

ADVANCE CARE PLANNING

An Evaluation of the Effects of Implementing an Evidence Based Advance Care Planning
Program on Patient/Family Satisfaction with End of Life Care

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Dedication

I would like to dedicate this project first to my husband Tim who was by my side through this entire program with constant encouragement. He was my number one editor for all my papers. Next, thank you to my kids who did not see me as much as usual, I hope that I have could provide for you an example of if you set your mind to something you can accomplish it. And lastly to Dr. Jean Barry who has provided a high level of mentorship, helping me to see things just a little differently on a routine basis. This whole project is dedicated to my father – I was able to use the advance care planning process prior to knowing it even existed. It provided the insight I needed to give him the most appropriate end of life care. I love you Dad.

Abstract

Advance directive information has been required since the Patient Self Determination Act of 1991. However, just the requirement of a conversation about an advance directive has not demonstrably resulted in having an advance directive that is easy for advocates to implement when the time arrives. Advance care planning has been identified by the Institute of Medicine as a program that can assist patients and caregivers to create and document a quality end of life care plan. Research supports that implementation of a patient centered plan will decrease stress and anxiety of the family members, and increase the quality of end of life for the resident while also increasing resident and family satisfaction. This project evaluation focused on patient and family satisfaction with end of life care. The implementation of this advance care planning project was successful, and in fact, exceeded the goals determined. This is supported by the data analysis indicating a statistically significant difference between pre-implementation and post-implementation data.

Keywords: advance care planning, ACP, end of life, satisfaction, advance directive

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An Evaluation of the Effects of Implementing an Evidence Based Advance Care Planning
Program on Patient/Family Satisfaction with End of Life Care

Providing end of life care can be very complicated when end of life choices are not well understood by those making the decisions and/or providing the care. This can occur when patients have not had the opportunity to share their life (and death) goals and values with their advocates – the person(s) making the end of life decisions when the patient is unable to do so for themselves. While the focus of this project evaluation is patient/family satisfaction with end of life care one cannot ignore the implication of increased costs in the final years of life. Research shows that increased spending at the end of life does not increase quality of end of life care (Curtis, Engelberg, Bensink, & Ramsey, 2012; Healthcare Finance Management Association [HFMA], 2012).

As the U.S. population ages, the concern of managing chronic disease is increasing. The current healthcare system was not developed to manage an increasing population of chronically ill patients. Significant changes in the current healthcare system will need to occur to ensure appropriate care (financially and humanistically to support quality end of life care) is available for the aging population with chronic diseases (Lynn & Adamson, 2003). Berwick, Nolan, and Whittington (2008) began this evolution with the introduction of *The Triple Aim* which focuses on population health, care for the individual, and healthcare cost reduction.

The Triple Aim is a strategy to redesign healthcare ensuring the system will not only last into the future, with an appropriate focus on access to care, but also to ensure that it is the best quality at the lowest cost. If equitable access to healthcare will be available in the future for the aging population, chronic disease (population health) and end of life care (care of the individual)

need to be evaluated against *The Triple Aim* to ensure patients are being cared for appropriately (Berwick et al., 2008).

Because the final phase of life includes living with potentially fatal chronic illnesses, most healthcare expenditures by and for the elderly occur during these final years. It is important to ensure healthcare delivered during these declining years is appropriate and meets the patient's desires and goals for quality care at the end of life (HFMA, 2012; Lynn & Adamson, 2003). The work of determining the patient's end of life care desires began with the Patient Self-Determination Act.

The Patient Self-Determination Act (PSDA) went into effect in 1991, requiring healthcare entities to offer advance directive information to patients, allowing the patients to predetermine the level of care rendered, should they not be able to make healthcare decisions independently (H.R.4449 - 101st Congress (1989-1990), 1990). In theory, this would prevent unwanted, extensive treatment during the end of life. However, research shows the advance directive is not the complete solution to honoring patients' choices (Houttekier, Cohen, Cools, & Deliens, 2012; Kass-Bartelmes & Hughes, 2004; Tilden et al., 2012). Forlini & Goldberg (2014) suggest a conversation needs to occur, optimally with the patient, an advocate, and a trained facilitator, to understand the patient's values and goals for living. This facilitated conversation is the foundation of an advance care planning program.

While the literature indicates both an increase in the completion and availability of advance directives following the implementation of an advance care planning program, the question remains whether any of this makes a difference to the patient and family (Bischoff, Sudore, Miao, Boscardin, & Smith, 2013; Engelhardt et al., 2006; Hammes, Rooney, & Gundrum, 2010).

Investing in honest, facilitated conversations with the patient and advocate has the potential to make end of life decisions less stressful, create less anxiety, and increase satisfaction for both the patient and their families (American Hospital Association [AHA], 2012; Briggs, Kirchhoff, Hammes, Song, & Colvin, 2004; Brinkman-Stoppelenburg, Rietjens, & van der Heide, 2014; Detering, Hancock, Reade, & Silvester, 2010; Dy, Apostol, Martinez, & Aslakson, 2013; Gesme & Wiseman, 2011; Hebert, Prigerson, Schulz, & Arnold, 2006; Tierney et al., 2001; Wilson, Kottke, & Schettle, 2014). The organization that is the focus of this project evaluation currently has a process that ensures do not resuscitate (DNR) orders are addressed. However, there is no current process that includes a facilitated conversation with patients/family/advocate related to end of life priorities. With minor investments of education time, documentation follow up, and post-implementation chart review, a successful and evidence based advance care planning program can be implemented and evaluated for process and clinical outcomes.

There is a significant amount of literature available related to advance directives and advance care planning. Also, there are some well-designed studies that support the notion that advance care planning programs at the end of life can positively affect patient and family satisfaction and subsequently quality of care at the end of life (Brinkman-Stoppelenburg et al., 2014; Detering et al., 2010; Morss Dy, Shugarman, Lorenz, Mularski, & Lynn, 2008). This project promotes patient-centered care while focusing on the specific outcome of patient and family satisfaction with end of life care, as well as several directly related process outcomes.

Patient-centered care is more than a patient-specific care plan; it must be respectful and responsive to patients values and choices which drive patient care (Lusk & Fater, 2013; Motley, 2013). Through patient and advocate education there is empowerment which will ultimately lead

to self-determination (Garces-Ozanne, Kalu, & Audas, 2016). This empowerment and self-determination will lead to inclusion of family member/advocate in decision making (Institute of Medicine [IOM], 2001; Lusk & Fater, 2013; Morgan & Yoder, 2012). Implementation of an evidence based advance care planning program will assist in supporting the appropriate level of end of life care while increasing the quality of end of life and meeting the patient's values and goals through patient-centered care.

Problem Statement

The PICOT (patient population, issue of interest/intervention, comparison intervention, outcome, and timeframe) question that needs to be addressed is: Will implementation of an advance care planning program as compared to usual and customary care increase patient/resident and family satisfaction with end of life care in a Midwest long term care and rehabilitation resident population twelve months after program implementation (Melnyk & Fineout-Overholt, 2015)?

The American Academy of Nursing (AAN) states proactive planning and care coordination for chronic disease is an urgent public health concern. The report further states advance care planning programs are critical to ensure that end of life care reflects the values, preferences, and beliefs of the patients and their families (AAN, 2013; Tilden et al., 2012). According to the Institute of Medicine (2015) report *Dying in America*, elderly patients are being admitted to the hospital at the end of life and care given is inconsistent with the patient's end of life care preferences. This may be due to patients not having an advance directive or if there is an advance directive, the document is not clear enough to guide his or her family in determining what level of care should be delivered (Brinkman-Stoppelenburg et al., 2014; IOM, 2015).

This lack of advance directive document availability and the need for care coordination at the end of life was the driving factor for the implementation of an advance care planning program at a Midwestern rehabilitation and nursing center. The advance care planning program implemented is well supported in the literature for success in increasing the end of life documentation and decreasing the stress and anxiety of patients and their families (Briggs et al., 2004; Detering et al., 2010).

Evidence Based Initiative

Based on the amount of available literature and the level of evidence within the body of work directly related to advance directives and advance care planning, there is enough research to support this project implementation. While most of the literature supports implementation of an advance care planning program, there are some well-designed studies that support the notion that advance care planning programs supporting the end of life decisions can positively affect patient and family satisfaction (Brinkman-Stoppelenburg et al., 2014; Detering et al., 2010; Morss Dy et al., 2008).

There are several objectives for this program implementation; however, this doctoral project will focus on the program evaluation and the specific outcome of patient/resident and family satisfaction with end of life care along with a few important process outcomes focused on documentation (e.g. presence of advance directive in the chart and the health information exchange and documentation of the facilitated conversation).

A literature review was conducted using the CINAHL Complete, Medline, and PsychInfo databases with the parameters of the search from 1990 – 2015. The search parameter of 1990 was chosen because of the correlation with the initiation of the PSDA. Search terms included: advance care planning; palliative care; advance directive; satisfaction; and end of life. There

were several thousand articles identified in the initial search. Many the articles did not include satisfaction as an outcome when related to end of life planning (refer to the PRISMA Diagram in Figure 1 for more detail on literature search results). However, because the research associated with an increase in satisfaction is high level evidence and of strong design (two randomized control trials [RCTs], and two systematic reviews), there is sufficient evidence to support an advance care planning program implementation while focusing on the outcome of increased patient/resident and family satisfaction.

The focus of the literature review is on the adult patient population, more specifically the elderly long term care patients/residents; therefore, exclusion criteria eliminated any articles related to pediatrics. Also excluded were any non-English articles, and any articles that were not research studies. Studies from outside of the United States were included if they were published in English. After a review of all titles and relevant abstracts, the final eight articles that met the inclusion criteria included both systematic reviews and research articles that focused on advance care planning in adult populations, satisfaction, and, quality of end of life care (see Table 1 for evidence hierarchy comparison and article synthesis).

Based on Melnyk and Fineout-Overholt's (2015) hierarchy of evidence (refer to Figure 2 – The Hierarchy of Evidence Pyramid) there are two systematic reviews (level 1), three randomized control trials (RCTs – level 2), one retrospective comparison or control trial (level 3), one descriptive study and one qualitative study (level 5). Because the focus of this project is satisfaction with end of life care, it is worth noting that 50% of these eight studies mentioned satisfaction as an outcome of advance care planning related to end of life care.

The available literature related to advance directives and advance care planning focuses primarily on the completion of the advance directive and the availability of that document in the

medical record. More than 50% of the studies reviewed are high level evidence (levels 1-3) presenting strong research to support that implementation of an advance care planning program will increase the quality of end of life care and increase patient and family satisfaction.

There are some limitations of the literature identified in this review. These limitations include: most of the current research studies were single site in nature, creating a concern related to replicability and generalizability of the studies and, since there have been only a few international research studies, the research is lacking in ethnic diversity. However, despite the identified limitations, there is sufficient quality evidence to support the implementation of an advance care planning program.

Areas of awareness that may impact an advance care planning program are identified in some of the lower-level evidence studies. The studies that document patients/residents, families, and advocates will respond based on their acceptance and readiness for change are important to recognize. This allows information to be shared at appropriate timeframes throughout the process. It is also critical to remember that having an advance directive document is not enough, as that does not give the advocates enough information to make appropriate decisions. A facilitated conversation is an essential element of the advance care planning process and will aid in filling the information gap.

It is critical in today's healthcare environment that care delivered must include patient-centered care especially at the end of life (Lusk & Fater, 2013; Motley, 2013). Investing in strong facilitated conversations with the patient and advocate will make end of life decisions less stressful, create less anxiety, and increase satisfaction for both the patient and their families (Briggs et al., 2004; Detering et al., 2010; Weathers et al., 2016; Wilson et al., 2014).

Conceptual Models

The American Organization of Nurse Executives (AONE) has developed leadership competencies for nurse executives. One of these competencies is “Leadership” which outlines the need to use theory for program implementation and organizational change (AONE, 2011). The theoretical model used to support this project implementation is the chronic care model (Wagner, 1998). The framework supporting the evaluation of this project is the consolidated framework of implementation research (Damschroder et al., 2009).

Theory/Conceptual Framework – Chronic Care Model (CCM)

Developed by Wagner and colleagues in the late 1900s, the CCM (see Figure 3 – the chronic care model) was developed to focus on redesigning ambulatory care to support primary care offices in meeting the national quality improvement initiatives (Coleman, Austin, Brach, & Wagner, 2009; Wagner, 1998). However, the literature shows it can effectively be applied in any type of healthcare setting and target population with the goals of: improved outcomes; provider satisfaction; and lower healthcare costs (Chronic Care Model [CCM], n.d.; Findley, 2014; McEvoy & Barnes, 2007).

The CCM is an effective model for an advance care planning program implementation because one of the main elements of the CCM is the notion of moving care for patients with a chronic illness from an acute and reactive state to being a proactive one. A second main element is to have an actively informed and involved patient. Implementing these two elements into patient-centered care can ensure appropriate end of life care is delivered.

The CCM is comprised of six major elements that contribute toward successful patient-provider interactions as well as improved outcomes (Gammon, Berntsen, Koricho, Sygna, &

Ruland, 2015; Wagner, 1998). The six major areas are: self-management support; decision support; delivery system design; clinical information systems; healthcare organization; and community resources (CCM, n.d.; Coleman et al., 2009; McEvoy & Barnes, 2007; Stroebel et al., 2005). This model defines no processes that guide its application, therefore, it is the responsibility of the organization using the model to define the parts and how they blend into the organizational plan to support project implementation (Hroschikoski et al., 2006).

After reviewing the six elements, the CCM elements important to the advance care planning program implementation and those that must be evaluated prior to program implementation include: the health system (leadership support and, organizational culture of process improvement); delivery system design (moving from reactive to proactive); decision support (use of evidence-based guidelines); clinical information systems (information must be available across disparate electronic health records); and, self-management support (emphasizing the patient's need for driving care). To gain a better understanding of these elements, they will be reviewed individually with an explanation of how they may be important to this project.

Health system.

The health system (leadership support and organizational culture) was evaluated through a comprehensive organizational assessment to ensure success of this project implementation. The need to complete an organizational assessment is supported by the American Association of Colleges of Nurses (AACN) Doctorate of Nursing Practice (DNP) Essentials – Essential II “Organizational and Systems Leadership for Quality Improvement and Systems Thinking”. The DNP is prepared to be an expert in nursing practice focusing on practice that is innovative and evidence-based, and applies the credible research findings of the research focused nurse (AACN, 2006).

The causal model (see figure 4) was used as the framework to complete the organizational assessment (Burke & Litwin, 1992). The causal model is very complex. However, to ease understanding of the model, Burke and Litwin (1992) have placed the more significant variables at the top of the model demonstrating these variables have a stronger influence on systems change. For example, the leadership and organizational culture variables have a greater impact on the potential for change within an organization than does the work unit climate.

Burke and Litwin (1992) divided the variables into transformational (influenced by the external environment) and transactional (a reciprocal approach – a quid pro quo scenario). Leadership and organizational culture are examples of the transformational variables.

Leadership, the third variable in the causal model, refers to the leaders of the organization who set the direction of the organization and serve as role models for all of the employees (Burke & Litwin, 1992). In the rehabilitation and nursing center, the leadership includes the nursing manager; the long-term care administrator; the medical director of the rehabilitation and nursing center; and the president of the organization.

The president is a leader with a clear vision for the organization which strongly corresponds with the system's vision of caring for the community. The president is also very innovative and understands the need to creatively manage healthcare spending. She is passionate about doing what is right for the patient.

The long-term care administrator has worked in the long-term care industry his entire professional life. His initial role was with a for-profit company. He admits he enjoys working more for a not-for-profit company because there is more focus on the patient (quality care) than on the bottom line. He is also passionate about his patient population and has stated that he goes

to work every day to work for the residents within the rehabilitation and nursing center. He is very supportive of change resulting in improved patient care.

The role of the long-term care nursing manager was open at the time of the assessment. It has since been filled by the interim manager. The previous manager was in the role for several years. Change management was not one of her strengths; she was not as supportive of the changes needed to keep pace with the evolving healthcare environment. While she was passionate about the residents and staff, she was unable to embrace change. She has left this role to fill another position within the organization. The recent turnover in this role could negatively impact the readiness for change. The new manager is relatively inexperienced; she could be seen as a peer and not someone who has the authority to implement any change.

The medical director of the rehabilitation and nursing center is a geriatrician within the healthcare system medical group. He is very competent in his practice and is verbally supportive of change that benefits the residents/patients. However, his schedule has not allowed him to participate with planning or to attend implementation committee meetings. He is very supportive of the advance care planning program implementation, but his lack of involvement prevents him from hearing the most recent information related to facilitated conversations. This inhibits him from supporting the advance care planning process with the residents as he rounds.

The senior leadership team is very supportive of change and is willing to present change as positive within the long-term care environment. The frontline management, although verbally supportive of change, does not consistently exhibit the qualities that support planning and implementation of change. The recent turnover in the long-term care nurse manager and the lack of involvement of the medical director of the rehabilitation and nursing center could produce a negative impact on the implementation. More conversation and education should occur to ensure

that these two leadership roles are more positive about the change that needs to occur so they could better support the program implementation.

Culture is the personality of the organization. It is the set of rules, values, and principles that guide organizational behavior (Burke & Litwin, 1992). The rehabilitation and nursing center culture is one of support for the residents. Based on the Eden AlternativeTM, the staff at all levels want to do what is right for the residents; they want the residents to feel as if they live in a community made up of various neighborhoods. Often the staff are scheduled in the same “neighborhoods” (e.g. a hallway) within the facility so the residents get to know the staff and their families. This culture is all part of the Eden AlternativeTM (Hinman & Heyl, 2001). The staff truly believe in patient-centered care and want the residents to have the life and the end-of-life that the residents desire. Based on this organization assessment, rehabilitation and nursing center leadership and the organizational culture will support this project implementation to ensure success.

Delivery system design.

The delivery system design in the CCM refers to the movement from reactive care to proactive care. Initially this was a change designed for the primary care environment from reactive care to preventive medicine (Coleman et al., 2009; Wagner, 1998). However, this element speaks to exactly what advance care planning programs emphasize – a proactive facilitated conversation with the patient and the advocate (Sudore & Fried, 2010; Woytkiw, 2010). Healthcare in general must move to a proactive model in all aspects of patient care, including end of life care, to be effective and sustainable in the future (Hickman, Rolley, & Davidson, 2010). With this proactive approach, it is important for the patient to be the center of

the decision making especially related to end of life care to ensure that care given is appropriate and meets the patient's/resident's desires (Lusk & Fater, 2013).

Decision support.

The element of decision support refers to the use of evidence based initiatives. AACN Essentials III – “Clinical Scholarship and Analytical Methods for Evidence Based Practice” calls for review of the research to ensure program implementation is evidence based (AACN, 2006). Also, the AONE leadership competency “Knowledge of the Health Care Environment” outlines the nursing leader as responsible for ensuring practice is evidence based and outcome measurements are collected (AONE, 2011).

The Respecting Choices[®] advance care planning program is evidence based, is well documented in the literature and has been successfully implemented in several locations (Briggs, 2014; Forlini & Goldberg, 2014; Hammes et al., 2010; Hickman, Hammes, Moss, & Tolle, 2005; Pecanac, Repenshek, Tennenbaum, & Hammes, 2014). This same advance care planning program has been implemented at the rehabilitation and nursing center and is the program to be evaluated for this project.

Clinical information systems.

The clinical information systems element of the CCM refers to the availability of patient information longitudinally across disparate electronic health records (EHR). There are a number of documents published related to electronic patient records and the need to have patient information available at the point of service since President George W. Bush made an executive order to nationally implement interoperable electronic health information technology (Executive Order No. 13335, 2004).

For advance care planning to be effective, documentation must be accessible for review where ever the patient is seen for healthcare services, and where ever care decisions are made. Global access to documents was an important initiative when implementing the advance care planning program at the rehabilitation and nursing center. In fact, one of the roles required for implementation is a staff member who will upload the end of life decision documentation to a health information exchange (HIE). This ensures any healthcare provider will be able to provide patient-centered care which has been identified by the Agency for Healthcare Research and Quality (AHRQ) as a way to begin meeting the goals documented in the IOM (2001) report *Crossing the Quality Chasm* (Finkelstein et al., 2012). Advance directives and the documentation of the facilitated advance care planning conversation is critical information that must be available anywhere in the healthcare system to ensure appropriate care and to prevent unnecessary care that does not meet the patient's end of life care plan.

Electronic health information is identified as one of the AACN DNP Essentials. Essential IV – “Information Systems/Technology and Patient Care Technology for the Improvement and Transfer of Health Care” calls for the use of technology to support and improve patient care (refer to table 2 for DNP Essentials demonstrated in this project) (AACN, 2006). It is imperative that the use of technology is monitored to support patient care and that healthcare leadership encourages the progression of technology to ensure a complete longitudinal interoperable health record. This will support patient centered quality end of life care (Filipova, 2015).

So in review the CCM has several critical elements that support the focus of the advance care planning program implementation. Several of these elements also support the AACN DNP Essentials required for completion of a successful DNP education. Refer to table 2 for a

complete list of DNP Essentials demonstrated in this advance care planning program implementation evaluation.

Implementation (Evaluation) Model – Consolidated Framework for Implementation Research (CFIR)

Many implementation science theories have been developed, most with overlapping constructs. However, the definitions and terminology are not consistent across these theories leading to inconsistent evaluation of implementation research outcomes. The consolidated framework for implementation research (CFIR) was developed by a group of implementation researchers from the Veterans Administration and the University of Michigan to reconcile these inconsistencies. The CFIR is meta-theoretical; it is a synthesis of constructs from various existing theories. These constructs had different labels but often the definitions of the constructs overlapped. This overlap of definitions made consistent outcome evaluation challenging. The CFIR consolidates these constructs providing consistent definitions while providing a structure to organize findings across studies (Damschroder et al., 2009).

The CFIR consists of five domains with several constructs within each domain (refer to figure 5 for CFIR diagram, domain, and construct description). Researchers are able to choose the constructs that will be most effective for their project implementation and evaluation (CFIR, n.d.; Damschroder et al., 2009).

The five domains are:

- Intervention characteristics – This domain has eight constructs (intervention source; evidence strength and quality; relative advantage; adaptability; trialability; complexity; design quality and packaging; and, cost) and refers to the characteristics of the intervention being implemented.

- Outer setting – Includes four constructs (patient needs and resources; cosmopolitanism; peer pressure; and, external policy and incentives) that include economic, political, and social context of the community in which the organization sits.
- Inner setting – Five constructs (structural characteristics; networks and communication; culture; implementation climate; and, readiness for implementation) that refer to features of structural, political, and cultural contexts through which the implementation process will occur.
- Characteristics of the individuals involved – Five constructs (knowledge and beliefs about intervention; self-efficacy; individual state of change; individual identification with organization; and, other personal attributes) referring to the individuals involved in the implementation. People have power, they make choices, and can influence others; this is a significant role (Greenhalgh, Robert, Macfarlane, Bate, & Kyriakidou, 2004).
- Process of implementation – Consists of four constructs that are common across other organizational change models (planning; engaging; executing; and, reflecting and evaluating) which could be a series of sub-processes that may or may not be interrelated and are not required to occur sequentially. These activities can be readdressed as often as needed to implement successfully (CFIR, n.d.; Damschroder et al., 2009).

The success of the CFIR has been well documented (Breimaier, Heckemann, Halfens, & Lohrmann, 2015; Damschroder, Goodrich, Robinson, Fletcher, & Lowery, 2011; Damschroder & Lowery, 2013; Ilott, Gerrish, Booth, & Field, 2013; Kirk et al., 2016; Liang et al., 2015).

Because this model allows for the identification of facilitators and barriers of a successful implementation, the CFIR will be used in this doctoral project to address any identified barriers and to ensure future implementations will be successful.

A benefit of using the CFIR as an evaluative tool is the flexibility of using the domains and constructs that are pertinent to the program implementation. The rehabilitation and nursing center advance care planning program implementation will be evaluated using several constructs from most of the CFIR domains.

Prior to implementation, all eight constructs of the “intervention” domain were evaluated to be sure the program implementation was the right program for this location (refer to appendix C for a description of CFIR domains and constructs). All constructs were met positively; the advance care planning program is an evidence based program designed and successfully implemented within a Midwestern rehabilitation and nursing center. The evidence shows successful trialability and adaptability of the advance care planning intervention by the many implementations not only in the United States, but internationally as well (Brinkman-Stoppelenburg et al., 2014; Detering et al., 2010; Engelhardt et al., 2006; McMahon, Knight, Fried, & Sudore, 2013; Morss Dy et al., 2008; Schickedanz et al., 2009). After a successful review of the “intervention domain” constructs, all task force members and organizational leadership agreed this program was the right program to implement at the rehabilitation and nursing center.

After implementation, several constructs in the other domains were assessed for success. The construct in the “outer setting” domain most applicable to this project is the patient needs and resources. Certainly, the resident population in the rehabilitation and nursing center is the right population for the advance care planning program. There was a need for facilitated

conversations and a structured advance care planning program identified within this Midwestern rehabilitation and nursing center as evidenced by the pre-implementation chart review. The pre-implementation data results of 6% documented conversations show a lack of consistent documentation of end of life care conversations. This rehabilitation and nursing center also had the resources necessary to implement this program with minimal cost to the organization.

The next domain addressed is the “inner setting” and the constructs assessed review the culture and the readiness for change within the organization. The culture in the rehabilitation and nursing center is defined by the Eden Alternative™ philosophy which is very much structured around the residents (Hinman & Heyl, 2001). If the program being implemented improves the care for the residents, the staff will be supportive of the change.

The rehabilitation and nursing center’s health system has a very strong foundation in quality improvement which helps the rehabilitation and nursing center climate for change be a positive environment. The staff in the rehabilitation and nursing center are always interested in quality initiatives benefiting the residents. The rehabilitation and nursing center staff made this implementation a topic of conversation every morning as they reviewed the quality initiatives that are on the “monitoring daily improvements” (MDI) board. This conversation allowed them to make changes immediately in processes that were not working as intended.

The construct addressed within the fourth domain of “individuals” is about the knowledge and beliefs about the intervention. The frontline staff that had specific roles within the process were educated on the program and what their role involved. The remaining staff supporting this program received generic education on the advance care planning program and why it was important to implement within that rehabilitation and nursing center. There was a celebratory kick-off party with all the staff on site the day of implementation which set the stage

for success. The advance care planning program was implemented in December 2015. The staff remained very engaged and supportive of this program and were able to verbalize the benefits this advance care planning program brings to the residents and their families.

The final domain in the CFIR framework is the process of implementation. This includes the planning, engaging, executing, and evaluating constructs. All four constructs have been completed. The evaluation construct is the focus of this formative evaluation project and will determine the success of the implementation.

Need and Feasibility Assessment of the Organization/Population

Most healthcare expenditures by the elderly occur within the last few years before death. While the ultimate goal of an advance care planning program is not based on the financial aspects, it makes sense to focus efforts on ensuring that healthcare delivery during those waning years is appropriate and meets the patient's values and desires for quality end of life care (Fisher, Esty, Chang, & Goodman, 2011; Hogan, Lunney, Gabel, & Lynn, 2001; Lynn & Adamson, 2003). The proposed project site is a rural hospital within a larger health system, located approximately 70 miles north of Grand Rapids, MI. It is a critical access hospital with 25 beds and a fully staffed 24-hour emergency department. It is identified as one of the top two employers (more than 460 employees) in a northern rural county and has roots that date back to 1885. The Rehab and Nursing Center ("The Center") is one of the services available at the hospital campus.

The Center, a 54 bed long term care facility, is one of six long term care facilities in the state that have been identified as an Eden AlternativeTM facility. Eden AlternativeTM facilities are designed to decrease the institutionalization of long term care centers transforming the nursing home from a location the elderly went to die into a "human habitat" where older people

would go to live and thrive. The philosophy of the Eden Alternative™ has been documented to improve the functionality of the residents by changing the culture of the organization (Hinman & Heyl, 2001).

The Center has a multi-disciplinary clinical team of approximately 55 staff members caring for the residents. The clinical staff includes registered nurses (associate degree nurses [ADN] and bachelor of science nurses [BSN]), social workers (MSW), nursing assistants, and licensed practical nurses. Associate degree nurses (ADN) comprise much of the registered nursing staff (ADN – 73%; BSN – 27%). This delineation is important because the literature supports higher quality of care and improved outcomes with higher level of nursing education (Blegen, Goode, Park, Vaughn, & Spetz, 2013; IOM, 2011).

While the Center retrospective data related to documentation of code status upon resident admission to the center is at 56%, there is no current evidence-based program to drive end of life decision making for the residents. Documentation of a facilitated conversation with resident and advocate was only at 16%, all of which speaks to the need for the implementation and evaluation of an advance care planning program.

Project Plan

The final DNP project is a culmination of the of the knowledge gained throughout the DNP program. The focus of the final DNP project is threefold: 1) to evaluate evidence based practices; 2) to determine the success of the project implementation; and 3) to disseminate the findings to support others in their implementation.

This DNP project will add advance care planning clinical outcomes evaluation to the application of evidence into practice. While not generalizable research, the practice knowledge gained will support and aid the implementation of an advance care planning program.

Purpose of Project with Objectives

As the U.S. population ages, chronic disease management is becoming more of a concern. The current healthcare system is not strong enough financially nor is it designed to medically manage an increasing population with chronic diseases. Healthcare must undergo an evolution to ensure cost appropriate and humanistic care is available for those who are aging and suffer from chronic diseases (Hopp et al., 2015; Lynn & Adamson, 2003).

The concept of advance directives is not new. In fact, the Patient Self-Determination Act requires a discussion of advance directives occurs with each patient admitted to a hospital or long term care facility. However, research shows documentation of these conversations, availability of the advance directive in the medical record, and care consistent with end of life wishes, has not been successful (Briggs et al., 2004; Hammes et al., 2010; H.R. 4449, 1990; IOM, 2015; Van Leuven, 2011).

A strong advance care planning program will assist in supporting the appropriate level of end of life care while meeting the patients' values and goals. Investing in well-facilitated conversations with the patient and advocate will make end of life decisions less stressful, create less anxiety, and increase satisfaction for both the patient and their families (Briggs, 2014; Briggs et al., 2004; Detering et al., 2010). For these reasons, implementation of an advance care planning program at the rehabilitation and nursing center is necessary. The program for implementation is similar to the Gundersen Lutheran Respecting Choices program. There are three phases in this program: 1) First Steps[®] which is appropriate for anyone older than 18 years of age who is healthy or who has a chronic disease but has never had an advance care planning facilitated conversation; 2) Next Steps[®] is offered to patients who have advanced chronic

disease; and, 3) Last Steps[®] is offered to anyone who is anticipated to expire within the next 12 months (Gundersen Health, n.d.).

The objectives for this advance care planning project implementation were:

- Successfully implement the Last Steps[®] phase of the advance care planning program.
- Complete a minimum of 20 facilitated conversations over the 12 months following implementation.
- Successfully complete all necessary documentation to ensure appropriate end of life care and upload to the health information exchange.
- Increase both patient/resident and family/advocate satisfaction with end of life care by completing and documenting facilitated conversations.

Type of Project

Because the advance care planning program was an implementation project in the rehabilitation and nursing center that began in December 2015, a formative evaluation was completed on this project. Formative evaluation is becoming more popular with the increase in implementation science and the need for accurate assessments and data to support implementation of evidence based science.

There are several ways to define formative evaluation. However, the essence of the definition is that formative evaluation is an evaluation or assessment process developed to identify potential/actual influences on the effectiveness of an implementation project (Stetler et al., 2006). In other words, the focus of a formative evaluation is to help in identifying any barriers for future implementations, and determine the success of the implementation through a thorough review of the implementation objectives.

Setting and Needed Resources

The implementation of the advance care planning program, based on the Gundersen Model (Briggs et al., 2004; Hammes et al., 2010; Pecanac et al., 2014), was in a rehabilitation and nursing care facility, part of a larger healthcare system, with approximately 50 beds located approximately 70 miles north of Grand Rapids, MI. Prior to a new program implementation, and to ensure success, it is critical to conduct an organizational assessment to determine the organization's readiness for change.

The AACN documented eight essentials for the Doctorate in Nursing Practice. Essential II, "Organizational and Systems Leadership for Quality Improvement and Systems Thinking," focuses on the need for DNP leaders to determine the feasibility of program implementation and to provide ongoing improvement of health outcomes and patient safety (AACN, 2006).

Similarly, the American Organization of Nurse Executives (AONE) outlines five competencies that document leadership skills common among successful nurse executives. The competency called "Business Skills" identifies the ability to manage strategically, including the identification of a strategic direction, completion of a strengths, weaknesses, opportunities, threats (SWOT) analysis prior to program implementation (see appendix D for project SWOT analysis), and to measure and analyze the performance of implemented program(s) (AONE, 2011). The DNP leader must evaluate care delivery to ensure it meets the current and future needs of the patient populations, supports quality care, as well as appropriate management of healthcare costs.

An organizational assessment of the Center was completed utilizing the Burke and Litwin's causal model of organizational performance and change (Burke & Litwin, 1992). The causal model has 12 variables that could affect an organization's readiness for change. The

analysis of the organization assessment identified that for a successful advance care planning program implementation it is critical to focus on three of the 12 causal model variables: external environment; leadership; and task requirements and individual skills/abilities. These three variables were the most likely to affect the implementation of the project if not addressed. By reviewing and addressing these variables, it allowed a successful implementation of the advance care planning program ensuring healthcare cost reduction while providing quality outcomes and value-based patient-centered care.

The patient population that was the focus of this implementation and evaluation includes any patient/resident that is expected to expire within the next 12 months. This is the criteria for the facilitated conversations occurring in the Last Steps[®] phase of the Respecting Choices[®] advance care planning program.

Because this specific advance care planning program template is well defined, the staff roles required for a successful implementation are prescriptive and include:

- Project Implementation/Support
- Administrative Leader/Support
- Two trained facilitators
- Site Lead
- Advance care planning support personnel
- Medical Director.

These roles were filled with Center staff (i.e. social workers, administrator, secretary, etc.).

Other resource needs included the documents necessary to record the facilitated conversations; and, internet and computer access to upload the documentation to the electronic health record and to the health information exchange (HIE).

Design for the Evidence-based Initiative

The design of this project is an evaluation of process (focused on documentation) and clinical (focused on resident/advocate satisfaction) outcomes for the advance care planning program implemented at the Center in December 2015. The implementation was managed through a task force whose membership consisted of key roles within the program implementation. There was oversight of this project by a steering committee consisting of community members and key senior leadership team members.

Because this advance care planning program has been adopted within the larger health system as their advance care planning program (MyLife Care Planning), there is a department that manages all advance care planning program implementations within the organization (Spectrum Health, n.d.b.). The approved work plan template was completed outlining all the steps necessary to successfully implement this program. Education was completed for the facilitators; supplies were purchased to ensure documentation of the conversations; and, training was completed for the staff member to upload the documentation to the HIE. The current workflow was evaluated and changes were made to ensure all processes for the new workflow were incorporated

The target population was identified. There was conversation at the task force level around the need to use a tool such as the “MDS Mortality Risk Tool” to identify the participants (Porock, Parker-Oliver, Petroski, & Rantz, 2010). However, the decision was made to begin with all new residents admitted that met the criteria while the staff identified current residents that also met criteria. Based on resident turnover data, the goal of 20 facilitated conversations over 12 months was set.

Participants/Sampling and Recruitment Strategies

The Last Steps[®] phase of the advance care planning program is focused on those patients/residents who are expected to expire within the next 12 months. Therefore, all newly admitted residents to the Center are evaluated by the admissions staff who determine if there is a current advance directive in place. If the resident has an advance directive, the admissions staff evaluate the document against the requirements for the advance care planning program. If the resident's documentation requires updating based on the needs of the advance care planning program, the resident name is added to a list of potential participants and is reviewed by the physician, nursing staff, social work. Those newly admitted residents who based on an assessment will expire within 12 months were the first participants approached. The second group of participants were current residents who met criteria.

Both the resident and the advocate agreed to a facilitated conversation to participate. After both the resident and the advocate have agreed to participate, the conversation was scheduled with a facilitator.

Measurement: Sources of Data and Tools

The focus of this project is an evaluation of program process and of patient and family satisfaction outcomes. The methodology was a mixed methods approach measuring and analyzing both qualitative and quantitative data. Pre-implementation quantitative data were collected via chart review of the last 50 residents who died at the Center. The focus of the data collection prior to the program implementation was threefold: the presence of advance directives in the paper chart as well as those documented within the electronic health record; documentation of resident's end of life care wishes; and if the resident's end of life wishes were respected (post-expiration). Post-implementation quantitative data were collected to compare the

documentation of the advance directive in the chart and the documentation of the residents’ end of life wishes.

Post-expiration data collection and analysis related to respecting residents’ wishes at the end of life was not able to be completed during this project due to time limitation. However, this is important data that should be collected and reviewed, completing the picture of the importance of the advance care planning process.

Pre-implementation data for the presence of advance directives in the chart, documentation of any conversations around the advance directive, and advance directives uploaded to the HIE were collected through a retrospective chart review prior to project implementation. However, patient/family satisfaction data were not available prior to the program implementation because satisfaction surveys specific to advance care planning were not completed with the previous process of documenting an advance directive.

Post-implementation quantitative data were collected through chart review while the resident and family satisfaction results were collected via a paper survey after the facilitated conversation was completed. The post-implementation chart review data include: presence of advance directives in the chart (paper or electronic); presence of an advance directive uploaded into the HIE; documentation of the facilitated conversation including a summary of end of life care wishes; and resident and advocate satisfaction survey results (see Table 2- Clinical and Process Outcomes Data Information).

Table 2

Clinical and Process Outcomes Data Information

Outcomes	Data Type	Statistical Test	Data Collection Tool	Pre-implementation data	Expected Outcome	Actual Outcome
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Total conversations completed	Ordinal	n/a	n/a	0	>=20	34
Presence of advance directive in the chart (paper and electronic)	Categorical Dichotomous (Yes/No)	Chi-square	Chart review documentation tool	68%	>=92%	100%
Presence of advance directive uploaded into the health information exchange (HIE)	Categorical Dichotomous (Yes/No)	Chi-square	Chart review documentation tool	0%	>=92%	100%
Documentation of facilitated conversation	Categorical Dichotomous (Yes/No)	Chi-square	Chart review documentation tool	16%	>=92%	100%
Resident satisfaction scores with ACP process	Ordinal (5 point Likert Scale)	Simple descriptive	Patient/Resident satisfaction survey tool	n/a	4 or greater for each question	4.69
Family satisfaction scores with ACP process	Ordinal (5 point Likert Scale)	Simple descriptive	Advocate satisfaction survey tool	n/a	4 or greater for each question	4.82

The satisfaction survey, consisting of four questions using a five point Likert scale with 1 anchored on “not at all” and 5 anchored on “very much,” rates resident/advocate satisfaction of the advance care planning conversation (refer to appendices A and B for resident and family satisfaction survey tools respectively). Although psychometric properties have not been established for the resident/advocate satisfaction survey tool, the tool was developed with the original advance care planning program at Gundersen Lutheran, and, staff who have implemented this advance care planning program have successfully disseminated and analyzed the results from this survey.

Steps for Implementation of Project, including Timeline

The advance care planning program implementation design followed the recommended implementation plan for the Respecting Choices[®] program. An implementation team of key stakeholders was identified to outline the objectives of the program. The implementation plan included the frequency of meetings; identification of the target population; identification of staff to fill key roles; critical background information to collect; key process review including the documentation system to be used, educational materials needed, and the location of the completed documentation; workflow redesign; and communication and education plan.

The leadership and planning structure for this project included a task force (membership included all key roles for program implementation) and an executive steering committee whose membership included senior leaders from the organization, interested community members, and frontline leaders of both the current project and potential future department implementations of this program (e.g. cardiopulmonary rehab and outpatient oncology). The task force meetings included conversations focused on barriers and facilitators for success and operational tasks.

The task force meetings were initially scheduled on a bi-weekly basis and then moved to a monthly basis after implementation. The executive steering committee met on a quarterly basis. The focus of this group was to remove any barriers from current and future implementations and to determine the next steps for implementation (which department; the number of implementations, etc.).

The timeline for this project implementation began in July 2015 with the identification of the key stakeholders, implementation task force, and the gathering of baseline data. Identification and education of the implementation staff roles was completed by September 2015 while the facilitator training occurred in October 2015. The project was initially scheduled for

full implementation in November 2015 but due to some staffing challenges the implementation was delayed until December 2015.

Project Evaluation Plan

Project evaluation is key to determining the success of a program implementation. DNP nurses, as health systems leaders, are called to implement and evaluate evidence based projects (AACN, 2006; AONE, 2011). Evaluation can be defined as “attributing value to something, by gathering reliable and valid information about it in a systematic way, and by making comparisons, for the purposes of making more informed decisions...” (Øvretveit, 2014, p. 7).

Quantitative data.

The pre- and post-implementation data collected are categorical (dichotomous) data and ordinal data. The pre- and post-implementation chart review data (advance directives in chart, advance directives in HIE, and documentation of conversation) are considered dichotomous–variables that have only two categories or levels, in this case yes/no (Plichta & Kelvin, 2013; Vogt & Johnson, 2011). Data needed for program objective and process evaluation were collected through retrospective chart reviews using a data collection tool and are considered dichotomous data (refer to appendix E for the Data Collection Tool). The data collected for the resident and advocate satisfaction survey is ordinal data and will be analyzed through a review of simple descriptive statistics.

Number of conversations by month.

As previously documented, the trained facilitators approached residents/family that met criteria for the advance care planning facilitated conversation. The implementation goal determined by the task force was to complete 20 conversations over a 12-month period which immediately followed the program implementation (December 2015–December 2016).

However, due to the timeline required for the completion of this DNP project, data were collected and analyzed for an 11-month period (December 2015–November 2016). The team was very successful in completing facilitated conversations and, in fact, exceeded their goal by 70% for a total of 34 conversations (see Figure 6 for Completed Conversations Each Month).

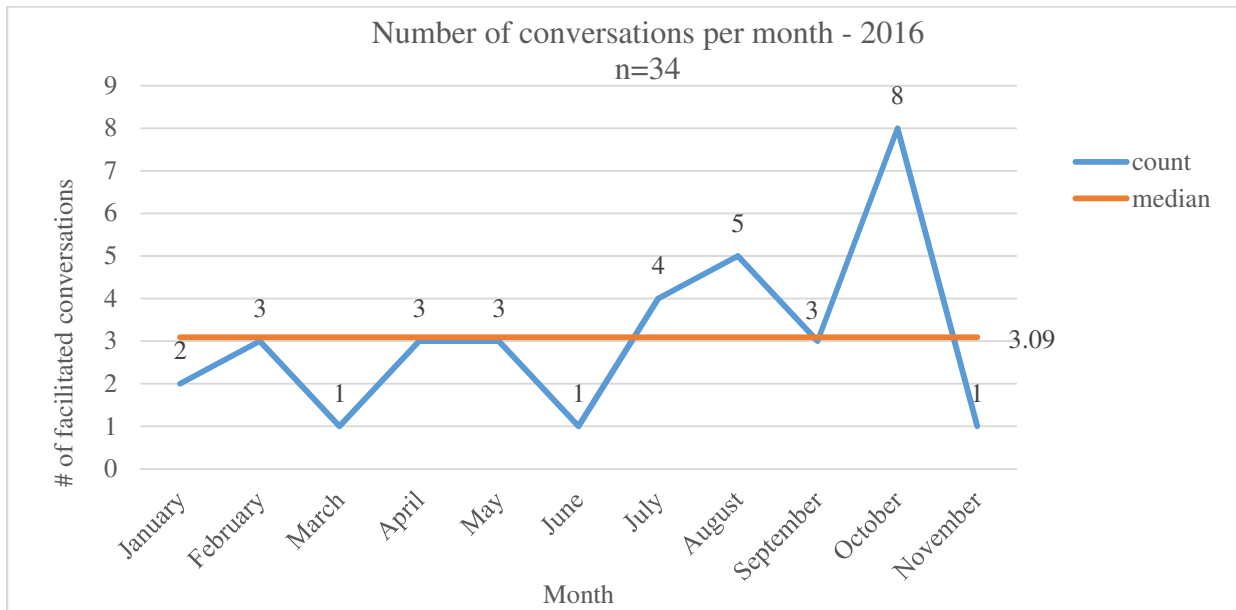


Figure 6. Completed Conversations Each Month.

Patient/advocate satisfaction survey results.

Data were collected to evaluate all goals outlined for this project implementation. Resident/advocate satisfaction data were collected using a satisfaction survey tool with a 1-5 point Likert scale. The satisfaction data (Likert scale) were considered ordinal because there are two or more levels that can be ordered or ranked (Vogt & Johnson, 2011).

According to Polit and Beck (2012), a typical response rate for survey data collection is less than 50%. The satisfaction survey response rate from the residents and the family/advocates was sufficient at 55%.

While there are several data points that were available for comparison (pre- and post-implementation), resident/advocate satisfaction data were not collected pre-implementation.

Therefore, post-implementation survey data were analyzed against the goal established by the task force of a Likert scale result of greater than or equal to four. These results are exhibited as measures of central tendency (a mean and median score) for each question from the Likert scale survey results and are documented in a graphical format (see Figure 7 Patient/Family Satisfaction Survey Results).

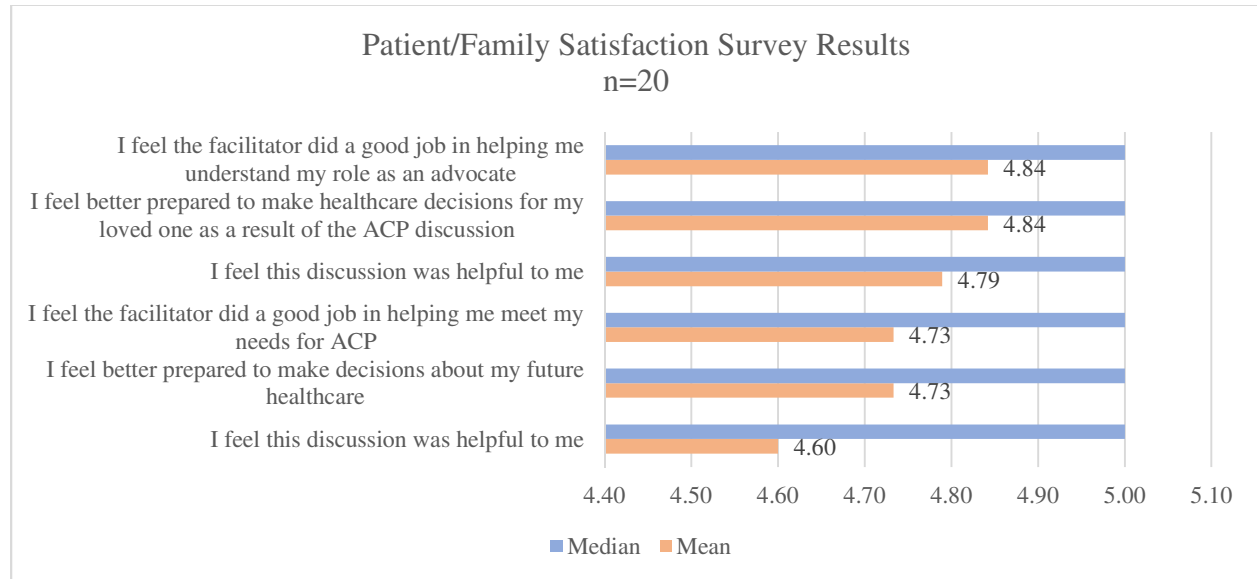


Figure 7. Patient/Family Satisfaction Survey Results.

As visible on the graph (refer to figure 7) of the survey results, the mean resident satisfaction score is between 4.60-4.79, and the mean family/advocate satisfaction score is between 4.79-4.84, both above the stated goal of 4.

The quantitative data analysis for the presence of documentation was completed by running a Chi-square test on data retrieved from the chart reviews pre- and post-implementation. The Chi-square test is completed to determine if two categorical variables are associated in any way and if that association is statistically significant. More specifically, it tests for the association between two nominal or dichotomous variables (Plichta & Kelvin, 2013; Polit & Beck, 2012; Vogt & Johnson, 2011). Therefore, since the data are categorical and dichotomous,

they met the criteria for a Chi-square test to determine if there was statistically significant change between the pre-implementation and post-implementation data (Polit & Beck, 2012; Vogt & Johnson, 2011). The Chi-square test for each dichotomous variable was completed using IBM SPSS Statistics Version 20 software. The Pearson Chi-Square *p-value* will be reported (as opposed to the Fisher's Exact) because the $n > 30$ (Polit & Beck, 2012).

Advance directive in chart results.

The results of the data collection for the advance directive document availability within the electronic record (chart) show a post-implementation result of 34 (100%) “yes” and 0 (0%) “no” (see Figure 8 Bar Graph of Pre- and Post-Implementation Advance Directive in Chart Results and Table 4 Data Results for Advance Directive in Chart). A Chi-square test for the presence of an advance directive in the electronic medical record was completed. The results indicate a statistically significant difference between the pre- and post measurement data with a Chi-Square $p < .001$.

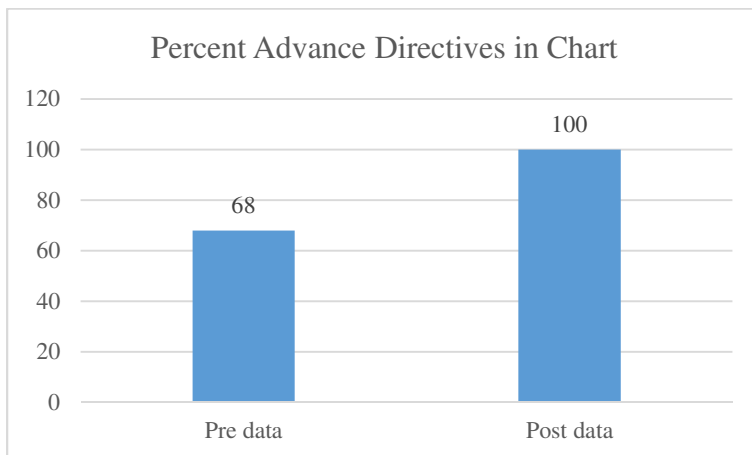


Figure 8. Bar Graph for Advance Directive in Chart.

Table 4

Data Results for Advance Directive in Chart.

	Advance Directive in Chart		
	<i>n</i>	Yes	No
Pre	50	34 (68%)	16 (32%)
Post	34	34 (100%)**	0 (0%)

***p*<.001

Advance directive uploaded to HIE results.

The results of the data collection for the advance directive document uploaded into the HIE show post-implementation results of 34 (100%) “yes” and 0 (0%) “no” (see Figure 9 Bar graph of Pre- and Post-Implementation Advance Directive in HIE and Table 5 Data Results for Advance Directive in HIE). A Chi-square test for the presence of an advance directive in the HIE was completed. The results indicate a statistically significant difference between pre- and post-measurement data with a Chi-Square *p*<.001.

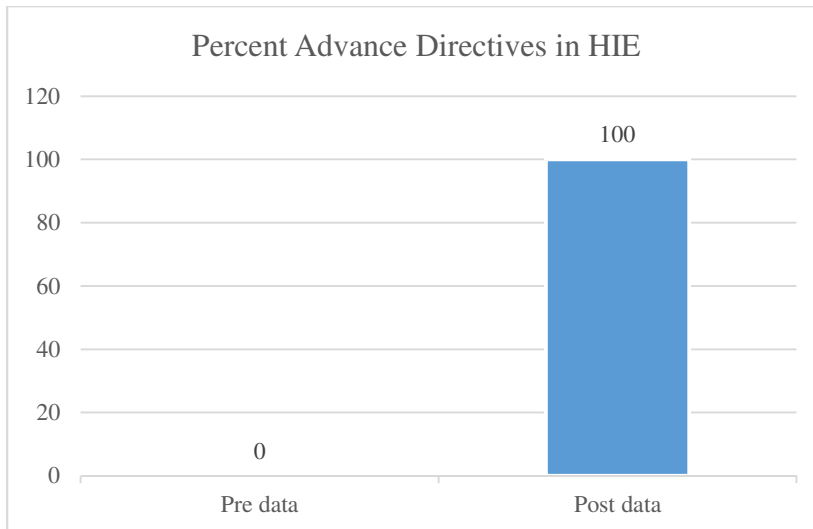


Figure 9. Bar Graph for Advance Directive in HIE.

Table 5

Data Results for Advance Directive in HIE

	Advance Directive in HIE		
	<i>n</i>	Yes	No
Pre	50	0 (0%)	50 (100%)
Post	34	34 (100%)**	0 (0%)

** $p < .001$

Facilitated conversation documentation results.

The results of the statistical analysis for the facilitated conversation documented in the patient chart show post-implementation results of 34 (100%) “yes” and 0 (0%) “no” (see Figure 10 Bar Graph of Pre- and Post-Implementation Conversation Documentation and Table 6 Data Results for Conversation Documentation). A Chi-square test for the presence of the documentation of a facilitated conversation in the patient chart was completed. The results of the Chi-square test provide evidence of a statistically significant difference between pre- and post-measurement data with a Chi-Square $p < .001$.

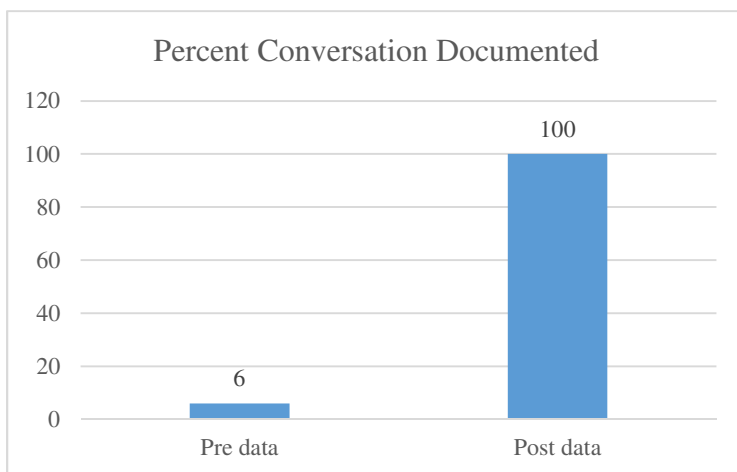


Figure 10. Bar Graph Results of Conversation Documentation.

Table 6

Data Results for Conversation Documentation

	<i>n</i>	Facilitated Conversation Documented	
		Yes	No
Pre	50	3 (6%)	47 (94%)
Post	34	34 (100%)**	0 (0%)

** $p < .001$

As mentioned earlier, the data collected prior to the advance care planning program implementation indicate a lack of overall documentation (advance directives in the chart, advance directives uploaded to the HIE and conversation documentation). After the program was implemented, data were collected monthly. The compilation of that data indicates an improvement in documentation. The results of the analysis of these data suggest because of the advance care planning program implementation, the improvement in the presence of advance directives in the chart, uploaded to the HIE, and facilitated conversation documentation was achieved.

Ethics and Human Subjects Protection

This author anticipated this project evaluation to be deemed as quality improvement in regard to needing IRB approval. However, to ensure protection for patients/residents and their advocates application was made to the Grand Valley State University Human Research and Review Committee (HRRC) and the organization's Institutional Review Board (IRB) to determine if this project meets research criteria. The Grand Valley State University Human Research and Review Committee and the organization's IRB determined this project did not meet the definition of covered human subjects research and therefore was "not research" (see appendix J for the exemption letter from the HRRC and organizational IRB).

Budget

Implementation of the advance care planning program did not require any significant financial support (estimated at <\$1000). The staff filling the necessary roles for implementation are current Center staff. Some potential budgetary considerations included: wage coverage for facilitator education (approximately \$500); educational documents, e.g. pamphlets for the residents and advocates as well as posters for the staff (approximately \$100); and, facilitator documentation tools, e.g. facilitated conversation documentation form and advance directive forms (approximately \$200). These documents while not considerably expensive will be ongoing expenses for this program to be successful.

Stakeholder Support/Sustainability

The advance care planning program supports quality patient care while decreasing healthcare costs. The leadership is very supportive of the implementation of this program within the Center. A key stakeholder quadrant was completed based on executive steering committee conversations (see figure 11). The stakeholder quadrant is a visual depiction of the stakeholders that had the most influence or power as well as those who had a high interest in the program. Influence goes from low to high on the vertical axis while interest moves from low to high on the horizontal axis (Bryson, 2011).

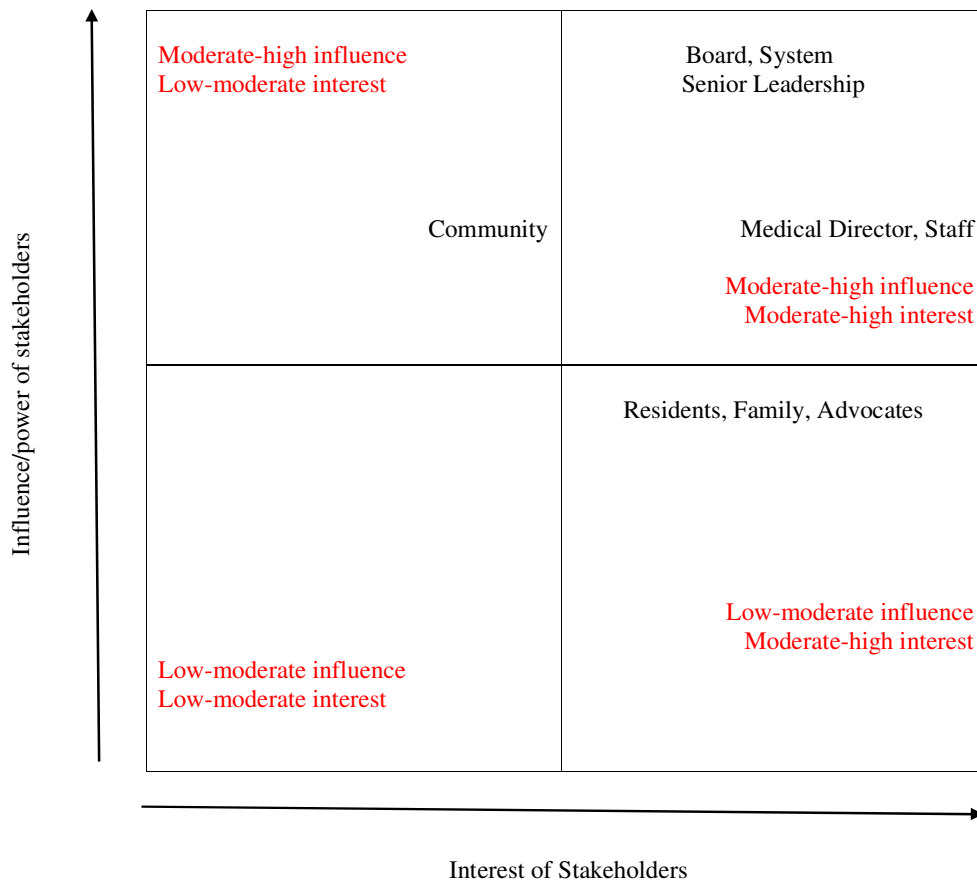


Figure 11. The Stakeholder Quadrant Model for the Center Advance Care Planning Program Implementation.

The key stakeholder quadrant for this project implementation demonstrates that the hospital board, the system, and the senior leadership have a high interest in the success of this program as well as having a high level of influence on the implementation (Bryson, 2011). Because the residents, family, and advocates have a vested interest in this program as it benefits them by increasing the quality of end of life care, the quadrant depicts that the residents, family, and advocates have a moderate amount of power over the implementation but have a high level of interest in the success. Based on conversations with the executive steering committee, the community at large has a moderate level of interest in the project and has a moderate amount of

influence over programs that the hospital implements. The medical director and the staff have moderate influence over the project implementation and have a moderate to high amount of interest in the project.

It was important to visualize and understand the position of the key stakeholders and the potential influence they had over the program implementation. Certainly, the stakeholder influence could have impacted the success of the program. By outlining the amount of influence and power the stakeholders had over the program implementation, the task force was able to mitigate any potential barriers prior to beginning implementation therefore increasing the chance of success.

The sustainability for this project was built into the implementation project plan. The staff roles required for the success of the implementation are filled by current staff within the department. Should those roles be vacated, they would need to be filled to fulfill the other portion of their responsibilities as well as the role with the advance care planning initiative.

The organization is very strong in its use of quality improvement processes and has added the facilitated conversation processes (including the conversation, documentation, and uploading to the HIE) as a quality indicator on their “managing daily improvement” (MDI) board. This allows them to discuss the successes or barriers around this project daily, allowing for quick resolution of issues ensuring systematic integration of the process into the daily workflow. This information was reviewed during the evaluation of the project and is reported as qualitative data.

Implications for Practice

Because research shows the advance directive is not the complete solution to honoring patients’ choices (Kass-Bartelmes & Hughes, 2004), an advance care planning program with a facilitated conversation is critical to understanding the patient’s life values especially related to a

quality end of life. Optimally, this conversation includes a surrogate decision maker or advocate, the patient, and a trained conversation facilitator. Having this facilitated conversation to better understand the values of the patient is the foundation of an advance care planning program (Forlini & Goldberg, 2014).

It is critical in today's healthcare environment that end of life care must be patient centered (Briggs et al., 2004; Gesme & Wiseman, 2011; IOM, 2014). Patient centered care is more than a patient specific care plan, it must be respectful and responsive to patients' values and choices which then drive patient care. It must also include patient or a family member/advocate involvement in decision making (IOM, 2001; Lusk & Fater, 2013; Morgan & Yoder, 2012). A strong advance care planning program will assist in supporting the appropriate level of end of life care while meeting the patient's values and goals.

Plans for Dissemination of Outcomes

The DNP Essentials were developed by a nursing task force to identify the essential components of a nursing practice doctorate thus distinguishing it from the traditional research focused doctorate (table 2 identifies the DNP Essentials demonstrated by this project). AACN Essentials III—"Clinical Scholarship and Analytical Methods for Evidence Based Practice" calls for the dissemination of findings from evidence based implementation (AACN, 2006). Therefore, nursing leaders are charged with disseminating the translation of evidence into practice (AONE, 2011). Dissemination is the communication of knowledge gained from an implementation evaluation or research (Dudley-Brown, 2012), and it is important with any new learnings that process, outcomes, and evaluation are shared to ensure the growth of knowledge and research.

The plan for dissemination of this program implementation evaluation was initially shared with the leadership within the Center supporting the work completed and to aid in determining the next location for implementation. This work has been shared through a poster presentation, and it is also the desire of this author to publish a manuscript disseminating the outcomes of this implementation project as well as present the findings at a conference. A presentation abstract has already been submitted to present at the American Organization of Nurse Executives Leadership Conference in 2017.

Throughout the final DNP project, it is important to evaluate the DNP Essentials addressed during the project completion. Several DNP Essentials were addressed during this evaluation project (Essential I, II, III, IV, VI, VII, VIII). The project required a literature search and review to ensure the program was evidence based; leadership of an interdisciplinary implementation team; use of concepts addressing gaps in healthcare and support of the evaluation of the project implementation and outcomes. There is a thorough review of all Essentials and competencies demonstrated through the completion of this project in Table 3.

The dissemination of this advance care planning evaluation is critical to improve the quality and appropriateness of end of life care. The outcomes of this evidence based project support that a successful implementation of an advance care planning program will improve documentation of a facilitated conversation, increase the documentation of advance directives in the HIE and in the patient's chart. These outcomes are important for the end of life caregivers to provide quality patient-centered care at the end of life.

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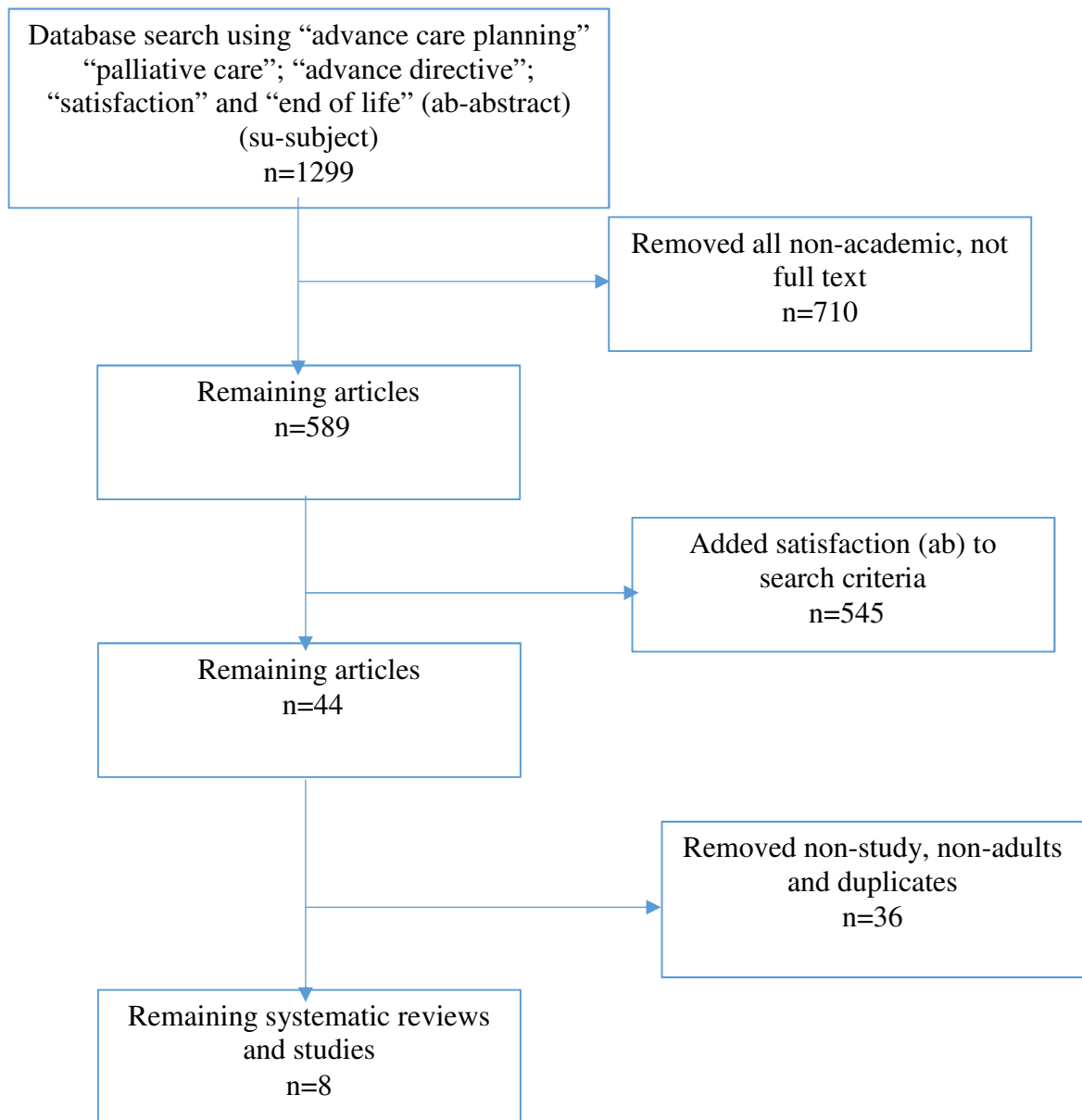


Figure 1. PRISMA diagram. This PRISMA diagram outlines the results of a literature search completed using the databases of Medline, CINAHL Complete, and PsychInfo with the terms “advance care planning” “palliative care”; “advance directive”; “satisfaction” and “end of life” (ab) (su).

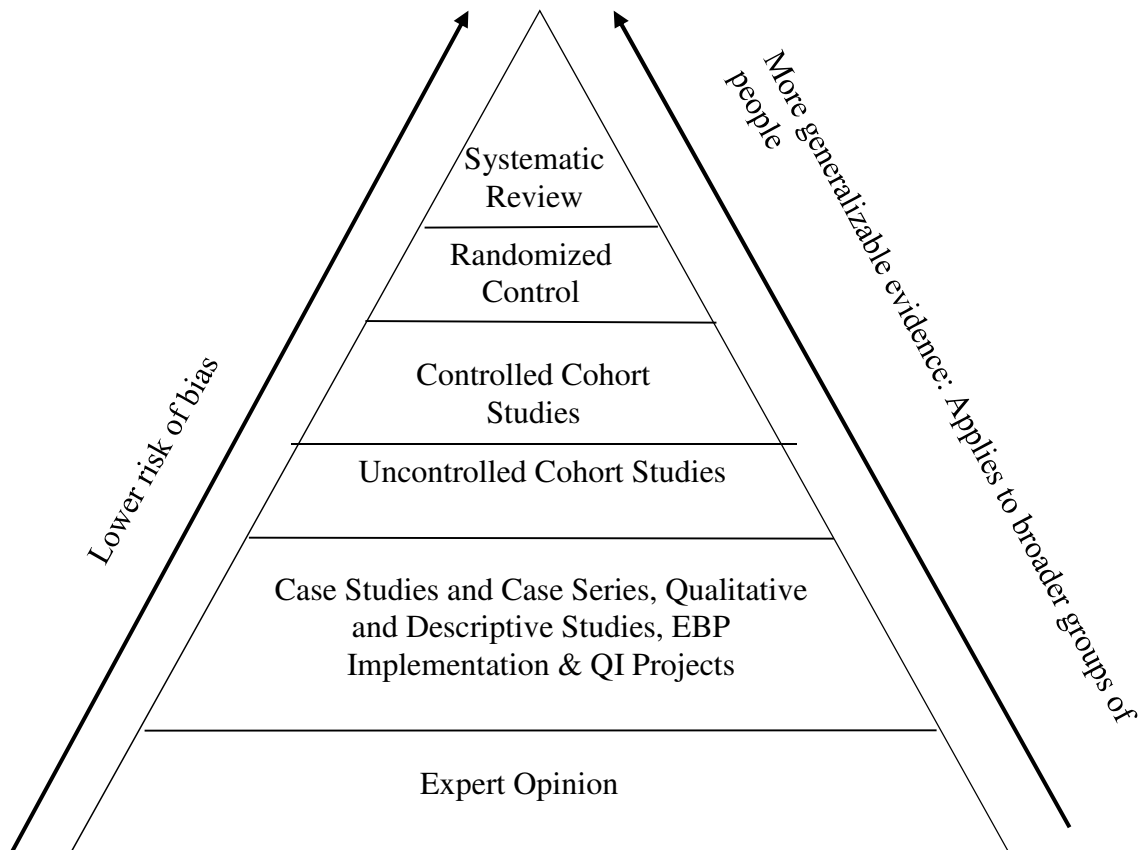
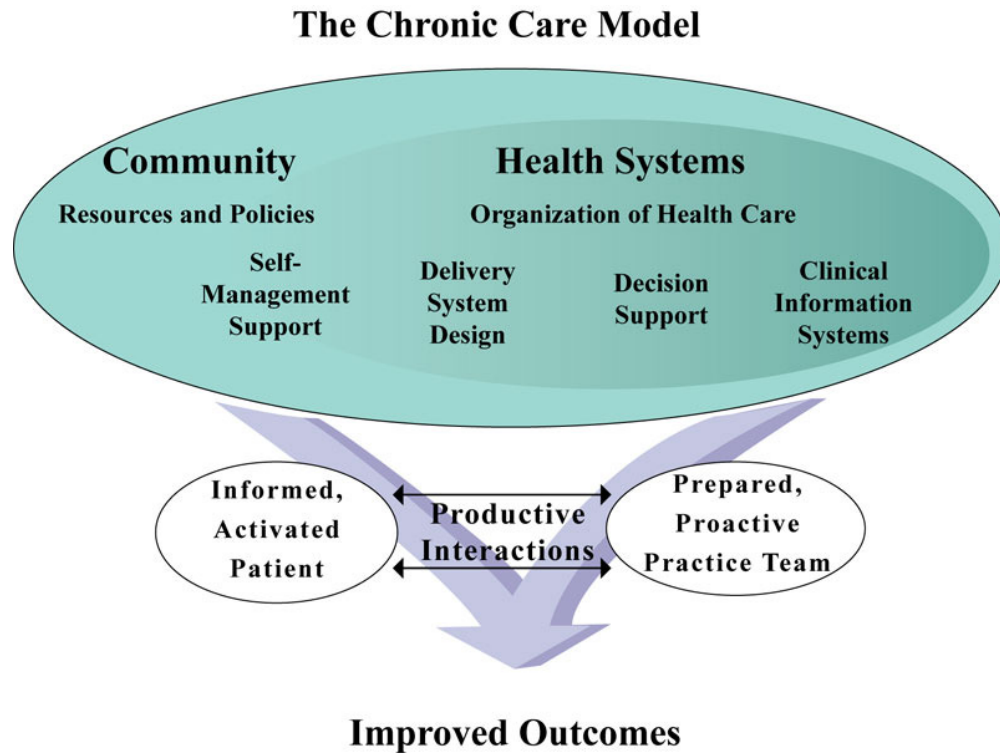


Figure 2. The hierarchy of evidence pyramid. This hierarchy of evidence pyramid provides guidance about types of research that will be able to provide reliable answers to clinical questions. The higher the level of evidence, the more confidence the clinicians have that the intervention being studied will produce the same results (Melnyk & Fineout-Overholt, 2015, p. 92). Used with permission from Wolters Kluwer Health (see Appendix F.)



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Figure 3. The chronic care model. The model highlights the importance of an active informed patient/resident and a proactive prepared health care team (understanding the values and the goals of the resident). Clinical Information Systems are important in allowing wide access to the patient's/resident's advance directive documentation (reproduced with permission of AMERICAN COLLEGE OF PHYSICIANS in the format Thesis/Dissertation via Copyright Clearance Center, see Appendix G). Retrieved from:

<http://www.improvingchroniccare.org/index.php?p=Chronic+Care+Model&s=124>

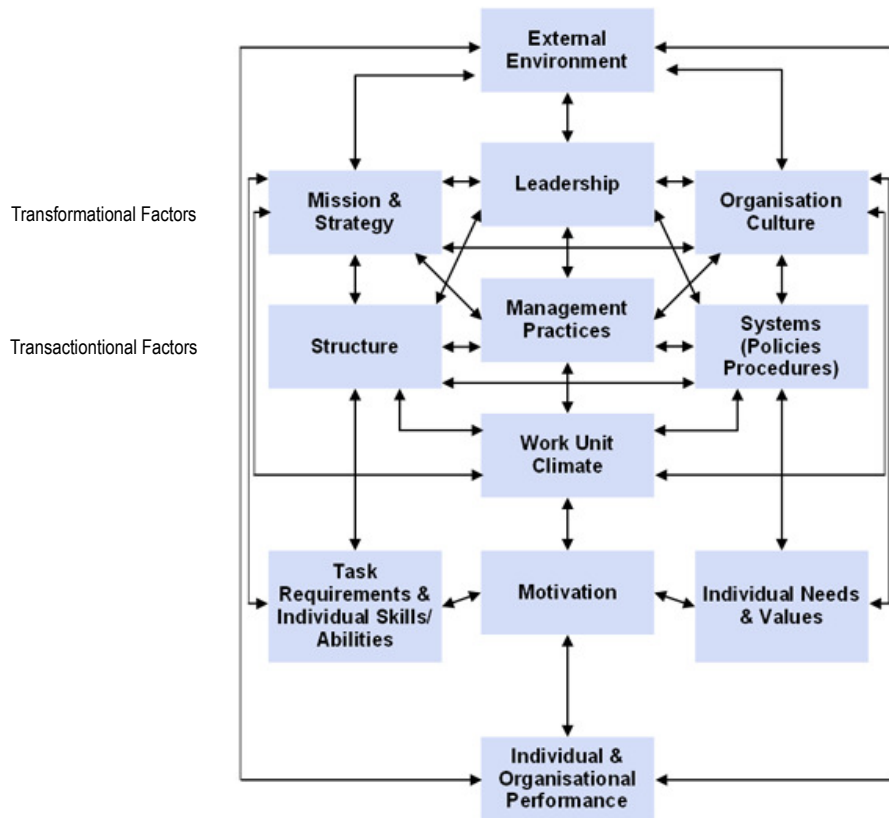


Figure 4. The causal model of organizational performance and change. This model is complex with bidirectional arrows connecting all variables. These arrows outline the important interdependence between variables, each variable can influence another variable. (Burke & Litwin, 1992). Used with permission from Sage Publishing email received 4.1.16 (refer to the Appendix H).

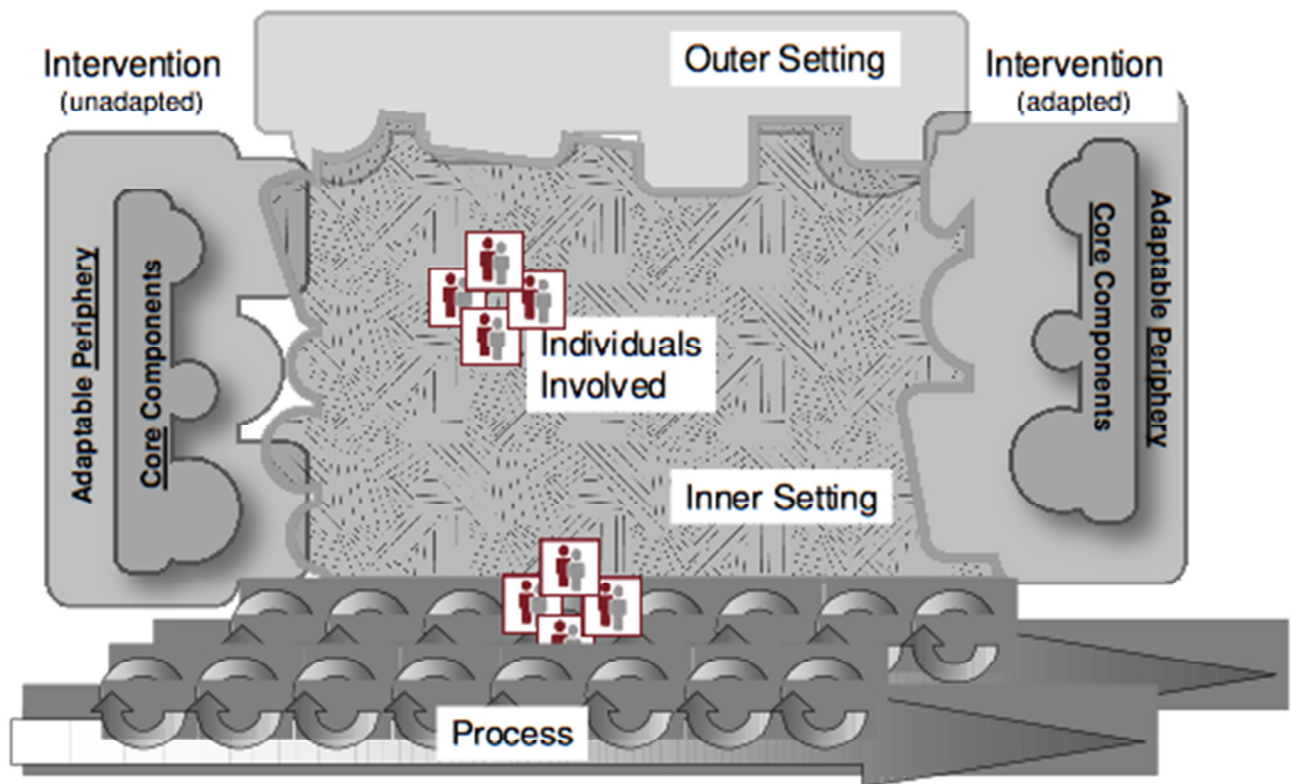


Figure 5. Diagram of the CFIR. This diagram of the CFIR depicts the five major domains of the framework (intervention; inner and outer settings; individuals involved; and process). All pieces of the puzzle when implementing an intervention, therefore the puzzle like pieces. Process is very complex and is often competing with other processes being implemented within an organization and therefore has several moving wheels throughout the process (Damschroder et al., 2009). Used with permission per personal email from L. Damschroder (see Appendix I).

Table 1

Synthesis Table

Study Author	Year	Number of Participants	Mean Age	Study Design	Evidence Hierarchy	Intervention	Major Findings
Briggs, L. A.	2004	N=27	Mean age 68.7; 62% women in experimental group and 80% men in the control group	Randomized Control Trial	Level 2	Experimental group received a one hour interview related to Patient Centered-Advance Care Planning.	The authors found that by increasing the advocates' understanding of the values and goals of the patients, there is an increase in congruence in decision making at the end of life.
Brinkman-Stoppelenburg, A.	2014	N=113	N/A	Systematic review	Level 1	The authors completed a systematic review of 113 articles pertaining to the effect of advance care planning on the quality of the end of life.	Six of the 45 studies with advance directives reported that there was an association between advance directives and patient and family satisfaction, quality of life, and quality of death and dying.
Detering, K. M.	2010	N=309	85 yr (intervention group) 84 yr (control group)	Randomized Control Trial	Level 2	Advance Care Planning was delivered to 125 of 154 patient assigned to the intervention group.	Advance care planning improves end of life care and patient and family satisfaction and reduces stress, anxiety, and

							depression in the survivors.
Engelhardt, J. B.	2006	N=418	Ages included: 1 – <40 yrs 4 – 40-49 yrs 16 – 50-59 yrs 22 – 60-69 yrs 53 – 70-79 yrs 26 – >=80 yrs Mean = 70.72	Randomized Control Trial	Level 2	The advanced illness coordinated care program (AICCP) participant met with a coordinator for assistance with provider communication, care coordination, and support.	The AICCP improved satisfaction with care and helped patients develop and revise advance directives.
Hammes, B. J.	2010	1995/96: N=400 2007/08: N=540	80 yrs in both data collections	Retrospective comparison	Level 3	Implementation of the Respecting Choices advance care planning program with review to determine sustainability.	The data show a significant increase in presence of advance directives (90% vs 85%); it was in the medical record at the time of death (99.4% vs 95.2%).
McMahon, R. D.	2013	N=69	Patient mean age-78 Surrogate mean age-57	Ethnographic Analysis - Qualitative Study	Level 5	A consistent scripted interview with probing questions to determine what activities best	Responses were grouped into themes. Results identified that advance directives alone were not sufficient to prepare

						prepared the participants for decision making.	patients and advocates for complex decision making. The two highest-ranking themes were: values clarification (88.4%) and informing family/friends of wishes (87%).
Morss Dy, S.	2008	N=32	N/A	Systematic review	Level 1	Search on Medline and the Database of Reviews of Effects – the review included any relevant qualitative studies and intervention studies that identified satisfaction as an outcome from 1990 to 2005.	Researchers have conceptualized satisfaction in palliative care; and different types of palliative care interventions can improve satisfaction. However, it is not often included as an outcome.

Schickedanz, A. D.	2009	N=143	Participant mean age was 61	Descriptive study	Level 5	Participants enrolled in an advance directive study and developed two advance directives; after 6 mo. they were interviewed to identify barriers to the advance care planning process.	This study was researching the barriers to completing an advance directive. The most frequent barrier identified at each advance care planning step was that patients felt that the advance directive was irrelevant.
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Table 3

Project Evidence of DNP Essentials

DNP Essential	Evidence from Project
I. Scientific underpinnings for practice	<ul style="list-style-type: none"> • Evaluation of the implementation of an evidence-based program • Evaluation based on evidence-based framework
II. Organizational and systems leadership for quality improvement and systems thinking	<ul style="list-style-type: none"> • Evaluation of a new care delivery approach that meets the needs of the specific patient population • Program will ensure quality of end of life care • Program evaluation will ensure effective strategies are in place to manage potential ethical dilemmas at the end of life
III. Clinical scholarship and analytical methods for evidence-based practice	<ul style="list-style-type: none"> • Literature review completed ensuring evidence was strong enough to support implementation • This DNP student functioned as the expert consultant in relation to the program implementation • Designed an effective evaluation strategy • Program evaluation outcomes will be disseminated through poster presentation; board presentation; and application to AONE for presentation
IV. Information systems/technology and patient care technology for the improvement and transformation of health care	<ul style="list-style-type: none"> • Program evaluation and monitoring of outcomes of care • Use of technology to ensure access to longitudinal patient chart and advance directive
VI. Interprofessional collaboration for improving patient and population health outcomes	<ul style="list-style-type: none"> • Lead an Interprofessional team to implement advance care planning program • Lead the evaluation and analysis of the program implementation
VII. Clinical prevention and population health for improving the nation’s health	<ul style="list-style-type: none"> • Synthesized concepts related to population health in evaluating interventions to address population health and address gaps in care
VIII. Advanced nursing practice	<ul style="list-style-type: none"> • Use of conceptual and analytical skills to evaluate this program implementation • Demonstrated advance levels of clinical judgement, systems thinking, and accountability in the evaluation of this evidence-based program to improve quality of end of life

Appendix A

Patient Satisfaction Survey Tool

Date _____ Facilitator name _____

PATIENT SATISFACTION SURVEY AFTER LAST STEPS ACP DISCUSSION

Please circle your level of satisfaction with the advance care planning discussion you just had:

1. I feel that this discussion was helpful to me.

1	2	3	4	5
(not at all)				(very much)

2. I feel better prepared to make decisions about my future health-care.

1	2	3	4	5
(not at all)				(very much)

3. I feel the facilitator did a good job in helping me meet my needs for advance care planning.

1	2	3	4	5
(not at all)				(very much)

4. Is there anything you think the facilitator could have done better to help? Please comment below if you have suggestions.

Appendix C

Description of the five CFIR domains and constructs within each domain

Domain 1: Intervention – characteristics of the intervention itself
<ul style="list-style-type: none"> • Intervention source: Perception about whether intervention is externally or internally developed • Evidence Strength & Quality: Perception of the quality and validity of evidence supporting the belief that the intervention will have desired outcomes • Relative Advantage: Perception of the advantage of implementing the intervention versus an alternative solution • Adaptability: Degree to which an intervention can be tailored to meet the needs of an organization • Trialability: Ability to test the intervention on a small scale, and to reverse course if warranted • Complexity: Perceived difficulty of implementation • Design Quality & Packaging: Perceived excellence in how the intervention is bundled and presented • Cost: Cost of the intervention and costs associated with implementing the intervention
Domain 2: Outer Setting – factors external to the organization
<ul style="list-style-type: none"> • Patient Needs & Resources: Extent to which patient needs are accurately known and prioritized by the organization • Cosmopolitanism: Level of connectedness and networks with other organizations • Peer Pressure: Competitive pressure to implement an intervention • External Policy & Incentives: external strategies to spread interventions, including policy and regulations, mandates, recommendations and guidelines, etc.
Domain 3: Inner Setting - characteristics of the organization implementing the intervention
<ul style="list-style-type: none"> • Structural characteristics: Age, maturity, or size of the organization • Networks & Communication: Nature and quality of webs of social networks and the nature and quality of formal and informal communications within an organization • Culture: Norms, values, and basic assumptions of a given organization • Implementation climate: Relative priority of implementing the current intervention versus other competing priorities • Readiness for Implementation: Access to resources, knowledge, and information about the intervention
Domain 4: Individuals - characteristics of the individuals involved in implementation
<ul style="list-style-type: none"> • Knowledge and Beliefs about Intervention: Individual staff knowledge and attitude towards the intervention • Self-efficacy: An individual's belief in their capabilities to execute the implementation • Individual State of Change: Phase an individual is in as he or she progresses toward skilled, enthusiastic, and sustained use of the intervention • Individual Identification with Organization: Individuals' perception of the organization and their relationship and degree of commitment to the organization • Other Personal Attributes: Personal traits such as tolerance of ambiguity, intellectual ability, motivation, etc.
Domain 5: Process – processes of implementation
<ul style="list-style-type: none"> • Planning: Planning for the implementation • Engaging: Engaging individuals in implementation processes • Executing: Executing the implementation plan • Reflecting & Evaluating: Reflecting and evaluating the progress of implementation

(Damschroder et al., 2009 – Used with permission, refer to Appendix I)

Appendix D

Strengths, Weaknesses, Opportunities, and Threats (SWOT) Analysis

Strengths	Weaknesses	Opportunities	Threats
<ul style="list-style-type: none"> • Leadership is supportive of the implementation • Frontline staff are engaged and excited about the project • Patient population is ideal for Last Steps® conversations • The organization has purchased the Respecting Choices® advance care planning program which includes all educational materials and program design materials • Facilitator training is available at no cost to organization employees • Should not require additional FTEs to implement this project 	<ul style="list-style-type: none"> • Frontline management not strong enough to ensure staff complete tasks • The medical director is not often onsite to encourage patients to have facilitated conversations • Training required prior to implementation which may produce some delay of implementation • Facilitators must complete 20 conversations per year 	<ul style="list-style-type: none"> • Provide advance care planning education to the patients/residents and the community • Improve documentation and accessibility of advance directives • Improve quality and satisfaction of end of life 	<ul style="list-style-type: none"> • Perceived negative impression in the community – talking people into being a no code • Residents and advocates may not be ready or interested in the facilitated conversation

Appendix E

Data Collection Tool

pre-implementation data	AD in EMR	documentation of conversation in chart	AD uploaded to HIE	comments
Chart 33	Yes	Yes	No	
Chart 34	Yes	Yes	No	
Chart 16	Yes	No	No	
Chart 4	Yes	No	No	
Chart 16	No	Yes	No	
Chart 47	Yes	No	No	
Chart 49	No	No	No	
Chart 43	No	No	No	
Chart 15	Yes	No	No	
Chart 36	Yes	No	No	
Chart 35	No	No	No	
Chart 38	Yes	No	No	
Chart 44	Yes	No	No	
Chart 50	No	No	No	
Chart 48	Yes	No	No	
Chart 37	Yes	No	No	
Chart 42	No	No	No	
Chart 46	Yes	No	No	
Chart 41	No	No	No	
Chart 40	Yes	No	No	
Chart 45	Yes	No	No	
Chart 39	Yes	No	No	
Chart 51	Yes	No	No	
Chart 23	Yes	No	No	
Chart 22	Yes	No	No	

Chart 21	No	No	No	
Chart 30	Yes	No	No	
Chart 19	Yes	No	No	
Chart 18	Yes	No	No	
Chart 17	Yes	No	No	
Chart 14	No	No	No	
Chart 13	No	No	No	
Chart 12	Yes	No	No	
Chart 11	Yes	No	No	
Chart 10	No	No	No	
Chart 9	Yes	No	No	
Chart 8	Yes	No	No	
Chart 7	No	No	No	
Chart 6	Yes	No	No	
Chart 5	No	No	No	
Chart 2	No	No	No	
Chart 24	No	No	No	
Chart 25	Yes	No	No	
Chart 26	Yes	No	No	
Chart 27	No	No	No	
Chart 29	Yes	No	No	
Chart 30	Yes	No	No	
Chart 31	Yes	No	No	
Chart 32	Yes	No	No	
Chart 28	Yes	No	No	

68%

6%

0%

Post-implementation data	AD in EMR	documentation of conversation in chart	AD uploaded to HIE	comments
1/25/16	yes	yes	yes	
1/5/16	yes	yes	yes	
2/24/16	yes	yes	yes	
2/22/16	yes	yes	yes	
2/19/16	yes	yes	yes	
3/25/16	yes	yes	yes	
4/1/16	yes	yes	yes	
4/1/16	yes	yes	yes	
4/27/16	yes	yes	yes	
5/2/16	yes	yes	yes	
5/27/16	yes	yes	yes	
5/27/16	yes	yes	yes	
6/1/16	yes	yes	yes	
7/6/16	yes	yes	yes	
7/6/16	yes	yes	yes	
7/12/16	yes	yes	yes	
7/26/16	yes	yes	yes	
8/17/16	yes	yes	yes	
8/18/16	yes	yes	yes	
8/30/16	yes	yes	yes	
8/31/16	yes	yes	yes	
8/31/16	yes	yes	yes	
9/6/16	yes	yes	yes	
9/27/16	yes	yes	yes	
9/20/16	yes	yes	yes	
10/4/16	yes	yes	yes	
10/11/16	yes	yes	yes	
10/20/16	yes	yes	yes	
10/20/16	yes	yes	yes	

10/19/16	yes	yes	yes	
10/19/16	yes	yes	yes	
10/20/16	yes	yes	yes	
10/14/16	yes	yes	yes	
11/14/16	yes	yes	yes	
	100% AD	100%	100%	

Appendix F

Permission to use the Evidence Pyramid

RightsLink Printable License

5/29/16, 21:20

**WOLTERS KLUWER HEALTH LICENSE
TERMS AND CONDITIONS**

May 29, 2016

This Agreement between Julie A Bulson ("You") and Wolters Kluwer Health ("Wolters Kluwer Health") consists of your license details and the terms and conditions provided by Wolters Kluwer Health and Copyright Clearance Center.

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Number of figures/tables/illustrations	1
The ID numbers of the figures/tables/illustrations are...	evidence hierarch pyramid figure 5.2
Will you be translating?	no
Reusing current or a previous edition	current edition
Circulation/distribution	50
Order reference number	None
Title of your thesis / dissertation	Will Implementation of an Advance Care Planning Program Increase Patient / Advocate Satisfaction with End of Life
Expected completion date	Dec 2016
Estimated size (number of pages)	120
Requestor Location	Julie A Bulson 1908 8th st NW


GRAND RAPIDS, MI 49504

Appendix G

Permission to use Chronic Care Model

Copyright Clearance Center

5/31/16, 19:42



Note: Copyright.com supplies permissions but not the copyrighted content itself.

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Order Date: 05/31/2016

Payment Information

Julie Bulson
brownja@mail.gvsu.edu
+1 (616)7910475
Payment Method: n/a

If you paid by credit card, your order will be finalized and your card will be charged within 24 hours. If you choose to be invoiced, you can change or cancel your order until the invoice is generated.

Order Details

Effective clinical practice : ECP

<p>Order detail ID: 69800270 Order License Id: 3879601277006 ISSN: 1099-8128 Publication Type: Journal Volume: Issue: Start page: Publisher: AMERICAN COLLEGE OF PHYSICIANS Author/Editor: American College of Physicians-- American Society of Internal Medicine ; Alliance of Community Health Plans</p>	<p>Permission Status: ✔ Granted Permission type: Republish or display content Type of use: Thesis/Dissertation</p> <p>Requestor type: Author of requested content</p> <p>Format: Print, Electronic</p> <p>Portion: image/photo</p> <p>Number of images/photos requested: 1</p> <p>Title or numeric reference of the portion(s): Chronic Care Model</p> <p>Title of the article or chapter the portion is: Chronic disease management: what will it</p>
---	---

Appendix H

Email Permission Supporting use of Burke and Litwin Causal Model

From: "permissions (US)" <permissions@sagepub.com>
Subject: RE: Burke Litwin Causal Model
Date: April 1, 2016 at 13:31:55 EDT
To: "Julie Bulson" <brownja@mail.gvsu.edu>

Dear Julie,

Thank you for that information. You can consider this email as permission to use the material as detailed below in your upcoming scholarly project. Please note that this permission does not cover any 3rd party material that may be found within the work. You must properly credit the original source, *Journal of Management*. Please contact us for any further usage of the material, including republication.

Best regards,
Michelle Binur

Rights Coordinator

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USA

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From: Julie Bulson [mailto:brownja@mail.gvsu.edu] **Sent:** Friday, April 01, 2016 5:42 AM
To: permissions (US) **Subject:** Burke Litwin Causal Model

Thank you for your rapid response, this article was published in the Journal of Management 1992 18:523. Doi: 10.1177/014920639201800306. The article is "A Causal Model of Organizational Performance and Change" by Burke and Litwin.

Let me know if there is anything more I can do to assist.

Thank You,

Julie

On Thursday, March 31, 2016, permissions (US) <permissions@sagepub.com> wrote:

Dear Julie Bulson,

Thank you for your request. In order to proceed, we will need to know where the material originally was published (journal/book title, article/chapter title, author name, publication date, etc...). Once we have this information, we can further review your request.

Best regards,

Michelle Binur

Rights Coordinator

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From: Julie Bulson [<mailto:brownja@mail.gvsu.edu>] **Sent:** Thursday, March 31, 2016 12:36 PM **To:** permissions (US) **Cc:** julie bulson **Subject:** Burke Litwin Causal Model

Dear Sirs, I am in the final year of my Doctor of Nursing Practice program. I'm drafting my organizational assessment and would like permission to include a figure of the Burke Litwin Causal Model in my scholarly project.

I attempted to go to the Sage Publishing page and find the journal but was not able to locate it and therefore could not complete the RightsLink tool for permission.

Please advise.

Thank you,

Julie Bulson, MPA, BSN, RN

GVSU Alum '99 and '07

DNP student

Appendix I

Email approval for use of CFIR diagram and description table

From: **Damschroder, Laura** Laura.Damschroder@va.gov 
Subject: RE: [EXTERNAL] CFIR diagram
Date: September 28, 2016 at 09:50
To: Julie Bulson brownja@mail.gvsu.edu, VHAANN HSRD CFIR VHAANNHSRDCFIR@va.gov

Hello –

You have permission to use the CFIR diagram (see Slide 3). It's published in Additional File 1 with our 2009 paper. I've played around with other diagrams but this one (it's included in the attached power point document) is the classic version.

Good luck with your proposal!

Laura

From: Julie Bulson [mailto:bulsonj@mail.gvsu.edu]
Sent: Tuesday, September 27, 2016 7:09 PM
To: VHAANN HSRD CFIR
Subject: [EXTERNAL] CFIR diagram

I am using the CFIR for my DNP project and I'm looking for a diagram for the CFIR that I can include in my proposal as an appendix. If you have will you be willing to share it with me and then also an email approval to use the diagram in my project documents?

Thank you in advance for anything you can do for me.

Julie Bulson, MPA, BSN, RN, NE-BC
GVSU Alum '99 and '07
DNP student
email: bulsonj@mail.gvsu.edu



CFIR Summary Slides
Classic 2010.pptx

From: Damschroder, Laura Laura.Damschroder@va.gov
Subject: RE: [EXTERNAL] Description of the five CFIR domains...
Date: December 13, 2016 at 09:45
To: Julie Bulson brownja@mail.gvsu.edu



Yes, this is no problem.

L

From: Julie Bulson [<mailto:brownja@mail.gvsu.edu>]
Sent: Sunday, December 11, 2016 8:11 PM
To: Damschroder, Laura
Subject: [EXTERNAL] Description of the five CFIR domains...

Dr. Damschroder, I'm finding the need to also include the table titled "Description of the five CFIR domains and constructs within each domain" that we in your 2009 article. I would like to get permission from you to also add this to my final project. I've found that this table is a great way to assist the readers in understanding the framework just a little better.

Thanks,

Julie Bulson, MPA, BSN, RN, NE-BC
GVSU Alum '99 and '07
DNP student
email: brownja@mail.gvsu.edu

Appendix J
Research Exemption Letters



DATE: November 29, 2016

TO: Julie Bulson, MPA, BSN
FROM: Grand Valley State University Human Research Review Committee
STUDY TITLE: [981019-1] Evaluation of the Effects of Implementing an Evidence Based Advance Care Planning Program on Patient/Family Satisfaction with End of Life Care

REFERENCE #: 17-064-H
SUBMISSION TYPE: New Project

ACTION: NOT RESEARCH
EFFECTIVE DATE: November 29, 2016
REVIEW TYPE: Exempt Review

Thank you for your submission of materials for your planned research study. It has been determined that this project:

Does not meet the definition of covered human subjects research* according to current federal regulations. The project, therefore, *does not* require further review and approval by the HRRC.

Exempt protocols do not require formal approval, renewal or closure by the HRRC. Any revision to exempt research that alters the risk/benefit ratio or affects eligibility for exempt review must be submitted to the HRRC using the *Change in Approved Protocol* form before changes are implemented.

Any research-related problem or event resulting in a fatality or hospitalization requires immediate notification to the Human Research Review Committee Chair, Dr. Steve Glass, (616)331-8563 AND Human Research Protections Administrator, Dr. Jeffrey Potteiger, Office of Graduate Studies (616)331-7207. See HRRC policy 1020, Unanticipated problems and adverse events.

Exempt research studies are eligible for audits.

If you have any questions, please contact the Office of Research Compliance and Integrity at (616) 331-3197 or rci@gvsu.edu. The office observes all university holidays, and does not process applications during exam week or between academic terms. Please include your study title and reference number in all correspondence with our office.

*Research is a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge (45 CFR 46.102 (d)).

**SPECTRUM HEALTH**

Human Research Protection Program
Office of the Institutional Review Board
100 Michigan NE, MC 038
Grand Rapids, MI 49503
616.486.2031
irb@spectrumhealth.org
www.spectrumhealth.org/HRPP

NON HUMAN RESEARCH DETERMINATION

December 1, 2016

Julie Bulson MPA, BSN
Spectrum Health
100 Michigan St. NE
Grand Rapids, MI 49503

SH IRB#: **2016-294**

PROTOCOL TITLE: Evaluation of the Effects of Implementing an Evidence Based Advance Care Planning Program on Patient/Family Satisfaction with End of Life Care

Dear Ms. Bulson,

On December 1, 2016, the above referenced project was reviewed. It was determined that the proposed activity does not meet the definition of research as defined by DHHS or FDA.

Therefore, approval by Spectrum Health IRB is not required. This determination applies only to the activities described in the IRB submission and does not apply if changes are made. If changes are made and there are questions about whether these activities are research involving human subjects, please submit a new request to the IRB for a determination.

A quality improvement project may seek publication. Intent to publish alone is insufficient criterion for determining whether a quality improvement activity involves human subject research. However, please be aware when presenting or publishing the collected data that it is presented as a quality improvement project and not as research.

Please be advised, this determination letter is limited to IRB review. It is your responsibility to ensure all necessary institutional permissions are obtained prior to beginning this project. This includes, but is not limited to, ensuring all contracts have been executed, any necessary Data Use Agreements and Material Transfer Agreements have been signed, documentation of support from the Department Chief has been obtained, and any other outstanding items are completed (i.e. CMS device coverage approval letters, material shipment arrangements, etc.).

Your project will remain on file with the Office of the IRB, but only for purposes of tracking research efforts within the Spectrum Health system. If you should have questions regarding the status of your project, please contact the Office of the IRB at 616-486-2031 or email irb@spectrumhealth.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Jeffrey Jones".

Jeffrey Jones MD
Chair, Spectrum Health IRB