Their partnership was critical in ensuring that eligible residents were cognitively able to consent to inclusion in the feasibility assessment and those who were not, had opportunity to participate through consent provided by the appropriately authorized individual. However, the logistics of consenting when diarrhea was present and when the resident met inclusion criteria required rapid identification of the appropriate consenting individual, contacting them to discuss the assessment, then ensuring the consent document was completed before stool specimen collection occurred. This process was rarely accomplished in a single day and often took hours of time invested by the individual researchers. It is noteworthy that there is significant variation regarding when families and LARs are present in the

LTCF. Some visit regularly, even daily, and others may visit once a month or even less frequently, especially for residents with families living in another state. Visits often occurred in the evening and on weekends, so researcher work hours required ongoing adjustment. In addition, in some facilities there was an unexpected number of residents whose care was provided under the oversight of state guardianship as there were no family members of record. Enrolling those individuals in research was an additional challenge and, since the feasibility assessment had time sensitive activities (e.g., stool specimen collection), the time delay often prevented them from having opportunity for participation. Challenges included: 1) rapid identification of eligible residents to approach for informed consenting; 2) identification and contact of family members and LAR for participation request and consent signatures; 3) the logistics of working with facility personnel to establish those family and LAR connections and establishing first contacts with them; 4) obtaining signed consent form documents from family members and LARs quickly enough to obtain a stool specimen from the resident; and 5) researcher time spent in facilitating the entire consent process and accounting for that variable in their workflow.

Management of Clinical Samples

Inclusion in the feasibility assessment involved determining how collection of a stool specimen could occur. Healthcare staff uniformly stated that they would prefer to collect the specimen and assist the resident with personal hygiene regardless of their continence or incontinence status. Approximately half of the residents were stool incontinent, so specimen collection was viewed as part of care dignity. Therefore, collaboration with the resident care staff so the specimen could be collected and handled appropriately became a core focus. Labelling of a specimen to include both resident identification and feasibility assessment study information (e.g., date and time of collection) was considered. Further, processes were evaluated regarding methods for specimen movement to a temperature-stable and temperature-monitored refrigerator at the LTCF while awaiting transport for testing at the University laboratory. Research personnel checked for availability of appropriate laboratory refrigerators and procedures for specimen retrieval and periodic transport to the study laboratory via a courier service or by research personnel. The chain of custody of the specimen and the monitoring of conditions of the specimen (e.g., temperature of the laboratory refrigerator and temperature of the transport container) required a level of logistical coordination that could be successful only with the assistance of the facility resident care personnel. Challenges included: 1) identification of residents for whom a stool specimen was needed; 2) coordination of stool specimen collection with the facility staff; 3) ensuring appropriate documentation that identified the resident, time of stool collection, and time placed in the facility laboratory refrigerator for storage; 4) provision of all feasibility assessment materials, including monitored refrigerator, for the facility so items were readily available; 5) communication with facility staff to ensure specimen identification thereby facilitating transport arrangements initiated by research personnel; and 6) accurate documentation of the chain of movement and custody of the specimen by research personnel.

Navigating the Medical Record Systems

Just as medical record systems are varied among hospitals, the same is true for LTCFs. There were three variations in medical record systems among the group of fourteen facilities involved in the feasibility assessment. These variations included: 1)

those with a completely paper chart; 2) a combination of paper systems and one or more electronic record systems; 3) or completely electronic. The electronic medical records systems, however, consisted of differing components. For example, provider orders might be in one system, nursing documentation in another, and documentation used by nursing assistants in yet another. Research teams were required to master, and meet, the facility credentialing processes in order to gain entry into those records. Once knowledgeable about the various systems, researchers had to learn where important notations regarding resident care were made (e.g., stool episodes), location of resident characteristics (e.g., resident demographics) to determine eligibility for inclusion, and provider documentation of assessment and stool testing. Challenges included: 1) awareness of the existing documentation systems; 2) arranging and completing credentialing requirements for medical record access; 3) arranging to collect data each day at the facility if remote or electronic access not possible or not allowed; 4) identifying opportunities for remote access and the necessary permissions; 5) awareness regarding documentation the researchers could see for review versus documentation actually present but available for review only by personnel with differing authorizations; and 6) ongoing communication with individual facility information technology staff to ensure access as allowed.

Study Team Workflow

Despite our extensive experiences in clinical research involving hospitals and hospitalized patients, the feasibility assessment represented the first time the University of Louisville Division of Infectious Diseases faculty and researchers approached LTCFs regarding research participation. Assignment of researcher personnel and time allocations were initially led by those hospital experiences. The feasibility assessment enabled the research team to identify the differences between anticipated workflow and actual workflow necessary for research in LTCFs. Workflow included time spent in learning about the individual facilities and their perceptions regarding research. This demonstrated the need to account for two levels of work. One level involved time management by faculty leading the research process and the second level involved the time management by the actual research teams. Faculty spent time learning about the facilities, establishing the relationships necessary for introducing research to the LTC environment, and learning how to address the needs of the facilities, medical directors, providers, and administration. Researchers needed to spend time learning about the operations of each facility and understanding how their workflow needed to occur at the individual facility level so resident and staff engagement could be maximized. Logs were kept of interactions and changes to workflow. Frequent meetings and communications occurred among faculty, key research personnel, and LTCF personnel to ensure questions and concerns were immediately addressed and barriers to the feasibility assessment were removed. Challenges to the workflow included: 1) recognition of the numbers of personnel needed to be involved in initial and ongoing discussions regarding research in the LTC environment; 2) minimizing the number of researchers at each LTCF to minimize disruption while allowing for relationship development; 3) workflow adjustments necessary in relation to resident needs and facility personnel needs; 4) determination of when meetings were necessary on-site and when meetings could be held via telephone or video conference; 5) how workflow changes impacted personnel time (e.g., working hours) and transportation (e.g., movement of

research personnel across multiple LTCFs); 6) how workflow discoveries could impact the feasibility assessment and when they could be expected to impact a larger more comprehensive study; and 7) how to quantify workflow needs so they could be incorporated and scaled into a comprehensive study budget.

Discussion

This feasibility assessment found that conducting research in LTCFs was very different in almost every aspect from research conducted in the hospital setting. The challenges identified in research mirrored those outlined by Lam and colleagues. In their meta-analysis regarding research in LTCF, they identified eight themes that included facility/owner/administrator factors, resident factors, staff caregiver factors, family caregiver factors, investigator factors, ethical/legal factors, methodological factors and budgetary factors [5]. Our work provided additional depth to their findings by providing a specific context for LTCF research. The clinical research effort involved in establishing relationships were deemed as the most important, most challenging, and the most satisfying. The depth of concern regarding the safety and dignity of the LTCF residents was uniformly evident and became the guiding principle in conversations regarding research and the ultimate desired outcomes. The feasibility assessment also found that each LTCF is unique and time must be spent in understanding the operational aspects of the facility as well as the needs of the staff and the residents. Each LTCF had a strong desire to learn about infection prevention and that desire for education became a unifying factor for the research team and the facility personnel. Research teams consistently reported conversations with LTCF personnel who had personal experiences with CDI, often involving friends and family members. This served to heighten interest in the feasibility study and strong participation in education events. This shared interest helped shape how information from the feasibility assessment could be used to provide important information impacting the safety of the residents and the care activities of the staff. As we continue to move into an age where healthcare information is available through electronic means, results showed the barriers to research as well as health information access due to variations, inconsistencies, and currently available technologies.

As the population ages and care is increasingly provided in settings other than hospitals, it is essential to ensure that research activities are performed in settings such as long term care. This approach is relevant for care provided in the US as well as care provided internationally. Certainly the long term care environment could be considered “unstable” for research, but that instability can be successfully addressed. Without access to knowledge regarding presence of disease and actions that may alter the course of disease and its toll, improvements in resident outcomes will be hobbled. The findings of this feasibility assessment were limited as results were obtained from a small sample of US LTCFs and focused on a single project. Nevertheless, the finds are important for use when planning any study involving LTCF as they represent distinctly different and new challenges for adding knowledge to the greater healthcare continuum. Results from this feasibility assessment will be used as a basis to determine a more comprehensive population-based incidence of *C. difficile* infection through the City of Louisville Diarrhea (CLOUD) study scheduled to begin in the fall of 2019.

Acknowledgements

We would like to extend appreciation to the long term care facilities and their administrative and healthcare personnel staff who worked with us on the feasibility assessment and helped identify, address, and overcome, the many barriers that exist in establishing clinic research partnerships.

Role of the Funding Source

Funding for the feasibility assessment provided by Pfizer, Inc. No review or approval of this manuscript was sought or provided.

Conflict of Interest

There are no conflicts of interest identified by any of the authors other than the funding for the research provided by Pfizer, Inc.

Author Contributions

JR and SP designed the feasibility assessment protocol and provided critical review of the manuscript. RC and DB were responsible for primary writing and editing of the manuscript. DB, SF and SP worked with the researchers to gather the data for this project. KG, VS, and BA led the research teams in the

LTCFs. BK and SK were researchers working in the LTCFs gathering data and working with the staff. All authors have reviewed and approved the final version of this manuscript.

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