**Research Article**

**Academic-Practice Partnership Promotes Student Engagement in Palliative Care**

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**Abstract**

**Background:** The novel coronavirus disease 2019 (COVID-19) pandemic highlighted the importance of advance care planning and discussion about goals of care prior to serious acute illness. Many coronavirus patients died without significant others present, leaving end of life decisions in the hands of nurses who were at the bedside during patients’ final moments. Thus, sit is imperative that nurses are comfortable and competent in having advanced care planning and end of life care conversations. Nursing students have very little knowledge and practice with having these essential conversations with patients and their families.

**Objective:** The overall objective was to explore the impact of an academic/practice partnership intervention on nursing students’ attitudes towards communication skills and attitudes towards caring for patients at the end of life.

**Design:** This project used a pretest- posttest design.

**Setting:** University classroom setting of a BSN program and a local hospital clinical setting.

**Participants:** A sample of 145 students from the BSN program; 68 enrolled in the first semester, 42 in the third semester, and 35 in the fourth semester of a BSN nursing program.

**Methods:** Multiple imputations by using Multivariate imputation were used to analyze data. For each response variable, the imputation was performed thirty times using PROC MI procedure in SAS 9.4 statistical software. After imputations, to evaluate the effects of independent variables on survey scores, linear regression was used using PROC MIXED procedure in SAS.

**Results:** Changes were noted in overall scores of student’s attitudes toward communication and caring for the dying.

**Conclusions:** Academic and practice partnerships can increase the awareness and use of resources available for teaching in the classroom and clinical settings to increase the comfort levels of nurses on the front lines as they care communicate and care for patients facing advanced care planning decisions.

**Keywords:** Academic Practice Partnerships;Nursing Education; Palliative Care

**Background**

Advanced Care Planning (ACP) has been identified as an essential component in providing quality healthcare [1]. Advanced care planning is critically important to be sure a patient's needs are met. Many may find themselves in situations where they are unable to make their own decisions for end-of-life care, leaving clinicians and family members in situations of trying to guess the person’s wishes. The ACP process should center on having conversations with family members and clinicians about advanced care decisions, including palliative care [1]. The novel coronavirus disease 2019 (COVID-19) pandemic highlighted the importance of advance care planning and discussion about goals of care prior to serious acute illness. The COVID-19 pandemic placed tremendous stress on healthcare systems. One important element to the best possible response to the pandemic was to “ensure clinicians have high-quality discussions both about advanced care planning for individuals in the community, especially those of older age and with chronic illness, and about goals of care with patients or their families when patients have illness that requires hospitalization” [2]. While 92% of Americans say that talking with their loved ones about end-of-life care is important, only 32% have done so [3].

Of all healthcare professionals, nurses spend the most time with the patient and family [4]. The pandemic revealed the significance of the need for advanced care planning conversations. Many coronavirus patients died without significant others at the bedside, leaving comfort measures and end of life decisions in the hands of the nurses who were at the bedside during patients’ final moments. Advanced care planning is a wayto help respect patient’s wishes by ensuring they receive the types of comfort measures and treatment plans they desire at the end of life. Thus, it is imperative that nurses are competent in talking with patients and families about decisions and palliative care options for care when serious illness is diagnosed. Many nurses and nursing students have very little knowledge and practice with having essential conversations with patients and their families. This issue is present even among nurses who have a high frequency of interacting with patients and families about end-of-life topics such as palliative care. The purpose of this article is to describe an academic-practice partnership to promote palliative care conversations in the acute care setting.

Palliative care is a multidisciplinary approach that typically encompasses dealing with a patient upon a terminally ill or serious illness diagnosis and through the treatment process to comfort and improve symptoms [5]. The National Hospice and Palliative Care Organization (NHPCO) [6] utilizes the National Consensus Project’s definition of palliative care. Palliative care is “patient and family-centered care that optimizes quality of life by anticipating, preventing, and treating suffering. Palliative care throughout the continuum of illness involves addressing physical, intellectual, emotional, social, and spiritual needs and to facilitate patient autonomy, access to information and choice” (2019, para 1).

Palliative care teams work with the patient, family, and patient’s other doctors to provide support for optimal quality of life [7]. Integrating palliative care content into and threading this content throughout nursing curricula is supported by the American Nurses Association (ANA) [8] and the Hospice & Palliative Nurses Association (HPNA) who together published a joint report, *Call for Action: Nurses Lead and Transform Palliative Care* [9]. Palliative care is considered one aspect of providing evidenced based practice that will assure our population receives the highest possible quality of care throughout the lifespan [10].

According to Schroeder and Lorenz [11], nurses spend more time with patients and families than any other health professional as they face serious illness. Collectively, nurses have demonstrated a commitment to palliative care, with some nurses showing even greater initiative by focusing their practice on the treatment of end-of-life patients. Nurses and nursing care providers provide the most direct care to patients at the end of life. The COVID-19 pandemic visitor restrictions have created an environment where nurses on the front lines are the only ones present at the bedsides of the dying. Yet, evidence indicates that many feel ill-prepared for the complexity of palliative care [12]. Palliative and end of life care is not thoroughly explored in most nursing programs, leaving new healthcare professionals unprepared for these situations [13]. The curricula of undergraduate nursing programs lack education in palliative and end-of-life care. If the topic is covered, it is generally within isolated lectures and rarely as a full course. According to Hermann CP, et al. [14], interprofessional collaboration leads to better health outcomes. The authors state although interprofessional educational experiences are important to prepare nurses to communicate effectively, there have been few successful projects for nurse educators to use as models. With the growing demand for nursing competence in palliative care, curricula must adapt to also place emphasis on this important topic [15]. Therefore, opportunities for incorporation of palliative care education into undergraduate Bachelor of Science in Nursing (BSN) curricula are important to consider. Research has demonstrated that patients facing serious, life-limiting illnesses and their families benefit from receiving palliative care [8]. The literature revealed examples of educational projects that are designed to help nurses and nursing students communicate effectively and compassionately with patients and their families regarding palliative care. Results of these studies indicated nurses have an increased level of confidence in the ability to convey a caring attitude and develop a caring relationship through communication through participation in such projects [4,13,15,16,17,18]. Many of these projects were either online courses or simulated experiences. Scant literature exists regarding narrative interventions to assist providers in communication [18].

This research is the result of an academic-practice partnership between the university's traditional BSN program and a hospital’s palliative care/ethics team. The hospital’s palliative care team contracted with Dr. Angelo Volandes to use short videos to introduce patients/families to palliative care. The university nursing department was granted access to the videos to use them in the class and clinical settings to increase student knowledge of palliative care and allow the students to practice communication skills surrounding this topic. Students also had the opportunity to initiate the same video intervention in the clinical setting based on the availability of patients/families with palliative care consults.

The hypothesis was that educating nursing students in each semester through practical clinical experiences involving patient interaction, palliative care videos, as well as didactic education would enhance and impact their understanding of the importance of palliative care and potentially improve their communication attitudes and attitudes toward caring for the dying. Prior to initiation, the project was approved by the Institutional Review Boards for the university and hospital.

**Intervention**

The local hospital purchased a set of videos created by Angelo Volandes, M. D., M.P.H., a professor at Harvard Medical School and internist at Massachusetts General Hospital.

According to Klein [19] the videos deliver educational messages about various health conditions and show patients undergoing life-sustaining procedures. The videos help patients understand that receiving intensive care at the end of life may not produce the results they seek. Extensive research has been conducted to determine the impact of the videos on patients’ preferences showing those who view the videos have a better understanding of their disease and associated success of various interventions than those who receive this information only from verbal explanation [20,21,232. These videos are now used in more than 35 large health systems nationally through the nonprofit organization, Advanced Care Planning Decisions, for a nominal cost. A clinician must be present when a patient views one of the videos in order to be sure there is a follow up discussion [19].

For the current study, the video “What is Palliative Care?” was chosen to be shown both in class to students and in the clinical setting to patients and families. The video was introduced to three cohorts of nursing students throughout the curriculum. All students in each cohort were invited to participate. Consent was obtained from those students who agreed to participate.

Participation was voluntary and had no effect on the course grades. After consent was obtained, a pre-survey was conducted to determine baseline scores. Cohort 1 was first introduced to the topic in fall semester during the Professional Nursing Practice course, then again in spring semester in the Adult Health I Nursing course. This same cohort was exposed again in year 2 in the fall semester in the Community Health Nursing course. Cohort 1 received the most exposure as it occurred over 3 semesters. Cohort 2 was first introduced to the topic in spring semester during the Community Health Nursing course. Then in year two this same cohort received exposure in fall semester in Adult Health Nursing II course and the Leadership Capstone course.

Cohort 3 students received the least amount of exposure and were introduced to the videos in spring during Adult Health II and in the Leadership and Management Capstone course. The video watched by both students in the classroom and patients and families in the hospital was entitled, “What is Palliative Care". In addition to the “What is Palliative Care” video, other videos shown were based on what disease process the patient had and the content covered in class.

The class educational content layout was as follows:

**Junior 1:** Intro to Professional Nursing; video shown in class, class content included Overview of Dying in America [23], The Conversation Project, palliative communication, ethical decision making, and Video Discussion Aids to Promote Advance Care Planning [24]. Case studies were reviewed and communication techniques were practiced in class.

**Junior 2:** Adult I; video shown in class. Students who were in clinical at the clinical partner site, showed the video “What is Palliative Care” to at least one patient who had a palliative care consultation in collaboration with a palliative care team member when available. Students had the opportunity to show the video to selected patients/families and be present when a member of the Palliative Care Team had the conversation with the family.

**Senior 1:** Community Health; video shown in class, students – paired with home health nurses who request palliative care consult. Show the video “What is Palliative Care” to at least one patient, if appropriate. Went to the home with the palliative care team for the family meeting and conversations if possible.

**Senior 2:** Adult II and Leadership; video shown in class. Students who were in clinical at the clinical partner site, showed the video “What is Palliative Care” to at least one patient who had a palliative care consultation in collaboration with a palliative care team member when available. Students had the opportunity to show the video to selected patients/families and be present when a member of the Palliative Care Team has the conversation with the family. Complete post survey at the end of the semester (Table 1).

|  |  |  |  |
| --- | --- | --- | --- |
| **Cohort** | **Fall 2018** | **Spring 2019** | **Fall 2019** |
| Junior 1 Cohort 1 | NURS 3103- Professional Nursing \*Consent all students \*Conduct Pre-Survey \*Show: Video in class \*Conduct Post-Survey |  |  |
| Junior 2 | NURS 3107 – Adult Health I | \* Show: Video 1st week of class. \*Implement Intervention in Clinical Setting \*Conduct Post-Survey |  |
| Senior 1 Cohort 2 | NURS 4110 - Community | \*Consent all students \*Conduct Pre-Survey \*Show:” What Is Palliative Care?” Video 1st week of class. \*Implement Intervention in Clinical Setting \*Conduct Post-Survey | \*Show:” What Is Palliative Care?” Video 1st week of class. \*Implement Intervention in Clinical Setting \*Conduct Post-Survey |
| Senior 2 Cohort 3 | NURS 4111- Adult Health II | \*Consent all students \*Conduct Pre-Survey \*Show: Video 1st week of class. \*Implement Intervention in Clinical Setting in consult with Palliative Care Team \*Conduct Post Survey | \*Show:” What Is Palliative Care?” Video 1st week of class. \*Implement Intervention in Clinical Setting in consult with Palliative Care Team \*Conduct Post Survey |
| Senior 2 | NURS 4112- Leadership | \*Show:” What Is Palliative Care?” Video 1st week of class. \*Implement Intervention in Clinical Setting in consult with Palliative Care Team \*Conduct Post Survey | \*Show:” What Is Palliative Care?” Video 1st week of class. \*Implement Intervention in Clinical Setting in consult with Palliative Care Team \*Conduct Post Survey |

**Table 1:** Implementation Design.

**Methods**

**Aim and Objectives**

This article presents the academic/practice partnership designed to enhance student comfort with communication about palliative care and patient/family wishes for dealing with serious illness. The overall objective was to explore the impact of the intervention on nursing students’ attitudes towards communication skills and attitudes toward caring for patients at the end of life. The specific research questions were as follows:

Was there a change in student attitudes about comfort in communication with patients/families?

Was there a change in student attitude toward the care of the dying?

Was there a difference among the students with three semesters of exposure regarding attitudes about communicating with end-of-life patients?

**Design**

This project used a pretest- posttest design. All students who consented were surveyed at the beginning of the study to obtain a baseline and then again at the end of each semester. The intervention included class and clinical experiences with conversations about palliative care.

Students in the three different cohorts of the BSN program were surveyed. During class time in the first semester, students were introduced to The Conversation Project [3], palliative care communication, ethical decision making, and Video Discussion Aids to Promote Advance Care Planning [24]. They reviewed case studies and practiced communication in class. In the second and third semesters, students watched the video “What is Palliative Care” [24]. Students who had clinical rotations at the participating hospital were able to show the video “What is palliative care” to a patient/family who had a palliative care consultation ordered. This process was in collaboration with a staff nurse or faculty member present. The students had a brief script they followed to introduce the material.

**Population and Sample Selection**

A sample of 145 students from the BSN program consented and completed the pre- survey. Of the 145 students, 68 were enrolled in the first semester, 42 in the second semester, and 35 in the fourth semester of the four-semester nursing program. Participation post survey response rates decreased throughout the study and varied among classes.

**Statistical Methods**

Many participants at the second time point of the evaluation did not respond to the survey, therefore, the multiple imputation method was adopted to handle the missing data in response variables PAS, NAS and FATCOD. The performance of the multiple imputation has been studied intensively in literature and has shown to perform favorably [25,26,27]. In addition to this, multiple imputations method can account for the statistical uncertainty in the imputations as opposed to single imputation [28]. In this paper, we carried out the multiple imputations by using Multivariate imputation by chained equations (MICE), sometimes referred as “Full conditional specification (FCS)”. As we have variables of varying type (e.g. continuous and categorical), the multiple imputations by MICE performs better than MCMC Multiple imputations [29]. For each response variable, the imputation was performed thirty times using PROC MI procedure in SAS 9.4 statistical software. After imputations, to evaluate the effects of independent variables on PAS, NAS and FATCODE, we used linear regression by using PROC MIXED procedure in SAS. Furthermore, the results from these analyses were combined by using PROC MIANALYZEto form one inference for each peach procedure.

**Measures**

**Communication Skills and Attitude Scale (SCAS)**

Communication Skills Attitude Scale (CSAS) was used to establish baseline student’s attitudes [30] and repeated as a post-test at the end of each semester. The SCAS is a 26-item questionnaire designed to assess the attitude about communication skills. The instrument is divided into positive attitude scale questions (PAS) and negative attitude scale (NAS) questions, measured on a 5-point Likert scale. It is one of the most widely used scales for measuring communication skills among health care professionals [31].

**Frommelt Attitudes Toward Care of the Dying Scale (FATCOD) Form B**

The Frommelt [32] Attitudes Toward Care of the Dying Scale (FATCOD) Form B is a 30-item scale designed to measure attitudes toward caring for dying patients. All items are measured on a 5-point Likert scale. It has been widely used in health care education and clinical settings [33]. The FATCOD was used to establish baseline student’s attitudes and repeated as a post-test at the end of each semester.

**Results**

(Table 2,3) below summarizes the number of respondents for each cohort and their response rates. It can be observed that most students responded to the first survey, but most of them did not respond to the second evaluation time point.

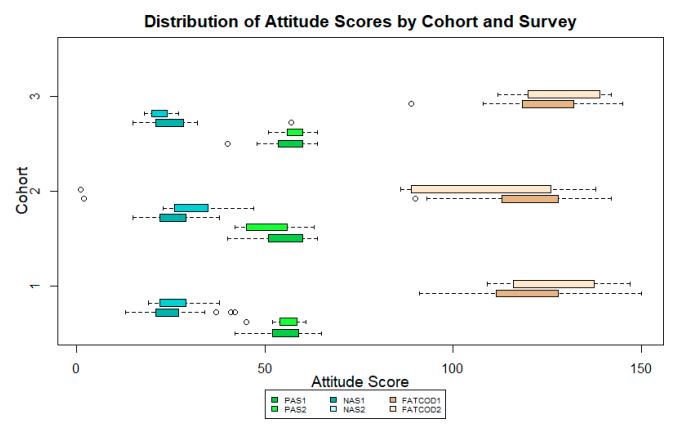
|  |  |  |  |
| --- | --- | --- | --- |
|  | N | Survey 1 (response rate) | Survey 2 (response rate) |
| Cohort 1 | 75 | 68 (90.7 %) | 16 (21.3 %) |
| Cohort 2 | 60 | 42 (70.0 %) | 10 (16.7 %) |
| Cohort 3 | 43 | 35 (81.4 %) | 10 (23.3 %) |

**Table 2:** Number of participants and response rates by cohort and time point.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | PAS (Mean ± SD) | | NAS (Mean ± SD) | | FATCOD (Mean ± SD) | |
|  | Survey 1 | Survey 2 | Survey 1 | Survey 2 | Survey 1 | Survey 2 |
| Cohort 1 | 55.1 ± 5.5 | 55.8 ± 4.0 | 25.0 ± 5.9 | 55.8 ± 5.3 | 119.8 ± 12.2 | 126.9 ± 12.2 |
| Cohort 2 | 54.5 ± 6.2 | 50.1 ± 7.2 | 25.4 ± 4.9 | 31.2 ± 7.4 | 117.3 ± 22.2 | 100.0 ± 39.0 |
| Cohort 3 | 56.1 ± 5.2 | 57.5 ± 4.0 | 25.0 ± 7.3 | 22.2 ± 2.9 | 125.2 ± 11.3 | 129.2 ± 10.7 |

**Table 3:** Descriptive Statistics for the PAS, NAS and FATCOD by cohort and time point.

(Figure 1) demonstrates that there is not an observable change in PAS and NAS scores in different survey time points. Furthermore, there is not an obvious change in Attitude Scores when comparing different cohorts with the only exclusion of FATCOD. Cohort 3 has higher FATCOD scores compared to the two other cohorts.



**Figure 1:** The plot above displays the distribution of Attitude score by Cohort and Time of taking the survey.

From the table below (Table 4), it can be observed that the majority of responders are Female (86.1% in Cohort 1, 86.2% in Cohort 2 and 92.1% in Cohort 3). The age groups are balanced by cohort, while almost all of the respondents from Cohort 1 are Juniors and from Cohort 2 and 3 are Seniors.

|  |  |  |  |
| --- | --- | --- | --- |
|  | Cohort 1 | Cohort 2 | Cohort 3 |
| Gender |  |  |  |
| Male | 10 (13.9) | 8 (13.8) | 3 (7.9) |
| Female | 62 (86.1) | 50 (86.2) | 35 (92.1) |
| Age |  |  |  |
| 18-27 years | 57 (79.2) | 31 (53.5) | 22 (57.9) |
| 28-65 years | 15 (20.8) | 27 (46.5) | 16 (42.1) |
| Semester |  |  |  |
| Junior | 71 (95.8) | 0 (0.0) | 0 (0.0) |
| Senior | 1 (1.4) | 58 (100.0) | 38 (100.0) |

**Table 4:** Distribution of demographic variables in each of the cohorts.

(Table 5) displays the estimates of the effect of cohort, survey (time point of taking survey), gender, age, and semester on each of the attitude scores. We can see that the data fail to show that there is a significant change in any of the attitude scores over time. In addition, there is no significant difference by gender and semester in the attitude scores.

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | PAS |  |  |  | NAS |  |  |  | FATCOD |  |  |  |
|  | β |  | CI 95% | P value | β |  | CI 95% | P value | β |  | CI 95% | P value |
| Intercept | 56.1 | 53.6 | 58.5 | 0.0001 | 24.6 | 21.9 | 27.2 | 0.0001 | 127.1 | 118.5 | 135.6 | 0.0001 |
| Cohort 1† | 1 | -6.5 | 0.78 | 0.78 | -4.7 | -12.7 | 3.3 | 0.25 | -0.8 | -25.7 | 24.1 | 0.95 |
| Cohort 2† | -2.8 | -5.2 | -0.3 | 0.03\* | 1.9 | -0.8 | 4.5 | 0.16 | -10.9 | -18.3 | -3.5 | 0.04\* |
| Survey§ | 0.6 | -1.7 | 2.9 | 0.61 | -1.7 | -3.8 | 0.5 | 0.13 | 1.2 | -5.1 | 7.5 | 0.71 |
| Gender¶ | -1.7 | -4.5 | 1.1 | 0.22 | 2.5 | -0.6 | 5.5 | 0.11 | -2.4 | -10.9 | 6.1 | 0.57 |
| Age†† | -0.4 | -2.1 | 1.3 | 0.64 | 2.2 | 0.1 | 4.3 | 0.04\* | -4.2 | -9.7 | 1.4 | 0.14 |
| Semester¶¶ | -1.7 | -8.8 | 5.5 | 0.64 | 4.4 | -3.1 | 11.9 | 0.24 | -2.1 | -24.6 | 20.8 | 0.85 |
| \*Significant at 0.05 level  †Reference category is cohort 3  §Reference category is second time point  ¶Reference category is Female  ††Age 18-27 years vs 28-65 years which is reference category  ¶¶Junior vs senior which is reference category | | | | | | | | | | | | |

**Table 5:** Effects of predictor variables in the attitude scores.

There is a significant effect of cohort in the attitude scores. Specifically, students from cohort two have 2.8 units lower PAS compared to cohort three (p value=0.03). A significant effect is observed in FATCOD scores too. Students from cohort two have FATCOD scores 10.8 units lower than the students in cohort three. A significant effect is observed when comparing NAS between age groups 18-27 years old and 28-64 years old. Younger nursing students have 2.5 units higher NAS compared to students that belong to the 28-64 years old category.

**Discussion**

The recent COVID-19 pandemic has re-emphasized the importance of the topic of palliative care and how it is crucially important for health care deliverers to have conversations about advanced care decisions. Identifying which interventions facilitate improved communication skills and increased comfort levels of nursing students when discussing advanced care planning topics are imperative in illuminating the path to discovering how toimprove nurses comfort levels and attitudes toward caring for the dying.

Our study showed that among the factors taken into consideration, gender did not have a significant effect on change in comfort scores. NAS scores showed higher scores among younger participants. There was not a significant difference when comparing comfort scores immediately before and after receiving the intervention. However, cohort had a significant effect depending on the cohort number (cohort two and three have a significant difference, where students from cohort two had on average worse comfort scores compared to those from cohort 3).

The study could not establish the effect of Semester (comparing junior vs senior students) on comfort scores. There are multiple factors that may have influenced this, among which there can be mentioned the fact that scores did not change significantly over time (no matter the intervention, there was not a significant change in the scores as the intervention was being applied). Another reason may be due to the failure by the study participants to complete all the surveys, which means that it cannot be determined what the effect of intervention was on comfort scores after receiving it.

Referring to the original research questions posed by this study: 1) Was there a change in student attitudes about comfort in communication with patients/families? Yes, there was a change in the overall scores of students’ attitudes towards communication. The younger students showed an increase in negative attitude scores regarding comfort in having conversations with patients. Overall, CAS scores were higher in Cohort 3.

2) Was there a change in student attitude toward the care of the dying? Yes, there was a change in the overall scores of students’ attitudes towards caring for the dying. The most significant changes were noted in cohort 3, which were senior 2 level students. These students were in their last semester of nursing school. Perhaps the differences in scores could be attributed to more clinical and patient care experience and more class time discussion of the subject matter. 3) Was there a difference among the students with three semesters of exposure regarding attitudes about communicating with end-of-life patients? This question was unable to be answered with data collected.

Overall, educating nursing students through practical clinical experiences involving patient interaction, palliative care videos, as well as didactic education improved their communication attitudes and attitudes toward caring for the dying. Academic-practice partnerships to promote palliative care conversations in the acute care setting could be one way to increase nurse’s communication skills and comfort levels with having the conversation with patients, families and improving their attitudes when caring for the dying.

**Limitations**

This study was limited by the number of palliative care consult patients available in the clinical setting during the time of the study. Few students had the opportunity to show the video in the clinical setting in large part due to the lack of participation of the nurses in the clinical setting. Prior to beginning this study, the clinical practice partner had voiced a lack of use of the video resources by the nurses on the units despite having the necessary support of the Ethics Team and availability of the technological equipment.

**Conclusion**

The results of the study could impact how faculty at universities teach students in health professions programs about palliative care. Collaborative partnerships between nursing academia and clinical facilities such as the one presented in this study could provide greater feedback on how hospitals and academia could utilize resources to result in better patient outcomes through conversations. Future studies could identify the best approach and which interventions nurse educators could implement to prepare students on how to comfortably approach the subject with patients and how to be a patient advocate on the topic of palliative care. Patients could benefit by having these important conversations earlier on in their diagnosis or prior to their hospital stay. Increasing awareness of important topics such as “What is Palliative Care” will allow patients to get a better understanding of how to approach their illness, what to expect as time goes on, and make better informed decisions on health care. With a broader goal, the hope is that over time, academic and practice partnerships will continue. Together, these partnerships can increase the awareness of and use of resources available from organizations for use in the classroom and clinical settings which will in turn increase the comfort levels of nurses on the front lines as they care for patients facing end of life. Now more than ever new graduate nurses and seasoned nurses need to be comfortable having end of life and advanced care planning conversations. This will help ensure patient’s wishes for end-of-life care are both clear and implemented when the time comes.

**Declared Conflict of Interest**

This research did not receive any funding from special agencies in the public, commercial, or non-profit sector

**Ethical Approval**

This study was reviewed and approved by the University Institutional ReviewBoard (Reference # H19015 ) and has been performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendment.

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