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**Project Title:** Patient-Centered Approach to Advance Care Planning

**Abstract:** DESCRIPTION: (Provided by the Applicant) This application is re-submitted in response to PA-01-124, Patient-Centered Care: Customizing Care to Meet Patients' Needs. For a decade, attention has been given to the use of Advance Directives and Advance Care Planning (ACP) as ways to improve end-of-life care. We know from the literature, and from our own research on end-of-life care that these efforts have not been successful. The overriding inadequacy of past efforts is their lack of patient-centeredness. That is to say, they have not been grounded in a clear understanding of patients' preferences, values, and wishes, nor did they include surrogates. Based on theories regarding decision-making and patient education we have developed Patient-Centered Advance Care Planning (PC-ACP). This intervention is designed to improve patient and surrogate knowledge of ACP, increase the congruence between patient and surrogate in treatment decisions, decrease the patient's and surrogate's conflict in making such decisions, and increase the consistency between patient preferences and the actual care they receive. The ACP intervention is conducted with the patient in the presence of surrogate. The specific aims are (1) To test the efficacy of PC-ACP on patient and surrogate outcomes both immediately following receipt of the intervention and at six months and (2) To test the efficacy of PC-ACP on patient and surrogate outcomes at the time the patient first encounters a medical complication or during end-of-life care where the surrogate is required to make decisions. A randomized trial will be conducted with patients and surrogates experiencing conditions that put patients at high risk for dying within the next year - end-stage renal disease, and end-stage heart failure. Subjects (patient-surrogate pairs) will be randomized to PC-ACP or a control group. The control group will receive "usual care." Subjects will complete measures of clinical and demographic data when they enter the study. Outcome measures will be assessed at two end points, at the time of the first medical complication that requires surrogate decision-making and/or at six months. If successful, the knowledge gained from this research will be useful in redesigning the federally mandated assessment of Advance Directives into an improved process of Advance Care Planning to better fit the spirit of the Patient Self Determination Act.

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## Research Plan

### A. Specific Aims

This application is being re-submitted in response to PA-01-124, "Patient-centered care: Customizing care to meet patients' needs." We are proposing to test the efficacy of a patient-centered intervention that is designed to improve care for patients and their surrogates in situations where the patient is at high risk for having complications and end-of-life care needs.

Over the past decade, attention has been given to the use of Advance Directives and Advance Care Planning as ways to improve end of life care. These efforts, however, have not been successful. The most striking evidence of this problem is seen in the landmark study, SUPPORT, but other data support this conclusion. The overriding reason for the failure of past efforts is that they have not been patient-centered. That is, they have not established a clear understanding of patients' preferences, values, and wishes. Specifically, deficiencies of past efforts have been evidenced by patient and surrogate lack of knowledge, lack of consistency between patients' wishes and caregivers' actions, conflict about end-of-life decision making for surrogates, inconsistency of actual treatments with documented preferences, and high levels of surrogate stress. It is clear that the current practice of assessing Advance Directives on admission to a hospital by multiple levels of employees is unfortunately superficial and often not effective. These deficiencies show up at several critical junctures in patient care, but especially during episodes of acute medical complications that require surrogate decision-making and, most markedly, in situations wherein end of life is imminent. Shared decision-making between the patient and surrogate needs to be enhanced in order for patient preferences to prevail when patients cannot speak for themselves.

The patient-centered intervention to be tested in the proposed study is called Patient-Centered Advance Care Planning (PC-ACP). It is based on a melding of two theoretical perspectives, the Interactive Decision-Making Model and the Representational Approach to patient education. PC-ACP is grounded in the idea that establishing a clear understanding of a patient's cognitive representation of his/her health problem is a prerequisite to patient-centered decision-making, care planning, or information provision. Once a patient's representation has been carefully assessed, it is possible to provide information relevant to that representation and to facilitate choices that are consistent with the patients' values and beliefs.

The specific aims of this study are:

1. To test the efficacy of PC-ACP on patient and surrogate outcomes:
  - a. immediately after the intervention
  - b. and at six months post intervention.
2. To test the efficacy of PC-ACP on patient and surrogate outcomes at the time of the patient's first post-intervention medical complication that requires surrogate decision-making, or during end-of-life care.

The hypotheses to be tested are:

1. PC-ACP will be superior to usual care, immediately following the intervention with respect to the following:
  - a. patient and surrogate knowledge of ACP
  - b. congruence between patient preferences and surrogate's understanding
  - c. patient decisional conflict
2. PC-ACP will be superior to usual care, at the time of the first subsequent complication or during end-of-life care with respect to the following:
  - a. consistency between surrogate actions and patient preferences
  - b. consistency between actual care and documented patient preference
  - c. surrogate decisional conflict
  - d. surrogate stress
3. PC-ACP will be superior to usual care, at six months (when the patient did not have complications/death) with respect to the following:
  - a. patient and surrogate knowledge of ACP
  - d. congruence between patient preferences and surrogate's understanding
  - e. patient decisional conflict

## B. Background and Significance.

Both the total number of elderly and the proportion of the population who are elderly are increasing resulting in an increase in chronic illnesses, changes in how people are dying, and changes in the choices patients are required to make to manage their illnesses. When patients are competent to make decisions, they may express their wishes about the options presented to them in managing their illness. When they become incompetent because of disease progression or other factors, surrogates may need to make decisions in the patients' stead. Advance Care Planning (ACP) is a process of interaction with the patient to discuss the patient's desires for future care needs. ACP ideally results in the completion of an AD. Advance Directives (ADs) are documents in which patients indicate their wishes and which typically include designating a decision maker if the patient becomes incompetent.

### B.1.a. Advance Care Planning as a Decision-Support Intervention.

To improve end-of-life care, national initiatives have recommended the development of more effective strategies to assist individuals and their families in determining future medical wishes and insuring these wishes are honored<sup>1-3</sup>. In advocating end-of-life reform, the Institute of Medicine has defined a "good death" as "...one that is free from avoidable distress and suffering for patients, families, and caregivers; in general accord with patients' and families' wishes, and reasonably consistent with clinical, cultural and ethical standards"<sup>4</sup>. Consistent with discovering what the wishes of patients and families are, the concept of advance care planning has emerged to remedy the inadequacies of advance directive initiatives<sup>5-9</sup>.

Advance care planning has been defined as a process of assisting individuals in understanding their medical condition and potential future complications; understanding the options for future medical care (specifically as it relates to their health condition); discussing the choices with family, loved ones, health care team, and others as needed; and reflecting upon these choices in light of personal values and goals, and religious, and cultural beliefs<sup>5</sup>. Several other authors have advocated such similar definitions of ACP<sup>10-14</sup>. ACP is an important element of quality end-of-life care; however, there is little agreement on the necessary components of an effective planning process, nor has there been any empirical work supporting its beneficial effects. Although the quality of patient-clinician discussion about end of life is associated with satisfaction with care and with increased clinician knowledge of patients' wishes<sup>15</sup>, there have been no prospective studies evaluating outcomes of advance care planning discussions. Research on advance care planning still focuses on the completion of advance directives<sup>16</sup>, and discussions are limited to technology rather than focused on goals of care and context<sup>17</sup>. Although Ditto and colleagues' randomized controlled trial<sup>18</sup> was not successful in significantly improving accuracy of surrogate judgment, they found that an advance care planning intervention had a number of psychological benefits for patients and their families in terms of producing a sense of mutual understanding and comfort with end-of-life decision making.

### B.1.b. Advance Directives.

For over a decade, efforts to promote patient self-determination through the completion and documentation of written plans, i.e., advance directives, have largely failed<sup>9, 19-22</sup>. Even when advance directives are completed, their impact is not clear. The most striking evidence of this problem is the landmark study, SUPPORT, a large, multi-site study, which documented shortcomings in communication, frequency of aggressive treatment, and the characteristics of hospital death. Of the 9100 patients in the SUPPORT study, 50% of conscious patient were reported by their families to be dying in pain, 38% spent at least 10 days in the ICU<sup>23</sup>, and the cost implications were staggering<sup>24</sup>. For these patients, the placement of written advance directives placed in their medical records did not guide medical decision-making beyond naming a healthcare proxy or documenting general preferences in a living will<sup>9</sup>. Others have also found that ADs have neither positive nor negative effects on patient satisfaction, well-being, and costs<sup>25</sup> and even when written, may not be available.

**B.2. Role of the Surrogate.** One of the basic tenets of advance directives is the ability to designate a surrogate decision maker in the event of incapacity. While the role of the surrogate decision maker has been legalized in all 50 states, the effectiveness of the surrogate in fulfilling responsibilities as a patient advocate has not been realized. Surrogates are often uninformed, unclear about their role, unsupported or disregarded by professionals in fulfilling their role, or lack understanding of their responsibilities<sup>18, 26-28</sup>. Even when patients

reported having conversations with a chosen surrogate regarding future medical decisions, surrogates' knowledge of specific patient preferences was only weakly related to the patient's wishes<sup>29</sup>.

Moreover, surrogates may even decrease the effectiveness of advance directives. Delay in presenting the advance directive, unavailability of surrogates, and conflict between the dictates of the advance directive and the wishes of the surrogate are such examples<sup>30,31</sup>. Efforts to improve communication between the surrogate and the patient regarding future medical decisions failed to demonstrate increased congruence in hypothetical situations<sup>18,32</sup>.

A few studies achieved success. The most notable, The La Crosse Advance Directive Study, was conducted from 1995-1996 by Hammes, a Co-Investigator in this proposal<sup>5</sup>. He achieved remarkable success with increasing the completion rate of advance directives following an extensive educational collaborative advance directive education program implemented across all local health care organizations in a five zip code area. Of 540 decedents, 85% had a written advance directive, and almost all these documents were in the decedents' medical record. Moreover, treatment preferences expressed in advance directives were consistently followed while making end-of-life decisions. The extent of the study is more detailed in Hammes' prior work. Other studies found that advance directives eased the difficulty in making medical treatment decisions for medical practitioners in hypothetical cases<sup>33</sup> and, in a retrospective study, reduced the stress associated with family decision-making<sup>34</sup>.

### **B.3. Past Inadequacies in Advance Care Planning.**

While most studies aimed at improving the effectiveness of advance care planning have demonstrated less than hoped for results, they have identified several key deficiencies in current approaches. Collectively these deficiencies revolve around the lack of a patient-centered approach. Specifically these deficiencies are as follows. Interventions that aim only to increase the completion of advance directives often result in documents that are too vague to guide decision making and are unrelated to the patient-specific treatment decisions that most patients with chronic illness must understand<sup>35</sup>. Advance care planning interventions that include only a checklist of treatment decisions, or limited decisions such as CPR, do not meet the patient's needs of integrating these decisions into their understanding of their current medical condition, goals and values, religious or cultural beliefs or life experiences<sup>7,36</sup>. Interventions that do not provide patients with realistic prognostic information and clarification of medical condition result in patients believing they have a better prognosis than is accurate, leading them to choose more aggressive life-sustaining treatments<sup>37</sup>. Interventions that merely achieve the legal designation of a surrogate without including this person in discussions, assisting them to understand their role, and exploring the depth of moral authority the patient chooses to grant them will result in continued ineffectiveness of the surrogate in adequately representing the wishes of the patient<sup>28,38</sup>. Interventions that do not train professionals in facilitating discussions about end-of-life care will result in continued avoidance, skepticism and fear in initiating timely and effective conversations<sup>39-43</sup>. Interventions that place accountability for advance care planning with only one professional will result in fewer resources to meet the patient's needs, decreased initiation due to time and competency constraints and few opportunities to weave advance care planning into the fabric of the patient's overall care<sup>44</sup>. Interventions that neglect the importance of integrating advance care planning within the context of the patient's personal relationships will lessen the opportunity for shared decision making among involved parties<sup>14,31,45-47</sup>. Lastly, interventions that evaluate the effectiveness of advance care planning from too narrow a perspective i.e., the completion of a document, will neglect the awareness that the purpose of planning involves at least three domains: selecting a decision-making process, deciding what authority surrogate decision makers will have, and determining and clarifying values and preferences<sup>48</sup>.

## **B. 4 The Theoretical Underpinnings: Constructing a Patient-Centered Approach**

### **B. 4.1 Interactive Decision-making Model.**

The Interactive Decision-making Model (IDM), originated from several economic principles and decision theories, and has recently been used to guide studies on health care decision-making behaviors at the end-of-life<sup>49</sup>. The IDM provides a framework consistent with current health care decision-making situations. The rise of consumerism and patient empowerment has shifted the emphasis from passive patient informed consent to more proactive patient informed choice.

There are three constructs in this theory: *decision problem*, *patient-related factors*, and *context*. According to Pierce and Hicks<sup>49</sup>, *decision problems* consist of the relevant information that must be considered in selecting a proffered alternative. Therefore, the degree of individuals' satisfaction with the

decision process is determined by the degree to which the choice is consistent with their values<sup>49-51</sup>. *Patient-related factors* include values or utility (the attractiveness of an outcome<sup>52</sup>), preference for participation, decision style (affected by preference for participation including deferring responsibility, avoidance, information seeking, and deliberation), expectations, psychological and physical state, and risk perceptions. Patient-related factors are the way patients approach the decision problem and the amount of control they prefer in making a decision. In *context*, patient-provider interaction is a crucial aspect of the decision process<sup>53</sup>. Studies exploring the exchange of information between patients and physicians in the decision context have shown that there is incongruence between what clinicians believe patients should know and what patients want to know<sup>54</sup>. In addition, individuals often make decisions based on what they believe is important for themselves, their families, and their lives rather than on the statistical odds of success of therapeutic alternatives.

Decisional conflict arises when there is disjunction between the presented alternatives and the individuals' values, when there are competing alternatives with uncertain risks and outcomes, when trade-offs between equally valued options are required, or when the decider anticipates regret over rejecting potentially positive options<sup>53,55</sup>. The IDM provides useful components to develop strategies to improve the quality of patient-healthcare provider communication, the quality of the decision, and patient choice consistent with personal values. Thus, decision-support interventions guided by this theory focus on alternatives, benefits, and risks; tailoring of information to a patient's clinical risk profile; provision of detailed descriptions of the benefits and risks in functional terms; use of probabilities, when these are available, to describe the likelihood of benefits and risks; asking patients to consider their values; and emphasis on choice and shared decision-making<sup>56-58</sup>.

IDM will be used to guide this study. Although specific instruments have not been associated with this theory, we will be measuring the concepts of decision style (in Treatment Decision-making Role Preference) and decisional conflict (in Decision Conflict Scale). The match with our planned intervention and related outcomes is consistent. The specific intervention used in this study is based, in turn, on the Representational Approach<sup>59</sup>, discussed below, which derived from the Common Sense Model of Illness Representation.

#### **B. 4.2 A Representational Approach to Patient Education**

In addition to being influenced by IDM, the PC-ACP was derived from the Representational Approach to patient education<sup>59</sup>. Donovan and Ward<sup>59</sup> used social science theory -- particularly Leventhal's Common Sense Model of Illness Representation)<sup>60</sup> -- to develop an innovative approach to patient education, the Representational Approach.

To understand the Representational Approach it is helpful to consider some elements of the theories from which it was derived. According to Leventhal<sup>60</sup>, an illness representation is the set of thoughts (whether medically accurate or not) that a person has about a health problem. An illness representation has five dimensions: identity, cause, time-line, consequences, and cure/control<sup>61-63</sup>. Identity refers to how one describes the symptoms of a health problem. Cause refers to an individual's beliefs about the origin of the health problem. Timeline relates to temporal ideas, such as the acute, chronic, or cyclic nature of the problem. Consequences are ideas about the short- and long-term outcomes of the problem. Cure/control refers to beliefs about the extent to which one can control or cure a health problem. Representations serve as a cognitive framework for interpreting and processing new information.

Based on these ideas Donovan & Ward developed the Representational Approach to patient education. Central to this approach is the idea that encouraging individuals to describe their illness beliefs along the five dimensions of illness representation described above can set the stage for highly effective patient-centered informational intervention. First, through a detailed discussion of illness beliefs, patients have an opportunity to examine them carefully and to comment on them. During this discussion, the status of existing beliefs that are barriers to optimal coping can be mitigated by explicitly discussing the limitations, or consequences, of adhering to and acting upon those beliefs. Second, once an individual's illness representation has been assessed, educational information can be presented in a highly contextual manner such that the new information will be seen as an intelligible and plausible replacement for existing beliefs. Third, discussing the benefits of replacing existing misconceptions with plausible information can promote the acceptance of new information.

In PC-ACP decision-making, facilitators provide information relevant to the patients' representation of their medical condition and assist patients to make choices that are consistent with their values and beliefs. Operationally, this is accomplished in five steps: *representational assessment; exploring misconceptions; creating conditions for conceptual change; introducing replacement information; and summary*. Through a detailed discussion of illness representations, patients can examine their own belief systems and the limitations or outcomes of continuing with misconceptions. This process provides the context where the

interviewer presents new information, individualized to the patient, and its benefits so that the misconceptions can be replaced<sup>59</sup>. A co-author of this publication is an investigator in this proposed study to ensure the quality of the adaptation of the approach to advance care planning. See the Appendix for the actual interview schedule used which adapts this Representational Approach to the advance care planning interview.

#### **B. 4.3 Advantages of the PC-ACP Relative to Other Advance Care Planning Interventions.**

There are several reasons why this intervention offers significant improvements in the investigation of advance care planning outcomes:

It is patient-centered, focusing on the patient's understanding of his/her condition.

It provides disease specific information that is related to the patient's current health status, potential for complications and understanding of prognosis.

It presents potential life-sustaining treatment decisions that are real, not hypothetical. Patients are presented with decisions that their chosen surrogate may actually need to make in situations where the outcome for the patient is uncertain or may cause prolonged suffering.

It includes the patient's chosen surrogate decision-maker as a necessary ingredient for successful advance care planning. **The surrogate is present for the interview.** The surrogate is involved in not merely understanding the patient's medical condition, but what the values and goals of the patient are, and what role the surrogate will be expected to play. There is critical interchange in information regarding the authority the patient wants to grant the surrogate. The surrogate is provided an opportunity to clarify information and explore misconceptions.

It is delivered when the patient is not in a medical crisis, which allows for more time for adequate and complete discussion and time for reflection and inclusion of others in the decision-making process if needed.

It integrates the Representational Approach to Patient Education which focuses first on assisting individuals to understand their medical condition and the high potential for sudden complications, to explore values and goals and to begin weighing the benefits and burdens of any life-sustaining treatment compared to personal values and goals. Past interventions have focused on eliciting patient's decisions regarding single life-sustaining treatments, e.g. CPR, and the completion of an advance directive. Past interventions have ignored the time and skill it takes to assist an individual in truly being informed, integrating their goals with the chances of successful outcomes from life-sustaining interventions, and involving others who may be helpful in the decision-making process.

It is delivered by trained professionals and does not assume that any single professional has the skill, time, or interest in attaining competency in this level of advance care planning.

#### **C. Prior work UW-Madison Investigators:**

##### **Dr. Kirchhoff**

Dr. Kirchhoff has been administratively responsible for research in two consecutive University Hospitals, has published on the conduct of clinical research, e.g.,<sup>64,65</sup>, and has conducted her own research in the ICU. She has had experience conducting funded complex clinical trials, usually multi-site, such as this proposed study, in oncology clinics<sup>66</sup>, in a rehabilitation unit<sup>67</sup>, and in the ICU<sup>68</sup>. She has skill in negotiating the conduct of research while maintaining the integrity of the intervention<sup>69</sup> and is able to conduct careful research in multiple busy clinical settings, while acknowledging clinicians' issues and accommodating numerous demands in the "real world" of care. She has skill in conducting research involving multiple health care professionals as they cluster for care in clinical settings.

From 1992-1997 she was the principal investigator of a T32 on nursing interventions in which she taught pre and post doctoral students how to develop, refine, test and evaluate interventions and how to maintain scientific integrity in their research. She was responsible for recruiting and evaluating the trainees, scheduling seminars, and reporting to NINR. She conducted research with some of the trainees<sup>70-72</sup>. Since moving to Madison in 2000, she has been involved with the School of Nursing's T32 on Patient-Centered Interventions as one of the training faculty. One of her doctoral students has received pre-doctoral funding from this T32. Faculty and funded pre- and post-doctoral fellows have monthly seminars and group projects, such as collaborating on a manuscript on the definition of Patient-Centered Interventions<sup>73</sup>. This environment offers a unique opportunity for the activities of the grant.

In the last few years, her research has focused on end of life in the ICU. Dr. Kirchhoff's initial studies on this topic described end-of-life care in ICU from the perspective of nurses and families in focus groups. In these studies, four focus groups of nurses (total n=24)<sup>74</sup> and four of families (total n=8)<sup>75</sup> from 8 ICUs in two hospitals were conducted with Deseret Foundation support, a private local foundation. In the ICU nurses' focus groups, they described "good end-of-life care" as ensuring that the patient was as pain-free as possible and

that comfort and dignity were maintained. They stressed that involvement of the family was crucial. Also important was a clear, accurate prognosis and continuity of care. Nurses said lack of agreement among family or caregivers, lack of certainty about prognosis, and communication problems created stress for them while providing end-of-life care<sup>74</sup>. In the ICU families' focus groups they reported that none of them had anticipated a need for ICU. Exacerbation of the patient's pre-existing condition led them into the hospital and, once there, they were caught in a vortex of events that led, directly or indirectly, to the ICU. Families consistently requested more information, explanations, and time for discussion with their health care providers. These communication concerns emerged as a recurring theme in their stories. Family members were caught between what they knew were the patient's wishes to have a dignified death and the reluctance of physicians to concede that additional treatment was futile<sup>75</sup>. In these situations, when the physician was available, options for treatment presented, and family decisions honored, the family expressed confidence that the best possible outcome had been achieved.

On a national level, ICU nurses were asked to rate "obstacles" and "helps" to quality end-of-life care in the ICU<sup>76</sup>. Items for the questionnaire were developed from reviewing the transcripts from the nurse focus groups<sup>74</sup>. The questionnaire was mailed to 300 randomly selected AACN members with a response rate of 69%. Items relevant to the current proposal that were rated as medium to large obstacles were issues such as the family not fully understanding the meaning of life support, not accepting the patient's poor prognosis, requesting more technical treatment than the patient wished, or fighting among themselves about the use of life support. Helps to the family centered on having greater agreement among the patient, family, and physician concerning direction of care, dying with dignity, and family acceptance of the prognosis. Nurses had discomfort and conflicts around providing aggressive and excessive life-saving measures particularly when they were not in accord with the patient's advance directives, or discomfort with giving painful treatments to dying patients. Having clarity about patient wishes and family awareness of these wishes would solve many of these problems.

In another study<sup>77</sup>, a convenience sample of 31 nurses from ICUs in three hospitals identified what preparatory information should be offered to families to prepare them for the patient's death following withdrawal of life support. The design of the questionnaire used was guided by Self-Regulation Theory<sup>78</sup>. Johnson identified four features that should be used in preparatory information for patients, used in this case for families of patients: the physical sensations (signs of impending death of the patient that are visible, audible, etc. to the family), temporal characteristics of the event, environmental features, and the cause of the patient's signs. These results will be used to develop an intervention to prepare families for withdrawal of life support.

Recently funded by NIA is work with Hauser on the Wisconsin Longitudinal Study where the cohort is now in their early 60's. Kirchhoff is part of an interdisciplinary team on two grants in which a part of the effort is to uncover variables associated with advance care planning and end-of-life planning.

Dr. Kirchhoff's ongoing end-of-life work includes both interviews and questionnaires to measure families' satisfaction with end-of-life care in ICU, in-patient hospice, nursing homes and a community-based elder care program. During data collection in this study, a question is asked is about whether the patient had specific wishes or plans about the type of medical treatment she did or did not want. In the first ICU family interviewed, a husband answered that his wife had no wishes but later in a question about the presence of an Advance Directive, he stated she had one. This example shows that there seems to be a major disconnect in the ICU families' perception of the documents as guiding care according to patients' wishes, although this did not appear to be true in any of the hospice families.

In summary, advance care planning while the patient is able to participate and while the surrogate is present would eliminate or reduce many end-of-life conflicts in ICU found in this past work. This proposed intervention study builds on the only known effective end-of-life work<sup>5</sup> that is receiving recognition at present by those researching end-of-life in the ICU, e.g.,<sup>6</sup>. Collaboration between the UW-Madison and Gundersen Lutheran is extremely strong. It began with nursing contacts between the two sites for research and educational purposes. The ACP work as a preparation to the pilot work will be detailed in the sections of the other investigators. The pilot work resulting from the collaboration between Dr. Kirchhoff and the Gundersen Lutheran staff and intended to support this proposal will be detailed here.

**Pilot Work for this Proposal.** At Gundersen Lutheran Medical Center, the pilot study of the PC-ACP was conducted. Patients (male=16, female=11) with their paired surrogates were randomly assigned to the experimental group (4 open-heart surgical patients [OHS], 4 end-stage congestive heart failure [CHF], and 5 end-stage renal disease [ESRD] patients) or the control group (4 OHS, 5 CHF, and 5 ESRD). Surrogates were

asked what they thought the patient would prefer about life-sustaining treatments before the PC-ACP. The same data were collected from them after the PC-ACP. About 85% of the experimental surrogates paired with these patients, changed their thoughts about the patient's preferences in at least one situation of Statement of Treatment Preferences after the PC-ACP intervention. The congruence in specific treatment preferences between patient and surrogate was significantly higher in the experimental than the control group ( $p=.008$ ). In particular, the experimental group demonstrated perfect congruence in clarification of the decision-making authority, whereas the control group showed that 50% of the pairs demonstrated congruence. Achieving this level of congruence is exceedingly important for situations in which the patient becomes incapacitated. Empirical studies have shown that, no matter how detailed an advance directive is, it is likely to be of limited value if there has been no communication between the patient and surrogate<sup>28,79</sup>. Moreover, in many clinical situations, even when patients have an advance directive and even if the AD pointedly includes or excludes the contingent medical procedures, decisions are made after discussion with surrogates. Thus, exercising a Statement of Treatment Preferences following in-depth discussions and achieving the surrogate's understanding of patient's preferences may provide immeasurably valuable guidance to the surrogate in the future.

Experimental patients' satisfaction with the quality of patient-clinician communication was significantly higher than that of control group ( $t = 2.1, p = .043$ ). This information was evidence of the skill of the interviewer that these types of discussions were not too upsetting or potentially harmful, as suggested by some professionals. Likewise, the patients' decisional conflict regarding preferences for future medical care was significantly lower in the experimental group than in the control group ( $t = -3.21, p = .004$ ).

In summary, pilot data demonstrate that surrogates are not consistently congruent with patient preferences despite previous discussions or long-term relationships with the patient. PC-ACP is effective in improving congruence. PC-ACP can significantly increase the shared decision-making between patient and surrogate while decreasing patient decisional conflict. What is yet to be determined is: stability of that improved congruence over time, the impact of PC-ACP on later surrogate decision making, and whether the findings will be replicated at another setting. This proposal is designed to accomplish those ends.

### **Dr. Ward**

Dr. Ward has been a clinical researcher for almost 15 years. Her work has addressed coping with cancer, with a particular focus on pain and symptom management. Only the portion of her prior work that is most relevant to the current proposal will be reviewed here -- the development of the Representational Approach to patient education<sup>80</sup>. A series of intervention studies led up to their development of the Representational Approach.

The first of these studies involved testing an intervention based on Johnson's Self-Regulation theory<sup>78</sup>. They tested whether an intervention comprised of sensory and coping information about opioid side effects combined with corrective information about patients' beliefs would enhance pain management<sup>81</sup>. Because those effect sizes were small, they conducted a second study in which they strengthened the intervention by tailoring the content that had been used in the first study<sup>82</sup>. Once again, effect sizes were small. The results of these two studies were critical in leading Ward and colleagues to reconsider how to provide the most potent educational intervention. They speculated that the interventions they had thus far tested were insufficiently powerful because they did not explore the basis for patients' beliefs. Johnson's self-regulation theory emphasizes the need for accurate and specific schema in order to guide the selection of coping strategies. In this sense, it serves as an excellent guide for choosing *what* to teach in novel situations in which a knowledge deficit exists (e.g., prior to beginning radiotherapy or prior to undergoing a new medical procedure). However, in situations in which individuals have well established, but medically unsound, beliefs based on prior experiences, simple information provision may not be sufficient.

This thinking led to their development of the Representational Approach to patient education. They used social science theories -- particularly Leventhal's Common Sense Model (CSM) of Illness Representation<sup>60</sup> and Hewson and Thorley's theory of conceptual change<sup>83</sup>-- to develop a new approach to patient education<sup>59</sup>. They recently completed the first test of the Representational Approach to patient education called a Representational Intervention to decrease cancer pain (RIDcancerPain). Based on the Representational Approach to patient education described earlier (section B), RIDcancerPain was developed, pilot tested and revised. Then a randomized trial was conducted to compare RIDcancerPain to a standard educational intervention (SEI) for adults (N=176) with cancer pain. Hypotheses were that RIDcancerPain would be more effective than SEI in decreasing patients' beliefs that are barriers to reporting pain and using analgesics with a

resultant decrease in pain severity and improved quality of life (QOL). Outcome variables (pain severity, pain interference with life activities, and overall QOL) and mediating variables (barriers) were assessed at baseline, and one and two months post intervention. Most hypothesized effects were supported. The change in barriers from T1 to T3 mediated the effect of the intervention on the change in pain severity from T1 to T3. The data support that the Representational Approach is a very promising approach to patient education, and that more research is needed to test the extent to which this approach is useful in a variety of patient education situations.

### **M. Song, RN**

Mi-Kyung Song is a critical care nurse who is now a doctoral candidate. She is collecting her dissertation data on the immediate impact of ACP in Open-Heart Surgical Patients. Cardiac surgeons have had concern about having ACP discussions prior to surgery and Ms. Song will soon have data on the emotional response to the PC-ACP interview prior to surgery. She has minored in Biostatistics and has been involved in several research projects since her master's program. Her research relevant to this proposal during her doctoral program consists of several studies.

She conducted the data analysis for a clinical study on health care providers' perceptions of withdrawal of life-support<sup>84</sup>. She participated in a cross-sectional descriptive study on family experience of death in an ICU or Hospice settings. She also assisted Dr. Kirchhoff with two studies recently funded by NIA.

### **Prior Work Gundersen Lutheran Investigators:**

#### **Dr. Hammes**

Dr. Hammes was the principal investigator in the La Crosse Advance Directive Study conducted from 1995 to 1996<sup>5</sup>. This was a multi-institution, retrospective study of end-of-life care of a general population of 95,000 people. The study included two hospital systems, three medical clinics, six long-term care facilities, three home health/hospice organizations, and the County Health Department. Investigators collected end-of-life information on over 1,000 adult deaths occurring over an 11-month period<sup>5</sup>. The prevalence of written advance directives was 85%. Almost all (95%) these documents (95%) were in the decedent's medical record. Almost all advance directive documents requested that treatment be forgone as death neared. Treatment was forgone in 98% of the deaths. Treatment preferences expressed in advance directives seemed to be consistently followed while making end-of-life decisions.

Dr. Hammes<sup>85, 86</sup> helped develop and test a new type of interview with patients who had metastatic cancer, a patient/provider interaction. This instrument was initially developed through discussions with national experts and through focus groups with providers and patients. The interview that was developed was structured and designed to help patients with metastatic cancer and their chosen loved-one to explore what it meant to live well in the last months of life. Results indicated that patients found these conversations to be very meaningful and helpful. Each patient in this pilot study was assisted in some way to make choices about what it meant to live well at that point.

Currently, Dr. Hammes is a co-investigator with Dr. Schwartz in a research project recently funded that will prospectively test in two Massachusetts cities the advance care-planning program he developed in La Crosse, WI<sup>5</sup>. The pilot work for this proposed research has already been published<sup>87</sup>. The investigators will compare the outcome of the La Crosse approach in a control and intervention group in two different populations over a 5-year period.

#### **L. Briggs, RN**

Linda Briggs is an Assistant Director for Advance Care Planning (ACP) and has a history of commitment and dedication to improving end-of-life decision making through her past roles as critical care nurse, and presently as an ethics consultant. Ms. Briggs has led several quality improvement projects related to ACP at Gundersen Lutheran. She initiated a plan to address ACP issues stemming from cases presented to the Ethics Committee dealing with postoperative open-heart surgical patients. This plan included interviews with the cardiovascular surgeons and nurse practitioners as well as testing a preoperative ACP interview script. She later expanded this interview script to end-stage heart and renal failure patients. She has directed the current pilot study "Patient-Centered Approach to Advance Care Planning" that enrolled 27 pairs of patients and surrogate. She is the main professional delivering the intervention and training others.

Ms. Briggs directed a project to expand the role of the RN in advance care planning at Gundersen Lutheran. Following a needs assessment, she developed a computer based training module on the role of the RN. This module is currently used in the competency orientation program. She co-authored an article on the role of the RN in end-of-life decision-making<sup>88</sup>.

This outstanding professional has been responsible for curriculum development and professional training for the nationally recognized advance care planning program, Respecting Choices®. She also developed, tested, and implemented a competency based Instructor Certification as an optional component to Respecting Choices®.

Ms. Briggs is a consultant for the recently funded research project in Massachusetts directed by Drs. Hammes and Schwartz that will compare the outcome of the La Crosse approach in two different populations. The pilot project for that research has been accepted for publication.

### **Consultant: Ms. Campbell**

Ms. Campbell is an advanced practice nurse in the Palliative Care Service at Detroit Receiving Hospital. She is part of a collaborative, interdisciplinary, nurse-directed practice for the care of patients who are not expected to survive hospitalization. The role consists of direct patient care as primary provider; consultation to hospital staff regarding end-of-life care and bioethics; education of hospital staff, medical staff, residents, and students regarding end-of-life issues and care; clinical research; and leadership through co-chair of the Hospital Ethics Committee. The practice has managed more than 3000 dying patients under the direction of this advanced practice nurse since 1988.

She was a member of the Institute of Medicine's Committee on Care at the End-of-Life which published the report "Approaching Death"<sup>1</sup>. She has received awards annually for her contributions to the literature, practice, committee work and commitment to a number of organizations. She has more than 30 publications relating to end-of-life care and is one of the experts in dying patients in acute care settings. Her book, Foregoing life-sustaining therapy: How to care for the dying patient<sup>89</sup>, is used in in-patient palliative care services.

She is completing doctoral requirement this year and her dissertation is on the development and psychometric testing of a Respiratory Distress Observation Scale for patients with impaired consciousness. The American Association of Critical Care Nurses funded her dissertation work with a Clinical Practice Grant. She is uniquely qualified to consult on this proposal with both her vast end-of-life experience and her background in biometrics.

## **D. 1 Design and Methods.**

### **D. 1.1 Design.**

The design used will be a randomized, stratified by setting and patient population, post-test only control group design. It is expected that the effect sizes of the intervention between two settings and between two patient populations could be different. For this reason, pairs of patient and surrogate will be randomized within each setting and disease condition.

Pretests of outcomes were thought to be not appropriate. Pre-measures taken before the intervention will be strictly demographic data, potential blocking variables (previous ADs), or potential moderators (Treatment Decision-making Role Preference). The study will be conducted in a similar fashion at two different Wisconsin healthcare organizations in LaCrosse and Madison. All patients will receive "usual care" appropriate for their institution as well as the procedure(s) specific to their assigned treatment group.

After the pre-measures are obtained, pairs of eligible patients and their designated surrogates will be randomized to an experimental ACP Interview group (E) or to the control group (C) (see Figure 1). C pairs will have their proximal outcome measures taken upon entry into the study (as a control for proximal measures in the E group). Immediately after randomization, the E group will receive the PC-ACP intervention. The surrogate is present and listens to the interview.

Two end points for the study are planned. At one end point, six months, the same outcome measures (patient and surrogate knowledge of ACP, congruence between patient preferences and surrogate's understanding, and patient decisional conflict) will be obtained. This end point is used to assess the stability of the improvement in congruence between patient and surrogate. An alternative end point will occur for those patients who have had a complication or death requiring surrogate decision-making before the six-month follow-up. This end point is used to assess the impact of PC-ACP on surrogate decision making. The

outcomes measured are: consistency between surrogate actions and patient preferences, consistency between actual care and documented patient preferences, surrogate decisional conflict, and surrogate stress.

#### D1.1.2 Potential problems with the control group

During the pilot study, the control group patients and surrogates sought additional ACP information following completion of the Statement of Treatment Preferences. Despite this, they still were significantly different on all measures from the E group. We will use this same design because we need to have comparable measures at both proximal and distal data collection for comparison with the E group. Although there may be a slight treatment effect in the control group, the need for comparable outcome measures at the same time points outweighs the slight treatment effect that might occur because of collecting those measures.

#### D. 1.2 Settings.

##### Gundersen Lutheran Medical Center in LaCrosse, WI

Gundersen Lutheran has 325 beds, 26 medical clinics, >1 million clinic visits/year, and three other affiliated hospitals. They have 365 physicians and serve the border towns of WI, MN, and IA. They are the Western Medical Campus for UW-Madison School of Medicine and the Western Clinical campus for the UW-Madison School of Nursing. They have been a leader in Advance Care Planning in the country and offer national workshops on the topic.

##### St. Marys Hospital Medical Center in Madison, WI

St. Marys and its affiliated physician group, Dean Medical Center, together own and manage over 22 primary care clinics, which include more than 60 physicians outside of Dane County. A partnership between Dean, St. Marys and the Monroe Clinic in Monroe, WI expands services to residents in Green County, WI, and counties in northern Illinois. Since 1972, St. Marys also has been affiliated with the University of Wisconsin School of Medicine's three-year family practice residency program. Having a second site away from LaCrosse will add to the generalizability of the findings since LaCrosse has been active in Advance Care Planning for a decade. St. Marys Hospital Medical Center nurses are the first in Madison to earn the prestigious Magnet Recognition for Excellence from the American Nurses Credentialing Center (ANCC) of the American Nurses Association. Awarded by the foremost authority on nursing, this national designation is the highest level of recognition that can be given to nursing organizations in health care. St. Marys is one of only four medical centers in the Midwest to have achieved this level of recognition.

#### D. 2 Subjects.

**Patients** will be recruited from clinics at either of two Midwestern health care organizations. **Their designated surrogate** will also be included, paired with the patient. The two special populations of patients chosen for this study are: end-stage congestive heart failure (CHF), and end-stage renal disease (ESRD). These patient populations present different typologies of end-of-life scenarios. CHF patients have a steady decline possibly with remissions or exacerbations. Dialysis patients have the possibility of discontinuing a single technology supporting their life, which could result in an abrupt end-of-life. These two groups may experience sudden decline or complications leaving an unprepared surrogate.

**CHF** is one of the leading causes of death in the United States, accounting for more than 30,000 deaths and 700,000 hospitalizations annually<sup>90</sup>. In the Study to Understand Prognosis and Preferences for Outcomes and Risks of Treatment (SUPPORT)<sup>91</sup>, formulas used to predict a six-month prognosis were ineffective for patients with end-stage chronic illness. The chance of a six-month survival was estimated to be greater than 50% even within 3 days of death. During the last one year of life, CHF patients report a slow decline in functional status and an increase in symptoms of dyspnea, pain, and confusion. As mental functioning decreases, patients with CHF have difficulty retaining information<sup>92</sup>. Evidence exists that as an individual's cognitive abilities decrease, preference for life-sustaining treatment increases<sup>93</sup>. Studies on the type of information provided to CHF patients have revealed a lack of disclosure of prognosis by physicians, despite acknowledgement from the patient that he/she was dying<sup>94</sup>.

Place figure 1 here

Patients with **ESRD** are getting older, living longer and enduring more complications of their illness. In the past 5 years, the greatest increase in the use of dialysis has been seen in individuals 75-84 years old. The incidence of co-morbidities is significant: 50% have diabetes, 42% have coronary artery disease, 40% have congestive heart failure, and 23% have peripheral vascular disease<sup>95</sup>. The risk of death while on dialysis is related to the presence of the following co-morbidities: a serum albumin of less than 3.5, poor nutritional status, poor functional status and such sentinel events as acute myocardial infarction and above the knee amputation. For these sentinel events, survival at one year is less than 50%<sup>96</sup>. Added to this reality is the fact that 40-70% of patients are either not referred to a nephrologist prior to initiating dialysis, or have emergent dialysis<sup>97,98</sup>. This has an obvious impact on their ability to fully participate in an informed way in making important decisions about their care. There is also an emerging issue regarding the futility of dialysis under certain situations<sup>96</sup>; the recommendation is that dialysis not be started, or withdrawn when the patient's life expectancy is less than six months, he/she is not a candidate for kidney transplant, he/she has peripheral vascular disease, ongoing problems of vascular access or he/she is failing to thrive. The Clinical Practice Guidelines additionally recommend a shared decision making model in assisting individuals and their families in making the decision to initiate or withdraw dialysis. They emphasize the importance of informed consent, estimating prognosis, developing advance directives, implementing time-limited trials, and offering palliative care<sup>96</sup>.

#### **D. 2.1 Inclusion Criteria.**

Patients will meet the following criteria before they will be considered eligible to participate in the study:

- Must be at high risk for impending death in the next 12 months by (a) being currently enrolled in the Heart Failure Clinic and/or have a New York Heart Association Classification of Class III or IV heart failure (See Appendix), OR (b) meeting the high risk criteria for end-stage renal failure (See Appendix). See Criteria of Eligibility for these two medical conditions are in the Appendix.
- Patients must have received and reviewed the routine materials regarding advance care planning and advance directives (usual care)
- Patients must have decision-making capacity, i.e., able to communicate, able to understand information, able to make choices and give rationale
- Patients must have an individual who is willing to be a surrogate decision maker
- Patients must be 50 years of age or greater and read, write, and speak with English as their primary language.

The rationale for the patient criteria is that those selected are at high risk and, therefore, should be prioritized for an in-depth interview about preferences (the intervention) rather than that care usually offered to all patients on admission. Ability to make decisions and have a surrogate are essential for the provision for the intervention; older age, illness and co-morbidities create a need for the intervention.

Surrogates must be over 18 years of age and read, write, and speak English as their primary language.

#### **D. 2.2 Target Sample Size.**

Sufficient numbers of patients in both illness conditions are available at both sites. The refusal rate thus far in the pilot sample has been about 20%. Reasons were: the surrogate would not want to participate, there was no surrogate, one patient was too ill, or the patient did not want to talk about Advance Directives at all. In the pilot study, attrition (over time for other than disease progression) was not measured since only proximal measures were taken immediately after the intervention. According to intervention studies on advance directives and advance care planning in the past, 8 to 31% refusal or dropout rate has been reported<sup>16, 18, 99, 100</sup>. Sample size considerations included whether the data are considered to have a hierarchical nature or are independent of each other, the randomization scheme used, and the need to have sufficient sample size in the two alternate end points (1) first complication or (2) 6-month follow up. Six months was selected since these patients had a one year life expectancy and a six-month time period is more likely to produce comparable cell sizes for distal outcomes.

We propose sampling 280 pairs of patients and surrogates in each site (see marginals in Table 1 below). This will provide 280 pairs of patients and surrogates per disease condition (CHF and ESRD), with a total study sample of 560 pairs of patient and surrogate to provide sufficient power at the .90 level for multiple tests. Recruitment of the 560 pairs of patient and surrogate over a 2½-year patient accrual period would

require recruiting approximately 9 - 10 patients per month per disease condition. See D.6.2.6 for power discussion.

Table 1. Sample Size by Site and Disease Condition

Disease condition	Site		Total
	St. Marys	Gundersen Lutheran	
CHF	140 patients paired with 140 surrogates	140 patients paired with 140 surrogates	<b>280 pairs</b> of patients and surrogates
ESRD	140 patients paired with 140 surrogates	140 patients paired with 140 surrogates	<b>280 pairs</b> of patients and surrogates
Total	<b>280 pairs</b>	<b>280 pairs</b>	<b>560 pairs</b>

### D. 2.3 Women and Minorities.

These patients were available at St. Marys Hospital in 2001 by condition, race, and gender. They are provided by patient group.

#### St. Marys: CHF Population

	American Indian	Asian/Pacific Islander	Black, not Hispanic	Hispanic	White, not Hispanic	Other	N
Male			1.3%		97.9%	0.8%	677
Female		.64%	2.3%	1.15%	94.6%	1.28%	780

#### St. Marys: Chronic Renal Failure Population

	American Indian	Asian/Pacific Islander	Black, not Hispanic	Hispanic	White, not Hispanic	Other	N
Male		6.9%	15.3%	4%	67.9%	5.8%	274
Female		15%	14%	7.36%	62.5%	.6%	163

At Gundersen Lutheran, ethnicity and gender data were not available by disease condition. A proxy for those proportions is the overall inpatient admissions data listed below. Numbers of available in each group are as follows. ESRD patients are seen in dialysis center for the first month and then go to nearby satellite clinics for continuing dialysis. At present there are 112 patients with 75 being new in 2001. Gender ratio is about 56% male. Race is 89.7% Caucasian, 1.5% American Indian and 8.8% other inclusive of the relatively substantial Hmong population in the area. CHF clinic patients number 487. This clinic has 100-200 referrals/year. Males are 59%. Patients are predominately white, aside from one Black, one Hmong, and two American Indians.

#### Gundersen Lutheran Inpatient admissions for 2001

	American Indian	Asian/Pacific Islander	Black, not Hispanic	Hispanic	White, not Hispanic	Other	N
Male	0.44%	1.04%	0.52%	0.32%	97.47%	0.21%	7507
Female	0.53%	1.14%	0.48%	0.11%	97.68%	0.07%	9051

#### **D. 2.4 Participation of Children.**

According to the Patient Self-Determination Act (PSDA) of 1991, only individuals 18 years of age or older may express and document their wishes for future medical care via an advance directive. Since chronic illness in older adults, 50 years or older, is the focus, children would not fit the goals of the study for inclusion as a patient. Surrogates, however, could be as young as 18 and still be able to make decisions under the PSDA. They would then fall within the NIH definition of child.

#### **D. 3 Recruitment Procedures.**

In the ESRD or CHF clinics, a listing of current patients who meet the high-risk criteria for each disease condition will be developed by clinic staff. These patients will be approached by clinic staff at their next scheduled clinic appointment and be invited to participate in the study. Clinic staff will be provided a checklist on which to assess eligibility. If the patient is interested, and meets criteria, a member of the project staff will explain the study further and obtain informed consent. During this contact, patients will be asked to select a surrogate decision-maker who may be willing to participate as well. If the surrogate is present, this individual will be asked to participate with the patient at that same clinic visit if possible. If not, or if the surrogate could come for the next clinic visit, he/she would be requested to participate at that time. A phone call to the patient will be made a few days before their clinic appointment reminding the patient to bring the surrogate for the next visit.

#### **D. 4 Experimental Protocols.**

##### **D. 4.1 Care-as-usual.**

##### Gundersen Lutheran Usual Care Related to Advance Care Planning

All patients are approached on admission and asked if they have an advance directive and/or if they would like more information. They are provided with an information card describing their right to have an advance directive and this information is distributed in the patient's rights handbook. This is documented on the Admission assessment form. If the patient desires more information, the following materials are given: "Making Choices" information booklet & planning guide and a Power of Attorney for Healthcare (POAHC) document. This is documented on the Advance Care Planning Education record. If the patient desires assistance in completing the POAHC document, a referral is made to pastoral care or an Advance Care Planning Facilitator skilled in having these discussions and providing assistance. Completed POAHC documents are placed in a consistent place, i.e., the "green sleeve" in the patient's medical record.

Additionally, pre-dialysis patients are asked to attend a class on pre-dialysis information. Two nurses teach the class once a month. If the patients are elderly and/ or have many co-morbid conditions, the nurses talk about withholding or withdrawing dialysis. The care managers and social worker cover more specific information about advance directives once the patient starts dialysis. This topic is reviewed periodically but at the least every year when the patients have their "annual care conference".

##### St. Marys Usual Care Related to Advance Care Planning

Information regarding patient's advance directive status is obtained by nurses on each hospital admission and recorded on the Patient Profile. Written information on advance directives and the patient's right to have an advance directive is distributed via the Patient Information Guide on admission. If the patient has a copy of the complete Power of Attorney for Health Care or Living Will, the document is filed in front of the patient's medical record, and a dated "Advance Directive Reviewed" sticker is placed after the document has been signed by patient and two witnesses on the same date that it is reviewed. If there are questions about the document, a referral is made to pastoral care or patient and family services. If the patient does not have an advance directive and desires one, or desires additional information, the registered nurse assessing the patient is to notify Patient and Family Services or Pastoral Care for assistance in completing the advance directive. If an advance directive is mailed to the hospital, Patient and Family Services staff reviews the document for completeness. Incomplete forms are sent back to the patient with a letter of explanation. Control group patients will experience care as usual in both institutions.

##### **D. 4.2 PC-ACP — Provided to the Experimental Group.**

Experimental patients will have received usual care in regard to advance care planning at each institution before admission to the study. In addition, they will receive the Patient-Centered Advance Care Planning (PC-ACP) interview.

The PC-ACP is a scheduled interview with a consenting patient and a chosen surrogate decision-maker, delivered by a trained facilitator and lasting 1 to 1 ½ hours. The interviewer begins by explaining the purpose as an opportunity for the patient/surrogate to understand and think about the life-sustaining treatment choices the patient would want if he/she became unable of making decisions in the future, and the surrogate would need to make decisions in the patient's behalf. The patient/surrogate are reminded that the intent of the interview is to explore the patient's understanding, introduce new information as needed and promote dialogue between them.

The first stage of the interview (10-15 minutes) assesses the patient's understanding of the current medical condition, related symptoms, and potential complications. This information is used later during stage four of the interview when replacement information is provided. The first stage also explores the meaning of the illness to the patient in terms of how it has affected his/her life, what makes life worth living, and what is expected of the current plan of care. This information is useful for the patient later in the interview when they reflect on whether the burden of a particular life-sustaining treatment matches their goals for living well.

The second stage of the interview (10 minutes) explores misconceptions the patient may have regarding planning for future medical decision-making e.g. advance care planning. Previous hospitalizations and experiences with family/friends who have been seriously ill or have died are explored to assess what the patient learned from those experiences, and how they may have helped or hindered their ability to plan for themselves. Another misconception that is explored is the quality of advance care planning discussions they have had with their family and surrogate. Often patients feel they have had enough discussion, but as the interview progresses, they often are surprised by the misconceptions the surrogate has regarding preferences.

Stage three of the interview is brief (5 minutes). It is intended to assist the patient and surrogate to appreciate the value of understanding specific treatment choices the patient is likely to experience in the future, and why discussing preferences is important to the surrogate who would need to make decisions in the patient's behalf. The result of these types of discussions is a more prepared surrogate who will be able to truly represent the patient's wishes. Permission to give new information to the patient is requested.

Stage four of the interview (30-40 minutes) uses a disease-specific Statement of Treatment Preference document to help the patient understand their potential complications and the kinds of treatment decisions the surrogate may be asked to make. This document allows the facilitator to introduce replacement information, such as why they are at risk for certain complications and the benefits and burdens of a particular life-sustaining treatment (e.g., CPR). The characteristics of an ideal surrogate decision-maker are emphasized and the ability of the surrogate to honor the patient's choices is explored. The option of choosing another surrogate is given. Last, the importance of documenting the decisions the patient has made by placing them in the medical record is reviewed. The facilitator develops a follow-up plan for completing any written documentation with the patient and surrogate.

Stage five (5 minutes) summarizes the value of the discussion for both the patient and surrogate, the need for future discussions as situations and preferences change and the expectation that the patient is more likely to have their wishes honored in the future.

#### **D. 4.2.1 Training of individuals on the PC-ACP.**

The PC-ACP requires professionals who are skilled in the content, techniques, and delivery of the study intervention. Ms. Briggs developed the training program taught by Gundersen Lutheran Medical Center and has been offering national training programs in advance care planning. She will be responsible for training all interviewers at both sites. A competency-based educational approach will be used to train nurses who are selected to implement the PC-ACP. At the Gundersen Lutheran site, Linda Briggs and Elaine Colvin have conducted the pilot study. They and an additional one or two more nurses will be the interveners. At St. Marys, Mi-Kyung Song, already trained at one of the national meetings, and two other nurses will be trained. Elaine Colvin and Mi-Kyung song have had experience in ACP and have attended training. All interviewers will participate in the training to achieve maximum consistency and successfully complete the training competences as described elsewhere.

The Training Program for facilitators of the PC-ACP will consist of the following:

1. To attain knowledge in basic skill of advance care planning facilitation, individuals will be required to read "Respecting Choices Advance Care Planning Facilitators Manual." This manual has been used in the Gundersen Lutheran advance care planning course for over a decade and is included in the Appendix.
2. The individuals will then read Donovan and Ward<sup>59</sup> and discuss with Dr. Ward how the ACP interview will be structured according to the Representational Approach.

3. Successful (90%) completion of a knowledge posttest.
4. Completion of a self-study educational module on Advance Care Planning with Special Patient Populations, to include:
  - a. Chronic illness: Challenges to Planning for Future Medical Care, including end-of-life care.
  - b. Selected content related to one of the following areas: End-stage CHF and ESRD (depending on which patient population the individual will be working with.
  - c. The Representational Approach (RA) to Patient Education with Advance Care Planning. Behavioral criteria will be established to emphasize the expectations for performance the participants must achieve. (Professor Sandra Ward, who is a colleague of the PI at the University of Wisconsin, is a Co-investigator on this study. She and her colleagues developed the concept of the RA to patient education, which is being extended to encompass end-of-life patient education in the proposed study.)
5. Participation in practice role-play scenarios utilizing the Representational Approach to Patient Education for ACP with special patient populations of end-stage CHF and ESRD. Each individual will have an opportunity to review the expected behavioral criteria and begin to apply them in simulated situations. Feedback on the achievement of clearly defined behaviors will be provided following each scenario to allow for monitoring of individual progress.
6. Demonstration of competency in administering the PC-ACP by facilitating one role-play scenario related to the patient population the individual will be working with

#### **D. 4.3 Quality Control for the Intervention.**

Since it is expected that mastery of competency requires practice at achieving expected behaviors, each individual will be monitored by the project director at one, two and three month intervals. Those conducting the interview will be observed by Ms. Briggs at least once a month during data collection to ensure that techniques do not drift. Ms. Briggs will also receive the data sheets, consents, and chart audits to track study progress.

#### **D. 4.4. The Role of the Physician/Follow-up interview activities.**

While physicians are not conducting the PC-ACP interview, they will be instrumental in supporting the importance of ACP to their patients and families, and in addressing any concerns that emerge from the interview. Patients will be instructed to inform their physician of any concerns that arise during the interview. If patients and/or their families have unanswered questions regarding their medical condition, potential complications, benefits/burdens of life-sustaining treatment choices, they will be referred back to their physician or appropriate health care provider to seek clarification and/or support. Patients will be assisted in developing specific questions they have for their physician and be encouraged to discuss any issues or treatment decisions with any other professional, such as a religious advisor. Interviewers will document the essence of the interview in the medical record for communication to all care providers and will directly initiate communication with the physician if issues are identified that require immediate attention, e.g. a patient requests a Do-Not-Resuscitate order. Any treatment decisions made by a patient will be documented in the medical record as evidence of their wishes in accordance with the standard practice for documenting advance directives by each organization.

*Both Dr. McBride (10%) and Dr. Akosah (5%) will assist in the implementation of the study by coordinating with the medical staff at each site. Both physicians will participate in selected staff meetings and will be available to assist with problems requiring communications with physicians or patient care specifically. They are not involved in administering the intervention or collecting data. We expect that they will be involved in communication with physicians who have patients in the study, problem solving around clinical issues that arise, and assistance in staff meetings. Dr. McBride is involved in the panel in Year 1 & 4.*

#### **D. 4.5. Future Clinical Application of the Intervention.**

During the pilot study, the scheduled PC-ACP typically lasted 1 to 1 ½ hours and required a trained facilitator for delivery. While this time and resource utilization may present obstacles to later implementation within a health care delivery system, there are several practical suggestions to overcome these concerns. First, the CHF and ESRD patients are typically managed through a clinic that provides consistent caregivers and regularly scheduled appointments. The PC-ACP should be delivered over several clinic visits and therefore integrated into routine disease-management care. In fact, this type of delivery could offer an advantage over a concentrated, lengthier discussion. Additionally, the group of trained facilitators who deliver

the intervention may come from a team of interdisciplinary members who can make referrals to one another when time constraints exist, thus lessening the responsibility to only one professional. This team of trained, interdisciplinary professionals could also establish advance care planning clinic hours that would ease some scheduling difficulties and availability for referrals. Last, when patient-centered advance care planning occurs, surrogates are informed and prepared to be decision-makers and specific preferences are documented, the time and resources utilized during end-of-life situations will likely decrease. There will be more timely and appropriate life-sustaining treatment decisions made, less stress on family and healthcare providers in determining treatment preferences, and fewer resources used to support all involved parties as they struggle with making the “right” decisions, or decisions the patient would want them to make.

## **D. 5. Data Collection.**

### **Pre-Data Collection Procedures**

#### **Oversight Panel**

A multidisciplinary oversight panel will be convened twice; the first time will be to assist with the implementation of the study. In the beginning of the study they will review all the instruments, consent documents and data collection plans as has been done in PI’s previous end-of-life studies<sup>74, 101</sup>. Members of this group in the past have included: chaplains, physicians, nurses, and social workers from acute care and hospice care. They will advise the research team on: issues of sensitivity at difficult times, comprehension under stress, and wording suggestions. They will review procedures for data collection and make suggestions. A noted consultant in end-of-life issues, Ms. Campbell, will join this panel.

*The entire sample is 560 pairs. The panel will review only one of two end points, death/complications. Those pairs without this end point will not be reviewed by the panel but rather will have a second measurement of Statement of Treatment Preferences and Knowledge of ACP. We projected in our initial submission that 50% or less would be in the death/complications group that would be reviewed by the panel. In the resubmission we made changes in accord with reviewers’ suggestions to decrease the time of the distal measurements to 6 months post intervention. With this shortened time period, we expect even fewer to have complications or deaths requiring decisions to be made.*

*The panel process will occur as follows. Ms. Campbell and Dr. McBride will convene the panel. The first meeting will review all the instruments and the procedures. This review will serve to orient the panel to the study as well as provide an opportunity for recommending slight changes in wording for increased sensitivity. Following data collection, potential categories will be constructed for those in one of two end points who did have complications/death: no decisions were made (e.g., sudden death), clear concordance with patient decisions, clear lack of concordance, and unclear. At the panel’s second meeting following data collection, they will be re-oriented to the study, briefly review the clear cases for agreement/disagreement and spend most of their time on the unclear cases. They will be asked to do their reviews separately first and when voting is not unanimous, to discuss the cases. None of the panel members making decision will be aware of group assignment (E vs C), and project staff present will have been instructed to avoid such discussion.*

#### **Data Collection on Entry to the Study**

All patients and surrogates who consent to participate in the study will have received the usual ACP from the institution. They will complete the Demographic Data Sheet and the Treatment Decision-Making Role Preference. A Chart Audit will be done to assess documentation of the patient’s previous advance care planning or Advance Directives. See Figure 1 for data collection from enrollment to study end.

#### **Proximal outcome measures**

These measures are completed immediately following the interview in Group E or upon admission to the study in Group C.

Patient/surrogate pairs will complete the following data collection tools separately and without discussion: Knowledge about Advance Care Planning and Statement of Treatment Preferences (specific to disease state, i.e., CHF, ESRD). If patient/surrogate require the investigator to read each tool, then the patient/surrogate will be physically separated to prevent merging of data. The patient’s statement of Treatment Preferences will be placed in the patient’s chart. In addition, the patient will be asked to complete the Decisional Conflict Scales.

#### **Process outcomes**

At the same time as the proximal measures, patient/surrogate pairs in both E and C groups will complete the Quality of Patient-clinician Communication about End-of-life Care separately as a manipulation check. Within two weeks on study, there will be a review of charts to assess quality of the documentation of advance care planning discussion (for E and C groups) and the quality of the documentation of disease-specific treatment preferences (for E group only).

### **Distal outcome measures**

There are two alternate endpoints for the distal measures. One is when there is a death or a complication when the consistency of the surrogate's decisions will be compared with the patient's stated preferences. This consistency will be scored in Panel Rating Form. The research assistants will track all enrolled patients until the end of the data collection or until death. Both groups of patients will be followed either in the hospital, if admitted, or in the clinic if they have scheduled visits. Clinic logs and hospital admissions will be checked against the list of enrolled patients every 1-2 days to assess complications or changes in the illness trajectory. Following clinic visits or hospitalizations, the chart will be reviewed to assess complications and decisions made by the patient. Follow up continues until death or until patients are censored with the end of data collection. The surrogate will be contacted by phone one month after the death or complication to find out the preferred method of gathering the final data, phone or mail. Surrogate's decisional conflict and stress will be measured 1 month following the patient's death for both experimental and control groups, using Decisional Conflict Scale and the Impact of Event Scale.

In the alternate second end point for Knowledge of ACP and the congruence between patient and surrogate in Statement of Treatment Preferences will be reassessed at six months if death or complications have not already occurred (see Figure 1). Patient Decisional Conflict will also be reevaluated at this follow-up. These individuals (patients and their surrogates) will be contacted by phone followed by mailing distal outcome measures with a stamped envelope.

**D. 5.2 Summary of Measures.** Table 2 presents all the measures, by category, and concepts measured. Table 3 presents all measures for experimental and control groups by time period measured.

Table 2. Data Collection Instruments, Concepts Measured, and Time of Measurement

<b>Concepts measured</b>	<b>Tools</b>
	<b>Pre-measures</b>
Patient and surrogate demographic data	Demographic Data Sheet
Presence of ADs	Chart Audit Form
Patient decision style	Treatment Decision-making Role Preference
<b>Hypothesis 1. Immediate impact of PC-ACP following intervention</b>	
1.a Patient and surrogate knowledge	Knowledge of ACP
1.b Congruence between patient and surrogate	Statement of Treatment Preferences (specific for CHF and ESRD)
1.c Patient decisional conflict	Decisional Conflict Scale
<b>Hypothesis 2. Impact of PC-ACP on care provided for first complication or death</b>	
2.a Consistency between surrogate decisions and documented patient preferences	Panel Rating Form, Patient Medical Record, and Patient's Statement of Treatment Preferences
2.b Consistency between actual care and documented patient preferences	Panel Rating Form, Patient Medical Record, and Patient's Statement of Treatment Preferences
2.c Surrogate decisional conflict	Decisional Conflict Scale
2.d Surrogate stress	Impact of Event Scale
<b>Hypothesis 3. Later impact of PC-ACP at six months follow-up</b>	
3.a Patient and surrogate knowledge	Knowledge of ACP
3.b Congruence between patient and surrogate	Statement of Treatment Preferences (specific for

**D. 5.2.a. Entry to Study Measures (See Appendix)****Demographic Data Sheet (A single form)**

It consists of two sections, one for patient to complete, and one for the surrogate. Each section includes age, gender, race, marital status, education, household income, religious preference, and insurance status. This form also includes one question of the patient's perceived prognosis<sup>102</sup> and the surrogate's perception of the patient's perceived prognosis.

**Chart Audit Form (A single form)**

This form was assesses the presence and type of an advance directive, individuals involved in an advance care planning discussion, issues discussed, and documentation of advance care planning discussion and its quality. The documented quality of discussion is evaluated by single item rating from "1 (minimal or almost no discussion)" to "4 (evidence of an in-depth and comprehensive conversation)". It will be completed before (pre-measure) and after the intervention (as a process measure) by medical record audit.

**Treatment Decision-Making Role Preference (A single form for the patient)**

This instrument was developed by Degner and Sloan<sup>103</sup> to determine what roles people actually want to assume in selecting medical treatments. Five options of this instrument indicate roles that the patient and physician could assume, ranging from the patient selecting his own treatment through a collaborative model to a scenario where the physician alone made the decision. Patients select one of the five options, which represents his/her preference (e.g., "I prefer to make the final selection about which treatment I will receive."). Findings from a study conducted by Degner and Sloan<sup>103</sup> suggested that the impact of being diagnosed with a life-threatening illness might influence preferences to participate in decision making. Thus, this information may serve as a moderator in the ACP decision-making.

Table 3. Measures in Experimental and Control Groups

Experimental group	On enrollment	Immediately following the PC-ACP interview	One month after first complications or death	Six months follow-up (those who did not have complications or death)
1. Demographic Data Sheet	P & S			
2. Chart Audit	P			
3. Treatment Decision-making Role Preference	P			
4. Knowledge of ACP		P & S		P & S
5. Statement of Treatment Preferences		P & S		P & S
6. Decisional Conflict Scale		P	S	P
7. Quality of Patient-clinician Communication (process outcome)		P & S		
8. Panel Rating Form			O	
9. Impact of Event Scale			S	
Control group	On enrollment		One month after first complications or death	Six months follow-up (those who did not have complications or death)
1. Demographic Data Sheet	P & S			
2. Chart Audit	P			
3. Treatment Decision-making Role Preference	P			
4. Knowledge of ACP	P & S			P & S

5. Statement of Treatment Preferences	P & S		P & S
6. Decisional Conflict Scale	P	S	P
7. Quality of Patient-clinician Communication (process outcome)	P & S		
8. Panel Rating Form		O	
9. Impact of Event Scale		S	

Note. P = Patient, S = Surrogate, O = Oversight Panel.

#### **D.5.2.b. Outcome measures (See Appendix)**

##### **Knowledge of ACP (One form for patient and one form for surrogate)**

This instrument has been revised since the pilot study. Some items have been rewritten, and four new items have been added. This revised instrument consists of 10 items with three response categories, i.e., “true”, “false”, and “don’t know”. These items assess patient’s/surrogate’s understanding about patient’s medical condition, purposes of an AD and ACP, and issues related to ACP, such as the role of surrogate. The higher scores indicate the higher understanding of ACP. Two experts in ACP and one nursing faculty whose expertise is psychometrics assisted with the revision process to achieve content validity of the instrument. Reliability of this instrument is currently being assessed in a study.

*The original Knowledge of ACP instrument demonstrated low reliability ( $\alpha < .60$ ). Ms. Song who will serve as a project director for the study revised the instrument. She has been conducting her dissertation study about a patient-centered approach to ACP with open-heart surgical patients and their surrogates. In this study, she is using the revised Knowledge of ACP to assess patients’ and their surrogates’ knowledge about advance care planning as well as testing its reliability. She has calculated reliability coefficients for this instrument with 15 pairs of patients and their surrogates:  $\alpha = .82$  for patients and  $\alpha = .85$  for surrogates. Thus, we believe that the revised instrument will be able to measure patients’ and surrogates’ level of knowledge of ACP.*

##### **Statement of Treatment Preferences – Factorial Survey (One form for each of the two clinical conditions and for patient/surrogate)**

This factorial survey tool developed by Hammes and Briggs<sup>104</sup> is used to document the treatment preferences of patients as well as the surrogate’s understanding of what the patient would want. It represents situations that are likely to occur given the patient’s disease and, if they occur, often leave the patient unable to make decisions, thus requiring surrogate decision-making. Situations (vignettes) that are disease specific to reflect patients’ values and preferences for end-of-life treatments are provided. In the first two situations, patients and their surrogate will choose one of three options, “to continue all treatment and keep on fighting”, “to stop all treatment, to prolong my life”, and “don’t know”. For the third situation where the patient has a sudden event causing his/her heart and breathing to stop, the patient will make decision of either “do not attempt CPR” or “attempt resuscitation”. One item clarifies the decision-making authority a patient wishes to grant the chosen surrogate (patient’s form) and the surrogate’s understanding of that clarification (surrogate’s form). The options are “strictly follow the wishes”, “do what the surrogate think is best at the time”, and “don’t know”. The composite congruence between patient’s decisions and surrogate’s understanding of them will be assessed by ordinal scores rating from “4 (perfectly congruent in all three situations and clarification of the decision-making authority)” to “0 (incongruent in every item)”.

##### **Decisional Conflict Scale (DSC) (Forms for the E and C patients; one form used for E and C surrogates only when first complications/death occurs)**

The DSC was derived from the construct of decisional conflict developed to measure a state of uncertainty about the course of action to take<sup>105</sup>. It consists of three subscales: three items of uncertainty, nine items of selected factors contributing to the uncertainty, and four items of perceptions of effective decision-making. Each subscale is formatted with a five-point statement scored from 1 (strongly agree) to 5 (strongly disagree), meaning high scores indicate higher decisional conflict. The DSC demonstrated a test-retest reliability coefficient of .80 and .78 - .92 for internal consistency. This tool has been revised for this study to represent decision-making regarding future medical treatment. In our pilot study, the internal

consistency of the revised instrument for patients was .75 across patients (n = 27) in all disease conditions. Only Patients will complete this form at the proximal measures and at 6 months. Surrogates complete the form when they have made decisions (at complications or end-of-life care of the patient).

#### Quality of Patient-Clinician Communication about End-of-life Care (Forms for the E & C Patient/surrogate)

The instrument will be used, as a process outcome, to evaluate the quality of communication regarding end-of-life decisions that occurs between the patient/surrogate and the nurse providing the PC-ACP Interview. This instrument consists of four items to determine the quality of patient-clinician communication about end-of-life care and a single generic-rating question. Items are rated on a 3-point scale with degree from “no” to “definitely yes”, meaning that the higher scores indicate the higher satisfaction with the quality of communication. Good internal consistencies have been reported in AIDS patients (Cronbach’s alpha .81)<sup>15</sup>. In our pilot study, the internal consistencies for patients and surrogates were .87 and .88, respectively.

#### Panel Rating Form (A single form)

The form was developed to evaluate whether medical treatments provided and surrogate’s decisions were consistent with patient’s wishes. For those patients who have died or suffered complications, a chart audit of selected events, e.g., cardiopulmonary resuscitation, will be conducted and placed on the Panel Rating Form. It includes date of death or first subsequent complication, surrogate’s decisions regarding life-sustaining treatments, and medical treatment provided, and finally the panel’s judgments regarding consistency with patient wishes.

The second time the Oversight panel will be convened is at the end of data collection. These individuals will be familiar with the study from the first meeting, will be from settings other than those reviewed or will not have a conflict of interest if from the same settings, but will have the necessary experience to make the required judgments. Panel members will be given the Panel Rating Form and the most recent copies of patient’s and surrogate’s statements of treatment preferences for each patient who died or who had first subsequent complication. They will be asked to judge (1) if care was in accord with the patient’s statement of treatment preferences and (2) whether any surrogate’s decisions made were consistent with the surrogate’s most recent statement of treatment preferences and the patient’s statement of treatment preferences. A 2/3 majority will constitute a decision but consensus will be attempted through discussion. Consistency of surrogate’s decisions or actual care with patient wishes will be scored from 0 (not consistent at all) to 10 (consistent) after the panel’s judgments reach consensus through discussion.

#### Impact of Event Scale (IES) (A single form for the surrogate in E and C)

The IES<sup>106</sup> has been widely used to measure stress following a stressful specific life event. It consists of 15 items that comprise two additive scales, avoidance (denial and numbness), and intrusion (unbidden images and thoughts). The 8-item avoidance subscale includes items such as “I was aware that I still had a lot of feelings about it, but I didn’t deal with them.” The 7-item intrusion subscale includes item such as “I had trouble falling asleep or staying asleep.” Items are rated on a 4-point scale with frequency from “not at all” to “always”, and possible score ranges are 0-40 for avoidance subscale and 0-35 for intrusion subscale. Higher scores represent higher stress. Internal consistency of the IES is .86 overall, and .78 and .82 for each of the avoidance and the intrusion subscale, respectively. Test-retest reliability for the total stress scores is .87 overall, and .89 for the intrusion subscale, and .79 for the avoidance subscale.

### **D. 5.3 Data and Safety Monitoring Plan.**

#### Data Quality and management

Data entry is an ongoing process so that entry is accomplished generally within a week after the data have been collected. The data manager regularly checks for out-of-range values or logical inconsistencies. A double-check system is used to assure accuracy and consistency of coding. Entered data is compared to the original raw data to assure accuracy.

Data will be stored on the hard drive of the office computer. Each night when data have been entered, the file will be automatically downloaded to a ZIP disk and transferred to a remote site Unix database system for storage. Thus, three copies of data files are stored in different places (hard drive, ZIP disk and NT). Experienced personnel, who are highly skilled, maintain our computer database system and files. Weekly reports are generated to show the status of all subjects on study.

The project office is a locked room to which only study personnel have access. Keys are tracked through a centralized School of Nursing system. Study personnel are trained in the ethics of protecting confidentiality through course work, in discussion with the PI, and by completing the NIH course on protecting

human subjects. A training program is being written to ensure compliance with HIPAA regulations protecting patient health information. When available (projected by 2003), all staff members will complete the training.

#### **D.5.4 Coordination of the Project**

Dr. Kirchhoff is responsible for coordination across sites for all aspects of the project. She has been active in these two sites for other endeavors (presentations, educational events, and other research). She will visit the sites as needed. St. Marys is about 10 minutes from her office and Gundersen Lutheran is about 2 hours away. Ms. Briggs will coordinate across sites for the intervention training and ongoing assessment of the performance. Dr. Ward will ensure that the implementation of the intervention stays true to the Representational Approach across sites. All data will be delivered to UW-Madison where Dr. Brown is responsible for data management and analysis across sites. All except Dr. Brown will be required to visit both clinical sites to provide that coordination.

The site directors, both of whom live in Madison, will meet with the PI at least monthly to coordinate efforts. Weekly email or phone contact will occur in between. Ms. Briggs is in frequent email and phone contact while in LaCrosse. She will coordinate site-specific issues with Dr. Hammes. Site directors manage the day-to-day activities, such as recruitment and data collection, communication with physicians and clinic staff at each site, and contact the PI as needed for problem solving.

#### **Safety.**

The level of risk in this study is primarily that of emotional arousal in consideration and planning for eventual death. The Principal Investigator will be primarily responsible for safety, however; safety monitoring is the responsibility of all members of our research team. There may be concerns about premature withdrawal of life support and related legal issues. In the experimental group, the likelihood that care is in accord with patient's preferences is higher than in "usual care" and that is one of the reasons for the conduct of this study.

**D.6.1 Data Analysis.** The analyses will proceed in the following stages: (1) descriptive analyses will be conducted to understand distributions, the amount and reason for missing data, and the relationships among the variables, and (2) hypotheses testing.

**D.6.1.1 Descriptive Analyses:** A necessary first step in our investigation is the description of our data. Patients and surrogates demographic characteristics, patient's perceived prognosis and surrogate's perception of it, patient's Treatment Decision-making Role Preference, and previous ADs and ACP will be assessed using descriptive analyses. Means, standard deviations, range of scores will also be calculated for all outcome measures, i.e., Knowledge of ACP, Congruence, Decisional Conflict, Quality of Patient-clinician Communication, Consistency of surrogate's decision or actual care, and surrogate stress. Bivariate relationships will be assessed using various measures of association contingent upon the description of the data distributions. Tests for linearity, independence and distributional assumptions (i.e., normality) will also be conducted. Analysis of missing data will then be conducted to assess the level and reasoning of missingness, with the consideration of imputation<sup>107</sup>.

#### **D.6.1.2 Hypotheses Testing**

Analysis will be organized by these hypotheses, which are stated for statistical testing.

1. The immediate impact of the PC-ACP on the promotion of shared decision-making between the patient and surrogate:
  - a. Patient and surrogate Knowledge of ACP scores in the experimental group (E) will be significantly higher than those of the control group (C).
  - b. The composite scores of Congruence in Statement of Treatment Preferences between patient and surrogate in the experimental group (E) will be significantly higher than that of the control group (C).
  - c. Patient Decisional Conflict Scale scores in the experimental group (E) will be significantly lower than those of the control group (C).
2. The later impact of (PC-ACP) on care provided for the first subsequent medical complication requiring a surrogate decision or during end-of-life care:
  - a. The scores (from the Panel Rating Form) demonstrating consistency of surrogate decisions with documented patient's preferences in the experimental group (E) will be significantly higher than those of the control groups (C)

- b. The scores (from the Panel Rating Form) demonstrating consistency of actual care provided with documented patient's preferences in the experimental group (E) will be significantly higher than those of the control group (C).
  - c. Surrogate Decisional Conflict Scale scores in the experimental group (E) will be significantly lower than those of the control groups (C).
  - d. Surrogate stress scores from the Impact of Event Scale in the experimental group (E) will be significantly lower than those of the control groups (C).
3. The later impact of (PC-ACP) on the promotion of shared decision-making between the patient and surrogate at six months follow-up (when the patient did not have complications/death):
- a. The significant difference between E and C in patient and surrogate Knowledge of ACP scores will maintain over time (from immediately following intervention to six months follow-up).
  - b. The significant difference between E and C in composite scores of Congruence (Statement of Treatment Preferences between patient and surrogate) will maintain over time.
  - c. The significant difference between E and C in Patient Decisional Conflict Scale scores will maintain over time.

#### D.6.1.2.a Intervention Analysis - Hypothesis 1

**Hypotheses 1a and 1c: Knowledge of ACP and Decisional Conflict.** The treatment effect and treatment effect by disease group for knowledge of ACP and Decisional Conflict will be assessed using general linear mixed model ( $y = X\beta + Zu + e$ ) providing special parametric structures on the covariance matrices.

**Hypothesis 1b: Statement of Treatment Preferences.** The intervention analysis is also concerned with assessing treatment effects and treatment effect by disease group on patient and surrogate congruence (0-4 ordinal composite congruence) of decisions of treatment preferences to likely illness scenarios. An extension of the generalized linear model (generalized estimating equation – GEE<sup>108</sup>) will be used to assess treatment effect on the composite scores of congruence in Statement of Treatment Preferences between patient and surrogate measured just after intervention. This type of model applies to cases where an observation can fall into one of many  $k$  categories, where binary data are considered a special case where  $k = 2$ . If there are  $m_i$  observations in a subpopulation  $i$ , then the probability distribution of the number falling into the  $k$  categories  $y_i = (y_{i1}, y_{i2}, \dots, y_{ik})$  can be modeled by the multinomial distribution, with  $\sum_{j=1}^k y_{ij} = m_i$ . The multinomial model is an *ordinal* model since the categories have a natural order.

#### D. 6.1.2.b Intervention Analysis - Hypothesis 2

**Hypotheses 2a – 2d: Panel Rating Form, Decisional Conflict, and Impact of Event Scale.** The treatment effect and treatment effect by disease group and site analysis for these outcomes will be evaluated using the general linear mixed model.

#### D. 6.1.2.c Intervention Analysis – Hypothesis 3

If 50% mortality and 30% dropout rate are taken into account, as described in D.2, there would approximately be 196 patients and 196 their surrogates who may respond to the distal measures at six-month followup. These outcome measures completed by 196 pairs of patients and surrogates will be matched with their respective proximal outcomes to examine the maintenance over time of the treatment effect.

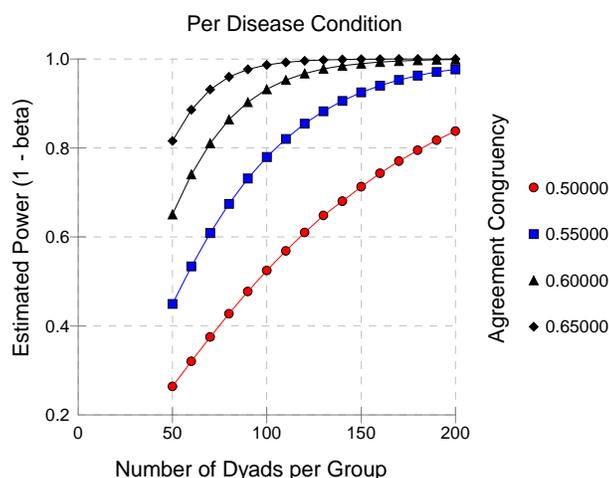
**Hypotheses 3a and 3c: Stability of Knowledge of ACP and Decisional Conflict over time.** The treatment effect and treatment effect by disease group for these two outcomes will be assessed at six months follow up. The general linear mixed model  $y = X\beta + Zu + e$  for repeated measures allows the  $Zu$  portion to model variation within experimental units. This model also allows a rich assortment of covariance structures on  $e$ <sup>109</sup>. These models will be built for both patients and surrogates separately.

**Hypothesis 3b: Stability of Congruence in Statement of Treatment Preferences.** The intervention analysis concerned with assessing treatment effects and treatment effect by disease group on the stability of congruence will be assessed immediately after intervention and six months follow-up. An extension of the generalized linear model (generalized estimating equation – GEE<sup>108</sup>) for repeated measures will be used based on the use of an ordinal scale of congruence.

**D.6.1.2.d Covariates and Propensity Score Methods.** Covariates may be included in both our longitudinal and non-longitudinal models of treatment effects, and are best incorporated based on *a priori* theoretical reasoning. A number of possible confounding covariates have been recognized by the researchers (e.g., perceived prognosis, number of complications experienced, and decision style). Although the models will

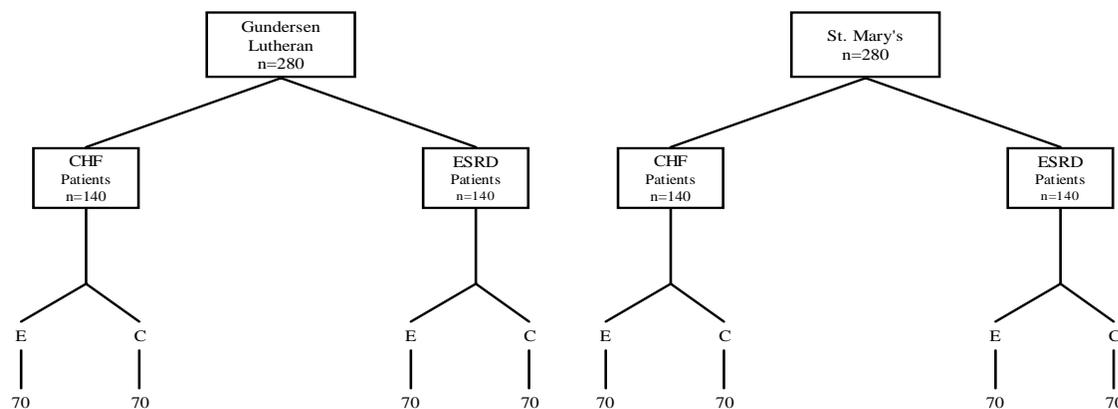
contain these recognized covariates, we also plan to better control possible confounding from unknown covariates in the analysis, by using propensity scores. Rosenbaum and Rubin defined the propensity score as ‘the conditional probability of assignment to a particular treatment given a vector of observed covariates’<sup>110</sup>. For instance, they suggest that a stepwise logistic regression analysis could be used to estimate a propensity score  $q(x_i)$ , for each subject  $i$ , ( $i=1, \dots, N$ ). In which case, the dichotomous dependent variable is receiving treatment ( $T_i = 1$ ) versus not receiving treatment ( $T_i = 0$ ) with independent variables including clinical and socio-demographic variables that are hypothesized to be related to receiving treatment. A propensity score can be estimated for each subject from the logistic model. The propensity score is incorporated into subsequent analyses of treatment effectiveness. As a result, the bias that is associated with the hypothesized confounders is reduced. To the extent that treatment assignment is ignorable through the propensity adjustment, the analyses will yield unbiased estimates of treatment effectiveness.

**D.6.2 Sample size and power.** Sample size for this study will be based on a hierarchy of tests of outcomes, beginning with the treatment effect on patient/surrogate congruence (hypotheses 1b and 3b). Projected sample size per treatment group was based on both pilot data and previous research findings establishing a range of baseline congruence values (i.e., 35%-70% agreement)<sup>111, 112</sup>. We will assume the lower agreement figure of 35% in our calculations, and assume that this value is constant. Projected sample sizes to establish power at .90 ( $1 - \beta$ ), assuming a moderate treatment effect post-intervention, which is a 71% increase in agreement congruence (35% baseline value to increase to 60% value) provides a sampling of approximately 140 patients/surrogates pairs will be required in E and C groups per each site to maintain a .10 beta error level (power = .90).



Our pilot data on a small sample of combined disease group patients and surrogates indicated a 257% increase in immediate post-intervention agreement congruence. We feel that our anticipated moderate effect is conservative and reasonable. However, data regarding time effect in patient/surrogate congruence and consistency between surrogate’s decision and patient’s preferences and between actual care and patient’s preferences (hypotheses 1b, 2a and 2b) are not available since only proximal outcomes were measured in our pilot study. Therefore, it can be seen that a sampling of approximately 70 patients/surrogates will be required in E and C groups to maintain a .10 beta error level (power = .90). Smaller effect sizes were also modeled in the figure, for example, indicating that a sampling of approximately 200 patient/surrogates per treatment group would be required to assess a “small” treatment effect with the sample power ( $1 - b = .80$ ) (small effect would be a 43% increase in congruence, from 35% to 50%).

Based on our pilot studies of treatment effect in patient and surrogate Knowledge of ACP and Decisional Conflict post-intervention, small to moderate treatment effects were discovered. Sample size based on these pilot data indicate that a sampling of 280 patient/surrogates per treatment group will provide sufficient power to detect these outcome changes, except for stress scores for which no data were available. Therefore, we propose sampling 280 pairs of patient and surrogate per group (E and C). This will also provide 280 pairs of patient and surrogate per disease condition, with a total study sample of 560 pairs of patient and surrogate to provide sufficient power at the .90 level for these multiple tests. Recruitment of the 560 pairs of patient and surrogate over a 2 ½ year period would require recruiting approximately 9 – 10 patients per month per disease condition. The following diagram shows our sampling strategy for pairs of patients/surrogates.



Sampling will be based on a convenience sampling of accessible patients encountered per disease group at the two study sites during the study period. Once a patient has been recruited for the study per disease group per site, they will be randomly assigned to treatment condition using a stratified sequential randomization scheme. This scheme will be based on simple urn randomization per disease state per site and will continue until treatment arms n's are achieved (e.g., E = 280, C = 280). This approach will balance for site and disease state.

**D. 7 Timetable.**

During the start-up, IRB approval will be obtained at each site. Project directors will meet with appropriate personnel from each clinic at each site to discuss the study procedure, recruitment of patient/surrogate pairs, and the selection of staff from each clinic who will receive training in the PC-ACP intervention. Training curriculum and materials will be prepared. Project personnel will be trained in study protocols and data collection procedures. Other related study materials will be prepared.

Table 2. Timeline for the proposed study

Year	Year 1		Year 2		Year 3		Year 4		
Month	1	6	12	6	12	6	12	6	12
<b>Oversight committee</b>									
Review instruments/ Process	→								
Review data									→
<b><u>Treatment &amp; Follow-up</u></b>									
Patient accrual, consent and Intervention								→	
Data collection									→
<b>Data analysis, Write-up and Dissemination</b>									→

**E. Protection of Human Subjects.**

E. 1.a. Human subjects involvement

Inclusion criteria

Subjects for this study are **patients and their surrogates**. Patients will meet the following criteria before they will be considered eligible to participate in the study:

- Must be at high risk for impending death in the next 12 months by (a) being currently enrolled in the Heart Failure Clinic and/or have a New York Heart Association Classification of Class III or IV heart failure (See Appendix), OR (b) meeting the high risk criteria for end-stage renal failure (See Appendix). See Appendix for Criteria of Eligibility for the two medical conditions.

- Patients must have received and reviewed the routine materials regarding advance care planning and advance directives (usual care)
- Patients must have decision-making capacity, i.e., able to communicate, able to understand information, able to make choices and give rationale.
- Patients must have an individual who is willing to be a surrogate decision maker.
- Patients must be 50 years of age or greater and read, write, and speak English as their primary language.

Surrogates must be over 18 years of age and read, write, and speak English as their primary language.

The rationale for the criteria is that the patients selected are at high risk and, therefore, should be prioritized for an in-depth interview about preferences (the intervention) over and above that usually offered to all patients on admission. Ability to make decisions and have a surrogate are essential for the provision of the intervention; older age, illness and co-morbidities create a need for the intervention.

Patients must meet all inclusion criteria described in the section D.2.1. Patient's decision-making capacity will be assessed by clinical nurses at each clinic who identify potential participants based on the disease-related criteria. Patients who are considered as having a lack of decision-making capacity will not be included in the study. According to the Patient Self-Determination Act of 1991, patients and surrogates must be 18 years of age or older to legally document their wishes for future medical care and to be a decision-maker. This Act also addresses that completing such legal documents should not be forced by health care providers. Therefore, children under 18 years of age will not be included in the proposed study, and only those who meet the above criteria and their surrogates will be asked to participate

### **Target sample size**

We propose recruitment of 560 pairs of patients and surrogates over a 2 ½ year period; this would require recruiting approximately 9 – 10 patients per month per disease condition. We will include 140 pairs of patients and surrogates per group (E and C) in each site, or 280 pairs/site. This will provide 280 pairs of patients and surrogates per disease condition (CHF and ESRD) or 140 pairs per disease in each site, with a total study sample of 560 pairs of patients and surrogates.

#### **E.1.b. Sources of research material**

Subjects will complete self-report measures. Medical record data will be collected.

#### **E.1.c. Potential risks**

The proposed study may create potential risk of psychological burden to the patients who have never considered discussions of future end-of-life treatment options. However, our pilot data demonstrated that experimental patients' satisfaction with the quality of patient-clinician communication was significantly higher than that of the control group. In addition, patient's decisional conflict regarding preferences for future medical treatments in experimental group was significantly lower than that of control group. Therefore, it is expected that the risk of psychological burden caused by the interview would be minimal: rather, the PC-ACP intervention can satisfy patient's need of discussing and planning for future medical treatments that they would want if they become unable to make decisions for themselves.

We will be approaching surrogates at times of stress (patient's complication or one month after the death) find out their decisional conflict and the impact of the event. Sometimes family members find it helpful to discuss the issue but the difficulty of completing forms at that time will be done with sensitivity or not at all if the surrogate declines. We will repeat knowledge, congruence and decisional conflict measures at six months after entry to the study if death or a complication has not occurred.

### **E.2. Adequacy of protection against risks.**

#### **E.2.a. Recruitment**

Project staff will approach clinical staff in the CHF or ESRD clinic to assess the availability of eligible patients that day. Clinical staff then will approach these patients on the clinic visit to discuss the study, assess their willingness to participate in the study. If they are interested, a member of the project staff will explain the study further and obtain informed consent. During this contact, patients will be asked to select a surrogate decision-maker who may be willing to participate as well. If the surrogate is present, these individuals will be asked to participate with the patient at that same clinic visit if possible. If not, or if the surrogate could come for the next clinic visit, they would be requested to participate at that time. A phone call will be made a few days before their clinic appointment reminding them to bring their surrogate for the next visit. Project staff will

provide patients with informed consent forms (for the patient and surrogate), which includes the purpose of the study, the study procedure with randomization, potential risks and benefits.

#### **E.2.b. Procedures to minimize risk**

Risk of distress is minimized by providing the telephone number of the PI and the IRB on the consent form. See Data & Safety Monitoring described above. Risk of loss of confidentiality will be minimized by storing all data in locked drawers in locked file room that only research personnel have access to. Data will be reported as group data so that no individual could ever be identified.

In order to coordinate the study with ongoing medical care, physicians will be informed of any concerns that the interview may generate as well as the progress and outcomes of the study in general on an ongoing basis. If patients and/or their families have unanswered questions regarding their medical condition, potential complications, benefits/burdens of life-sustaining treatment choices, they will be referred back to their physician or appropriate health care provider to seek clarification and/or support. Interviewers will document the essence of the interview in the medical record for communication to all care providers and will directly initiate communication with the physician if issues are identified that require immediate attention, e.g. a patient requests a Do-Not-Resuscitate order. Any treatment decisions made by a patient will be documented in the medical record as evidence of their wishes in accordance with the standard practice for documenting advance directives by each organization.

The proposed study may create potential risk of psychological burden to the patients who have never considered discussions of future end-of-life treatment options. However, our pilot data demonstrated that patient's satisfaction with the quality of patient-clinician communication in the E group was significantly higher than that of control group. In addition, patient's decisional conflict regarding preferences for future medical treatments in experimental group was significantly lower than that of control group. Therefore, it is expected that the risk of psychological burden caused by the interview would be less than that of "usual care", rather, the PC-ACP intervention can satisfy patient's need of discussing and planning for future medical treatments that they would want should they not be able to make decisions at a later date. Surrogates in the E group should have less stress than those in "usual care" since they will be aware of the patient's preferences which has helped surrogates in the past. More frequently than not, patients choose to forego life-sustaining treatments when they have choices. In this study the E group of patients will be specifically questioned about this choice, their choice documented in their medical record and an assessment made if care is consistent with this choice. This activity should increase the patient's chances of getting care they prefer over those patients in the "usual care" groups.

Gundersen Lutheran Medical Center Investigators conducted the pilot study with IRB approval from their institution. The University of Wisconsin investigators received IRB approval to code, analyze, and summarize the pilot data. If this study is funded, these same two IRBs will be approached to review the study, instruments, and informed consents. Additionally St. Marys Medical Center IRB will be approached. It is highly probable that there will be slight variations in consent documents between the two sites because of IRB conditions.

#### **E.3. Potential benefits to the subjects and others.**

Although the assessment of ADs is federally mandated on admission to the hospital, the practice has become meaningless and ineffective. If our intervention is effective, the intent of the legislation may be fulfilled by applying a more in-depth assessment of patient preferences for those at high risk. To have care in accord with patients' wishes whenever possible is an important goal of Americans who fear dying attached to machines and unable to speak for themselves. A strong surrogate can give voice to patient preferences at a time like this. When surrogates make decisions to remove life support, it is one of life's most difficult decisions. We intend that the stress associated with that decision be minimized as much as possible, by knowing that the decision was made in accord with patient preferences.

#### **E.4. Importance of knowledge to the field**

The knowledge to be gained may change the way we assess patient preferences and may enhance care provided at the end of life. Institutions are laboring under the federal mandates, providing assessment of ADs to all rather than performing an in-depth assessment of patient preferences when warranted. Benefits could include reduced costs of end-of-life care since many patients may choose to forgo life-sustaining treatment if their functional ability is limited. Instead, since we ask in a hurried manner, with minimal patient-specific information provided, we may not obtain what the patient actually prefers.

#### **Women and minority Inclusion.**

The adequate representation of both genders and members of minority groups in our study is of great importance. Although the two settings of the study bring some diversity of patients, Caucasian will be a predominant race (see D.2.3) in the study. We will attempt to represent the gender and racial/ethnic distribution at each site. In order to include more members of minority groups, every potential subject in a minority group who meet the inclusion criteria will be invited to participate in the study, especially when there are more patients available than can be seen that day. In addition, efforts will be made to hire a minority intervener to aid in recruitment of minority subjects.

*Because the initial work was accomplished in the Gundersen-Lutheran and UW-Madison settings, we chose those two cities for our request for funding. La Crosse serves an area of rural Wisconsin, which would meet the definition of priority populations defined by AHRQ. Madison has been becoming more diverse over the last few years. A quick review of minority admissions at St. Marys Hospital yielded a change from 6% minorities in 2001 to 11% in 2003. Every attempt will be made to include all eligible minorities in both settings. Briefly the following strategies will be used: when more than one patient is available for inclusion in the study, minorities will be chosen and clinic staff will be asked to assist with the recruitment of minorities in their clinics. After funding is secured, it is possible to submit an administrative supplement to add a site in Milwaukee. Initial discussions have uncovered settings with clinics of primarily African-American or Hispanic and Hmong patients. Both Dr. Kirchhoff and Dr. Ward have colleagues in Milwaukee that are willing to assist.*

**F. Vertebrate animals—Not applicable**

**G. Literature cited**

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