Published in final edited form as:

Appl Nurs Res. 2008 November ; 21(4): 232–236. doi:10.1016/j.apnr.2006.10.006.

Tales from the field: what the nursing research textbooks will not tell you

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Abstract

The process of conducting nursing research can be far more complicated than what is described in nursing textbooks, particularly when the investigation is conducted in a new and unfamiliar care setting. This article describes a number of unexpected events and outcomes associated with implementing what was considered, at the onset, a well-designed research study under the leadership of experienced investigators. Lessons learned, which are believed to be valuable to both neophyte and seasoned researchers, are reviewed.

1. Introduction and overview

As fairly “seasoned” investigators, we (our research team) thought that we had encountered more than our fair share of unanticipated and unusual challenges to conducting clinical research. For example, during a study that examined immune and affective outcomes among caregivers of persons with dementia (Garand et al., 2002), a previously healthy laboratory assistant, with whom we had contracted to analyze killer T cells, had a psychotic break, yielding invalid and unusable data. In another study that evaluated a discharge intervention to determine posthospitalization outcomes for persons with depression (Buckwalter & Abraham, 1987), the second author had carefully reviewed hospital admission records for the prior year and determined that most depressed patients were admitted and discharged around the Christmas holiday period. Based on these data, she anticipated enrolling and intervening with a large number of subjects in the months of December and January and scheduled her data collection activities accordingly. Additionally, to control for systematic differences among admitting psychiatrists (choice of medications, use of ECT vs. psychotherapy, etc.), she elected to study only the patients of the one psychiatrist who had the largest volume of patients in the research setting. However, what the investigator failed to appreciate was that the psychiatrist would make a last minute decision in mid-December to take his family to Disney World for a 3-week vacation and would not be admitting any patients during the critical data collection period.

Further, as teachers of research methods courses in our respective disciplines and as mentors to pre- and postdoctoral fellows, as well as to junior faculty, we have always advised our students to carefully plan their research procedures, to pilot test studies to uncover and

address unanticipated problems in the field, and to “be prepared” for unexpected twists and turns in the research process that could threaten internal validity of findings or hamper achievement of desired sample size and composition. Little did we know that this sound advice would come back to haunt us, as we set out to study anxiety-related symptoms of persons with dementia who resided in assisted living facilities (ALFs).

The goal of this article is to review and discuss a number of unexpected events and outcomes associated with implementing what was considered, at the onset, a well-designed research study. Unanticipated difficulties with recruitment, challenges associated with internal review board (IRB) processes, and unexpected outcomes in data collected are reviewed.

2. Study plans: what we thought would happen

The overall aim of our pilot study was to set the stage for subsequent effectiveness testing of a multiphase management strategy for persons with dementia-related anxiety and agitation. The ultimate goal of our interdisciplinary research team was to develop treatment strategies that involve systematic evaluation and intervention plans that optimize care from a nursing, medical, environmental, and pharmacological perspective and that enhance daily function and promote “aging in place” once at the assisted living (AL) residence. The need for this multimodal, nonpharmacological approach was based on literature that report that discharge from AL to nursing home care was often the result of cognitive-related deficits in function and associated behavioral symptoms and that average residence for persons with dementia was only 18 months.

The first-year feasibility study (Phase I) began the process by examining and refining data collection instruments, procedures, and inclusion criteria; evaluating the acceptability and usefulness of proposed screening and outcome measures; and exploring the role of genetic risk factors in the development of late-life anxiety. Phase I was also designed to allow for modifications of the Progressively Lowered Stress Threshold Model (Hall & Buckwalter, 1987) intervention for application with older adults in AL settings and for the development of a caregiver manual for use in the Phase II intervention/medical management study to be conducted in the second year of the investigation.

3. Getting started: what did not work

As planned, the first 3 months of the project were dedicated to reviewing tools, preparing packets, printing IRB-approved advertising materials, and reconfirming relationships with the two AL facilities that agreed to participate. Because dementia-specific facilities were recruited to participate, an assumption that subjects (older adults in AL) would be unable to sign informed consent documents for themselves was made by investigators and the IRB. Instead, consents would need to be signed by designated family members (following protocols outlined in our IRB process related to next of kin). Thus, procedures set forth in the research proposal included use of advertising posters to be placed in strategic locations in the AL residences, materials to give family members and staff, and use of informational meetings to facilitate staff cooperation and recruiting family members to sign informed consent documents on behalf of their loved ones.

Posters were placed, informational handouts were left in public areas, one staff informational meeting was held, and a family-oriented meeting was scheduled but canceled by the facility due to bad weather. However, family members who volunteered to sign consents that allow their loved ones to participate in our research did not appear. The often hectic Thanksgiving-followed-by-Christmas season ensued, making it increasingly difficult to attract family or staff to attend informational meetings. Feeling our frustration with the

lack of enrollees, the director of nursing (DON) of one facility (called ALF-A here) graciously invited research staff to attend the annual Christmas party, which was well attended by family members, creating an opportunity to speak to family members about the project, hand out informational flyers directly, and answer questions/concerns at the beginning of the holiday party. This opportunity was expected to serve as an effective recruitment vehicle, and in anticipation, the Phase I principal investigator (PI) arrived an hour early to assist staff in party preparations. While arranging trays of cookies, she was summoned by a frantic staff member, screaming, "Come quick! Something's terribly wrong with Mr. T!" As the only nurse in the facility (the DON was on vacation), the PI ran to Mr. T's room to find him seizing approximately every 2–5 seconds. Unfamiliar with the resident, the PI subsequently asked staff to read her chart information on current diagnoses and medications, as well as past medical history, while she instituted seizure precautions and timed and evaluated the seizures. She also contacted Neurology staff at a nearby hospital for guidance and support and instructed ALF-A staff to call emergency medical technicians (EMTs) to assist with Mr. T, whose seizures continued for the next half an hour unabated. After the EMTs arrived and were briefed by the PI, they decided to transport Mr. T via ambulance to a nearby acute care hospital for further evaluation and treatment. Following his departure from ALF-A, the PI wrote chart notes and spent time talking to Mr. T's family via telephone about the incident and subsequent transfer. A considerable amount of effort was expended on one son, in particular, who was angry about the expenses associated with transport by ambulance. Needless to say, by the time the incident with Mr. T was resolved, the holiday party was almost over, and the "window of opportunity" to inform and consent family members was lost.

Researchers soon realized that plans to hold information-sharing meetings at the two facilities were impractical, as most family members either resided outside the local community or had competing demands for their time. Informational posters and brochures were also not effective in eliciting participation. As before, the DON of ALF-A recognized that recruitment was not proceeding as planned and offered to send informational letters to all family members, alerting them to the project and asking that they return a postage-paid form that indicates whether they were interested in being contacted or not. Of the 24 family members contacted in ALF-A, 14 responded in the positive, 4 in the negative, and the rest did not respond at all. Of the 30 family members contacted in the other facility (called ALF-B), 5 responded that they were interested, 12 responded that they were not interested, and the remaining 13 did not respond.

The nearly opposite response in the two facilities, one positive and the other negative, was puzzling. However, thoughtful review of circumstances in the two facilities highlighted the fact that the DON in ALF-B changed three times before data collection began. Thus, the high turnover situation among facility leadership may have created an atmosphere of instability and uncertainty among family members that may account for families' reticence to participate in research. Specifically, the letter announcing the project and requesting that family members contact the PI was sent by an "unknown" DON, a person with whom families did not have an established alliance. This change in leadership was a surprise to both families and researchers. When researchers contacted ALF-B to arrange a time to bring preposted return envelopes to be included with the informational letters, we were referred to the newly appointed DON who assumed the position only days earlier, following the unexplained termination of the prior DON. In ALF-A, where family consents were more easily obtained, the same person had served as the DON for many years and knew all families well.

After letters were sent by DONs, responses filtered in over months, and in most cases, substantial additional time was required to contact the family member (e.g., repeated

telephone calls, e-mail messages, postal correspondence), explain the study, and sign consent forms. A regrettable choice of words in the letters left some family members with the impression that *they* needed to be available for in-person interviews. As a result, several family members who lived a long distance from the area wrote us kind notes about their lack of availability but wished us well in our efforts (e.g., “We live in Arizona now, so can’t help, but hope you do well in your project.”). Despite efforts to clarify our intentions with this group, reaching families to discuss possible misunderstandings was difficult, and the opportunity was more often lost.

Because Phase I recruitment was slow, another facility was invited to participate. Following the protocol established earlier, letters to family members were initiated by the facility, with preposted return envelopes to the PI included. Although the facility was amenable to mailing these materials to family members, the facility volunteer who stuffed the envelopes erroneously mailed all forms back to the PI and not to family members. This error again slowed the process, and returns from this facility were minimal.

In summary, Phase I recruitment was very slow due to a variety of unanticipated factors such as (a) the IRB-mandated need to wait for family members to contact the research team regarding their willingness for family members to participate in the study and to sign consent forms, (b) high attrition rates among AL leadership (i.e., three new DONs in the course of a year at one facility), (c) problems with volunteers incorrectly mailing informational materials related to the study, and (d) thwarted recruitment opportunities due to unexpected resident medical crises.

4. Collecting the data: what we did not expect

The data collection process involved both direct assessment of AL residents and proxy interviews of staff regarding anxiety and depression symptoms that they observed in the subjects. Although research reports estimated the “average time” needed to interview staff using caregiver-rated forms, staff interviews were regularly more time consuming than was expected. The extra staff time required to participate in the research posed a problem, mostly because staff *not* being interviewed became jealous of those who were “sitting around talking” and complained to administration. From our perspective, however, staff were not “malingering” (avoiding work) but, instead, were regularly unable to distinguish “anxiety” symptoms from more global behavioral symptoms such as agitation or aggression. Considerable redirection and education were needed to focus on anxiety. In other situations, scale-related questions stimulated stories that centered on perceptions of poor care and problems in the facility, requiring time to sensitively respond to staff’s perceptions as well as creating ethical dilemmas for the researchers in terms of the amount of time taken to complete the research scales.

Additional problems arose in ALF-B, which were related to finding staff who were knowledgeable about the resident and who were capable of answering caregiver rated scales and to persuading them to take time out from their busy day to complete the Phase I study forms. This was considerably less troubling in ALF-A, but the time burden for staff to complete instruments was clearly an issue.

Another unexpected snag occurred in summer when our IRB renewal was already due. To comply with internal expectations for the completion of our initial IRB approval, our project was approved 3 months earlier than we were prepared to initiate the project. As a result, our “yearly” IRB renewal occurred 9 months into the project at an inopportune time when we were planning a modification based on experiences to date. Regrettably, our renewal was part of the newly initiated conversion from paper to electronic filing, and combined modifications and renewals were not permitted. Moreover, no one on the research team was

familiar with the electronic filing process, and end-of-summer commitments precluded anyone from attending educational programs related to use of the newly instituted system. Not surprisingly, we delayed filing until the last possible opportunity and then accidentally (and erroneously) included misinformation in the renewal. Given the glut of similar problems encountered in this first round of electronic renewals, it was nearly 8 weeks before approval was granted for our project to resume.

5. Who we wanted and who we found: subjects meeting criteria

Despite difficulties with recruitment, 17 subjects were enrolled and interviewed by August (when our IRB renewal was pending), nearly meeting the goal of evaluating 20 subjects during Phase I. Given experiences to date, study inclusion and exclusion criteria, which were based on an extensive review of the literature and clinical experiences, were critically reviewed.

For inclusion in the study, subjects must

1. meet *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV)* criteria for dementia and National Institute of Neurological and Communication Disorders and Stroke/Alzheimer's Disease and Related Disorders Association criteria for probable or possible Alzheimer's disease (AD),
2. have a Hamilton Anxiety Scale (HAM-A) score of 18 points or more,
3. have a Cornell Scale for Depression in Dementia (CSDD) score of 9 or less,
4. have a Mini Mental Status Examination (MMSE) score between 15 and 23 at screening,
5. have no major sensory impairment that would prevent study participation,
6. have a decision-making representative (for residents unable to provide consent),
7. have an informant who has had contact, on a weekly basis, with the resident during the prior month,
8. be more than 60 years old (regardless of gender).

Subjects were excluded in the study if they

1. meet *DSM-IV* criteria for other current psychiatric disorders (predating onset of AD) besides AD,
2. meet *DSM-IV* criteria for substance abuse or dependence,
3. are receiving psychotropic medications other than a cholinesterase inhibitor,
4. have a history or presence of significant neurological condition, for example, seizures, encephalitis, and neoplasm,
5. have any active, unstable medical condition(s) that impair cognition and psychosocial function,
6. require electroconvulsant therapy (ECT) or psycho-tropic drugs based on the investigator's judgment.

Our analyses indicated that all 17 subjects met *DSM-IV* diagnostic criteria for dementia, but none met criteria for anxiety levels using the HAM-A cutoff of 18 points. Overall, few subjects endorsed anxiety symptoms on the HAM-A, as the mean anxiety score was 4.35 for our sample of 17 subjects. All subjects met Inclusion Criterion 3 for depression levels (<9 on the CSDD), with an average rating of 4.00. About half of the sample (9/17) met Inclusion

Criterion 4, with this sample being significantly more impaired than desirable (e.g., mean MMSE score was 13.82). All but one subject, who was legally blind, met Inclusion Criterion 5 for no sensory impairment. All subjects met Inclusion Criteria 6 (regarding having a legally authorized representative to provide consent), 7 (related to having an informant who has had contact, at least, on a weekly basis), and 8 (being more than 60 years old; average age, 84.57 years; range, 76–91 years).

With regard to exclusion criteria, only 12 of the 17 subjects met Criterion 1, which is related to the presence of other psychiatric diagnoses, as 4 subjects were diagnosed with depression and 1 had amnesic disorder. All 17 subjects met Exclusion Criteria 2 (no substance abuse), 4 (no history of neurological conditions), 5 (presence of an unstable medical condition), and 6 (required ECT or psychotropic medication in the investigator's opinion). Most important, only 2 of the 17 subjects met Exclusion Criterion 2, which is related to the absence of psychotropic medication use. Many subjects were on one or more antipsychotic, antidepressant, or anxiolytic medications (e.g., 30 psychotropic medications were prescribed to 15 subjects).

In total, none of the first 17 subjects enrolled met inclusion criteria as originally outlined, either because they did not meet the threshold level for anxiety or, more often, because they were taking one or more psychotropic medications. We suspect that the two phenomena (low levels of anxiety symptoms and regular use of antianxiety, antipsychotic, and antidepressant medications) go hand in hand. That is, subjects did not exhibit anxiety symptoms because they were sufficiently well medicated to avoid occurrence of these often troubling symptoms.

6. Taking time out: Rethinking feasibility

Based on our 9-month formative analysis (3 months later than planned because of the stumbling blocks encountered), data collection as originally designed was suspended (while awaiting approval of our IRB renewal) and time was devoted to reconceptualization of study outcomes, design, instrumentation, and sites. Because Phase I was a feasibility study, the information learned was quite valuable and was used to shape changes in subsequent research. For example, our research team devised an alternative data collection plan, shifting recruitment away from dementia-specific ALFs to “regular” AL residences. We believe that engaging “regular” ALFs, versus those dedicated to the care of older adults with dementia, may facilitate identification of individuals with cognitive impairment who experience behavioral symptoms but before psychotropic medications are prescribed to “control” the behaviors. We also think that broadening the scope of assessment to individuals who may have “early” dementia, including mild cognitive impairment, may be advantageous in identifying persons with anxiety symptoms.

As mentioned earlier, following our renewal, we submitted an IRB modification to accommodate what we learned in the first 9 months of the project. The primary shift was refocusing on care in “regular” AL facilities (vs. dementia-specific facilities), which included changes in recruiting both facilities and subjects within facilities, strategies to obtain informed consent, and assessment of anxiety and related problems. Internally, we developed a new model for evaluating subjects based on their cognitive screening scores and made additional plans for the intervention phase that was now 3 months behind schedule. Specifically, adjustments in assessment scales were undertaken to assure more accurate assessment of mental status, adding a new anxiety subscale to rate anxiety symptoms and adding questions related to wandering behavior to facilitate comparison of our data to a large AL project in Maryland. Additional plans included collecting facility information, caregiver perspectives, and a qualitative assessment of anxiety and anxiety-related

outcomes. The addition of a qualitative component that queries staff about their definition of anxiety and asks them to describe an example of these symptoms was included to identify staff training needs as a component of the project and development of an intervention.

Despite disappointments and frustrations experienced in our Phase I feasibility study, a number of important lessons were learned, which are of value to experienced as well as neophyte researchers. These include the following: (a) the value of conducting a formative analysis, approximately midway through the study; (b) the value of conducting feasibility/pilot studies prior to a major research effort; (c) the importance of having a “Plan B” when things do not go as planned (and they invariably will!); (d) the need to qualitatively assess proposed research environments (in our case, two AL facilities) in addition to reviewing literature when making plans; and (e) the need to allow plenty of time for project revisions both for the funding source and the IRB.

Acknowledgments

With support from the National Institute of Nursing Research (NINR/F33NR009156) and the Gerontological Nursing Interventions Research Center NIH#P30 NR03979 [PI: Toni Tripp-Reimer, PhD, RN, FAAN, The University of Iowa College of Nursing] and the Hartford Center for Geriatric Nursing Excellence The John A. Hartford Foundation [PI: Kathleen Buckwalter, PhD, RN, FAAN, The University of Iowa College of Nursing]. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the National Institute of Nursing Research nor The John A. Hartford Foundation.

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