Effectiveness and Side Effects of Oral Analgesics for Acute Pain in the Elderly

By

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Abstract of Master's Paper

Pain is a common presenting complaint of patients seen in the emergency department (ED), accounting for up to 78% of visits. Inadequate pain control has been recognized by the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) as a significant problem, and regulations have targeted improving the management of persistent pain as a priority for physicians. Patients 65 years and older are particularly vulnerable to persistent pain because pain has a greater impact on function in elderly adults and because elderly adults are more likely not to receive pain medication compared to non-elderly adults. The research component of this master's paper is a study of the effectiveness and side effects of analgesics for the management of acute pain in patients 65 years and older seen in an emergency department. Eligible patients discharged from the ED following a pain-related visit were interviewed one week post-discharge to assess levels of pain and side effects from analgesics prescribed. No significant differences in persistent pain were seen between patients prescribed opioids and those prescribed non-steroidal anti-inflammatory drugs (NSAIDs), though the trend suggests that there is a higher level of persistent pain in those prescribed opioid analgesics independent of initial pain score, race, gender and level of education. Pain may be persistent in this group because one third of patients stopped taking the prescribed opioid medication despite continued pain. Of the patients who stopped taking their opioid medications, 40% stopped secondary to adverse side effects.

A systematic review of the literature was conducted with the goal of comparing opioids and NSAIDs for management of acute pain. There is a paucity of literature comparing these analgesics in the short term management of pain. There is a need for further research in analgesic use for the management of short term pain in elderly adults in order to reduce the burden of persistent pain in this important, growing, and vulnerable population.

Original Research Paper

Effectiveness and Side Effects of Commonly Prescribed Analgesics in the Elderly Seen in the Emergency Department

Abstract

Elderly adults commonly visit the emergency department for the evaluation and treatment of acute painful conditions. However, under treatment of pain is common in elderly adults, in part because of provider and patient concerns about side effects of analgesics. This places elderly adults at increased risk for persistent pain, which is associated with functional decline and decreased quality of life. Side effects from long term use of both opioids and nonsteroidal anti-inflammatory drugs (NSAIDs) in elderly adults have been described, but little is known about the safety or efficacy of the short term use of these medications for the treatment of acute pain in the elderly. We conducted a prospective study at a single emergency department (ED) providing care for a large and diverse population of elderly adults. A sample of patients 65 years or older with an eligible pain-related ED visit and a pain score of 4 or more who were discharged home were contacted one week after their ED visit. Pain was assessed using a 0-10 numeric rating scale with moderate or severe pain defined as a score of $\geq$4. Of 102 eligible patients, interviews were conducted with 41 individuals. Of these, 20 reported taking opioids and 8 reported taking NSAIDs. The proportion of patients with persistent moderate or severe pain at one week was high in both groups: 68% among those taking opioids vs. 50% among those taking NSAIDs (p=.38). Side effects were more common in patients taking opioids than in those taking NSAID (72% vs. 25%, p=.02). Our results suggest that current management of acute pain in elderly

adults discharged from the ED is inadequate and that the frequency of side effects is high in patients taking opioids. Further research is needed to determine methods to improve the management of acute pain in this important, growing and vulnerable population.

Introduction

Inadequate treatment of pain is a major public health concern. In the 1990s, the Joint Accreditation of Healthcare Organizations (JAHCO) recognized the magnitude of this problem and formally initiated recommendations for increased attention to pain management.[1-3] The issue of acute pain management is particularly important in the emergency department (ED), where pain is the most common presenting chief complaint.[4] The elderly are one group found to be particularly likely to receive inadequate treatment of pain.[3, 4] This disparity in the management of acute pain in older versus younger adults indicates an unmet need for analgesia amongst elderly ED patients. In addition, persistent pain in this population has been shown to significantly reduce sense of well being and quality of life, and correlates with progression of a disability. [5]

Treatment guidelines for acute pain in the elderly population have been slow to develop. One potential reason is that little evidence exists to guide the optimal treatment of acute pain in older adults.[6] Previous studies have identified a number of side effects from the long-term use of opioids and non-steroidal anti-inflammatory drugs (NSAIDs) among the elderly, including falls, dizziness, constipation, gastrointestinal bleeding, renal insufficiency, and exacerbations of congestive heart failure.[7,8]Concerns about exposing the elderly to the side effects associated with chronic use of commonly administered pain medications complicates decisions about treating acute pain in elderly patients.[9] An additional challenge is that few studies have examined the effectiveness and side effects of short term pain medication use in the elderly.

In order to improve understanding of the effectiveness of common pharmacologic treatment options for acute pain in the elderly, we conducted a prospective study of a sample of patients 65 years and older discharged from the ED after a pain-related visit. The objectives of the study were to describe the frequency of prescriptions (or recommendations) for NSAIDs versus a

prescription for opioids, compare the effectiveness of these two classes of medications, and compare the occurrence of commonly reported side effects.

Methods

Study design and Study Population

This study is a prospective cohort study conducted at the University of North Carolina at Chapel Hill (UNC) Hospital System, an 800 bed tertiary care center located in Chapel Hill, North Carolina. Subjects were identified using emergency department (ED) electronic medical records. To be eligible, the following criteria had to be met: (1) patient ≥ 65 years of age, (2) discharged home following an ED evaluation, (3) chief complaint of acute musculoskeletal pain, fracture or laceration, (4) a recorded pain score in the ED of > 3, (5) English speaking. Discharge diagnoses for all potentially eligible patients were also reviewed to ensure that the pain was not due to an alternative cause. Only patients with a chief complaint and a discharge diagnosis consistent with burn, fracture, laceration or musculoskeletal pain were included. For example, a patient who presented with back pain but was diagnosed with a kidney stone would not be included. Patients with other forms of pain such as headache, chest pain, or abdominal pain were not included. Patients needed to be able to conduct phone interviews themselves; patient proxies were not accepted. Additionally, we excluded patients who were (1) not oriented to year or location at the time of phone call interview, and (2) residing in a nursing home.

During a 12-week study period (March 2011- May 2011), we contacted all eligible patients approximately 4-7 days after they were discharged from the ED following a pain-related visit.

Data collection

Visits to the ED were reviewed daily to identify eligible patients. Data were abstracted from the electronic records of the emergency department and assessed for eligibility criteria. All eligible patients were contacted by phone. We attempted contact at least 3 times between 4 and 7 days following discharge. For those contacted, verbal informed consent was obtained and patients completed a brief telephone survey. Surveys were conducted by study investigators and research assistants using a standard script. All research assistants completed training in the protection of human research subjects and conducted a mock telephone call prior to participation in the study. Additional questions regarding the quality of the survey were completed after each interview. Data for each patient were either directly entered into a spreadsheet, or recorded on paper and later double-entered into the spreadsheet in order to avoid errors in data entry.

Measures

The primary exposure of interest was comparing those who took at least one dose of an opioid with those who took NSAIDs. An opioid prescription was considered given if it was either recorded as given in the medical record or reported to be given by the patient at one week follow-up. The primary outcome was the patient's self-reported pain score on the day of the phone call interview, assessed using a 0 to 10 numeric rating scale. We assessed the presence of specific side effects including constipation, tiredness, nausea, vomiting, dizziness and falls. We assessed side effect interference and pain interference with general activity as a single item from the brief pain inventory. Demographic information including age, race and education levels was self-reported.

Data Analysis

T-tests for continuous variables and chi-square tests for categorical variables were used to compare the demographic characteristics and ED pain scores for subjects who took opioids and subjects who took NSAIDs. The proportion of patients with moderate or severe pain at one week was compared between patients who received opioids and those who received NSAIDs. Mean pain scores at one week were also calculated to serve as additional comparison between opioid and NSAID users. The proportion of patients with each side effect was calculated. In addition, the proportion of patients reporting any side effect was calculated. These proportions were compared between opioid and NSAID users using chi squared analysis In addition mean pain scores were calculated adjusting for pain severity in the ED, age, race, and education level. A p-value <.05 was used to indicate significance for all statistical tests.

Results

Over the course of the 3 month study period, 2,432 individuals over the age of 65 seen in the Emergency Department were screened. 102 subjects were identified as eligible to participate. Forty-one of these subjects were enrolled in the study. The remaining were not enrolled because they were unable to be reached (n=60) or unwilling to participate (n=1). Of these 41 enrolled subjects, 20 took at least one dose of opioid analgesic and 8 took NSAIDs only.

The average age of subjects was 73 years with no significant difference between the opioid and NSAID groups (Table 1). Similar initial pain scores (7 on 0 to 10 scale) were observed in both groups. Both gender (60% female, 40% male) and race (75% Caucasian, 25% African American) were similar in both of the groups. The only notable difference between those subjects in the opioid and NSAID groups was in education level.

Persistent moderate or severe pain was observed in 68% of those taking opioids and 50% in those taking NSAIDs (Table 2). After adjusting for ED pain score, race, education and gender, percentages of patients with moderate or severe pain were 69% of opioid users and 59% of NSAID users (Table 3). There was no significant difference in the levels of persistent pain in either unadjusted or adjusted analyses.

Despite the high percentage of subjects with persistent pain, 12 of 20 opioid users were completely satisfied with their care and 6 were somewhat satisfied. Among NSAID users, 6 of 8 were completely satisfied and 2 were only somewhat satisfied.

There were clinically important differences in the percentages of reported side effects between patients taking opioids and patients taking NSAIDs (Table 2). Although individual side effects did not show any statistical significance, 72% of those taking opioids had at least one side effect compared to 25% of those on NSAIDs (p=.02). Of those taking opioids, 7 (40%) reported tiredness and 4 (20%) reported nausea. In those taking NSAIDs, 2 reported tiredness (25%) and no subjects reported nausea.

Among those prescribed opioids, 33% did not take the full prescription. Of those who stopped taking the opioids, 40% listed side effects as a reason for discontinuing the opioids. NSAID users were not asked to quantify their NSAID use.

Of the 20 subjects asked about their opinion on taking opioid analgesics, 3 did not like the idea of taking opioids because of worries about side effects while 5 were reticent to take opioids because in general they were against taking medications. 12 of these subjects were ready to take opioids if they felt the needed them. No subjects expressed a reticence to take opioids because of fear of addiction.

Discussion

No significant differences were seen in the levels of persistent pain between those receiving opioids and those taking NSAIDs at one week post-discharge from the ED. However, several distinct trends were observed. Elderly ED patients given a prescription for opioids may have increased persistent pain levels even when accounting for initial pain score. There are several ways to interpret this finding. Either NSAIDs and opioids are equivalent in their analgesic effects or those given opioids did not use their prescription effectively and thus had a shorter course of analgesic use. In fact our data show that over one-third of subjects taking opioids stopped taking their prescription. Forty percent of those stopping their prescription listed side effects as a reason implying that treating these side effects may increase compliance for those using opioids.

While the difference in individual side effects between opioid users and NSAID users was not significant, opioids users had statistically significant higher presence of at least one side effect. There is an obvious trend for increased side effects in opioid users. This is not in itself surprising since it is known that opioids have the potential to cause significant side effects. However, it is interesting to note that several of the most common side effects such as nausea and constipation are very treatable.

In this description of analgesic use in the elderly population, the assessment of attitudes towards pain medications showed a general willingness to take medications when necessary. Less than 10 percent of subjects were worried about side effects, and not a single subject expressed concern about addiction. This analysis of attitudes indicates than this population does not harbor a preconceived prejudice against opioids. This differs from research on chronic opioid users where fear of addiction is a leading indicator for under-use of opioid prescriptions.[10]

Thus, one of the keys to reducing the burden of persistent pain in this vulnerable population is to prevent side effects that could be decreasing adherence to pain medications. In a study in Quebec of chronic opioid users, one-third of patients eventually receive a prescription for a laxative, but only 2% in the same study received it at the initiation of the opioid. The authors similarly call for concurrent prescriptions to ameliorate side effects before they interfere with adherence. [11]

According to this study, side effects appear to influence the rates of persistent pain. Therefore, future studies may examine the effect of secondary prescriptions on the completion of opioid prescriptions. In addition, although this study focused on the patient outcomes of analgesic use in the elderly, future studies should additionally examine the comparative safety. While studies have compared long term safety of analgesics in the elderly, a short term safety comparison would help determine appropriate prescribing guidelines in this population. [8]

Limitations

The major limitation of this study is the small sample size. Power calculations completed before the initiation of this study showed a sample size of 150 is needed to detect a difference of 15% in proportion of patients with persistent pain with 80% power and an alpha of .05. With a sample size of 40, the probability of detecting a difference is very small. A major limitation in this study is the potential for confounding. Even with a large sample size, other factors may play in a role in the physicians decision to give opioids or NSAIDs. By using propensity scores in future studies, this affect of the confounding could be diminished. In addition, the prospective cohort design of the study can only show correlative effects, not causal. In order to establish the effect of opioids or NSAIDs on persistent pain a randomized trial design must be employed. We were not able to contact more than half of eligible patients. It is possible that we

were unable to contact some of these individuals because they had been hospitalized as a result of either inadequate treatment of pain or as a complication of their analgesic treatment.

Despite these limitations, this study shows a high level of persistent pain in those over the age of 65 at one week. In addition, a trend showing a greater percentage of opioid users in persistent pain than NSAID users indicates inadequate pain control especially among those receiving such opioids prescriptions. The notable number of opioid users who stopped taking their prescription as a result of side effects shows a need for further studies to explore this phenomenon.

Table 1. Characteristic of those prescribed opioids and NSAIDs in >65 aged adults seen in the Emergency Department for acute pain and discharged home.

	Medication		
	All (n=41)	Opioid (n=20)	NSAIDs (n=8)
Age (mean+/-SD)	73 +/- 8	72 +/-7	75 +/- 9
Race			
white	75%	76%	75%
black	25%	23%	25%
Gender			
male	40%	40%	37%
female	60%	60%	62%
ED Pain Score (0-10) (mean +/- SD)	7 +/- 2	7 +/- 2	7 +/- 2
Education level			
< high school	41%	50 %	25%
> high school	59%	50%	75%

Table 2. Unadjusted porportion of side effects and persistent pain in opiod and NSAID users >65 years of age seen in the Emergency Department for acute pain and discharged home.

	Unadjusted % in those with filled opioid rx n=20	Unadjusted % in NSAIDs users n=8	p-value
% of those with persistent pain (pain >3/10)	68	50	.38
Pain at follow up (mean +/- SD) (0-10)	3.9 +/- 1.7	4.4 +/- 4	
% with side effects			
Any side effect	72	25	.02
Tiredness	41	25	.45
Nausea	20	0	.18
Vomiting	6	0	.47
Falls	5	0	.56
Unsteadiness	9	12	.79
Constipation	23	0	.14

Table 3. Adjusted* proportions of patients with persistent pain.

	Opioid users	NSAID users	P-value
% of those with persistent pain (pain >3/10)	69%	59%	.69

*Adjusted for initial pain score, race, gender, age and education.

Systematic Review

Effectiveness and Adverse Effects of Analgesics used for Acute Pain in Adults treated in Outpatient Settings

Introduction

Pain is one of the most common chief complaints in the emergency department (ED) and outpatient setting.[4] It is the primary reason for up to 78% of patient visits to the ED.[12] Despite the high prevalence, many studies have shown inadequate analgesia in high proportions of those discharged from the ED. [13] This may be a result of a paucity of guidelines regarding appropriate analgesic choice in various populations.

Physicians are often reticent to prescribe addictive substances, such as opioids, to vulnerable populations. In addition, recent studies show increased mortality with the use of chronic opioids.[8] However, few studies have compared the short term use of opioid analgesics with the short term outcomes from NSAIDs (non-steroid anti-inflammatory drugs)

This systematic review summarizes the literature describing the effectiveness and side effects of analgesic treatments for acute pain in adults seen in an outpatient setting.

Methods

Eligibility Criteria: To be included, articles had to report results of original research studies examining use of analgesics in acute pain treatment in the outpatient setting. The population of interest is adults who are living independently. The intervention for this population was any type of analgesic drug. Studies only reporting analgesic use for intraoperative or post-operative pain were excluded. The primary outcome of interest was the effectiveness of pain treatment. A secondary outcome was side effects of the medication. Only reports that were already published

in English in the last 10 years were considered. All studies included were original research, irrespective of study design. Comments and opinion pieces were not eligible.

Search Strategy and Study Selection: A search was completed on 3/15/2011 using MesH terms "analgesics" and "opioids drug utilization" with limits of adults (>18) and "published within the last 10 years". Hand searches and cross-reference searches were also completed. Initial review of titles focused on removing all articles relating to chronic opioid use and cancer-related analgesic use. A second title review focused on removal of all studies concerning intraoperative or post-operative use of analgesics. During abstract review, each abstract removed was classified according to the reason for removal (eg duration, population). All searches were completed by one author (CM).

Data Extraction: Information from each of the studies was extracted using a standardized form. The form included study citation, objective, follow-up period, type of opioids used, sample size, and study results.

Assessment of Potential for Bias: Potential for bias was assessed for each study. Potential for selection bias, measurement bias, confounding, and judgment of internal and external validity were assessed on a scale (0-3). A composite value of good, fair and poor was allocated to each study based on the prior assessments of bias, validity and confounding. No studies were excluded based on quality.

Results

Study Selection

In total, the search yielded 808 titles. Title review removing chronic use and post-operative use of analgesics yielded 70 articles. Abstract review generated 3 studies meeting all inclusion criteria (Figure). All other studies were removed for one of the following reasons: wrong publication type, wrong duration, wrong setting, wrong population or wrong outcomes.

Study Characteristics

Study characteristics were abstracted for each of the three articles meeting inclusion criteria. All three studies had similar designs using a follow-up phone call after a pain related visit by the patients. The follow up period varied from 24 hours (Garbez et al)[15] to 2 weeks (McIntosh et al)[14] In addition, all three studies were conducted as follow-up after an emergency department visit. McIntosh et al further narrowed the reason for the visit to orthopedic injuries.[15] The sample size for the Garbez study was the smallest with a total of 29 patients, while McIntosh enrolled 150 patients and Johnston et al enrolled 871 (Table 1) [14,15,16]

Qualitative Description of Studies

Potential for selection and measurement bias, as well as confounding and internal and external validity for each of the selected studies were assessed by one author (CM). The potential for measurement bias was intermediate to significantly high for all three of the studies. Little information was provided about the interviewers for any of the three studies. The paucity of information concerning any of the demographic characteristics of the populations in each of the studies leads to a large potential for confounding. Similarly it would be difficult to assess external validity given that the reader is not informed about the type of population. An overall judgment of poor, fair, or good was assigned to each of the three studies based on the prior

assessments of bias and validity. Both the McIntosh and Johnston studies were rated fair, while the Garbez study was rated poor secondary to small sample size and high potential for bias (Table 2).

Description of Findings

There were several common findings among the three papers identified in this systematic review. All three found that roughly one third of adults being seen for acute pain have persistent pain at 4-14 days. This finding was consistent despite the fact that each of the three studies used different durations for follow-up. In addition, both the McIntosh and Garbez studies showed around one fifth of patients who were prescribed prescriptions did not fill them.[14, 15] The high rates of persistent pain in all three studies suggest that current analgesic practice for acute pain is ineffective for a substantial proportion of patients.

As to answering the question of side effectives of analgesics in acute pain management, only McIntosh et al addresses this question. In this study, 26% of subjects experienced side effects.[14] Of the side effects examined in the study, nausea and dizziness represented the most common (both 9%). Constipation (2%) and pruiritis (2%) were less common.

Discussion

This systematic review highlights the paucity of literature regarding the use of short term analgesics in acute pain in adults in the outpatient setting. It is important to note that the majority of papers regarding the subject of analgesics fit into two categories. Primarily, studies about analgesics in adults consider long term treatment of chronic pain and side effects of long term treatment. Secondly, most studies of the effectiveness and side effects of acute pain

treatment focus on post-surgical patients. The gap in the literature is in the treatment of acute pain for adults with pain secondary to musculoskeletal pain or other disease processes that are not related to surgery.

In considering the quality of these studies, the McIntosh and Johnston papers were judged to be "fair" quality while the Garbez paper was judged to be of "poor" quality. All three studies used convenience sampling and none of the studies accurately demonstrates characterization of the population studied. The Garbez et al study was of limited quality due to the small number of subjects, and only 16% retention rate.[15] Though these papers suggest that there are several clinically relevant issues in the assessment of acute pain in adults, in general they lack a large sample size and high quality of design.

The agreement between all three papers about the inadequacy of pain treatment is compelling. Even after considering the limitations of the individual studies, the consensus of at least moderately high persistent pain levels is sufficient to consider it a trend. In addition, the side effects findings in McIntosh's study are substantial. [14] Although the sample size is small, the difference between side effects and magnitude of side effects are enough to warrant further investigation.

The small number of studies found in this review and the lack of scientific rigor of studies shows a gap in the current academic knowledge surrounding the management of acute pain. This review shows that persistent pain remains an issue in the treatment of acute pain, in addition side effects of analgesics may have quite a high prevalence. This represents a clear need for larger studies focusing on the effectiveness and side effects of acute pain management in adults.

Limitations

Since this gathering of articles as well as the process of narrowing the articles was only completed by one person, there is a significant potential for missing relevant studies. In addition, aside from Medline, no other databases were used. Also, the limitation of 10 years since publication potentially limits selection of articles, including initial drug trials. As with many systematic reviews, it was also limited to articles only in English.

Conclusion

While acute pain management in adults is a common and fundamental component of medical care, little research has been completed to demonstrate the effectiveness and side effects of commonly used analgesics. In this review, three articles addressing these issues were reviewed. Although only two of the studies were judged to be of "fair" quality, all three papers demonstrated compelling clinical issues involved in acute treatment of pain. The three studies agree that persistent pain is a continuing issue for many patients. Additionally, side effects appear to effect one quarter of patients taking analgesics. Future studies should further examine the types of side effects, and the change in pain levels from initial visit to follow-up. In addition, studies should examine separately the effectiveness of opioids and NSAIDs.

Figure. Study inclusion and exclusion.

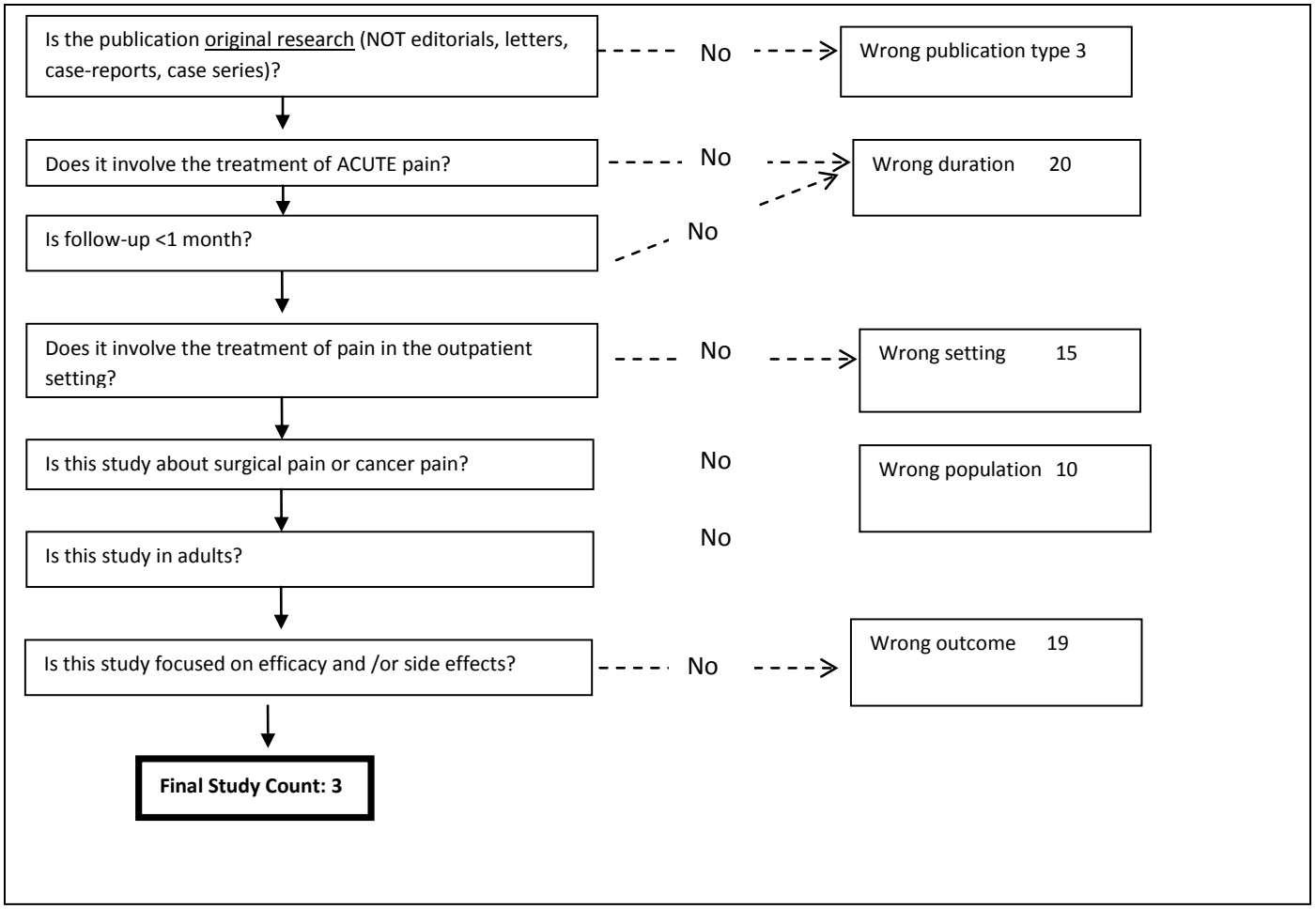

Table 1. Characteristics of three included studies.

Study Title	Objective	Sample size/Study design	Population	Follow-up period	Types of analgesic	Results
Pain management after discharge from ED[14] McIntosh et al, 2002	Assess prescription filling practices, side effects of meds, and adequacy of pain relief	150 patients with orthopedic injuries, retrospective cohort	Level 1 trauma center ED, excluded chronic pain, Mean age= 41	7-14 days	NSAIDs and opioids	26% side effects, 77%-92% had adequate pain relief, 17% did not fill prescription,
Pain after discharge: A Pilot Study of Factors Associated with Pain Management and Functional Status[15] Garbez et al, 2006	Evaluate patient satisfaction with pain medications and continued pain after ED discharge	29 patients-phone calls for BPI and NRS, prospective descriptive study	All pain complaints, Mean age= 43 years. Northern California.	24-96 hours post discharge	All, no subgroup analysis	90% filled prescription, 78% used prescription, 41% moderate persistent pain
Pain in the Emergency Department with one-week follow-up of pain resolution[16] Johnston et al, 2005	Determine use of analgesics in ED and unresolved pain at 1 week post discharge	N=871 Pts with all types of pain seen in ED. Call at one week, retrospective cohort	Two EDs in Canada. Unknown characteristics	1 week	All, no subgroup analysis	35% reported persistent pain at one week. Factors predicting persistent pain: female, MSK pain, higher pain on discharge, and pain for 48 hours before ED visit.

Table 2. Measurement of bias and quality of selected studies. Scale + (little) to +++ (significant).

Study Title	Selection Bias	Measurement Bias	Confounding	Internal validity	External Validity	Overall Judgment (good, fair, poor)*
Pain Management after discharge in the ED[14] McIntosh et al, 2002	++ Convenience sampling, 96% contacted	+++ Interviewer-unknown concordance, very small sample size, no p-values,	++ Characteristics of population unknown	+	++ Don't know characteristics of population, SES etc	Fair
Pain after discharge: A Pilot Study of Factors Associated with Pain Management and Functional Status[15] Garbez et al, 2006	+++ Unknown, part of a larger study. Only 16% of larger study were contacted-unknown why.	++ Interviewer-unknown concordance, very small sample size, no p-values,	++ Characteristics of population unknown..	+ All types of pain	+ No characteristics of population, SES.	Poor
Pain in the Emergency Department with one-week follow-up of pain resolution[16] Johnston et al, 2005	+ Systematic convenience sampling, that was additionally validated.	++ Interviewer-unknown concordance.	++ Characteristics of population unknown	+	++ Characteristics still mostly unknown	Fair

*Overall judgment was based on the cumulative biases in the prior columns.

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APPENDIX TELEPHONE SURVEY

TELEPHONE SURVEY SCRIPT
PROSPECTIVE OBSERVATIONAL STUDY OF THE EFFECTIVENESS AND SIDE EFFECTS OF PAIN MEDICATION IN ELDERLY PATIENTS FOLLOWING A PAIN-RELATED EMERGENCY DEPARTMENT VISIT

Note
Italics indicates what the interviewer says

PLEASE ENTER INTERVIEWER'S INITIALS

_____

PLEASE RECORD THE PATIENT'S ID

_____

Part 1: Consent

Begin Phone Call.

Hi, my name is _____, I'm calling from UNC. Is _____ available to talk? I'm following up on your recent visit to the emergency department. I'm calling because I would like to find out how you are doing. I would like to know whether you would be willing to answer a couple of questions for a study. Your participation in this survey is completely voluntary. All the information I receive from you by phone, including your name and any other identifying information will be strictly confidential and will be kept under lock and key. I will not identify you or use any information that would make it possible for anyone to identify you in any presentation or written reports about this study.

1. Did patient consent?

Yes No

2. If patient did not consent, what was their reason?

_____

_____

Part 2: Pain and Pain Interference Assessment

Thank you being willing to answer a few questions. We are interested in understanding the care you received during your recent emergency department visit.

3. *On a scale from zero to ten, where zero means no pain and ten equals pain as severe as it could be, how would you rate your pain today?*

_____ (0-10)

4. *In the past week, how much has pain interfered with your general activity on a scale of 0 to 10, where 0 mean the pain has not interfered at all and 10 means the pain has completely interfered?*

_____ (0-10)

We would like to know if the medicine you were given when you left the emergency department were helpful for you.

5. *Did the physician in the Emergency Department recommend or prescribe any medications to take home?*

Yes No

6. *Have you taken any pain medication not recommended or prescribed at the time of your visit to the Emergency department, including over the counter medications?*

Yes No

	Medication 1	Medication 2	Medication 3
7. *Do you know the names of the medications and dosing of either prescribed OR recommended?*	Yes No _____ _____	Yes No _____ _ _____ _	Yes No _____ _____
8. *After the ER visit, did you ever take the medication?*	Yes No	Yes No	Yes No
9. IF NO to 8: *Why didn't you take the medication?*	I didn't think I needed it It was too expensive I couldn't easily g to the pharmacy I haven't had a chance Other: _____	I didn't think I needed it It was too expensive I couldn't easily get to the pharmacy I haven't had a chance Other: _____	I didn't think I needed it It was too expensive I couldn't easily get to the pharmacy I haven't had a chance Other: _____
10. IF YES to 8: *Did you stop taking the medication for any reason?*	Yes No	Yes No	Yes No
11. IF YES to 10: *Which of these bests describes the reason why you stopped taking the medication?*	I didn't need it anymore The side effects stopped me I ran out	I didn't need it anymore The side effects stopped me I ran out Other:	I didn't need it anymore The side effects stopped me I ran out Other:

	Other: _____	_____	_____

PART 3: Side Effects

I am now going to ask you about any side effects you may have had after the visit to the Emergency Department. If you have had any of them, I will ask you to rate how much this side effect has disturbed your normal life. The scale is from 0-10; 0 being no effect and 10 being severely affected the way you normally lead your life.

Side effect	Scale 0-10:	Which medication do you feel this is from? Medication # (from question 3)	Can you tell me more about this?
12. Tiredeness			
13. Nausea			
14. Vomiting			
15. Dizziness			
16.Unsteadiness			
17. Falls			
18. Constipation			

19. *Have you done anything to treat these side effects?*
    Yes No
20. IF YES to 19: *What have you done?*
    _____
    _____
21. IF YES to 20: Has *it helped make these problems go away?*
    Yes No
22. *Was someone with you in the Emergency Department?*
    Yes No
23. *How involved was this person in your visit?*
    A lot
    Somewhat
    Very Little
    Not at all
24. *Was information given to you about different pain medications to go home with?*
    A lot
    Somewhat
    Very Little
    Not at all
25. *Did you participate in decision regarding pain medications to go home with?*
    A lot
    Somewhat
    Very Little
    Not at all
26. *How satisfied were you with the pain medication you were sent home with.*

A lot
Somewhat
Very Little
Not at all

27. *What is your general attitude toward taking prescription pain medications such as Vicodin or Percocet? Would you say that it is fine to take these medications or would you rather not?*

It is fine to take these medications

I would rather not because of side effects

I would rather not because I don't want to be addicted

I would rather not because I don't like to take medication in general

Other_____

PART 6: Miscellaneous

For a person of your age, in general, thinking about your health before your visit to

8. *the Emergency Department, would you say your health was:*

Excellent

Very Good

Good

Fair

Poor

29. What is the highest grade or level of schooling that you have completed?

_____

AND CATEGORIZE:

Less than 8 years

8-11 years

12 years or completed high school

Post high school training

Some college

College graduate

Post graduate level

30. *Do you think, or has anyone ever told you, that you have chronic pain?*
Yes No

31. *Is there anything else that you would like to tell me about your visit to the Emergency Department?*

_____

_____

Before we end, I would like to ask you a couple of simple questions.

32. *Can you tell me what year it is?*
Correct answer?
Yes No

33. *Can you tell me what town you live in?*
Correct answer?
Yes No

Thank you for taking time to complete this survey. This survey will help identify effectiveness of both prescription and non-prescription pain medications. Feel free to call Dr. Platt-Mills at (919) 843-5931 with questions about the research study or the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Part 7: Done by interviewer

34. PATIENT AGE

_____

35. PATIENT CHIEF COMPLAINT

_____

36. # OF DAYS AFTER DATE OF EMERGENCY DEPARTMENT VISIT

_____

37. DISCHARGE PAIN MEDICATIONS

_____

38. INITIAL EMERGENCY DEPARTMENT PAIN SCORE

_____

39 PATIENT'S GENDER
M F

40. PATIENT'S RACE
White African American other:

QUALITY OF SURVEY

41. How would you (the interviewer) rate the quality of the information obtained in this interview.

Excellent
Good
Fair
Poor
Inadequate (interview terminated or too poor to be included)

42. If the quality of the information obtained in the interview was NOT excellent, what were the reasons?

_____
_____

APPENDIX 2: EMF/SAEM GRANT

Emergency Medicine Foundation
Information Page

Full Name with Titles:__Courteney Lyn MacKuen, BS, MPH Candidate, MD Candidate__

Name of Institution:___University of North Carolina_____

Grant Category:_____EMF-SAEM Medical Student Grant: Clinical Research_____

Project Title:____ Prospective Observational Study of the Effectiveness and Side Effects of Pain Medication in Elderly Patients Following a Pain-Related Emergency Department Visit___

Amount Requesting:_____$2,400_____

Mentor, if applicable:___Timothy Platts-Mills. MD_____

ABSTRACT AND AIMS

Inadequate treatment of pain is a major public health concern. In the 1990s, the Joint Accreditation of Healthcare Organizations (JAHCO) recognized the magnitude of this problem and formally initiated recommendations regarding pain management. [1] The issue of pain management is particularly important in the Emergency Department, where pain is the most common presenting complaint.[4] Non-whites and the elderly have been found to be particularly likely to receive inadequate treatment of pain.[3, 4] Elderly patients who present to the emergency department (ED) with pain are less likely to receive pain medication than younger patients.[6,4] Disparities in the management of acute pain in older vs. younger adults indicates an unmet need for analgesia amongst elderly ED patients.

One potential reason for this oligoanalgesia in the elderly is that little information exists about optimal treatment of acute pain in older adults.[6] Previous studies have identified a number of side effects from the long term use of opioids and NSAIDs for the elderly, including falls, dizziness, constipation, gastrointestinal bleeding, renal insufficiency, and exacerbations of congestive heart failure.[7] The existing literature on side effects associated with the chronic use of commonly administered pain medications makes decisions about treating pain in elderly adults difficult.[9] An additional challenge facing the practicing emergency physician is that few studies have looked at the effectiveness and side effects of short term pain medication use in the elderly.

We propose a prospective study of patients 65 and older discharged from the ED after a pain-related visit. The primary outcome for the study will be pain symptoms assessed by phone interview at one week. Secondary outcomes will include pain interference with function as well as an assessment of common side effects including constipation, falls, and health care utilization. The purpose of this study is to develop a clearer understanding of the effectiveness of different pain management options for acute pain in the elderly.

Specific Aim 1: Characterize pain medication prescriptions, dispensations, and use by elderly patients following an emergency department evaluation for acute pain.
Hypothesis 1: We will collect ED and one week outcome data on 350 patients age 65 or older discharged from the ED after evaluation for acute pain. Both quantitative data, such as pain scores, and qualitative data such as prescription filling rates will be collected.
Specific Aim 2: Assess frequency, severity and impact of side effects associated with opioids and NSAIDs at one week following an ED evaluation for acute pain.
Hypothesis 2: Short term side effects are common in elderly adults taking opioids and commonly result in a decision to discontinue treatment. Side effects from NSAIDs are less common and less severe.
Specific Aim 3: Describe pain severity at one week in elderly adults taking opioids, NSAIDs, or no pain medications following an ED evaluation for acute pain and determine whether there is a difference in the effectiveness of pain control amongst the two commonly used classes of pain medications after controlling for factors related to pain severity, ED diagnosis, and sociodemographic factors.
Hypothesis 3: Opioids will be more effective than NSAIDs in reducing persistent pain even after controlling for initial pain severity, ED diagnosis, and sociodemographic factors.

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STAY WITHIN MARGINS INDICATED

RESEARCH PROGRAM

Significance

As of yet, there are no published studies which examine the effectiveness of the outpatient management of acute pain following an ED visit in elderly adults. This study is needed to develop a richer fund of knowledge about the treatment of acute pain in the elderly. Physician concerns about the misuse of medications, interactions with other medications, side effects and toxicities likely contribute to the undertreatment of pain in older adults. Quantitative information about the use, effectiveness, and side effects of short courses of pain medication for the treatment of acute pain in the elderly will allow physicians to make informed decisions about management of acute pain in this important, growing, and vulnerable population.

Innovation

This research will focus on characterizing outcomes in elderly patients with acute pain. Factors such as varying rates of prescription filling and the fear of side effects may influence the treatment of pain in the elderly. Our study will capture valuable information about the rates of and reasons for persistent pain following an ED visit for acute pain in the elderly. In addition, while the long-term effects of opioids have been an area of focus in literature, few studies have examined the short term outcomes of the elderly using opioids or NSAIDs for acute pain treatment.

Approach

This is a prospective cross-sectional study of elderly individuals discharged following an ED evaluation for acute pain. Eligible subjects will include all patients age 65 years and older discharged to home from the UNC ED after a visit for burn, fracture, laceration, or musculoskeletal pain with a documented pain score in the ED. Patients will be identified using the ED's electronic medical record system (T-system EV). Chief complaints for patients 65 and older will be reviewed in order to identify patients with one of the above conditions. Discharge diagnoses for all potentially eligible patients will also be reviewed to ensure that the pain was not due to an alternative cause. Individuals meeting these criteria will be contacted 4-7 days after their ED visit. Patients will need to be able to conduct phone interviews themselves; patient proxies will not be accepted. If the patient does not agree to consent, an attempt will be made to discover a reason for non-consent in order to reduce selection bias. After informed telephone consent, all subjects will complete a 15 minute telephone survey (see appendix). This survey will include a 6 item cognitive screener, sociodemographics, pain symptoms, interference of pain with physical and social activities, and questions concerning side effects of medications

This study is expected to enroll 15-17 patients a week. The primary outcome of this research will be an analysis of the effectiveness of opioids and NSAIDs in controlling pain 4-7 days after the initial ED visit. Our primary aim is to describe pain symptoms one week after a pain-related ED visit and the proportions of patients with pain who are taking various types of medications. Additionally, the effectiveness of opioids and NSAIDs will be compared using multivariable logistic regression with the outcome of moderate or severe pain vs. no or mild pain at one week. The inclusion of covariates in the logistic regression model will depend on results of bivariate analyses. We anticipate adjusting for ED pain severity, the cause of pain, age, race, comorbid disease and living situation. Secondary outcomes will include the effect of pain on physical function and emotional health and the presence of side effects including nausea, constipation, falls, repeat ED visits, and hospitalizations after discharge. Chi-squared tests will be used to compare the proportions of patients with specific side effects taking each type of medication. All data collection should be completed by December 2011 to allow time for data analysis and drafting of the manuscript.

CONTINUATION PAGE

STAY WITHIN MARGINS INDICATED

DESCRIPTION OF AWARD YEAR

Before receipt of grant

Obtain IRB approval.

Convert paper survey to electronic version.

Finalize standard operating procedures for data entry, data downloads, and data storage with assistance from Abbey Whittington (data manager).

July 1st, 2011- December 1st, 2011

Collect data on patients from UNC Emergency Department. We anticipate identifying 22 patients per week meeting inclusion/exclusion criteria and 16 patients per week consenting to participate and completing the survey. Meet with data manager periodically to review data for completeness. ensure data collection is ongoing.

Attend Grantee Workshop in Dallas. Discuss progress on grant, troubleshoot any relevant difficulties.

October 2011. Attend ACEP Scientific Assembly in San Francisco, including EMF photo session and recognition reception.

December 2011-February 2012

January 2012. Submit Final Progress report to EMF/SAEM.

Meet with Fran Shofer, statistician, to begin data analysis.

Design relevant graphs for Results section.

February 2012- June 2012

Write manuscript for publication.

Submit manuscript for publication.

Design poster.

After June 2012

Attend ACEP Scientific Assembly/Research Forum and present poster presentation of research.

CONTINUATION PAGE

STAY WITHIN MARGINS INDICATED

PERSONAL STATEMENT

While I have spent countless hours in the electrophysiology lab and revising IRBs, this grant represents for me the unique opportunity to lead a research project from its conception to completion. Since college, I have worked in various capacities on numerous research studies, all of which have helped me to develop the required skill set to effectively assume a greater leadership role. At Grinnell College, I undertook a three-year long research project on post-synaptic transmission in crayfish neuromuscular junctions. My research took me to the psychiatry department at Duke University, where I spent two summers investigating the relationship between neurosteroid levels and post-traumatic stress disorder symptoms in veterans. From this experience, I learned about working on a large scale project, how to manage a large data set and, importantly, began to appreciate the connection between basic science research and clinical medicine. Another formative research experience was my job as a clinical coordinator for several pediatric neurology studies at the NIH the year prior to my starting medical school. All of these experiences have shaped my attitude and confirmed my commitment to research. My clinical training during my first three years as a medical student have expanded my appreciation of research as I have had the opportunity to care for patients whose care and quality of life was directly improved by new medical developments. As I am now pursuing a Masters in Public Health before completing my medical degree, my fund of knowledge about designing and executing research projects continues.

I am committed to this research project and would greatly benefit from a grant that would allow me to challenge myself in a new role as an investigator of a prospective research project. I have already completed an in-depth review of literature pertaining to the treatment of pain in the elderly. This review confirmed there is a significant gap in knowledge regarding the treatment of acute pain the elderly. Our study will provide important information about the effectiveness and side effects of pain medication used by older adults following an ED visit for acute pain. It is my hope that the results of this study will be the basis for additional research that will improve the care of elderly patients. I have spent the past several months working with Dr. Platts-Mills devising the appropriate approach to assessing the effectiveness and side effects of pain management following an emergency department (ED) visit in elderly adults. I am looking forward to initiating data collection as well as the subsequent analysis and manuscript preparation phases of the project.

Dr. Platts-Mills has guided me towards appropriate resources to learn how to write a survey, decide on inclusion and exclusion criteria, and write a grant. Dr. Platts-Mills has encouraged me to take my own initiative on all aspects of this project while remaining actively involved in critical decisions. This grant would enable me to dedicate several months of the next year to carrying out this project, which would involve personally interviewing patients, analyzing results, and drafting a manuscript.

Both acute pain management and the assessment of the elderly adult will be important issues for me in my future work as an emergency physician. This research will not only help me to further explore this area of medicine, but will help me to learn research skills that will be useful as I pursue a career as a clinician scientist. My prior research experiences, my academic work towards a Masters in Public Health, my interest in the subject, and the strong support available to me at UNC including an outstanding mentor position me to succeed in this study of pain management in the elderly.

ROLE OF PARTICIPANTS

Courteney MacKuen, **Student/PI:** Ms. MacKuen has a strong research background and educational foundation in study design. She will be in charge of leading the study from its conception to its publication. She will interview all subjects, enter data, and work with the biostatistian, Dr. Shofer, to complete data analysis. She will also be responsible for the first draft of the manuscript.

Dr. Timothy Platts-Mills, Mentor/PI: . Dr. Platts-Mills has a broad background in clinical research and mentoring. He has first authored eight peer-reviewed original research studies. Dr. Platts-Mills has been recognized for his outstanding emergency medicine teaching with the UNC Department of Emergency Medicine's Socrates Award for the last two years in a row. He has successfully mentored four trainees (B. Ferguson, K Dhah, B. Leacock, and G. Burke) in clinical research and these relationships have led to publications and career advancement for all mentees. His role in this investigation is PI/mentor. He will oversee all decisions made in the research, and ensure accurate data collection and secure data storage.

Dr. Frances Shofer, B**iostatistician** is the research director for UNC's Department of Emergency Medicine, and has extensive experience in epidemiologic and biostatistical issues related to analyses of ED-based cohort data. Dr. Shofer will provide statistical and epidemiologic support for the project.

Abbey Whittington, M.Sc. Mrs. Whittington has formal training and extensive experience as a data manager on projects examining pain outcomes in ED-based cohorts. Mrs. Whittington will train the medical student in the development and implementation of a protocol and related syntax needed to convert survey data into a usable form in PASW 18.02 (SPSS, Chicago, IL).

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Courteney Lyn MacKuen	Medical Student
eRA COMMONS USER NAME (credential, e.g., agency logir	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
Grinnell College, IA	B.S.	05/2005	Biology
Gillings School of Public Health, University of North Carolina	MPH	05/2011	Health Care and Prevention
University of North Carolina School of Medicine	M.D.	05/2012	Medicine

A. Personal Statement

I am well-suited for this grant because I am a medical student with a strong interest in academic Emergency Medicine. I have been actively involved in several research studies prior to medical school and am currently pursuing a Master's in Public Health. Both my academic pursuits and experience in research have prepared me to excel as a student PI on this project.

B. Positions and Honors

2007-Present UNC SOM Jean McCoy Graham Scholarship,
Merit-based scholarship awarded for scholastic ability and a desire to serve the sick and improve public health. This scholarship pays for the tuition and fees of medical school.

2008-2009 Albert Schweitzer Fellowship, Albert Schweitzer Fellowship Association,
The Albert Schweitzer Fellowship is awarded to selected students state-wide who create a proposal for an intervention to help serve the health needs of the underserved. This fellowship is an interdisciplinary program designed to better prepare students for life in public service, while providing guidance in the initiation of a project targeted at underserved populations. Along with a partner, I used the fellowship to initiate an HIV testing clinic and outreach program in Durham, NC.

2005 Graduated with Honors in the field of Biology from Grinnell College

2001-2005 Merit Scholarship from Grinnell College
Received a partial tuition scholarship based on academic achievement and extracurricular involvement for four years at Grinnell College.

2003 Noun Scholarship, Grinnell College

This competitive summer grant scholarship funds research for undergraduate students. I used this support to explore the relationship between neurosteroid and PTSD at Duke University in Durham, NC.

C. Selected Peer-reviewed Publications

Neuroactive Steroids and Suicidality in Posttraumatic Stress Disorder. Marian I. Butterfield, Karen M. Stechuchak, Kathryn M. Connor, Jonathan R.T. Davidson, Chungsheng Wang, Courteney L. MacKuen, Anne M. Pearlstein, and Christine E. Marx. *American Journal of Psychiatry*, 2005. 162: 380-382

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Timothy F. Platts-Mills, MD	Assistant Professor Department of Emergency Medicine University of North Carolina-Chapel Hill
eRA COMMONS USER NAME (credential, e.g., agency login) Timothy_Platts-Mills	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
Harvard College	BA	06/96	Environmental Science and Public Policy
University of California Los Angeles, School of Medicine	MD	06/03	Medicine
University of California San Francisco, Fresno	Resident	6/06	Emergency Medicine
University of California San Francisco, Fresno	Chief Resident	6/07	Emergency Medicine

A. Personal Statement

The goal of Courteney MacKuen's research project is to obtain insights into the outpatient management of acute pain in the elderly and to provide Courteney with some additional exposure in the development, management, and write up of clinical research. I am committed to ensuring that the study is conducted in a manner that maximizes Courteney's opportunities for independent learning and which also produces valid results in a manner which is respectful to patients and protects their privacy. I have a broad background in clinical research and mentoring. I have first authored eight peer-reviewed original research studies. I have benefitted from exemplary mentorship from Dr. Greg Hendey (UCSF-Fresno), Dr. Charles Cairns (UNC) and Dr. Samuel McLean (UNC). As a senior resident, I received the national resident academic achievement award form the Council of Residency Director for my research conducted during residency. I have also twice been recognized as a senior reviewer for Annals of Emergency Medicine. I have mentored four trainees (B. Ferguson, K Dhah, B. Leacock, and G. Burke) in clinical research and these relationships have led to publications and career advancement for all mentees. I have been recognized for my outstanding emergency medicine teaching with the UNC Department of Emergency Medicine's Socrates Award for the last two years in a row. In summary, I have a demonstrated record of commitment to excellence in emergency medicine research, successful mentorship, and outstanding teaching.

B. Positions and Honors

Positions and Employment

2007- Assistant Professor, Department of Emergency Medicine, University of North Carolina, Chapel Hill, NC

Other Experiences and Professional Membership

2005- Member, Society of Academic Emergency Medicine, Academy of Geriatric Emergency Medicine

2005- Member, American College of Emergency Medicine, Geriatric Emergency Medicine Section

2005- Reviewer, Annals of Emergency Medicine

2009 Oral presentation on the triage of elderly patients at the National American Geriatrics Society meeting

Honors

1996 Magna Cum Laude with Honors, Harvard College
1996 Thomas T. Hoopes Prize for Outstanding Scholarly Work, Harvard College
1997 Michael C. Rockefeller Memorial Fellow, Papua New Guinea
1997 Fulbright Fellow, Papua New Guinea
2003 Intern of the Year, University of California San Francisco-Fresno
2006 Borba House Staff Research Award, University of California San Francisco, Fresno
2006 Top 50 Reviewers for Annals of Emergency Medicine
2007 Resident Academic Achievement Award - Council of Emergency Medicine Residency Directors
2009 Socrates Teaching Award – University of North Carolina, Chapel Hill
2010 Senior Reviewer, Annals of Emergency Medicine

C. Peer-reviewed Publications

Most relevant to the current application

1. Platts-Mills TF, Biese K, LaMantia , Zamora Z, Patel LN, McCall B, Egbulefu F, Busby-Whitehead J, Cairns CB, Kizer JS. Nursing home revenue source and information availability during the emergency department evaluation of nursing home residents. *J Am Med Dir Assoc*. 2010 (accepted).
2. Platts-Mills TF, Leacock B, Cabanas J, McLean SA. Emergency medical services use in the elderly: analysis of a statewide database. Prehosp Emerg Care. 2010;14:329-33.
3. LaMantia MA, Platts-Mills TF, Biese K, Khandelwal C, Forbach C, Cairns C, Busby-Whitehead J, Kizer JS. Predicting admission to the hospital and returns to the emergency department for elderly patients. Acad Emerg Med. Accepted. 2010;17:252-9.
4. Platts-Mills TF, Travers D, Biese K, et al. Accuracy of the Emergency Severity Index triage instrument for Identifying elderly emergency department patients receiving an immediate life-saving intervention. Acad Emerg Med. Accepted. 2010;17:238-243.

Additional Publications

1. Platts-Mills TF, Campagne D, Chinnock B, Snowden B, Glickman LT, Hendey GW. A comparison of video laryngoscopy versus direct laryngoscopy for emergency department intubations. Acad Emerg Med. 2009 Sep;16(9):866-71.
2. Platts-Mills TF, Hendey GH, Ferguson B. Teleradiology interpretations of emergency department computed tomographic scans. J Emerg Med. 2010;38(2).
3. Tonna JE, Lewin MR, Hahn IH, Platts-Mills TF, Norell MA. A prospective, multi-year analysis of illness and injury during summer travel to arid environments. Wilderness Environ Med. 2009;20:107-12.

4. DeKoning EP, Hakenwerth A, Platts-Mills TF, Tintinalli JE. Epidemiology of burn injuries presenting to North Carolina emergency departments in 2006-2007. Burns. 2009;35:776-82.
5. Platts-Mills TF, Stendell E. Lewin MR, Moya M, Dhah K, Stroh G, Shallit M. An experimental study of warming intravenous fluids in a cold environment. Wilderness Environ Med. 2007 Fall;18(3):177-85.
6. Platts-Mills TF, Lewin MR, Wells J, Bickler P. Improvised cricothyrotomy provides reliable airway access in an un-embalmed human cadaver model. Wilderness Environ Med. 2006;17(2):81-86.
7. Platts-Mills TF, Lewin MR, Ma S, Madsen T. The oral certification examination. Ann Emerg Med. 2006;47(3):278-82.
8. Platts-Mills TF, Burg MD, Snowden B. Obese patients with abdominal pain presenting to the emergency department do not require more time or resources for evaluation than nonobese patients. Acad Emerg Med. 2005;12(8):778-81.

D. Research Support

Ongoing Research Support

KL2 RR025746-03 Runge (Institutional K1L2 PI) 07/01/10 - 5/01/13

Persistent Pain and Function Decline in Elderly Adults after Motor Vehicle Collision
The goal of this project is to develop an emergency department research network and collect pilot data assessing the influence of psychological, cognitive, crash-related, and sociodemographic factors on the development of chronic post-MVC musculoskeletal pain and associated functional decline in patients 65 years of age and older.
Role: PI
Amount: $100,000

NCTraCS $10K Pilot Grant Platts-Mills (PI) 01/01/10-12/01/10
Identifying Predictors of Persistent Pain in Older Patients Following Minor Motor Vehicle Crash
Role: PI
Amount: $10,000

UNC Jr Faculty Development Award Platts-Mills (PI) 01/01/10-12/01/10
Identifying Predictors of Persistent Pain in Older Patients Following Minor Motor Vehicle Crash
Role: PI
Amount: $7,500

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Shofer, Frances S	Research Professor of Emergency Medicine Director of Research, Emergency Medicine
eRA COMMONS USER NAME	University of North Carolina

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
Univ. of Pennsylvania, Philadelphia, PA	BA	1977	Biochemistry
Univ. of Pennsylvania, Philadelphia, PA	PhD	1983	Epidemiology

A. Personal Statement

I am currently the Research Director and Professor of Emergency Medicine at the University of North Carolina at Chapel Hill. I will serve as the biostatistician on this grant. For more than 20 years, I have been working in EM research and have developed an expertise in the design, management, data analysis, and evaluation of clinical research studies of ED based studies. My primary responsibility is to collaborate with ED faculty on research projects from concept through publication. I have also played a major role in mentoring junior faculty, residents, medical and undergraduate students in research design, epidemiology and biostatistics. I have successfully mentored 5 fellows, 11 residents and more than 20 medical students of which the majority have presented at national emergency medicine meetings (10 have won awards for best presentation/poster) and have produced manuscripts that have been published in peered reviewed journals.

B. Positions and Honors

Faculty Appointments:

08/84-07/89	Lecturer, Section of Epidemiology, Department of Clinical Studies, School of Veterinary Medicine, University of Pennsylvania
07/89-07/91	Lecturer, Emergency Services, Department of Medicine, University of Pennsylvania School of Medicine
12/91-03/02	Adjunct Assistant Professor of Epidemiology, Department of Clinical Studies, School of Veterinary Medicine, University of Pennsylvania
03/02-07/07	Adjunct Associate Professor of Epidemiology and Biostatistics, Department of Clinical Studies, School of Veterinary Medicine, University of Pennsylvania
07/07-06/09	Adjunct Professor of Epidemiology and Biostatistics, Department of Clinical Studies, School of Veterinary Medicine, University of Pennsylvania
07/08-06/10	Adjunct Professor of Occupational Medicine, Department of Emergency Medicine, School of Medicine, University of Pennsylvania

06/09-present	Research Professor of Emergency Medicine, Department of Emergency Medicine, School of Medicine, University of North Carolina

Other Professional Experience:

1980	Teaching Assistant Fellow, Program for Epidemiologic Research and Training, University of Pennsylvania
1980-1983	Data Analyst, Division of Clinical Research, The Institute for Cancer Research, Fox Chase Cancer Center, Philadelphia, PA
1983-1984	Biostatistical Consultant, Department of Clinical Studies, School of Veterinary Medicine, University of Pennsylvania
07/91-05/09	Senior Research Investigator, Department of Emergency Medicine, University of Pennsylvania School of Medicine
07/99-06/09	Statistical Reviewer, Society for Academic Emergency Medicine, Lansing Michigan
06/09-present	Director of Research, Department of Emergency Medicine, University of North Carolina School of Medicine

Honors:

1977	University of Pennsylvania B.A. Cum Laude

C. Selected Peer-reviewed Publications of 250

1. del Portal DA, Shofer F, Mikkelsen ME, Dorsey PJ Jr, Gaieski DF, Goyal M, Synnestvedt M, Weiner MG, Pines JM. Emergency department lactate is associated with mortality in older adults admitted with and without infections. Acad Emerg Med. 2010 Mar;17(3):260-8
2. Weisenthal BM, Chang AM, Walsh KM, Collin MJ, Shofer FS, Hollander JE: Relation between thrombolysis in myocardial infarction risk score and one-year outcomes for patients presenting at the emergency department with potential acute coronary syndrome. Am J Cardiol. 2010 Feb 15;105(4):441-4.
3. Meisel ZF, Armstrong K, Mechem CC, Shofer FS, Peacock N, Facenda K, Pollack CV: Influence of sex on the out-of-hospital management of chest pain. *Acad Emerg Med.* 2010 Jan;17(1):80-7.
4. Chang AM, Shofer FS, Tabas JA, Magid DJ, McCusker CM, Hollander JE. Lack of association between left bundle-branch block and acute myocardial infarction in symptomatic ED patients. *Am J Emerg Med*. 2009 Oct;27(8):916-21.
5. Baren J, Campbell CF, Schears RM, Shofer FS, Datner EM, Hollander JE. Observed Behaviors of Subjects During Informed Consent for an Emergency Department Study. *Ann Emerg Med.* 2009 Nov 20.
6. Mittal MK, Shofer FS, Baren JM: Serious Bacterial Infections in Infants Who Have Experienced an Apparent Life-Threatening Event. *Ann Emerg Med.* 2009 Oct; 54(4):523-7
7. Hollander JE, Chang AM, Shofer FS, McCusker CM, Baxt WG, Litt HI. Coronary computed tomographic angiography for rapid discharge of low-risk patients with potential acute coronary syndromes. Ann Emerg Med. 2009 Mar;53(3):295-304.
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13. Hollander JE, Chang AM, Shofer FS, McClusker CM, Baxt WG, Litt HI: Coronary Computed Tomographic Angiography for Rapid Discharge of Low-Risk Patients With Potential Acute Coronary Syndromes. *Ann Emerg Med.* 2009 Mar;53(3):295-304..
14. Chang AM, Shofer FS, Weiner MG, Synnestvedt MB, Litt HI, Baxt WG, Hollander JE: Actual Financial Comparison Of Four Strategies To Evaluate Patients With Potential Acute Coronary Syndromes. *Acad Emerg Med.*, 15(7):649-55, 2008 Jul. 2008
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D. Research Support:

Ongoing

DHS-10-OHA-122-001 Cairns (PI) 07/01/10-06/30/12
North Carolina Bio-Preparedness Collaborative (NCB-Prepared)
The goal of this Department of Homeland Security/Office of Health Affairs funded project is to develop and to enhance bio-surveillance capabilities, including EMS, ED and ICU care and management systems.
Role: Epidemiologist

HRSA-10-062 Greg Mears (PI) 09/01/10-08/31/13
EMS and Pediatric Trauma: A North Carolina Population Based Performance Improvement Intervention and Evaluation Using Multiple Linked Healthcare Databases
The goal of this project is to develop a web-based educational training course on the recognition, assessment and triage of pediatric injuries
Role: Epidemiologist/Biostatistician

DTNH22-10-R-00402 Greg Mears (PI) 09/01/10-03/31/12
EMS and Pediatric Trauma: A North Carolina Population Based Performance Improvement Intervention and Evaluation Using Multiple Linked Healthcare Databases
The goal of this project is to develop a web-based educational training course on the recognition, assessment and triage of pediatric injuries
Role: Epidemiologist/Biostatistician

Completed (10 years)

NIEHS 5-R25-ES012591-0 Edward Emmett (PI) 09/01/03-06/30/07
Community Exposure to Perfluorooctanate
The goal of this project was to determine the blood levels and effects of a community exposure to the fluoronated octanate C8.
Role: Epidemiologist/Biostatistician

R01-MH 60915 Alan Beck (PI) 01/01/99-12/31/03
Early cognitive intervention for suicide attempters
Role: Epidemiologist/Biostatistician

R49-CCR316866 Alan Beck (PI) 09/01/99-08/30/02
Early cognitive intervention for suicide attempters
Role: Epidemiologist/Biostatistician

RESOURCES

Facilities:

Laboratory:

The UNC-CH Department of Emergency Medicine has a dedicated clinical research laboratory located within the clinical UNC-CH Hospital Emergency Department (in addition to standard clinical hospital laboratory services equipped with point of care stat testing). This research laboratory includes a "wet lab" for processing blood, body fluid and tissue specimens, as well as dedicated equipment (centrifuge, refrigerator and -70 C freezer). This laboratory is operated and maintained by dedicated clinical research personnel. This allows for true point of care clinical research specimen collection, processing and storage.

Clinical:

The University of North Carolina Hospitals (UNC-CH) main hospital is an 800-bed tertiary teaching hospital in Chapel Hill that serves as a referral hospital for the State of North Carolina. UNC-CH is a certified Level I trauma center, State Burn Center, and JCHAO certified Stroke Center. The UNC-CH ED has dedicated imaging (CT scanner, ultrasound), diagnostic (triage, patient evaluation units) and physiologic monitoring (cardiac, critical care) capabilities. CERTN Scholars will have access to an ED census of 68,000 patients/year. The racial distribution of ED patients trends as follows: Caucasian 53%, Black 30%, Hispanic 11%, Asian 1%, American Indian/Alaskan Native 1%, other 2%. Approximately 25 % of the volume includes children (age <21).

The Department of Emergency Medicine has dedicated clinical research resources available to researchers, including a dedicated RN clinical research coordinator (with 15 years of clinical research experience) and research assistants which allow for virtually 24/7 coverage for clinical research screening and enrollment. In addition, the Department of Emergency Medicine has a dedicated clinical research director (PhD with over 300 publications) and a dedicated research design/methodology mentor (DrPH with over 250 publications).

Clinical research processes have been integrated with clinical information and care systems to allow for electronic screening of potential ED patients for clinical studies. In addition, the clinical research team has experience in verbal consent and short form consent necessary for rapid consent in time-sensitive ED studies. In addition, the research team has performed studies using exception from informed consent and waiver of consent protocols.

Importantly, UNC-CH last year saw sufficient number of patients relevant to this proposal: burns (n=281), trauma (n=2599), severe trauma (n=599 yellow/red alerts).

UNC-CH has had a residency in emergency medicine for over 15 years, currently with 30 residents and 25 attendings who are certified by or eligible for certification by the American Board of Emergency Medicine. Reseachers will have the option of expanding enrollment for clinical trials to the WakeMed system in Raleigh (EM residency and Pediatric EM Fellowship partner) which offers access to another Level I trauma center (WakeMed) and 3 other EDs in Wake County with an additional annual volume of approximately 250,000 patients per year, including 115,000 pediatric patients. All of these WakeMed EDs are within a 25 min drive of UNC-CH and the WakeMed has additional 55 UNC EM adjunct faculty members.

RESOURCES

Animal: N/A

Computer:

The UNC Department of Emergency Medicine has dedicated server farms for the collection, operation and analysis of the statewide emergency data systems, including the NC Disease Event Tracking and Epidemiological Collection Tool (NC DETECT) and the NC Pre-hospital Medical Information System (PreMIS). NC DETECT is a near real-time statewide emergency department (ED) database, which is developed and maintained by the Department of EM at UNC-CH, in collaboration with the NC Division of Public Health. NC DETECT incorporates the patient's chief complaint data on approximately 4.5 million ED visits annually and thus, it is uniquely positioned to address cardiovascular and trauma patients. PreMIS collects data on patient encounters in virtually all emergency medical services (EMS) systems across North Carolina, approximately 2 million EMS patient visits annually.

As part of the NC Bioprepardness Collaborative (NCB-Prepared.org), the Department of Emergency Medicine works closely with the RENCI computing institute (http://www.renci.org/) and the NC State Virtual Computing Laboratory (vcl.ncsu.edu) and the SAS Institute (www.sas.com) to develop innovative approaches to emergency data collection and analysis.

In addition, the Department has multiple personal computers and printers. We have previously used multiple methods of data collection, informed consent, and obtained full support of the IRB, privacy board and IT security administrators for our electronic surveillance system to identify patients with key disease processes relevant to the Scholar's work. All research coordinators have access to the electronic ED status board, which shows the patient's chief complaint and ED location to help rapidly identify patients who might be eligible for enrollment. All data collectors have access to administrative databases needed to determine test orders, length of stay and medical record follow-up. Scholars will have their own PCs, described under office space.

Office:

The research coordinators have cubical space located in the Departmental offices. All personnel have computers and internet access. Additionally, research coordinators and the project manager have a 200 s.f. office dedicated to emergency medicine research in the UNC Hospital first floor with full computer access. Scholars will have their own dedicated office space, in the same suite as the PI, built especially for and shared by research fellows (no other residents or fellows). This office space has with a desktop computer with internet connection, standard software loaded to include Microsoft Office Suite, telephone, ample desk space and lockable storage and filing space.

RESOURCES

Other:

NC TraCS Institute: This CTSA supported program has core resources available, including Biomedical Informatics, Clinical Data Management, Clinical Research Resources, Community Engagement, Core Labs (Biobanking, Pharmacometrics, Genomics, Proteomics, Metabolomics), Clinical and Translational Research Innovation Program and a Research Recruitment Office.

Videoconferencing

UNC-CH has three studios for videconferencing, located in the connecting NC Cancer Hospital, within a 3 minute walk of the offices. In addition the Department of Emergency Medicine has a dedicated, portable Polycom videoconferencing system. These systems are currently in use for joint training conferences with UNC-CMC in Charlotte and WakeMed in Raleigh.

Program Director/Principal Investigator (Last, First, Middle): Platts-Mills, T./ MacKuen, C.

DETAILED BUDGET FOR INITIAL BUDGET PERIOD DIRECT COSTS ONLY	FROM 07/01/11	THROUGH 06/30/12

List PERSONNEL *(Applicant organization only)*
Use Cal, Acad, or Summer to Enter Months Devoted to Project
Enter Dollar Amounts Requested *(omit cents)* for Salary Requested and Fringe Benefits

NAME	ROLE ON PROJECT	Cal. Mnths	Acad. Mnths	Summer Mnths	INST.BASE SALARY	SALARY REQUESTED	FRINGE BENEFITS	TOTAL
Tim Platts-Mills	PD/PI							0
Courteney MacKuen	Student PI	12				1,200		1,200
Abbey Whittington	Data Manager	4				884	277	1,161
SUBTOTALS →								2,361

CONSULTANT COSTS	0
EQUIPMENT *(Itemize)*	0
SUPPLIES *(Itemize by category)* pens-15 notebooks-24	39
TRAVEL	0
INPATIENT CARE COSTS	0
OUTPATIENT CARE COSTS	0
ALTERATIONS AND RENOVATIONS *(Itemize by category)*	0
OTHER EXPENSES *(Itemize by category)*	0
CONSORTIUM/CONTRACTUAL COSTS	DIRECT COSTS
SUBTOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD *(Item 7a, Face Page)*	$ 2,400
CONSORTIUM/CONTRACTUAL COSTS	FACILITIES AND ADMINISTRATIVE COSTS
TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD	$ 2,400

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CONTINUATION PAGE

STAY WITHIN MARGINS INDICATED

OTHER SUPPORT

KL2 RR025746-03 Runge (Institutional K1L2 PI) 07/01/10 - 5/01/13
Persistent Pain and Function Decline in Elderly Adults after Motor Vehicle Collision

The goal of this project is to develop an emergency department research network and collect pilot data assessing the influence of psychological, cognitive, crash-related, and sociodemographic factors on the development of chronic post-MVC musculoskeletal pain and associated functional decline in patients 65 years of age and older.

There is no scientific or budgetary overlap with the current proposal.
Recipient: Dr. Platts-Mills
Role: PI
Amount: $100,000

NCTraCS $10K Pilot Grant Platts-Mills (PI) 01/01/10-12/01/10
Identifying Predictors of Persistent Pain in Older Patients Following Minor Motor Vehicle Crash

There is no scientific or budgetary overlap with the current proposal.
Recipient: Dr. Platts-Mills
Role: PI
Amount: $10,000

UNC Jr Faculty Development Award Platts-Mills (PI) 01/01/10-12/01/10
Identifying Predictors of Persistent Pain in Older Patients Following Minor Motor Vehicle Crash

There is no scientific or budgetary overlap with the current proposal.
Recipient: Dr. Platts-Mills
Role: PI
Amount: $7,500

CONTINUATION PAGE

STAY WITHIN MARGINS INDICATED

STATEMENT OF CONDITIONS

STATEMENT OF CONDITIONS GOVERNING THE
EMERGENCY MEDICINE FOUNDATION GRANT

It is understood that any Emergency Medicine Foundation Research Grant approved by the Emergency Medicine Foundation will be made with the following conditions:

1. Institutional overhead is not allowed.
2. The principal investigator's institution is associated or organized for humanitarian purposes and is not a profit making organization.
3. All reports of work achieved with this grant will acknowledge the support of the Emergency Medicine Foundation and his or her co-sponsor, if applicable.
4. Any discovery that arises from work supported in part by the Emergency Medicine Foundation will be submitted for publication. Two copies of each publication will be furnished to the Emergency Medicine Foundation.
5. Independent progress reports by the applicant will be submitted to the Emergency Medicine Foundation mid-project, and within thirty days of completion of the funding period. Additional reports may be required. The Emergency Medicine Foundation will maintain the copyright of all such reports.
6. Participation in Emergency Medicine Foundation recognition reception during the American College of Emergency Physicians Scientific Assembly is required. Grant money may not be used for travel to this event.
7. Participation in the Emergency Medicine Foundation Grantee Workshop is required. The Grantee Workshop will be held in Dallas, TX. Grant funds may not be used for travel, however, the Emergency Medicine Foundation will reimburse travel expenses.
8. Participation in Research Forum to give a poster presentation is required. This event takes place at the end of your project. Research Forum is held each year during the American College of Emergency Physicians Scientific Assembly. Grant money may not be used for travel.
9. If all requirements are met, funding will begin on July 1st. The Emergency Medicine Foundation reserves the right to terminate payments under this grant at its sole discretion.
10. If the named principal investigator leaves the institution or terminates research in the designated field, all remaining funds revert to the Emergency Medicine Foundation. If unused funds exist at the completion of the project, all remaining funds revert to the Emergency Medicine Foundation.

CONTINUATION PAGE

STAY WITHIN MARGINS INDICATED

11. Patent rights will conform to institutional standards. If none exist, the Emergency Medicine Foundation reserves the right to protect such interests.

12. No research proposal will be funded unless the principal investigator and the Fiscal Officer of the sponsoring institution affirm:

    a. That the investigation(s) proposed in this application are endorsed by the Animal and/or Human Subjects Committee or other designated body of the preceptor's institution, and
    b. That any research involving human subjects conforms with the principles of the Helsinki Code of the World Medical Association, and
    c. Research involving animals or human subjects must be approved by the institutional review board (IRB), or its equivalent, and a copy of the approval or pending approval sent with this application. IRB approval must be documented prior to dispensation of Emergency Medicine Foundation funds.
    d. That research involving vertebrate animals will conform with the "Guiding Principles in the Care and Use of Animals" as approved by the Council of the American Physiological Society.
    e. Research involving vertebrate animals must have approval from the institutional Animal Care and Use Committee.

12/17/10 _____ / Courteney MacKuen
Date Signature of Principal Investigator Type Name of Principal Investigator

_____ / Timothy F. Platts-Mills, MD
Date Signature of Mentor, if applicable Type Name of Mentor

12/20/10 _____ / Barbara Entwisle,PhD, Interim
Date Signature of Fiscal Officer Type Name of Fiscal Officer

Acting for
Barbara Entwisle, PhD

CONTINUATION PAGE

STAY WITHIN MARGINS INDICATED

LETTER OF SUPPORT FROM PRECEPTOR, DR. PLATTS-MILLS

UNC SCHOOL OF MEDICINE

University of North Carolina at Chapel Hill
Department of Emergency Medicine
Timothy F. Platts-Mills, MD
Assistant Professor
tplattsm@med.unc.edu

December 20, 2010

SAEM / EMF Grants
2340 South River Road, Suite 200
Des Plaines, IL 60018

Re: Courteney MacKuen
SAEM/EMF Medical Student Research Grant

Dear Reviewers:

I am writing this letter in enthusiastic support of the application of Courteney MacKuen for a **SAEM/EMF Medial Student Research Grant. Courteney is currently a fourth year medical student at UNC Chapel Hill taking an additional year to obtain a Masters in Public Health.**

Commitment to Emergency Medicine and Research Potential

Courteney approached me three months ago with an interest in conducting a research study focused on an aspect of emergency medical care as part of her Masters in Public Health. At that time she expressed her strong interests in doing a residency in emergency medicine. Since then, Courteney and I have worked closely together to develop the protocol for her proposed study. The study Courteney has developed will examine pain, the effect of pain on physical function, and side effects from pain medications in older adults discharged from the emergency department (ED) after a pain-related visit. Courteney has completed a comprehensive literature review on the subject, has read extensively about the assessments of the relevant outcomes, and has spent time with both Dr. Shofer and myself developing the analytic approach and the sample size estimate for this study. Through this work, Courteney has clearly demonstrated a genuine interest in doing a research project well and an impressive set of academic and interpersonal skills. Courteney's project will give her an opportunity to learn more about research methodology but also teach her about the challenges of conducting clinical research. I am confident that Courteney has the skills needed to overcome such challenges and that her project is well suited to her and my abilities. I am very pleased to continue working with Courteney over the coming year, and I think she is and will continue to be deserving of recognition for her work.

Courteney's prior research experience has prepared her well for this project and also demonstrates a commitment to academic inquiry. She is a co-author on a study examining the effects of hormones on rates of suicide attempts in patients which she contributed to during college, and she spent a year prior to starting medical school as a clinical coordinator on an NIH trial. She is currently supported by a merit based scholarship at UNC School of Medicine. Since coming to medical school, Courteney received the Albert Schweitzer Fellowship, a public service award, with which she opened an HIV testing clinic for the underserved. By the time of her award period, she will have completed her classes towards a Master's in Public Health. She has chosen emergency medicine for her residency training and plans to combine her interests in public health and emergency medicine in her future career.

As Courteney's mentor for her research project, I have provided her with guidance during the past 3 months in developing the proposed project. As we go forward, I will support her in data

♦ Phone: (919) 966-5933 ♦ Fax: (919) 966-3049 ♦ http://www.med.unc.edu/emergmed ♦
♦ 1st Floor, Physicians Office Building ♦ 170 Manning Dr, ♦ Campus Box #7594 ♦ Chapel Hill, NC 27599-7594 ♦

CONTINUATION PAGE

STAY WITHIN MARGINS INDICATED

collection, data management, data analysis and manuscript preparation. Additionally, I will be responsible for the conduct of the study and the safe-keeping of all patient-identifiable information. Courteney's project will parallel my own project examining outcomes in older adults after motor vehicle collision (NIH 5KL2RR025746-03). Her project uses several of the elderly-specific assessment tools that I have chosen for my study, and our experiences completing this study should complement one another nicely. My career development award provides me with sufficient protected time to ensure that Courteney will receive close supervision and mentorship. Courteney will also have access to the research resources of the Department of Emergency Medicine and the Department of Anesthesia, with whom I have a joint appointment.

I am committed to teaching and mentoring emergency medicine researchers. I have mentored four prior trainees for research. I currently direct the journal club for UNC's 30 resident program in emergency medicine. For my teaching, I was selected by the residents for the department's Socrates Teaching Award for both 2008-2009 and 2009-2010. In regard to my own work, I am strongly committed to a successful career as an independent researcher conducting important investigations into understanding the development of persistent pain following injury in elderly adults and developing interventions to manage acute pain and prevent persistent pain in this population. This is a challenging but important and rapidly growing population of emergency medicine patients and there is considerable need for further work in this area. Courteney's project will not only teach her about clinical research and provide her with further insights into the rewards of a career in academic emergency medicine, but also provide answers to clinically important questions about the effectiveness and side effects of the outpatient treatment of pain in the elderly.

In conclusion, Courteney MacKuen is an excellent candidate for the SAEM / EMF medical student research grant. She has a strong interest in academic emergency medicine, and I am confident that I will be able to provide exceptional mentorship for Courteney. Please do not hesitate to contact me with any questions, comments or for further information at (919) 843-1400 or tplattsm@med.unc.edu.

Sincerely,

Timothy F. Platts-Mills, M.D.
Assistant Professor
Department of Emergency Medicine
University of North Carolina

CONTINUATION PAGE

STAY WITHIN MARGINS INDICATED

LETTER OF SUPPORT FROM DEPARTMENT HEAD, DR. CAIRNS

UNC SCHOOL OF MEDICINE

University of North Carolina at Chapel Hill
Department of Emergency Medicine
Charles B. Cairns, MD, FACEP, FAHA
Professor and Chair
ccairns@med.unc.edu

December 16, 2010

SAEM / EMF Grants
2340 South River Road, Suite 200
Des Plaines, IL 60018

Re: Courteney MacKuen
SAEM / EMF Medical Student Research Grant

Dear Reviewers:

I am writing this letter in enthusiastic support of the application of Courteney MacKuen for a SAEM / EMF medical student research grant. Ms. MacKuen is a **medical student at the University of North Carolina at Chapel Hill**. She is currently completing a Masters in Public Health at as part of her medical school training. For her proposed project, her mentor will be Dr. Timothy Platts-Mills, who is an **Assistant Professor in the Department of Emergency Medicine.**

Research and Leadership Potential

Ms MacKuen has shown an extensive interest in research over her short career. She has published on work that she completed during college, and spent a year prior to starting medical school as a clinical coordinator on an NIH trial. She is currently supported by a full merit based scholarship at UNC School of Medicine. Since coming to medical school, Ms. MacKuen received the Albert Schweitzer Fellowship, with which she opened an HIV testing clinic for the underserved. She is actively interested in emergency medicine and plans to combine her interests in public health and emergency medicine in her future career. During the past 2 months, Ms. MacKuen has worked closely with Dr. Platts-Mills to familiarize herself with the existing literature on the management of pain in the elderly and to develop a protocol for their proposed study. This project will give Ms. MacKuen an opportunity to learn about research methodology, the collection of clinical data, data management, data analysis, and manuscript preparation. I think that this grant will help her to further a lifelong research career in emergency medicine.

Ms. MacKuen's mentor for her research project will be Dr. Platts-Mills. Dr. Platts-Mills is focusing her research on the development of persistent pain following injury in older adults. For this work, Dr. Platts-Mills has received a career development award (NIH 5KL2RR025746-03). His primary project for this award is a longitudinal observational study of pain and physical function outcomes for patients age 65 and older who experience motor vehicle collision. The project that Ms. MacKuen will undertake with Dr. Platts-Mills is related to Dr. Platts-Mills area of interests because it will provide initial estimates of the effectiveness and side effects of commonly prescribed pain medications in elderly adults following emergency department discharge. Ms. MacKuen's and Dr. Platts-Mills' research efforts will additional be supported by Dr. Fran Shofer, a nationally-recognized expert in the analysis of ED-based observational data.

Dr. Platts-Mills has clearly demonstrated a commitment to teaching and research mentorship. He has mentored four prior trainees for research. Dr. Platts-Mills currently directs the journal club for our 30 resident program in emergency medicine. Impressively, his student and resident

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♦1st Floor, Physicians Office Building ♦ 170 Manning Dr, ♦ Campus Box #7594 ♦ Chapel Hill, NC 27599-7594 ♦

CONTINUATION PAGE

STAY WITHIN MARGINS INDICATED

reviews have been consistently excellent with over 90% of medical students and residents giving him all fives on a scale of one to five. The qualitative review comments frequently emphasize his personal dedication, enthusiasm, and innovative approaches in teaching. Consistent with these reviews, he was selected by the residents for the department's Socrates Teaching Award for 2008-2009 and 2009-2010. I am confident that Dr. Platts-Mills has the skills and commitment necessary to serve as an outstanding mentor for the proposed project.

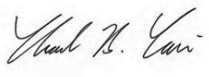
Institutional Commitment

The Department of Emergency Medicine at UNC is active in both emergency medicine and geriatric clinical care, research and training. For example, the Department of Emergency Medicine currently has over 25 active extramurally funded research projects totaling over $11 million annually, including funding from the NIH, CDC, DOD, DARPA, Duke Endowment and the American Heart Association. This research has resulted in numerous national presentations and over 100 published manuscripts this year.

I certify that the Department has the dedicated space and support personnel to assure completion of Ms. MacKuen's proposed research project. Our research resources include access to emergency department patients at the UNC Hospitals Level 1 Trauma Center (65,000 annual census). We have dedicated clinical and laboratory research support personnel. In addition, the Department has recently recruited five established and federally funded clinical and outcomes researchers (PhD, DrPH, MD/PhD) with expertise in public health, epidemiology and biostatistics. Ms. MacKuen and Dr. Platts-Mills will also continue to benefit from the methodologic and analytical support of Dr. Frances Shofer, who will serve as the research design and statistical consultant to the project.

In conclusion, Courteney MacKuen is an excellent candidate for the SAEM / EMF medical student research grant. She has a strong interest in academic emergency medicine and is well supported by a strong junior faculty mentor along with outstanding institutional support. Please contact me for any questions, comments or for further information at (919) 843-3045.

Sincerely,



Charles B. Cairns, M.D.
Professor and Chair
Department of Emergency Medicine
University of North Carolina

APPENDIX

SURVEY

TELEPHONE SURVEY SCRIPT
PROSPECTIVE OBSERVATIONAL STUDY OF THE EFFECTIVENESS AND SIDE EFFECTS OF PAIN MEDICATION IN ELDERLY PATIENTS FOLLOWING A PAIN-RELATED EMERGENCY DEPARTMENT VISIT

Key
Italics is what the interviewer says
CAPS MEANS TO RECORD OR DO SOMETHING
Bolding and underlining is used for organization

Part 1: Obtained from the Electronic Medical Record
1. PLEASE ENTER INTERVIEWER'S INITIALS
RECORD _____
2. PATIENT DOB
3. PATIENT CHIEF COMPLAINT
4. DATE OF EMERGENCY DEPARTMENT VISIT
5. DISCHARGE PAIN MEDICATIONS
6. INITIAL EMERGENCY DEPARTMENT PAIN SCORE

Part 2: Consent
Begin Phone Call.
Hi, my name is _____, I'm calling from UNC. Is _____ available to talk?
GO TO TELEPHONE CONSENT

7. Did patient consent?
RECORD YES NO
8. If patient did not consent, what was their reason?
RECORD FREE TEXT

Part 3: Cognitive Assessment
Thank you for your willingness to participate in this study. I would like to ask you a couple of questions before we begin.

Cognitive Assessment
I would like to ask you some questions that ask you to use your memory. I am going to name three objects. Please wait until I say all three words, then repeat them. Remember what they are because I am going to ask you to name them again in a few minutes. Please repeat these words for me: APPLE—TABLE—PENNY. (Interviewer may repeat names 3 times if necessary but repetition not scored.)

9. Did patient correctly repeat all three words? Yes No

10. *What year is this?*
CORRECT? RECORD: Yes(1) /No (0)

11. *What month is this?*
CORRECT? RECORD: Yes(1) /No (0)

12. *What is the day of the week?* 0 1
CORRECT? RECORD: Yes(1) /No (0)

What were the three objects I asked you to remember?
13. *Apple* _ 0 1
14. *Table* _ 0 1
15. *Penny* _ 0 1
16. RECORD TOTAL SCORE – SUM RESULTS OF QUESTIONS #10-15 (MAXIMUM SCORE = 6):

CONTINUATION PAGE

STAY WITHIN MARGINS INDICATED

IF SUBJECT HAS MISSED 2 OR MORE OF THE ABOVE QUESTIONS:

Thank you for your time and participation in this study, those are all the questions I have for you right now.

IF SUBJECT HAS MISSED 1 OR 0 OF ABOVE QUESTIONS: CONTINUE TO NEXT SECTION

PART 4: Pain and Pain Interference Assessment

Now I am going to ask you a few questions about your recent visit to the Emergency Department.

17. Why did you go to the Emergency Department?

FREE TEXT RESPONSE

18. Did the physician recommend or prescribe any medications to take home?

RECORD: Yes No

	Medication 1	Medication 2	Medication 3
19. Do you know the names of the medications? RECORD: Yes No			
20. Did you fill the prescription? RECORD: Yes No			
IF NO 21. *Why didn't you fill the prescription?* I didn't think I needed it It was too expensive I couldn't easily get to the pharmacy I haven't had a chance Other			
22. Did you take any of this medication? RECORD: Yes No			
IF NO: 23. *Which of these bests describes the reason why you did not?* I didn't need it anymore The side effects stopped me Did not refill the prescription Other			
24. Did you stop taking the medication for any reason? RECORD: Yes No			
IF YES: 25. *Which of these bests describes the reason why you stopped taking the medication?* I didn't need it anymore The side effects stopped me I ran out Other			

26. Have you taken over the counter pain relief such as Tylenol, Motrin or Advil since you left the Emergency department?
RECORD : Yes No

27. One a scale from zero to ten, where zero means no pain and ten equals pain as severe as it could be, how would you rate your pain today?
RECORD (0-10)

28. Where is your pain located?
FREE TEXT RESPONSE

Please answer the following question about pain interfering with your life with a number from 0 to 10, where 0 is no interference and 10 is complete interference. During the past week, how much has pain interfered with your:
29. General Activity (0-10):_____
30. Mood (0-10):_____
31. Walking Ability (0-10):_____
32. Normal work (includes both work outside the home and housework) (0-10):_____
33. Relationships with others (0-10):_____
34. Sleep (0-10):_____
35. Enjoyment of life (0-10):_____

PART 5: Side Effects
I am now going to ask you about any side effects you may have had after the visit to the Emergency Department. If you have had any of them, I will ask you to rate how much this side effect has disturbed your normal life. The scale is from 0-10; 0 being no effect and 10 being severely affected the way you normally lead your life. Then I will ask you whether you feel that the side effects are from any medication.

Side effect	Scale 0-10: No effect-----Major effect	Which medication do you feel this is from? Medication # (from question 20)	Can you tell me more about this?
36. Nausea			
37. Vomiting			
38. Dizziness			
39.Unsteadiness			
40. Falls			

41. *Have you done anything to treat these side effects?*
RECORD: YES NO
42. IF YES: *What have you done?*
FREE TEXT RESPONSE
43. IF YES: *Has it helped make these problems go away?*
RECORD: YES NO

PART 6: Miscellaneous

44. For a person of your age, in general, thinking about your health before your visit to the Emergency Department, would you say your health was:
RECORD:
Excellent
Very Good
Good
Fair

Poor

45. *Have visited or contacted a doctor since your visit to the Emergency Department?*
RECORD: Yes/NO

46. IF YES- *For what reason did you visit or contact your doctor?*
RECORD: I was told to return
I am still in pain
I am worried about side effects
Other-FREE TEXT

Now, I would like to ask some questions about you.

47. What is the highest grade or level of schooling that you have completed?
RECORD: FREE TEXT

AND CATEGORIZE:

Less than 8 years
8-11 years
12 years or completed high school
Post high school training
Some college
College graduate
Post graduate level

48. This next question is about what type of place you live. I am going to read the options, and you can choose which best fits your situation.
Assisted Living, adult care home, or family care home that is not a nursing home.

Independent Living. By that I mean in a home, apartment, or senior apartment that is not a nursing home

Don't know

Other (free text response)

49. How would you categorize your race of ethnicity?
RECORD:
White, not Hispanic or latino
White, Hispanic or latino
Black or AA
Asian
American Indian or Alaskan Native

Native Hawaiin or other pacific

50. What other medications do you take? Please include both prescription and non-prescription medications. Include medications taken daily, and as needed. (Name, dosing, route, frequency)

For each of these medications please indicate if the prescription is new.

RECORD FREE NOTE

51. What other medical conditions do you have?

RECORD FREE NOTE

52. Apart from your recent visit to the Emergency Department, have you been given a prescription for pain medication in the last year?

RECORD: Yes No

53. Do you think, or has anyone ever told you, that you have chronic pain?

RECORD: Yes No

Thank you for taking time to complete this survey. This survey will help identify effectiveness of both prescription and non-prescription pain medications. Feel free to call Dr. Platt-Mills at (919) 843-5931 with questions about the research study or the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

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STAY WITHIN MARGINS INDICATED

PROOF OF IRB SUBMISSION
TO: Timothy Plattsmills
Emergency Medicine
CB:7594

FROM: Biomedical IRB

DATE: 12/23/2010

RE: Notice of Receipt of Initial Submission on 12/23/2010
STUDY #: 10-2346

STUDY TITLE: Prospective Observational Study of the Effectiveness and Side Effects of Pain Medication in Elderly Patients Following a Pain Related Emergency Department Visit

Your submission for the above-referenced study has been received by the Office of Human Research Ethics and will be reviewed by the appropriate IRB.

Please refer to the above study number when corresponding with our office about this study.

If this is an initial application and you disclosed any potential conflict of interest in "Part A.3" it must be resolved with the COI review committee before your study can be reviewed by the IRB. Further information can be obtained at http://coi.unc.edu or 919.843.9953.

All other questions about your submission should be directed to 919.966.3113.

CC:
Samuel McLean, Anesthesiology
Courteney MacKuen, School Of Public Health

IRB Informational Message—please do not use email REPLY to this address

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ETHICS

1. RISKS TO THE SUBJECTS

a. Human Subjects Involvement and Characteristics

Characteristic of subject population:

Patients of any race, gender or ethnicity aged 65 years and older who were seen in the Emergency Department with a burn, fracture, laceration, or musculoskeletal pain as the primary reason for their visit and discharged home will be included in the study. Patients will be identified using University of North Carolina Emergency Department's electronic medical record system (T-system EV). Chief complaints for patients 65 and older will be reviewed in order to identify patients with one of the above conditions. Discharge diagnoses for all potentially eligible patients will also be reviewed to ensure that the pain was not due to an alternative cause such as a renal stone. Patients with other forms of pain such as headache and chest pain will not be included.

Inclusion criteria:

Patients age 65 or older seen and discharged home from the UNC Emergency Department after a visit due to a burn, fracture, laceration, or musculoskeletal pain.

Exclusion criteria:

1. Non-English speaking patients
2. Patients without a phone
3. Patients without a pain score recorded in the Emergency Department
4. Patient with cognitive impairment as indicated by a six-item screener cognitive assessment score of 4 or less.
5. Incarcerated patients

Anticipated Subject Population Size:

In order to detect a 15% difference between the proportion of patients experiencing persistent moderate or severe pain at one week for patients taking NSAIDs vs. opioids with 80% power and an alpha of .05, we will need a minimum 138 patients receiving each class of pain medication. We do not know whether all patients with a pain-related condition discharged from the ED will be sent home with pain medication or what proportions will be taking an opioid or NSAID. In order to account for these uncertainties and to allow for sufficient power to perform an adjusted analysis, we have added 25% to the sample size estimate. This yields an estimated sample size of 350 patients.

Approximately 60 patients age 65 or older are discharged from the UNC Emergency Department each week. Of these, about half have a pain-related visit. Among those 65 or older with a pain related visit to the ED, roughly 80% have a pain score documented. Based on these estimates, about 24 patients per week will meet the study inclusion criteria per week. Based on results from an ongoing similar study by our colleagues (personal communication with Kevin Biese and Brenda McCall 11/29/10), we anticipate contacting and obtaining consent from 65% of patients who meet the inclusion criteria. This will allow for data collection on 16 patients a week or about 70 patients a month. Given a study duration of 5 months, roughly 350 patients will be enrolled.

b. Sources of Materials

The subject information gathered from University North Carolina's Electronic record system, including name, age, phone number, and chief complaint and discharge medications will be recorded in a password protected file. Study personnel will attempt 3 times to contact each patient within the 4-7 day follow-up period before the subject is deleted from the password protected file.

To protect the confidentiality of the data, a unique research ID number will be assigned to each participant that is reached by telephone. Only de-identified data will be used for analysis. Data linking the patient's unique research ID number and identifying information will be only be stored on a password protected computer in the locked project office. All patient identifiable information will be destroyed upon completion of the project. In addition, the data obtained during surveys will be located on Department of Anesthesiology servers. These servers are equipped with afirewall, are password protected, and are kept in a locked room

Once data collection is complete, all patient identifiers will be removed and only the de-identified data will be kept for data analysis. No patient identifiers will be kept beyond the end of the study. This data will be collected only for the purpose of this study.

All investigators and research staff involved in this project will have completed training in the protection of human research participants per guidelines issued by the U.S. Department of Health and Human Services, Office for Human Research Protection. A required component of staff training will consist of techniques in the maintenance of confidentiality of all information reported by research participants.

c. Potential Risks

Risks to subjects are minimal. There will be no intervention in this study. Discussion of a recent Emergency Department visit and ratings of pain contain minimal risk of harm to subjects.

2. ADEQUACY OF PROTECTION AGAINST RISKS

a. Recruitment and Informed Consent

Potential subjects will be identified by our research team from the pool of all patients 65 years of age and older that present to the ED. Subjects meeting the inclusion/ exclusion criteria specified above will be contacted. Consecutive patients will be contacted by phone by a member of the research team. If the patient declines participation in the study, the subject will be asked to state a reason. This information will be used to assess for selection bias due to differential enrollment of eligible study subjects. The identity of the subject will only be known to the caller and each subject will be assigned a study identifier which will be used to separate the identity of the patient from information collected during the study.

b. Protection Against Risk

This study represents minimal risk to subjects. The only potential risk relates to confidentiality. The PHI will be stored in a password protected file on a password protected computer. If the subject consents, they will be given a study identification number and will be deleted from this file. If the subject declines, they will be deleted from this file. If the patient is not able to be contacted with 7 days after discharge from ED, they will be deleted from this file. All patient identifiers will be deleted at the end of the study.

There will be no need for data and safety monitoring as this study does not involve an intervention.

3. POTENTIAL BENEFITS OF THE PROPOSED RESEARCH TO THE SUBJECTS AND OTHERS

Benefits to subjects are minimal, however, they will be receiving a phone call 4-7 days after discharge and if the subject continues to have concerns regarding medications or his or her ED visit, they will be given appropriate resources including the UNC nurse link line at 919-966-7890.

4. IMPORTANCE OF THE KNOWLEDGE TO BE GAINED

Benefits to society will be the scientific knowledge gained about how best to manage acute pain in the elderly. Understanding the effectiveness and side effects of commonly used treatments for pain will add to existing knowledge about how best to treat pain in elderly adults. With minimal risk to subjects, this benefits to society outweigh the risks to human subjects.
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5. DATA AND SAFETY MONITORING PLAN (if applicable)

This study consists of a telephone survey thus a data and safety monitoring plan is not applicable.

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TELEPHONE CONSENT SUBMITTED TO UNC IRB 12/23/10
IRB Study #_____ *(Leave blank if new submission.)*

Hello, my name is_____. I am a (student/faculty member/staff member) from the University of North Carolina at Chapel Hill conducting a research survey about patients over the age of 65 in the Emergency Department. Your participation in this survey is completely voluntary. This means that you do not have to participate in this survey unless you want to.

The purpose of this research study survey is to look at the management of patients over 65 in the Emergency Room. We estimate that approximately 250 people will enroll in this study. You will be asked to complete a series of questions about your recent visit to the Emergency Department. This should take about 15 minutes. There is a small chance that some of the questions may make you feel uncomfortable. You don't have to answer those questions if you don't want to. In fact you don't have to answer any question that you do not want to.

All the information I receive from you by phone, including your name and any other identifying information will be strictly confidential and will be kept under lock and key. I will not identify you or use any information that would make it possible for anyone to identify you in any presentation or written reports about this study. If it is okay with you, I also would like your permission to look at the medical record from your recent ED visit after we get off the phone. When I finish with all the phone surveys from everyone who has agreed to participate, I will group all the answers together. There will be no way to identify individual participants.

In this study, the only risk to you might be if your identity were ever revealed. But I will not even record your name with your responses, so this cannot occur. There are no other expected risks to you for helping me with this study. There are also no expected benefits for you either. However, the results of this study we help doctors understand how to treat patients like you.

This study is being paid for by UNC. Portions of Dr.Platt-Mills's and his research team's salaries are being paid by this funding.

Do you have any questions?

You can also call Dr. Platt-Mills at (919) 843-5931 with questions about the research study. All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject you may contact, anonymously if you wish, the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu. Would you like me to repeat either of these phone numbers?

Do I have your permission to begin asking you questions?

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