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A Randomized Trial of Heart Failure Disease Management in Skilled Nursing Facilities (SNF Connect): Lessons Learned

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Abstract

Background/Aims—Conducting clinical trials in Skilled Nursing Facilities (SNF) is particularly challenging. This study describes facility and patient recruitment challenges and solutions for clinical research in SNFs.

Methods—Lessons learned from the SNF Connect Trial, a randomized trial of a heart failure disease management vs. usual care for patients with heart failure receiving post-acute care in SNFs, are discussed. Description of the trial design and barriers to facility and patient recruitment along with regulatory issues are presented.

Results—The recruitment of Denver-metro SNFs was facilitated by key stakeholders of the SNF community. However, there were still a number of barriers to facility recruitment including: leadership turnover, varying policies regarding research, fear of litigation and of an increased workload. Engagement of facilities was facilitated by their strong interest in reducing hospital readmissions, marketing potential to hospitals and heart failure management education for their staff. Recruitment of patients proved difficult and there were few facilitators. Identified patient recruitment challenges included: patients being unaware of their heart failure diagnosis, patients overwhelmed with their illness and care, and frequently there was no available proxy for cognitively impaired patients. Flexibility in changing the recruitment approach and targeting SNFs with higher rates of admissions helped to overcome some barriers.

Conclusion—Recruitment of SNFs and patients in SNFs for clinical trials is challenging. Strategies to attract both facility and patient participation are warranted. These include, aligning study goals with facility incentives and flexible recruitment protocols to work with patients in “transition crisis”.

Keywords

Heart failure; clinical trial; skilled nursing facility

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Introduction

Skilled nursing facilities (SNF) provide seniors and individuals with disabilities post-hospitalization short-term rehabilitation, a benefit covered by Medicare Part A. Unlike nursing homes or long term residential care, SNFs provide patients rehabilitation after hospitalization with the goal of reestablishing prior level of functioning before hospitalization. Patients needing SNF care are typically older and more frail than their counterparts who return home from the hospital.^{1,2} To cut costs and improve quality of care, Medicare rules are changing from a fee-for-service to a value-based purchasing model for SNFs. These sweeping changes in SNF care are anticipated to incentivize quality improvement in SNF care. However, research significantly lags behind changes in policy partly because research in the SNF environment has proved immensely challenging.

Despite recognition 20 years ago that research within SNFs was crucial and uniquely challenging, few advances have been made since that time.^{3,4} Several investigators have identified root causes of challenges to clinical research in SNFs.⁵⁻⁸ First, the patient population-- frail older adults - are difficult to recruit due to comorbidities, poor mobility, cognitive impairment, lack of patient perceived benefit and difficulty obtaining informed consent.^{3,9} Second, SNFs have been coined “unstable environments” for clinical research due to high rates of staff turnover, relatively short length of stay for patients and unpredictable external forces, such as frequent regulatory monitoring and change.¹⁰ Third, research in SNFs requires additional attention to trial design and methodology including assessing the potential barriers to conducting the research and their effects on the validity of the study.¹⁰ Without knowledge about the operation of SNFs and careful consideration of barriers to research in such environments, the investigation can fail to get off the ground. Additionally, the highly regulated environment does not offer any incentives to participate in research and facilities often fear regulatory repercussions. Finally, many interventions considered to be standard of care in younger and non-institutionalized individuals have no evidence of benefit, or harm, in SNFs, simply because those in SNF are often excluded from research trials. Thus, equipoise often exists in applying research to the SNF population, where it does not in the hospital or community setting.

To address the lack of research conducted in SNFs and to aid in future SNF research, we present lessons learned from our ongoing trial: A Randomized Trial of Heart Failure Disease Management in SNF (SNF Connect).¹¹

Methods and Results

The SNF Connect study

SNF Connect is a randomized cluster trial which investigates if a heart failure disease-management program in SNF will decrease rehospitalizations, emergency visits and mortality compared to usual care. Heart failure is an important chronic condition to study because of the high burden of disease in SNF, contribution to poor quality of life, functional decline, and frequent readmissions.¹² The study recruitment period from July 2013 to October 2017 is being conducted in 35 SNFs in the Denver-metro area. The intervention arm is run by a registered nurse who delivers a 7-component intervention which includes clinical

care and discharge measures. Patients in usual care are followed by chart review to abstract the same 7 components as in the intervention arm.

Trial design considerations

Heart failure disease management is well established at improving outcomes in community populations.^{13,14} Guidelines for heart failure care are well described and backed by years of research.^{15,16} However there is no evidence as to whether heart failure disease management will make a difference for older adults in SNF despite heart failure being a common cause of readmission from SNF.¹⁷

Although it is important to know if SNFs can conduct effective disease-focused management programs, we first need to know if a program under “ideal conditions” will improve outcomes. Since most of the individuals in SNF have multiple co-morbidities, a disease-focused intervention may be too narrow to have meaningful improvement in outcomes. Therefore, the trial is designed as a randomized controlled trial with an intervention delivered by research staff according to protocol. If SNF staff were asked to deliver the disease management program, there would be enormous variability between facilities and clinician adherence to the intervention and the fidelity of the program would be lost. This would make it impossible to know if heart failure disease management actually works at all.

Facilitators of facility recruitment

Understanding the culture of SNF care in the region and identifying and connecting with key partners helped facilitate study initiation. Fostering relationships with community-based providers helped to begin conversations with the SNFs. SNF care in Denver lent itself to engaging facilities since it has a well-organized Colorado Medical Directors Association, which meets monthly. These meetings predominantly include medical directors but also facility personnel and representatives from the Colorado-based trade organization, Colorado Health Care Association. The members provided introductions to multiple facilities in the Denver area, vouched for us as a study team and advocated for the importance and value of conducting research in SNFs. For facilities in which we had no introductions, meetings with the executive director were arranged in order to gain an understanding of SNF readiness and willingness to participate in research. This approach was less successful. At the initial discussion regarding facility participation, potential benefits to the facility were delineated and evidence to the alignment of the study to facility missions.

The intervention and outcomes of the study were of particular interest to SNFs in that heart failure is considered a *potentially preventable readmission* as defined by Medicare. Facility leadership took a keen interest in learning how to reduce readmissions since the Centers for Medicare & Medicaid Services will soon initiate penalties for potentially preventable readmissions from SNF. The study was also appealing to SNFs for the purpose of marketing to hospitals by demonstrating a commitment to quality improvement. While participating SNFs received no financial incentives for participating, they were offered access to their own study data regarding heart failure care upon completion of the trial, to gain insight into their own heart failure care. Lastly, the SNFs were offered free educational seminars (to be

conducted at the conclusion of the study) for SNF staff to learn how to better manage care for patients with heart failure.

Barriers to facility recruitment

We found that there were 4 main issues that impacted facility recruitment. First, leadership turnover was frequent; changing the primary contact for each SNF. More often than not, we were not informed of leadership change and the change was discovered due to a prolonged break in contact. This loss of engagement resulted in having to re-establish connections with new leadership and get them on board with the study, greatly delaying its start.

Second, policies regarding research greatly differed between companies, some required extensive legal contracting and others no contract at all. Time required was unpredictable and could include permissions from local, regional and/or national corporate leadership. Determining the responsible parties in the different organizations was challenging and the process could take up to up to 3 months. Face to face meetings were key to getting SNFs on board with the study. Facility leadership was different depending on the company and it was important to understand the hierarchy. This was accomplished best by speaking with the executive director or the director of nursing. We found that once the local facility leadership staff were on board, they would advocate for the study and shuttle the process through the corporate hierarchy if necessary. Once corporate approval was achieved, the various SNFs within that company were easier to recruit and often eager to participate. Facilities that did not participate, which were few, were the ones in which we were unable to arrange the face to face discussion with facility leadership or national leadership refused participation.

Third, fear of litigation related to study activity was a common concern from SNFs. Concerns raised regarding research participation included fear of putting patients at “undue risk” from study procedures and/or violation of the Health Information Portability and Accountability Act. Patients had to be screened by study staff prior to being approached. Most facilities accepted a Health Information Portability and Accountability Act waiver from the University of Colorado Institutional Review Board in order for staff to screen patients. One company did not feel this was legally acceptable so an alternative method of patient screening was required in those facilities. SNF staff had to identify appropriate patients, approach, and gain permission for study staff to speak with them. This proved cumbersome for SNF staff and few patients were recruited from these facilities. The State will arrive at any SNF unannounced to conduct routine or investigative surveys. Many SNFs were concerned regarding how the State would perceive researchers in the building and many asked us to discontinue study activities during state surveys. Although we complied with this request, the concern may be unfounded in that discussion with state surveyors indicate that they are supportive of research collaboration in the SNFs.

Fourth, concern for an increased workload on staff was a common concern raised by SNF leadership. Recognizing this barrier, the study was specifically designed so as not to require any additional work from the SNFs themselves. Of key importance was the ability for study staff to directly log onto the SNFs' electronic medical records to screen for eligible patients. Due to distance between facilities, remote screening was vital so the study staff could target visits to SNFs with eligible patients which greatly increased our reach. In a minority of

SNFs without remote electronic medical record access, the SNFs had to alert study staff of new SNF admissions, no screening required. This flexibility in screening was an important aspect of our success in working with multiple facilities and recruiting participants.

Lessons learned

Recruitment of SNFs in Denver lent itself well to the introduction to SNFs by the Colorado Medical Directors Association. However, we still found that the recruitment of facilities proved somewhat difficult but once word of mouth traveled amongst the SNFs and corporate leadership was on board, the process of recruitment snowballed especially for SNFs within the same company. Some of the lessons learned in facility recruitment included the need to foster relationships with the SNF community, the importance of face-to-face meetings with facility leadership, allowance of enough time for corporate approval, relaying potential benefits to SNF participation, ensuring all efforts were made for patient safety and confidentiality, and assurance that the facility staff would not be burdened with an additional workload. Even though complete separation of study procedures from facility based activities was essential to the study design, it was likely one of the barriers to our successful recruitment. Participation of the facility staff in the research may have improved patient engagement and increased enrollment. However the trade-off was assuring fidelity of the intervention and avoiding additional work burden for SNF staff. Remote access to the electronic medical record was key since it allowed us to target study resources to the SNFs with admission of patients with heart failure. Otherwise time taken for distance traveled between SNFs to screen for patients would be prohibitive to adequate recruitment.

Facilitators to patient recruitment

The SNF patient is a patient in “transition crisis” as they have just been discharged from the hospital and after rehabilitation return home. The patient has to adjust to a new environment while still being quite sick. Flexible timing for recruitment has been critical to addressing this challenge.^{5,7,8,18} Recruitment is one of the biggest challenges for most trials, however the lack of collective experience in recruiting patients from SNFs makes it even more difficult.

The recruitment of patients proved to be one of the biggest challenges for the SNF Connect study. As part of the study design, the study is conducted by the study staff only and requires very little, to no, assistance from the SNFs themselves. Therefore, in the case of our trial we had very few facilitators to aid in the recruitment of participants.

Barriers to patient recruitment

There were 4 issues that impacted patient recruitment: First, screening for eligible participants is not straightforward due to poor documentation and diagnostic uncertainty as to which patients had heart failure.¹⁹ It was important to identify if the lack of documentation would result in missing eligible patients. Therefore, all SNF admissions were reviewed for a heart failure diagnosis. If no heart failure diagnosis was found but the patient did have a cardiac diagnosis or heart failure medications, they were eligible if they also had signs/symptoms or a self-reported history of heart failure. This strategy was time-consuming and labor-intensive since we screened every new SNF admission. We found that all eligible

patients had a cardiac diagnosis on their hospital discharge summary. Therefore, after about 6 months, we modified the screening protocol to use any cardiac diagnosis as a screening trigger to reduce burden of work.

Second, there was variability in the number of SNF admissions between and within SNFs. SNFs vary in the number of admissions, including by month and season. We found a decline in admissions in spring/summer months, especially after flu season. Seasonal variability can impact recruitment numbers especially for short-term studies. Additionally, it took time to learn what types of patients different SNFs admitted. Some SNFs admitted patients with heart failure frequently, and some rarely. Some had many more cognitively impaired patients which were much harder to recruit (difficulty to gain proxy involvement). We had to learn where our time was best spent and how to maximize eligible patients to enroll. This was only possible by spending time in each SNF and learning their patient population.

Third, the refusal rate for eligible patients was high with approximately 37% of eligible patients enrolling. We found that if we approached the patient too early in their SNF stay – within the first 24 hours – they were much less likely to participate. Therefore, we limited recruitment to after the first 48 hours of admission. This adjustment to increase recruitment does come at a cost since patients who rapidly return to the hospital (within 2 days of SNF admission) will not be enrolled. We also broadened the enrollment period, from 4 to within 7 days of admission. The most unexpected reason for failed enrollment was the SNF patient was unaware of their own heart failure diagnosis (20% of eligible patients).

Fourth, difficulty obtaining proxy consent is common for demented or cognitively impaired patients in SNF.^{20,21} This proved to be a difficult challenge for our study given that patients must be able to pass a cognitive test in order to consent for themselves. For cognitively impaired patients, proxies were contacted via telephone to ask for permission for their family member to participate in the study. However, obtaining proxy consent proved to be extremely difficult either due to no known proxy for the patient, lack of proxy response, fear that the study would add “another thing to their plate”, or were unable to come in or to sign the consent form by email. Of the total refusals, 9% were proxy refusals.

Lessons learned

Overall, the study demonstrated a need for flexibility and re-strategizing in order to improve recruitment. Learning the case-mix for each SNF proved helpful to enroll patients. The most effective strategy to improve recruitment was increasing the number of participating facilities and targeting the facilities with the most admissions of the eligible patient population.

Regulatory considerations

When conducting research in SNFs, there are a number of regulatory and ethical issues that must be addressed. We worked closely with the University of Colorado Institutional Review Board to assure subject protections, without overwhelming the trial with regulatory constraints that would deem the study impossible. The 2 important determinations were:

First, the study was designed such that the SNF was not “engaged” in research according to Office for Human Research Protections engagement guidance which requires a SNF to obtain a Federalwide Assurance or an Institutional Review Board reliance agreement.²² The Federalwide Assurance can prove to be a no-go barrier. Most SNFs and/or SNF corporations do not initiate research or have a federally-registered Institutional Review Board and therefore delegate to the Institutional Review Board at the principal investigator's institution. Some Institutional Review Boards are unwilling to serve as the Institutional Review Board of record for multiple outside facilities due to liability concerns.²³ Additionally, it is common for institutions to require the unaffiliated community partner to obtain their own Federalwide Assurance to enter into a reliance agreement for Institutional Review Board review.^{23,24} Though obtaining a Federalwide Assurance is a relatively simple process, it is a cause for reluctance for community institutions to become involved.^{25,26} By design the SNFs were not “engaged” in the research, this allowed us to conduct the research without SNFs needing to obtain a Federalwide Assurance or an Institutional Review Board reliance agreement, or needing to train facility staff in best research practices, human subject research protections, and Health Insurance Portability and Accountability Act requirements for research.

Second, waiver of Health Insurance Portability and Accountability Act was granted by the Institutional Review Board due to impracticability of the research with Health Insurance Portability and Accountability Act's requirements. The Health Insurance Portability and Accountability Act rule limits access to and disclosure of patients' protected health information. For research in SNFs, the most significant obstacle is access to potential subject protected health information in the process of recruitment, because pre-screening occurs before the investigator has had a chance to obtain Health Insurance Portability and Accountability Act authorization from the patient. Subject identification and pre-screening is laborious, places a significant burden on SNF staff, and an obstacle to successful recruitment. Therefore, the waiver of the Health Insurance Portability and Accountability Act allowed research staff to conduct pre-screening and was paramount to the success of patient recruitment.

Conclusion

Successful trials in SNF require careful planning at the trial design phase and will greatly benefit from having stakeholders involved to assure that the trial and corporate missions are aligned. The lessons learned from the SNF Connect study may prove helpful to researchers looking to develop the evidence base for this vulnerable population and uniquely challenging setting. Due to the impending Centers for Medicare & Medicaid Services' policy changes, SNFs are more open to trialing new strategies to learn how to improve the quality of care and reduce readmissions. Therefore, now is an ideal time to work closely with SNFs to develop an evidence base that is greatly needed in this complex care environment.

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References

1. Allen LA, Hernandez AF, Peterson ED, et al. Discharge to a skilled nursing facility and subsequent clinical outcomes among older patients hospitalized for heart failure. *Circ Heart Fail.* 2011; 4:293–300. [PubMed: 21447803]
2. Dolansky MA, Xu F, Zullo M, et al. Post-acute care services received by older adults following a cardiac event: a population-based analysis. *J Cardiovasc Nurs.* 2010; 25:342–349. [PubMed: 20539168]
3. Ouslander JG, Schnelle JF. Research in nursing homes: practical aspects. *J Am Geriatr Soc.* 1993; 41:182–187. [PubMed: 8426043]
4. Lipsitz LA, Pluchino FC, Wright SM. Biomedical research in the nursing home: methodological issues and subject recruitment results. *J Am Geriatr Soc.* 1987; 35:629–634. [PubMed: 3584766]
5. Kolanowski A, Mulhall P, Yevchak A, et al. The triple challenge of recruiting older adults with dementia and high medical acuity in skilled nursing facilities. *J Nurs Scholarsh.* 2013; 45:397–404. [PubMed: 23859475]
6. Mody L, Miller DK, McGloin JM, et al. Recruitment and retention of older adults in aging research. *J Am Geriatr Soc.* 2008; 56:2340–2348. [PubMed: 19093934]
7. Hanson LC, Gilliam R, snf Lee TJ. Successful clinical trial research in nursing homes: the Improving Decision-Making Study. *Clin Trials.* 2010; 7:735–743. [PubMed: 20729251]
8. Zermansky AG, Alldred DP, Petty DR, et al. Striving to recruit: the difficulties of conducting clinical research on elderly care home residents. *J R Soc Med.* 2007; 100:258–261. [PubMed: 17541093]
9. Provencher V, Mortenson WB, Tanguay-Garneau L, et al. Challenges and strategies pertaining to recruitment and retention of frail elderly in research studies: a systematic review. *Arch Gerontol Geriatr.* 2014; 59:18–24. [PubMed: 24745811]
10. Buckwalter KC, Grey M, Bowers B, et al. Intervention research in highly unstable environments. *Res Nurs Health.* 2009; 32:110–121. [PubMed: 19035619]
11. Boxer RS, Dolansky MA, Bodnar CA, et al. A randomized trial of heart failure disease management in skilled nursing facilities: design and rationale. *J Am Med Dir Assoc.* 2013; 14:710.e5–710.e11.
12. Mor V, Intrator O, Feng Z, et al. The revolving door of rehospitalization from skilled nursing facilities. *Health Aff (Millwood).* 2010; 29:57–64. [PubMed: 20048361]
13. Ahmed A. Quality and outcomes of heart failure care in older adults: role of multidisciplinary disease-management programs. *J Am Geriatr Soc.* 2002; 50:1590–1593. [PubMed: 12383160]
14. McAlister FA, Stewart S, Ferrua S, et al. Multidisciplinary strategies for the management of heart failure patients at high risk for admission: a systematic review of randomized trials. *J Am Coll Cardiol.* 2004; 44:810–819. [PubMed: 15312864]
15. Yancy CW, Jessup M, Bozkurt B, et al. 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *J Am Coll Cardiol.* 2013; 62:e147–e239. [PubMed: 23747642]
16. Hunt SA, Baker DW, Chin MH, et al. ACC/AHA guidelines for the evaluation and management of chronic heart failure in the adult: executive summary a report of the American College of Cardiology/American Heart Association Task Force on practice guidelines (Committee to revise the 1995 guidelines for the evaluation and management of heart failure): Developed in collaboration with the International Society for Heart and Lung Transplantation; endorsed by the Heart Failure Society of America. *Circulation.* 2001; 104:2996–3007. [PubMed: 11739319]
17. Jurgens CY, Goodlin S, Dolansky M, et al. Heart failure management in skilled nursing facilities: a scientific statement from the American Heart Association and the Heart Failure Society of America. *J Card Fail.* 2015; 21:263–299. [PubMed: 25863664]
18. Gismondi PM, Hamer DH, Leka LS, et al. Strategies, time, and costs associated with the recruitment and enrollment of nursing home residents for a micronutrient supplementation clinical trial. *J Gerontol A Biol Sci Med Sci.* 2005; 60:1469–1474. [PubMed: 16339336]
19. Heckman GA, Foebel AD, Dubin JA, et al. The value of admission clinical data for diagnosing heart failure in long-term care. *Can Geriatr J.* 2013; 16:147–155. [PubMed: 24278092]

20. Barnes C, Conner D, Legault L, et al. Rehabilitation outcomes in cognitively impaired patients admitted to skilled nursing facilities from the community. *Arch Phys Med Rehabil.* 2004; 85:1602–1607. [PubMed: 15468018]
21. Pressler SJ. Heart failure patients in skilled nursing facilities: evidence needed. *Circ Heart Fail.* 2011; 4:241–243. [PubMed: 21586734]
22. US Department of Health & Human Services. [Accessed 23 June 2016] Engagement of institutions in human subjects research. 2008. <http://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/>
23. Silverstein M, Banks M, Fish S, et al. Variability in institutional approaches to ethics review of community-based research conducted in collaboration with unaffiliated organizations. *J Empir Res Hum Res Ethics.* 2008; 3:69–76.
24. Wolf LE, Croughan M, Lo B. The challenges of IRB review and human subjects protections in practice-based research. *Med Care.* 2002; 40:521–529. [PubMed: 12021678]
25. Newgard CD, Lewis RJ. The paradox of human subjects protection in research: some thoughts on and experiences with the Federalwide Assurance Program. *Acad Emerg Med.* 2002; 9:1426–1429. [PubMed: 12460850]
26. Cartwright JC, Hickman SE, Bevan L, et al. Navigating federalwide assurance requirements when conducting research in community-based care settings. *J Am Geriatr Soc.* 2004; 52:1567–1571. [PubMed: 15341563]