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An Educational Intervention to Increase Advance Directive Completion

Kimberly Harlow

In Partial Fulfillment for the Doctor of Nursing Practice Degree

Regis University

March 25, 2016

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## **Executive Summary**

### **Problem**

When medical care is delivered in accordance with patients' wishes at the end of life it leads to greater patient empowerment, enhances patient comfort and dignity while relieving suffering, and decreasing hospital costs. Advance Directives (ADs) are one means of clearly documenting patient preferences for end-of-life care. Unfortunately, completion rates for advance directives remains low with an average completion rate of only 25%. The PICO question this study addresses is: In hospitalized patients on an inpatient Cardiology unit (P) does an educational plan for patients (I), in comparison to usual care which does not include education for patients (C), result in a change in the number of completed advance directives (O)?

### **Purpose**

The purpose of this project is to create an evidence-based educational intervention for patients about advance directives and to assess its effectiveness in increasing advance directive completion rates.

### **Goal**

The goal of this project is to increase the completion rates of advance directives and, ultimately, to increase patient involvement in their end-of-life medical care decisions.

### **Objectives**

The project objectives are to design an educational intervention for hospitalized patients to increase their understanding of advance directives, to implement this intervention on a small sample of patients, and to assess the effectiveness of this intervention in increasing the completion of advance directives.

### **Plan**

After identification of the problem following from a needs assessment and a review of evidence-based literature the following plan was designed: A small sample of cardiology inpatients was divided into a control group and a treatment group. The treatment group received education about advance directives utilizing a provider discussion and a written booklet. All patient charts were reviewed for the presence or absence of an advance directive at discharge. The data was then analyzed using a comparison of percentages.

### **Outcomes and Results**

The project objectives were met. An educational intervention was designed and administered to 29 subjects in the treatment group. Thirty-one subjects in the control group received usual care. The results showed a completion rate of advance directives of 69% in the treatment group and only 3% in the control group. This is a 66% increase in completion rates for those receiving the intervention. These results suggest that the educational intervention resulted in an increase in advance directive completion.

## **Acknowledgement**

With deep gratitude to the faculty at Regis University for your guidance and support. To Dr. Lora Claywell, my Capstone Chair, who helped to guide me throughout this process. To my clinical mentor, Dr. Lisa Marr, for your good humor, wisdom, and counseling during the course of this project. Finally, to my husband, John, for your unfailing encouragement and support. Without you, I'm not sure I would have made it through.

**Table of Contents**

I.	Preliminary Pages.....	i
	A. Copyright Page.....	ii
	B. Executive Summary.....	iii
	C. Acknowledgment.....	iv
	D. Table of Contents.....	v
	E. List of Tables.....	vii
	F. List of Figures.....	vii
	G. List of Appendices.....	vii
II.	Problem Recognition and Definition.....	1
	A. Project Purpose.....	1
	B. Problem Statement.....	2
	C. PICO Question.....	3
	D. Project Significance, Scope, and Rationale.....	4
	E. Theoretical Foundation.....	4
	F. Literature Selection, Systematic Process and Scope of the Evidence.....	5
III.	Review of the Evidence.....	6
	A. Background of the Problem.....	6
	B. Systematic Review of the Literature.....	6
IV.	Project Plan and Evaluation.....	9
	A. Market/Risk Analysis.....	9
	B. Strengths, Weaknesses, Opportunities, and Threats (SWOT).....	9

C.	Driving and Restraining Forces.....	11
D.	Need, Resources, and Sustainability.....	12
E.	Feasibility, Risks, Unintended Consequences.....	13
F.	Stakeholders and Project Team.....	14
G.	Cost-Benefit Analysis.....	15
H.	Mission, Vision, and Goals.....	16
I.	Outcomes Objectives.....	17
J.	Logic Model.....	18
K.	Population/Sampling Parameters.....	19
L.	Study Setting.....	20
M.	Study Design.....	20
N.	Protection of Human Subjects.....	21
O.	Instrumentation Reliability/Validity and Statistics.....	21
P.	Reliability.....	22
Q.	Validity.....	22
R.	Statistics.....	22
S.	Data Collection and Treatment Procedure.....	23
v.	Project Findings and Results.....	24
A.	Objective One.....	24
B.	Objective Two.....	25
C.	Objective Three.....	25



D. Discussion of Results.....28

VI. Limitations, Implications for Change, Recommendations.....29

    A. Limitations.....29

    B. Implications and Recommendations for Practice Change.....29

    C. Recommendations for Future Studies.....30

VII. Summary.....31

VIII. References.....32

**List of Tables**

I. Table one: Frequencies.....25

II. Table two: Percentages.....26

III. Table three: Chi Square Tests.....26

**List of Figures**

I. Figure One: Bar Chart.....28

**List of Appendices**

Appendix A: Logic Model.....37

Appendix B: SWOT Analysis.....39

Appendix C: Budget and Required Resources.....40

Appendix D: Timeframe.....41

Appendix E: Instruments Used in Educational Intervention.....42

Appendix F: IRB Approval Letters.....44

Appendix G: CITI Training Certificate.....47

Appendix H: Agency Letter of Support.....48



## An Educational Intervention to Increase Advance Directive Completion

### **Problem Recognition and Definition**

In our current medical system treatments that are provided to patients at the end of life are not always in accordance with patients' wishes. The Patient Self Determination Act (1991) stipulates that health care institutions must provide information to all patients about their right to make end-of-life care decisions (Emanuel, Weinberg, & Gonin, 1993). This directive is based on the foundational idea that when medical care respects patients' wishes it leads to greater patient empowerment and may enhance patient comfort and dignity while relieving suffering, decreasing hospital costs, and increasing referrals to hospice (Neumark, 1994).

Patients' wishes for end-of-life care are not always known. Sometimes this is because patients have not had a discussion regarding their wishes for end-of-life care and sometimes it is because these discussions have not been codified or well documented in the medical record (Bernacki & Block, 2014). Advance directives (ADs) are one means of clearly documenting patient preferences for end-of-life care. This author is employed in a large medical facility which has no standardized protocol for discussing ADs with patients or documenting ADs in the medical record. This institution has begun addressing this problem from many directions including creating a standardized AD form, creating a protocol for entering this document into the medical record, educating providers on how to use the document, and creating an educational plan for patients about ADs.

### **Project Purpose**

This project was developed to address the low completion rate of advance directives in the primary investigator's institution with the ultimate goal of encouraging patient involvement in their own end-of-life medical care. There is a large body of evidence indicating that educating

patients about advance directives increases patients' awareness of and completion of advance directives (Tamayo-Velazquez et al., 2009). The literature indicates that the type of educational intervention is crucial in how it impacts completion rates. Specifically, evidence shows that a discussion combined with a written or video explanation of advance directives is most effective (Durbin et al., 2010). The purpose of this project was to create an evidence-based educational intervention for patients about advance directives that combines a written explanation with a discussion and to assess its effectiveness in increasing advance directive completion rates.

### **Problem Statement**

This project grew out of the author's awareness that current clinical practice in end-of-life care is often deficient in that it frequently does not involve a consideration of patients' wishes. Currently, in the United States, it is common for patients to receive prolonged, aggressive medical care at the end of life (Levi & Green, 2010). This level of medical care may or may not be in alignment with patients' wishes. Advance directives developed as a response to this situation. An advance directive is a document that allows patients to express preferences for medical care and to prioritize treatment goals in advance of serious illness or end-of-life scenarios (Butler, Ratner, McCreedy, Shippee, & Kane, 2014). Despite the widespread availability of advance directives and the impetus for health care facilities to discuss advance directives with patients, most Americans do not have a completed advance directive. The average completion rate for advance directives in all populations in the United States is about 25% (Silveira, Witale, & Piette, 2014). The current rate of advance directive completion for patients on the cardiology service, in which this Capstone project was conducted, is only 16% (A. Jacobs, personal communication, August 4, 2014).

The idea for this project was born out of a concern that many patients in this author's institution were not being involved in their own end-of-life medical decisions and thus, may not be receiving medical care in line with their wishes. With an awareness that advance directive completion has the potential to increase patient involvement in these decisions this project was developed to promote the completion of advance directives in this institution.

### **PICO Question**

This project was an evidence-based practice (EBP) project in which an educational intervention was completed. The project was internal to the agency and was intended to inform the agency of issues regarding health care quality, cost, and patient satisfaction. The results of this project were not meant to generate new knowledge or be generalizable across settings but rather sought to address a specific population, at a specific time, in a specific agency.

Capstone projects utilize the acronym "PICO", rather than stating a formal research hypothesis. The acronym stands for: Population or Disease (P), Intervention or Issue of Interest (I), Comparison group or Current Practice (C), and Outcome (O) and is usually framed as a question (Melnik & Fineout-Overholt, 2011, p. 31). The question this study addresses is: In hospitalized patients on an inpatient cardiology unit (P) does an educational plan for patients (I), in comparison to usual care which does not include education for patients (C), result in a change in the number of completed advance directives (O)? When this statement is placed in the PICO format it reads:

P: Adult patients with decisional capacity on an inpatient cardiology unit.

I: An educational intervention which includes a written booklet and a discussion about advance directives that is presented to patients during their inpatient hospitalization.

C: Current practice which includes no standardized form of advance directive patient education.

O: Change in the number of patients with completed advance directives.

### **Project Significance, Scope, and Rationale**

This Capstone project was created to address the low rate of advance directive completion in a large urban hospital. The intervention was an education plan directed at patients. In order to assess the effectiveness of this intervention, this project was designed as a pilot project, conducted with a small, limited number of patients, on an inpatient cardiology service. The number of patients involved in this project was 29 in the intervention group and 31 in the control group. Data collection was completed over a timeframe of 60 days.

### **Theoretical Foundation**

The core intervention in this project was an educational plan for adult learners. Malcolm Knowles developed a theory of adult learning entitled Androgogy (Knowles, Holton, & Swanson, 2005) in which adult learning is detailed and differentiated from child learning. This theory identifies six principles of adult learning: need to know, self-concept, experience, readiness to learn, orientation to learning, and motivation. This theory framed the development of an educational intervention for adults in this project. Following the guidance of this model, the educational intervention to assist adult learners with ADs included a focus on why patients might need to know about ADs, incorporated patients' previous experience with end-of-life decision making, aligned completion of ADs with patients' goals, focused on why AD completion may be relevant to patients and families, provided practical assistance with AD completion, and recognized the importance of readiness to learn before engaging in instruction.

Sanford (2000) applied Jean Watson's Human Science model (Watson, 1988) to education theory and developed a unique model of education which incorporates a nursing caring focus. This model proposes that education is most effective when it is a part of a caring relationship between partners. As partners, learners are considered equal participants in the learning experience. Additionally, Sanford's model postulates that for any learning to be effective it must be deemed meaningful and relevant to both learner and teacher. This model had direct applicability to this Capstone project. This project focused on an educational intervention to increase completion of ADs. With recognition that, when discussing advance directives, patients and their families may feel anxiety, stress, sadness, and anticipatory grief, this investigator understood that education on ADs was more likely to be successful if it was grounded in an empathetic and caring relationship. Sanford's model was a useful guide in developing the educational intervention for this project by directing attention to the importance of caring relationships between the teacher of the material and the patient. Sanford's model also guided this project in drawing attention to the fact that it is not only necessary to have a caring relationship but also for the presenter of the AD education to be able to assess the relevancy of this material for the patient/learner.

### **Literature Selection, Systematic Process, and Scope of the Evidence**

There is a large body of evidence-based literature available regarding advance directives and educational interventions to increase advance directive completion. For this project a review of the literature was conducted using a comprehensive search of peer-reviewed studies from 2009 to the present. The literature review was conducted using the Cumulative Index to Nursing and Allied Health Literature, PubMed, Cochrane, and Google Scholar databases. The search terms included advance directives, patient education, end-of-life care, and terminal care. The

total number of studies reviewed was 150. Thirty of these were directly applicable to this project because they specifically addressed effective educational interventions and obstacles to completion of advance directives. Five of the studies included in this literature search were large meta analyses, four were randomized controlled trials, three were qualitative descriptive studies, eight were quasi-experimental studies, and nine were prospective cohort studies.

## **Review of the Evidence**

### **Background of the Problem**

Advance directives were developed in the United States in the 1960s and were first introduced into the legislative process in California in 1976. They were quickly adopted in all of the remaining states. The Patient Self-Determination Act, passed in 1991, requires that all health-care facilities receiving federal funds must offer patients the opportunity to complete an advance directive (Tamayo-Velazquez et al., 2009). For many healthcare facilities, compliance with this requirement may be as cursory as offering patients a brochure or handout about advance directives with no follow up or assistance with completion (Durbin, Fish, Bachman, & Smith, 2010). As a result, completion rates for advance directives remain low. There is a large body of evidence-based literature that examines the problem of low completion rates of advance directives. The literature falls into several distinct categories. These categories include the current rate of AD completion, reasons why ADs are not completed, and interventions that have been proposed to increase the rate of AD completion. The following paragraphs will examine each of these topics.

### **Systematic Review of the Literature**

A recent comprehensive survey of Americans (Rao, Lin, & Laux, 2013) found a 26.3% completion rate of ADs. Elderly Americans generally have a higher AD completion rate.



Hospitalized elderly persons have an AD completion rate of as high as 72% in some areas (Silveira, Witala, & Piette, 2104). Another article found that 64% of patients admitted to a cardiology critical care unit did not have completed ADs (Johnson et al., 2012). This study found that those more likely to have an AD were older, white, and had family present. Thirty percent did not have a good understanding of what ADs were.

VanScoy et al. looked at factors that impact the completion of ADs and found that there was no difference in race, gender, or health care utilization but there was a difference in age, religious affiliation, number of children, marital status, disease chronicity, having made end-of-life decisions for others, and who asked the patient about ADs (VanScoy, Howrylak, Nguyen, Chen, & Sherman, 2014). Waite found that literacy skills were strongly associated with AD completion. This study found that when subjects had a 5<sup>th</sup> grade or lower reading level the rate of AD completion was quite low. They speculated that this was due to lack of education about ADs or inability to read most AD forms (Waite et al., 2013). Mueller looked at readability of state-sponsored AD forms and found that none were at the 5<sup>th</sup> grade reading level or below (Mueller, Reid, & Mueller, 2010). Several studies looked at the relationship between race and AD completion. One found that Latino ethnicity was a significant negative predictor for having had a discussion about ADs (Fischer, Sauaia, Min, & Kutner, 2012). Another study looked at Native American completion rates of ADs and found that ADs were completed at the same rate as non-Native subjects when best-practice communication techniques were utilized by providers (Marr, Neale, Wolfe, & Kitzes, 2012).

Some of the literature looked at how to improve communication involved in discussions of advance directives. Other articles looked at specific interventions that have been created and tested to increase AD completion. This section will review both aspects.

Bernacki and Block (2014) in a systematic review of observational and interventional studies, found that best practices for end-of-life communication include sharing prognostic information, eliciting preferences, understanding fears and goals, and family involvement. A randomized controlled trial conducted by Rhondali, et al. (2014) found that discussions focused on autonomy were no more or less effective than discussions focused on beneficence. Fine (Fine et al., 2010) conducted a systemic review of physician-patient communication at end-of-life and found that physicians tend to focus on medical and technical aspects. They recommend greater attention to emotional issues. Perry and Seymore (2014), in a systematic review, identified eight categories of provider-patient communication and delineated the pros and cons of each but did not make recommendations.

Several articles looked at the timing and or the setting of AD discussions. Hinderer and Ching (2014) conducted a study which supports community based nurse-led interventions. Burge, et al (2013) in a qualitative analysis, found support for group settings for AD discussions. A study by Evangelista (Evangelista et al., 2012) found that consultation from specialist palliative care providers increased AD completion from 28% to 47%.

Much of the literature looks at specific types of interventions to increase completion of ADs. There are trials of video interventions (Toraya, 2013, & Volandes et al., 2009) which show increases in AD completion with video education. Other trials looked at using decision aids to assist patients with AD completion (Butler, Ratner, McCreedy, Shippee, & Kane, 2014, and Levi & Green, 2010). These trials found that decision aids can be helpful for patients making AD decisions. Two large systematic literature reviews looked at how various educational interventions help to increase AD completion (Durbin, Fish, Bachman, & Smith, 2010, and (Barrio-Cantalejo et al., 2010). Both of these large reviews found that there is strong evidence to

support the combination of a discussion with a provider with any other type of educational interventions. Both found that AD completion rates are only modestly increased with written or video education alone but when these educational interventions are combined with a discussion there is a significant increase in AD completion. As a result of this research review, this Capstone project included a discussion as well as a written brochure in the intervention.

## **Project Plan and Evaluation**

### **Market/Risk Analysis**

This Capstone project focused on patients in a large urban hospital in the southwest. It is the largest health care provider in the county and is the only level one trauma center in the state. It is also the safety net system for uninsured or underinsured patients in the county. As such, the hospital serves a diverse range of patients with complex medical conditions, many of whom are vulnerable and underserved. The project was conducted with a small subsection of this larger population.

The county served by this hospital is an unusual area in many respects. It is a mixture of extreme poverty and affluence. It is largely urban and yet contains significant rural areas and areas lacking in infrastructure. It has an unusual racial and ethnic mix with more Hispanics than non-Hispanic Whites and has a very large population of urban Native Americans (Bernalillo County Community Health Council [Bern Cty], 2010). There are substantial differences in overall mortality and morbidity between different socioeconomic groups. Death rates from almost all causes are highest in low socioeconomic groups and lowest in high socioeconomic groups

### **Strengths, Weakness, Opportunities, and Threats (SWOT)**

A SWOT analysis is a structured tool for evaluating the strengths, weaknesses, opportunities, and threats of a project (Zaccagnini & White, 2014). Strengths are those things that provide support to a project including resource availability and other advantages. This Capstone project had many strengths including strong support from the cardiology and palliative medicine services, a principle investigator with many years of experience in discussing advance directives with patients, a concurrent hospital-wide drive to increase completion of advance directives, a project team already in place focusing on advance directives, open access to patients on the cardiology service, and a health literacy office available to assist with development and printing of educational materials.

Weaknesses are those internal aspects of a project that could be improved, that are resource-poor, or that might otherwise negatively impact the project (Zaccagnini & White, 2014). For this Capstone project weaknesses included a limited time-frame for data collection, the principle investigator's time restraints, and patient availability (while access to patients was open patients were not always available due to diagnostic procedures and other activities).

Opportunities and Threats are those things external to the project that might be involved in successful project completion (Zaccagnini & White, 2014). One opportunity of this project was provided by the American Heart Association which has created a national program of guidelines for treating congestive heart failure. This program is called Get with the Guidelines and offers benefits to hospitals that comply. One of the recommended guidelines is that all patients admitted to a hospital with congestive heart failure be given the opportunity to discuss and complete advance directives (Yancy, 2015). This project directly benefited the hospital in addressing compliance with this guideline. Other opportunities in this project included increasing providers' knowledge of and comfort with discussing advance directives with

patients. In the future, the project may be implemented hospital-wide and may provide direction and guidance to all medical providers in having these conversations. The project may also ultimately allow more patients to be involved in their own end-of-life care plans thus creating more alignment between patients' wishes and the care received.

Threats to this project's success could have included resistance from the cardiology staff to implementation of a new process for addressing advance directives. It was imperative to have the cooperation of the nursing, medical, and administrative staff on the cardiology unit in order to properly carry out this project. Another potential threat to this project could have come from the fact that many people are involved in various aspects of increasing advance directive completion and documentation in the hospital. There was a risk of duplication of effort among these people. To address this threat, it was necessary to carefully coordinate activities among the various interested parties. See appendix B for a SWOT analysis table.

### **Driving and Restraining Forces**

The most significant driving force impacting this project was the new emphasis the American Heart Association is putting on completion of advance directives in heart failure patients nationwide. The Get with the Guidelines program (2015) encourages hospitals to have documentation of advance directives for every congestive heart failure patient admitted as an inpatient or seen in clinic (Yancy, 2015). Because of this there is a strong push in the principle investigator's hospital to comply with this guideline. Many hospital resources are being devoted to achieving this goal. This project was one, among several, currently being undertaken by the hospital to improve advance directive completion and documentation (D. Dodendorf, personal communication, May 21, 2015).

Potential restraining forces also existed to counter the forward progress of this project. These involved the potential resistance from staff to new procedures and policies to address completion of advance directives. The known procedures were haphazard and inconsistent but they were familiar and well understood by the staff charged with carrying them out. It could have been difficult to overcome this resistance and educate staff about new ways to present advance directives to patients. This potential restraining force was overcome by careful education and coordination with the cardiology staff.

### **Need, Resources, and Sustainability**

According to Zaccagnini and White (2014) a needs assessment identifies the gap between a current condition and an ideal condition and involves consideration of changes in regulations and clinical requirements. This Capstone project focused on a clearly unmet need to increase the number of completed advance directives. This need has been identified at the national level by many authors who note that completion of advance directives contributes to improved patient outcomes and that current completion rates are very low (Barrio-Cantelejo et al, 2010, Butler, et al 2014, & Fisher, et al, 2012). According to the Institute of Medicine's 2014 report "Dying in America: Improving Quality and Honoring Individual Preferences Near the End of Life" (Institute of medicine [IOM], 2014), public education about advance care planning is a growing national priority and all health care organizations should provide materials about end of life care to patients and families. This need has also been identified by local healthcare facilities as they work toward compliance with the American Heart Association's Get with the Guidelines directives. Additionally, evidence indicates that a higher completion rate of advance directives correlates with a decrease in medical costs at the end of life (Durbin, Fish, Bachman, & Smith, 2010).

The material resources for this project were small and cost effective. Implementation required patient educational materials in the form of a patient education booklet. Printing costs of this booklet were covered by the hospital's office of health literacy. This office also reviewed the booklet for readability and assisted in formatting. This project also utilized a discussion guide which was in the form of a laminated card used during the patient education session. The costs for printing and laminating this card were also covered by the health literacy office. All patients received an advance directive document. This document was already available and paid for by the hospital and did not accrue any extra costs to this project. Data was recorded on a laptop computer and an iPad, both of which were already owned by the principle investigator. Human resources included the principle investigator's time in project implementation, data collection and data analysis. Additionally, human resources were provided by the health literacy office, and the office of quality improvement. As noted here, all costs for this pilot project were covered by the institution or by the primary investigator. If this project were to be conducted without such financial support an estimation of these costs is as follows: lead educator costs (\$2500), printing costs (\$280), technical equipment (\$1650), statistician costs (\$200). See appendix C for a breakdown of these cost estimates.

This project was developed in direct response to a need in this hospital for significant improvement in completion rates of advance directives. Everyone involved in the project was invested in the creation of real and sustainable change. While this project was a pilot project which was limited in duration and number of participants it has the potential to lead to widespread practice change throughout the hospital. Project sustainability will then depend on dissemination of results and education of hospital providers. Dissemination of results may occur through town halls, peer-reviewed journals and professional websites. Provider education will

be essential in order to equip providers with the knowledge and ability to continue the patient education intervention. This may be accomplished by presentations to resident and attending physicians, nursing staff, and social service staff. The cost to educate providers in continuing this patient education project would be approximately \$50/hour and would be provided by a dedicated staff educator or by the primary investigator (D. Dodendorf, personal communication, March 20, 2016).

### **Feasibility, Risks, Unintended Consequences**

This study was small and limited in the number of study participants and timeframe. Because of the limited size and time allotment the study was feasible to implement. The study held minimal risks to study participants. Like all studies, there was a small but conceivable confidentiality risk. All necessary measures were taken to prevent any breach of confidentiality. There was also the possibility that discussions about end-of-life care would provoke a mild degree of emotional distress in some study participants. However, no study participants voiced this concern. In fact, most mentioned that they were grateful for the opportunity to discuss advance directives. There were no known unintended consequences for study participants or for the organization.

### **Stakeholders and Project Team**

Zaccagnini and White (2014) define stakeholders as those people who are affected by the project. Stakeholders included people internal to and external to the hospital itself. For this Capstone project internal stakeholders included the Medical Director of the cardiology service, the Chief Quality Officer, the nurse educator and unit director of the cardiology unit, the project team, patients on the cardiology service, and the Chief Quality Resident. External stakeholders included the American Heart Association which developed the Get with the Guidelines



directives, insurers interested in the possible cost savings that result from advance directive completion, and people in the community who may benefit by completion of advance directives among themselves and their families.

The project team included Kim Harlow, the principle investigator who was responsible for project development, design of educational materials, data collection, and data analysis. Dr. Lora Claywell, Capstone Chair, who was responsible for overall project guidance and direction. Dr. Lisa Marr, clinical mentor, who assisted in navigating administrative hurdles and well as integrating this project into the hospital's overall mission to increase advance directives. Diane Dodendorf, Chief Quality Officer, who assisted in coordinating and integrating this project with other work on advance directive completion.

### **Cost-Benefit Analysis**

A cost-benefit analysis allows a project director to make a comparative assessment of all of the benefits anticipated from a project and all of the costs that will be incurred to perform the project and to sustain the changes that result from it (Brent, 2014). Zaccagnini and White (2014) recommend that costs and benefits be quantifiable if at all possible, however, they recognize that some benefits that accrue from a project may be relatively difficult to measure and quantify. In order to conduct a cost-benefit analysis the costs of the project must be tabulated, the benefits must be identified and quantified, if possible, and then the costs must be weighed against the benefits in order to determine if the benefits are worth the costs (Zaccagnini & White, 2014).

The total costs necessary to implement this project included material costs, investigator time, data management technology costs, staff costs, and statistician costs. For this project materials were provided by the hospital at no cost to the investigator. These materials included patient education booklets, discussion guide laminated cards, and advance directive documents.

Investigator time was provided by the principle investigator and was given at no cost. Data management technology was provided by the principle investigator's personal laptop and iPad and was provided at no cost. See appendix C for an estimate of the actual total costs of this project. If this intervention is sustained beyond this pilot project, then costs will be accrued by the hospital to train staff to carry on the intervention. In that event, the cost for implementing and carrying on the educational intervention will include material costs for the educational booklet and laminated discussion guides. Advance directive documents are already provided by the hospital and would not be an additional cost. Further implementation would require training providers in advance directive education or hiring a dedicated patient educator. The cost of staff training is estimated to be approximately \$50/hour and the materials costs are estimated to be approximately \$3 per patient (\$150 per bundle of 50 booklets and discussion guides).

Potential benefits from the project are significant. Two authors in the American Journal of Public Health point out that end-of-life care consumes approximately 30 percent of Medicare expenditures. They believe that increasing the completion rate of advance directives would lower these costs and do so while respecting patients' values and wishes (Morhaim & Pollack, 2013). A study by Halpern and Emanuel (2012) found that advance directives were associated with a significant reduction in end-of-life spending. On average, end-of-life spending decreased \$5585 per person when an advance directive was completed. If this association of cost reduction with advance directives holds true at this institution the financial benefit would be significant if widespread implementation of this project results in an increase in advance directive completion rates. Clearly the benefits that can potentially accrue from this project strongly outweigh the costs making this project highly desirable from a cost-benefit perspective.

### **Mission, Vision, and Goals**

The mission of this Capstone project was to increase the completion rates of advance directives in a large urban hospital and thereby improve end-of-life care, increase patient autonomy, and decrease the cost burden to the hospital of unwanted end-of-life medical interventions. The vision that guided this project was that, with increased patient involvement in end-of-life care, as measured by advance directive completion rates, patients and their families will experience greater satisfaction and less harm at this vulnerable time of life. Because the population addressed in this project only included patients admitted with a diagnosis of heart failure, the future vision is that this population will be expanded to include all patients admitted to the hospital. The method employed to accomplish this mission was education for patients about advance directives with the underlying assumption that the more knowledge patients have about advance directives the more likely they will be to complete one. The primary goal of this project was to increase advance directive completion rates through an educational intervention for patients. A secondary goal was to support hospital compliance with the American Heart Association's "Get with the Guidelines" program which requires documentation of advance directives.

### **Outcomes Objectives**

In order to reach these goals this project needed to meet several objectives. These objectives were 1) to design an educational intervention for hospitalized patients to increase their understanding of advance directives; 2) to implement this intervention on a small sample of patients; and 3) to assess the effectiveness of this intervention in increasing the completion of advance directives.

The primary outcome for this Capstone project was an increase in completion of Advance Directives by the study population. There are currently no national benchmarks for AD

completion rates. As described above, several investigations have revealed that current rates for AD completion in the United States range widely from 10% to 70% depending on the population in question. The Capstone population was drawn from cardiology inpatients. Previous hospital data on patients on the cardiology service indicate that there is, on average, a 16% rate of completion of ADs as measured by AD documentation in patients' electronic health records (A. Jacobs, personal communication, August 4, 2014). This project aimed to reach a target of 32% completion of ADs among the study population which would be an improvement of 100% but still well within the average range of AD completion among the U.S. population.

The study compared the number of completed ADs in the study group to the number of completed ADs in the control group. For the purposes of this study a completed AD was defined as an advance directive document which has been completed and signed by a patient and has then been scanned into their electronic health record (EHR). A code status note or a surrogate decision-maker note was not defined as a completed AD. A patient or family report of a completed AD also did not meet the study criteria. Measurement of this outcome was done by review of each participating patient's electronic medical record. If a completed AD was scanned into their record by the time of their discharge it was counted as having met the criteria for AD completion.

### **Logic Model**

This evidence-based educational project was based on a conceptual model which delineated all available support for the project, the constraints which include the limitations on the project, and the activities that were undertaken. This model also depicted the project outcomes. These were divided into the immediate outcomes of the project activities and the overall expected outcomes, both short and long-term. The conceptual model, when presented in

graphic form, indicates the order in which the project proceeded - starting with supports and constraints and leading to activities and outcomes. This model can also be depicted in a table as a logic model. See appendix A for both models.

### **Population/Sampling Parameters**

This study used a convenience sample drawn from the inpatient population of a cardiology service in a large urban hospital. This population was chosen because there was very strong support from the cardiology service in this institution for developing a method to increase completed ADs. The cardiology service was willing to partner with the primary investigator in supporting this study.

The population for this study was drawn from patients admitted to the hospital with the diagnosis of congestive heart failure. Eligible patients were identified by coordination with the director of the cardiology service. The cardiology director reviewed all admissions that had an associated diagnosis of congestive heart failure and, when those patients met the criteria for active heart failure, he activated the “heart failure plan”. He sent a daily list of patients with an activated heart failure plan to the primary investigator via secure email. For the purposes of this study, any patient who was admitted with an activated heart failure plan was eligible for consideration for study inclusion. From this group of potential subjects, the following categories of patients were excluded: 1) patients who already had an AD scanned into their chart; 2) patients who had a diagnosis of delirium or dementia or who lacked decisional capacity (as identified by chart review); and 3) patients who did not have the functional capacity to participate in the study. Functional capacity was determined by the Director of the cardiology service. He reviewed each subject’s New York Heart Association’s score (which is an indicator of functional capacity) and determined if each subject had or did not have the physical capacity

to participate in an hour-long teaching session. Patients who were assigned to the intervention group were given an opportunity to accept or decline participation in the study.

### **Study Setting**

This study was completed in a large urban hospital in which this author is employed. This hospital is a publicly supported, multi-hospital system that serves as the “safety net” hospital for county residents and is the only level one trauma center in the state. It is also a teaching hospital affiliated with schools of medicine, nursing, and pharmacy. This hospital serves a diverse range of patients with complex medical conditions, many of whom are vulnerable and underserved.

See appendix H for the agency letter of support.

### **Study Design**

This was an experimental study using a randomized, controlled design. Those patients who were eligible for the study were divided into two groups using small block randomization to create an intervention group and a control group of approximately equal size (Sealed Envelope Ltd., 2015). The intervention group received an educational intervention and the control group received usual care which did not include education about ADs. The intervention was composed of two parts: a written booklet and a verbal discussion. The booklet was developed by the primary investigator prior to the study and was finalized by the Health Literacy office to insure readability at a fifth grade reading-level. The Health Literacy office also validated the booklet for readability and comprehension using a pre-existing protocol. The purpose of the booklet was to educate patients about the purpose and contents of an advance directive.

In addition to the booklet, the intervention included a discussion about advance directives. This discussion followed a discussion guide which was developed by the investigator prior to the study. The discussion guide was validated by inpatient palliative medicine providers

who are experts in this content area. After validation, the discussion guide was printed onto a laminated card and was used to direct the flow of the discussion. The purpose of the discussion guide was to serve as a general reminder of the points to be covered. See appendix E for the booklet and discussion guide.

All patients who met the inclusion criteria over a consecutive six-week period were reviewed for participation in this study. The rationale for choosing a six-week period was to increase the sample size to approximately 30 participants in each group. See appendix D for the Capstone project timeframe.

### **Protection of Human Subjects**

This project was approved by the Institutional Review Boards for both Regis University and the hospital in which this project took place. The study participants were not drawn from a vulnerable group. All subjects were adults with decisional capacity and did not include the very young, very old, institutionalized or mentally ill. Additionally, all participants were required to give informed consent before they were included in the study. There was the possibility that discussions about end-of-life care could have provoked a mild degree of emotional distress in some study participants. For this reason, there was a statement in the consent form that states that participation may cause emotional distress due to the content of the subject.

The data was recorded anonymously with no identifiers attached. Each subject was identified by code only. The data base was developed by the investigator and was stored on a password-protected computer. See appendix F for IRB approval letters and appendix G for CITI training certificate.

### **Instrumentation Reliability/Validity and Statistics**

Data collection for this study was done by chart review and did not require a validated instrument. However, there are some threats to reliability and validity in the study design.

### **Reliability.**

Reliability in data collection involves “determining if the instrument is consistent and will give the same results if the research is replicated” (Terry, 2015, p. 159). This study design may have a threat to reliability in that the intervention was a conversation conducted by the primary investigator. The impact this conversation had on the outcome could have been influenced by the conversational and interpersonal skill of the investigator. The study results might not be replicable if future investigators have a different skill level in conducting difficult conversations. For this reason, the study was designed to use a discussion guide to help standardize the discussion and mitigate against variations in investigator skill level.

### **Validity.**

Validity is measured internally and externally. External validity pertains to the generalizability of the study results (Terry, 2015). In this study the population was selected from hospitalized patients with congestive heart failure. These patients may be unique in their both illness and severity of illness compared to the general population. For this reason, external validity may be a study limitation.

Internal validity considers whether an observed outcome was caused by the intervention or by extraneous factors (Polit, 2010, p. 402). In this study there are several extraneous factors that might impact the outcome. These include illness type, severity, experience with advance directives, and readiness to learn. The study was designed to limit the impact of extraneous variables by creating a control group with the same extraneous factors as the study group.

### **Statistics.**



Assessment of the outcome was done by a simple computation based on completed ADs in the medical record. To statistically analyze this data a comparison of percentages between each group was calculated. Additionally, a chi Square test of independence was run to analyze this data (Polit, 2010).

### **Data Collection and Treatment Procedure**

All eligible subjects were divided into two groups; an intervention group and a control group. The subjects were randomly assigned into one of these two groups using small block randomization. Small block randomization was accomplished by use of an online tool called Sealed Envelope (Sealed Envelope Ltd., 2015) which allowed the investigator to create two randomly assigned groups of approximately equal size. Those subjects assigned to the intervention group were given a consent form and an explanation about the study and its purpose. All subjects in this group were given the opportunity to refuse participation but no subjects chose to do so. A waiver of informed consent was requested and granted by both Institutional Review Boards for those subjects in the control group.

For this Capstone study the primary investigator was responsible for delivering the intervention to all of the subjects in the intervention group. All subjects in the intervention group signed the consent form prior to participation in the study. The booklet and the discussion were offered to patients at the same time. Approximately one hour was scheduled for each patient in the intervention group. This time allotment was chosen in order to allow ample opportunities for subjects to review the written material, engage in the discussion, and ask questions. The primary investigator was available for follow-up visits during each patient's hospital stay if requested by the patient.

The outcome measure for the Capstone project was the number of completed ADs scanned into the subjects' charts at the time of discharge. The primary investigator reviewed all charts of the intervention and control groups at discharge and recorded the presence or absence of a scanned AD.

The data was recorded anonymously with no identifiers attached. The data base was developed by the investigator and was stored on a password-protected computer. All data was entered into an excel spreadsheet. All subjects were coded as to whether they were in the control or intervention group and as to whether they had an advance directive on discharge or did not. Each subject was given a numerical identifier (1-60). The code for treatment group vs control group was 1=treatment; 2=control. The code for presence or absence of an advance directive was 1=no advance directive; 2=presence of advance directive. After the study was completed the data was analyzed to statistically compare the two groups in terms of number of completed ADs.

### **Project Findings and Results**

This Capstone project had three primary objectives. The first two objectives were to design an educational intervention for hospitalized patients to increase understanding of advance directives and to implement this intervention on a small sample of patients. The third objective was to assess the effectiveness of this intervention in increasing the completion of advance directives. This section will address how each of these objectives was met but will focus on the third objective: the evaluation of the effectiveness of the intervention.

#### **Objective One: Design an Educational Intervention**

The educational intervention for this project was designed by the principle investigator prior to initiation of the project. It included an educational booklet and a discussion guide. The

development of both the booklet and the guide were based on evidence-based practices as indicated by the literature. As discussed above, the literature strongly supports the combination of a verbal and written educational format for advance directives (Durbin et al., 2010). The booklet and guide were validated for readability and content prior to initiation of the project.

### **Objective Two: Implement the Intervention**

Sixty subjects were included in this study. The educational intervention was delivered to 29 subjects within a six-week time period. There were 31 subjects in the control group who did not receive the educational intervention. The study ran between November 15, 2015 and December 31, 2015. None of the subjects in the intervention sample refused participation. Additionally, none of the subjects reported distress over the material or required follow-up discussion to address questions. The educational intervention required about 30 minutes, on average, to deliver.

### **Objective Three: Assess the Effectiveness of the Intervention on Increasing AD Completion**

To assess the effectiveness of the intervention on AD completion it was necessary to compare the number of completed ADs between the intervention group and the control group. In order to do this the frequencies (counts) of patients in each category were tabulated and compared. The results showed that, of the 29 patients in the intervention group, 20 had a completed AD at the time of discharge. Of the 31 patients in the control group only one had a completed advance directive at the time of discharge. Table one presents these data.

**Table 1: Frequencies**

	<b>AD Present</b>	<b>AD Absent</b>	<b>Total</b>
<b>Treatment</b>	20	9	29

<b>Control</b>	1	30	31
<b>Total</b>	21	39	60

This data can be converted into percentages which allows for a direct comparison of percentages in each group. Table two presents the data in percentages.

**Table 2: Percentages**

	<b>AD Present</b>	<b>AD Absent</b>	<b>Total</b>
<b>Treatment</b>	68.9%	31.1%	48.3%
<b>Control</b>	3.2%	96.8%	51.7%
<b>Total</b>	35%	65%	100%

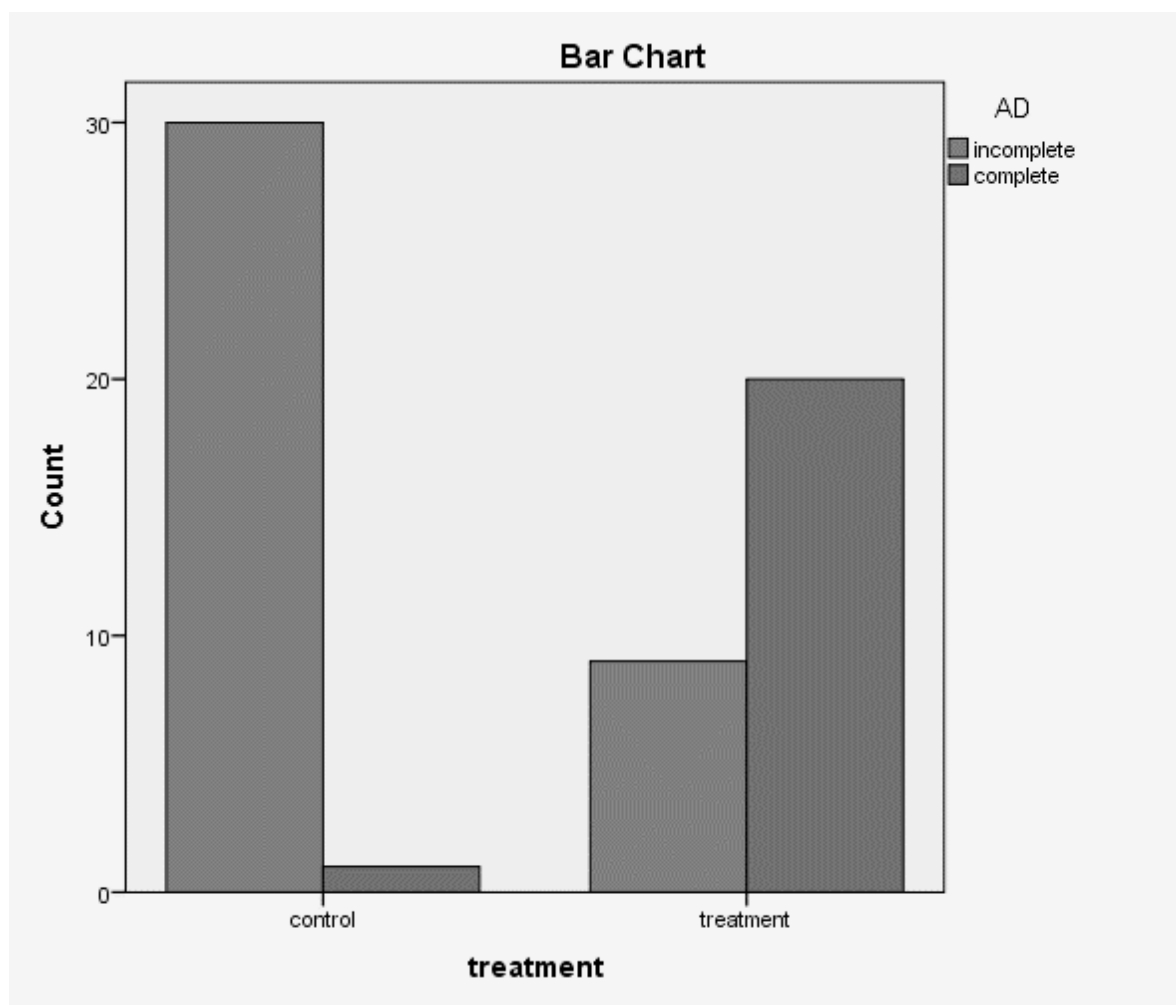
To summarize these results, approximately 69% of the treatment group had an advance directive on discharge while only 31% did not. The control group had an approximately 3% completion rate of advance directives compared to 97% that did not have completed advance directives. In the entire sample there was a completion rate of advance directives of 35%.

Because this data is nominal there can be no calculation of means, ranges, or standard deviations and it does not allow for higher level inferential analysis. Additionally, using this data for aggregate analysis does not provide useful information because no previous aggregate data was collected to use as a basis of comparison. However, this data can be analyzed by using a chi square test of independence. Table 3 presents these results from a chi square analysis.

**Table 3: Chi-Square Tests**

	Value	df	Asymptotic Significance (2- sided)	Exact Sig. (2- sided)	Exact Sig. (1- sided)
Pearson Chi-Square	28.463 <sup>a</sup>	1	.000		
Continuity Correction <sup>b</sup>	25.647	1	.000		
Likelihood Ratio	32.934	1	.000		
Fisher's Exact Test				.000	.000
Linear-by-Linear Association	27.989	1	.000		
N of Valid Cases	60				

This analysis has a large Pearson chi square value (28.463) and an asymptotic significance of .000. This shows a statistically significant correlation between the intervention and the number of completed advance directives with a p value of <.001. Figure one shows a bar chart depiction of these data.



**Figure 1: Bar Chart**

### **Discussion of Results**

The data analysis indicates that there is a significant association between the patient education intervention and the completion of advance directives. Patients who received the educational intervention were more likely (by 66%) to have completed an advance directive

than those who did not receive the intervention. The original question posed for this Capstone project is: In hospitalized patients on an inpatient cardiology unit does an educational plan for patients, in comparison to usual care which does not include education for patients, result in a change in the number of completed advance directives. The data suggest that the answer to this question is that the educational intervention does result in a change in completed advance directives in this population.

### **Limitations, Implications for Change, Recommendations,**

#### **Limitations**

As addressed above, there are weaknesses in this study in terms of reliability and validity. The study was conducted with only one investigator which may impact study replicability. It is not clear if the same results would be obtained if the intervention was delivered by other investigators. The study was conducted with a small and unique sample of patients. It is not clear that the same results would be obtained from a more diverse sample and if these study results are representative of the general population.

Because this study was designed to capture only categorical data it was limited in the number of statistical tests that could be run. While the study data show a robust result, according to Treiman (2014), categorical data that rely on the comparison of percentages will give only a limited understanding of a subject because it does not allow for comparison of means, ranges, or standard deviations. He recommends further data collection, using interval or ratio level data, to allow for a deeper and more informative analysis.

#### **Implications and Recommendations for Practice Change**

This Capstone study lends strong support for educating patients about advance directives by a combination of written and verbal formats. The study results indicate that when this is done

the number of completed advance directives increases significantly. The literature indicates that when patients have advance directives in place many outcomes improve including patient and family satisfaction, decreased costs of medical care, and care that is delivered at the end of life being more closely aligned with patients' wishes. In order to support these outcomes, interventions that have been shown to increase advance directive completion should be considered as part of routine patient care. Therefore, a strong recommendation for practice change supported by this study is to include a written booklet and a discussion with a provider about advance directives for all patients admitted to the hospital. If the results of this study can be generalized to the overall hospital population this intervention would result in a significant increase in completed advance directives which would then result in overall improved outcomes of medical care at the end of life. These results also have implications for outpatient providers as well as for communities, in general. Further studies should be done to evaluate this type of educational intervention for ambulatory patients as well as for healthy community members. If studies show similar results in these populations, then this type of education should be considered on a larger scale. Advance practice nurses are well positioned to initiate this type of change in their local health care facilities, as well as through community health initiatives and through health policy change.

### **Recommendations for Future Studies**

While the data collected and analyzed for this Capstone project indicate that patient education will result in an increase in the completion of advance directives, the study limitations mentioned above should be addressed in future studies. Because the comparison of percentages does not allow for robust conclusions regarding the mean, range, and standard deviation one recommendation is to conduct more robust study to measure outcomes on a continuous scale.



For example, a study could examine patient knowledge about advance directives prior to and after an educational intervention. Another methodological weakness mentioned above is the small sample in a unique population (cardiology inpatients). A recommendation is that future studies be designed with larger samples and different groups to allow for more robust conclusions about the population.

### **Summary**

There is a great deal of evidence that supports the fact that advance directives help to improve medical outcomes for patients at the end of life and also help to prevent unnecessary and unwanted medical expenditures. Many studies have looked at interventions to increase the completion of advance directives in the population. The literature supports education of patients as one means to increase advance directive completion and supports using a combination of discussion and written material in order to do this most effectively. This Capstone study was created to test the effectiveness of using a combination of discussion and written material on completion of advance directives in a small sample of patients. The study results strongly support the use of this intervention in to increase the completion of advance directives. While it was beyond the scope of this study to assess the effect of this intervention on patient satisfaction or decreased medical expenses, future studies may look at the effect of this intervention on these outcomes and may show that this intervention is one step that leads to improved patient outcomes and better management of healthcare resources.

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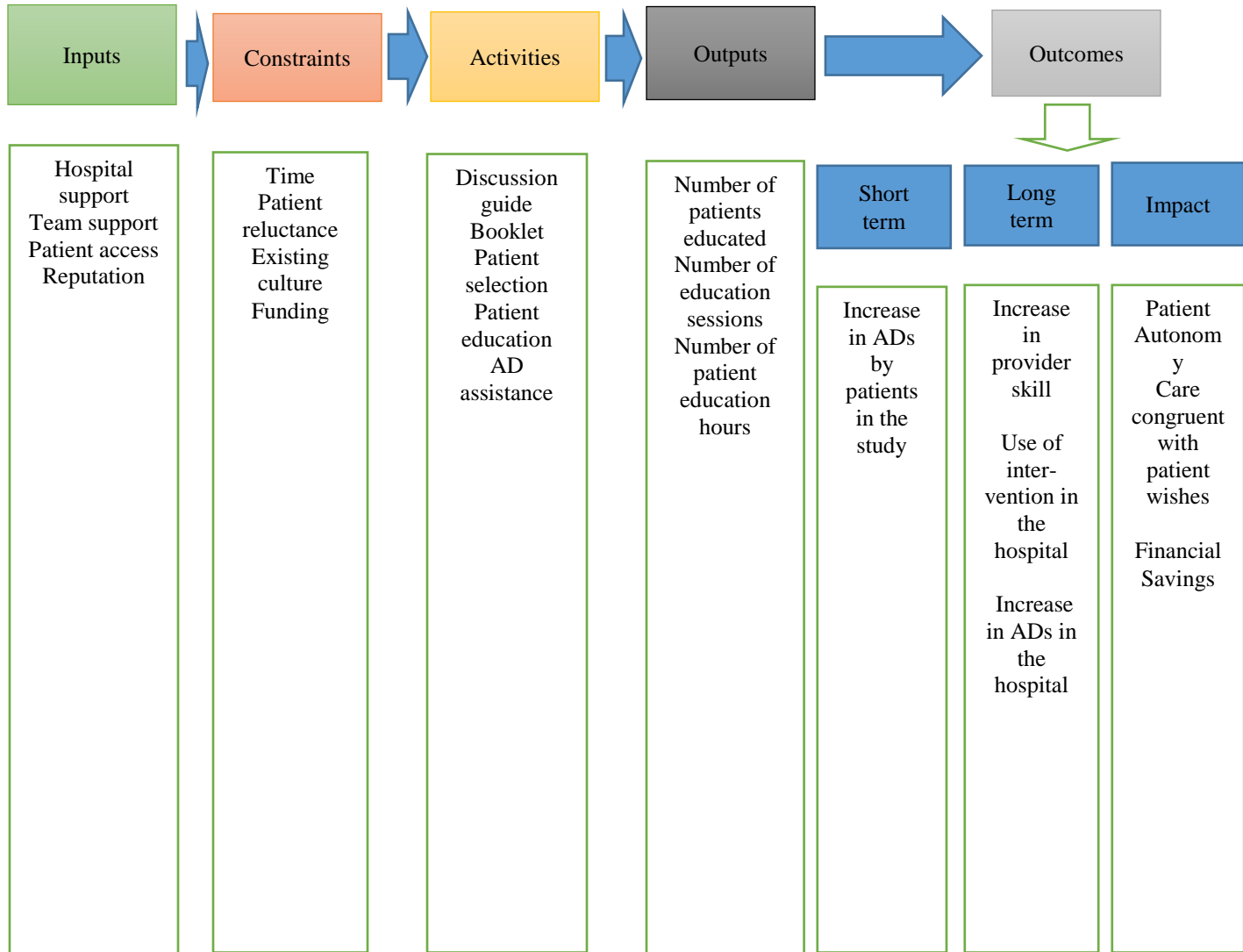
## Appendix A

### Logic Model

Inputs	Constraints	Activities	Outputs	Outcomes/Impacts
Support from the inpatient Cardiology service and the Palliative Care team	Time limitations of the principle investigator	Create discussion guide which will standardize AD presentation	Number of patients educated/counseled	Short term: Increased completion of ADs by patients in study
Hospital drive to increase completion of Advance Directives (ADs)	Reluctance on part of patients and families to engage in discussion of ADs	Create educational booklet	Number of educational sessions	Long term: Hospital-wide use of discussion guide and booklet in patient education
Team in place to work on completion of ADs	Existing culture in Cardiology unit/staff which may resist innovation	Patient recruitment/selection focusing on Cardiology inpatients with decisional capacity	Number of hours spent in patient education	Long term: Increased number of completed ADs in hospital-wide population
Open access to patients on the Cardiology service	Limited financing for large scale printing of materials	Education/counseling of selected patients using discussion guide and booklet		Long term: Increased provider knowledge about how to have AD conversations
Established reputation in the hospital regarding delivery of palliative care		Provide AD document and assist in completion if patients request this		Impact: Increased ADs lead to greater patient autonomy
Time available to meet and counsel patients				Impact: End of life care more congruent with patient wishes
Funding for printing of				Impact: Financial savings

educational materials				due to less aggressive end of life care
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**Conceptual Model**





## Appendix B

### SWOT Analysis

<p style="text-align: center;"><b>Strengths</b></p> <p>Support – Cardiology, Palliative Medicine, Hospital</p> <p>Experience – primary investigator</p> <p>Project Team in place</p>	<p style="text-align: center;"><b>Weaknesses</b></p> <p>Limited time – primary investigator</p> <p>Limited patient availability</p> <p>End-of-life subject matter may be distressing</p>
<p style="text-align: center;"><b>Opportunities</b></p> <p>Increase compliance with AHA guidelines</p> <p>Increase provider knowledge</p> <p>Increase patient autonomy</p>	<p style="text-align: center;"><b>Threats</b></p> <p>Cardiology staff resistance</p> <p>Duplication of efforts throughout hospital</p>

## Appendix C

### Budget and Required Resources

<b>Capstone Required Resources</b>	<b>Justification</b>	<b>Costs of Pilot Project</b>	<b>Actual Costs if not supported by hospital</b>
DNP Investigator	Project lead, patient educator, data collector	Time volunteered - \$0	\$51 x 50 hours = \$2550
Educational Materials	Booklet Laminated discussion guide AD document	Formatting and printing provided by health literacy office at no cost - \$0	40 booklets (from printing shop) = 117.50 Laminated discussion guide (from printing shop), 25 = \$19.66 AD documents (from printing shop) 240 = \$163.58
Technical equipment	iPad for data collection Personal computer for data storage and analysis	Provided by principle investigator at no cost - \$0	iPad (from Apple store) = \$629.00 data package for iPad (from Verizon) = \$21.99 MacBook Air laptop computer (from Best Buy) = \$999.99
Statistician	Data analysis	no cost - \$0	Freelance online statistician assistance = range between \$20/hr - \$55/hr. Estimated need is 5 hours (at \$40/hr) = approximately \$200 total
<b>Total Cost</b>		<b>\$0</b>	<b>\$7,552.46</b>

## Appendix D

### Timeframe

<b>Activity</b>	<b>Time</b>
Complete Consent Form	June 12, 2015
UNM HSC IRB application submitted	June 22, 2015
Capstone proposal completed	June 29, 2015
Capstone presentation	July 10, 2015
Regis IRB application submitted	August 17, 2015
Finalize booklet and discussion guide	August, 2015
Initiate study	November 15, 2015
Data Collection	November 15 – December 31, 2015
Data Analysis	January, 2016
Write Final Paper	March 2016
Capstone Defense	April 2016

## Appendix E– Instruments Used in Educational Intervention

### Advance Directive Booklet



Advance  
Directives\_8-5-15\_ENC

### Discussion Guide

#### ADVANCED DIRECTIVE DISCUSSION TEMPLATE—the basics (side one)

- Choose a quiet, comfortable location. In outpatient setting, allow about 15 minutes to discuss ADs.
- Ensure correct people are present
- Ask permission to talk about future planning
- Assure patient and family that, while difficult to discuss, ADs are routine and are very important
- Talk in simple, NON MEDICAL, terms
- Frame discussion in terms of patient specific prognosis and try to elicit goals and values rather than offer “Chinese menu” of choices out of context of current medical condition. Some examples:
  - “I’m so relieved that you are in good health now. It is important to think of what may happen in future when you may not be doing so well. What kind of things are important to you in your medical care.”
  - “While your heart seems to be stable now, have you thought about what may happen if it becomes weaker in the future?”
- Assure patient and family that this is a process rather than a procedure. Taking time to think about future goals and decisions and coming back is perfectly normal and encouraged.
- Assure patient and family that advanced directives can be changed in the future and that this is encouraged especially if medical conditions change
- Lastly, reassure that the goal of the advanced directive is to provide the best care consistent with a patient’s own goals and values

#### ADVANCED DIRECTIVE DISCUSSION TEMPLATE—nuts and bolts (side two)

- Advanced directive is a LEGAL form with 2 parts that allows patients to have control over their own care even if they become too sick to speak for themselves.
- Patients can fill out the form alone, with family, with the assistance of a social worker or medical provider. It does NOT need to be notarized.
- It is best to fill out when stable or healthy
- Patients keep a copy for themselves and a copy is made to enter their medical records
- You can change this document at any time
- The most important part of the advanced directive is the Power of Attorney. Pick a person who could make the best decisions on your behalf consistent with your goals/values. Sometimes this is a spouse, sibling, child, friend.
- Make sure to talk to that person about your goals!

- **The next part talks about specific medical decisions. (You should feel free as a medical provider to make recommendations specific to the patient in the context of their medical issues. For example, recommending DNR to a patient with metastatic cancer is warranted.)**
  - **CPR (encouraged to talk about resuscitation in terms of death—heart or breathing stopping with subsequent resuscitation attempt)**
  - **Intubation**
  - **Artificial nutrition/hydration**
  - **DNR**
- **Encourage patients (again) to talk with family, friends, surrogate, POA and come back. Always frame in terms of individual patient.**

## Appendix F – IRB Approval Letters

### UNM HSC IRB:



*Human Research Review  
Committee Human Research  
Protections Office*

August 18, 2015

Lisa Marr, MD, FACP  
LMarr@salud.unm.edu

Dear Dr. Marr:

On 8/6/2015, the HRRC reviewed the following submission:

Type of Review: Initial Study  
 Title of Study: An Educational Intervention to Increase Completion of Advance Directives  
 Investigator: Lisa Marr, MD, FACP  
 Study ID: Submission 15-184  
                   ID: 15-184  
 IND, IDE, or HDE: None

Submission Summary: Initial Study  
 Documents Approved:
 

- Advance Directive Discussion Guide submitted 07/17/2015
- Kim Harlow v06/23/2015
- Advance Directive Booklet submitted 07/17/2015
- Consent form v8/11/2015

Review Category: EXPEDITED: CATEGORIES (5) Data, documents, records, or specimens and (7)(a) Behavioral research.

Determinations/Waivers: Requires a signed Consent form.  
 Informed Consent waived for screening for eligibility for QI project only.  
 HIPAA Authorization on record; signed HIPAA required.  
 HIPAA Authorization waived for screening for eligibility for QI project only.

Submission Approval Date: 8/6/2015  
 Approval End Date: 8/5/2016

Effective Date: 8/18/2015

The HRRC approved the study from 8/6/2015 to 8/5/2016 inclusive. If modifications were required to secure approval, the effective date will be later than the approval date. The “Effective Date” 8/18/2015 is the date the HRRC approved your modifications and, in all cases, represents the date study activities may begin.

Before 8/5/2016 or within 45 days of study closure, whichever is earlier, you are required to submit a continuing review. You may submit a continuing review by navigating to the active study and clicking the “Create Modification / CR” button.

---

The University of New Mexico • MSC08 4560 • 1 University of New Mexico • Albuquerque, NM 87131-0001 • Phone 505.272.1129 • Fax 505.272.0803 • [hsc.unm.edu/som/research/hrrc](http://hsc.unm.edu/som/research/hrrc) •

BMSB B71

Page 1 of 2

Please use the consent documents that were approved and stamped by the HRRC. The stamped and approved consents are available for your retrieval in the “Documents” tab of the parent study.

This determination applies only to the activities described in this submission and does not apply should you make any changes to these documents. If changes are being considered and there are questions about whether HRRC review is needed, please submit a study modification to the HRRC for a determination. A change in the research may disqualify this research from the current review category. You can create a modification by clicking Create Modification / CR within the study.

In conducting this study, you are required to follow the Investigator Manual dated April 1, 2015 (HRP-103), which can be found by navigating to the IRB Library.

Sincerely,



Thomas F. Byrd, MD  
*HRRC Chair*

BMSB B71

Page 2 of 2

## Regis University IRB:

### REGIS UNIVERSITY

OFFICE OF ACADEMIC GRANTS

IRB – REGIS UNIVERSITY

November 15, 2015

Kim Harlow  
510 Aliso SE  
Albuquerque, NM 87108

**RE: IRB # 15-267**

Dear Ms. Harlow:

Your application to the Regis IRB for your project, “An Educational Intervention to Increase Advance Directives”, was approved as an expedited study on November 4, 2015. It is approved per OHRP Category of Research #5 and #7.

If changes are made in the research plan that significantly alter the involvement of human subjects from that which was approved in the named application, the new research plan must be resubmitted to the Regis IRB for approval. Projects which continue beyond one year from their starting date require IRB continuation review. The continuation should be requested 30 days prior to the one year anniversary date of the approved project’s start date. A completion report of the findings of this study should be sent to the IRB.

In addition, it is the responsibility of the principal investigator to promptly report to the IRB any injuries to human subjects and/or any unanticipated problems within the scope of the approved research which may pose risks to human subjects. Lastly, a final report should be submitted at completion of the project and it is the responsibility of the investigator to maintain signed consent documents for a period of three years after the conclusion of the research.

Sincerely,

  
Patsy McGuire Cullen, PhD, CPNP-PC  
Chair, Institutional Review Board  
Professor & Director  
Doctor of Nursing Practice & Nurse Practitioner Programs  
Loretto Heights School of Nursing  
Regis University

cc: Dr. Lora Claywell





## Appendix G – CITI Training Certificate

### COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM) COURSEWORK REQUIREMENTS REPORT\*

\* NOTE: Scores on this Requirements Report reflect quiz completions at the time all requirements for the course were met. See list below for details. See separate Transcript Report for more recent quiz scores, including those on optional (supplemental) course elements.

- **Name:** Kimberly Harlow (ID: 4657129)
- **Email:** kharlow@regis.edu
- **Institution Affiliation:** Regis University (ID: 745)

- **Report ID:** 15200952
- **Completion Date:** 02/03/2015
- **Expiration Date:** 02/02/2018
- **Minimum Passing:** 80
- **Reported Score\*:** 100

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED
Belmont Report and CITI Course Introduction	02/03/15
History and Ethical Principles - SBE	02/03/15
The Federal Regulations - SBE	02/03/15
Assessing Risk - SBE	02/03/15
Informed Consent - SBE	02/03/15
Privacy and Confidentiality - SBE	02/03/15
Regis University	02/03/15

**For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.**

#### CITI Program

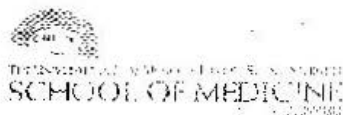
Email: [citisupport@miami.edu](mailto:citisupport@miami.edu)

Phone: 305-243-7970

Web: <https://www.citiprogram.org>

- **Institution Unit:** Nursing
- **Phone:** 5052393653
- **Curriculum Group:** Human Research
- **Course Learner Group:** Social Behavioral Research Investigators and Key Personnel
- **Stage:** Stage 1 - Basic Course

## Appendix H- Agency Letter of Support



Department of Internal Medicine  
 MSC10-3550  
 1 University of New Mexico  
 Albuquerque, NM 87131-0001  
 (505) 272-4868 Office  
 (505) 275-9174 Fax

### Letter of Agreement

July 29, 2015

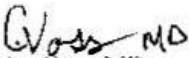
To Regis University Institutional Review Board (IRB):

I am familiar with Kim Harlow's research project entitled *An Educational Intervention to Increase Advance Directives*. I understand the Department of Internal Medicine's involvement to be allowing the primary investigator to review the electronic health records of those patients admitted with congestive heart failure, to provide a discussion and educational booklet to a sub-group of these patients (randomly selected) with the goal of education about advance directives, and to review these patient's charts at discharge to assess the presence or absence of an advance directive.

I understand that this research will be carried out following sound ethical principles and that participant involvement in this research project is strictly voluntary and provides confidentiality of research data, as described in the proposal.

Therefore, as a representative of the UNM Department of Internal Medicine I agree that Kim Harlow's research project may be conducted at our agency/institution.

Sincerely,

  
 Carolyn Voss, MD  
 Department Chair  
 Department of Internal Medicine  
 cvoss@unm.edu