New York State Department of Health Dementia Grants Program
2003-2005 Grant Funded Project

Empowering Direct Care Providers in Breaking the Barriers to Alleviating Pain in Dementia

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I. The goal of this project was to promote the early detection of pain in nursing home residents with dementia in order to alleviate suffering and improve the quality of life for these individuals. We also sought to add to the body of knowledge regarding the pain experience in residents with Alzheimer's disease.

The study objectives were to develop a pain assessment tool for use in residents with dementia, to demonstrate its usefulness in improving clinical outcomes and to analyze whether residents with Alzheimer's disease respond differently to pain assessment and treatment.

The major research questions that were addressed in the project were as follows:

1. Can a measurement tool be developed to assess pain in residents with dementia who are unable to verbalize their symptoms?
2. Can the use of this tool lead to improvements in the physical, functional and behavioral health of residents with dementia by promoting early diagnosis and treatment of pain?
3. Do residents with Alzheimer's disease respond differently to pain assessment and treatment when compared to residents with other forms of dementia?

II. The project was undertaken in response to a request for proposals by the Department of Health in the area of pain assessment and management. The pain assessment tool developed and validated represents a new intervention. Many pain assessment scales exist, although at the time this project was initiated none were proven effective in use with nursing home resident with dementia.

The availability of a pain assessment tool is an essential component of any plan incorporating pain management into routine daily care for residents with dementia. Pain

cannot be optimally managed unless it can be measured. The resident's primary care giver – the certified nursing assistants who work most closely with the resident – must be able to identify a resident who is in pain. If detection is inaccurate at this level, then pain management will be ineffective. The tool produced in our study is appropriate for routine use by certified nursing assistants. The manual produced at the conclusion of this study describes how to use the newly developed pain assessment tool, catalogues pain syndromes and discusses interdisciplinary pharmacologic and non-pharmacologic strategies for pain management in residents with dementia.

An important result of the study was to raise awareness of the need for pain assessment and management in residents with dementia. Education of primary caregivers was provided which included use of the tool, general causes of pain and interventions for management.

The results of the project may assist skilled nursing facilities to comply with governmental regulations. Federal and state agencies require that long-term care facilities have pain assessment and management programs for all of their residents including those with dementia. The medical literature provides little specific effective programs, approaches or protocols on reducing pain and improving function. The use of this newly developed tool may help facilities comply with these regulatory mandates.

The availability of the pain assessment tool will also promote further study to understand the pain experience in residents with Alzheimer's disease. Without the ability to assess pain effectively, these studies will remain inconclusive. In the search for a cure for this devastating disease, the healthcare community needs to understand the full physiological effects of this illness.

The results of this project may aid in the development of comprehensive, state-of-the-art programs and protocols to manage pain in nursing home residents with dementia. It is essential that facilities understand how to best structure the delivery of care by optimizing the use of personnel and building an interdisciplinary system that recognizes the unique contributions made by each member of the health care team. We need to ultimately create a practice setting that offers necessary resources for effective pain management as well as an environment that promotes attitudes and values that are essential for these efforts.

III. The study design was observational and interventional. The project was a collaborative effort involving the Long Island State Veterans Home (LISVH) and the John J. Foley Skilled Nursing Facility (JJF), both located in Suffolk County, New York. The LISVH is a 350-bed state-operated facility caring for veterans of the United States military forces. JJF is a 264-bed skilled nursing facility operated by the Suffolk County Department of Health Services. The study was conducted over a 31-month period between March 1, 2003 and August 31, 2005.

All study participants were required to provide informed and written consent. Because of the nature of our study population, this was provided by surrogate decision-makers in all cases. The study was approved by the Stony Brook University Committee on Research Involving Human Subjects.

Participants were eligible for the study if a diagnosis of dementia was present in the medical record. Participants were not excluded based on type or severity of dementia, age, sex or co-morbid medical conditions. Verbal and non-verbal participants were included. LISVH participants were enrolled from all units in the facility, including a 55-

bed dementia unit. John J. Foley participants were primarily drawn from the facility's dementia unit.

The study was divided into Phase I and Phase II components. Phase I began in January 2004 and ended in July 2004. Phase II began in October 2004 and ended in April 2005. Enrollment of participants began prior to January 2004 and ceased in June 2004. Phase I utilized the "Observational Pain Assessment Tool for Dementia Residents" (attachment 1) and the "Clinical Data Form" (attachment 2). The pain assessment tool was designed for use by certified nursing assistants, nurses and other direct care providers. This tool was developed after a review of available literature and with the input of direct care staff. Direct care staff received instruction on the use of the tool prior to study initiation. The clinical data tool was solely used by study investigators. The tool was designed to collect basic demographic data and resident-related information that would serve as our pain "gold standard".

After statistical analysis, Phase II utilized the modified "Observational Pain Assessment Tool for Dementia Residents" (attachment 3) and the "Minimum Data Set (MDS) Tool for Dementia Residents" (attachment 4). The modified pain assessment tool was composed of statistically significant elements from the Phase I tool and was designed for use by direct care staff. Direct care staff were instructed on the use of the tool prior to initiation of Phase II. The MDS tool contained elements related to resident function, quality of life and other factors. This tool was utilized solely by study investigators.

During Phase I, direct care staff was instructed to use the pain assessment tool twice daily, once during the day shift and again on the evening shift for the six-month

duration of Phase I. Clinical data forms were completed by study investigators once during the Phase I period.

Direct care staff were instructed to use the modified pain assessment tool weekly or when a resident appeared to be in pain during Phase II. The MDS tool was completed by study investigators prior to and at the completion of Phase II.

Data was entered into an ACCESS database and exported to SAS v.8 (SAS Institute Inc., Cary NC) for analysis with PROC FREQ and PROC GENMOD. The associations between each item on the Phase I pain assessment tool and an objective indicator of pain from the clinical data form were determined with odds ratios and statistical significance (p-values) obtained from GEE (Lang & Zeger, 1986) using an exchangeable correlation matrix to accommodate the repeated measurements for the same subjects across time.

The Phase I pain assessment tool was comprised of 41 items (i) divided into 5 domains: Facial Expression (i=9), Behavior (i=8), Mood (i=6), Body Language (i=9), and Activity Level (i=9). To determine the association of each item with pain, an objective indicator (yes/no) of pain was constructed based on the presence of one or more of the following criteria: past medical history of pain-related illness, diagnosis of arthritis, neuropathy, vascular insufficiency, cancer, pressure ulcer, fracture, and past use of pain analgesics such as acetaminophen, NSAID, opioid, topical anesthetic, COX-2 inhibitor and other pain medication. A decision criteria of $p < 0.05$ and $OR > 1.5$ was used to retain items for the Phase II pain assessment scale.

Phase II statistical analysis was conducted utilizing the McNemar test (Conover, 1980) for MDS items with 2 categories and the Bowker's test for symmetry

(Bowker, 1948) for items with more than 2 categories (both tests available in the FREQ procedure in SAS). All items contained in the Phase II MDS tool were analyzed for change over the six-month study period. An Alzheimer's disease sub-group was identified from the clinical data form and analyzed separately.

IV. Of the 182 Phase I participants, 142 were enrolled from LISVH and 40 from JJF. Phase II began with 144 participants, 110 enrolled from LISVH and 34 from JJF. 105 participants completed Phase II of the study (Figure 1.).

The characteristics of the 182 study participants are summarized in Table 1. The mean age of the enrollees was 81 years with a male/female ratio of 2.5 to 1.0. 31 (24%) of the participants (data on 129 residents) had a GDS score significant for depression **(**≥ 6/15**)** and 71 (41%) of the enrollees (data on 172 residents) had a diagnosis of Alzheimer's disease exclusively. The participants were moderate to severely cognitively and functionally impaired with 143 (88%) scoring 20 or less on the MMSE (data on 162 residents) and 165 (92%) dependent in 2 or more ADL's (data on 180 residents).

Phase I data are summarized in Table 2. A total of 22,689 pain assessments were administered during the study period and 70 were excluded from the analysis because more than one item was scored for a category. Administrations ranged from as little as one to as many as 264 per participant. Items were considered statistically significant if a p-value of < 0.05 and odds ratio > 1.5 was achieved. For items statistically significant for the absence of pain, an odds ratio < 1.0 was achieved. JJF participants had acetaminophen excluded from the analysis.

Phase I data was analyzed to determine if day or evening shift observations differed significantly related to the 41 items on the pain assessment tool. No statistically significant differences between day and evening observations were found.

Phase II data are summarized in Table 3. In all, 2,527 assessments were analyzed for 105 participants completing the study period. 1,744 (69%) assessments were administered on the day shift, 758 (30%) on the evening shift, and 25 (1%) on the night shift. Symmetry analysis to determine change did not reach statistical significance for 24 of 26 items. Item "sad facial expressions" (p 0.0029) showed statistically significant improvement while item "transfer" (p 0.0471) showed deterioration during the Phase II period. The Phase II Alzheimer's disease subgroup analysis failed to reveal any statistically significant change for all items during the study period (data available on 39 residents).

Phase II analysis also revealed information related to a numerical pain score (Table 4) and direct care staff intervention (Table 5) when pain was detected. Using a pain score of ≥ 1 as the threshold, 719 (29%) assessments indicated the presence of pain and required evaluation. 1,793 (71%) assessments (score of 0) indicated the absence of pain and further evaluation was not required. Of the 719 assessments at or above the numerical pain threshold, 612 pain evaluations were performed. In over three-quarters (76%) of these evaluations, the CNA solely took action. 132 (22%) of the assessments required CNA/nurse or nurse intervention. Intervention rarely involved direct notification of the medical staff member by the CNA.

V. This study was a collaborative effort between two Suffolk County skilled nursing facilities and included an initial study population of 182 residents. A pain assessment

tool for dementia residents was developed and validated during the course of the project. This tool was developed through review of the existing literature and with the input of the direct care providers (primarily CNA's) who would perform the assessments. The pain assessment tool was easy-to-use, took only minutes to perform, required minimal training and was not administered by study investigators. The large number of assessments and participants in the study strengthened the statistically significant findings used to develop the final tool.

During the study period, CNA's were instructed about observing residents for pain. This led to prompt detection of pain and the multiple assessments reinforced the observation for pain as part of their daily routine. The communication between CNA's and licensed staff was strengthened and the CNA's role as a key player in the interdisciplinary team was greatly enhanced. As a result of this study, direct care providers were empowered to break the barriers of pain alleviation in residents with dementia.

The study had a number of limitations and barriers. Lack of a control group impacted statistical analysis. With the assistance of the General Clinical Research Center's (GCRC) biostatisticial staff, models were developed to overcome this obstacle. Although the initial study group was fairly large, the dropout rate was substantial

Of the initial 182 enrollees, 105 participants completed the full study for a dropout rate of 42%. The majority of dropouts were as a result of resident death during the 31-month study period. The informed and written consent process was cumbersome. In all cases, surrogates were required to authorize consent for the residents enrolled. This often led to multiple telephone calls, numerous mailings, faxes and other delays that

significantly hampered the consent process. When undertaking research projects in a frail, elderly nursing home population these obstacles are often unavoidable and inherent to the process. A shorter study period and/or less complicated consent process may better serve research studies in the nursing home setting.

The study lacked a reliable pain "gold standard". Investigators found difficulty developing this benchmark in the absence of an objective indicator of pain, i.e., blood test, diagnostic study, etc. The clinical data form provided the best available standard and was based on clinical information from the medical record. The subjectivity of pain investigation applied to the direct care providers' assessment of pain as well. The observer-to-observer variation is much greater for a study of this kind but the extremely large numbers of assessments might mitigate some of this effect.

VI. There were 3 major research questions addressed in this study. The first question was directed to the development of a pain assessment tool for dementia residents. This study clearly demonstrated that an easy-to-use, uncomplicated pain assessment tool could be developed. The tool was accepted by direct care providers and extremely useful as an observational instrument for residents with dementia. This study not only successfully developed a tool, but statistically validated its content using a novel pain standard. In addition, use of the instrument empowered the direct care providers to detect pain early and on a regular basis for the residents under their care.

The question related to residents' clinical improvement with use of the pain assessment tool remains unanswered. Study investigators were unable to demonstrate improvement in the areas of physical function, behavior and quality of life. The study group was moderately to severely functionally and cognitively impaired at baseline and

therefore small but statistically insignificant improvements may have been difficult to uncover. In addition, the Phase II six-month study period may have been too short to determine any effect. A majority of participants were below the threshold for depression (76%) and therefore a potentially reversible pain etiology was not prevalent. Since pain is only a single factor in a nursing home resident's physical function and quality of life, a reliable pain assessment tool may be ineffective in leading to significant clinical improvements. Because of significant co-morbid medical illnesses, decline in function and quality of life is often unavoidable despite optimal pain assessment and management strategies. Further study is required to determine if this validated pain assessment tool is effective in improving resident function and quality of life.

Finally, in a subgroup analysis of residents with Alzheimer's dementia, the study was unable to demonstrate a positive impact on function and quality of life with use of the pain assessment tool. The same reasons for demonstrating lack of positive effect in other nursing home residents apply to residents with Alzheimer's dementia. The small number of Alzheimer's residents studied (31) may also have led to insignificant statistical results.

The study findings will be presented at the New York Medical Directors Association Fall Educational Symposium on November 11, 2005. Presentations will be made to the staff at both the Long Island State Veterans Home and John J. Foley Skilled Nursing Facility. Dissemination of study results at the Greater New York Hospital Association Continuing Care Leadership Coalition (CCLC), New York Association of Home Services for the Aging or American Geriatrics Society conferences will be considered.

Submission for publication to a medical journal such as the Journal of the American Geriatrics Society or Annuals of Long Term Care is a long-term objective as well.

Figure 1. Flow diagram of study

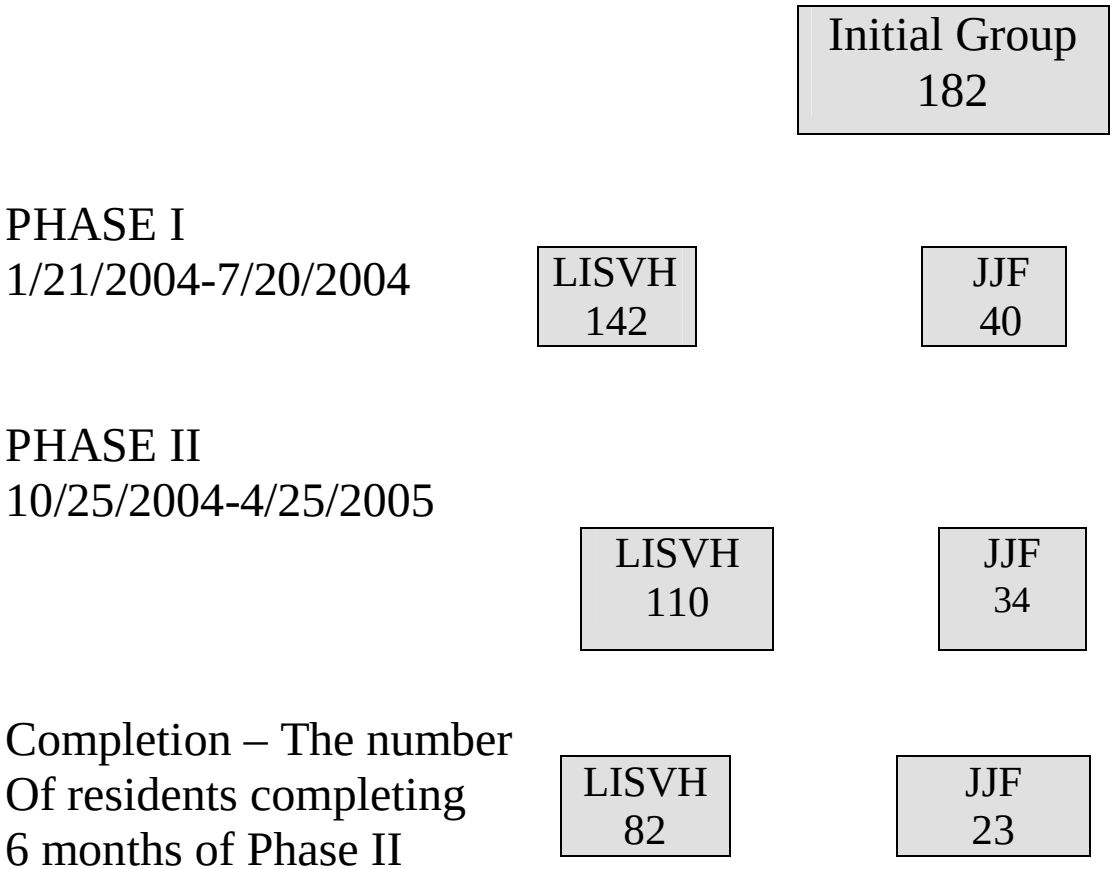

Table 1. Characteristics of study participants

- 182 from both facilities
  - Sex: 130 male, 52 female
  - Age: Mean 81 years [54-95 years]

  - GDS: Data on 129 residents
    - § 31 (24%) scored ≥ 6/15

  - MMSE: Data on 162 residents
    - § 76 (46.9%) scored 0-9/30
    - § 67 (41.4%) scored 10-20/30
    - § 19 (11.4%) scored ≥ 21/30

  - Dementia Type: Data on 172 residents
    - § 71 (41%) Alzheimer's type exclusively

  - ADL's (eating, dressing, bathing, transfer, toileting): Date on 180 residents
    - § 15 (8.3%) scored < 6=1 or less ADL's
    - § 61 (33.9%) scored 7-13 = at least 2 ADL's
    - § 104 (57.8% scored > 14 = at least 4 ADL's

Table 2. Phase I analysis

ITEM	ODDS RATIO	95% CONFIDENCE RATIO	P VALUE
Relaxed	0.77	0.61 – 0.97	0.03
Scared	2.61	1.35 – 5.06	0.0044
Fearful	2.67	1.12 – 4.58	0.0228
Normal	0.83	0.47 – 0.88	0.0059
Calling out	2.69	1.39 – 5.21	0.0033
Moaning	2.94	1.67 – 5.16	0.0002
Pleasant	0.72	0.54 – 0.95	0.0204
Whiny	1.98	1.14 – 3.43	0.0158
Tense	1.69	1.07 – 2.65	0.0238
Rigid	2.53	1.21 – 5.29	0.0139
Moves easily	0.57	0.41 – 0.81	0.0017
Hand wringing	2.27	1.05 – 4.87	0.0364

TABLE 3. PHASE II ANALYSIS - MDS

MDS ITEM	P-VALUE
Unpleasant mood in morning	0.9999
Insomnia/change in usual sleep pattern	0.8013
Sad facial expressions	0.0029 *
Crying, tearful	0.8013
Repetitive physical movements	0.0719
Withdrawal from activities	0.5724
Reduced social interaction	0.8013
Wandering	0.2743
Verbally abusive	0.9659
Physically abusive	0.8494
Socially inappropriate	0.9477
Resists care	0.3107
Transfer	0.0471 *
Locomotion on unit	0.3620
Dressing	0.0880
Eating	0.3620
Toilet use	0.6056
Bathing	0.7717
Pain Frequency	0.1290
Pain Intensity	0.9999
Number of Medications	0.1117
Antipsychotics	0.9999
Antianxiety	0.9999
Antidepressant	0.9999
Hypnotic	0.9999
Overall change in care needs	0.7055

TABLE 4. PHASE II ANALYSIS – PAIN SCORE

SCORE	**NUMBER OF PARTICIPANTS (N=2512)**
0	1,793 (71%)
1	220 (9%)
2	157 (6%)
3	89 (4%)
4	94 (4%)
5	159 (6%)

TABLE 5. PHASE II ANALYSIS – INTERVENTION

INTERVENTION	**NUMBER OF PARTICIPANTS (N=612)**
CNA took action	466 (76%)
CNA took action and nurse notified	73 (12%)
CNA took action, nurse notified and Medical Staff notified	7 (1%)
Nurse notified	59 (10%)
Nurse and Medical Staff notified	3 (< 1%)
Medical Staff notified	4 (< 1%)