Neil Samuel Ghiso Fellowship Final Report

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Summary:

I have been honored over the past year to receive the support of the Neil Samuel Ghiso Fellowship. Under the tutelage of gifted clinicians and teachers, it has enabled me to explore and experience topics on which I hope to continue to build my career around. I also wish to acknowledge the constant support of my mentors Drs. Mary Buss and Susan Block as well as the Department of Psychosocial Oncology and Palliative Care Team of Dana Farber Cancer Institute/Brigham and Women's Hospital. My Ghiso Fellowship had two primary goals 1) to gain exposure to the clinical practice of palliative care and care for the terminally ill through shadowing and 2) to learn more about clinical research within the context of palliative care and end-of-life care. In this summary, I will discuss separately these two aspects of my project, my successes, my challenges, and my thought process. I will also discuss current and future endeavors encouraged by my involvement with the Neil Ghiso Fellowship, my experience with mentorship and finally a personal reflection of what this time has meant to me.

1) Shadowing

I conceptualized this aspect of my project with several objectives in mind: I wanted to witness a variety of ways in which Palliative and End-of-Life medicine are practiced (in and out patient) and to spend time with different types of practitioners (nurse practitioners, palliative care fellows, attending physicians, and physicians assistants) in both child and adult settings. I also intended to spend some time with a Hospice nurse

visiting her patients and in a Skilled Nursing Facility. Given my interest in oncology, I also wanted to witness some of the ways in which an oncologist might handle End-of-Life and Palliative Medicine in contrast to Palliative care practitioners. Additionally, I wanted to have some aspect of my shadowing experience be somewhat longitudinal in nature such that I might see how patients, families and clinicians dealt with evolving goals of care and new challenges.

I spent the majority of my time with the Intensive Palliative Care team of Brigham and Women's Hospital/Dana Farber Cancer Institute with Drs. Lida Nabati and Eytan Szmuilowicz. Patients are admitted to this unit when they require intensive symptom management or when difficult family dynamics make the care of their disease more challenging. As a member of the team I attended morning patient and teaching rounds. I was involved in the discussions of strict medical care, such as how to best relieve pain or nausea and also the psychosocial aspects of care. After these discussions, I joined either an attending or a fellow when s/he went to see his/her patients. Depending on the situation, I either actively participated in the conversation with the patient and family or spent time afterward in a private space talking about the experience and asking questions. What I enjoyed most about this experience was the breadth of my exposure to many different patients and families and ways in which they managed to cope with the symptoms of their disease and their future. I also appreciated the opportunity to witness difficult conversations either as an individual patient-doctor conversation or in a family meeting.

As one might imagine, the patients seen by this team are quite sick and spent extended periods of time with the team and many of them were readmitted to the floor

after a period of time spent at home. As a consequence, I felt like I more opportunity to know some of these people and with each day got to know a bit more about their story and who they are as people. This is in contrast to many of my other shadowing experiences in which I might witness a single in depth, meaningful, conversation, but never the outcome of that conversation or what the follow-up might be. I felt fortunate to watch experienced clinicians (and fellows in training) support their patients and continue talking about difficult family meetings or ask his/her patient about what s/he thought after reflection.

One of my greatest worries about spending a summer (and possibly a future career) thinking about and witnessing the suffering of patients and families was the emotional toll that I might experience. I worried that it might be too much to take on a daily basis. In my experience over the summer, I found incredibly sensitive and supportive teams, who regularly asked if I had questions or thoughts about the patients seen that morning and how I was doing. The space was provided to talk about experiences. With support and knowing that there was always someone to talk with, it became much more bearable than I expected. The summer did help me crystallize some of my limits. To explain what I mean, I want to use my time spent at Children's Hospital as an example. Toward the end of my summer, I spent a week with Drs. Tamara Vesel and Bradd Hemker of the Pediatric Advanced Care Team (PACT) at Children's Hospital. While I felt sad at the time and "in the moment", it wasn't until my fiancée commented that I didn't seem like myself that I realized just how much spending time in this field affected me. It was too much for me to spend time with such sick children and witness the pain of their parents. At this time I recognized, for me, the limitations of a journal

and how important it is to debrief and pay attention to how you are processing and thinking about your experiences and to talk about them.

This was my first in depth exposure to clinical medicine, never before had I participated in conversations about the medical management of electrolyte imbalances and how best to treat pain while simultaneously thinking about the psychosocial aspects of care and how to talk with patients about difficult topics. As my third year approaches and I become immersed in clinical medicine, I am grateful that I have framed my medical education with the lessons of Palliative Medicine. The holistic approach, emphasis on communication and families is important to me and I feel lucky to have had such wonderful teachers as my first brush with clinical medicine.

2) Clinical Research on Delirium

To accomplish the second goal I worked with Dr. Mary Buss to design a pilot project to better understand what it is like for advanced cancer patients who recover from an episode of delirium, as well for their clinicians and caregivers who care for that patient during the delirium. Together we spent time, beginning last February, thinking about how best to design a study for a vulnerable patient and family population and thinking about what information would be most useful and how to obtain that information in a sensitive and caring way. For example, by definition, delirium alters a patient's ability to give informed consent to participate in a study. In what way can we ensure that the patient is cognitively intact and able to understand what s/he is consenting. We chose to use standard screening methods to detect delirium and require that the patient be well again for two days before approaching them to participate. Beyond being sensitive to the

interests of patients in families, the complexities of research etiquette were completely foreign to me, such as asking an oncologist if his/her patient could participate in a study.

The study was originally meant to be attached to a larger study that she was conducting, however due to a number of events that resulted in Dr. Buss starting a new job at the Beth Israel Deaconess, my study became a stand alone study. I wrote an Internal Review Board application to allow us to conduct research on human subjects; designed patient, caregiver, and clinician consents; optimized validated quantitative questionnaires for our use; and collaborated with our fellow researchers. As the situation, availability and support changed, the project went through various revisions and reformulations, and finally the IRB application was submitted. Unfortunately, additional delays in reviewing were such that it wouldn't be finished until the very end of August when school was beginning again. Knowing that Dr. Buss would no longer be able to be at the Brigham to help me run the study and knowing what my second year of medical school schedule entailed, we decided to let the project go. I have attached a pared-down version of my IRB application for the study that I designed with Dr. Buss which outlines what I learned about delirium, its prevalence and its importance with respect to good End-of-Life and Palliative Medicine as well as its effects on family members and clinicians.

I learned a lot about how one thinks about human research and how one might go about learning more about such a sick and vulnerable population such that care can be improved in a systematic and tested manner. Yet I now recognize that no matter how hard you as an individual work, there are many layers of bureaucracy and support that are necessary for you to be ultimately successful getting the project off the ground, never

mind the difficulties one might encounter when actually conducting the research. Regardless, the opportunity left me really interested and grateful that I had the opportunity to be exposed so intimately with clinical research. The proposal is written, the consents ready such that if I ever decide to take the project up again, much of the work is already done and will just need to be revised.

Present and Future:

For me the most obvious effect of my involvement with the Ghiso Fellowship, is my ability to raise awareness of these issues among my classmates. The exposure to clinical medicine that resulted in my ability to have real patients in mind when thinking about drug dependence and addiction, how pain is manifest, fear of death, hesitancy to enter hospice care, and the challenges of caring for patients and families in these difficult situations has been amazing and empowering. There have been several poignant tutorial and small group mini-case experiences in which I could talk about my experiences. Specifically, a pharmacology discussion around the use of Patient-controlled analgesia (PCA pump) and its importance in good pain control as well as a tutorial-based discussion of hospice and decision making at the end-of-life in relation to lung cancer.

I currently help run the HMS Palliative Care Student Interest Group. The connections that I made with faculty through the fellowship have allowed me to invite faculty to talk about the multiple dimensions of pain and suffering, the use of complimentary and alternative medicine for symptom control. The group also runs a book club with faculty and students to discuss issues around terminal illness, suffering and dying, which I have been actively involved in organizing over the last two years. I am also working on promoting a student elective entitled Living with Life-Threatening

Illness and make it more second-year-medical-student-friendly. I feel a great responsibility to encourage conversation and awareness around these issues and regret that more attention is not paid to them in the course of our standard medical education. I am incredibly fortunate to have had dedicated time to think about, explore and witness care in this context.

Through my involvement with the fellowship and resulting visibility to faculty, I was contacted by a resident at MGH who was looking to establish a volunteer program known as No One Dies Alone in which volunteers are available on call to sit with dying patients either when family does not exist, isn't available in an acute setting or to give family respite. The program is still in its infancy and early organizational states, but I am happy to be involved and hope that such an important source of support will be available to patients and families.

Challenges, Successes, & comments on mentorship:

I feel really positively about my exposure to the clinical practice of taking care of gravely ill patients and those in need of intensive symptom management. I enjoyed the breadth of my time shadowing and feel like I was able to experience what I set out to and learn some things about what I can tolerate and what I can't along the way. The attention that I received from the clinicians who I shadowed was more than I ever could have expected. I expected to be a "fly on the wall" and an observer of conversations not a participant. My questions were always welcomed, encouraged and appreciated. The clinicians that I worked with functioned more like teachers and it made my experience so much more rich and memorable. The opportunity to ask questions of patients and engage

in conversations about their life experiences and feelings about hospice or relationship with their illness were invaluable.

The most challenging and difficult aspects of my project surrounded my clinical research project. My mentor changed institutions early in the project necessitating reorganization of the project and altered expectations about what might actually be feasible. Dr. Buss was as supportive as she could possibly be and made extra efforts to make it a worthwhile experience for me even when it became clear that the project was not going to happen. She organized an opportunity for me to spend time with a clinical research team screening patients for a study in elderly patients who were delirious upon entering the hospital. We tried to make the best of an unfortunate situation and at times it was very difficult to realize that the project that I had worked so hard on was not going to happen. In the future, I'm not sure how I could have made this work much better than it did. I have wondered whether it might have been useful to get more of the research application finished prior to the start of the summer, but with job changes and major alterations to the project mid-stream, I'm not sure that would have made much difference. In spite of the frustration, or perhaps because of the frustration, I know that I gained immensely from the preparation of the application and thinking about the research in additional to the wonderful clinical exposure that I received.

As mentors, Drs. Susan Block and Mary Buss were very supportive and made great efforts to make the fellowship a good experience for me. They were both incredibly generous with time and genuinely concerned about my progress and how I was coping. I feel very fortunate to have had many extended conversations with Dr. Buss about the practice of medicine and some of the ethically controversial aspects of End-of-Life

Medicine, such as Palliative Sedation. They are both doctors with whom I intend to remain in touch and continue to seek mentorship from.

Reflection:

The past year has been filled with an extraordinary amount of "life": I started medical school, my grandfather got very sick and died unexpectedly, my sister graduated from college and moved across the country, I got engaged, my grandmother fell and died and my fiancée's grandmother died. This was the context in which I experienced my fellowship. It made the family sitting around their dying mother or the wife remembering fondly how she met her husband mean something all together more important and significant than it would have otherwise.

In the early spring, my grandfather became suddenly gravely ill after suffering a large heart attack that resulted the formation of multiple blood clots that lodged themselves downstream in his legs. My grandfather was also living with advanced Alzheimer's disease and could not understand what was going on nor could he verbalize what he was thinking or experiencing, but it was clear to all of us that he was afraid. When the extent of his heart attack became clear and that the damage to his legs irreversible, my family made the decision to enroll him in hospice. My grandfather had clearly expressed his wishes many years before by filling out a living will. Yet we all felt so powerless and like everything was happening at a speed too fast to process fully what was going on. It was upsetting and painful to witness. Not five months later, my grandmother fell and broke her hip and died shortly there after.

When my grandfather died, I was in the middle of classes, learning about diseases in a very de-humanized way- learning statistics and tissue-based disease processes while

looking through a microscope. It was upsetting to read about the disease processes that lead to my grandfather's death in black and white text all presented with such little emotion or indication of what it meant for someone to actually experience these processes. In contrast, when Nana died I had already spent more than a month working with the Palliative Care team observing conversations between patients and doctors, witnessing the human side of medicine and becoming more familiar with the process that families go through. It more closely matched what I was feeling and I was able to observe illness as so much more than cells, tissues and black and white text. Thus, perhaps paradoxically, it was actually helpful to me to be so immersed. Additionally, I felt I was gaining some of the skills to help support my family and to have a better sense as to what questions to ask and what I could do to make it easier for my family.

When I was planning my project and discussing it with a faculty member and talking about how I wanted to see what it was like taking care of very sick patients and if it was something that I could bear, she said to me that at the beginning of medical school you are much more like a patient than you are like a doctor. That there is a "desensitization" and process of acquiring coping skills that happens over years of clinical work that makes some of the extremely sad patient and family stories easier to bear. She could not have known how true this would become over the summer. Yet, while difficult at times when certain scenarios in the hospital reminded me of recent events with my own family, it was empowering to learn about what could be done such that I could offer support to my own family or my fiancée's family when our grandmothers were dying.

The experiences afforded to me by my involvement in the Neil Ghiso fellowship were very professionally rewarding and gave me great satisfaction to know that I was framing my medical school education with exposure to a specialty that I think represents the way medicine "should" be practiced. The experience was also personally satisfying and helped me feel helpful during times in my life when I had previously felt helpless. My personal life events over the past year lent a meaning to my fellowship that marks it as one of the most important things I have done for myself. For this and the support I have received from my mentors, teachers and the foundation itself, I am immensely grateful.

Addendum: Part of my IRB application

1.0 INTRODUCTION

1.1 Overview

Suffering is not limited to the experience of physical pain. While cognitive impairment can sometimes be considered part of the "dying process;" nonetheless, delirium-related symptoms can cause significant distress in both patients and family members[1-5]. Furthermore, delirium is very common and occurs in 25-50% of cancer patients with advanced disease [6-10] and in up to 85% of cancer patients in the time leading up to death[11]. Palliative care focuses on treating symptoms and other sources of distress in patients near the end of life. Yet, we have only just begun to understand the effects of this very common problem on patients and their caregivers.

This study seeks to fill important gaps in current understanding of how patients, their caregivers and their clinicians experience an episode of delirium and how it impacts quality of life. A series of quantitative questionnaires and the opportunity to talk about their experiences will enable an exploration of the issues that arise in and around patients with delirium who subsequently recover from delirium. The data in this study will allow us to design future clinical interventions to improve the quality of life for both advanced cancer patients and their caregivers during this difficult time.

1.2 Background and Rationale

Delirium is an acute confusional state in which global brain dysfunction is characterized by alterations in consciousness and attention along with cognitive, behavioral (e.g. agitation), and perceptive (e.g. hallucinations) disturbances[12, 13]. It can be the result of a single or combination of organic causes and medication use.

Delirium is a very common condition and occurs in 25-50% of patients with advanced cancer[6-10] in up to 85% of cancer patients in the time leading up to death[11]. It is one of the most common and most feared side effects of pain medications[14] thereby limiting optimal management of pain in cancer patients[15-17]. While a smaller study found that patients found delirium- related hallucinations of dead relatives soothing and welcoming[18], more recently, a larger study revealed that 95-100% patients who recovered from an episode of delirium with delusions or hallucinations experienced high levels of distress[19]. When approaching death, patients desire: adequate pain and symptom management, mental awareness, involvement in decisions about treatment preferences, not to be a burden to their loved ones and the opportunity to prepare for death[20-22]. By its very nature, delirium may prevent or impede a patient from achieving each or all of these goals, yet the relationship between delirium and these patient-reported goals at the end of life is not adequately addressed in the literature. Instead, the literature has focused on mortality and health services outcomes, such as hospital length of stay, rates of institutionalization and cost[23-25]. Palliative care focuses on treating symptoms and other sources of distress in patients near the end of life. Yet, we have only just begun to understand the effects of this very common problem and its effects on patients who recover from an episode of delirium.

Delirium is associated with decreased survival[24, 26] and patients are less able to care for themselves, based on their increased likelihood of being discharged to a facility rather than home[27]. Thereby potentially increasing caregiver stress if the episode happens at home and/or making it necessary for the caregiver to make medical decisions for his/her loved one. A recent study demonstrated that caregivers who perceived their loved ones as delirious were twelve times more likely to have Generalized Anxiety Disorder (GAD)[28]. In fact, more than two-thirds of the bereaved family members of cancer patients, perceived delirium-related symptoms, except somnolence, as distressing or very distressing.[29] Delirium has the potential to have a tremendous impact on a patient's and family's quality of life, as patients lose their ability to communicate effectively with family members[30, 31].

It can be very challenging to care for a delirious patient as a clinician. Using a numerical scale (0-4) to assess delirium-related distress, Breitbart and colleagues found that nurses caring for delirious patients reported a delirium-related distress level of 3.09[19]. Clinicians are constantly striving to balance unanticipated patient conditions and unyielding workload[32] potentially generating a distressing work environment. Clinicians face the demanding situation of providing care for someone who is disoriented, perhaps agitated and who may hallucinate and/or act in a manner that calls for interventions actions that could oppose the will of the patient[33] to maintain the standard of care and protect the patient from harm. Brajtman et al. [34] cite the importance of additional education, fostering team work and the importance of presence in order to enhance nurses' ability to care for these patients and their families.

Although increased morbidity and mortality associated with delirium is well established, almost no studies have investigated the patient, caregiver and formal caregiver psychological sequelae to these physical outcomes[18, 19, 29]. These studies fail to explore

the nature of this experience, how patients and families understand the episode and determine what makes it distressful. There are gaps in our understanding of delirium from patient, caregiver and formal caregiver perspectives. Our proposed study seeks to examine the effects of delirium on patients, their caregivers, and formal caregivers As to better understand what the experience means to those involved. Through a set of one-time quantitative questionnaires with patients, caregivers and clinicians, this study will triangulate an episode of delirium as to enable an exploration of the issues that arise in and around patients with delirium who subsequently recover from delirium.

1.0 OBJECTIVES

Broadly, this study aims to enrich understanding of this particularly common and distressing condition and fill important gaps in current understanding of how patients, their caregivers and their clinicians experience delirium. We will triangulate the same episode of delirium and gather information to identify issues that are of common concern to each group and issues that are of unique concern to each group (i.e. of concern to caregivers, but not clinicians or patients). This will be accomplished by a series of quantitative questionnaires with patients, family caregivers and clinician.

Aim 1: To assess symptom burden in patients who recover from delirium

Aim 2: To assess patient and care giver quality of life after an episode of delirium

Aim 3: To assess frequency and distress of delirium-related symptoms in patients, caregivers and clinicians of patients who recover from delirium.

2.0 RESEARCH SUBJECT SELECTION

We will enroll advanced stage cancer patients admitted to the Intensive Palliative Care Unit (IPCU) or general oncology patients who are followed by the Pain and Palliative care (PPC) team at Brigham and Women's Hospital (BWH). Patient-identified primary caregivers and clinicians will subsequently be enrolled for these same patients. Delirium is a common reason for referral to the PPC team and admittance to the IPCU and we anticipate being able to enroll 40 patient-caregiver-clinician triads.

Eligibility: The target population is hospitalized adult oncology patients who experienced and then recovered from delirium, their caregivers, and their clinicians. Specific criteria include:

- 18 years or older
- Fluency in English
- Inpatient on the general oncology (with a palliative care consult) or palliative care service at the time of delirium
- Two days positive screen for delirium with CAM (confusion assessment method. See below.) followed by at least two days negative screen to assure recovery (N.B. The CAM is routinely documented by the palliative care team on all patients they follow).
- Identification of a caregiver willing to participate

- Ability to give informed consent

We chose to require two days with a positive CAM for delirium to ensure a true, clinically relevant episode of delirium. Due to the waxing and waning nature of delirium, we have chosen to wait until patients have two consecutive days (after being identified with delirium) of a negative CAM. This should avoid approaching patients who may still have some element of delirium, but test negative on the CAM for one day. By requiring two days free from delirium, we will interview patients when they have fully recovered from the delirium episode.

Caregiver & clinician eligibility:

- 18 years or older
- Fluency in English
- Identified by patient as involved in patient care
- Ability to give informed consent

Clinicians eligible to be interviewed will include anyone with substantial clinical responsibilities for the patient during the delirium, including: attending physicians (palliative care or oncology), residents, fellows, physician assistants, medical students, nurses, nurse practitioners and social workers.

Exclusion criteria include:

- Enrollment in this study on a previous admission
- Life expectancy less than five days.

3.0 RESEARCH STUDY ENTRY

Recruitment: Prior to opening the study for enrollment, the study will be presented to the Intensive Palliative Care Unit and the Pain and Palliative Care program at Dana Farber Cancer Institute (DFCI) at one of their scheduled weekly conferences.

The research associate (RA) will attend the daily rounds of the PPC team to obtain a list of new patients seen by the team and review their eligibility.

Furthermore, as delirium is a common reason for referral, the study will be presented to the nursing staff on the Intensive Palliative Care Unit, to help identify eligible patients.

Once a patient is identified, the primary oncologist will be contacted to inform them that their patient is being approached for enrollment in this study.

Study Enrollment: At the initial encounter, the research assistant will explain the nature of the study and ask the patient if s/he is willing to participate. Interested patients will then sign informed consent forms before completing any study procedures. At intake, the research assistant will collect basic demographic information, including: patient age, gender, race, ethnicity, highest education completed, income, primary tumor site, stage of cancer, length of delirium episode and whether the delirium was hospital acquired or the patient was admitted with delirium.

At the time of enrollment the patient will be provided with the questionnaires. The RA will be available at this time to help the patient complete the surveys, if desired or they can be picked up at a later time (usually the same or next day). If the patient agrees, we will also ask permission to contact the caregiver and a clinician involved in their care regarding his/her willingness to complete a similar set of questionnaires.

If possible, the RA will meet with caregivers when they are at the hospital visiting the patient. If this cannot be arranged, then the RA will telephone the caregiver (with the patient's permission) to set up a time to meet and discuss the study. The RA will explain the nature of the study, obtain informed consent and then administer the questionnaires to the caregiver. Total time for caregivers to complete the questionnaires is estimated to be under 30 minutes. If caregivers are unable to complete the questionnaires at that time, the RA will arrange to return to pick up the questionnaires (again usually within the same or next day). For caregivers unable to complete the questionnaires, the RA will try to arrange to pick up the questionnaires at a scheduled office visit or have them mailed to the PI. Caregivers who have not completed questionnaires within 1 week of patient discharge will not be contacted further about the study.

Clinicians who cared for these patients during their delirium will also be asked to complete a questionnaire about their experience caring for the patient during the delirium. Estimated completion time is estimated at 10 minutes. Once they signed informed consent, the clinician will be presented with the questionnaire and asked to complete it at that time. For clinicians unable to complete it immediately, the RA will arrange to pick up the completed questionnaire within 48 hours and e-mail the clinician a reminder regarding the study, if she has not received completed survey in the agreed upon time. All surveys must be completed within 7-10 days of the patient's last day with delirium, so clinicians will not receive any reminders after that time. To avoid introducing the perspective of one individual clinician too heavily into the study, we will attempt to identify a new or unique caregiver for each patient-caregiver dyad interviewed. For example, if Dr. Smith is the attending oncologist for both subject A and B and completed an interview for subject A, then the nurse or social worker or resident physician for subject B will be asked to complete the questionnaires.

Due to the sensitive nature of querying subjects during this vulnerable and difficult time, Dr. Block, a psychiatrist with expertise in palliative care, has agreed to have a psychiatrist/social worker available to all individuals who participate in this study and request it or whom we identify as requiring psychiatric assessment or counseling, because of distress demonstrated during the interview. Sarah Murphy, LICSW, has agreed to be the social worker available to counsel patients who experience any distress related to this study.

All study subjects will have the opportunity to opt out of the study, skip an item or items, or not complete the interview at any time during the interview.

5.0 Study Design and Methods

5.1 Design/Study Type

This is a pilot study designed to collect data via questionnaires on patient symptom burden and delirium-associated distress, patient and caregiver quality of life and clinician distress associated with caring for delirious patients.

5.2 Selection of Instruments

Several questionnaires have been chosen to gather more precise information about the experience of delirium and to provide context for the information gathered in the questionnaires. The details about each instrument and how it is being used is below.

Assessing Delirium: The delirium assessment is not actually part of the study measures, but is performed and documented daily by the clinicians for on the palliative care service. It will be used to help identify patients eligible for the study. In order to be eligible for this study, patients must screen positive for at least two days for delirium using the Confusion Assessment Method (CAM) and then demonstrate recovery by screening negative for at least two days. The CAM is a validated tool used to detect delirium in medically ill, hospitalized patients[37]. It assesses four factors: acuity of onset, inattention, disorganization of thinking, and altered level of consciousness, based on the diagnostic criteria for delirium in the DSM-IIIR[38]. Patients receive a point for the presence of each of these four factors. A score of three or greater indicates delirium. Sensitivity and specificity are greater than 90% as compared to a formal psychiatric assessment of delirium. Inter-rater reliability is also high (κ=0.81)[37]. The CAM can be completed in less than ten minutes and has been used as a diagnostic tool in numerous studies in both geriatric and oncology populations[39-42] For the purposes of this pilot study, the RA will review the charts of patients that have been referred by the palliative care team for the presence of a positive CAM (indicating the presence of delirium) followed by two days with a negative CAM (indicating recovery from the delirium).

Assessing Delirium-Related Symptoms: Morita's quantitative evaluation of delirium-related symptoms[29] is a questionnaire designed to both screen for the presence of characteristic delirium-related symptoms and when present, to determine how distressing these symptoms were to patients, caregivers and clinician. This questionnaire asks whether the patient experienced insomnia, somnolence, memory disturbance, thinking difficulty, communication difficulty, disorientation, irrelevant/incoherent speech, hallucinations, delusions, physical restlessness, inappropriate behavior, or mood liability and how often (not at all, sometimes, often or very often). The second portion of the questionnaire asks the respondent to rate the symptoms, when present as not at all distressing, not so distressing, distressing, or very distressing. The questions were designed based on the Memorial Delirium Assessment Scale (MDAS) and the Delirium Rating Scale[29, 43-45].

Assessing Quality of Life: We will use the McGill Quality of Life (MQOL) assessment in palliative care to assess the patient's quality of life. It has five subscales: physical symptoms, physical well-being, psychological symptoms, support and existential issues. The MQOL has good construct validity, reliability- ranging from 0.73-0.88[46], acceptance

by the user poptulation[47] and responsiveness to change. We chose the MQOL over a number of other instruments[48, 49] because of its strong testing background and its ease of use. Of note, the physical subscale of the McGill asks patients to report on the presence and the level of bother of any physical symptoms. Thus, the McGill provides a measure of symptom burden in addition to a measure of patient quality of life.

Caregivers quality of life will be assessed using the Caregiver Quality of Life- Cancer (CQOLC) instrument and using the Caregiver burden scale (CBS). The CQOLC seeks to elucidate the severity of fears, stress and impact of illness on the caregiver's life by rating a series of 15 questions on a four-point scale. This instrument was validated in a study by Weitzner et al. and found that the CQOLC has good test-retest reliability (0.95) and internal consistency (0.91)[50]. The CBS considers the demand and difficulty level of tasks associated with caring for a loved one who is severely ill, such as performing household tasks, assisting the patient with getting in/out of bed and providing emotional support to the patient.

5.3 Description of Intervention

Not applicable. This is not an interventional study. The study only involves a one-time completion of questionnaires from patients, caregiver and a clinician as described above.

5.4 Data Collection

The data will be collected while the patient is in the hospital, although, on occasion, it may be necessary to schedule a later date to pick up the completed surveys at a more convenient time and place for the study participant.

Pre-Enrollment	**At Entry**	**Questionnaire administration**		
Patient	Patient	Patient	Caregiver	Clinician
Patient identified through PC team Confirm eligibility criteria	Age Gender Primary site of cancer Stage of cancer Reason for admission Delirium on admission (Y/N) Number of days with delirium Medications Previous CAM data	Morita MQOL	Morita CQOL-C CBS	Morita

PC- Palliative Care; CAM- confusion assessment method; Morita- Morita's qualitative evaluation of delirium-related symptoms; MQOL- McGill Quality of Life questionnaire; CQOL-C- Caregiver Quality of life in Cancer questionnaire; CBS- Caregiver Burden Scale.

5.5 Description of Study Process

5.51 Instrument Administration:

The study is a one-time collection of data from questionnaires that will administered to cancer patients who have recovered from an episode of delirium, their caregiver and a clinician who cared for the patient during an episode of delirium. Patients who have been identified as having delirium, followed by two days without delirium (as demonstrated by the Confusion Assessment Method. See above.) will be approached by the RA about the study. For those who consent, the RA will present the questionnaires to the patients and give them the option to assist them in completing the questionnaires (i.e. read the questions aloud and have the patient answer verbally) or complete them in writing. Patient questionnaires are estimated to take under 20 minutes to complete, even for patients who require assistance.

Caregivers, who have been identified by the patient, will be contacted by the RA. Once consented, the RA will offer to assist in completing the questionnaire or have the caregiver complete them in writing independently with the RA arranging to return to pick up the questionnaires. Completion of the caregiver questionnaires is estimated to take a maximum of 30 minutes. It is expected that most caregivers will complete the surveys while visiting the patient during their hospitalization, but other arrangements to pick up the surveys (ie during an outpatient visit) will be made if more convenient for the caregiver.
Finally, a clinician, identified either by the patient or via the chart, will be asked to complete a written questionnaire that should take under 10 minutes to complete.

Of note, the questionnaires will not contain any patient identification data. The study patient will be identified on the surveys by the study ID number only. Information linking the study ID number to the patient's name and medical record number will be kept separately in the locked office of the PI.

Prior to the initiation of the study, the RA will be trained to use each of the above instruments by the PI, an expert in end-of-life and palliative care. Initially the RA will observe Dr. Buss administering questionnaires. Then, the RA will administer them while being observed by Dr Buss, prior to administering them independently.

5.52 Intervention Administration

The intervention is simply the administration of the instruments listed above.

5.53 Special Concerns:

Given that this study seeks to study a patient and care giver population who are very ill and especially vulnerable, special care and sensitivity will be employed to minimize the impact and inconvenience of this study. Patients are being identified by the palliative care team, a group especially sensitive to patient's needs and invested in minimizing burden to patients. The PI is trained in palliative care. Care has been taken in designing this study to minimize burden to this vulnerable population.

5.54 Compensation:
There is no compensation for participating in this study.

5.6 Adverse Reactions and their Management
5.61 Reporting Adverse or Unanticipated Events:
Adverse reactions from administering the surveys are not anticipated. The RA and/or PI should be contacted immediately if clinicians, patients, or caregivers experience or learn of any adverse effects. Any serious adverse event will be reported using the forms found on the institutional protocol website, http://www.dana-farber.org/res/OPRS/advevent/irbguidelines.asp. A report will be submitted via interoffice mail or hand delivered.

5.62 Anticipated Reactions:
While significant adverse events are not anticipated, completion of the questionnaires may cause mild embarrassment, distress, anger or anxiety for patients. All subjects will be informed of this possibility in the informed consent document.

5.63 Reaction Management:
Subjects may drop out of the study at any time, if they feel they are experiencing adverse effects from it. All subjects have the option to skip any item that they find distressing on the questionnaires. Those experiencing considerable anxiety or distress that was brought on by discussing the study will have to option to meet with a social worker. Sarah Murphy, LICSW, Department of Care Co-ordination (SWRL 260, telephone:617-632-6463; page: 42124) has agreed to be available for this role.

6.0 STATISTICAL ANALYSIS
This is a pilot study with primarily descriptive aims, so no formal power calculations have been performed. Targeted accrual is 40 patient-caregiver-clinician triads, which will result in 120 completed surveys. Simple descriptive statistics, such as frequencies and proportions will be calculated. Differences in mean distress scores for the three group (patients, caregivers and clinicians) will be tested using analysis of variance. Dichotomous responses will be compared using the Fisher's exact test. Data collected in this pilot study will also allow us to determine the standard deviation on key items, which will inform the design and power calculation of future studies. All analyses will be conducted using SAS version 9.1 (SAS Institute, Cary, NC).

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