Self Reported Pain Diary for Assessment of Chronic Pain in the Communicative, Cognitively Intact Nursing Home Resident

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ABSTRACT

This paper describes a clinical project using a self-reported pain diary for the assessment of chronic pain in the communicative, cognitively-intact nursing home resident. There are estimates of chronic pain among nursing home residents that range from 4 – 83%. The goal of this clinical project was to evaluate a chronic pain diary in relation to its effectiveness and efficiency in accurately assessing pain among nursing home residents. Assessment has been identified as a major barrier in the control of chronic pain, and the self-report is accepted as the most reliable measure of a person’s pain. The self-reported pain diary’s validity and reliability have been demonstrated in acute and chronic pain assessment in the community, and in acute and chronic care. If improved assessment can also be demonstrated in this selected nursing home population, the assumption is that improved pain control will follow.

Data gathered for the study included baseline data of the participating residents’ records, using the facility’s usual protocol for the assessment of chronic pain for 14 days prior to the implementation of the pain diary. That data was then compared to the data collected for 14 to 28 days after completion of the pain diary. Data related to changes in pain levels, nurses’ documentation, and medication usage are reported. A paired t test was used for the data analysis.

Twenty-one residents participated in the project. In reviewing pain levels, only seven of those twenty-one residents had pain levels recorded prior to the diary, and following the use of the diary. Findings related to those pain levels did indicate an increase in the pain levels following the diary’s use, as the literature had predicted they would, when emphasis is placed on pain assessment. The difference in the number of pain-related nursing documentation entries measured before and after the diary approached significance at a p value of 0.067. The increased number of scheduled pain medications used before the diary and after the diary did show
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significance with $p=0.015$. The pain levels, reported before and after the diary, increased, and the use of “as needed” medications also increased. Ultimately, the sample size was too small to provide any statistical significance in three of the four areas studied. The findings, however, do support a multi-site feasibility study using the chronic pain diary.
EXECUTIVE SUMMARY

This paper describes a clinical project to determine the feasibility of using a chronic pain diary for assessing and diminishing pain among nursing home residents. It is the intent of this project to first establish the diary’s feasibility at the pilot-level. If supported by the data, it is suggested that its feasibility then be tested in a larger group where its significance in assessing and managing pain could be more reliably measured.

If the data supports the use of the chronic pain diary in the nursing home population, the project manager has included a comprehensive business plan outlining risk-management, education, and financial programs. Utilizing the Iowa Model for Evidence Based Practice (Titler, Kleiber, Steelman, Rakel, Budreau, Everett, Buckwalter, 2001), the proposed program relies heavily on institutional support, and requires continuous study and planning.

The chronic pain diary evolved when, with the best available evidence, there were estimates of chronic pain that ranged from 4 to 83%, depending on the variables used to assess the pain. With the evidence also supporting assessment issues as major barriers in chronic pain control, the project manager adapted Dr. Karen Dunn’s chronic pain model (Dunn, 2004, 2005) and identified the self-report, when possible, to be the most reliable assessment (American Geriatric Society, 2002).

The diary utilizes the numeric pain scale with word descriptors (no pain, moderate pain, worst pain imaginable), with measurement at rest and with movement. It also contains a body diagram for location(s) of pain, word descriptors for the type of pain, and a free space for resident comments. In this clinical project plan, the project manager obtained consent and was responsible for resident education related to the use of the diary. Finally, the plan outlines a process by which the diary is placed at the resident bedside and collected. The diary is proposed
as an intervention that could ultimately emphasize the presence of chronic pain, with subsequent pain management.

Based upon the literature, in cancer and non-cancer pain, and in acute and chronic pain, the self-reported pain diary has resulted in improved assessment and increased the use of pain medications. This project addresses chronic pain in nursing home residents, a population in which the diary has not yet been tested. The diary’s feasibility in assessing and managing pain in the nursing home population was the focus of this pilot project (Follick, Ahern, and Laser-Wolston, 1984; Hoekstra, Bindels, vanDujin, Schade, 2004; Schumacher, Kořesawa, West, Dodd, Paul, Tripathy, Koo, Miaskowski, 2002).

Veney and Keluzny (1998) identify efficiency, effectiveness, and outcome as the three main measures to identify a project’s success. These measures are utilized to guide the clinical project evaluation process.
INTRODUCTION TO CLINICAL PROJECT

Purpose

The purpose of this clinical project was to design a method for testing the effectiveness and efficiency of a chronic pain diary in assessing and managing pain in a small group of nursing home residents. Based upon the results, methods used could form the basis for a multi-site project. Ultimately, if feasibility is demonstrated, the long-term goal is to implement the diary for use in nursing homes. The mission / vision is improved chronic pain control in the nursing home population, achieved via the self-reported pain diary.

Goals

1. The goal of this clinical project was to assess the effectiveness and efficiency of a self-reported chronic pain diary by measuring nurses’ documentation of pain, participants’ pain levels, and the number of scheduled and as needed (prn) medications taken for each participant.

2. IF effectiveness is demonstrated, the project manager will be able to demonstrate how the self-reported pain diary could be implemented in the chosen facility and how it could be sustained.

3. IF effectiveness is demonstrated, the project manager will be able to demonstrate how the self-reported pain dairy could be implemented in a multi-site project. This project would include a larger number of nursing home residents, of at least 100 participants, so that findings could be more statistically significant.

4. IF effectiveness is demonstrated, the project manager will be able to offer an implementation program that includes a clinical project timeline, as well as budget, communication, risk management, and education plans.
Significance

Chronic pain management is poor. The significance of this clinical project is the provision of an improved assessment tool that is practical and reliable in assessing chronic pain in the communicative, cognitively intact nursing home resident. It is assumed that, with improved assessment, improved pain control will follow. In terms of efficiency, it is proposed that improved pain control, achieved through conventional methods, will decrease the utilization of expensive medications, procedures, and treatments used in clinics for refractory chronic pain.

PROBLEM DESCRIPTION

Problem Definition: Assessment

There are estimates of chronic pain among nursing home residents that range between 4% and 83%. Most studies report a prevalence range of 45 - 83% (Allcock, 2002; Cooner and Amorosi, 1997; Fox, Raina, Jadad, 1999; Teno, Mor, weitzen, Wetle, 2001; Teno, Kabumoto, Wetle, Roy & Mor, 2004; Weiner, Peterson, Ladd, McConnell, Keefe, 1999). It should be noted that the 4% prevalence rate was found when the question asked was related to “daily pain that was at one or more times excruciating in the previous week” (Teeno et al, 2004; p. 762).

Assessment has been identified as the first step in achieving good pain management (AGS, 2002; Horner, Hanson, Wood, Silver, Reynolds, 2005). Assessment of chronic pain has been identified as a major barrier in the recognition of chronic pain. Self-report, when possible, is considered the most reliable measure of pain (AGS, 2002; Wen-Chieh, Lum, Mehr, Kane, 2006). The diary has been demonstrated to be an effective and reliable tool for reporting pain and other symptoms in older persons in the community and in hospice and palliative care (Follick et al, 1984; Hoekstara et al, 2004; Schumacher et al, 2002). The project manager could not find literature indicating that the diary had been tested in the nursing home population.
Population Target Described: Nursing Home Population

According to a 1991 report written by Kemper and Murtaugh, more than 2 million older Americans resided in approximately 17,000 Medicare-certified nursing homes, with 43% adults 65 and over admitted to a nursing home before the end of their lives. In a 2001 report, published by the Centers for Disease Control and Prevention (Sahyoun, Pratt, Lentzner, Dey, Robinson), that profile has been changing somewhat. In 1997, 51% of the elderly nursing home residents were age 85 or older, compared to 45% in 1985. The report states: “trends in nursing home usage suggest that older persons may already be living in the community longer and entering nursing homes later and sicker than before” (p 6).

According to the Agency for Health Care Policy and Research (AHCPR) report on long-term care, more than 70% of nursing and personal care home residents are women, 66% are widowed. Forty percent are demented and about 60% require assistance with multiple activities of daily living.

The communicative, cognitively intact nursing home resident population was chosen because the most commonly used pain assessment scales have been validated in users that are able to communicate and are cognitively intact (Bird, 2003; Herr, K and Mobily, PR, 1993; Manz, BD; Mosier, R; Nusser-Gerlach, MA; Bergstrom, N; Agrawal, S, 2000; Taylor, LJ & Herr, KK, 2003). The project manager did not find a documented record of the self-reported pain diary being studied in the nursing home population.

Clinical Environment Described

Nursing homes are staffed primarily by licensed practical nurses and nurse aides, and have been identified as having a high staff turnover rate. In a recent six-state study, the 1-year turnover rates were 56.4%, 39.7%, and 35.8% for certified nurse aides, licensed practical nurses,
and registered nurses respectively (Castle and Engberg, 2006). The level of care for the residents in these facilities includes skilled, intermediate and personal.

According to recent studies related to the clinical environment of a nursing home, the consequences of staff turnover include increased facility costs, lower job satisfaction of staff, and overall lower resident quality of care (Castle & Engberg, 2006; Caudill & Patrick, 1991; Straker & Atchley, 1999). The results also show that for all caregivers, higher turnover is associated with higher bed counts, low staffing levels, for-profit ownership, and lower quality (Castle & Engberg, 2006; Caudill & Patrick, 1991; Straker & Atchley, 1999).

Where This Population Problem Usually Exists

Chronic pain is defined by the American Geriatric Society (2002) as “...a painful experience that continues for a prolonged period of time that may or may not be associated with a recognizable disease process”. Based upon a literature review, the American Geriatrics Society guidelines, and the latest Cochrane Reviews, a great deal of work remains in almost all aspects of chronic pain management.

Dr. Ferrell’s early work (Ferrel et al 1995) studying the prevalence rate of chronic pain in the nursing home resident, and subsequent research in this area (Allcock, 2002; Cooner et al, 1997; Fox et al, 1999; Teno et al, 2001; Teno et al, 2004; Weiner et al, 1999) places the prevalence rate somewhere between 4% and 83%. This wide range of variability seems to depend on the group studied, their mental status, their demographics (male, female, nationality, age), their stoicism, the wording of the questions asked, the severity of the pain in question, the assessment methods, as well as the methods and biases of the persons reporting, the resident’s willingness to report, and the reasons for research participation. It is this huge gap in the
assessments of chronic pain in the nursing home population that directed this clinical project toward improved assessment in that population.

Interest in pain control mounted throughout the mid 1990s, and in its 2002 report, the American Geriatrics Society concluded that all persons entering the health care system deserved to be professionally assessed for any type of pain (AGS, 2002). Although the issues related to the management of chronic pain and the multiple sources of pain in the elderly, the scope of this clinical project related to chronic pain assessment in the communicative, cognitively intact, nursing home resident (AGS, 2002; Allcock, 2002; Blyth, March, Bernabie, Jorm, Williamson, Cousins, 2001; Ferrell et al, 1995; Ferrell et al, 1999; Kung, Helme & Gibson, 1999; Mantyselka, Kumpusalo, Takala, 2001; Parmelee, Katz, Lawton, 1991).

In an effort to address chronic pain in nursing homes, the US Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS) identified the “percent of residents who have moderate to severe pain” as one of its eight “chronic care-quality measures”, and deserving of national reporting. This chronic pain diary offers a possible improved measure in assessing the presence of chronic pain. As of November, 2004, the national rate for moderate to severe pain in nursing homes was reported as 7%, and in Kentucky nursing homes, 6% (Abt, 2004).

Constraints

Anticipated

The communication and risk management plans are formal analyses (see appendix E) to identify possible risks or barriers to the project’s success. In this clinical project, the sponsors originally identified minimal risks to the residents and to the project’s success. It should be noted, however, that in the process of continuous evaluation, as the project evolved, many other
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barriers were noted. These are addressed in the section on actual constraints / resolution. The stakeholders’ anticipated constraints included:

1. staff might fear additional work, dispensing of additional medications, and additional, more time-consuming record-keeping (stakeholder discussions);
2. staff may not understand the significance of improved assessment (stakeholder discussions);
3. residents may not want to take the time to complete the diaries, or they might forget to do so (stakeholder discussions);
4. residents may be reluctant to participate in research (stakeholder discussions);
5. even if the residents were compliant in completing the diary, and the staff willing to collect it, the information may not be recorded or related to the appropriate persons so that change could be effected (stakeholder discussions); and
6. residents might actually experience increased frustration and mood status changes when more attention is brought to the chronic pain state (Janssen, S; Spinhomven, P; Arntz, A, 2004).

LITERATURE

Review of Evidence / Data Supporting the Existence of the Problem

Difficulties in assessment (Ferrell et al, 1990; Ferrell et al, 1995; Herr, 2002; Parmelee et al, 1993), assessment capabilities of the resident or care provider, and the need for education for all involved in pain control (Engle et al, 2001; Ersek, 2003; Ferrell, 1994; Herr, 2002; Weissman, 2000) have contributed to an overall lack of ability to trust the documented pain record. Assessment is identified as a major barrier in identifying residents in chronic pain. Research consensus is that the most valid report is that of the person in pain, providing that person can communicate the pain (AGS, 2002; Blomqvist & Hallberg, 1999; Bloomqvist, 2002;

Early research study by Follick et al (1984), supported the reliability and validity of a diary in the assessment of chronic pain-ridden patients. Researchers in a cancer-related pain study also found the diary useful in guiding pain assessment, enhancing a sense of control, and making communication easier (Schumacher, Koresawa, West, Dodd, Paul, Tripathy, Koo, Miaskowski, 2002). In three separate pilot studies, reliability, feasibility and compliance were studied in frail, elderly palliative care clients. These researchers also concluded that the diary was a reliable and valid method for monitoring symptoms of patients in the palliative phase of their treatment (Hoekstra et al, 2004).

One of the main advantages of a daily diary is the ability of the resident to report pain at the time the pain is experienced. Other methods of assessment are often carried out in a “single moment” in time, when a health care provider is making rounds or completing a report. Recall-based and retrospective assessments rely on the resident’s memory. Both reconstruction of a pain event and descriptions of the pain may be distorted over time (Roelof, Peters, Patijn, Schouten, Vlaeyen, 2004). A copy of the chronic pain diary may be found in Appendix A.

STAKEHOLDERS

Description / Information Needs of Each Group

The sponsors for this clinical project included faculty on the researcher’s committee: Dr. DB, Dr. JG & Dr. KH. The faculty committee was part of the continuous input-team that guided the clinical project toward success. They required clear definition of the problem and evidence supporting clinical project goals. With this information, they assisted the project manager in identifying problems and offered suggestions that would contribute to the clinical project’s success, based upon their expertise and experience in managing health care changes.
The administrative staff at the facility were key sponsors because they had the ability to make decisions affecting the organization and its commitment to the clinical project. They too required details of the clinical project, rationale, and process, so that they could appropriately adjust each of these components to the needs of their facility. They participated in the record-keeping related to the data collected in the diaries. The budgetary needs were minimal at the clinical project level.

The sponsors required continuous review of the most recent literature pertinent to the problem and its solution, as well as regular updates related to the clinical project’s progress. In supplying this information to the sponsors, support was garnered, and sponsor recommendations allowed the project manager to make continuous adjustments to the process.

The role of pain control is largely a physician-controlled role at this time in Kentucky. Nurse practitioners have recently obtained prescription privileges for controlled substances (LRC, 2006). This emphasizes the importance of involving and gaining the support of the physicians and nurse practitioners involved in the nursing home resident’s plan of care.

The stakeholders for this clinical project included residents, residents’ significant others, nurse aides, nurses, physicians, and physical, speech and occupational therapists, nursing home administrative staff, and the nursing home ombudsman. If the results of this project support further study in a multi-site project, external stakeholders, such as senior citizen groups, American Association for Retired Persons (AARP), and politicians in the community (rural county in Kentucky) would be approached for input, support and feedback. The needs of the stakeholders included understanding of the clinical project goals, and the process, so that they might enable the project manager to better understand the target population’s needs, encourage stakeholder support, anticipate barriers, and garner community support.
The team members for this clinical project included faculty that directly assisted in the accomplishment of the clinical project goal: Dr. DB, advisor and faculty liaison; Dr. JG, mentor; Dr. KH, expert in pain assessment in the elderly, and Dr. AO, expert in clinical project management. These key people were part of the continuous evaluation team offering suggestions and moving the clinical project through completion, and toward success.

Team members on the unit, including JM (education nurse at rural county nursing home), LM (MDS coordinator), staff nurses and nursing assistants, and any significant others that influenced and encouraged the utilization of the self-reported diary, were all part of the team. Problems they identified or solutions they offered, affected clinical project success.

DESIGN OF THE CLINICAL PROJECT

Goal

The goal of this clinical project was to design a method for testing the effectiveness and efficiency of a chronic pain diary on a small group of nursing home residents. Four outcomes were selected to evaluate the effectiveness of the diary. These included participants’ pain levels, number of pain-related nursing documentation entries, and the number of scheduled and as needed (prn) medications taken for each participant, before and after the implementation of the pain diary.

Study Questions / Clinical Project Objectives

The study questions included:

1. What is the difference between pain levels before and after participants’ use of a chronic pain diary?

2. What is the difference in the number of pain-related nursing documentation entries before and after participants’ use of a chronic pain diary?
3. What is the difference in scheduled and as needed (prn) medication usage before and after participants’ use of a chronic pain diary?

Clinical project evaluation objectives addressed the outcomes of the diary, its effectiveness, and its efficiency, and included:

- What is the outcome? Will there be a difference in the staff-reported pain levels, documentation, and medication usage, before and after the diary?
- Is the pain diary effective? Is pain assessed and better treated after the diary?
- Is it efficient? If the results support the use of the pain diary, is it sustainable when budget and staffing issues are considered?

The study assumptions included:

- The pain levels may increase with the utilization of a pain diary.
- Better assessment will result in better pain management.
- Better pain management will include increased use of medications.

Activities/ Components of Clinical Project Design

Clinical Project Design-Description

This clinical project used a quasi-experimental design, assessing the effect of a self-reported pain diary on participants’ pain levels, nurses’ documentation of pain, and scheduled and as needed (prn) medications taken for each participant. Using a paired design, for a before-and-after measurement, the same group of subjects was studied twice, once at baseline (or 14 days prior to the diary) and again, fourteen days following diary utilization (the after-measurement). Each participant, then, was serving as his or her own control. The study covered a six-week period for each resident, two weeks baseline data before the diary, two weeks utilizing the diary, and two weeks data after the completion of the diary.
The Iowa Model of Evidence Based Practice (Titler, 2002) guided the definition of the study problem, as well as a possible solution to the problem. The Iowa model focuses on: continuous review of the best evidence available to define the existence of the problem; analysis of successful, as well as unsuccessful efforts to solve the problem; the utilization of guidelines from national agencies or organizational groups; and specific objectives with action plans and measurable outcomes affecting the population, the staff and the budget. The model is actually an algorithm that sometimes sends the researcher in a different direction, for further research, consultation with experts, or the further definition of scientific principles.

When the best evidence defined: the presence of chronic pain as a major health problem; assessment as a major barrier in identifying chronic pain; the self-report, when possible, to be the most accepted assessment method; and the diary proven reliable as a self-reporting method, the project manager set up a clinical project to determine the feasibility of the using the chronic pain diary in the nursing home population. The activities for this project included the following details:

1. The charts of residents were reviewed before and after the diary, for documentation suggestive of pain.
2. Those charts with positive pain indicators were then reviewed for residents that were cognitively intact and communicative.
3. Residents that met inclusion criteria were asked to consent for study participation.
4. The project manager visited daily to assist with completion / collect diaries from participants.
5. Resident reports of pain were given to staff each day, after diary was completed.
Sample

Selection Procedures of the Participants / Representativeness of the Sample

All nursing home residents whose records documented any indication of pain were considered for inclusion. Race, age, and gender were tracked but did not affect inclusion.

Inclusion / Exclusion criteria

The Minimum Data Set (MDS, record required by CMS for facilities receiving federal funding) was used to identify residents that were cognitively intact (with scores on Section B 4 on the MDS of “0” or “1”) and communicative (with scores on Section C4 on the MDS of 0 or 1).

As stated above, the cognitive status of the residents was determined by their most recent Minimum Data Set (MDS), which is completed quarterly, and with any change in the status of the resident. Section B4 rates the cognitive skills for daily decision-making. A rating of 0 (independent) denotes that decisions are consistent and reasonable; a rating of 1 (modified independence) denotes some difficulty in new situations only. Residents with ratings of 0 and 1 were identified as cognitively intact.

The communicative status was likewise determined by the MDS section C 4, 0 or 1. In the MDS, the rating 0 denotes that the resident makes himself or herself understood, and the rating of 1 denotes that the resident is usually understood. Residents with ratings of 0 and 1 were identified as communicative.

There were no non-English speaking residents in the facility. No resident that met the inclusion criteria was excluded for any reasons, including age, race, or gender.

Recruitment Procedures

Once residents were selected, the residents were approached with an explanation of the clinical project and their choice in participating. It was explained that the clinical project would
take 14 days and that it would require approximately five minutes per day. Participants were told that the project manager was only an assessment person, but that it was hoped that better pain control would come with better assessment.

*Human Subjects Protection*

The consent form is given in the appendix G. The form assured the resident of privacy and of the ability to withdraw from the clinical project at any time. The residents were assured that participation or failure to participate would not preclude them from any privileges for pain assessment that they currently had. Each participant was given a copy of the consent form.

**Methods**

*Procedures / Processes*

For those residents meeting inclusion criteria and agreeing to participate, a diary was placed at their bedsides. The project manager explained that she would be visiting daily to assist in the completion of the diaries, collect the diaries, and attend to any questions or concerns the staff, stakeholders, or residents might have. The step-by-step process for the project manager included:

- Review chart data for indicators of pain: pain entries, pain meds, pain diagnoses, and
- review Minimum Data Set for communicative and cognitive status.

If the resident met inclusion criteria, the research nurse entered the participant’s room, introduced and explained the pain project, and asked for consent. If consent were given, the nurse completed one day’s diary with the participant, left a card-stock copy of the project manager’s name and contact information, a copy of the consent form, and a copy of the diary for the subsequent day.

The project manager then:
• explained that the diary could be completed any time, or when the project manager returned the next day, and that the time of the day should be noted;

• explained that the project manager would not suggest numbers, but would explain that 0 implies “no pain”, “5” implies “moderate pain”, and that “10” is the “worst pain imaginable”;

• explained that there should be a pain level marked for when he / she is moving around;

• explained that there should be a pain level marked for when he / she is resting;

• explained that there can be as many location marks for pain as that person has;

• explained that there should be a mark for every word descriptor that matches the experienced pain;

• explained that there should be an estimate of how many hours that day that he / she experienced pain;

• explained to participant that the diary information would be collected daily by the project manager, and reported to the nurse at the end of each day (only the participant’s exact report was given to the nurse); and

• that this process would be repeated for 14 days.

• Note: Participants were told that the project manager was only an assessment person, but that it was hoped that better pain control would come with better assessment.
Once the population had been selected, baseline levels were determined for participants. The project manager determined each resident’s mean pain level by averaging the resident’s pain rating over the 14 day period preceding the use of the diary, and again for 14 days after its completion. Likewise, nursing entries related to pain and medication usage were reviewed for the 14 days prior to the diary, as well as 14 days following the completion of the diary. Medication usage was subdivided into the number of scheduled and as needed (prn) pain medications ordered.

One of the project manager’s assumptions was that the pain level would actually increase with the self-reported pain diary, and that there would be a subsequent increase in analgesic use. It has been demonstrated in the literature that, when a nursing home improves their pain assessment process, the nursing home may actually report a higher percentage of pain prevalence. This statistic represents an increased awareness, focus, and recognition of pain presence, rather than an actual increase in the resident’s report of pain severity (Cadogan, Schnelle, Al-Sammarrai, Yamamoto-Mitani, Cabrera, Osterweil, Simmons, 2006; Center for Medicare and Medicaid Services Information Sheet, 2005).

The nursing documentation related to pain entries was evaluated for each participant by calculating the number of pain-related entries. A paired t test was used, comparing data 14 days prior to the use of the pain diary, to the data gathered for the 14 days after the completion of the diary. Likewise, mean pain levels were scored for each of the participants before and after the diary, using a paired t test, as well as the number of scheduled and as needed pain medications ordered, before and after the diary, for each of the participants.

Use of Consultants
The consultants for this clinical project included all stakeholders, and especially the team of nurse researchers assisting and advising the project manager, Dr. DB, Dr. JG, and Dr. KH. Clinical project plans and proposals were reviewed by these nurses throughout the clinical project plan. Faculty advisor DB, and statistician KM, were consulted for appropriate statistical analyses.

**Instruments / Validity and Reliability**

The instruments used in the diary are a collection of instruments that have been utilized in pain assessment over the past 20 years. The six sections of the diary are explained below.

The most commonly used pain scales, including the visual analogue scale (VAS), the verbal rating scale (VRS), the numeric rating scale (NRS), the McGill pain questionnaire (MPQ) and the Wong-Baker faces scale, have proven valid and reliable in the communicative, cognitively intact population (Bird, 2003; Herr and Mobily, PR, 1993; Manz et al, 2000; Taylor, & Herr, 2003). Consistency between scores on the five scales was good for those persons with none to moderate cognitive impairment. It should also be noted that repeated explanation has been demonstrated to improve completion rates for all the scales, and that this repetition should be part of the education plan (Closs, Phil, Barr, Briggs, Cash, Seers, 2004).

Only the numeric rating scale (NRS) combined with the Graphic Rating Scale (GRS, descriptor words no pain, moderate pain, worst pain) are used in this diary in an effort to decrease confusion. This scale was chosen because of its universality and the project manager’s ability to use the numbers in quantifying results (Closs et al, 2004; Taylor & Herr, 2003; Wynne, Ling, Remsburg, 2000). It is also the main scale utilized by the nursing home participating in this clinical project.

The scales are given for both rest and activity. On the diary, the resident is also asked how many hours of the day pain is experienced. There is strong evidence suggesting that the
pain duration, along with those factors that aggravate and/or alleviate the pain, should guide the practitioner in the overall management of pain (AGS, 2002; Fink, R, 2000).

The location of the pain has been documented as an important assessment finding in determining the type of pain and its most appropriate management. The location of the pain has also been demonstrated to be a determinant of functional impairment experienced by the aging population (Lichtenstein, Dhanda, Cornell, Escalante, Hazuda, 1998). For these reasons, the location of the pain is also a part of the pain diary.

The word descriptors “achy, heavy, tender, splitting, tiring, exhausting, throbbing, shooting, stabbing, sharp, and cramping” are included in the diary. These descriptors assist the care provider in determining the type of pain the resident is experiencing, and which pharmacotherapy or intervention is most appropriate (AGS, 2002; Blomqvist, & Hallberg, 1999; Fink, 2000; Lichtenstein et al, 1998).

The time of day is given on the diary to determine if the timing of the entry affects the ratings given. The project manager is unsure of its importance. Most elderly complaints of pain involve musculoskeletal problems (AGS, 2002), which often dissipate after the person has been out of bed for 30-60 minutes, and the question arises that the timing of the entry might be pertinent.

The last section of the diary allows the resident to “self-report” any aspect of the pain or how that resident generally feels that day. Dialogue suggestive of depression or interrupted sleep patterns, or functional status may be implied by the resident’s own words. These quality of life issues have been implied in residents that suffer with chronic pain (AGS, 2002; Dunn, 2005; Haefeli and Elfering, 2005). For a sample diary, see appendix A.

Description of Setting and Planned Time Line for the Clinical Project

Rationale for Choice of Setting
The facility chosen was one of two nursing homes interviewed. The first nursing home had been recently sold and the administrator was unsure of the purchasing company’s research policies. The second facility, and the one chosen, had recently received an award for “nursing home of the region”. The administrator and director of nursing at that facility immediately welcomed the opportunity to participate in a pain initiative. The staff and physicians were informed that the research emphasis was on chronic pain assessment.

The nursing home is a 130-bed, not-for-profit facility with an administrator, director, and assistant director of nurses, as well as two nurses serving as MDS coordinators. There is a staff of 25 nurses and 75 nurse-aides. Additionally, there are 23 dietary staff, twelve housekeeping, five maintenance, two social services, six activities directors, and ten therapists (physical, occupational, speech, restorative and respiratory). The turnover rate is approximately fifty percent. The director of nurses does not feel that this estimate is correct and that their method for estimating turnover is inadequate.

*Gantt Chart / Time Line*

This clinical project plan for the self-reported pain diary evolved over a period of one year, after reviewing and grading evidence suggestive of insufficient management of chronic pain in the nursing home population. The plan follows timelines and deadlines as suggested by the Iowa Model for Evidence Based Practice, and may be applied to a multi-site project. There is a Gantt chart describing these timelines in Appendix B.

Resources required to implement the clinical project

Financial outcomes were identified. The system for measurement included budgetary costs as they pertain to increased nursing time in assisting the resident to complete the diary, in-service education time related to the diary, time in making entries as directed by the resident, as well as collection time. Staff nursing time and time spent by the two full time MDS
coordinators, could possibly be reduced if the entries in the nursing notes and MDS record were based upon the daily diary report. At the request of the Internal Review Board, and because of Health Insurance Portability and Accountability Act (HIPAA, 1996) regulations, direct-care personnel were not directly involved in this feasibility project (Internal Review Board communication, February, 2006).

The project manager met with an MDS Coordinator to determine if she thought time would be saved by a chronic pain diary report. She immediately answered that the diary would save her time. There are two registered nurses assigned to the MDS data, for the one-hundred twenty-five residents currently living in the facility (LR, MDS coordinator, Nov 17, 2005).

A plan and process for continuous education of a facility whose staff turnover rate is 50%, was determined to represent the largest cost. It was speculated that this cost could easily be recovered if the diary achieved improved assessment of pain through relatively inexpensive pain medications, with less utilization of the more expensive pain centers and treatments. Literature suggests that pain control would result in decreased loss of functional status and treatment for mood disorders (Dunn, 2004, 2005), decreasing the cost of care for persons with uncontrolled chronic pain.

A detailed budget can be found in Appendix F.

Clinical Project’s Expected Measurable Outcomes

The clinical project’s expected measurable outcomes included a comparison of pain levels, documentation, and medication usage, before and after the use of the chronic pain diary. The entire project covered a six-week period where these variables were reviewed for two weeks prior to the diary, the diary was completed for two weeks, and the variables were then reviewed for the two-week period following the diary. The study questions included:
1. What is the difference between pain levels before and after participants’ use of a chronic pain diary?

2. What is the difference in the number of pain-related nursing documentation entries before and after participants’ use of a chronic pain diary?

3. What is the difference in scheduled and as needed (prn) medication usage before and after participants’ use of a chronic pain diary?

Summary

The focus of this clinical project was to evaluate a chronic pain diary’s effectiveness and efficiency in accurately assessing pain among nursing home residents. The financial, communication, education, and risk-management plans relate to the sustainability and success of this clinical project and any subsequent studies related to the chronic pain diary. If this small-scale feasibility study can integrate each of these plans and identify the strengths, weaknesses, and risks involved, maximizing and minimizing as appropriate, there is much more possibility of a larger feasibility study’s funding and success.

The next step in this process, then, is to involve other researchers to obtain funding for a larger feasibility study, collecting data from a greater number of participants. If a larger feasibility study can demonstrate results that show significance and reliability, the comprehensive business plan (including financial, communication, education and risk-management plans) is in place for a chronic pain diary program.

Assessment has been identified by the American Geriatric Society as the first step in achieving good pain management (AGS, 2002). The goal of this project was to design a method for testing the effectiveness of a chronic pain diary in assessing pain for a small group of nursing home residents.

The Future
It is hoped that the findings of this clinical project will lead to further study of the chronic pain diary. If this data supports its use as an efficient and effective method for assessing chronic pain in the communicative, cognitively-intact nursing home resident, it is suggested that the future diary would be an electronic one at the bedside, one that will compute data, report pain levels to care-providers (independent of direct care staff, except for recording of the resident report), and result in a more efficient, cost effective, and successful pain management plan.

FINDINGS

Results of Analysis by Study Questions, Including Outcomes

Four outcomes were selected to evaluate the effectiveness of the diary. The study questions and results of the t tests calculated on data collected are as follows:

1. What is the difference between pain levels before and after participants’ use of a chronic pain diary?

Outcome:

Pain levels for 14 days prior to pain diary:  M=5.71 (numeric pain scale 0-10)
Pain levels for 14 days following diary:  M=6.29
t=-1.549
p = .172
N=7

It should be noted that, of the 21 participants, only seven participants had pain levels entered any of the 14 days prior to, and following the diary.

2. What is the difference in the number of pain-related nursing documentation entries before and after participants’ use of a chronic pain diary?

Outcome:
Number of pain-related nursing entries 14 days prior to pain diary: \( M=1.95 \)

Number of pain-related nursing entries 14 days following diary: \( M=3.14 \)

\[ t=-1.933 \quad p=.067 \]

\( N=21 \)

3. What is the difference in medication usage before and after participants’ use of a chronic pain diary? As needed medications? Scheduled medications?

Outcome:

as needed (prn) pain medications used 14 days prior to chronic pain diary: \( M=5.33 \)

as needed (prn) pain medications used 14 days following diary: \( M=5.67 \)

\[ t=-.190 \quad p=.851 \]

\( N=21 \)

Outcome:

Scheduled pain medications used 14 days prior to diary: \( M=.86 \)

Scheduled pain medications used 14 days following the diary: \( M=1.48 \)

\[ t=-2.648 \quad p=.015 \]

\( N=21 \)
At the time of the project, the nursing home had 123 residents. Of the 123 residents, 53 met the inclusion criteria. Of those 53 residents, 24 reported chronic pain. Of those 24, one person declined participation, one died, and one left the facility before the project was complete. The remaining 29 residents meeting inclusion criteria denied experiencing chronic pain.

Twenty-one nursing home residents participated in this project. Seventeen of the 21 residents were Caucasian; the remaining four were African American, comprising 81% and 19% respectively. Eighteen women and three men participated, comprising 86% and 14% respectively. The average age of the participants was 74.86 years. According to a 2001 study on trends in nursing homes (Sayhoun et al), the US nursing home population consisted of 75% females, 89% Caucasian, 6% , and the average age 82.6 years. The participants in the study included more females than the national nursing home population might predict, more African Americans, and an average age less than 10 years that of the national average.
Given the results, and the amount of missing data, it is estimated that approximately 100 residents would be needed to test the efficacy of the diary. It is proposed that a larger feasibility study, spanning several nursing homes, be funded and conducted that would yield more reliable and significant findings.

Four outcomes were selected to evaluate the effectiveness of the diary. A number of issues arose in relation to the selection of these outcomes in the event a multi-site project is initiated:

- How can pain levels be appropriately measured when there is no documentation of pain levels over the study period?
- How long should the study continue after the diary’s use, when it is noted that physicians are required to visit every 60 days.
- Should the direct-care personnel (providing personal care and giving medications) assist the participant in completing the daily diary?
- Should the diary be completed daily for one week, and then at different intervals, based upon stability of diary data?
- Is it a reasonable goal that some of the nursing home residents can eventually complete the diary without help?
- Can data be analyzed that examines the relationship between the number of scheduled medications given and the number of as needed medications requested?
- Should side effects such as sedation, nausea and constipation be tracked?
Should practitioners be questioned regarding their attitudes toward pain control and prescribing opioid analgesics?

If residents do not complete the diary, should it be renamed a “screening tool”?

For a complete and detailed summary of the data collection, see appendix H.

Analysis of the Fiscal and System Impacts of the Clinical Project

The fiscal impacts of this project should reflect cost savings related to the decreased personnel time of the nursing staff and MDS coordinators. Direct care personnel would initially have an increased time commitment, both in education/in-servicing, and in time spent recording data on the diary. Time would eventually be recouped as the residents became familiar and comfortable with the diary. The clinical study manager estimated her time in recording to be less than five minutes per resident on any day, and less than one minute once the resident was familiar with the diary. In-servicing costs are addressed in the budget. It should be noted that the medication nurse aides dispensing medications at the facility, already receive education related to pain levels using the numeric scale. The rest of the diary is very simple to use and self-explanatory (appendix A).

The increased cost of pain medicines to Medicare A residents would represent a part of the total cost to the nursing home, but is often recouped by the facility when the MDS report supports increased medication coverage. These residents represent about 16% of the population. Those residents with Health Maintenance Organizations and Passport (comprising approximately 1-2% of this facility’s population) would also represent a direct cost to the nursing home, that cost also recoverable through the MDS report. The remaining 80% of the residents rely on Medicaid with Medicare A and D coverage for medications. The nursing home does not sustain a direct medication cost for these residents (SR, Billing Supervisor, June 1, 2006).
Pain is believed to affect mood, functional status, and quality of life (Dunn, 2001). When each of these factors is negatively effected, the facility is challenged with costs related to depressed mood, behavior modification, and increased personnel time spent related to resident assistance with activities of daily living. The cost of more expensive treatment modalities and pain clinics for refractory chronic pain should also be considered in cost savings.

Evaluation of Issues Related to Changing Systems

Consistent with growing emphasis on patient rights to have pain controlled, several organizations have issued guidelines and recommendations for the assessment and treatment of chronic pain. The American Geriatric Society first issued Clinical Practice Guidelines for pain in 1988 (AGS, 1998). Since that time, the Agency for Health Care Policy and Research (1994), the Federation of State Medical Boards (1998), the American Academy of Pain Medicine (1996), the American Pain Society (1996), the American Bar Association Commission (American Bar Association, 2000), and the Joint Commission for Accreditation for Healthcare Organizations (JCAHO, 1999, 2001) have all issued standards, against which they believe pain assessment and management should be measured.

Assessing pain has become the fifth vital sign. Law suits for failure to assess and treat pain are growing in number. The allegations for which monies have been awarded include failure to monitor and treat pain, pain medications not provided as ordered, and failure to provide the proper dosage of pain medication (Certified Nurse Anesthetist, 2005). In 2001, a California jury decided that a doctor’s failure to treat pain in an elderly cancer patient violated an elder abuse statute. That family was awarded $1.5 million (painlaw.org, retrieved 4/4/06).

In a report by the Centers for Disease Control (CDC, 2004), America is aging, with more Americans living longer and the proportion over age 65 growing rapidly. Improved medical care and prevention efforts have dramatically increased life expectancy, producing a major shift in the
leading causes of death from infectious diseases and acute illnesses, to chronic diseases and
degenerative conditions. It is estimated that the average 75-year-old has three chronic conditions
and uses five prescription drugs. The CDC reports: “Beginning in 2012, nearly 10,000
Americans will turn 65 every day, and by 2030, 20% of the population will have passed their 65th
birthday” (p4).

The health care system is not adequately prepared for the growing numbers of elderly
reported above. The CDC (2004) reports that there are too few health care providers specifically
trained in geriatrics, and that there is a gap between what is known and what is needed to be
known. Systems should be in place that address: funding for geriatric training, methods for
incorporating research into practice, adoption of new change methods, the support of
professional organizations in affecting change, and recruiting practitioners into gerontology.

Attitudes, Values, and Beliefs

It is estimated that 90% of pain can be adequately managed (McCaffery and Pasero,
1999). McCaffery and Pasero identify the problems that exist in pain management to involve
three main areas: the healthcare system, health professionals and patients. McCaffery and
Pasero explain that cultural contexts influence professionals and the way they diagnose and treat
pain. Problems in the system occur when the health professional lacks knowledge and skill, and
when their attitudes and values do not support pain management. Patients contribute to the
problem due to their fear of addiction, and lack of knowledge related to pain management.

Objectivity is another issue related to pain assessment. The Western culture has
demanded that objective parameters be used to measure pain, despite the fact that chronic pain is
not necessarily accompanied by physiological evidence. Practitioners have difficulty
understanding and accepting a patient’s report of pain when their behavior does not
communicate the presence of pain (McCahon, Strong, Sharry, Cramond, 2005; AGS, 2002;
McCaffery and Pasero, 1999; Turner and Clancy, 1986). Likewise, the literature supports the fact that pain is treated differently when a physiological cause can be identified (Halfens, Evers, Abu-Saad, 1990).

**Actual Constraints / Resolution**

The issues listed below include some of the anticipated constraints, with comments regarding their actual effect on the project outcome. Other issues emerged as the project manager worked through the project. Proposed resolutions are given.

1. Direct care personnel may be reluctant to have an additional task, requiring additional time. There was no evidence that this anticipated constraint occurred. All personnel appeared to be willing to treat pain according to resident needs.

2. Treatment complications such as increased sedation level and decreased mental status might result from opioid analgesics (AGS, 2002).

   There were no reported or documented cases of increased sedation or decreased mental status from medication changes.

3. Other side effects such as nausea, constipation, and gastrointestinal problems are associated with the treatment of chronic pain (AGS, 2002).

   Constipation was an identified problem.

   Solution: Bowel protocol will be established for any addition or increase of opioid analgesia.

   Gastrointestinal (GI) irritation / nausea – actual problem.

   Solution: GI protocol will be established for any addition of non-steroidal or steroidal anti-inflammatory agent.

4. Care givers may be reluctant to believe resident report of pain (AGS, 2002; Cadogan et al, 2006; McCahon et al, 2005).
Reluctance was actually reported by several staff members, and physicians, especially in residents that had documented behavior problems, or who appeared to be active, out of bed, and participating in activities (BM, March, 2006).

Solution: Review literature and reports related to believing and trusting the patient report.

5. Nurses may be reluctant to believe pain diary recorded by nurse aides (BM, conversation at facility, May, 2006)

After the fourteen-day diary was completed, several nurses agreed that they may be reluctant to accept the diary reports that are completed by the residents via the nurse aid’s recording.

Solution: Facilitate a discussion regarding nurses’ need to address problems with nurse aides whose reports they do not trust.

6. Care providers may be reluctant to prescribe scheduled and controlled substances (AGS, 2002; Cramer, Galer, Mendelson, Thompson, 2000).

There was no evidence that prescribers were reluctant to order controlled substances.

7. Resident may be reluctant to take prescribed medications.

Several residents reported reluctance to ask for and take as needed or prn medications. Literature also supports the “silent sufferers” (Watkins, Wollan, Melton III, Yawn, 2006).

Solution: Educate prescribers regarding the value and preference of scheduled medications as well as the residents’ reluctance to ask for medications that are “not ordered” for them (AGS, 2002); and

8. Health care provider may fail to use alternative pain therapies when more appropriate than medications (Baier, et al, 2004; Barry, Kerns, Duong, Iannone, Reid, 2004;
There were several residents whose pain appeared to be pain-related to sources other than musculoskeletal or neuropathic pathologies, such as abdominal cramping, strained muscles, and depression.

Solution: Record resident report exactly as stated, allowing prescriber to analyze cause of pain and appropriate management. Facilitate discussions related to alternative therapies, such as physical therapy exercises, heat and cold appliances, massage.

9. Some nurses are not comfortable with approaching the provider for a change in pain therapy (BM, conversation, March 2006).

Solution: Nurses and practitioners, as pain champions, should be asked to respond to the pain assessment. Possibly, technology could assist in the transfer of the diary information to the provider directly.

10. When the original clinical project was conceived, the project manager thought that many of the residents would complete the diary themselves. In reality, that never happened. Each resident waited for the manager to ask the questions. The reason for the residents’ failure to record on the diary is unknown. It is speculated that possibly the resident enjoyed the interaction of completing the diary with the project manager. If this program were implemented in a nursing home, the nurse aids would be assisting the residents in recording the resident reports. Discussion should occur regarding data from these reports as they are incorporated into the chart document.
Analysis of Impact of Technology on Problem

The electronic diary has been demonstrated to be a “valid and feasible method for documenting patients’ pain perception” (Gaertner, Elsner, Pollmann-Dahmen, 2004, p 259). In this 2004 study, a paper pain diary and electronic diary were compared. The patient satisfaction was higher for the electronic diary, but there were higher numbers of missing values in the electronic data. However, there was no significant difference between the two diaries in assessing the documented pain and symptom intensity. Their sample included patients with cancer and non-cancer related pain.

In another study, a group of physicians treating patients experiencing chronic low back pain, utilized an electronic diary to record episodes of pain, pain intensity and reactions to pain. The data was transferred to a personal computer. Compliance in completing the diaries was approximately 76% (Roelofs et al, 2004).

These examples demonstrate the ease in which pain-related data could be sent directly to the provider managing the pain, resolving issues of communication from a specific facility. The diaries in both studies listed above, however, were used in samples where the ages of the participants were younger than that of the average nursing home resident. Based upon the results of this small project, the entry of data registering the resident’s report, would most likely be in the hands of the direct care personnel.

EVALUATION OF CLINICAL PROJECT

Questions or Objectives Addressed by the Clinical Project

Four outcomes were studied to test the effectiveness of the pain diary in this small group of nursing home residents. The study questions are given below with explanatory remarks related to the data interpretation.
1. What is the difference between pain levels before and after participants’ use of a chronic pain diary? Although not statistically significant due to the small number of participants, the pain levels did increase as the literature suggested they would, once a facility focused on the presence of pain. More important than the trend in the data, is the fact that only 7 of the 21 participants reporting pain, had any pain levels noted for both the periods preceding and following the use of the pain diary. It should also be noted that the mean pain level before the diary for those seven was 5.71, and 6.29 after the diary was completed.

2. What is the difference in the number of pain-related nursing documentation entries before and after participants’ use of a chronic pain diary? Although not statistically significant, the finding did approach significance at p=0.067. The number of pain-related nursing documentations increased from a mean of 1.95 entries per resident to a mean of 3.14 entries per resident.

3. What is the difference in scheduled and prn medication usage before and after participants’ use of a chronic pain diary?

   The mean number of as needed (prn) medications per resident increased from 5.33 medications before the diary to 5.67 following the diary. It should be noted that an expected result would be a decrease in as needed or prn medications, as there is an increase in scheduled medications.

   The mean number of scheduled medications per resident increased from 0.86 per resident to 1.48 per resident. This result had a p value of 0.015.

   It should be noted that the prevalence rate for moderate to severe pain reported for the participating nursing home was 0%, that of Kentucky as 6%, and that of the nation as 7%. Of the 123 residents in the nursing home at the time of the study, the 21 participants
reported chronic pain at this facility, with mean pain levels of 5.71, representing 17% of the population. According to a Twycross, Harcourt, and Bergl survey (1996), pain scores of four to five were found to “affect a patient’s daily functioning”, and scores of six to seven were found to “interfere with enjoyment of life”.

It should be further noted that this number of 21 participating residents, in a facility of 123 residents, does not include those that did not want to participate in the project, nor those that did not meet the inclusion criteria. Additionally, it does not include those persons referred to in the literature as “silent sufferers”, persons who suffer silently, without reporting the pain (Watkins, Woolan, Melton, Yawn, 2006).

Questions that Could Not be Addressed (Limitations, Delimitations)

- This project studied pain medications. In many of the cases, it was apparent that alternative methods of pain control would have been preferred. For example, one lady’s report described classic symptoms of irritable bowel syndrome, and responded well to anti-gas medication. Another lady’s report described muscle fatigue from operating a wheel chair, and would most likely have benefited from physical therapy and strength training. The physician for one resident stated that the pain rating was related to the resident’s behavior disorder, and may have benefited from a change in medication directed at the behavior.

- The project manager is a nurse practitioner that has worked with palliative care for twenty years. The staff may respond differently to diaries from a palliative care nurse than they would to a diary reported by a nurse’s aide, despite the fact that the diary is the resident’s self report.
It is possible that JCAHO’s new initiative on pain influenced the nursing home administration to be more responsive to the pain diary than the administrators would normally be (JCAHO, 2001).

Reflections on the Creative Approach (Pros / Cons)

The beauty of the self-reported diary used in this clinical project is its simplicity. The diary addresses many of the main factors necessary to identify the sites and causes of pain, their duration, and their relation to movement. Yet the person completing the diary does not require any medical education to assist another in completing it. This is an important issue since, in the nursing home arena, it is often a nurse aide delivering direct care at the bedside. Under the nurse practice act in Kentucky (LRC, 2006), a nurse aide is not allowed to assess the client.

In reviewing the diary and its parts, what is obviously missing are the factors that aggravate and relieve the pain. There is also no place to note when the pain medication was last received, if it worked, and how the pain was leveled before and after the medication (AGS, 2002; Baier et al, 2004; Shaw, 2006).

The diary is also missing a system by which the health care provider directly receives the information. In the current proposed paper and pen system, the nurse aide records the resident’s self report. This report is then transcribed onto a graphic sheet with other vital information and reported to the nurse. The nurse must then report the information to the health care provider, or that provider could access the information on the transcribed graphic sheet of the resident chart (BM conversation, March, 2006).

If e-health were universally available, the resident record and the provider’s information would be contained within one system. The resident’s report would be unmistakable and immediately available to the health care provider, as demonstrated by several studies using an
electronic diary in reporting pain data (Gaertner, Elsner, Pollmann-Dahmen, Radbruch, Sabatowski, 2004; Roelofs et al, 2004; Aaron, Mancl, Turner, Sawchuk, Klein, 2004).

Reflections on the Evaluation Study Process ( Appropriateness to Problem / Questions)

The evaluation study process was effective at evaluating some of the effects of the pain diary, but certainly not all. The process evaluated pain levels, nurse documentation, and medication usage, two weeks prior to the diary’s use, and two weeks following the diary’s use. The diary itself was in place for two weeks, making the study period six weeks in all. It would yield very helpful information to re-evaluate resident pain levels over a longer period of time, in a timed series, or longitudinal study, for example, every three months (Gibson, Woodbury, Hay, Bol, 2005; Veney and Kaluzny, 1998).

As noted earlier in this report, all pain is not best treated by analgesics. For this reason, it would have been helpful to also study non-analgesic medication interventions, such as physical therapy, hot and cold applications, psycho-therapy, distraction, and behavior modification (AGS, 2002; Baier, et al, 2004; Barry, Kerns, Duong, Iannone, Reid, 2004; Cramer, Galer, Mendelson, Thompson, 2000; Gallagher, 2005; Guzman, Esmail, Karjalainen, Malmivaara, Irvin, Bombardier, 2004; Llewellyn-Jones et al, 2003).

Reflections on a Multi-site Project

At the onset of the project proposal, it was not anticipated that so few residents would have pain level entries for a full two-week period. Because the findings indicated that only seven of the 21 participants had pain level entries both before and after the diary, comparison of pain level changes after the diary was impossible for 66% of the participants. In order to gain more meaningful results, a multi-site project is proposed, with a minimum of 100 participants.

Reflections on Resolution of Constraints
Staff turnover and budget were identified as actual problems. The education plan and budget addresses these issues. The budget is given in appendix F, and the education plan in Appendix C. Communication and risk management plans follow in appendices D and E. These plans are aimed at addressing the barriers identified as anticipated constraints.

The project manager has proposed to the nursing home that she would like to initiate the diary as part of their assessment protocol. If the facility agrees, it is suggested that internal and external stakeholders, including physician champions, be consulted on the process and protocol. Educational programs that are repeated on a regular basis have been found to improve assessment and subsequent pain control (AGS, 2002; Weissman, 2000).

It is suggested that a regular program be offered at each orientation, with experienced staff present to participate in the discussion. The program would include Joint Commission’s guidelines on the management of pain in the nursing home resident, the Patient’s bill of rights as they relate to pain (Twycross, Harcourt, and Bergl survey, 1996), the diary itself, and pertinent findings related to pain control, pain medications, and alternative therapies. Changing the tool to make it better will be a point of emphasis, and of ongoing importance. Methods of data transmittal will also be determined.

Conclusions

*Broad Summative Statements*

*Relate to Evidence and Data Supporting the Existence of the Problem*

The data collected in this small clinical project lends limited credibility to the use of a chronic pain diary in assessing pain in the nursing home population. The data demonstrates, that with some modifications, a multi-site study would be feasible.

*Recommendations*
Recommendations include further study of the pain diary in a multi-site project with a minimum of 100 participants. Pain level entries before and after the pain diary were found in only 7 of the 21 participants. If pain levels are used to evaluate pain and response to pain management, sufficient numbers of participants will be needed if this facility’s pain level entries represent typical entries at other nursing homes around the country. If the results of a multi-site project support the use of a chronic pain diary as an effective and efficient assessment method, the long term recommendation is the implementation of a chronic pain diary program for assessment of pain in the communicative, cognitively intact, nursing home resident.
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ACKNOWLEDGEMENTS

My husband and children

My mentors

My friends
Appendix A:  Self-reported pain diary /Date:        Time:__

How badly does it hurt when you are resting? Circle a number.

<table>
<thead>
<tr>
<th>No pain</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
</table>

How badly does it hurt when you are moving? Circle a number.

<table>
<thead>
<tr>
<th>No pain</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
</table>

Mark each spot where you hurt with an ‘X’

How does your pain feel?
Mark as many as you like.

- _____Achy
- _____Heavy
- _____Tender
- _____Splitting
- _____Tiring
- _____Exhausting
- _____Throbbing
- _____Shooting
- _____Stabbing
- _____Sharp
- _____Cramping

How many hours of the day are you in pain?____________

Describe below how you are feeling today:

__________________________________________
## Appendix C

<table>
<thead>
<tr>
<th>Task</th>
<th>Description</th>
<th>Months</th>
<th>Jan</th>
<th>Feb</th>
<th>Mar</th>
<th>Apr</th>
<th>May</th>
<th>June</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td><strong>Clinical project Questions:</strong></td>
<td></td>
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<tr>
<td></td>
<td>What is the difference between pain levels before and after the use of a chronic pain diary?</td>
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<tr>
<td>1.1</td>
<td>What is the difference in the nursing documentation before and after participants’ use of the chronic pain diary?</td>
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<tr>
<td>1.2</td>
<td>What is the difference in medication usage before and after participants’ use of the chronic pain diary?</td>
<td></td>
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<tr>
<td>2</td>
<td><strong>Development of Methodology</strong></td>
<td></td>
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<tr>
<td></td>
<td><strong>Responsible:</strong> Project manager</td>
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<tr>
<td>2.1</td>
<td>Complete work on diary and process</td>
<td></td>
<td></td>
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<tr>
<td>2.2</td>
<td>Evaluation of implementation plan</td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>2.3</td>
<td>Sponsor input / evaluation</td>
<td></td>
<td></td>
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<tr>
<td>3</td>
<td><strong>Operational Supports</strong></td>
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<tr>
<td>3.1</td>
<td>Internal Review Board Date / Approval</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>3.2</td>
<td>Educational program complete for staff</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>3.3</td>
<td>Completed final copy of diaries printed</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td>3.4</td>
<td>Baseline data established for participants</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Contact information printed for staff / residents</td>
<td></td>
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<tr>
<td>3.5</td>
<td>Reminder 'placards' printed for staff / residents</td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td>3.6</td>
<td>Sponsor / stakeholder / team input</td>
<td></td>
<td></td>
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<td></td>
<td></td>
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<td>3.7</td>
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<tr>
<td>4</td>
<td><strong>Clinical project at selected facility</strong></td>
<td></td>
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<tr>
<td>4.1</td>
<td>Selection of inclusion population</td>
<td></td>
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<tr>
<td>4.2</td>
<td>Interview / consent of selected population</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
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<tr>
<td>4.3</td>
<td>Self reported diary for two-wk period begins</td>
<td></td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>4.4</td>
<td>Investigator visits facility daily x 2 weeks</td>
<td></td>
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<td></td>
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<tr>
<td>4.5</td>
<td>Collect diaries daily</td>
<td></td>
<td></td>
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<tr>
<td>4.6</td>
<td>Continuous feedback from staff / residents</td>
<td></td>
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<tr>
<td>4.7</td>
<td>Pain levels, nurse notes, meds tracked x 2 wk p diary</td>
<td></td>
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<td>4.8</td>
<td>Continuous feedback from sponsors / stakeholders</td>
<td></td>
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<tr>
<td>5</td>
<td><strong>Clinical project Management and Coordination</strong></td>
<td></td>
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<tr>
<td>5.1</td>
<td>Presence at site / interest in feedback</td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>5.2</td>
<td>Trouble shoot problems / barriers</td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td>5.3</td>
<td>Compare baseline data with data 2 wk after diary</td>
<td></td>
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<tr>
<td>5.4</td>
<td>Determine if diary has support for program status</td>
<td></td>
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<tr>
<td>5.5</td>
<td>Approach facility(ies) with proposed business plan</td>
<td></td>
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<tr>
<td>6</td>
<td><strong>Milestones and Deliverables</strong></td>
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<tr>
<td>6.1</td>
<td>Guideline for methodology</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>6.2</td>
<td>Clinical project complete</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>6.3</td>
<td>Business Plan for ‘program’</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>6.4</td>
<td>Program Status (if clinical project indicates)</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>6.5</td>
<td>Final Report of clinical project</td>
<td></td>
<td></td>
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</tbody>
</table>
**Education Plan:**
(to be utilized if the pilot study demonstrates feasibility)

TO: Nursing Home Staff member (nurses’ assistants, nurses, physical therapists, speech therapists, physicians):

My name is Kathy Hager. I am a project manager working on a clinical project aimed at helping caregivers assess chronic pain in communicative, cognitively-intact nursing home resident. The clinical project involves the use of a personal pain diary (attached) to be used only by the resident. The resident may ask the staff member to make an entry, but the entry should only include words used directly by the resident. Daily entries should be made, and the diary data will be entered on the resident graphic record.

Background information on my clinical project:

- Chronic pain is defined by the American Geriatric Society (AGS) as a “painful experience that continues for a prolonged period of time that may or may not be associated with a recognizable disease process” (AGS, 2002).

- There are estimates of chronic pain prevalence in the nursing home resident that range from 4% to 83%. This wide range of variability seems to depend on the group studied, their mental status, their demographics (male, female, nationality, age), their level of pain severity, their stoicism, assessment methods, as well as the methods and biases of the person reporting, the resident’s willingness to report, and reasons for research participation (Ferrell et al 1995; Cooner et al, 1997; Weiner et al, 1999; Fox et al, 1999; Teno et al, 2001; Allcock, 2002; Teno et al, 2004).

- Assessment is identified as a major barrier in identifying residents in chronic pain. Research consensus is that the most valid report is that of the person in pain, providing that person can communicate the pain (Ferrrell, 1995; Ersek, 1999; Weissman, 2000;
The reliability and validity, as well as the feasibility and accuracy of the self reported pain diary, has been tested in persons with cancer and non-cancer related pain. In each case, the use of the diary has been supported, providing the person is able to communicate. Age has not been a factor (Follick et al, 1984; Schumacher et al, 2002; Hoekstara et al, 2004; Van Ganse et al, 2004).

The numeric rating scale (NRS) is used in this diary to decrease confusion. Many other scales have been validated and found to be reliable in identifying pain in the communicative resident. This scale was chosen because of its universality and its ability to quantify the results in numbers (Wynne et al, 2000; Taylor & Herr, 2003; Closs et al, 2004). In reviewing your pain assessment notes, it is noted that most of you at the nursing home use this method in assessing pain in the resident that is able to communicate.

Note: case studies of residents in the facilities, questions, answers.

- Discuss patients’ bill of rights as they pertain to pain.
- Discuss Joint Commission’s guidelines for chronic pain.
- Discuss litigation surrounding failure to control chronic pain.
- Discuss provider hesitance in prescribing controlled substances.
- Discuss importance of believing the resident’s report of pain.

Appendix D: Communication Plan for a Chronic Pain Diary Program
(to be utilized if the clinical project demonstrates feasibility).

A communication plan addresses who receives what information, how, and when. This is an essential element of the project plan as it establishes the expectations for what documents and work products the stakeholders can expect to receive and when they can expect to receive them.

Our goal in communicating about the clinical project is to:

- establish and maintain the clinical project credibility by communicating current status to all stakeholders, and to
- generate a common understanding of how the activities of this clinical project will improve the facility’s ability to achieve the goals of chronic pain control.

**Communication Points / Process**

1. Familiarity with diary – through in-service, posted communications in the units, daily presence of project manager for questions / answers. In-services will need to be part of the orientation process for new staff.
2. Nurses and nurse aids are asked to remind residents to complete the pain diary.
3. Nurses and nurse aids are asked to dictate self-reports of residents who are unable to write, or request that the aide record.
4. Understanding of the goal.... better pain assessment.... better pain control.
5. Collection method – simply pick up the diary at the designated frequency (daily) and assist the resident in completion if needed. (Ultimately, in a multi-site project, the diary would be collected, much the same way an I & O sheet is collected, and data transcribed)
6. The project manager will introduce the diary at a staff meeting. Suggestions and questions will be encouraged, and changes discussed, and made.

7. The stakeholders will be asked to identify issues that would impede success of the clinical project.

8. The results of this list and follow-up activities will be posted for the stakeholders.

9. As the clinical project is implemented, it is expected that some changes in the clinical project plan will be necessary. Changes will be communicated via memo.

10. If the clinical project supports a multi-site project, the role of the project manager will be assumed by personnel determined by the stakeholders.

11. The diary sheets will be similar to I & O sheets, and the data transcribed to a graphic. It will later be utilized by the care-provider and MDS coordinator. Electronic entry would be ideal.

12. At the beginning of the program, the project manager will visit daily to answer questions, take suggestions, and make necessary changes. Follow-up may be extended as staff and residents are comfortable with the process.

13. Suggestions for a better process are always welcomed.

Appendix E: Risk Management for Multi-site project / Program

Status (if pilot indicates feasibility)

A meeting will occur BEFORE implementation of the self-reported diary, involving all interested stakeholders, both internal and external, to determine actual physical risks related to the diary, and potential risks to the success of the program.
All stakeholders will be asked to identify possible risks for the residents related to the pain diary.

All stakeholders will be asked to identify possible risks for the project’s success.

The issues on the list will be discussed and follow-up, when necessary, will be communicated via memo.

Actions will be taken to reduce or minimize the identified risks.

Anticipated risks include:

1. Cost of regular in-servicing with high turnover of direct care personnel (approximately 50%).
2. Physician, nurse practitioner, nurse, nurse aide reluctance to believe the resident report.
3. Physician, NP reluctance to prescribe scheduled drugs.
4. Resident hesitance to take prescribed drugs.
5. Side effects of drugs including nausea, itching, confusion and constipation.
6. Risk of increased pain with continuous focus on pain.
**Self-reported pain diary**

**Per:** Nursing Home Administrator: average LPN: $21.00 / average NA: 11.50
There are @ 75 NAs / There are @ 25 nurses
Benefits: 2% $25.20 13.80

**Appendix F: Budget**

<table>
<thead>
<tr>
<th>ID #</th>
<th>EXPENSE ITEMS</th>
<th>Budget</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>E100</td>
<td>Business Unit Expenses</td>
<td></td>
<td></td>
</tr>
<tr>
<td>E101</td>
<td>Use of copier</td>
<td>$0.00</td>
<td>$0.00</td>
</tr>
<tr>
<td>E102</td>
<td>incidental costs.... Facility has agreed to absorb these costs/</td>
<td>$0.00</td>
<td>$0.00</td>
</tr>
<tr>
<td>E200</td>
<td><strong>In-service Education for self-reported diary</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>E201</td>
<td>In-service for staff: Nurse Aids (NAS), RNS, staff: 30 minutes long</td>
<td>907.50</td>
<td>$0.00</td>
</tr>
<tr>
<td></td>
<td>25 LPNs @ $ 25.20=780.00/ hr r // 75NAS @ 13.80/hr = 1,035.00 / 2 (1/2hour)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>E300</td>
<td>Office Supplies/Materials: make sure staff have input / change staff will have autonomy to alter forms as needed</td>
<td>907.50</td>
<td>$0.00</td>
</tr>
<tr>
<td>E301</td>
<td>Printed self reported diary, sequential dates,</td>
<td>$250.00</td>
<td>$0.00</td>
</tr>
<tr>
<td>E302</td>
<td>Printed education sheets for staff / orientation</td>
<td>$50.00</td>
<td>$0.00</td>
</tr>
<tr>
<td>E303</td>
<td>Printed log sheets to transcribe daily pain levels could be adapted to present graphic sheet at no additional costs?</td>
<td>$300.00</td>
<td>$0.00</td>
</tr>
<tr>
<td>E400</td>
<td><strong>Rewards and Recognition</strong></td>
<td>$300.00</td>
<td>$0.00</td>
</tr>
<tr>
<td>E401</td>
<td>Luncheon for staff to thank them in advance: number of staff: 40 x 10.00</td>
<td>$400.00</td>
<td>$0.00</td>
</tr>
<tr>
<td>E402</td>
<td>Luncheon after 3 months to thank them... get feedback:</td>
<td>$400.00</td>
<td></td>
</tr>
<tr>
<td>E500</td>
<td><strong>Internal Labor</strong></td>
<td>$800.00</td>
<td>$0.00</td>
</tr>
<tr>
<td>E501</td>
<td>NA time estimated @ 6 minutes/day/ resident = 0.1 hr x 30 residents x $13.80 / hr x 365 days /// 30 residents = 3 hours of NA time / day x 13.80 / hr x 365 days</td>
<td>15,111.00</td>
<td>$0.00</td>
</tr>
<tr>
<td>E502</td>
<td>Investigator time x 100 hours x $30.00 / hr // Project manager</td>
<td>$3,000.00</td>
<td>$0.00</td>
</tr>
<tr>
<td>E600</td>
<td><strong>Consultants</strong></td>
<td>18,111.50</td>
<td>$0.00</td>
</tr>
<tr>
<td>E601</td>
<td>Electronic palm diaries - determine cost feasibility / trial use</td>
<td>Free trial</td>
<td>$0.00</td>
</tr>
<tr>
<td><strong>Subtotal</strong></td>
<td></td>
<td>$0.00</td>
<td>$0.00</td>
</tr>
<tr>
<td><strong>EXPENSE TOTALS</strong></td>
<td></td>
<td>20,119.00</td>
<td>$0.00</td>
</tr>
</tbody>
</table>
Appendix G: Consent to Participate in a Clinical Project

SELF REPORTED DIARY FOR ASSESSMENT OF CHRONIC PAIN

WHY ARE YOU BEING INVITED TO TAKE PART IN THIS RESEARCH?

You are invited to take part in a clinical project about pain. You are invited because you live in a nursing home and have chronic pain. If you volunteer to take part in this project, you will be one of about 30-35 people to do so.

WHO IS DOING THE PROJECT?

The person in charge of this study is Kathy Hager, a doctoral nursing student from the University of Kentucky. She is guided in this project by Dorothy Brockopp, Ph.D., her advisor.

WHAT IS THE PURPOSE OF THIS PROJECT?

The purpose of this clinical project is to have you describe your own pain. By doing this study, we hope to learn where your pain is, if activity affects it, how bad it is, what it feels like, when it is the worst, and how long it lasts.

WHERE IS THE PROJECT GOING TO TAKE PLACE AND HOW LONG WILL IT LAST?

The project will be conducted at your nursing home, in your own room. Kathy Hager will visit you to see if you would like to participate. If you would like to participate, she will explain the diary, and ask you to sign this form. She may visit you daily, or any time you request her to visit. She thinks it will take you about five minutes a day to complete the diary. The total amount of time you will be asked to volunteer for this project is about two hours over the next two weeks.

WHAT WILL YOU BE ASKED TO DO?

You will be asked to complete the diary every day. On the diary you will:

- tell what time of the day you are answering the questions,
- describe where you have pain (can be more than one place),
- tell how bad the pain is, and
- tell what level your pain is when you are moving around, and what level it is when you are resting.

You will have a picture of a body on each diary sheet where you can mark an ‘X’ anywhere you have pain. You will also be asked to pick a number between ‘0’ and ‘10’ that best describes your pain. ‘0’ would tell us that you have no pain at that time. ‘10’ would tell us that it is the worst pain that you can imagine. Numbers between ‘0’ and ‘10’ are supposed to estimate how bad the pain is, somewhere between those numbers. If you have trouble understanding these numbers, the researcher will work with you to better understand it.

You will be asked to say what level of pain you have when you are moving around, and what level the pain is when you are resting.

One section on the diary is blank. You may choose to write nothing there, or you can in your own words describe how you are feeling.

ARE THERE REASONS WHY YOU SHOULD NOT TAKE PART IN THIS STUDY?
There are no reasons why you should not take part in this project, unless it would be upsetting to you to write about your pain.

**WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?**

There is always a chance that any medical treatment can harm you, and the treatment in this project is no different. We will do everything we can to keep you from being harmed. In addition to the risks listed below, you may experience a previously unknown risk or side effect, but we think that is very unlikely.

<table>
<thead>
<tr>
<th>Possible Risk/Side Effect</th>
<th>How often has it occurred?</th>
<th>How serious is it?</th>
<th>Can it be corrected?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Increased discomfort from talking about the pain that is not controlled</td>
<td>It is uncommon</td>
<td>Can be easily treated</td>
<td>Yes</td>
</tr>
<tr>
<td>Side effects from medications ordered for your pain, such as nausea, itching, gastrointestinal upset, constipation, confusion</td>
<td>Nausea and itching occur frequently but goes away within about a week. Gastrointestinal upset is common. Confusion is common with certain medicines</td>
<td>Nausea and itching are not serious and are self-limited. Can be serious because of its association with falls.</td>
<td>Our facility has a protocol for medicine to help prevent stomach problems and constipation. You will be monitored for increased sedation.</td>
</tr>
</tbody>
</table>

**WILL YOU BENEFIT FROM TAKING PART IN THIS PROJECT?**

There is no guarantee that you will get any benefit from taking part in this project. However, some people have experienced better pain control when they complete diaries describing their pain. We cannot and do not guarantee that you will receive any personal benefits from taking part in this study. Your willingness to take part, however, may, in the future, help doctors, and other persons involved in your care, better understand and/or treat others who have chronic pain.

**DO YOU HAVE TO TAKE PART IN THE PROJECT?**

If you decide to take part in the project, it should be because you really want to volunteer. You will not lose any benefits or rights you would normally have if you choose not to volunteer. You can stop at any time during the study and still keep the benefits and rights you had before volunteering. If you decide not to take part in this project, your decision will have no effect on the quality of medical care you receive. The staff will still ask you the same questions about your pain, as they did before you were asked to use the diary. That part of your care will not change.

**IF YOU DON’T WANT TO TAKE PART IN THE PROJECT, ARE THERE OTHER CHOICES?**

If you do not want to take part in the project, the staff will respond to your pain needs just as they have been doing in the past. There will be no penalties.

**WHAT WILL IT COST YOU TO PARTICIPATE?**

There is no cost for you to participate.

**WHO WILL SEE THE INFORMATION THAT YOU GIVE?**

We will keep private all research records that identify you to the extent allowed by law.

Your information will be combined with information from other people taking part in the project. When we write about the study to share it with other researchers, we will write about the combined information we have gathered. You will not be identified in these written materials. We may publish the results of this study; however, we will keep your name and other identifying information private.

Your family, your doctor, your therapists, your nurses, and your nursing assistants, will know that you are in the study. If anyone else is given information about your pain, it will only be so that this information might help future people in pain. In no case will your name be used.
We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is. For example, your name will be kept separate from the information you give, and these two things will be stored in different places under lock and key. You should know, however, that there are some circumstances in which we may have to show your information to other people. For example, the law may require us to show your information to a court.

Agents of the University of Kentucky may look at or copy pertinent portions of records that identify you.

**CAN YOUR TAKING PART IN THE PROJECT END EARLY?**

If you decide to take part in the project you still have the right to decide at any time that you no longer want to continue. You will not be treated differently if you decide to stop taking part in the project.

The individuals conducting the project may need to withdraw you from the project. This may occur if you are not able to follow the directions they give you, or if they find that your being in the project is more risk than benefit to you.

**WHAT HAPPENS IF YOU GET HURT OR SICK DURING THE PROJECT?**

It is very unlikely that you would be hurt because of something done during the project. However, if you believe you are hurt or if you get sick because of something that is done during the project, you should call Kathy Hager at 502 633 5251 or 502 682 0651 immediately. It is important for you to understand that the University of Kentucky will not pay for the cost of any care or treatment that might be necessary because you get hurt or sick while taking part in this study. That cost will be your responsibility. Also, the University of Kentucky will not pay for any wages you may lose if you are harmed by this project.

Medical costs that result from research-related harm can not be included as regular medical costs. The University of Kentucky is not allowed to bill your insurance company for such costs. You should ask your insurer if you have any questions about your insurer’s willingness to pay under these circumstances. Therefore, the costs related to your care and treatment because of something that is done during the study will be your responsibility.

**WILL YOU RECEIVE ANY REWARDS FOR TAKING PART IN THIS PROJECT?**

You will not receive any rewards or payment for taking part in the study.

**WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS, CONCERNS, OR COMPLAINTS?**

Before you decide whether to accept this invitation to take part in the project, please ask any questions that might come to mind now. Later, if you have questions, suggestions, concerns, or complaints about the study, you can contact the investigator, Kathy Hager at 502 633 5251 or 502 682 0651. If you have any questions about your rights as a volunteer in this research, contact the staff in the Office of Research Integrity at the University of Kentucky at 859-257-9428 or toll free at 1-866-400-9428. We will give you a signed copy of this consent form to take with you.

**WHAT ELSE DO YOU NEED TO KNOW?**

There is no institution or company providing financial support and/or material for this study.

You will be told if any new information is learned which may affect your condition or influence your willingness to continue taking part in this study.

_________________________________________    ____________
Signature of person agreeing to take part in the project                Date

_________________________________________
Printed name of person agreeing to take part in the project

_________________________________________    ______ ______
Name of [authorized] person obtaining informed consent          Date

_________________________________________
Signature of Investigator
<table>
<thead>
<tr>
<th>Resident Number</th>
<th>Gender</th>
<th>Age</th>
<th>No of Pain Entries 14 days prior to diary</th>
<th>No of Pain Entries 14 days during diary</th>
<th>Mean Pain Level 14 Days prior to diary</th>
<th>Mean Pain Level during diary</th>
<th>Mean Pain Level 14-28 days after completion of diary</th>
<th>Analgesics Ordered Before diary</th>
<th>Analgesics Given During/after diary</th>
<th>Analgesics Ordered During/after diary</th>
</tr>
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<tr>
<td>2</td>
<td>F</td>
<td>64</td>
<td>0 entries</td>
<td>1 entry 3/10: MD made aware of yellin</td>
<td>No pain level entries</td>
<td>No pain level entries</td>
<td>2/7/06 Gabapentin 100 tid</td>
<td>Just atcs given 2/19-3/4: Vicodin</td>
<td>4/10: increase gabapentin to 300 tid</td>
<td>2 prns during/after diary: 3/14 vicodin</td>
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<tr>
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<td>F</td>
<td>W</td>
<td>8</td>
<td>3</td>
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<td>Mean=4</td>
<td>Mean=5</td>
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<td></td>
<td>3/3-3/16</td>
<td>No c/o discomfort</td>
<td>0 entries</td>
<td>No c/o discomfort</td>
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<td>No pain levels</td>
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<tr>
<td>5.</td>
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<td>2/18-3/3</td>
<td>No s/s pain, No s/s pain, Denies pain</td>
<td>11 pain entries</td>
<td>10 pain entries</td>
<td>Mean=6</td>
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<td>3/4 - 3/21</td>
<td>out</td>
<td>6 pain entries</td>
<td>3/24; denies pain 3/27:</td>
<td>11 pain entries</td>
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<td>3/4 - 3/21</td>
<td>out</td>
<td>6 pain entries</td>
<td>3/24; denies pain 3/27:</td>
<td>11 pain entries</td>
<td>10 pain entries</td>
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</tbody>
</table>

**Notes:**
- Mean values represent pain levels.
- No new meds entries indicate no change in medication.
- During: indicates the time period when specific medications were taken.
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<thead>
<tr>
<th>Date</th>
<th>Pain Description</th>
<th>Pain Medication</th>
<th>Dosage</th>
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<td>Vicodin</td>
<td>8 mg</td>
<td>Dr. notified increase pain</td>
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<td>Dura-gesic</td>
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<td>q 4</td>
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<td>Neurontin 300 mg hs</td>
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<td>5/31</td>
<td></td>
<td>Lyrica 50 mg</td>
<td>q 4</td>
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</tr>
</tbody>
</table>

No aceta used

3/14: Prednisone 10 mg daily

3/18: change vicodin to ii tabs 5/500 q 4 prn

3/27: change vicodin to 7.5/750 i po q 4 prn

No aceta used
<table>
<thead>
<tr>
<th>Date</th>
<th>F</th>
<th>W</th>
<th>D</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>2/18-3/3</td>
<td>6</td>
<td>2</td>
<td>0</td>
<td>2 entries, 3/3: 10 pm: Darvocet N 100 tid atc &amp; q 6 hr. prn 2nd entry: 11:00: resident on light all night for something; prn pain, drink, bathroom, reposition, etc.</td>
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<tr>
<td>4/17 (after date): change lyrica to 100 mg tid</td>
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<td>2</td>
<td>0</td>
<td>Before: 28 Acet a 500 q 6 prn After: 9 No acetad</td>
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<td>Date</td>
<td>Pain Meds</td>
<td>Denies Need for Pain Meds</td>
<td>Lower Back Pain</td>
<td>Pain @ This Time</td>
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**Notes:**
- 2/21 x 2
- 2/22 x 2
- 2/23
- 2/24 x 2
- 2/27 x 3
- 2/28 x 3
- None in March before 3/7 up to April 4
- No aceta in March
- Darvon 10/325: x2
- Vicodin 5/325: x2
- Percocet x 4
- 3/29
- 3/30
- 3/31
- Aceta 3/27 x 1
- Vicodin 5/300: 10
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<th>PRNS After</th>
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<td>3/7 – 3/26 out of facility</td>
<td>6 days</td>
<td>9</td>
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<tr>
<td>3/27-4/9</td>
<td>1/0/ 2/1</td>
<td>8/2/0 05</td>
<td>3/16/06: Gaba: 600 qid</td>
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<td></td>
<td>3/30: Vicodin/a pap 7.5/5 00 p4 prn</td>
<td>3/18/06: new order Ultram 50, 1 q 4 prn</td>
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<td>4/3/ Naprosyn i BID 3/1: naprosyn discontinued</td>
<td>4/3/ 8/30/05 Vicodin 7.5/5 00 bid Discontinued with hospitalization (by mistake?</td>
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<td>4/8/</td>
<td>4/8/</td>
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<tr>
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*Self-reported pain diary*
## Self-reported pain diary

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<th>No. of entries</th>
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<th>Mean</th>
<th>Not reordered?</th>
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<td>5: Apaplex er q 4 prn</td>
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<td>April: none</td>
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</table>

### 10. 3/2-3/15
- **Entries:** 9
- **Pain Diary:** No entries
- **Mean:** 3/18: 8
- **Not reordered?**

### 11. 2/20-3/5
- **Entries:** 7
- **Pain Diary:** NONE
- **Mean:** 2/24/06 Acet a 2 q 4
- **Not reordered?**

### 11. 3/6 – 3/19
- **Entries:** 4
- **Pain Diary:** 3/22: no co pain
- **Mean:** 3/20-4/2

### 11. 3/20-4/2
- **Entries:** 4
- **Pain Diary:** 3/20-4/2
- **Mean:** 3/20-4/2

### 11. 3/29:
- **Entries:** 2/24/06 Prop ox 100/650 i
- **Pain Diary:** FEB
- **Mean:** 3/20-4/2

### 11. 4/8:
- **Entries:** 3/20-4/2
- **Pain Diary:** FEB
- **Mean:** 3/20-4/2

### 10. 3/2-3/15
- **Entries:** 9
- **Pain Diary:** No entries
- **Mean:** 3/18: 8
- **Not reordered?**

### 10. 3/16-3/31
- **Entries:** 7
- **Pain Diary:** 12/0
- **Mean:** 3/18: 8
- **Not reordered?**

### 10. 4/1-15
- **Entries:** 0
- **Pain Diary:** No entries
- **Mean:** 3/18: 8
- **Not reordered?**

### 10. 0 / 1 / 1/1
- **Entries:** 0
- **Pain Diary:** April: none
- **Mean:** 3/18: 8
- **Not reordered?**

### 11. 2/20-3/5
- **Entries:** 7
- **Pain Diary:** NONE
- **Mean:** 2/24/06 Acet a 2 q 4
- **Not reordered?**

### 11. 3/6 – 3/19
- **Entries:** 4
- **Pain Diary:** 3/22: no co pain
- **Mean:** 3/20-4/2
- **Not reordered?**

### 11. 3/20-4/2
- **Entries:** 4
- **Pain Diary:** 3/20-4/2
- **Mean:** 3/20-4/2
- **Not reordered?**

### 11. 3/29:
- **Entries:** 2/24/06 Prop ox 100/650 i
- **Pain Diary:** FEB
- **Mean:** 3/20-4/2
- **Not reordered?**

### 11. 4/8:
- **Entries:** 3/20-4/2
- **Pain Diary:** FEB
- **Mean:** 3/20-4/2
- **Not reordered?**

### 11. 3/20-4/2
- **Entries:** 4
- **Pain Diary:** 3/20-4/2
- **Mean:** 3/20-4/2
- **Not reordered?**

### 11. 0 / 1 / 1/1
- **Entries:** 0
- **Pain Diary:** April: none
- **Mean:** 3/18: 8
- **Not reordered?**
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Darvocet:  
N 100 i tid  
4/13:  
Vicodin bid & q 6 prn  
3/7  
3/9 x 2  
3/10  
3/11  
3/12 x 2  
3/13  
3/14 x 2  
3/15 x 2  
3/16 x 2  
3/17 x 3  
3/18 x 2  
3/19 x 3  
Darvocet: after: 19  
(17 ‘effective’) –  
3/20 x 2  
3/21  
3/22 x 3  
3/23 x 2  
3/25  
3/26  
3/30  
3/31  
no vicodin for April 12.

3/1-3/14  
3/15-3/28  
3/29-4/11  

12. W 8 6  
No entries  
3/21: no c/o pain  
3/29 no pain entries  

None  
None  
None  

8/11/05:  
Acet a 325 ii q 4 hr prn  
No prns before  

3/25/06:  
aceta 650 mg tid atc  
< 2,000/24 hrs  
(3/28)  
Tramadol 50 mg tid  
and prn (between Tyleonol)  
3/30:  
Tyleonol 650 mg po q 6hr & prn between Tramadol and prn  
4/10/06:  
Darvocet  

No prns after  
3/24, 3/26  

3/24 & 3/26 during  
None, after
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**Acetaminophen (Acet):**
- 6/20/02: 600 mg q 4 hr prn
- 2/27/06: 650 mg q 4 hr prn

**Vicodin (Vicodin):**
- 3/20, 3/24 after:
- New order for Vicodin 5/500 bid and q 4 prn
- 3/20: new order for Vicodin 5/500 bid and q 4 prn

**Gaba p:**
- 3/20: new order for Gaba p 600 mg, ii hs

**Meds:**
- No PRNS after
- During: No aceta in April
- After diary finished: no prns

**Study Dates:**
- 2/26-3/11
- 3/12-3/25
- 3/26-4/9
- 3/1-3/14
- 3/15-3/28
- 3/29-4/11
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### 17. F W 7 3

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</table>

#### Self-reported pain diary

**3/20:** Request Darvocet tid
**3/22:** No c/o pain

**3/30-4/12:**

No pain entries

**April:**

- **3/3:** Level 6-2
- **3/10:** Supervisors made aware of pts' need for incr. pain meds
- **3/20:** Change Darvocet to tid & q 6 hr prn
- **4/10:** Ultracet tid
- **4/10:** Relafen 750 mg ii tabs daily with food
- **Solumedrol 80 mg IM x 1**

**PRNS after:**

- **3/20:** Vicodin 5/500 q 6 prn
- **Vicodin atc**
- **4/10:** Ultracet tid
- **4/10:** Relafen 750 mg ii tabs daily with food
- **Solumedrol 80 mg IM x 1**

**No PRNS before:**

- **11/2**
- **2/05 Acet 500 atc tid**
- **2/27:** Amitr yptine 10 mg hs
- **2/27:** Darvocet N 100 bid and q 6 hr prn

**No PRNS after:**

- **3/20:** Change Darvocet to tid & q 6 hr prn
- **4/12:** No c/o pain noted

**Mean:**

- **6**

**Before total:**

- **4**

**After total:**

- **4**

**Before:**

- **X8**

**After:**

- **3/1**
### Self-reported pain diary

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<th>Mean = 8</th>
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#### Flowsheet

- 4/1: 5..2
- 4/2: 4..2
- 4/3: 4..4
- 4/4: 4..4
- 4/4: 4..4
- 4/10: 4..2
- 4/11: 10
- 4/11: 8..2

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Self-reported pain diary