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Chaplain Encounter Characteristics and Probability of Study Consent Among Palliative Care Patients From the Impact of Hospital-Based Chaplain Support on Decision-Making During Serious Illness in a Diverse Urban Palliative Care Population (PCCS) Study

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ABSTRACT

Chaplain Encounter Characteristics and Probability of Study Consent Among Palliative Care Patients From the Impact of Hospital-Based Chaplain Support on Decision-Making During Serious Illness in a Diverse Urban Palliative Care Population (PCCS) Study

By Meaghan Catherine Hart

In this paper, we review the difficulties of palliative care study recruitment, and then use data from the Impact of Hospital-Based Chaplain Support on Decision-Making During Serious Illness in a Diverse Urban Palliative Care Population (PCCS) study to investigate whether friend and family presence is associated with palliative care study consent.

There were 325 patients who consented or declined to consent to a second part of the PCCS study and were included in this analysis. The patients included in the study had an average of 1.3 diaries per patient before consent decision (423 diaries in total). The exposure of interest was presence of family and friends during chaplain encounters, and was analyzed two ways: as 'ever' or 'never,' and as percentage of encounters where family or friends were present. The exposure variable in the model with the binary 'ever' or 'never' coding for family or friend presence was not significant. The model analyzing the proportion of encounters where family or friends were present found a significant 40% decrease in the likelihood of consent for patients who had family and friends present at all PCCS diary encounters compared to patients with family and friends present at none of the PCCS diary encounters. The results indicate that family and friend presence is associated with palliative care study recruitment.

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BACKGROUND

Palliative Care Introduction

Patients with serious, life-limiting illnesses often experience disease and treatment effects on more than a medical level. Palliative care is targeted at improving quality of life for patients with advanced illnesses and their families by managing physical, psychological, social, and spiritual needs (1). Good palliative care is characterized by improved quality of life, lessened suffering at the end of life, and care that is in line with a patient's goals and wishes (2). At the primary study site for this analysis, the palliative care team is a multi-disciplinary team of doctors, nurse practitioners, social workers, and chaplains who interact with seriously ill patients and families with all diagnoses in all hospital units.

Spiritual Care in Palliative Care

Spiritual care is an integral part of palliative care. Receiving spiritual support is an important part of having good quality of life at the end of life and is associated with less aggressive medical treatments at the end of life (3, 4). Attending to religion and spirituality is one of the eight domains of clinical practices defined in the national consensus project for quality palliative care (5). Within palliative care, religion and spirituality are used interchangeably, because of considerable overlap between definitions and uses across medical and religious health organizations (5). Palliative care patients report that religion and spirituality are important aspects to adjusting to terminal conditions, and several studies have found that between 50% and 95% of palliative care patients report that religion and spirituality are important to them (5-11). Spirituality and

spiritual views can influence how a patient makes decisions at the end of life, specifically regarding the choice to have advance care planning or opting to have life prolonging procedures (4-8). A study from 2013 on the influence of spiritual support from religious communities on medical decision making among terminally ill patients found that there was an increased likelihood of engaging in aggressive care at the end of life among patients with higher amounts of spiritual support from religious communities (4). A qualitative study of ethnicity and end of life planning that included 68 African American and White cancer patients found that spirituality was associated with opting for life prolonging treatments (7). Religious faith can also influence medical decision making (8-9). A qualitative study of 374 men's preferences for end of life treatment found a significant association between religion and the desire to have lifesaving procedures at the end of life (8).

While a patient's illness advances, it becomes more difficult to participate and practice religion within the context of a spiritual and religious community because of limited accessibility to spiritual services and gatherings (5). In a qualitative study conducted in 2008 of 103 palliative care and usual care patients, the palliative spiritual care afforded to family members of patients who have passed away was reported to have provided benefit in almost double the amount of families when compared to people who stayed in the hospital for a non-palliative care visit (12). While spiritual support by staff is recognized by patients and palliative care providers as an important aspect of palliative care and is associated with improved quality of life for palliative care patients, the extent to and mechanisms by which spiritual support influences quality of life at the end of life is still unknown (5). Recent studies such as the chaplain encounter characteristics and

probability of study consent among palliative care patients from the Emory Palliative Care Chaplain Study (PCCS), the source of data for this analysis, have sought to investigate the role of the chaplains and spirituality in palliative care.

Family Involvement in Palliative Care

In a 2002 review of how clinical research can impact patients with terminal illnesses, social relationships and support were one of the six domains recognized as contributing to a 'good death' for a patient (13). In the review, the authors discuss how social support can ease the processes of dying, and how research studies have the opportunity to increase social support available for a patient by involving family members and other loved ones (13).

The palliative care community's definition of family is somewhat informal in that it is not uncommon for family and friends to be combined into the category of family during palliative care studies and palliative care receipt (14). Palliative care aims to support both patients and their families from a medical, social, and spiritual standpoint, because they are not only potential proxies for the patient, but are also recipients of the psychological support offered during care (5, 14-15).

Maintaining the wellbeing of family members and friends during palliative care is a difficult task. Often, families fear that the shift to palliative care means the general physicians have given up on the patient (15). During a 1990 qualitative analysis of 65 palliative care patients and family member or caregiver pairs, the researchers found that the grieving process for family and friends was frequently identified by both family and patients as one of the greatest problems experienced during palliation and the end of life

(14). Providing support for family as well as the patient during palliation is therefore an opportunity to enhance the quality of care and provide comfort throughout the grieving process.

Value of Research in Palliative Care

Conducting research within a palliative care population is necessary so that the standard of care can continue to be improved (16-20). Research gives healthcare providers the necessary evidence to improve or add aspects of care within their practice and to identify how to custom fit care to patient's specific needs at the end of life (13, 16, 18, 21). This supports research to help identify specific patient needs at the end of life so that unnecessary or worse treatments can be avoided (18).

As a field, palliative care is relatively new, so the methods for treating patients are still developing, making research all the more important. Take, for example, the effort to identify the best mode of pain medication delivery to palliative care patients with chronic pain. In a Canadian randomized double-blind crossover trial conducted in 1989, researchers investigated the methods of drug administration for pain management for patients with chronic severe pain. The findings brought to light that less frequent timed release pain medications were more effective then fast acting pain medications and helped determine what mode of pain medication delivery was the most comfortable for patients (22-23). While the study had a small sample size, it exemplifies the efforts of palliative care researchers to investigate how new medicines and techniques can simplify and improve symptom management (23). Following the Canadian study, researchers continued to investigate modes of pain medication delivery for patients with chronic pain.

For example, an American randomized control trial in 1998 also compared the efficacy of different modes of pain medication delivery for patients suffering from cancer pain and reached similar conclusions favoring timed release pain medications (24). These studies show that the intersection of ongoing research and care is the continued improvement in the field. Research advances palliative care teams' ability to provide 'a good death' where both dignity and comfort are present until the last moments of a patient's life (20).

CHALLENGES IN RESEARCH

Palliative care patients are those who are suffering from serious and debilitating diseases and may be approaching the end of life. Conducting research studies in this population is documented as being particularly difficult (16-17, 25). Historically, patient agreement to participate in palliative care studies shows that around 50-70% of potential participants sign on to studies. For example, in a 2001 interview study, 126 of 195 (65%) advanced cancer patients approached to participate in the study provided consent (25-29). There are, however, many potential barriers to participation in palliative care studies. Meta-analyses conducted within the past 15 years report that the most frequently cited barriers to consent include subject matter of the study, family and other social support, disease state, healthcare gatekeepers, ethical gatekeeping, and location (16-17, 25). Broadly speaking, these barriers can be categorized as issues of approval, engagement, and consent. Obtaining a better understanding of the barriers to palliative care study participation can help boost not only the quality of palliative care research, but also the quality of care for palliative care patients.

Securing Approval

IRB / ethics. The importance of respecting and protecting patients in healthcare has caused many researchers to conduct an in-depth analysis of the unique ethical issues in palliative care research (17, 19). Scientific value, favorable benefit to risk ratio for the patient and future patients, patient willingness to participate, informed consent, and patient protection are the main principles for ethical research (2, 17). All of these principles are enforced during the method development and Institutional Review Board (IRB) review of palliative care research studies (2, 17).

In the early stages of palliative care research, ethics review boards were a barrier to accessing potential participants in palliative care studies; however, this has become less frequent as palliative care has grown (18, 27-28, 30-31). Ethics boards that govern research ensure that participants or their proxies are able to make informed decisions prior to participating in research and are not exploited by researchers (13, 19, 25). The IRB ensures that the research recruitment and study methods comply with guidelines for ethical research, for instance that participation is completely voluntary, the decision of whether to participate does not affect the quality or level of care afforded to patients, and that patients are aware that the quality or level of healthcare they receive is not dependent on their participation (13, 19-20, 25).

Eligibility and consent criteria for palliative care studies are determined by the researchers and IRB (32). Identifying decision-making capacity, having procedures for an alternate consenter, and applying those to informed consent are all important aspects of patient recruitment and are integral to attaining IRB approval (6). Methodological challenges for obtaining informed consent within a palliative care population are great;

however, population characteristics that may affect patient ability to provide informed consent, such as mental acuity or physical consciousness, can be accounted for within the patient eligibility criteria (33).

Members of the research community have questioned the ability to navigate logistically and ethically sound research in the realm of palliative care (32). The deteriorated health state of palliative care patients has caused pushback from the research community when palliative care studies were proposed (34). Many feared that the mental, physical, and emotional states of palliative care patients made them unfit to consent to studies (19, 25, 34-36). Some believed that to conduct research on a palliative care population would result only in harm to the patients (34). The determination of cognitive fitness to enroll in a study can be a difficult process and can lead to incomplete informed consent forms (25). There was also the fear that proxies for patient consent were not capable of removing themselves from the process and could not objectively consent in place of the patient (14, 37). The aforementioned objections to palliative care research may have been legitimate. However, each of these issues is either covered during the IRB review process or was based on faulty assumptions about the palliative care patient population.

Palliative care does not represent a special case scenario for research studies, in fact the main ethical concerns exist in other areas of study as well (25). A 2010 review of palliative care-based ethical debates argues that in contrast to the belief that it is unethical to conduct research on palliative care populations, it is actually unethical to avoid researching palliative care populations because it impedes the establishment of quality palliative care (17). Not including palliative patients in research keeps them from being

able to include their voice in the body of research, and can lead to the development of irrelevant palliative care practices (32).

Some debate that the palliative care population is particularly vulnerable and participants in research at the end of life are victims of coercion, exploitation, and vulnerability; however, the aspects that make palliative care patients vulnerable are a risk in any experimental study (19, 35-36). In fact, a 2004 debate on whether palliative care patients should be considered a vulnerable population argues that defining the palliative care population as vulnerable is discriminatory and a detrimental barrier to adequate medical care (20, 35). The noted potential vulnerabilities within palliative care populations (financial burden, education, social wellbeing, spiritual wellbeing, psychological wellbeing) may be present in some palliative care patients, but it is discriminatory to assume that all patients within the cohort can be described as vulnerable (20, 35). With regard to the potential for palliative care patients to be particularly susceptible to coercion, exploitation, and vulnerability, all these topics must be addressed and controlled for by the investigator before receiving IRB approval to conduct the study (19).

Proxy Consent. The adequacy of family as a proxy for patients when they cannot give consent is a debated issue. Earlier studies have a more negative outlook on using relatives and caregivers as possible proxies for consent to palliative care trials and intervention studies (38). The main arguments for not using relatives as a proxy are that they may give consent for trials that the actual patient may not have participated in or that they themselves would not participate in, and that recruitment may cause distress to

family members who are approached for consent to palliative care trials (38). On the other hand, many researchers conclude that close friends or family members *should* serve as consent proxies, as this practice is already a socially and institutionally acceptable alternative to patient consent (39). Notably, family members and patients are often interdependent and in a somewhat similar care-receiving scenario, so they are able to act as the patient when consenting to studies (39).

Some criticisms to proxy enrollment include that family members may compromise the vulnerable population by enrolling in any study that could change the patient's life expectancy (32). A 2003 article from the *Journal of Pain and Symptom Management* that includes best practices for protecting palliative care patients notes that the desires of patients and their supporters could be potentially unaligned, creating a scenario where the actual voluntariness of the participant is unknown or overlooked (19). However, the ability of a proxy to provide objective informed consent for a patient is backed by research findings (14, 37). In a 2005 pilot study including 18 hospitalized patients questioned about hypothetical palliative care research scenarios, it was found that patients are comfortable with family members and proxies making enrollment decisions in cases where the patient is incapable of making autonomous decisions (40). In a 2003 literature review comparing patient and proxy views, it was found that throughout end of life research studies, proxies generally have a good understanding of patient condition and experience (37). Research shows that patients do not identify communication with their support team as a problem, and generally there is agreement between patient and proxy on symptoms and condition of the patient (14, 37). Proxies are capable of understanding palliative care from the patient's point of view, but whether there are

different motivations between patients and proxies when deciding to enroll in palliative care studies is still undetermined.

Securing Buy-in / Engagement

Health providers. Much documentation exists on the influence of health care staff on patient access for palliative care recruitment (30, 41-42). The palliative care team and other healthcare staff have been found occasionally to act as 'gatekeepers' who prevent researchers from accessing patients with worse prognoses or conditions (30, 41-42). A 2012 meta-analysis highlighted the importance of education and inclusion of health professionals during patient recruitment because of health professional concern with involving patients in studies if the study has not been thoroughly described to the health professional prior to recruitment (30, 41-42). Palliative care makes people feel cautious and protective towards the patients receiving care (43). Within healthcare, these feelings can be a serious issue because palliative care is generally started upon recommendation by the medical team (44). If the medical team does not recognize that a patient is in need of palliative care, the palliative care team will not be called in, thereby eliminating potential research participants from palliative care research (44).

It is important to note that while healthcare practitioners' goals in acting as gatekeepers are to protect patients, they may not be acting in accordance with the wants of the patient and actually be keeping patients from enrolling in a study the patient would want to be a part of (32). Healthcare gatekeeping for certain palliative care patients who are perceived by non-research staff to be unfit to participate in research restricts patient autonomy, reduces research quality, and can cause sampling bias (32). During a survey

conducted in 2003 about patient and palliative care nurse attitudes towards willingness to participate in hypothetical trials, it was found that both nurses and patients were more likely to agree to participate in palliative care research if they received more information about hypothetical trials than if they received less (42).

Patient availability. Reaching patients is a common methodological problem in palliative care studies (41). Many patients receiving palliative care are suffering from rapidly advancing diseases or rapidly deteriorating conditions, so healthcare decision making in response these changes can be quick (20). Also, effects of advanced disease state and rapid changes in physical status may result in symptoms such as exhaustion, which can influence patient willingness to start studies and be recruited (41).

Patient access is also difficult, because of patient exit from the current healthcare facility, death, or transfer to another facility (20). Many research articles, including a 2003 *Journal of Pain and Symptom Management* article on how to incorporate best practices into palliative care research, suggest the use of research protocols, such as early enrollment in palliative care studies, to anticipate and account for rapid changes in patient conditions (20, 28, 45). A key consideration in palliative care research is to take the rapidly changing disease states of patients in palliative care into account when planning recruitment (20).

Patient and family concerns. Researchers have raised the issue that conducting studies on palliative care populations limits the time and energy that the person has to spend with family and friends; however, other researchers propose that participation in

research is an opportunity to contribute to the participant's impact on others' palliative care journeys (17, 30). In patient and family interviews following palliative care research, responses from patients and family show that participants felt they gained more from their healthcare experience than non-participants; they did not find the time burden to be too much; they had very positive experiences while participating in research studies; and they were glad to have participated in the study (20, 26, 30, 32, 46). This shows that a conceptual barrier to research and consent -- that patients at the end of life and their families neither receive nor perceive any benefit from participating in palliative care research -- is not upheld by research findings.

Another issue of concern is highlighted in an article from 2003 on benefits and risks of research in palliative care, and is what the article author describes as comiogenic illness: the patient and their families experiencing negative emotional and psychological outcomes as a result of aspects of illness and treatment (20). While it can be argued that research studies have the potential to intensify comiogenic harm for patients and their families, it is possible to counter with the argument that palliative care is a holistic approach to quality of life towards the end of life, and without researching interventions that can diminish comiogenic harm for patients and families, the palliative care team is not fulfilling its defining goal of care (20).

A qualitative study conducted in 2010 on the experiences of acute stroke patients and their families found that a main goal was for patients approaching the end of life to have no distress (15). Participating in studies can help diminish the standard comiogenic harm presented in general care for palliative care patients because of the positive patient and family perspective on participation in research (20). Families and patients have a

positive view of participating in palliative care studies and often feel that they have become pioneers within the field (20). Perhaps involving families in recruitment from the start of a study instead of turning to them only if patient consent becomes difficult may have a positive effect on participation rates, especially since they are hypothetical gatekeepers for the patients themselves.

Securing Consent

The importance of conducting research for the benefit of the palliative care community has caused many researchers to launch further investigations into why patient recruitment is difficult (17, 30). Problems recruiting patients with certain attributes can lead to highly selected samples that impede the generalizability of studies (34). Knowing what characteristics are associated with patient consent in palliative care studies can therefore allow researchers to account for those potential difficulties during the sampling design (2, 17, 25). The existing research into palliative care study recruitment has shown that refusal to consent is multifaceted, and consent barriers include both internal patient characteristics and external factors (17, 30, 32).

The concept of receiving 'quality care' is somewhat synonymous with a practitioner's alignment of care with the most current findings in medical practices and technology within the medical field. Constant advances in technology, medicine, and medical practice make healthcare an environment of continual, fast-paced development. The ability of medical practitioners to provide quality care in a rapidly advancing field is therefore tightly coupled with the ability to conduct research on emerging medical advancements (2). The difficulty of conducting high-quality, robust studies due to issues

with patient recruitment is a barrier for palliative care providers who desire the best evidence-based care available for their patients (35).

Families and friends. Families and friends may discourage patients from participating in research if they think that it will detract from the patient's quality of life or the time available to spend with the patient (13). In a special report in the *European Journal of Cancer Care* in 2002, the author wrote that, "Families may, for example, resent patients participating in research if it takes time that could have been spent with the family, and may understandably be protective of the patient and not want them to be approached" (47). The author concern stated here shows the potential influence that family can have on a patient when deciding whether to enroll in a study. The intervention of family and friends in patient access is a potential cause of bias in patient recruitment for all palliative care studies; it is therefore important to determine if family and friends are associated with patient decision to participate in research.

Demographics. Demographic associations with patient consent have been a peripheral aspect of several palliative care studies. Studies have found that sex and education are not associated with patient consent, but race / ethnicity is associated with consent (25, 48). In a study of male veterans conducted in 2001, the men who refused to consent were more likely to be non-white (8). Findings of whether age is associated with consent are inconclusive (5, 25, 30, 48). For example, a 2012 meta-analysis included a study that found older age as an indicator of lower likelihood of consent to studies, but a study conducted in 2008 on advance care planning among 468 patients found that age

was not significantly associated with likelihood of consent (30, 48). Studies have also found that spirituality and religion also play significant roles in palliative care decision making at the end of life (7-8, 48).

Prognosis. Patient prognosis may influence the interest of potential participants, with around 40% of non-consenters to a 2011 study on research in hospice and palliative care citing wanting to spend time with their families as they are approaching death as a reason for not participating in research at the end of life (32). Researchers have raised the issue that palliative care research is too time consuming for patients who may have other matters to attend to and limited energy to execute those matters with as their illnesses or conditions continue to advance; however, palliative care study follow-ups have found that patients and their families did not perceive the time burden of study participation to be too great (17, 26).

*Diagnosis***.** Another patient aspect that may be involved in consent to palliative care studies is disease type (49). Evidence from the articles included in a 2012 meta-analysis on participation in end of life research shows that much of the initial research in palliative care was and remains to be focused on patients suffering from terminal cancers, so whether differing diseases are associated with a greater likelihood of participating in research is unknown (30).

In a 2008 qualitative study, 108 interviews were conducted with patients and caregivers who were asked questions regarding their reasons for participating in palliative care; patients reported a general desire to participate to expand the knowledge base of

their disease, to have a person to talk to and share their story with, to have a way to impact hospital services, to help future patients, and to access services and receive more information (32, 49). The aforementioned motivations may vary in intensity based on the history of research for a disease and therefore may result in systematic differences in likelihood of consents by disease.

Perceived Benefits. Many patients also choose to enroll in palliative care studies to receive physical, emotional, or social benefits (30, 32, 40, 42). Potential participants are willing to enroll in studies that may help to reduce pain, suffering, and general distress (40, 42). In particular, a study from 2003 on research in hospice and palliative care populations found that increased pain is an indicator of increased likelihood to participate in research (32). There may also be a psychological benefit from participating in palliative care research in that it allows the patient to act independently and demonstrate altruism, a luxury that is often diminished if not eliminated toward the end of life for palliative care patients (17-18, 20, 30, 40). Participating in studies may also help patients fulfill a spiritual need to contribute to the advancement of quality palliative care for future patients (13). Palliative care is adapted to satisfy patient needs, and participating in research may help fulfill one of those needs (43).

Consenters often feel that they have something to gain from participating in research (21). Participation in studies of palliative care (interview or intervention) are positive and empowering experiences for patients (30, 33). Patient reports of perceived social and physical benefits of study participation refute the argument that since palliative

care patients are at the end of life, they are incapable of receiving any benefits from participation in palliative care research studies (17, 30, 40, 42).

Concluding Points

Obtaining large and diverse samples is a difficult aspect of palliative care study design and implementation (30). Issues with recruiting large samples are described above. When palliative care patients with certain characteristics are overrepresented in a study sample, the results may not be generalizable to the entire palliative care population. Establishing well-defined protocols may help address potential selection bias, but the evidence base necessary to support the development of such protocols does not yet exist (30). Because palliative care is a younger medical field, standard sampling and measurement techniques have not yet been established (2). It can therefore be difficult to achieve validity in a study, especially when the measures of interest (such as pain, quality of life, and quality of spiritual support) are abstract (2). With small and homogenous samples, studies are at risk of presenting a view of palliative care populations that omits specific palliative care groups (2).

Determining what characteristics of the patient population are underrepresented in studies can help in the recruitment design for the study sample so that the study's results are valid, valuable, and generalizable to all patients receiving palliative care rather than just certain groups who are more likely to participate in research (2, 17). Relying on the medical team to recruit patients can also lead to flawed patient recruitment as they are less likely to refer patients they deem 'unfit' and may recruit fewer patients as the study continues and becomes less novel (50). Research on factors related to participation in

palliative care is necessary to enhance the knowledge base of palliative care population characteristics (17).

Much research has looked into caregivers' and patients' willingness to participate in trials, but none has looked into the influence of family on participation, despite the fact that family and designated surrogates are often tasked with end of life decision making for incapacitated critically ill patients (30, 51).

Purpose

The purpose of this study was to observe if there is an association between the presence of friends and family during palliative care chaplain encounters and subsequent enrollment into a qualitative study of palliative care. Family members are often seen as recipients of care along with the patient and are therefore the subjects of recruitment (36). While family and friends are considered recipients of care under the definition of palliative care, there are a few noted differences between patients and their families or friends who provide support and it would be egregious to assume that patients and family would make all the same choices during palliative care treatment (14, 37, 38, 40). Studies have noted the observable influence of physicians, medical staff, and caregivers on patient access to and enrollment in studies; however, the influence of family as a gatekeeper is more often theorized than assessed (17, 30, 41-42, 45). Despite positive therapeutic outcomes for patients and families who participate in palliative care research, less than half of palliative care patients report interest in survey or therapeutic-intervention research; identifying whether family and friends are one of the barriers to

patient interest in studies could therefore provide much needed insight into why patient interest is so low (32, 34, 52-53).

The research question analyzed in this study was whether there is an association between the presence / absence of friends and family with patients in palliative care and subsequent enrollment into a palliative care study. The presence of family and friends was assessed by palliative care chaplains who recorded the context of their encounters with patients. This study tested the null hypothesis that the presence of family and friends during chaplain encounters was not associated with subsequent enrollment in palliative care studies.

METHODS

Study Design

The study was a secondary analysis of encounter and recruitment data from the PCCS study. The PCCS study is a longitudinal study that collected daily diaries from chaplains who described encounters they had with patients with serious illness at Emory University Hospital Midtown, a tertiary academic-community hybrid hospital in an urban area in the south. The data analyzed came from the first phase of the study and are thus cross-sectional.

The PCCS study focused on chaplains and the activities and discussion topics they engaged in with patients with serious illness during their encounters, many but not all of whom also received palliative care. Chaplains were asked to fill out a record of these activities from a sample of their palliative care chaplain encounters during the day. Eligible patients were inpatients suffering from a "serious illness" (as determined by the chaplain) who received a chaplain visit and had at least one diary completed during the patient recruitment period.

The PCCS study had two parts. During the first part, the chaplains were the study subjects; from January to October 2013 they recorded diaries on patients they encountered who were suffering from advanced illness. No information that would allow identification of the patient was collected.

The second part of the study required patient consent for one or all of the following activities: medical record review, audio recordings of chaplain encounters, and follow-up patient interviews. The additional data collected on patients who consented included aspects of care available in the patient medical records, and patient and family

perspectives regarding chaplain care. Throughout the patient recruitment process, consent rates were consistently low, with around 13% of chaplain diary encounter patients consenting.

Eligible patients were approached within 24 hours of the chaplain encounter by one of six research assistants and were asked to consent to subsequent medical record access, audio recordings of future palliative care chaplain encounters, and/or a follow-up interview at a later date. The chaplain diaries for patients who did not provide consent were left anonymous, whereas the diaries for those who did consent were connected to information in their patient medical records.

The main focus of this analysis was on patient consent decisions, so information from the PCCS patient medical record access, audio recordings, and follow-up interviews was not included in the analysis because it was not available for patients who did not consent. Furthermore, while patients who gave definitive yes or no consent responses were considered eligible for the study, the study is further limited to patients whose chaplain diaries were completed prior to the patient being approached for consent.

Sample

Beyond the study inclusion criteria outlined above, for our analysis patients also must have been approached for consent for the PCCS study, consented or clearly declined to consent, and have had at least one chaplain reported encounter before consent or non-consent (Figure 1). Those patients who were discharged, passed away, moved to hospice, or could not give a definite consent or non-consent for other reasons were excluded from this study. Data from diaries had to have been collected before patient consent or non-

consent, have a valid time length (greater than zero), have a valid date (occur before the patient consented or declined to consent), and have entries for activities and topics of conversation. Following the diary exclusion criteria, 423 of the 1161 chaplain diaries met these criteria (Figure 2).

The final sample in this study consisted of 325 inpatients with advanced illness on whom 423 diaries were recorded from January 2013 through October 2013; who had at least one chaplain encounter with a diary entry; who were approached for consent for the PCCS study; and who consented or declined to consent.

Variables

During the recruitment phase of the PCCS study, each patient was given a unique identifier so that the consent decision could be tracked and diaries for the same patient could be grouped for later analyses. Using the patient identifiers, chaplain-reported diary characteristics were coupled with the final patient decision to consent or decline to consent to the second phase of the PCCS study.

The outcome of interest in this study was palliative care patient consent or non-consent to the PCCS study. Patients who consented to any part of the PCCS study were coded as consenters and those who declined to consent were coded as non-consenters.

The exposure in this study was presence of family and friends during palliative care chaplain encounters where diaries were recorded. Family and friend presence was coded as ‘ever’ if the patient had at least one family member or friend present during any of the chaplain reported diaries or ‘never’ if there were no family members or friends present during the chaplain reported diaries. For the second analysis, family and friend

presence was coded as the percentage of encounters where at least one family member or friend was present during a chaplain-reported diary.

In data analyses conducted as part of the PCCS study, two multi-question fields (activities that took place during encounter and topics of discussion) were condensed into separate two-cluster entities. To create these clusters, chaplain activities were first grouped into logically-rationalized clusters: religious practice activities, advance directive activities, prayer, touch, spiritual assessments, ministry of presence, active listening, and 'other' (a free form entry for chaplains). A cluster analysis was then run in SPSS using the Ward Linkage method, which resulted in a two-cluster solution. Activity Cluster 1 included chaplain encounters that had more activities that were interaction based (religious practice, 'other,' touch, prayer, and advance directives) and Activity Cluster 2 involved chaplain encounters that were more related to presence and listening (spiritual assessments, ministry of presence, and active listening). We called activity cluster 1 the "doing" cluster, and activity cluster 2 the "being" cluster.

SPSS was also used to run a Ward Linkage cluster analysis for the topics of discussion that took place between the chaplain and patient during the chaplain diary encounter. The cluster analysis resulted in a two-cluster solution. The topics of discussion cluster 1 consisted of chaplain encounters that were based more on aspects of care and life (work, financial concerns, hospice care, advance directives, family concerns, life reviews, diagnoses, prognoses, and medical care). Topics of discussion cluster 2 consisted of chaplain encounters where the topics of conversation were more existential (emotions, existential matters, spirituality and religion, and physical symptoms). We called conversation topics cluster 1 "practical matters" and cluster 2 "ultimate concerns".

A factor analysis was run to assess the chaplain's emotional response to the encounter. Chaplains were given twelve emotional qualities (confused, irritated, sad, confident, stimulated, thankful, optimistic, content, appreciated, tired, frustrated, and anxious) and asked to assess how to rate them from 0 (did not experience) to 4 (experienced a great deal). The factor analysis resulted in a one-factor solution (Cronbach's alpha 0.75) and the emotional qualities (negative emotions reverse coded) were condensed into a scale from 0 to 48 (where 48 is the most positive).

The chaplain-reported activities and conversations and the emotional indicators from the chaplain may have influenced the patient's decision to consent or not. For this reason, the clusters and scale were considered possible effect modifiers and confounders during this analysis.

Variables related to extent of chaplain exposure were included as potential effect modifiers and confounders. These variables were number of chaplain diaries before consent decision, and total amount of time (in minutes) spent during chaplain diary encounters before the consent decision.

The following variables were available for each patient in the dataset and were included in the analyses: identification number, final consent decision, proportion of encounters where family or friends were present, 'ever' or 'never' value for presence of family or friends during chaplain encounter, chaplain mood scale average from encounters, proportion of activities in cluster 1 ("doing" activities) chaplain encounters, proportion of topics of discussion in cluster 1 ("practical matters") encounters, total number of diaries for the patient, and total time spent during chaplain diary encounters.

Statistical Analysis

Diary and consent data were connected using individual patient identification numbers. The combined dataset was then cleaned to eliminate ineligible patients (figure 1) and diaries (see figure 2).

All subsequent data analyses were run using SAS 9.3 (SAS Institute, Cary, NC). We performed two separate sub-analyses: one where presence of family and friends during chaplain encounter was reported as 'ever' or 'never' (analysis 1) and one where the percentage of reported chaplain encounters where family and friends were present was reported (analysis 2).

Descriptive statistics were run for each variable in the dataset. Means and standard deviations were found for the continuous variables. Frequencies were found for the categorical variables.

Analysis one tested the model:

$$\text{Logit } P(\mathbf{X}) = \alpha + \beta_1 E + \gamma_1 V_1 + \gamma_2 V_2 + \gamma_3 V_3 + \gamma_4 V_4 + \gamma_5 V_5 + \delta_1 EW_1 + \delta_2 EW_2 + \delta_3 EW_3 + \delta_4 EW_4 + \delta_5 EW_5$$

where:

X = Consent (1 = consented, 0 = not consented)

E = 1 if family or friends present during chaplain encounter 'ever' or 0 if present 'never'

V_1= Proportion of chaplain encounters in the "doing" cluster

V_2= Proportion of chaplain encounters in the "practical matters" cluster

V_3= Chaplain mood scale average

V_4= Total time spent during chaplain diary encounters

V_5= Count of chaplain diary encounters

EW_1= The interaction of E and V_1

EW_2= The interaction of E and V_2

EW_3= The interaction of E and V_3

EW_4= The interaction of E and V_4

EW_5= The interaction of E and V_5

Analysis two tested the model:

$$\text{Logit } P(\mathbf{X}) = \alpha + \beta_1 E + \gamma_1 V_1 + \gamma_2 V_2 + \gamma_3 V_3 + \gamma_4 V_4 + \gamma_5 V_5 + \delta_1 EW_1 + \delta_2 EW_2 + \delta_3 EW_3 + \delta_4 EW_4 + \delta_5 EW_5$$

where:

E = Proportion of chaplain-reported encounters where family or friends were present

At the start of each analysis, collinearity diagnostics were run on the model by using a validated macro in SAS 9.3 (54). The macro produced a table of Condition Indices (CNIs) and variance decomposition proportions (VDPs). Collinearity problems were present if the largest CNI exceeded 20 and two VDPs exceeded 0.5 (55-56). The variable with the largest VDP was removed from the model and the collinearity macro was re-run. This process continued until the aforementioned conditions for collinearity violations were no longer met (55-56).

Effect modification was assessed using a hierarchical backwards elimination procedure (55). To start, the full models that remained after the collinearity diagnostics were run and a log likelihood test was run on the full models compared to models with no

interaction terms. If the tests resulted in a significant difference between the full models and the models without any interaction terms, a hierarchical backwards elimination procedure was used to determine which interaction terms were necessary to the model. Through the backwards elimination process, the interaction terms were assessed to see which were not significant, the least significant interaction term was removed and the reduced model was run. This process continued until only significant interaction terms remained in the model (57).

To maintain a hierarchically well-formulated model, any covariates that were lower order components for significant interaction terms were not considered for removal during the confounding assessment. The Odds Ratio (OR) estimate and precision (determined by the width of the confidence interval (CI)) of the models with all possible confounders (considered the 'gold standard' estimate) and models with all possible subsets of confounders were compared. If precision was relatively unchanged and the OR estimate was within 10% of that from the 'gold standard,' then the possible confounders were not controlling for confounding in the model and were eliminated. The models were run with all possible combinations of the confounders using the all possible confounders macro to determine which confounder or combination of confounders were necessary to control for confounding in the model (58). OR estimates and precision were compared for all possible models, and models with OR estimates within 10% of the OR for the 'gold standard' and relatively unaffected precision were considered possible final models. The most simple model with the least change in OR estimate and precision was chosen as the final model. The OR estimate and precision were checked at a 5% significance level for the final model to see if there was a significant effect.

RESULTS

Sample

The PCCS study included 992 patients who either had a diary recorded by a chaplain or were eligible to have a diary recorded by a chaplain. Of those, 196 (20%) were not encountered by a chaplain before being approached for consent to the second part of the study, so they were not included in this analysis. Another 471 (47%) of the patients died, were discharged, or otherwise never made a definite decision of whether to consent to the study, leaving 325 (33%) of the patients eligible for this analysis. During the PCCS study, the chaplains recorded a total of 1161 diaries. Only diaries associated with patients who were eligible for this study were included in the analysis, so the 588 (51%) diaries pertaining to patients who were ineligible were removed. Another 150 (12%) of the diaries were excluded because they had an invalid time and date, that is, they occurred after the patient had made their consent decision. After eliminating diaries that did not meet the inclusion criteria, 423 (37%) of the diaries remained for the analysis. After the elimination of all patients and patient diaries that did not meet the inclusion criteria, 325 patients with 423 diaries in total remained for the analysis.

Bivariate Analyses of Consent and Diary Characteristics

Overall, 130 (40%) of the patients included in the analysis decided to consent to the study. For the binary family and friend presence ‘ever’ category, 68 (36%) of the patients decided to consent to the study and 123 (64%) chose not to consent; in the ‘never’ category, 62 (46%) of the patients consented to the study and 72 (54%) of the patients chose not to consent. The chi-square result testing the association between ‘ever’

or ‘never’ presence of family and friends and consent or non-consent was non-significant (chi-square=3.73, $p > 0.05$, 1 df) (Table 1).

Overall the proportion of chaplain encounters where friends or family were present was 55%. Among the patients who consented the proportion was 47% and among the patients who declined to consent the proportion was 59%, the t-test evaluating if the difference between the proportion of encounters where friends and family were present among patients who consent or declined to consent was significant ($t = 2.19$, $p < 0.03$, 323 df) (Table 1).

The average number of diaries reported for all patients included in the analysis was 1.3. The average number of diaries reported for the patients who consented and those who declined to consent were both 1.3 (Table 1). The average total time spent by chaplains with all patients was 31.7 minutes; for the patients who consented the average total time spent was 31.9 minutes; and for the patients who declined to consent the average total time spent was 31.6 minutes (no significant difference found between times). The difference in total time spent with a patient between the patients who consented and declined to consent was non-significant (Table 1).

The proportion of encounters in the “doing” cluster for all patients was 56%; for patients who consented the proportion was 59%, and for patients who declined to consent the proportion was 55%. The t-test conducted to detect any significant difference in the proportion of encounters in the “doing” cluster between the consenters and non-consenters was not significant (Table 1).

The proportion of encounters in the “practical matters” cluster for all patients was 75%; for the patients who consented the proportion was 69%, and for patients who

declined to consent the proportion was 79%. The t-test conducted to detect any significant difference between the proportion of encounters in the "practical matters" cluster was significant (t = 1.97, p = 0.05, 323 df) (Table 1).

The average Chaplain Mood Scale Score for all patients was 39; for both the patients who decided to consent and the patients who decided not to consent the average Chaplain Mood Scale Score was 39 (Table 1).

Analysis 1: Family and Friends Present 'Ever' or 'Never'

Collinearity assessment. The highest CI was 56.6 for the initial model run resulting in the interaction term for family or friend presence and the Chaplain Mood Scale Score being removed from the model. When the reduced model was run without the term, the highest CI was 34.6, and the interaction term between family or friend presence and diary count was removed from the model. When the reduced model was run, the highest CI was 27.6 and the variable for Chaplain Mood Scale Score was removed from the model. When the reduced model was run, the highest CI was 19.1, lower than the cutoff of 20, so no more variables were removed for violations of collinearity.

Effect modification. The log likelihood test did not reveal a significant difference between the model with the remaining interactions terms and the model without ($p > 0.24$), so all interaction terms were removed from the model.

Confounding. All possible combinations of the confounders were assessed for the reduced model. The full-reduced model resulted in an OR of family presence 'ever' compared to family presence 'never' of 0.64 (0.41, 1.01). The model without any confounders resulted in an OR of 0.64 (0.41, 1.01). Because there was no apparent loss in precision or predictive power, all confounders were removed from the model.

Final model. The final model produced by the analysis included only the exposure variable and the outcome. The OR of 0.64 (0.41, 1.01) for likelihood of consent for family and friends 'ever' present compared to family and friends 'never' present produced by the model was not significant (Table 2).

Analysis 2: Proportion of Chaplain Encounters Where Family and Friends Were Present

Collinearity assessment. The highest CI was 54.9 for the initial model run resulting in the interaction term for family or friend presence and the Chaplain Mood Scale Score being removed from the model. When the reduced model was run, the highest CI was 30.9, and the variable for Chaplain Mood Scale Score was removed from the model. When the reduced model was run, the highest CI was 25.2 and the interaction term for family or friend presence and the diary count was removed from the model. When the reduced model was run, the highest CI was 17.8, lower than the cutoff of 20, so no more variables were removed for violations of collinearity.

Effect modification. The log likelihood test did not reveal a significant difference between the model with the remaining interaction terms and the model without ($p > 0.12$), so all interaction terms were removed from the model.

Confounding. All possible combinations of the confounders were assessed for the reduced model. The full-reduced model resulted in an OR of family presence for 100% of encounters compared to 0% of encounters of 0.62 (0.38, 1.01). The model without any confounders resulted in an OR of 0.60 (0.37, 0.95). Because there was no apparent loss in precision or predictive power, all confounders were removed from the model.

Final model. The final model produced by the analysis was significant and contained the exposure variable proportion of encounters where family and friends were present and the outcome variable of consent or non-consent. The OR of the likelihood of consent comparing family and friends present during all chaplain encounters to family and friends never present was 0.60 (0.37, 0.95). This OR indicates that when family and friends were present for all chaplain diary encounters were 40% less likely to consent to the study than patients whose family and friends were present at no chaplain diary encounters (Table 2).

DISCUSSION

This study investigated whether the presence of family and friends during chaplain encounters was associated with the decision to consent to a palliative care chaplain research study. Two models were used to analyze the outcome of consent or non-consent and the exposure variable presence of family and friends. The model that analyzed the exposure variable 'proportion of visits where family and friends were present' found a significant higher probability of consent for patients when family and friends were *not* present for any chaplain diary encounters compared to patients who had family and friends present at all chaplain diary encounters.

The alternative operationalization of the exposure variable did not produce a significant result. The 95% confidence interval for the exposure variable from analysis 1 of 'ever' or 'never' for family and friend presence during chaplain diary encounters indicated that the OR comparing consent among those with and without family or friends present was not significant (Table 2).

However, the second analysis, which assessed the proportion of chaplain diary encounters where friends and family were present, produced a significant effect for the presence of family and friends and consenting or not consenting. The exposure variable of percentage of chaplain encounters in which family and friends were present produced an OR of 0.60, where the odds of consenting to a palliative care study when friends and family are present during all chaplain diary encounters is 40% lower than the odds of consenting when friends and family are not present at all (Table 2). This result allowed us to reject the null hypothesis that that the presence of family and friends during

chaplain encounters was not associated with decreased subsequent enrollment in palliative care studies.

In palliative care, as in other specialties, if there are barriers to conducting high quality research, obtaining evidence to help define and improve the standard of care becomes difficult (2, 33, 40). Recruitment setbacks in conducting meaningful research within the palliative care patient community mean that the field is at risk of falling behind the standard of care provided in other areas of medical practice where patient recruitment may be easier(43).

The finding that the presence of friends and family is significantly associated with consenting or not consenting to palliative care studies is important (16-17, 25-29). Awareness of the factors that are associated with consent and non-consent can be incorporated in study-recruitment design to help avoid sampling bias (32). For example, evidence from previous studies shows that patients with different races / ethnicities have different likelihoods of consenting to studies in palliative care (5, 25, 30, 48). Researchers conducting studies in palliative care can adjust for factors associated with lower consent rates by systematically oversampling from patients with attributes associated with lower probabilities of consenting. Oversampling from these groups can help ensure that samples are more representative of the palliative care patient population.

Evidence from this analysis shows that the proportion of time that patients spend with family and friends during their hospitalization (as indicated by their presence during chaplain encounters) is also associated with consent and may be an inhibiting factor for patients with serious illness who are approached to participate in palliative care studies. The ways in which family and friends may influence consent, as well as overall care and

outcomes remain unknown. The increased probability of consent for patients without family and friends present during chaplain encounters is in line with existing theories on patient recruitment, that state that participating in research may be viewed as an opportunity by socially isolated patients who wish to interact with others (32). The negative association between the proportion of time family and friends are present during palliative care and subsequent enrollment into palliative care studies should be further investigated so that techniques such as oversampling from specific patient populations with lower likelihood of consenting can be put into place, to make research in the palliative care field applicable across all palliative care populations.

Strengths and Weaknesses

From a sample perspective, there are a few weaknesses to the study. The palliative care population included in the study was exclusively inpatient, so the results may not be applicable to hospice patients or patients receiving in-home treatment. Patient acknowledgment that religion is important differs by race / ethnicity, and this has the potential to impact the type of patients who accepted chaplain encounters and enrolled in the PCCS because the sample was limited only to patients who accepted chaplain encounters as part of their hospital care (25, 48). The patients who declined chaplain encounters could potentially have an entirely different likelihood of consenting.

It has been found that symptoms and pain related to disease and disease treatments have also been associated with palliative care study consent. This may have led to patients with higher degrees of pain enrolling in the study, but this was not reported

in the data (40). The chaplains were also in charge of whom they reported diaries for, so a systematic avoidance of patients with certain qualities may have occurred.

Several of the patients were unable to give a definite yes or no when approached for consent to the study. Although there are many reasons for the inability to give a definite yes or no, the ability to follow up with patients or their families to determine whether they would have consented would have been very helpful to the analysis. Age and disease state were also not reported for the study, but are known confounders for palliative care recruitment (17, 25, 30, 48-49).

We did not have a comprehensive measure of the presence of friends and family during the patient's palliative care stay; however, their presence in chaplain diary encounters could have been a proxy for the overall proportion of time that the patients had friends and family present with them at the hospital.

One of the major strengths of the study was that, in accordance with advice from earlier palliative care studies, patients were recruited early in their hospital stays (20, 28, 45). This gave patients more time to consider whether to consent for the study and allowed them to be approached before their disease progressed further. The study recruitment was also conducted over several months, so there were more patients eligible for the study than there would have been if recruitment had only lasted for a few months. The collinearity assessment conducted was also very conservative, so potential distortion of the model because of collinearity problems is less likely. Finally, although the measure of family and friend presence is potentially a significant indicator of social support and other quality of life resources for patients in palliative care, data on the

frequency of such visits to palliative care patients are not otherwise available in medical records.

Future Directions

The way in which the topics of conversation covered during chaplain encounters were associated with palliative consent at a bivariate level, and should be further explored.

Future analyses pertaining to family and friend presence that include the quality of the friend and family support (positive or negative) and family and friend attitude towards palliative care in addition to family and friend presence could elicit further information regarding how family and friends are associated with patient consent in palliative care studies.

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FIGURES

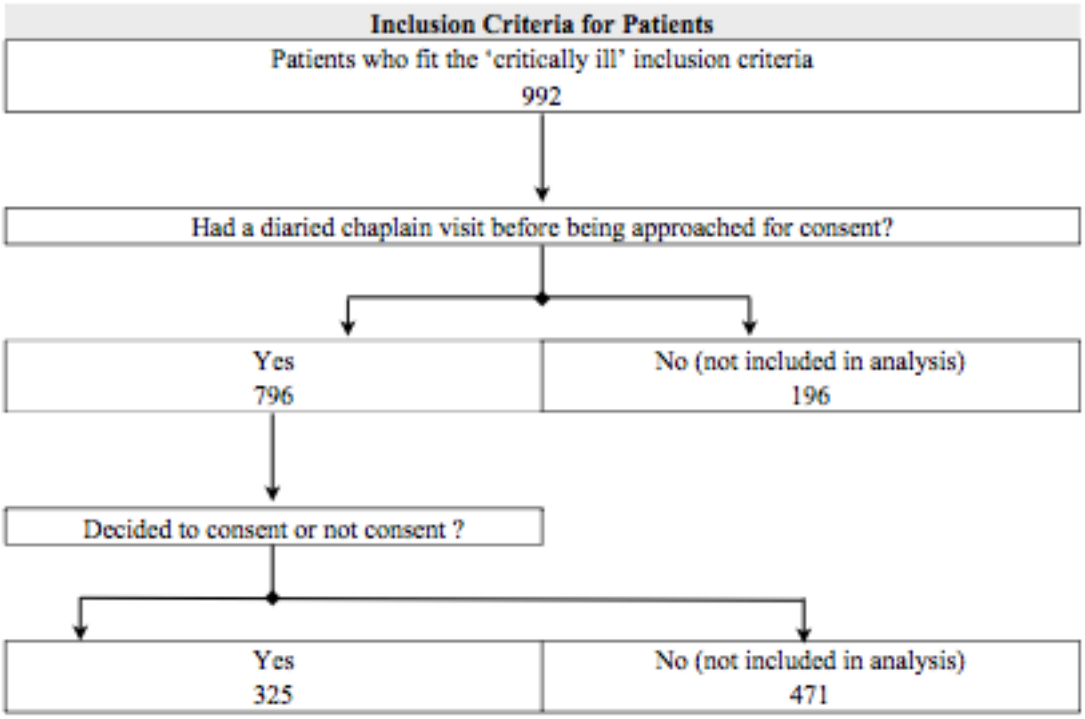

Figure 1

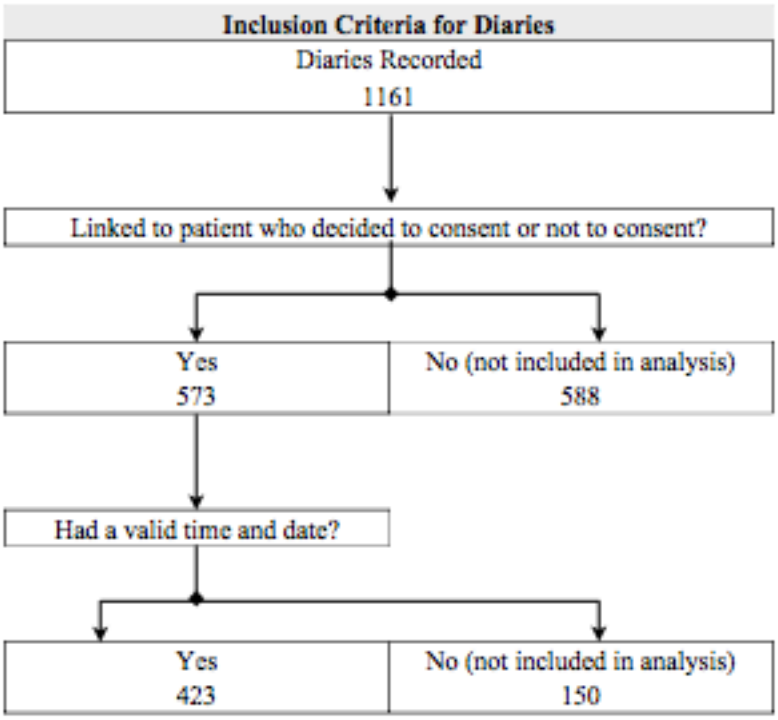
Inclusion Criteria for Diaries
Diaries Recorded
1161
Linked to patient who decided to consent or not to consent?
Yes
573
No (not included in analysis)
588
Had a valid time and date?
Yes
423
No (not included in analysis)
150

Figure 2

Table 1. Distribution of Diary Characteristics According to Consent Decision (Yes or No), PCCS[a] 2012-2013

Consent Decision	All		Consent		Non-Consent		Test Statistic[c]	P-Value
	Number or Mean	% or SD[b]	Number or Mean	% or SD[b]	Number or Mean	% or SD[b]		
Total	325	100	130	40	195	60		
Presence of Family and Friends							3.73	>.05
Ever	191	100	68	36	123	64		
Never	134	100	62	46	72	54		
Proportion of Chaplain Visits where Friends or Family were present	0.55	0.48	0.47	0.48	0.59	0.47	2.19	<.03*
Proportion of Chaplain Visits in "Doing" Cluster	0.56	0.48	0.59	0.48	0.55	0.49	-0.80	>.42
Proportion of Chaplain Visits in "Practical Matters" Cluster	0.75	0.42	0.69	0.45	0.79	0.40	1.97	0.05*
Chaplain Mood Scale Score	39	7.7	39	7.5	39	7.9	0.76	>.45
Number of Diaries	1.3	0.74	1.3	0.56	1.3	0.84	0.03	>.97
Total Time Spent for All Diaried Visits	31.7	22.2	31.9	21.0	31.6	23.0	-0.15	>.88

Abbreviations: N, number of patients, SD, Standard Deviation

[a] Impact of Hospital-Based Chaplain Support on Decision-Making During Serious Illness in a Diverse Urban Palliative Care Population Study

[b] Standard Deviation

[c] T-Test or Chi-Square

* Significant Result

Table 2. Modeling Results of Analysis 1 and Analysis 2, PCCS[a] 2012-2013

Model	β[b]	OR[c]	95% CI	*P* Value
1[d]	-0.15	0.64	0.41, 1.01	>0.05
2[e]	-0.52	0.60	0.37, 0.95	0.03

Abbreviation: OR, odds ratio. CI, confidence interval.

[a] Impact of Hospital-Based Chaplain Support on Decision-Making During Serious Illness in a Diverse Urban Palliative Care Population Study

[b] Regression coefficient for exposure variable

[c] Odds ratio comparing the odds of consent among patients with family present during all chaplain diary encounters to patients with family or fr

[d] Model from Analysis 1 including exposure variable (presence of family and friends 'ever' or 'never') and no other variables

[e] Model from Analysis 2 including exposure variable (proportion of encounters where family and friends present) and no other variables