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Effects of multidimensional vs. functional health literacy educational interventions on standardized patient-nurse interactions: A feasibility study

by

Kempa S. French

A dissertation submitted to the faculty of the Medical University of South Carolina in partial fulfillment of the requirement for the degree of Doctor of Philosophy in Nursing in the College of Graduate Studies.

College of Nursing

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Table of Contents

Acknowledgements

"Here I raise my Ebenezer (stone of help), hither by thy help I have come" Samuel

I Samuel 7:12

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Abstract

Background. Patients with limited health literacy (HL) are use fewer preventive services, access more emergent care and report poorer health outcomes than those with adequate literacy. Nurse have little consistent preparation to use HL competencies in practice, thus exacerbating risks for miscommunication and harm with patients of diverse literacy levels.
Purpose. The purpose was crafting educational interventions to compare effects of two contrasting theoretical approaches on HL practice uptake including initial assessments of a HL competencies tool.
Problem/Aims. For nine nurses and nursing faculty, did use of multidimensional versus functional HL educational strategies lead to changes in HL knowledge and HL- related behaviors in recorded standardized patient- nurse interactions? The four aims were to develop the Health Literacy Patient-Nurse Interaction Competencies Evaluation or HLP-NICE tool, craft two contrasting HL curricula and teaching approaches, evaluate intervention effects on HL knowledge and HL-related behaviors of participants, and then identify future research directions.
Design/Theoretical Basis. A sequential mixed methods feasibility study design compared effects of the contrasting implementations on HL knowledge and HL-related behavior changes of the nine randomly assigned participants. Zarcadoolas, Pleasant & Greer's multidimensional HL theoretical framework was integrated through HLP-NICE items and multidimensional teaching activities
Procedures. Preliminary qualitative case study methodology shaped standardized patient, teacher and HLP-NICE development through individual cognitive, focus group and expert panel interviews. A quantitative two group between subjects design assessed study feasibility. HL experiences and changes in HL knowledge were based on the Health Literacy Knowledge and Experiences Survey or HLK-ES scores. Kalamazoo Essential Elements Communication Competencies-Adapted or KEECC-A and HLP-NICE ratings evaluated communication and HL-related behavior changes.
Findings. HL knowledge did not increase overall for participants, nor was prior HL educational experience associated with HL knowledge gains. Increases in communication and HL-related behaviors were noted for both groups, although functional group gains were greater for KEECC-A communication ratings. Study implementation was feasible for enhancing short-term HL– related behavior changes although challenges existed in recruitment.
Conclusions. Improving acceptability for participation, creating additional standardized HL training resources, enhancing educational strategies and strengthening HLP-NICE psychometric support is warranted to advance HL integration in nursing educational and clinical practice.

Keywords: Health literacy (HL), functional, multidimensional, experiences, knowledge, HL-related behaviors, nursing competency, nursing education, nursing practice, standardized patient (SP)

Effects of multidimensional vs. functional health literacy educational interventions on standardized patient-nurse interactions: A feasibility study

A person's literacy level has been linked to their health status (Berkman et al., 2010) and well-being (Sudore, 2006), which has driven increases of health literacy (HL) research over the last three decades to examine relationships between literacy, health outcomes and literacy-related interventions (Berkman et al., 2010). The *National Action Plan to Improve Health Literacy*, a national framework of seven HL-related goals and interventions, was created to mitigate the negative health consequences of limited literacy (US DHHS-ODPHP, 2010). The plan recommended adoption of Universal Health Literacy Precautions principles of active listening, tailoring messages to patient preferences, confirming patient understanding through teach back, and providing a shame-free environment by all health system stakeholders. While the bulk of U.S. HL research and provider approaches have emphasized text-based interventions and patient literacy screening (Barry et al., 2013) less HL research has documented the influence of provider health-literacy based HL and communication practices on patient comprehension, level of engagement or health outcomes. A recent consensus study has proposed HL educational competencies and HL-related practices for health professionals (Coleman, Hudson & Maine, 2013) as an initial step to address gaps between provider educational preparation and clinical practice application. These competencies may be useful for evaluation of differing HL theoretical and pedagogical strategies for all health provider education, including nursing educational practice. The overarching question for this dissertation is as follows: Are current nursing educational curricula, didactic content and clinical experiences the most effective

educational approach for preparing baccalaureate nurses to practice HL competencies aligned with Universal Health Literacy Precautions and professional nursing standards?

Purpose

The purpose of this dissertation was to answer the overarching question by exploring contrasting HL theoretical approaches and evidence for implementation of Universal Health Literacy Precautions, by identifying the current status of HL competencies in nursing educational practice, and using identified gaps to create and test contrasting HL teaching interventions for promising trends in HL knowledge and HL-related behaviors. Given the minimal research into nursing HL competencies development, a rational and detailed comparison of the effects of multidimensional and functional health literacy on essential nursing health literacy competencies warranted further exploration. The research question was as follows: In a sample of recently graduated baccalaureate nurses and nursing faculty, does multidimensional versus functional health literacy educational strategies lead to significantly different outcomes of health literacy knowledge and health-literacy related behaviors, as seen in recorded standardized patient-nurse interactions?

To answer this question, the following four aims were addressed.

Aim 1. Develop and assess the Health Literacy Patient-Nurse Interaction Competencies Evaluation or HLP-NICE tool for psychometric signals of multidimensional and functional health literacy competencies seen in:

a. interrater reliability levels for Cohen's kappa (κ) of 0.4 or greater for ratings by the 2 standardized patients (SP) when using the HLP-NICE,
b. internal reliability using Cronbach's alpha (α) of 0.60 or greater,

c. content and construct validity from health literacy and nursing education stakeholder opinions, and
d. pre- and post-intervention convergent validity comparison with the Kalamazoo Essentials Evaluation Communication Competencies-Adapted or KEECC-A (Rider & Nawotniak, 2010).

Aim 2. Develop and refine two health literacy curriculum interventions exemplifying multidimensional versus functional theoretical perspectives with pre-intervention assessments from external stakeholders and post-intervention process evaluation modifications from the teacher-interventionist and external stakeholders.

Aim 3. Assess the effects of multidimensional versus functional health literacy teaching curriculum interventions on two randomly assigned groups consisting of 10 recently graduated baccalaureate nursing students and 10 nurse educators by comparing graduate nurse and faculty pre-intervention recall of prior health literacy experiences using the Health Literacy Experiences Survey (Cormier & Kotrlik, 2009) and post-intervention changes in:

a. health literacy knowledge scores using the Health Literacy Knowledge Survey (Cormier & Kotrlik, 2009) from nurse-participant self-report,
b. communication competency scores using the Kalamazoo Essentials Evaluation of Communication Competencies-Adapted or KEECC-A Instrument (Rider & Nawotniak, 2010) from standardized-actor ratings of nurse participants, and
c. health literacy-related behavior scores using the newly-developed Health Literacy Patient-Nurse Interaction Competencies Evaluation or HLP-NICE observational

checklist supporting select consensus-based health literacy participant competencies as rated by standardized patient-actors.

Aim 4. Identify what further development and testing the HLP-NICE observational checklist needs through analysis of quantitative observations of participant health literacy-related competencies and qualitative cognitive interviews with standardized patients and external stakeholders.

Background

The most recent national survey of US literacy levels, the 2003 National Adult Assessment of Literacy Survey (NAALS), measured the reading proficiencies of randomly sample of 19,000 American adults over the age of 16, and which included completion of 40 of the available 152 health-related literacy items for the first time (Kutner et al., 2007). The results suggested that 75 to 80 million (36%) of Americans may have basic or below basic (one = *below basic* to four = *proficient*) literacy proficiency, and therefore may have difficulty in correctly following medication instructions or completing consent or insurance forms without additional assistance. Those groups at greater risk for limited literacy were more likely to be over the age of 65, affected with multiple co-morbidities or disabilities, entering school speaking a language other than English, or at lower economic levels. NAALS health literacy assessments were limited to written proficiencies and taken out of their natural context, which may have reduced their relevance for health-related verbal competencies. The health literacy questions did not account for cultural preferences (Andrulis & Brach, 2007), the effects of provider communication on medication adherence (Lemer et al., 2009) or evaluate comprehension of medical information by the participant (Castro, Wilson, Wang & Schillinger, 2007; Schillinger et al., 2003).

Americans with lower literacy proficiency may have trouble navigating the current health care system, but health knowledge difficulties are not restricted to those at risk for limited literacy or with inadequate access to health care. Functional-based literacy approaches may neglect the health information needs, preferences and perspectives of the remaining 64% percent of patients who have adequate or advanced reading levels. Patient literacy screening instruments such as the Single Literacy Item Survey were intended to foster a better match of patient literacy level and patient learning needs using easy–to-administer tools (Chew, Bradley & Boyko, 2004). Identifying limited literacy levels, however, may not account for the impact of provider communication barriers and the limitations of written materials used to supplement patient education.

Castro and colleagues (2007) noted when assessing observations of 74 diabetic patients with low literacy and their providers, that 81 % of visits included providers' use of medical jargon without additional explanations. Jargon was used an average of four times per visit and particularly when making recommendations (37%) or providing patient instructions (29%). Comprehension of identified medical jargon terms evaluated through telephone surveys indicated that the 19 contacted patients had difficulty grasping the meaning of previously discussed medical jargon regardless if the words were presented with or without contextual cues (Castro et.al, 2007, p. S90). Comparisons between self-reported provider effectiveness and patient perceptions of the same interaction between 19 physicians and 145 patients at a NY internal medicine ambulatory clinic suggested that providers with lower communication competency skills tended to overestimate both the effects of their patient education on patient comprehension of health information [OR 0.33 CI (0.18, 0.62), $p<0.001$] and their own effectiveness as communicators [OR 2.71, CI (1.90, 3.88), $p <0.001$] (Lukoschek, Fazzini, & Marantz, 2003).

Schwartzenberg and colleagues (2007) surveyed the health literacy practices of 168 physicians, nurses and pharmacists. Those who participated reported the recent use of plain language, handing out written materials, and speaking slowly more often than recommended health literacy standards such as ensuring patient comprehension through teach-back and tailoring written materials to the patient. Nurses may also shortchange patients with adequate or high literacy levels by assuming that those patients can understand and apply complex and potentially unfamiliar medical concepts to their personal health situations. Nurse's health literacy awareness or assessments of patient literacy-related behavioral cues (Dickens, Lambert, Cromwell & Piano, 2013) also may not be most accurate when educating patients without confirmation of patient existing knowledge levels, learning preferences or major concerns. Dickens and colleagues (2013) described these disparities when comparing the screened literacy levels of 65 patients hospitalized for CHF and 30 nurses caring for them on two inpatient cardiac units. There was little agreement between the patient's Newest Vital Sign (Osborne et al., 2007) and SILS (Chew, Bradley & Boyko, 2004) screening results and the nurses' informal literacy assessments (Cohen's $\kappa = 0.09$). Over- or underestimation of literacy levels may lead nurses to assume that patients fully understand health instructions or that patient knowledge needs are met without additional confirmation.

According to these findings, provider knowledge about limited health literacy or literacy-related behavioral cues may not be the most reliable guide for HL and communication interventions based solely on screening results or behavioral assessments. Providers may not be using recommended evidence-based HL practices correctly or consistently in practice which implies insufficient educational preparation. The knowledge, skills and practices that nurses and other health providers develop are influenced by curricular threads, didactic course content and

clinical exposures from their professional preparation, Nursing educational research was examined for the quality and quantity of HL competencies used to educate baccalaureate nurses, and how HL competencies had been integrated in nursing educational theory, curriculum and practice.

Gaps in knowledge

Nursing education research has focused on traditional functional literacy definition and skills such as assessing nurse health literacy knowledge levels (Cormier & Kotrlik, 2009; Jukkala, Deupree & Graham, 2008; McCleary-Jones, 2012; Scheckel, Emery & Nosek, 2010), evaluating written materials (Shieh & Hosei, 2008) or conducting patient health literacy screenings (Sand-Jecklin et al., 2010). Nursing education HL research primarily used lower level descriptive designs such as surveys (Cormier & Kotrlik, 2009; Jukkala et al., 2008) or single site case studies (McCleary-Jones, 2012; Sand-Jecklin et al, 2010, Scheckel et al., 2010; Shieh & Hosei, 2008, Shieh et al. 2013; Zanchetta et al., 2013). Short-term student knowledge gains occurred after brief learning interventions (McCleary-Jones, 2012; Sand-Jecklin et al, 2010; Shieh & Hosei, 2008) but sustained learning retention or direct observation of health literacy practices in patient-student interactions was not evaluated.

Factors affecting reported outcomes include limited reliability and absence of reported validity testing (Jukkala et al., 2009; McCleary-Jones, 2012; Sand-Jecklin et al., 2010; Shieh & Hosei, 2008), researcher selection bias (Scheckel et al., 2010) and reliance on self-reporting without corroboration from additional data sources (Cormier & Kotrlik, 2009; Scheckel et al., 2010, Shieh et al., 2013, Zanchetta et al., 2013). Despite additional searches, published reports were not found regarding measurement of nurse educator HL competencies or how educator HL competencies might influence nursing student practices and learning outcomes. None of the

previous studies identified a theoretical framework for the educational interventions, tested long-term knowledge retention, evaluated the impact of student learning on observed patient outcomes or assessed the health literacy knowledge, skills and attitudes of those teaching health literacy competencies to future nursing professionals.

Design and methods

The feasibility study used a sequential mixed methods approach with preliminary instrumental qualitative case study data collection to inform the development of the two HL curricula, teaching strategies, and a researcher-created HL observational checklist quality. This qualitative information was used to create a logic model based on Bowen and colleagues (2009) feasibility focus areas. This model guided acceptability, practicality, implementation and integration evaluations of the quantitative two group between subjects approach assessing the effects of the teaching strategies on HL competencies. As part of the first aim, a panel composed of four health literacy, linguistic and nursing education experts evaluated the Health Literacy Patient-Nurse Interaction Competency Evaluation or HLP-NICE instrument (Appendix Q) for content validity using the content validity instructions and relevancy rating form in Appendix W (Di Iorio, 2005; Waltz, Strickland & Lentz, 2010). The researcher conducted one hour semi-structured cognitive interviews with a faculty member involved in simulation, a practicing nurse, a nursing student and both standardized patients (SP) to garner qualitative feedback regarding item or response quality and wording issues using a script, prompts and interviewing techniques (Appendix X) recommended by Willis (2005). Additional analysis from the expert reviewer panel, focus group and cognitive interview participant's feedback will be used to critically appraise and improve the HLP-NICE instrument before further research is undertaken. For the second aim, two nursing faculty and four junior-level student volunteers from courses other than

those taught by the researcher participated in a two hour focus group session using a semi-structured interview guide (Appendix Y) to share their nursing perspectives and experiences regarding the functional and multidimensional HL curricula (Appendix Z) and teaching plans (Appendices LL & MM) for relevance, accuracy and realism (Barbour, 2008). The focus group perspectives about limited HL behaviors and nursing HL practices were used to train the standardized patient-actors and teacher-interventionist in expected limited health literacy behavioral cues, potential patient responses and possible nursing actions.

The intervention utilized a quantitative between-subjects design to compare changes between pre- and post-intervention HL knowledge and HL-related behaviors to meet the third aim (Melnyk & Morrison-Beedy, 2012). Three recently graduated baccalaureate nurses and six nursing faculty members were recruited and then randomly assigned to the experimental multidimensional and control functional groups. Intervention effects were assessed by interactions with SP's reflected in KEECC-A communication (Appendix O) and HLP-NICE (Appendix Q) ratings by the SP's and researcher. The researcher was not directly involved in delivering the interventions; and was blinded to specific intervention assignments from the time that informed consent had been given until after data collection was completed.

After Institutional Review Board approval was obtained from both the academic institution and research site, participant consent was obtained (Appendices E, F). Participants were randomly assigned to either the multidimensional experimental or functional control group, and were recorded in a semi-structured simulation involving a congestive heart failure (CHF) discharge teaching interaction with the standardized patient at the university simulation lab (Appendix JJ). The objective was for nurses to ensure adherence to discharge instructions for a client with newly-diagnosed CHF, and who was also starting several new medications (Appendix

II). Participants also completed the demographic data survey (Appendix K) and both sections of the Health Literacy Knowledge and Experiences Survey (Appendices L, M), or HLKES (Cormier & Kotrlik, 2009) to complete the pre-intervention activities. Participants were given a link to complete the web-based knowledge module (Appendix KK) consisting of basic functional health literacy knowledge regarding prevalence and attitudes about limited literacy, health literacy functional and multidimensional evidence and practices, and recommended adoption of Universal Health Literacy Precautions (US DHS ODPHP, 2010). This one hour module used an unfolding patient case study approach with interactive activities and a 5 multiple choice questions to reinforce content mastery (Bastable, 2008). During the following two weeks, the face-to-face intervention sessions for each approach were conducted. Each teaching intervention consisted of a one hour long researcher-developed educational session conducted at a research site classroom by the trained teacher following a theoretically-specific script and similarly timed activities (Appendices Z, LL, MM). The educational sessions occurred at two separate times to reduce intervention contamination. When the educational intervention sessions were completed, participants returned within one to two weeks for the post-intervention evaluation to complete the second recorded standardized patient interaction and repeat the HL-Knowledge section of the HLKES (Cormier & Kotrlik, 2009). The study flow and participant allocation is reported in Appendix HH (Schultz, Altman & Moher for the CONSORT group, 2010).

Data analysis

Descriptive statistics were tabulated from participant completion of the demographic survey and the Health Literacy Experiences section of the HLKES (Cormier & Kotrlik, 2009) using appropriate univariate statistics. The continuous variables of self-reported age, past years in health care and faculty time worked were summarized using ranges, means, medians and

standard deviations (Table 1) The categorical variables of self-reported gender, race and ethnicity, past work (yes/no), grade point averages, type faculty teaching assignment and final degree achieved were reported as numbers and percentages (Table 2).

Reliability of the HLP-NICE was assessed in the following areas: inter-rater reliability of the instrument when used by the standardized patient and researcher using a Cohen's κ of 0.4 as the benchmark for acceptable agreement, and internal reliability between pre- and post-intervention scores of the HLP-NICE were set using the recommended Cronbach's α of .6 for new instruments (Waltz, Strickland and Lentz, 2010). Preliminary content validity of the HLP-NICE was assessed using the content validity index of 90% agreement or greater set as the benchmark for the expert panel data. Internal reliability of the HLK continuous scores as percentage correct from the HLKES (Cormier & Kotrlik) and KEECC-A pre- and post-intervention continuous scores were assessed using the recommended Cronbach's α of .7 for existing instruments (Waltz, Strickland and Lentz, 2010). Convergent validity was evaluated by comparing associations between HLP-NICE and KEECC-A continuous scores using Mann Whitney U statistic.

Data integrity checks and analyses were performed on the sample demographics and HLKES, HLP-NICE and KEECC-A pre- and post-intervention scores using SPSS v 23 (IBM, 2016). A normally distributed sample was evident with no outliers identified. The use of non-parametric statistics was suggested by the small sample size, and an inability to meet homoscedacity and linearity assumptions confirmed this decision. Significance was assessed at the alpha level of .05 with one tailed options for directional tests. For one participant, the last part of their pre-intervention recording had been lost due to a technological glitch. This problem was not identified until after the intervention was started. Rather than discarding the remaining

90% for the participant's 10 % "missing completely at random" data, missing values were substituted using the SPSS v23 (IBM, 2016) linear interpolation procedure (Waltz, Strickland & Lenz, 2010). Using substituted values, however, meant the interpretation of the results could be affected by the potential loss of variance and should be interpreted cautiously due to this effect.

Ethical protections

The human subjects of the feasibility study involved nursing faculty, practicing nurses, graduate and undergraduate students and nursing graduates who were older than 18, able to consent as adults, and who spoke and read English. Participation in the study was voluntary and assured through informed consent obtained by the research assistant, and every effort was made to protect the ethical rights and confidentiality of each participant and their accompanying written and recorded documentation. The use of de-identified information for the results database and not linking written codebook information with demographic data collection logs reduced potential breaks in confidentiality. A fireproof safety box was purchased to store hard copies of the focus group audio recordings, the audio-visual SP interactions, and all hard copies of the data and code books for safety and data protection. This locked safe will be kept in the researcher's locked office, accessible only to the researcher and appropriate personnel in the researcher's office in room 303 of the APSU McCord Building, Clarksville, TN 37044. All electronic data will be stored on the online password-protected firewalled server maintained for research purposes in the MUSC College of Nursing.

Key concepts and definitions

Literacy is defined as "the ability to read and write" (Mancuso, 2008) and was operationalized for this research as a person's measured reading ability. Patient literacy levels were assessed by their response to Single Item Literacy Screening question or SILS (Chew,

Bradley & Boyko, 2004) as having adequate, marginal or inadequate literacy abilities based on their self-reported need for assistance when completing medical forms. The underlying assumption was that nurses who identified patients with low literacy levels using SILS screening would be more likely to intervene with recommended HL practices. Health literacy has been functionally defined as "the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make health decisions" (Nielsen-Bohlman, Panzer, & Kindig, 2004, p. 31-32). For this research, functional health literacy was operationalized through participant use of readability and suitability pamphlet assessment scores in selecting written materials for the standardized patient. The underlying assumption was that nurses would match the reading burdens implicit in written health information to match the SILS-identified literacy level of the standardized patients.

The functionally-focused HL definition prominent in past HL research may not fully account for health information-seeking behavior of those with diverse literacy levels. As a result, a newer definition and concepts have expanded to include "the wide range of skills, and competencies that people develop to seek out, comprehend, evaluate and use health information and concepts to make informed choices, reduce health risks and improve quality of life" (Zarcadoolas, Pleasant & Greer, 2006, p. 55) in a more holistic multidimensional theoretical approach. Health literacy educational competencies were defined by Coleman and colleagues (2013) as "the knowledge, skills and attitudes that health providers need in order to address low health literacy with consumers of health care services and health information". Health provider knowledge, skills and attitudes are key components for competent HL practice, but this definition was more closely aligned with traditional functional definition used to guide the functional curricula and teaching interventions. Modifications of the definition were made for

participants in the expanded multidimensional group, because the HL knowledge, skills and attitudes taught were to be practiced with all patients with diverse literacy levels and backgrounds. A paradigm shift may be occurring in health provider and national awareness of multidimensional HL definitions. The most recent health literacy definition stated in CDC's Health Literacy Web-based training module includes multidimensional Hl competencies for patients, providers and organizations rather than focusing on patient or functional HL alone (CDC, 2015).

Health literacy knowledge was operationalized by the knowledge percent correct from the 29 multiple choice items of the HLKES (Cormier & Kotrlik, 2009). Health literacy-related behaviors were operationalized through observed KEECC-A communication and HLP-NICE HL-related behavior scores from recorded standardized patient-nurse interactions. The underlying assumption was that nurses with higher levels of KEECCA communication and HLP-NICE HL-related competencies would have more effective patient-centered interactions based on their application of HL knowledge and evidence-based HL practices.

Theoretical framework

The expanded multidimensional HL approach has potential to meet every patient's needs regardless of their literacy level (Nutbeam, 2008; Zarcadoolas et al., 2006). This more holistic approach builds on fundamental verbal, textual and media proficiencies to layer scientific, cultural and civic health literacy dimensions flexible enough to meet patient-centered health education needs beyond written proficiencies alone (Appendix NN). The call to restructure nursing practice and education beyond the traditional emphasis on tertiary care knowledge and technical skills has grown (Cronenwett et al. 2007, Cornett, 2010), but current nursing educational practices or student learning outcome evaluations may lack evidence of efficacy or

be taught inconsistently (Coleman, 2011). Existing nursing educational research and practice has not evaluated this HL approach in didactic or clinical research, but adopting Universal Health Literacy Precautions has potential to improve nursing communication practices. The multidimensional definition and supporting concepts indicate how providers can engage in patient interactions, but may not fully delineate how providers are to be introduced and educated using evidence-based strategies to develop essential HL competencies.

Edwards, Woods, Davies and Edwards (2012) proposed a multidimensional HL framework to describe patient formation of HL competencies in a five stage Health Literacy Pathway Model or HLPM. A 9 month longitudinal qualitative study explored how 18 chronic disease patients described acquiring health knowledge, self-management skills with identification of barriers or benefits in a skill-building process. Patient HL competencies were categorized using Kwan, Frankish and Rootman's multidimensional HL definition (2006) to "find, understand, appraise and communicate" health information across all contexts while integrating Nutbeam' s (2008) depiction of HL as a health asset rather than personal liability. Patients described the cultivation of HL knowledge, skills and actions in a non-linear progression which could be positively or negatively influenced by health professional's input, and by additional personal or emotional mediating or moderating factors.

Stage 1 of the HLPM occurred as patients built health knowledge through prior knowledge and appraisal of new information. Stage 2 occurred as patients extended existing or build new skills to gain additional understanding. Stage 3 occurred as patients practiced their HL skills to access and comprehend health information. Stage 4 occurred when diverse options were produced and examined by patients when thinking about barriers or benefits to adherence. Stage 5 occurred when patients shared final decisions. The HLPM is not dependent on identification of

literacy levels or written material readability levels, but scaffolds on existing knowledge levels, abilities, needs and preferences to promote self- care management and empowerment at a patient's or caregiver's desired autonomy level. The use of a structured but non-linear pathway such as the HLPM, when incorporated with Zarcadoolas, Pleasant and Greer's (2006) multidimensional concepts indicates one possible developmental approach to honing the HL competencies of nurses and other health providers. Study participants would progress through similarly structured stages to build HL competencies, with the expectation that teaching interventions based on a multidimensional model would result in HL knowledge and HL-related behaviors gains demonstrated in standardized patient-nurse interactions.

Brief manuscript descriptions

The first manuscript (French, 2015) explored a theoretical introduction to the traditional functional HL approach which targets limited literacy interventions as compared to the more holistic multidimensional HL patient-centered approach, and provided supporting rationale for adoption of Universal Health Literacy Precautions (US DHHS ODPHP, 2010). This manuscript was published in *Nursing Clinics of North America* March, 2015. The second manuscript (French, in review), an integrative review using Whittemore and Knafl's organizing framework and Critical Appraisal Skills Progamme or CASP research appraisal questions (Center for Evidence Based Medicine, n.d.), examined primary research in nursing education for HL competencies represented in educational practices, student learning outcomes and patient-related learning or health outcomes. The second manuscript was submitted to the *Journal of Nursing Scholarship* February, 2016 and is currently in review. The third manuscript (French, 2016) reports findings from the feasibility study evaluating the effects of the two different HL theoretical approaches on HL knowledge and HL-related behaviors for recently graduated

nurses. The manuscript includes a summary of initial reliability and validity signals of the HLP-NICE observational instrument to measure nursing HL competencies in patient interactions. The peer-reviewed poster of the findings was presented at the STTI - NLN sponsored Nursing Education Research Conference April 2016. The third manuscript will be submitted to the *Journal of Nursing Education* with final committee approval May 2016.

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Title: Transforming nursing care through health literacy ACTS

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Keywords: Health literacy, patient advocacy, patient education, patient-centered care, shared decision-making, teach-back, universal health literacy precautions

Key points:

- Limited or low literacy is associated with negative or poor health outcomes.
- All patients, regardless of literacy level, need accessible and actionable health information
- to make informed decisions about their health
- Universal Health Literacy Precautions are recommended to meet quality and meet safety standards for more health literate health care systems
- Front line nurses can transform their care by using ACTS consistently in patient and health system interactions to enhance patient-centered communication and effective care.

Outline:

Introduction

Problem

- Limited literacy prevalence
- Functional health literacy definition
- Patient literacy screening tools
- Limitations of literacy screening
- Barriers to patient understanding
    - over-emphasis on limited literacy
    - neglect of provider contributions to interactions
    - overdependence on written materials
    - Multidimensional health literacy definition
    - Challenges for front-line nurses

Education Strategies using ACTS (Table 1)

- Assess patient concerns, preferences, and values
- Compare patient information with available resources
- Teach 3, Teach Back
- Survey for additional learning needs and resources

Advocacy Strategies using ACTS (Table 2)

- Access health materials and environment for accessibility
- Collaborate with patients and peers to address identified problems
- Train with peers using health literacy competencies
- Survey evidence to support clinical and organizational practices

Evaluation

- National Action Plan to Improve Health Literacy

Discussion

- Universal Health Literacy Precautions

References

Synopsis: Limited patient literacy contributes to poorer health status, increased emergency room and hospital use, higher morbidity and mortality rates and less use of preventive health services. All patients, however, need health information which is accurate, accessible and actionable to make informed decisions about their health. A universal health literacy precautions approach has been recommend to empower patients through shared decision-making interactions. Nurses implementing a universal approach educate patients by assessing for patient concerns and preferences, comparing resources to identified needs, using teach-back to verify comprehension, and survey for other learning needs. Nurses advocate with patients to assess health system environments for user-friendliness, engage in patient collaborations to guide improvements, teach peers about key health competencies, and use ongoing surveillance to meet national health literacy standards. Consistent use of evidence-based health literacy practices by front-line nurses offers the potential for transformations in nursing care through stronger patient-nurse interactions and health system partnerships.

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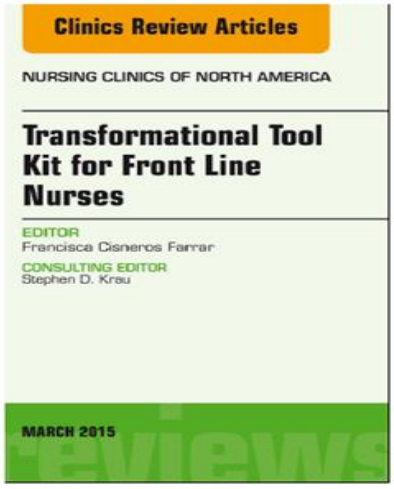

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Transforming Nursing Care Through Health Literacy ACTS

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KEYWORDS

• Health literacy • Patient advocacy • Patient education • Patient-centered care
• Shared decision making • Teach back • Universal health literacy precautions

KEY POINTS

- Limited or low literacy is associated with negative or poor health outcomes.
- All patients, regardless of literacy level, need accessible and actionable health information to make informed decisions about their health.
- Universal Health Literacy Precautions are recommended to meet quality and safety standards for more literate health care systems and providers.
- Front-line nurses can transform their care by using "ACTS" for educational strategies (assess, compare, teach, and survey) and advocacy strategies (assess, collaborate, train, and survey).
- Using ACTS consistently in patient and health system interactions can enhance patient-centered communication and effective care.

INTRODUCTION

After years of trying to conceive, a couple was overjoyed to find out that they were expecting their first child. The diagnosis of an ectopic pregnancy in the young woman's remaining Fallopian tube left the couple devastated by the knowledge that trying for another pregnancy would be futile.

> *Craving support and information, (she) waited for the medical professionals that were treating her to offer words of condolences or to give her medical information packets to leaf through. "I left the hospital with 18 staples, empty arms, and a huge hospital bill. Not one person tried to comfort me or say they were sorry for my loss."*[1]

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This true-life incident illustrates both opportunities and challenges for front-line nurses when interacting with patients in the current health environment. This young woman received life-saving medical and nursing care, but her educational and emotional needs were not met in her interactions with providers or the health care system. This experience, however, spurred her to seek more information about her diagnosis. She formed an online ectopic pregnancy support group and authored a book sharing information and stories about ectopic pregnancy for other families going through similar situations. The lack of effective health provider communication is not unique to this situation and underscores the urgency for front-line nurses to develop more successful patient-centered communication by incorporating health literacy competencies in all patient interactions.[2]

PROBLEM

Patients with limited or low literacy levels are more likely to report poorer health status levels,[3] use emergency and hospitals more frequently, use preventive health services and self-care management less frequently,[4] and have a 2-fold increased mortality risk for community-dwelling elders[5] compared with those with higher literacy levels.

Limited Literacy Prevalence

The most recent national survey of US literacy levels, the 2003 National Adult Assessment of Literacy, measured the reading proficiencies of a randomized sampling of 16,000 participants and included health-related literacy components.[6] The results suggested that 75 to 80 million (36%) Americans have basic or below basic literacy levels and may have moderate difficulty in correctly following medication instructions or completing consent or insurance forms without assistance. Those groups at greater risk for limited literacy were identified as those older than 65, affected with multiple comorbidities or disabilities, entering school speaking a language other than English, or with lower economic levels. National Adult Assessment of Literacy health literacy assessments were only for written proficiencies and taken out of the context of normal use, which may have limited their generalizability. The health literacy questions did not account for cultural preferences,[7] the effects of provider communication on medication adherence,[8] or comprehension of medical information by the participant.[9,10]

Functional Health Literacy Definition

The 2004 Institute of Medicine consensus report, Health Literacy: A Prescription to End Confusion, defined health literacy as "the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make health decisions."[11(pp34–35)] This definition reflects past and current health literacy research and practice priorities that emphasize reading skills such as patient reading abilities and the literacy burden of health information.[12,13] These functional literacy-based skills are used by many providers and health systems that seek to "diagnose" patients with limited health literacy through screening and "treat" identified literacy problems by simplifying written and audiovisual health information.

Patient Literacy Screening Tools

Screening for limited literacy may include provider recognition of patient literacy levels through patient behavioral cues or the use of patient screening tools such as the Test of Functional Health Literacy Assessment (TOFHLA), Rapid Estimate of Adult Literacy in Med (REALM), Newest Vital Sign (NVS), or Single Item Literacy Screening (SILS) questions.[14] Patient literacy screening instruments categorize reading abilities to

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estimate patient literacy levels. Older tools such as TOFHLA or REALM were based on word recognition, numeracy skills, and comprehension formats used in educational settings for student placement purposes. Newer tools attempted to reduce time and administrative burdens in clinical settings by tying literacy levels to common tasks such as reading nutrition labels (NVS) or patient-reported levels of assistance to complete medical forms (SILS).

Limitations of Literacy Screening

Use of screening results involves time and personnel for administration and may not lead to improved patient health outcomes or provider satisfaction with care given even when aware of patient literacy levels. Comparisons of outcomes for 182 diabetic patients with limited literacy seen by 32 physicians with knowledge of their patients' literacy levels versus 31 who did not, noted no significant improvement in patient diabetic control or provider satisfaction with care management.[15] These findings suggest that the time and personnel to administer screenings, document implementation, and follow up with patients may not improve interactions or outcomes for patients or their health care providers.

Health care providers may not always accurately identify low-literacy patients based on their health literacy awareness or literacy-related behavioral cues.[16–18] Dickens and colleagues[19] described these discrepancies when comparing the measured literacy levels of 65 patients hospitalized for congestive heart failure and 30 nurses caring for them on 2 inpatient cardiac units. There was little agreement between the patient's NVS and SILS scores and the nurses' informal literacy assessments ($\kappa = 0.09$). Over- or underestimation of literacy levels may lead nurses to assume that patients fully understand health instructions or that patient knowledge needs are met without additional confirmation. According to these findings, provider knowledge about limited health literacy may not be the most reliable guide for interventions based solely on screening results or behavioral cues indicating limited literacy.

Barriers to Patient Understanding

Americans with lower literacy proficiency may have difficulty navigating the current health care system, but knowledge barriers are not restricted to those at risk for limited literacy or with inadequate access to health care. Functional-based literacy approaches may neglect the health information needs, preferences, and perspectives of the remaining 64% of patients who have adequate or advanced reading levels.[20] Nurses may shortchange patients with adequate or high literacy levels by assuming that those patients can understand and apply complex and potentially unfamiliar medical concepts to their personal health situations.

The functional literacy skills approach has also neglected provider contributions as potential barriers to patient comprehension. Castro and colleagues[9] profiled provider use of medical jargon as observed in 81% of 74 visits between diabetic patients with limited literacy and their providers. Jargon was used an average of 4 times per visit, particularly when making recommendations (37%) or providing patient instructions (29%). The effect of jargon was further evaluated in postvisit telephone calls with a subsample of 19 patients. Respondents had difficulty remembering the meaning of medical terms or jargon used in the initial interaction regardless of whether additional contextual cues were provided by the interviewer (p. S90).[9] Plain language should be the goal for patient-nurse interactions, yet little research exists evaluating nurses' use of medical jargon with patients or the effects of nurses' use of jargon on patient health outcomes.

Additional factors that influence patient comprehension include the underuse of evidence-based health literacy practices reported by providers. Schwartzenberg

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and colleagues[21] surveyed the health literacy practices of 168 physicians, nurses, and pharmacists attending a health literacy conference. Conference participants reported using provider-centered rather than patient-centered strategies in their patient interactions during the week before the survey. Use of plain language, handing out written materials and speaking slowly more often were mentioned more than health literacy evidence-based practices such as tailoring written materials or instructions to patient-identified preferences or verifying patient comprehension through use of teach-back. Although diabetic control outcomes of those patients were significantly improved when physicians used teach-back techniques to confirm patient comprehension, use of teach-back was only observed for 20% of those interactions.[10] The potential for health improvement was diminished through the inconsistent use of practice standards, such as teach-back, and may be further reduced through lack of provider knowledge about health literacy standards. These barriers to verbal communication may also be worsened if written materials are used as the primary source of health information[12,13]

Interventions such as simplifying written health information may not lead to greater patient comprehension when patients are learning unfamiliar or complex health concepts. Wilson and colleagues[22] piloted an educational intervention to assess maternal comprehension about polio vaccine information with 37 low-income mothers at an urban walk-in immunization clinic. After screening for participant literacy levels, mothers randomly assigned to the control group read standard polio information, whereas the mothers in the experimental group read modified reader-friendly vaccine information. Both groups showed slight improvements in vaccine knowledge, but significant comprehension of key vaccine information was not evident in either group even with the simplified pamphlet.

The limitations of functional literacy-based interventions are seen in the initial patient scenario. The young woman did not have any overt risk factors for limited health literacy, and literacy screening would not have closed her health information gaps. Nurses in this situation missed an opportunity to provide suitable written health information, but written materials alone may not have provided the resources or emotional support to ease her grief and sense of loss. Her reading abilities did not reflect her information-seeking skills, self-motivation, or desire to locate and share health information with others experiencing an ectopic pregnancy. Her needs for accessible and actionable health information were equally as important as for women with low literacy in similar situations. Intervening with simplified materials alone would have provided key information and actions but may not have provided enough information to predict the actions she would have taken without verification or further discussion.

Multidimensional Health Literacy

To address these limitations, health literacy has also been conceptualized as "the wide range of skills and competencies that people develop to seek out, comprehend, evaluate and use health information and concepts to make informed choices, reduce health risks and improve quality of life.[23(pp196–197)]" This more holistic definition builds on a patient's literacy and numeracy skills to include the scientific, civic, and cultural patient influences patients use to translate health information into health-promoting actions. From a multidimensional health literacy perspective, patient health literacy levels are not a single benchmark linked to health risks. Instead, patient and provider health literacies are flexible and dynamic assets characterized by existing experiences and life skills within a range of contexts.[20] When nurses use multidimensional health literacy competencies in practice, they incorporate more patient-centered communication practices with all patients, not just those with limited or low literacy.

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Challenges for Front-Line Nurses

Front-line nurses face daily challenges in meeting their professional roles and legal and ethical responsibilities as care providers, educators, and patient advocates. Aging patients with multiple comorbidities, increasing culturally and linguistically diverse populations, technologically complex workloads, and economic pressures may affect the abilities of nurses to communicate safely and effectively with their patients. Although front-line nurses deal with these and other challenges in providing safe and effective care, opportunities also exist for nurses to transform their nursing practice by consistently using health literacy evidence in patient interactions. Nurses can become more effective patient educators by using the ACTS (assess, compare, teach 3, teach-back, and survey) in each patient interaction. Nurses can also use ACTS (assess, collaborate, train, and survey) with patients and peers to advocate for practical improvements in health care systems accessibility. The ACTS acronym can help front-line nurses be effective educators and advocates. The 2 ACTS should take place in all health setting interactions with patients, caregivers, family members, communities, and health systems.

EDUCATION STRATEGIES USING ACTS

Assess Patient Concerns

The first step in assessment is to begin patient interactions by identifying the patient's main concern. By asking the patient to identify their main concern, the focus and priority shifts from being nursing task oriented to a more patient-centered partnership. This patient-directed approach may more effectively target which topics or learning needs are vital to address for the interaction to have the intended outcomes. Asking the patient to voice his or her priority may remove blocks to learning that occur when patients are distracted by anxiety, pain, or issues unrelated to the immediate setting. Querying the patient about their main concern can be done within the context of the nursing task and provides a starting point for additional assessments about available resources or the involvement of significant others in health maintenance activities.

The second assessment step is to discover patients' learning needs and preferences to tailor suitable intervention. Asking patients what their baseline level of knowledge is and how they prefer to learn acknowledges patient or caregiver expertise about their health information and supports their desired level of control in shared decision making.

The third assessment step is to discover core patient values, which will provide cultural, social, and motivational contexts to frame interventions. The nurse should identify potential language, cultural, social, or physical influences, which can be used to work through patient barriers to care or improve patient adherence.

Compare Identified Patient Priorities and Needs with Resources

The comparison of patient-focused assessments with available materials and resources means that nurses use patient-identified learning needs and preferences to match relevant content to patient knowledge gaps. When nurses distill "need-to-know" information from available resources, they target essential concepts to foster greater patient comprehension of health information. The nurse would also account for patient cultural and language variations, sensory alterations, or technological advances to match the diverse range of patient abilities for existing or additional information. This information should be documented in the medical record to ensure that all team members can use this information when providing health services.

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Tailoring key information to patient preferences means that nurses can reduce overwhelming and sometimes confusing instructions into easier-to-remember concepts. The emphasis of key information should be on which actions the patient should take and not just on what patients should know. Nurses may also identify unsuitable or poorly matching patient resources, which could be modified or replaced based on patient feedback and nursing appraisal of usefulness over time. The key information would then be available for patients or caregivers to use as augmentation of the originally taught information or for further review in a less distracting environment to enhance adherence to critical health instructions or the follow-up plan of care.

Teach 3, Teach-Back

Teach 3, teach-back means that patients are taught 3 or fewer key actions, health information concepts, or care skills in short segments. Patients then restate the nurse's teaching in their own words or return demonstration of the skill. If patients have difficulty repeating or demonstrating information or skills correctly, then reteaching should be done until all information is repeated correctly. To start the process, nurses should foster a shame-free environment by acknowledging the nurse's responsibility for assuring patient learning in their opening statement. After patients repeat or demonstrate the main concepts or skills, the nurse has immediate feedback about patient misconceptions or difficulties in skill execution. The nurse can then give alternative explanations or modifications quickly to improve comprehension of the desired concepts or skills. This same process should be repeated until the learner has mastered all essential concepts or skills.

One concern that nurses may have about using teach-back is extra time to complete their routine tasks while using this process. These concerns may be allayed by viewing VA Palo Alto Project RED short training videos showing nurses using teach-back when discharging emergency room, mental health, and medical-surgical patients.[24–26] Poor and good examples of nursing communication are presented, but patient comprehension is significantly improved when teach-back strategies are used, although similar nursing time was spent in the demonstrated patient-nurse interactions. Research incorporating teach-back for adults with heart failure[27] and children with complex medication needs[28] supports consistent use of teach-back as leading to better comprehension, higher levels of adherence, and potentially more positive health outcomes.

Survey for Additional Needs

Nurses should survey patients for additional resources or unmet learning needs to close the communication loop. Closed-ended questions such as "Do you have any other questions?" may prematurely end the interaction and increase risks for insufficient information sharing by the nurse and patient frustration with unvoiced or unmet learning needs. The use of open-ended questions keeps the interaction patient focused while allowing for further exploration of patient needs or a natural resolution if concerns have been answered. Although the use of ACTS educational interventions with patients, caregivers, or families can foster health-literate communication, nurses can partner with patients and peers to advocate for a more health-literate organization using ACTS (Table 1).[13]

ADVOCACY STRATEGIES USING ACTS

Assess Health Materials and Health Environments

Nurses can advocate for their patients through assessment and selection of suitable health materials for their specific population using identified learning variations and

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Table 1
Education strategies using ACTS

Intervention	Components	Sample Questions/Nursing Actions
A = Assess	Assess patient main concern	"What is your main concern, as we get ready to talk about your (task, health condition)?"
	Assess patient learning preferences	"What do you know about your health condition?" "Everyone has different ways of learning and remembering information. How do you like to learn best?"
	Assess patient values and context	"What do you think is most helpful or most important for you to stay healthy? What keeps you from staying healthy?"
C = Compare	Compare assessment with available resources	Identify and highlight written material, or write down 3 key points to match the patient's concerns and values Look for alternative media for patients with sensory alterations, language variations, or technologic proficiencies
T = Teach 3, teach-back	Teach 3 key points using plain language and "chunk and check" Confirm each point for understanding, and reteach if not confirmed	"I want to make sure that I am as clear as possible, so could you share your understanding in your own words" or "Many times, I might go over information really quickly. To make sure I haven't gone too fast, what were 3 important points we talked about?" or "What 3 points will you tell/show your family/significant others about your health condition when you get home?"
S = Survey	Survey for additional questions or concerns	"What other questions or concerns do you have?"

information needs. There may be significant discrepancies, however, between the intents, goals, and perspectives of health information developers, health information providers such as nurses, and the patient population for the desired health information. More than 300 studies have documented significant and ongoing gaps between the reading levels necessary to comprehend most health materials and the reading abilities of the intended audience.[14] Nurses, patients, or other health providers may be minimally involved in the creation or evaluation of health materials, adding to this gap. Developers of health materials may not realize that health information resources are distributed with little additional explanation or confirmation of patient understanding by providers. Most health information available is commercially produced for broad distribution or to meet health system information goals and legal requirements. Nurses may assume that their patients can read and understand complex health information, as seen in discharges focused on getting signatures on the necessary forms and handing out additional reading materials and then stating, "Here, read this information when you get home." Even when simplified or language-specific materials are given, there is no guarantee that someone can read or be able to follow written discharge instructions, despite their verbal fluency or compliant demeanor.

To overcome these assumptions, nurses can use patient education suitability instruments such as the Suitability Assessment of Materials (SAM)[29,30] or Patient

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Educational Material Assessment Tool (PEMAT)[30] to gain greater knowledge of material content and context. Assessing the large amount of materials available may appear daunting but is doable if small amounts of materials are evaluated on a regular basis. Nurses may pregroup written materials or online media sites according to very low (2nd grade or less, sensory or language variations), limited (3rd–5th grade), or average (8th grade or higher) suitability levels to more closely match identified patient preferences and abilities. Nurses can then use categorized resources to target patient-identified preferences and values specific to their population. If this process is carried out over time starting with the most frequently used information, benefits may include potential cost savings and reductions of nursing time and effort because of better alignment of patient learning needs with existing resources.

Nurses can also be active participants in assessing their surroundings for user friendliness and accessibility. Most health environments are built with health provider convenience as a priority, and providers may have "expert blind spots" about confusing or difficult-to-understand signs, directions, or physical landmarks.[14] The *Health Literacy Universal Precautions Toolkit* created by Agency for Healthcare Research and Quality [23] contains modules to foster health team member buy-in for the evaluation process and self-assessments to identify strengths and areas for adjustments. Assessment results can then be used as the basis to plan improvements and to invite participation in partnerships to ensure that patient and health care system needs are adequately met.

Collaborate with Patients and Peers

Nurses in collaboration with patients and other peers can work to improve patient education materials. Patients or caregivers who actively participate with nurses in reviewing or modifying patient educational materials may identify information that is more readable, relevant, and actionable.[31] The expertise of language interpreters, medical librarians, social workers, lawyers, or adult educators may also be sought for material analysis or in locating additional resources. Ultimately, these partnerships may also support health system and national goals of having more engaged and health-literate communities or consumers if assessment results are included in health system improvements.[32]

Train with Peers to Implement Health Literacy Competencies

Training all health care team members to use evidence-based health literacy competencies is essential if patient, health system, and national health outcomes are to be achieved. Health provider preprofessional training in plain language, teach-back techniques, tailoring materials, or other health literacy competencies may be minimal or inconsistent across disciplines and insufficient for clinical practice without additional reinforcement.[14,33,34] These deficiencies can be alleviated through regular and standardized training opportunities for all members of health care organizations. Health literacy competencies may require the teaching and reinforcing health provider knowledge, skills and attitudes, and related attributes from health institutions beyond textual modification alone.[11,33] A recent consensus study has proposed health literacy educational competencies and health literacy–related practices for health professionals.[34] When interdisciplinary team members learn and apply health literacy knowledge, skills, and attitudes together, opportunities exist to build stronger team partnerships and gain benefits from sharing information about differing health roles, challenges, and perspectives.

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Survey Evidence to Maintain Standards

Routine surveillance of health literacy evidence should be part of health organizational efforts to support patient care safety standards. According to Joint Commission statistics, approximately 60% of all sentinel events can be traced back to communication errors.[35] The Joint Commission added patient- and family-centered communication in 2010 as a National Patient Safety Goal to address these constraints by improving existing communication and cultural competency practices of health facilities. The Commission provided a Roadmap to guide expectations for health system communication competencies when caring for patients with limited English proficiency or with sensory and language variations consistent with the Federal Title VI requirements.[35] Nurses who are involved in health system evaluation and quality improvements may lead organizational changes to meet or exceed Joint Commission accreditation standards and professional benchmarks outlined in the National Action Plan to Improve Health Literacy (Table 2).[36]

Table 2
Advocacy strategies using ACTS

Intervention	Components	Nursing Advocacy Actions
A = Assess health materials and environments for user friendliness	Use of readability, suitability instruments with scoring, categorized for future reference Agency for Healthcare Research and Quality Health Literacy Precautions Toolkit	Individual and group evaluation of health material suitability, targeted to population served Health environment assessment using health system evaluation tools
C = Collaborate with patients and peers to advocate for change	Patient and peer input regarding available health materials and health environments	Interviews Focus groups Peer and patient task forces to foster patient-centered environment
T = Teach and practice health literacy competencies	Peer practice to build health literacy competencies and teamwork opportunities	Develop and participate in interdisciplinary continuing education
S = Survey health systems for ongoing integration of evidence	Planned review and analysis of health system environment use of health literacy practices Joint Commission A Roadmap for Hospitals: Advancing Effective Communication, Cultural Competence and Patient- and Family-Centered Care	Participate in review of standards and evidence for accreditation and outcomes

EVALUATION

The National Health Literacy Action Plan details 7 overarching goals to evaluate health literacy clinical practices and guide health literacy research.[36] Support for health information accessibility and usability should occur in all contexts (goal 1), within US health care systems (goal 2) and throughout one's educational path (goal 3). Communities should be empowered to provide health information in nontraditional health settings, such as adult learning programs (goal 4) with the development of broader

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community-based partnerships (goal 5). Ongoing health literacy research (goal 6) and implementation of evidence-based health literacy practices (goal 7) would continue to refine and improve outcomes for individuals, communities, and health systems to reduce economic, physical, and emotional costs associated with limited health literacy. The assumptions of improvement in the Action Plan or Joint Commission communication standards may not be fully realized without support across the multiple health environments. There are no defined economic, social, or political incentives to implement the Health Literacy Action Plan or Joint Commission patient communication standards, and no timeline or clear benchmarks to evaluate the recommendations or effectiveness if met. Without further research and ongoing health system action, improvements may be minimal or short lived.

SUMMARY

A Universal health literacy precautions approach has been recommended as part of the Health Literacy Action Plan to limit medical errors or harm and enhance communication improvements for a more "health literate society."[2,36] Universal health literacy precautions such as plain language, teach-back, and highlighting or pointing out need-to-know knowledge should be implemented across all health environments by health literacy–proficient providers, actively engaged patients, and involved communities of interest. Nurses are the largest group of health care providers in the United States, and are poised through their daily interactions and relationships with patients, families, and health care systems to push for and integrate universal health literacy precautions.[35,36] Patients of all literacy levels may have difficulty understanding routine health information or instructions because of the innate complexity of medical language, unfamiliar health knowledge concepts, technology barriers, and health care system intricacies.[14,20] Overemphasizing functional literacy skills for assessments or interventions may inadvertently stigmatize those with lower literacy levels[16] or neglect the health information needs of patients with adequate literacy or varying cultural or language backgrounds.[7] Nurses can address these patient barriers to essential health knowledge through support for stronger patient and health system collaborations. When front-line nurses consistently use health literacy ACTS, transformations can occur as the foundation for more effective patient-nurse communication practices.

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An integrative review exploring health literacy competencies in baccalaureate nursing education

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Abstract

Purpose. To critically analyze studies published within the last decade about the quantity and quality of educational strategies to teach baccalaureate nurses health literacy (HL) competencies for use during patient interactions, based on comparisons to the nationally recommended approach.

Design. An integrative review using Whittemore and Knafl's methodological approach examined gaps between national health literacy competency standards and baccalaureate nursing education practices.

Methods. The *Cumulative Index of Nursing and Allied Health Complete (CINAHL), Academic Search Premier, Cochrane Database of Systematic Reviews, Dynamed, Educational Research Information Collection (ERIC), Google Scholar, Ovid Medline, PubMed* and eight additional nursing or HL content-specific journals were searched. Inclusion criteria were primary research reports published between January 1, 2004 and December 1, 2015, written in English, in peer-reviewed journals, and with baccalaureate nursing populations. Keywords applied were combinations of "health literacy", nurs*, communication and student.

Findings. Of the 588 unduplicated abstracts identified from the search, 16 full-text articles were screened with nine meeting the inclusion criteria. One article was excluded due to insufficient primary research documentation. Three interventional and five descriptive studies were then analyzed using Critical Appraisal Skills Programme (CASP) and HL-related criteria. Teaching interventions emphasized short-term knowledge gains or patient and textual assessments without evaluation of outcome effectiveness. Student practices and observations focused more on verbal interactions and interventions clarifying written or verbal health information for patients or caregivers. Minimal student reference was made to prior course content or text-based teaching approaches included in interventions. Studies were limited in design and sampling, lacked theoretical frameworks and long-term follow-up.

Conclusions. Future nursing education studies should expand HL theoretical approaches using multidimensional HL competencies, use stronger study designs and evaluate relationships among evidence-based HL teaching strategies, student competencies and patient learning outcomes.

Clinical relevance. Universal Health Literacy Precautions based on multidimensional HL competencies should be consistently practiced in baccalaureate nursing education to improve safety and nursing communication effectiveness, encourage greater patient engagement in self-care management, and potentially reduce economic health care costs.

Keywords. Health literacy, competencies, nursing curriculum, course content, clinical experiences, functional, multidimensional

An integrative review of health literacy competencies inclusion in baccalaureate nursing education

Patients with limited literacy or lower reading abilities are more likely to have poorer health outcomes, higher emergency room use and hospitalization rates, and greater morbidity and mortality rates than those with adequate literacy levels (Berkman et al., 2011). Increasing recognition of links between literacy and health status has driven the development of the *National Action Plan to Improve Health Literacy* (DHHS, ODPHP, 2010), the national framework of seven population-based goals for health literacy interventions. Health literacy (HL) has been defined as "the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make health decisions," (Nielsen-Bohlman, Panzer & Kindig, 2004, p. 31- 32). Early HL research approaches were patterned after educational literacy practices with instruments designed to screen patient reading levels and formulas to determine written material readability levels. This approach remains the most utilized in the US (Barry, D'Eath & Sixsmith, 2013) yet overlooks patient comprehension of written or verbal information (Al Sayah et al., 2014) and provider's (Castro, Wilson, Wang & Schillinger, 2007) or health system's (Paasche-Orlow, Schillinger, Greene & Wagner, 2006) contributions to health-related interactions. Patients at any literacy level, however, may have difficulty understanding or acting on health information due to the innate complexity of medical language, unfamiliar scientific or numerical concepts, technology barriers and health care system intricacies (Nutbeam, 2008).

An expanded multidimensional HL approach has emerged which addresses these limitations through attention to patient and provider competencies beyond text literacy and health care environments (Nutbeam, 2008; Zarcadoolas, Pleasant & Greer, 2005). Multidimensional HL incorporates "the wide range of skills, and competencies that people develop to seek out,

comprehend, evaluate and use health information and concepts to make informed choices, reduce health risks and improve quality of life" (Zarcadoolas, Pleasant & Greer, 2006, p. 55). This approach enlarges on basic literacy skills to integrate scientific, cultural and civic competencies including patient risk awareness, participation in speaking, level of civic engagement, cultural beliefs and values and ways of seeking understanding (Shaw et al., 2012). Multidimensional provider practices may require HL competencies beyond literacy screening (Coleman, Hudson & Maine, 2013) and may demand alternative health system strategies other than textual simplification or linguistic modifications (Baur, 2010; Brach et al., 2012).

The purpose of this integrative review is to critically analyze primary research studies published within the last decade about the quantity and quality of nursing educational strategies to prepare baccalaureate nurses to observe or use diverse health literacy competencies in patient interactions. These multifaceted competencies should align with the second goal of the National Health Literacy Action Plan (DHHS, ODPHP, 2010), which advocates for Universal Health Literacy Precautions to be adopted in the initial training and continuing education of all health professionals. Nurses may not be adequately educated in HL competencies as indicated by significant HL knowledge gaps (Dickson et al., 2013) and less-than-optimal HL nursing practices reported in surveys (Schwartzenberg et al., 2007) or observed in patient-nurse interactions (Al Sayah et al., 2014). Recent reviews of health care provider education have suggested that health literacy concepts are essential to provider preparation due to the interconnectedness of literacy levels, communication interactions and health status (Coleman, 2011; McCleary-Jones, 2015; Toronto & Weatherford, 2015). Evidence from this review can suggest additional strategies or recommendations to teach expanded and evidence-based HL practices and competencies in nursing curricula, course content and clinical practice.

Methods

Nine electronic databases were searched December, 2015: *Academic Search Premier, Cumulative Index of Nursing and Allied Health Literature (CINAHL) Complete, Cochrane Database of Systematic Reviews, Dynamed, Educational Resources Information Center (ERIC), Google Scholar. Ovid Medline, PsychInfo* and *PubMed.* The keywords in this first approach used combinations of relevant terms including "HL", nurs*, communication and student. Once the initial search identified one hundred fifty or fewer records, a manual abstract review was undertaken to reduce selection bias or missed records due to an overly-restrictive keyword search. The second approach was a purposive search of the following health communication or nursing-related journals: Journal of Community Health Nursing, Journal of Health Communication, Journal of Nursing Education, Journal of Nursing Education and Practice, Nurse Educator, Nursing Education Perspectives, Nursing Outlook and Patient Education and Counseling. The third approach, an ancestry review of references from the final sample, validated that the majority of HL evidence was based in medically-oriented or primary health care research and graduate health professional populations (Coleman, 2011) rather than undergraduate nursing educational research.

Inclusion criteria were English language, peer-reviewed primary research reports from January 1, 2004 through December 1, 2015 at the baccalaureate level. The 2004 date was chosen due to the release of the Institute of Medicine report *HL: A Prescription to End Confusion* (Nielsen-Bohlman et al., 2004) which substantial recommendations were made to support HL integration in research, academic and clinical practice. Exclusion criteria were editorials, explanatory reports, disciplinary recommendations, dissertations and theses and unrelated nursing or adult educational topics. Additional topic-specific exclusion criteria were for

"information" or online (internet or web) literacy, dental (oral) literacy, or literacy studies of registered or advanced practice nurses currently in practice. Figure 1 details the search outcomes using PRISMA flow chart adaptation (Moher, Liberati, Tetzlaf, Altman & The PRISMA Group, 2010).

Data Extraction and Coding

Critical Appraisal Skills Programme (CASP) quality questions (Centre for Evidence Based Medicine [CEBM], nd) and appropriate HL theoretical components were used to extract data for the analytical framework. CASP questions evaluate up to 12 research design-specific criteria as present *(yes)*, absent *(no)* or unclear (*can't tell*). Identification of study emphasis, design, implementation quality and relevance to prior research and current practice enhances uniformity for research conclusion validity. Data was appraised using the following CASP and theoretical parameters: research design, aims, HL definition and theoretical framework, sample characteristics and recruitment, HL unit of analysis or intervention, HL competency taught, practiced or observed in other provider interactions, reliability and validity measures (quantitative), rigor and credibility (qualitative), outcomes measures and findings. The design level and the quality, quantity and consistency of the results were compared to determine the strength of the findings (Whittemore & Knafl, 2005). Table 1 provides a summary of aims, design, sample characteristics and course, intervention, outcome measures/themes and primary conclusion in reviewed articles arranged chronologically by publication date.

Results

Research Designs and Aims

The reviewed sample was published between 2008 and 2013, and consisted of lower level descriptive designs such as teaching case studies (Shieh & Hosei, 2008), cross-sectional surveys (Cormier & Kotrlik, 2009; Jukkala et al. 2009) or qualitative thematic explorations of student experiences (Scheckel et al., 2010; Shieh et al., 2013; Zanchetta et al., 2013). Two quasi-experimental studies (Sand-Jecklin et al., 2010; McCleary- Jones, 2012) provided the highest evidence levels (Sand-Jecklin et al., 2010; McCleary- Jones, 2012). Quantitative study aims were focused primarily on measuring functional HL perspectives and knowledge gains, with limited connections made between student competencies and patient outcomes (Cormier & Kotrlik, 2009; Jukkala et al., 2009; McCleary-Jones, 2012; Sand-Jecklin et al., 2010; Shieh & Hosei, 2008). Aims described student perspectives and exemplars during hospital-based patient interactions as the majority of clinical experiences (Shieh et al., 2013; Scheckel et al., 2010; Zanchetta et al., 2013). No studies were excluded either for the lower quality design or unclear aims during data extraction.

HL Theories and Definitions

No HL theory was directly identified as a research framework or used for hypotheses testing with the quantitative teaching interventions. The HL definition most referenced by five of the eight studies was the Institute of Medicine's consensus definition (Nielsen-Bohlman et al., 2004) which emphasizes the impact of limited patient literacy in health care (Cormier & Kotrlik, 2009; Jukkala et al., 2009; McCleary-Jones, 2012: Sand-Jecklin et al., 2010; Scheckel et al., 2010). Operational definitions of functional HL concepts such as patient literacy screening (Sand-Jecklin et al., 2010) or written material evaluation (Shieh & Hosei, 2008) were

exemplified in existing (SAM, SMOG, SILS) and researcher-created instruments and questionnaires (Cormier & Kotrlik, 2009, Jukkala et al., 2009; McCleary-Jones, 2012; Sand-Jecklin et al., 2010). Of the three studies conducted after the 2010 release of the *National Health Literacy Action Plan* (DHHS, ODPHP, 2010), none referenced the plan's health provider education goals or addressed Universal Health Literacy Precautions practice standards.

Sample Characteristics, Size, Inclusion and Exclusion Criteria

Participants from seven studies included prelicensure baccalaureate degree students at American university nursing programs, with one Canadian group (Zanchetta et al., 2013). Of the 635 total number of participants, 603 reported gender, with 438 of those supplying additional racial and ethnic information. The predominantly female (520/603, 86%) White (491/603, 81%) student population characterized the sample with few racially (Black or African-American, 46/438, 8%; Asian 2/438, 0.33%; American Indian, Alaska Native, Native Hawaiian or Other Pacific Islander 0, 0%) or ethnically (Hispanic or Latino 0, 0%) diverse participants. The sample somewhat mimicked nursing school gender enrollment percentages but not racial and ethnic trends (AACN, 2015). Descriptions of student HL experiences solely from predominant cultural or linguistic perspectives may limit student or nurse educator development of civic or cultural competencies inherent to the expanded HL definition (Zarcadoolas et al., 2005). Student abilities to effectively address health disparities may be lessened or inappropriate if culturally and linguistically diverse patient preferences, values and beliefs are not used as the basis to provide patient-centered nursing care based on educational exposures alone in academic settings.

Students starting their professional education were included to introduce HL knowledge and skills early in the process (Sand-Jecklin et al., 2010). Those closer to completion were identified as capable of giving more detailed descriptions of targeted HL constructs (Scheckel,

Emery, & Nosek, 2010, p. 796) or as having more extensive clinical experiences (Cormier & Kotrlik, Shieh et al. 2013; Zanchetta et al.2013). Students could exclude themselves through activity non-completion (Cormier & Kotrlik, 2009; McCleary-Jones, 2012; Shieh et al., 2013) or be excluded if the end product did not align with the HL outcome targeted by the researcher (Shieh et al., 2013). Ethical treatment of students as a potentially vulnerable research population was evident through IRB approval for all studies. Table 1 includes sample sizes and course associations where reported.

HL Evaluations and Interventions

The most frequently used quantitative HL evaluation involved cross-sectional tests of HL knowledge (Cormier & Kotrlik, 2009; Jukkala et al., 2009; McCleary-Jones, 2012; Sand-Jecklin et al., 2010). Student observations about HL practices in their clinical experiences were described through self-reported survey (Cormier & Kotrlik, 2009) and unstructured (Scheckel et al., 2010) or semi-structured written reports (Shieh et al., 2013). Oral recollections occurred during individual (Scheckel et al., 2010; Zanchetta et al., 2013) and focus group interviews (Zanchetta et al., 2013). Teaching interventions focused on HL knowledge development (Shieh & Hosei, 2008; Sand-Jecklin et al., 2010, McCleary-Jones, 2012), textual HL skills, such as readability and suitability measures in assessment of written health materials (Shieh & Hosei, 2008) or assessment and recognition of patients with limited literacy (Sand-Jecklin et al., 2010). Nursing faculty HL competencies or student perspectives about HL curriculum, course content or clinical activities were not fully explored, making it difficult to compare how and when students were exposed to HL competencies as a baseline.

Outcome Measures

Research outcomes focused on changes in HL knowledge and skills practice through screening patient literacy levels and written material suitability, and affective perceptions of student's roles in patient education. Teaching effectiveness related to HL knowledge was determined by percentages of correct answers to items related to limited literacy prevalence, impact and interventions (Cormier & Kotrlik, 2009; Jukkala et al., 2009; McCleary-Jones, 2012; Sand-Jecklin et al., 2010). Participants' abilities to screen for patients with limited literacy was assessed through use of the Single Item Literacy Screening questions (Sand-Jecklin et al., 2010) Although students identified health literacy interventions that they would use to document their assessment based on the SILS response, these interventions were not carried out or evaluated for effectiveness with patients. Students and practicing nurses established written health material adequacy for low literate prenatal patients using SMOG readability grade levels and SAM suitability criteria (Shieh & Hosei, 2008). When queried, participants reported that they had varying educational exposure to the HL or related concepts. They *rarely* or *sometimes* saw HL skills role-modeled or used consistently in clinical practice (Cormier & Kotrlik, 2009). Only half (27/53, 53%) of students in one study remembered hearing the term or definition of health literacy in prior educational experiences (McCleary-Jones, 2012).

The most common qualitative exemplars were drawn from student written (Shieh et al., 2013) and verbal (Zanchetta et al, 2013) perspectives, with paradigm cases developed from those perceptions (Scheckel et al., 2010). The majority of exemplars described student HL skills when providing or observing patient education in hospital health care environments. These examples were interpreted by researchers as sufficient demonstration of student competencies for safe and effective HL practices, but these findings may be less credible without additional confirmation of

student effectiveness, patient- perceived beneficence or improved health outcomes. The observations reflected stated themes but themes or subthemes were not as clearly linked to HL theories, operational HL definitions or prior nursing teaching practices or approaches. No consensus emerged from the findings to suggest appropriate quantity, quality or placement of HL concepts and evidence throughout nursing educational experiences from the experiences described by students.

Reliability, Validity and Credibility

Reliability reporting was inconsistent or minimal, potentially affecting claims of accuracy for the bulk of HL instruments and knowledge tests used by the researchers. With the exception of detailed psychometric reporting for the HL-KES instrument (Cormier & Kotrlik 2009), test item analysis for HL knowledge or instrument reliability was infrequently reported or missing. Cronbach alpha results were less than the recommended 0.70 (0.17, McCleary-Jones, 2012; Di Iorio, 2006). Few reliability statistics were reported for three studies using HL knowledge tests (Jukkala et al., 2009; Sand-Jecklin et al., 2010; McCleary-Jones; 2012). Without further evidence of reliability, nurse-educators may have difficulty assessing the accuracy of student HL knowledge gains or the effectiveness of the interventions for instruments other than the HL-KES (Cormier & Kotrlik, 2009).

Validity reporting focused on face or content validity with minimal or missing support for construct or concurrent validity with the exception of the HL-KES psychometric evaluation (Cormier & Kotrlik, 2009). Concepts evaluated by surveys may have been related more to student personality characteristics, innate abilities, prior health knowledge or prior health care experiences rather than core HL concepts assessed by the Limited Literacy survey (Jukkala et al., 2009) or pre- and post-tests (Sand-Jecklin et al., 2010; McCleary-Jones, 2012). The

inconsistencies in documented reliability and validity assessment limits the finding significance to support changes in curricular emphasis, course content or clinical experiences.

Rigor and credibility in the qualitative studies included detailed data collection and analysis descriptions to support dependability. Researcher-participant relationships or role delineation. were less well defined. Whether a teacher-student relationship existed prior, during or after data collection was either not indicated (Shieh et al., 2013; Zanchetta et al., 2013) or when indicated appeared to be overly-selective purposive sampling with increased potential for researcher or selection bias (Scheckel et al., 2010, p. 796). Unacknowledged risks of selection bias, combined with sample homogeneity and limited linkage to prior educational experiences or broader theoretical concepts may lessen support for the transferability of researcher-identified conclusions or generalizability to support use in nursing educational practice.

HL Inclusion in Nursing Education

Barriers to student use of HL practices included deficits in knowledge of HL impact and interventions (Cormier & Kotrlik, 2009; Jukkala et al., 2009; McCleary-Jones, 2012) and limited opportunities to practice skills or attitudes other than functional HL or rudimentary patient education in clinical experiences (Cormier & Kotrlik, 2009; Zanchetta et al., 2014). HL knowledge gains were reported as significant when measured immediately after brief teaching interventions (Sand-Jecklin et al., 2010; McCleary-Jones, 2012), but without additional educational reinforcement and clinical assessments over time it is uncertain if the gains would be maintained or knowledge applied in clinical practice.

Barriers to patient engagement were noted by the average 9th grade readability levels of written information (Shieh & Hosei, 2008), language discordant health materials (Scheckel et al., 2010; Shieh et al., 2013), and observations of health care provider inattention to HL practices

when interacting with patients (Cormier & Kotrlik, 2009, Scheckel et al., 2010; Zanchetta et al., 2013). Patients reported asking for clarification from family members first rather than their health care providers (Sand-Jecklin et al., 2010), potentially increasing their risk for receiving inaccurate or harmful health information. Patient learning outcomes were implied as potential increases in comprehension (Shieh & Hosei, 2008; McCleary-Jones, 2012), self-care skills (Sand-Jecklin et al., 2010; Shieh et al., 2013) and decision making abilities through appropriate patient education interventions (Scheckel et al., 2010; Zanchetta et al., 2013; Shieh et al, 2013). While subjective student reports suggest that patient outcomes were improved when students or nurses intervened to enhance patient knowledge (Shieh et al., 2013; Scheckel et al., 2010), little objective evidence supported these conclusions. Actions meeting national or disciplinary calls for patient-centered care and clear nursing communication are unlikely to occur without more robust and objective evaluation criteria and tools to benchmark HL competencies of all health providers, including nurses.

Discussion

HL Competencies and Nursing Communication Educational Development

Nurses are expected to communicate essential health information verbally and use written materials appropriately when interacting with patients (Cronenwett et al., 2007; Smith & Zhosar, 2011). Communication and health literacy competencies are shaped by the extent a particular concept is included and reinforced throughout nursing curriculum, course content and clinical experiences. Educational strategies to bolster nursing communication include knowledge and attitude development through lectures or workshops (Jukkala, Deupree & Graham, 2009, Shieh & Hosei, 2008) and honing verbal skills and attitudes through peer role-play, or with standardized or simulated patients (Grant & Jenkins, 2014). Combining evidence-based verbal

communication competencies to reinforce teach-back or teaching to goal, with more effective targeting of health materials and information to client needs and preferences has potential to enhance patient-nurse interactions as part of a Universal Health Literacy Precautions approach. At this time, however, there is little evidence to support existing teaching interventions as fully responsible for improvements in student health literacy practices, patient interactions or health outcomes.

Review Strengths and Limitations.

This review presents one of the first critical appraisals of HL competencies research in nursing education with related effects on nursing communication. One limitation is the use of a single researcher to analyze the data, which can increase selection or data evaluation bias without additional peer review. The use of multiple data bases and search strategies to locate the studies, and data extraction using CASP criteria for a standardized approach addressed this limitation to reduce possible bias. Significant research from international nursing educational programs may have been overlooked if not reported in English. Detailed comparisons with other health professionals could have identified similarities in curriculum, course content and clinical experiences, but an expanded literature review and analysis was beyond the review's scope.

Strength of the Evidence.

While two studies used the higher level quasi-experimental pre- and post- teaching intervention evaluation (Sand-Jecklin et al., 2010; McCleary-Jones, 2012), the paucity of studies, significant design limitations and minimal support for reliability and validity challenge the relevance of the findings for nursing educational practice (Table 1). The overall low evidence level of study designs restricts the credibility or generalizability of the findings. Key weaknesses

in the data include small sample sizes focused on functional literacy knowledge, skills and attitudes without clear theoretical frameworks or minimal use of active learning strategies.

The lack of solid evidence to guide teaching approaches is problematic for the future of nursing education, but not limited to HL instruction alone. The authors of an updated integrative review of pre-licensure nursing communication research concluded with similar observations about gaps in communication strategies quantity and quality (Grant & Jenkins, 2014). This may be symptomatic of gradual and fragmented evidence integration throughout nursing (Benner, Sutphen, Leonard, & Day, 2010). Barriers to integration of HL evidence in effective teaching practices will continue to limit inclusion without adequate nursing educational research funding, additional institutional support, stronger and more appropriate research designs, aims aligned to relevant outcome evaluations, and psychometrically sound instruments to assess HL competencies.

Nursing Education Implications

Concerns have been raised about the adequacy of current nursing student educational preparation to practice within increasingly complex and diverse health care environments (Benner, Sutphen, Leonard, & Day, 2010). Calls have been made to restructure nursing practice and education to expand beyond the traditional emphasis on tertiary care knowledge and technical skills but limited evidence exists to support the effectiveness of current or revised nursing educational practices and competency evaluations (Benner et al., 2010, p. 6; Cronenwett et al., 2007). Nursing education promotes strong professional identities and provides for student clinical engagement in learning, but is not as effective in linking nursing knowledge and scientific concepts to actual nursing practice (Benner et al., 2010, p. 11-14).

Increasing HL knowledge, concepts and theoretical approaches to educational practice has been recommended by all eight studies and strongly encouraged by nursing education proponents (Cornett, 2010; Smith & Zhosar, 2011). These authors, however, referenced theoretical discussions of HL concepts or provided descriptions of teaching principles and predominantly functional literacy learning activities to use with nursing students. Functional health literacy approaches such as screening patients for literacy levels, however, has not provided strong evidence for relevant provider interventions, improved health outcomes or greater provider and patient satisfaction with care (Paasche-Orlow & Wolf, 2007). Adoption of Universal Health Literacy Precautions multifaceted approaches should more closely align nursing educational practice with National Health Literacy Action Plan recommendations.

Conclusion

This review of HL evidence in available nursing education studies suggests that HL evidence should be included in nursing education, and that significant deficits exist in the quantity and quality of nursing education research to implement HL best practices. The functional HL perspective predominant in nursing clinical and educational practice has provided limited evidence for basic nursing student HL competencies, sustained improvements in student health information communication or patient learning outcomes. The overemphasis on patient deficits and written materials evaluation neglects the impact of provider communication and innate power imbalances on patient-provider interactions. More rigorous and theoretically-based educational research is essential to link HL knowledge, skills and attitudes to improvements in nursing student competencies. Greater inclusion of HL knowledge, skills or attitudes in nursing education curriculum, course content, and student clinical experiences has potential for nurses to

consistently incorporate multifaceted HL competencies to meet Universal Health Literacy Precautions national recommendations in patient-centered care.

Table 1; Summary of health literacy competencies taught or described in BSN educational research

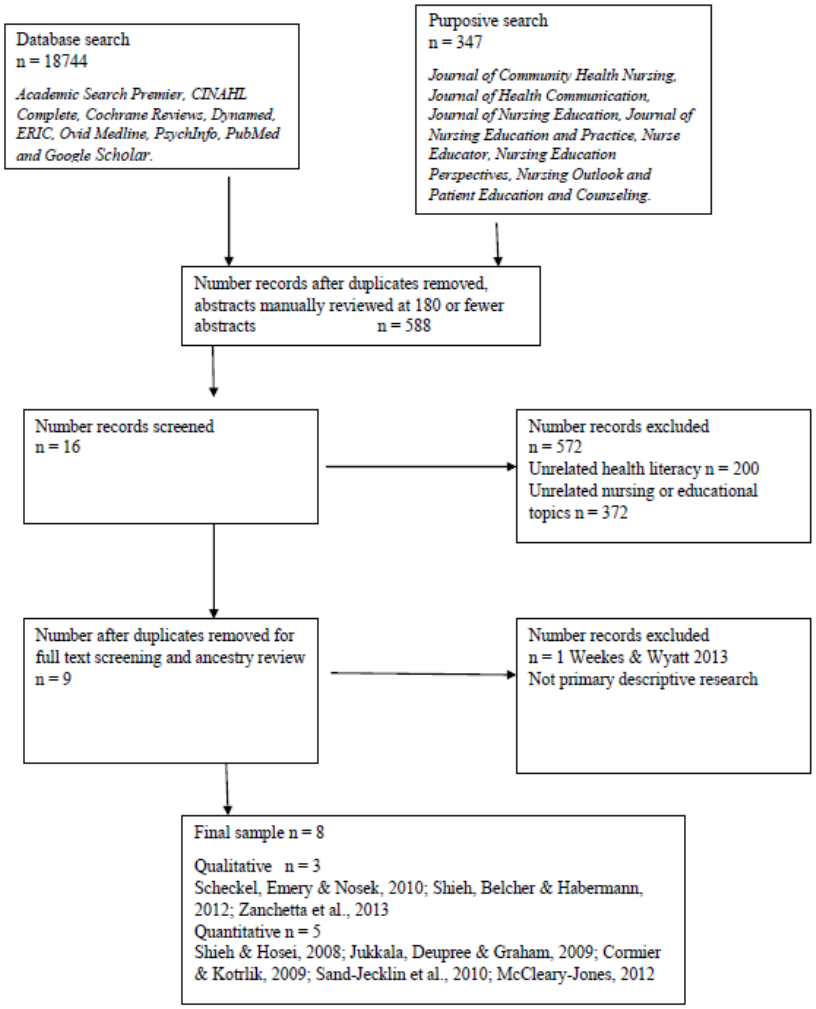
Author/s, (Year)	Primary Aim	Study Design	Sample & Course	HL Competencies	HL Educational Intervention	Outcome Measures or Themes	Main Finding
1. Shieh & Hosei (2008)	Compare written pamphlet ratings of students & practicing RNs	3 Phase Descriptive Case study; Post-intervention design	16 BSN senior students in Midwest 9 practicing RNs Community Nursing course	Pamphlet readability, suitability (Fundamental)	1 hour Health Literacy (HL) teaching SMOG readability & SAM suitability	SMOG readability formula SAM material suitability- 22 item observational checklist	Students rated written materials more suitable than practicing nurses ($p = .04$)
2. Cormier & Kotrlik (2009)	Identify HL knowledge and self-reported HL clinical experiences of senior BSN students	Descriptive Cross – sectional survey	361 BSN senior students from 8 Louisiana state universities Community Nursing	HL Knowledge learned and seen in clinical practice (Fundamental)	Health Literacy Knowledge & Experiences Survey (HLKES)	HL Knowledge: 29 question HL awareness survey HL Experiences: 9 questions of self-reported clinical exposure to HL use	Knowledge gaps: Limited knowledge about high risk populations and HL interventions Experience gaps- *rarely* or *sometimes* saw use of HL in practice
3. Jukkala, Deupree & Graham (2009) Course not reported	Assess the HL knowledge of health care providers	Descriptive Cross-sectional survey	230 health care providers (inc. nursing students) at southeastern HL conference	HL Knowledge learned (Fundamental)	Limited Literacy Impact Measurement survey (LLIM)	LLIM 8 question HL awareness survey administered to HL conference participants	Knowledge gaps: Effects of low health literacy (LHL) on health care systems
4. Scheckel, Emery & Nosek (2010)	Explore undergraduate nsg students' HL pt	Qualitative interpretive	8 BSN senior students at Midwestern university,	Teach to goal, use of questioning, alternates to written (Fundamental)	Pt experience question given 2 weeks before	Addressing HL Themes: Respecting languages-	Student patient education efforts include reports of HL such as return

Author/s, (Year)	Primary Aim	Study Design	Sample & Course	HL Competencies	HL Educational Intervention	Outcome Measures or Themes	Main Finding
	education clinical experiences	phenomenology, using Benner's hermeneutic approach	Course not reported	translating medical terms, analogies (Scientific, cultural) Verbal miscues & mismatches (Fundamental, Scientific, Civic, Cultural).Respecting cultural cues & language diversity	unstructured individual student interviews	Learning persistence, Helping patients understand-learning to teach, Promoting engagement-learning sensitivity	demonstration, assessment of pt capabilities and determining pt context
Authors, (Year)	Primary Aim	Study Design	Sample & Course	HL Competencies	HL Educational Intervention /Analysis	Outcome Measures/ Themes	Main Finding
5. Sand-Jecklin, Murray, Summers & Watson (2010)	Evaluate HL education intervention nsg student knowledge & HL concepts used in clinical practices	Quasi-experimental pre-post test retrospective data analysis of patient HL screening questions	103 BSN beginning students at Mid-Atlantic university: Introduction to Nursing/Health Assessment	HL Knowledge (Fundamental) Pt HL screening using Single Item Literacy Screening (SILS) questions (Fundamental)	Pretest, 20 minute HL teaching session, then Posttest; Student assignment Patient health assessment for care plan	8 researcher created pre & post-test questions HL awareness & knowledge Chew et al (2004) 3 Literacy Questions	Student HL knowledge gain in pre & post testing ($p = .000$) 43% of pts at risk for LHL based on responses to Chew et al. (2004) SILS questions
6. McCleary-Jones (2012)	Assess HL knowledge changes after online module presentation	Quasi-experimental pre-post test	59 BSN students, Junior year Pharmacology course	HL Knowledge (Fundamental)	5 question pre-test Online asynchronous health literacy knowledge and case study module 5 question	5 researcher created pre- and post-test questions: HL awareness and practices	Student HL knowledge gains noted in pre & post testing ($p = .001$)

Author/s, (Year)	Primary Aim	Study Design	Sample & Course	HL Competencies	HL Educational Intervention	Outcome Measures or Themes	Main Finding
					post-test		
7. Shieh, Belcher & Habermann (2013)	Explore HL practices of undergraduate nursing students when caring for clients with LHL	Qualitative thematic content analysis	59 final (6th) semester BSN students, Midwestern university, Nursing Research course	Questions for context, pt. behavioral cues, written material supplements (Fundamental) Explain med terms (Scientific) Pt empowered-question log (Civic) Translate HC system (Civic/Cultural) Verbal & linguistic mismatches (Cultural)	After qualitative research methods class, participants wrote retrospective story describing interaction of student with LHL patient Peer analysis of the stories prior to the final results submission	Themes: Sensing LHL by behavioral cues, promoting HL with multiple strategies, closing the loop with positive/negative feelings	Students are attentive to behavioral literacy cues and felt comfortable using a variety of strategies in diverse patient education situations.
8. Zanchetta, Taher, Fredericks, Waddell, Fine & Sales (2013)	Explore HL practices, barriers and curricular recommendations of undergraduate nursing students	Qualitative thematic content analysis using Freire's (1973, 2003) teaching philosophies as conceptual framework	16 final (year 4) students, Leadership and Professional Role Development course	Meet learning needs with verbal teaching/alt. media (Fundamental) HL Knowledge – lack of resources (Fundamental) & HL practices (Civic) HL technology access (Scientific) Consider cultural background,	3 Individual interviews or 3 focus group interviews starting with probing question of HL definition, structured guides	Themes: Awareness of barriers to becoming effective health educators, Students sensitivity to understanding HL within a critical perspective	Students were cognizant of LHL consequences for individuals and health system barriers. They were not comfortable intervening at higher levels without additional preparation. All recommended

Author/s, (Year)	Primary Aim	Study Design	Sample & Course	HL Competencies	HL Educational Intervention	Outcome Measures or Themes	Main Finding
				individualized teaching, alt. health education approaches (Civic/Cultural)			additional health education teaching, practice and health system support for HL interventions

Figure 1. Search outcomes flow chart. Keywords- "health literacy", nurs*, communication and student



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Submission for Journal of Nursing Education

Title: The feasibility of functional vs multidimensional health literacy teaching approaches in developing nursing health literacy competencies

Abstract:

This feasibility study examined the development and potential effects of functional vs multidimensional teaching interventions on the health literacy (HL) knowledge and HL-related behaviors of nine recently graduated baccalaureate nurse and nursing faculty. The intervention consisted of a one hour web-based HL didactic knowledge module followed by intervention-specific teaching sessions. Pre- and post-intervention HL knowledge was assessed using the Health Literacy Knowledge Survey (HLKES). Pre and post-intervention HL behavior in recorded interactions was evaluated using the Kangaroo Essentials Elements Communication Competencies-Adapted (KEECC-A) and Health Literacy Patient-Nurse Interaction Competencies Evaluation (HLP- NICE) observational checklists. HL knowledge changes were not different between groups ($p = .31$) based on HLK-ES percentages. Increases in communication and HL-related behaviors were noted for all participants based on KEECC-A and HLP-NICE scores ($p = .008$). No differences were noted between groups for HL-related behavior changes. Interventions were feasible and cost-effective for enhancing short-term HL–related behavior changes. Future research into training resources, educational strategies and validated measurement tools is warranted to advance HL integration in educational and clinical practice.

Keywords: Health literacy, nursing competencies, nursing curricula, outcome measurement, patient education, functional, multidimensional

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Literacy has long been associated with health status, health outcomes and health system impact. For those with lower literacy levels, health risks includes less use of disease control or health promotion measures (Keller, Wright & Pace, 2008) and higher morbidity and mortality rates (Sudore et al. 2006). Additional consequences include unnecessary ER use and higher hospital readmission rates (Berkman et al., 2010). Inefficiencies and harm related to the health effects of limited literacy are estimated to range from $106 to $238 billion annually in the U.S. (Vernon, Trujillo, Rosenbaum & DeBuono, 2007). Extensive research has described gaps between patient reading levels and the literacy demands inherent in the US healthcare system (Rudd & Keller, 2009), leading to an emphasis on patient literacy-based interventions to improve health outcomes. The *National Action Plan to Improve Health Literacy* (DHHS/ODPHP, 2010), a comprehensive framework of seven goals integrating health and literacy evidence, was formulated to promote a Universal Health Literacy Precautions approach for patients, organizations and health providers. Provider actions to be adopted include promoting shame-free and culturally-sensitive environments, incorporating plain language in written and verbal interactions and consistently verifying patient understanding through teach back techniques. Providers are expected to demonstrate these competencies at the completion of their educational experiences, but evidence-based research characterizing provider HL competency indicates that the competency preparation of providers, including nurses, is limited and of relatively recent origin (Coleman, 2011; Toronto & Weatherford, 2015).

Health literacy has been defined as an individual's *"…capacity to obtain, process, and understand basic health information and services needed to make health decisions"* (Nielsen-Bohlman, Panzer, & Kindig, 2004, p. 31-32). This definition has been used to guide past health literacy research, but may not account for the use of health information outside of formal health care settings, or fully explain how people use this knowledge to reach informed decisions or apply this knowledge to promote their health and well-being. Early health literacy research in the US emphasized patient literacy screenings and intervening for those with low or limited literacy levels. The majority of interventions used in this functional approach focused on written health literacy measures and patient abilities to read text. This approach is the one most commonly used in the US (Barry et al., 2013), yet neglects patient comprehension and the provider's contribution to health-related interactions and explanations (Castro et al. 2007; Schillinger et al.2003; Al Sayah et al. 2013). An updated AHRQ systematic review of 83 health literacy interventional studies suggested that isolated or single focus literacy approaches were less effective in ameliorating the effects of limited health literacy when compared to more intensive and multifaceted research strategies conducted over time (Berkman et al. 2010).

An alternative approach, multidimensional health literacy, includes patient competencies beyond text literacy, which include participation in verbal interactions, cultural beliefs and ways of seeking understanding (Shaw et al., 2012; Nutbeam, 2008, Zarcadoolas, Pleasant and Greer, 2005). However, incorporating multidimensional health literacy competencies may require development of expanded health literacy competencies by providers and organizations in addition to text literacy or written material modifications (Brach et al., 2012). A recent consensus study proposed health literacy competencies and health literacy-related practices for health professionals (Coleman et al., 2013), which may be useful for evaluation of differing theoretical and pedagogical strategies for evidence-based nursing education practice.

Nurses and other allied health professionals begin professional practice after completing undergraduate educational studies. Most health professional undergraduates may have minimal or no health literacy exposure throughout their curriculum, course content or clinical assignments (Coleman, 2011; Coleman et al., 2013, Cornett, 2010). Health literacy definitions and measurement are of relatively recent origin, which may add barriers to the quantity and quality of health literacy evidence integrated in provider education and practice. Reaching consensus concerning the addition of health literacy content in nursing education may be challenging given competing curricular priorities (Coleman, 2011; Toronto & Weatherford, 2015) and nursing curriculum demands, course content and external pressures regarding NCLEX testing and pass rates (Forbes and Hickey, 2009).

Nursing education research has focused more on traditional functional literacy skills, such as assessing nurse health literacy knowledge levels (Cormier & Kotrlik, 2009; Jukkala, Deupree & Graham, 2008; McCleary-Jones, 2012; Scheckel, Emery & Nosek, 2010), evaluating written materials (Shieh & Hosei, 2008) or conducting patient health literacy screenings (Sand-Jecklin et al., 2010). The majority of nursing education research has used lower level descriptive designs, such as surveys (Cormier & Kotrlik, 2009; Jukkala et al., 2008) or single site case studies (McCleary-Jones, 2012; Sand-Jecklin et al, 2010, Scheckel et al., 2010; Shieh & Hosei, 2008, Shieh et al. 2013, Weekes & Wyatt, 2013). Short-term student knowledge gains occurred after brief learning interventions (McCleary-Jones, 2012; Sand-Jecklin et al, 2010; Shieh & Hosei, 2008, Weekes & Wyatt, 2013), but sustained learning retention or direct observation of health literacy practices in patient-student interactions was not evaluated. Factors affecting reported outcomes included limited reliability and absence of validity testing (Jukkala et al., 2009; McCleary-Jones, 2012; Sand-Jecklin et al., 2010; Shieh & Hosei, 2008), researcher selection bias (Scheckel et al., 2010) and an overdependence on self-reporting with minimal corroboration from additional sources (Cormier & Kotrlik, 2009; Scheckel et al., 2010, Shieh et al., 2013, Zanchetta et al., 2013). These previous studies were limited through lack of identified theoretical frameworks, tests of long-term knowledge retention or evaluations of the impact of student learning on observed nurse-patient outcomes.

To address these research limitations, the current study was conducted to compare the effects of the more traditional functional HL teaching approach with an expanded multidimensional intervention in developing the HL knowledge and related behaviors of nursing students and faculty at a Southeastern baccalaureate nursing program. The intervention included an online didactic presentation of basic HL knowledge and evidence-based HL practices, followed by participation in intervention-specific face-to-face teaching sessions. The functional teaching approach focused on assessing and incorporating appropriate written materials, while the multidimensional approach emphasized identifying and incorporating patient-centered preferences to meet patient learning needs. Data were collected pre-and post-intervention to establish baseline HL experiences, knowledge and behaviors and to identify trending effects of the interventions. The study aims were to create and develop contrasting HL nursing curricula and pilot initial use of an observational HL competencies checklist in evaluating curricular outcomes. This study is one of the first to assess the feasibility of creating and using a health literacy-based tool evaluating differing health literacy approaches on the quantity and quality of health literacy practices directly observed in simulated patient- nurse interactions.

Methods

A sequential mixed methods research study design used preliminary qualitative reviews to hone the researcher-created HL observational checklist and quantitative data collection to craft the study of two curricular interventions for signals of difference (Creswell & Plano Clark, 2011). The results were then integrated to determine the feasibility of approaches and need for focus on areas for future development (Bowen et al., 2009). Institutional review board approval was obtained from the researcher's academic institution and the university research site before preliminary reviews or interventions were undertaken. Preliminary instrument development of the researcher-created Health Literacy Patient-Nurse Interaction Competencies Evaluation tool (HLP-NICE) was initiated to benchmark performance of observed evidence-based HL practices. Preliminary teaching activities focused on creation of the Web-based HL knowledge module, functional and multidimensional teaching interventions and unfolding case study (Bastable, 2014). Preliminary study preparation included research team recruitment and training activities designed to support recruitment and informed consent principles, to build team HL knowledge and to train standardized patients to rate observed HL practices consistently (Wallace, 2007). The HLP-NICE was then piloted to assess HL-related behaviors before and after participants completed either functional or multidimensional focused teaching interventions.

Qualitative Component. A qualitative case study design was employed in the development of an observational checklist to assess HL-related interactions, curricular interventions and teacher and standardized patient training (Green & Thorogood, 2014). Cognitive interviews were used to gather potential user reactions to wording comprehension and use of the HLP-NICE instrument (Willis, 2005). Content experts in health literacy, nursing and linguistics were surveyed for perceptions regarding HLP-NICE quality and relevancy to underlying HL concepts to calculate a content validity index (di Iorio, 2005). A focus group was convened to solicit student and faculty perceptions of limited health literacy.

Comment [FK1]:

Quantitative Component. The study interventions used a between subjects quantitative design for data collection and analysis to measure participant HL knowledge and HL-related behaviors before and after exposure to the two contrasting educational interventions. Intervention data included pre-intervention demographic and HLKES experience questionnaires, pre- and post-intervention questionnaires for HL knowledge yielding HLKES scores, and observational checklist scales to assess intervention trends through KEECC-A communication scores and HLP-NICE HL-related behavior scores.

Integrative Component. Designed as a sequential mixed-methods study (Creswell & Plano Clark, 2011), the qualitative and quantitative components were integrated and analyzed as to which feasibility focus areas were achieved, and which needed subsequent development as described by Bowen and colleagues (2009). Components identified as needing modification will be analyzed more intensively and merged to support HLP-NICE instrument quality and future

refinement (di Iorio, 2005; Willis, 2005), process acceptability or practicality, and intervention implementation (Bowen et al., 2009) in future research.

Qualitative Case Study. An instrumental case study methodology was appropriate in collecting preliminary qualitative data components to describe the story of "Mrs. Marika Smith", the intervention's unfolding case report patient (Stake, 1995; Baxter & Jack, 2008; Hyett, Kenney & Dickinson Swift, 2014). The primary purpose of this mixed methods feasibility study was not qualitative in nature, but preliminary data was needed to answer questions of how nurses might use HL competencies to communicate health information with "Mrs. Smith" and other individuals, and how to educate for and measure those competencies during a nursing discharge process. The case study boundaries were limited to nurses who had the minimum of a BSN degree, and who were giving discharge instructions in an acute care medical-surgical setting during a simulated-patient interaction. The first research issue was effective development and training of standardized patients and teacher to provide realistic and relevant teaching and evaluation interventions. The expectation was that nurses who participated in the study would gain HL knowledge to improve HL-related behaviors. The second issue was quality assessment of an observational checklist evaluating the quantity and quality of HL competencies nurses used when interacting with "Mrs. Smith". The conceptual framework undergirding the research was that HL involves more than text-based literacy alone, but adds fundamental, scientific-technological, cultural and civic contextual dimensions reflected in Zarcadoolas, Pleasant & Greer's (2006) HL definition and conceptual approach. Multiple embedded data sources with different levels of nursing experience and exposure were solicited to provide depth and richness to "Mrs. Smith's "story based on participant input.

The first research issue was addressed through convening a focus group consisting of two faculty and four junior-level nursing students to share, discuss, and construct their nursing knowledge and exposure to traditional functional compared to additional multidimensional HL concepts seen in curricular, course and clinical experiences (Barbour, 2008). As nurse faculty and as principal investigator, I had dual roles during the focus study which had to be ethically balanced between the desire to collect necessary data for the study and the power imbalance inherent in teaching and interacting with students as they reached the senior level. To deal with this potential conflict, a colleague from the psychology department with expertise in interviewing techniques facilitated the group while I was the silent observer who documented field notes regarding the emotional tone and group organizational changes, but did not actively participate in group discussions. One example of information that was used to inform SP characterizations of "Mrs. Smith" was reported by T1 in stating, "…I used to ER too and I would always hear that 'I can't read it without my glasses,' but I never heard anyone say, 'No, I can't read' ". This information was used when training the standardized patients to respond when given a CHF pamphlet to read by stating, "I don't have my reading glasses with me, so I will read it when I get home". This statement was used by the teacher to introduce triggers for nursing actions to assess the patient's reading abilities further during the interaction. When doing this initial reading of the focus group, the nature of nursing role defense versus patient needs to defend their self-image began to emerge as a theme, but needs further analysis of the transcripts and field notes to confirm this them or elicit additional themes and subthemes.

The second issue of HLP-NICE tool quality was addressed through two approaches: Individual cognitive interviews to evaluate tool wording and process quality (Willis, 2005), and an expert panel to assess agreement about tool relevance and congruency with the multidimensional HL definition (di Iorio, 2006). The semi- structured cognitive interviews were solicited from potential tool users including the two SP's, a junior level nursing student, a faculty member with expertise in simulation, and a practicing nurse. My role in this process was as the inside interviewer, but in order to reduce personal bias and increase standardization I used a scripted interview introduction and standardized interviewer responses. I hand recorded each interview to remain engaged in each hour-long discussion without contributing any remarks or observations beyond those previously scripted or to cue additional think aloud explanations. One example of information that was given to consider for modification was the use of the word "context", and unanticipated negative associations or lack of understanding which might occur with use of that word in one of the HLP-NICE items.

The second approach queried four experts in health literacy, nursing education and linguistics to explore HLP-NICE item congruence with the multidimensional HL definition related to nursing HL behaviors, and the tool's relevance for the assessment of HL behaviors (di Iorio, 2006). A content validity index of 88.9% approached the signal benchmark of 90% for face and content validity (di Iorio, 2006). I had completed a quality analysis prior to asking for panel participation (Willis, 2005), and many of the expert comments dove-tailed with my own initial quality perceptions. Several items were observed to be difficult to analyze objectively, so that wording changes might need to be considered for more understandable or precise verbiage. Information from the cognitive interviews and expert comments will be reviewed and incorporated before the next round of quality assessments is undertaken.

Teaching Strategy Development. Preliminary teaching activities focused on creation of the Web-based HL knowledge module, development of functional and multidimensional teaching interventions and the unfolding case study integrating HL concepts and practices from the case study and HL evidence-based literature. The Web-based module and teaching interventions scripts followed the researcher-developed "ACTS" acronym (French, 2015) synthesized from the current HL research, competency recommendations (Coleman et al., 2013; Cornett, 2010) and Universal Health Literacy Precautions recommendations (US DHHS ODPHP, 2010). Congestive heart failure (CHF) was chosen for the case report exemplar and standardized patient medical background due to condition frequency and Medicare-related economic incentives to reduce CHF 30 day readmission rates (White, Garbez, Carroll, Brinker & Howie-Esquivel, 2013). Didactic content included the prevalence and impact of limited health literacy, functional and multidimensional nursing interventions and introduced "Mrs. Marika Smith" as the geriatric case report patient with newly-diagnosed congestive heart failure (CHF) preparing for hospital discharge. The module concluded with support for Universal Health Literacy Precautions recommendations (USDHHS-ODPHP, 2010) as the expected standard of nursing care.

Health Literacy Tool Development. A literature search did not locate an existing instrument to assess nursing or health provider use of HL practices with patients, or to identify the effects of

HL competency development and effects on patient-nurse interactions. The Health Literacy Patient-Nurse Interaction Competencies Evaluation (HLP-NICE), was created to fill this gap using scale measurement design principles for guidance in development (DeVellis, 2012; Waltz, Strickland & Lentz, 2010). The 20 items of the Health Literacy Patient-Nurse Interaction and Communication Evaluation (HLP-NICE) were synthesized from HL standards culled from national educational programs designed for health providers with selected health literacy consensus competencies from an interdisciplinary panel of academic health professionals undergirding item concepts (Coleman et al., 2013). The frequency of HL practices observed in patient-nurse interactions were rated to provide a latent indicator of HL competencies.

Sample. The convenience sample initially consisted of eleven recently graduated baccalaureate nurses or nursing faculty recruited from a Southeastern public liberal arts baccalaureate nursing program. Former students from the previous two years and nursing faculty were invited to participate by word of mouth, online and hard-copy poster announcements with additional mailed invitations during the school break after graduation. Respondents were formally consented into the study by the research assistant, then randomly assigned to each cohort using a systematic randomization strategy (Waltz, Strickland & Lenz, 2010). Two of the recent nursing graduates (one male, one female) completed the first interaction but not the teaching interventions or second interaction leading to their data being excluded from the final analysis. The remaining nine participants included three graduates and six nursing faculty. Table 1 and 2 provides summaries of the demographic data.

Instruments. Participants completed the Health Literacy- Knowledge and Experiences Survey or HLKES (Cormier & Kotrlik, 2009) before the teaching interventions with only the Health Literacy-Knowledge (HLK) section repeated post-intervention. The HLKES is a 38 item questionnaire which contains two sections: 29 multiple choice health literacy cognitive knowledge questions (HLK) and nine items assessing the frequency of HL practices seen during nursing school clinical experiences (HLE). The HLK section multiple choice questions tested general health literacy knowledge in five content areas: Basic health literacy facts (six questions), limited health literacy information (four questions), patient literacy screening (six questions), written material guidelines (eleven questions), and intervention evaluation (two questions). The results were scored as correct or incorrect, with the percentage correct to benchmark HL knowledge with levels ranging from 0 – 100%. The HLE identifies exposure to subsets of clinical health literacy core (6) and technology (3) seen or practiced during one's nursing clinical education. The HLE section used a four point Likert-type scaled response or the self-reported recall section with responses ranging from 1 = *never* to 4 = *always*. The HLKES may have advantages over other HL knowledge instruments, such as Limited Literacy Impact Measurement (Jukkala, Deupree & Graham, 2009) or the McCleary-Jones multiple choice questions (2012), due to expanded conceptual evaluations and more robust reliability and validity evidence (Cormier & Kotrlik, 2009).

Participant communication competencies when interacting with simulated patients were scored using the second instrument, the Kalamazoo Essential Elements Communication Checklist Adapted or KEECC-A (Joyce, Steenburgh & Scher, 2010; Rider, 2010). The KEECC-

A is a seven item Likert-type four point rating scale which is used to evaluate medical student communication competencies based on the Kalamazoo I and II consensus statements. These seven competencies were characterized as follows: Builds relationships, opens the discussion, gathers information, understands the patient's perspective, shares information, reaches agreement and provides closure. There was no single communication competency instrument recommended for use in medical educational practice, but the original KEECC was noted to align well with the consensus competencies (Schirmer et al, 2005). The modified version was designed to increase ease of use and reduce administration time from 30 minutes to 7 minutes. Reliability and validity of the KEECC-A was reported when used to assess medical student communication competencies of (Joyce et al., 2010). Verbal communication of health information is one essential component of health literacy provider competencies (Coleman et al., 2013).

A literature search did not locate an existing instrument to assess nursing or health provider use of HL practices with patients, or to identify the effects of HL competency development and effects on patient-nurse interactions. The Health Literacy Patient-Nurse Interaction Competencies Evaluation (HLP-NICE), was created to fill this gap using scale measurement design principles for guidance in development (DeVellis, 2012; Waltz, Strickland & Lentz, 2010). The four categories of the HLP-NICE checklist were structured after those used in an educational intervention to improve health literacy competencies of medical students (Kripalani et al., 2006), but the addition of patient engagement and final assessment was necessary to capture starting and completing a communication interaction.

For each of the twenty checklist items, observed frequencies of HL practices were rated using six point Likert-type scale descriptors ranging from *0 = Not observed* to *4 = Excellent* in addition to a *Not applicable* (N/A) option. If N/A was selected, the participant would not be penalized for items which might not be relevant for a given situation. Completed ratings were summed and ranged from 0 - 80 if all 20 items were scored. If fewer than 20 items were rated, the final result would be based on the summed score divided by the total number of items evaluated for the total percentage. At this point in time, there was no minimum cutoff for an acceptable number of items completed to determine the summed or percentage score. Outcomes percentages or calculated means could then be used to identify a participant's individual competencies at one point in time or make comparisons across time.

Procedures. After consenting to participate in the quantitative study, the volunteers completed the demographic survey, HLKES and first recorded interaction. Participants were then given a link to access the researcher-created one hour long web-based module entitled "*Meet Mrs. Smith: Building health literacy competencies of nurses through ACTS."* Participants were then given time and location information to attend their theoretically- specific teaching session.

The one hour functional health literacy teaching session focused on assessing patient literacy levels and interventions based on nurse-identified problems. The Single Item Literacy Screening or SILS (Morris et al., 2006) for patient literacy screening, the Simplified Measure of Gobbledygook or SMOG as the readability formula and the Suitability Assessment Measurement or SAM written material evaluation checklist (Shieh & Hosei, 2008) characterized functional intervention practices.

Teaching activities focused on patient education improvement through:

A-Assessing patient literacy and material suitability levels,
C-Comparing reading levels with available materials,
T-Teaching and highlighting 3 key points in written materials, and
S-Surveying for additional learning resources or needs.

After brief review of didactic HL Knowledge content from the online module, participants worked in pairs using the SILS, SMOG and SAM to evaluate patient literacy levels, evaluate written material suitability and apply this information to "Mrs. Smith's" situation. Key functional learning points were detailed on an index card for future reference and participants completed a final reflection outlining how they might use these principles in practice.

The one hour multidimensional health literacy interactive teaching session included the didactic HL information, but also integrated multidimensional health literacy principles such as using plain language and common analogies, verifying patient comprehension and assessing and re-assessing patient concerns. Activities designed to foster multidimensional competencies were:

A- Assessing patient preferences and learning needs,
C-Comparing patient preferences to available resources and materials,
T-Teaching three key points focused on patient concerns, then confirming understanding through Teach Back, and
S-Surveying for additional concerns or learning needs through open-ended questions.

The final activity involved pairs of students practicing and critiquing peer interactions using a student-produced checklist as a process guide and cues for self-evaluation with essential learning points detailed on an index card for future reference. A final reflection was completed outlining key multidimensional information learned and how they might apply this health literacy knowledge in practice. All participants returned one to two weeks after attending their specific teaching session to repeat the HLK section of the HLKES and the recorded post-intervention discharge teaching interaction with the standardized patient.

Intervention Data analysis. Data integrity checks and analyses were performed using SPSS v 23 (SPSS, IBM 2016) with no outliers identified and a normal distribution. Descriptive statistics were tabulated from participant completion of the demographic survey and the HLE section of the HLKES (Cormier & Kotrlik, 2009) using appropriate univariate statistics. Self-reported age, past years in health care and faculty time worked were analyzed using ranges, means, medians and standard deviations (Table 1). Self-reported gender, race/ethnicities, past work (yes/no), grade point average range, type faculty teaching assignment and final degree achieved categorical variables were analyzed as numbers and percentages (Table 2). The use of non-parametric statistics was inferred by the small sample size and an inability to meet homoscedacity or linearity assumptions confirmed this decision. Significance was assessed at the alpha level of .05 with one tailed options for directional tests. For one participant, the last part of

their pre-intervention recording had been lost due to a technological glitch. This problem was not identified until after the intervention had started. Rather than discarding the 90% of remaining data for the 10% of that participant's "missing completely at random" data, missing values were substituted using the SPSS v23 (IBM, 2016) linear interpolation procedure (Waltz, Strickland & Lenz, 2010). Using substituted values, however, meant the interpretation of the results could be affected by the potential loss of variance and should be interpreted cautiously due to this effect.

Results

Table 3 presents HL knowledge and HL-related behavior instrument results pre- and post-intervention for the functional HL group compared to the multidimensional HL group.

Table 4 presents a post-hoc analysis using Bowen's and colleagues logic model (2009) to capture feasibility focus areas, how they were assessed and outcome benchmarks.

Discussion

Recall of health literacy experiences using HLE items suggested that participants did not see or use core and technology health literacy in practice (Table 3), which is similar to prior self-reported exposure (Cormier & Kotrlik, 2009). Acquisition of HL knowledge did not appear to have been affected by past amount of health experience or education (Table 1, 2). Health literacy knowledge did not signal an increase for participants, although five of nine participants (55.6 %) demonstrated HL knowledge gains. Increases in knowledge were greater, however, for the multidimensional HL compared to the functional HL group (Table 3). The teaching interventions did include a limited review of HL knowledge, but the primary emphasis was applying intervention-specific HL knowledge through individual and peer practice rather than retaining HL facts.

Gains in HL competencies did not appear to be dependent on gaining HL knowledge information or increasing discrete knowledge facts. The increases in HL-related HLP-NICE and KEECC-A communication scores occurred with no similar increases in HL knowledge (Table 3). This finding suggests that deliberative practice of action-based knowledge applied to HL-related behaviors may be more successful than teaching HL facts without additional application or thoughtful practice. Both functional and multidimensional groups signaled an increase in their HLP-NICE HL-related behaviors and KEECC-A communication competencies (Table 3). The functional HL group, however, increased their communication competencies reflected in KEECC-A more than the multidimensional HL group (Table 3). This finding may be due to greater participant familiarity and comfort levels in using written or textual materials when educating patients also seen in reported HLE results. Participants recalled using written materials as the most observed HL intervention in educational practice ($M = 2.78$, $SD = .87$) more than being taught HL concepts in their nursing program ($M = 2.22$, $SD = .44$), which was similar to initial reports (Cormier & Kotrlik, 2009). Declines in HLK instrument reliability occurred between pre- and post-intervention results (pre-Cronbach α .66; post-Cronbach α .42). This finding could be attributed to this study's use of the HLKES for pre- and post-testing rather than

the instrument's original design for cross-sectional survey purposes, or by discrepancies between factual knowledge measured by the HLK, but not emphasized by the teaching interventions. The KEECC-A was a reliable measurement of communication competencies even with the small sample size (pre-Cronbach α .77; post-Cronbach α .82). While reliability and convergent validity with the KEECC-A was signaled for the HLP-NICE (r_2 = .95, p = .00, correlation coefficient 1) the small sample, lack of power and effect size would not support evidence for reliability or validity based on these results.

The feasibility focus areas that were addressed in this study included acceptability, practicality, implementation and integration (Bowen et al., 2009) and are documented in Table 4 to identify lessons learned when considering future research interventions. The total time for pre- and post-interaction evaluations and the online and face-to-face interventions took approximately four hours spread out over a one-month time period, which was not perceived as unacceptable or overly time-consuming by participants who completed the study. Recruitment was challenging due to anticipated barriers such as inability to participate due to timing and family conflicts. Several graduates and faculty were interested in participation, but unable to do so due to time conflicts, such as moving from the area or family conflicts with the intervention dates available. One unexpected barrier noted was that of performance anxiety due to being recorded. This nursing program did not record simulations or student skills, so that the fear of being judged inadequate may have over-ridden the anonymity and confidentiality built into the research procedures Future attempts to address performance anxiety might include offering practice sessions recorded with a standardized patient, followed by self-evaluation to reduce performance fears. Sample diversity and size may have improved with additional consideration of participation convenience for the intervention activities. For future research efforts, finding another school of nursing within the geographical area as a research partner might widen the diversity and size of the recruitment pool.

Though creating a Web-based format to present standardized functional HL and multidimensional HL concepts was practical, there was no way to ensure that the online HL Knowledge module was viewed before the teaching intervention. Some participants reported difficulties viewing the online information, indicating technological access difficulties which may have interfered with knowledge retention. Offering the Web-link both asynchronously and as a one-hour on-site session before the one-hour teaching session would give participants the option to access the materials at their own convenience or to plan on attending the pre-teaching session time if technology issues occurred. Collaborating with psychology graduate students as standardized patients was practical and integrated interdisciplinary collaboration elements and objectivity regarding the interventions and performance interactions. The time conflicts, however, that students and simulated patients had with other work or school related responsibilities had an effect on completion of participant ratings by one of the standardized patients. To overcome this difficulty, recruiting culturally and ethnically diverse participants from senior citizen centers, community support groups or churches, and then having them train with psychology graduates might keep a consistent group of standardized patients available using an interdisciplinary approach without causing undue time or cost strains on individuals or groups. From this training, teaching scripts and recorded interactions could be developed as exemplars of good and excellent HL practices to train both standardized patients and integrate

healthier and more evidence-based communication role-models for nurses. While the HLP-NICE tool and two HL curricula and teaching strategies were initially developed for baccalaureate nurses, the concepts are applicable to effective communication for all health providers. Adapting these approaches to all nursing levels or expanding use of the HLP-NICE to evaluate real-life interactions may be possible once additional efficacy testing has been completed.

This feasibility study is one of the first studies in undergraduate nursing education to use a mixed methods research design incorporating randomized assignment, and evaluating contrasting theoretical approaches in developing HL provider competencies. Strengths included incorporation of diverse teaching approaches, such as the online standardized presentation of HL knowledge, active learning strategies such as peer-critiques and self-reflection, and use of standardized patients in simulated discharge interactions. In contrast to immediate evaluation of HL knowledge presentations (Sand-Jecklin et al, 2010; Weekes & Wyatt, 2013), the second knowledge test and standardized patient interaction were not completed until one to two weeks post-intervention. The results, therefore, were not based on immediate recall, but allowed for considerations of intervention effectiveness over a longer time than previously studied. Limitations include a lack of generalizability due to the small sample size of nine participants, lack of racial and gender diversity, and the effects of psychometric and data analysis issues on final results. The HLP-NICE offers a promising beginning to assessing the HL and communication competencies of nurses and nursing students, but could not be recommended as a reliable or valid instrument without additional modifications and re-testing with a larger and more diverse sample.

The study's purpose was to explore the feasibility of interventions exploring HL knowledge acquisition with the effects of prior HL experiences and impacts on health literacy-related behaviors or action changes. Previous clinical experiences or use of HL competencies in practice continues to be minimal, despite recognition of the risks of patient-provider miscommunication seen in national recommendations for Universal Health Literacy Precautions approach (USDHHS-ODPHP, 2010). Evidence-based HL practices may not be consistently used or effectively role-modeled, which adds challenges to existing nursing educational and clinical practice. Teaching or assessing functional HL knowledge and skills alone has characterized the majority of nursing education research (Jukkala, Deupree & Graham, 2009; Cormier & Kotrlik, 2009; McCleary-Jones, 2012; Sand-Jecklin et al., 2010; Shieh & Hosei, 2008). Students could relate both good and poor HL practices seen in clinical experiences (Shieh, Belcher & Habermann, 2013; Scheckel, Emery & Nosek, 2010; Zanchetta et al. 2013). Students did not feel, however, they had been adequately taught how to educate patients or how to advocate for health system improvements after identifying patient problems. All previous studies recommended additional HL concepts be taught and applied in nursing education, but no reported evidence had either framed findings with theoretically-based HL curriculum or linked increases in student HL knowledge to observed changes in HL-related behaviors or patient outcomes.

Gaps in current HL educational practices were addressed in this study to provide more rigorous evidence for diverse and interactive strategies to foster enhanced nursing health literacy competencies. All patients, regardless of literacy or language abilities, need understandable and actionable health information if they are to follow health instructions, use health resources

effectively and avoid preventable safety errors and costly readmissions. The health literacy competencies needed to provide patient-centered education should be threaded throughout the nursing curriculum, practiced in simulated educational and real-life patient clinical interactions, and reinforced for current nurses through continuing education activities. Universal Health Literacy Precautions provide evidence-based standards which nurses can use to collaborate more effectively with their patients in self-care management and shared decision-making. The findings of this feasibility study signal a new direction in nursing educational research, which shifts from HL cognitive knowledge acquisition to knowledge application advancing HL-related behavior changes.

Table 1. Sample demographic characteristics (continuous)

Demographic Characteristic	**Mean**	**SD**	**Range**
Age (n = 9)	44.89	16.58	22 - 69
Time (Yrs/months) of health care experience (n = 9)	16.89	17.21	0 - 45
Time as faculty member (n = 6)	7.67	8.82	1 - 23

Table 2. Sample demographic characteristics (categorical)

Demographic Characteristic	**Number (N= 9)**	**Percentage %**
Female Gender	9	100
Ethnicity, Not Hispanic or Latino	9	100
Race, African American or Black	2	22.2
Race, White	7	77.8
No past health care work outside of nursing school	1	**11.1**
Past health care work outside of nursing school	8	89.9
Graduation GPA 3 – 3.49	2	22.2
Graduation GPA 3.5 – 4.0	7	77.8
Final degree BSN	3	33.3
Final degree MSN	2	22.2
Final degree DNP	2	22.2
Final degree EdD	1	11.1
Final degree DNS	1	11.1
Faculty teaching med surgical	5	89.9
Faculty teaching maternal-child	1	11.1

Table 3. Pre- and post-intervention comparisons of HL Knowledge, Communication and HL-related behaviors

Instrument	**Pre-intervention**		**Post-intervention**		***p* value**
	Functional HL group (n = 4)	Multidimensional HL group (n = 5)	Functional HL group	Multidimensional HL group	
HL Knowledge: HLK-S: % correct (Cormier & Kotrlik, 2009)	m= 65.51 SD = 14.1 44.8 – 75.9	m = 63.5 SD = 14.9 48.3 – 82.8	m = 65.52 SD = 7.5 58.62 – 75.9	m = 77.2 SD = 6.3 68.9 – 82.8	.31
Communication: KEECC- A: Mean total scores (1 - 5/5) (Rider, 2010)	m = 2.57 SD = .37 2.14 - 3	m = 2.8 SD = .73 1.86- 3.71	m = 4.9 SD = .07 4.86 - 5	m = 4.5 SD =.37 3.86 – 4.85	.008
HL-related Behaviors: HLP-NICE: Mean total scores (0 - 4/4)	m = 2.23 SD = .41 1.9 – 2.83	m = 2.2 SD = .56 1.6 - 3	m = 3.8 SD = .25 3.47 - 4	m = 3.4 SD = .13 3.16 – 3.5	.008

Table 4. HL Study feasibility focus areas using Bowen & colleagues (2009) guidelines.

Aim	Feasibility focus area	Activities	Evaluation Method	Expected Outcomes	Outcome assessment/Comments
1. HLP-NICE development	1. Practicality	- Cognitive interviews with potential users - Content validity survey for relevance and agreement	- Review of cognitive interview comments -Review of content validity comments and ratings to determine a content validity index of agreement	- Tool qualities signaled in initial scale development - Tool alignment with MDM HL definition and constructs -	HLP-NICE practicality partially met. - Cognitive interviewees reported tool easy to understand, potential wording modifications needed for quality improvement -Content validity index 88.9%
2a. Developing Functional (F) or multidimensional (MDM) teaching strategies	2a. Implementation	- Focus group interviews using nursing faculty and junior students	- Review of focus group transcripts	- Degree of execution for teaching interventions - Success or failure of intervention execution - Amount or type of resources needed to execute-	Teaching strategy assessment for implementation partially met. -Focus group members described low literacy behavior cues, nursing expectations for pt education, focused on F more than MDM interventions -Resources needed: recording equipment & personnel to use, realistic simulation support (clothes, medical record, forms) -More in-depth analysis needed to refine future teaching approaches and resource allocation
2b. Recruiting and training standardized patients (SP) and teacher in HL competencies	2b. Practicality	- Preliminary phase SP and teacher training sessions -Development of SP and teacher training scripts	- Researcher assessment and SP/ Teacher feedback for intervention effects on SP and teacher abilities to successfully carry out HL competency assignments	- Positive/Negative effects on SP' s and participants - Ability of teacher and SP's to carry out teaching intervention and interactions	Team function practicality partially met. -Positive: Teacher/SP's recruited & trained in 8 hours total teaching sessions, SP rating criteria scripts, teaching F/MDM intervention scripts created - Positive: Teacher/SP successfully carried out interventions and interactions - Negative: Time and work conflicts once regular school term started for SP's – 1 unable to finish ratings

Aim	Feasibility focus area	Activities	Evaluation method	Expected Outcomes	Outcomes Assessment/Comments
2c. Recruiting participants for preliminary and intervention research	2c. Acceptability	- Comparison of participants to non-participant responses to identify perceived benefits & barriers of study inclusion	Informal survey, completion of all research activities -Number/percentage of participants who completed the interventions	-Perceived appropriateness for participation in BSN level research - Intent to complete the research process	Acceptability partially met. -Non-participants reported time, work conflicts and fear of being recorded as reducing acceptability - Mail not effective as recruitment strategy (>1% response rate) 9 of 11 (81.8%) completed research procedures
3a. HLP-NICE when used with F/ MDM approaches	3a. Practicality	-HLP-NICE pre- and post-intervention ratings	Review HLP-NICE inter-rater reliability scores and pre- and post HLP-NICE ratings, and informal survey for tool use, review of factors or effects of teaching interventions	- Tool ease or difficulty of use in rating SP interactions -Positive/negative effects of on participants or SP/Teacher performance	Tool practicality in use partially met - Positive: Tool took 10 minutes or less to complete, easy to follow -Positive: Tool inter-rater reliability $\kappa = .52$ - Negative- Took 2 attempts to reach inter-rater reliability between SP & researcher -Not assessed- use of tool for giving immediate feedback during interactions
3b. F/MDM teaching approaches	3b. Implementation	- Recorded teaching interventions -HLK pre- and post-intervention -HLP-NICE	Review of HLK pre- and post-ratings & recorded teaching sessions Review of HLP-NICE pre- & post-ratings	-Degree of intervention execution - Success or failure of intervention or tool execution -Amount or type of resources needed to execute	Implementation met: Interventions fully and successfully implemented with adequate resources to complete interactions and teaching interventions
4. HLP-NICE use with functional/ Multidimensional approaches	3c. Integration	Analysis and integration of HLP-NICE qualitative and quantitative findings	Review of final results and budget	- Perceived fit with BSN educational practice - Perceived sustainability - Costs to current nursing program, anticipated costs to academic programs	Integration partially met: Teaching interventions appears to be good fit for BSN practice, but needs additional analysis for sustainability, cost and resource estimates

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Manuscripts' Contributions to Integration of Health Literacy Competencies in Nursing Education

The inclusion of more robust health literacy evidence in undergraduate nursing educational curricula and practice has potential to inform communication competency development for nurses as well as other healthcare providers. Evidence-based recommendations for provider adoption of Universal Health Literacy Precautions (AHRQ, 2016) should be implemented as part of the *National Action Plan to Improve Health Literacy* third goal (U.S. DHHS ODPHP, 2010). Evidence-based practices recommended include both verbal and non-verbal competencies such as active listening techniques, plain language use, identifying and incorporation patient preferences and values, and using teach back to confirm understanding. Educational approaches to improve health literacy awareness and knowledge includes web-based training modules such as the CDC's *Health literacy for public health professionals* (CDC, 2015) and AHRQ's *Health Literacy Universal Precautions Toolkit for healthcare systems, 2nd edition* (AHRQ, 2016). These approaches support both current health literacy evidence and the Health Literacy Action Plan goals, but have not been mandated for use by the current academic or health care systems.

The information in these educational resources is targeted to practicing professionals rather than health professional students. Implementation may require significant amounts of faculty or staff engagement or administration time and facility support or collaboration to use the Toolkit materials. Online educational delivery may be more convenient and less resource-intensive than face- to face teaching interventions. However, a downside to using web-based delivery methods as the sole communication intervention is that they do not include active participant engagement. These educational delivery methods are not designed to evaluate

comprehension of the content, or if information presented is being applied in practice. If Universal Health Literacy Precautions are to be adopted as a standard part of every patient-provider interaction, then the preparation of all health care providers should shift away from the current emphasis on acquiring discrete HL knowledge facts to the more holistic and patient-centered multidimensional approaches.

Manuscript 1

Until recently, the traditional text-based functional perspective has underpinned HL research (Shaw et al, 2012) and guided the HL education of nurses and other health professionals (Coleman, 2011). Teaching approaches and nursing interventions targeting the population with low or basic reading proficiencies (36 %) neglects the health information needs of majority of the U.S. population (64%) with intermediate or advanced reading proficiencies and diverse health backgrounds. Over-emphasizing text-based intervention has ignored patient comprehension and provider or health organizational environment's contributions to health – related interactions and health system processes. The theoretical discussion reported in the first manuscript (French, 2015) argued that expanded multidimensional HL approaches and interventions may be more effective in preparing nurses to provide effective patient education and health system advocacy than current nursing HL educational approaches. Patient education and organizational advocacy would occur through nursing use of the researcher-created acronym ACTS based on current multidimensional HL evidence found in national recommendations (French, 2015; US DHHS ODPHP, 2010). ACTS in patient education consists of the following:

Assessing patient concerns and preferences,

Comparing assessment results with available resources and needs

Teaching three key points using teach back to confirm understanding, and

Surveying for additional questions or concerns using open-ended questions to complete the communication loop.

Patient advocacy improvements within health system would occur through nursing use of health system-centered ACTS:

Assessing health materials and environments for ease of use

Collaborating with patients and providers to identify needed changes

Teaching and working on health literacy competencies with other health providers, and

Surveying health systems for care quality

Outcome evaluations would then be used to support, modify or maintain integration of national HL standards. The expected outcomes when ACTS are consistently implemented by nurses might be more patient-centered communication practices within organizational environments responsive to patient preferences, values and cultural perspectives. These potential actions and anticipated outcomes need additional research to ascertain the most effective and practical implementation.

Manuscript 2

The IOM's 2004 report *Health literacy: A prescription to end confusion* (Nielsen-Bohlman, & Kindig, 2004) and DHHS's 2010 release of the national HL action plan pointed out gaps between patient literacy abilities and needs, and health care provider and system communication practices. Nurses have been assumed to address health information gaps as patient educators and advocates; however, the second manuscript's integrative review of health literacy competencies in BSN nursing education identified nine lower quality studies characterizing minimal baccalaureate nursing preparation in health literacy practices. Observable effects on patient interactions or health outcomes were not directly related to

descriptions of current nursing educational HL experiences or HL teaching activities. This lack of adequate theoretical or practice linkages to existing health literacy evidence suggests that more robust nursing educational research is needed to cultivate stronger curricular emphasis, and acceptable and practical means to evaluate student and patient outcomes to measure HL competency development. If nurses were educated and evaluated in the use of patient-centered communication practices with all patients, then potential reductions of health risks and communication-related errors may result from greater patient engagement in shared-decision making and increases in self-management of care.

Manuscript 3

The gold standard for evidence to change practice is a large scale randomized experimental study. The relatively recent identification of health literacy competencies, combined with nursing educational emphasis on text-based HL curricula and the lack of HL instruments made conducting a full study impractical without a degree of preliminary supporting research (Bowen et al, 2010). The feasibility study developed, and then described in the third manuscript (French, 2016) aimed to complete initial psychometric signals and intervention feasibility as groundwork for more in-depth research. The first aim focused on developing the HLP-NICE observational checklist through preliminary psychometric assessments. A content validity index from surveys of the four expert panel members indicated 88.9 % agreement for the HLP-NICE, which approached the recommended 90% standard (Di Iorio, 2006; Waltz, Strickland & Lentz, 2010). The HLP-NICE quality and clarity, were assessed by potential stakeholders including a nursing faculty member experienced in simulation, a nursing student, both standardized patients and a nurse in clinical practice using an interview protocol and prompts based on Willis's cognitive interviewing techniques (Willis, 2005). Results of these

preliminary assessments will be synthesized and integrated to improve HLP-NICE quality and wording before conducting future research as part of the fourth aim.

The second aim addressed development of the functional and multidimensional HL curricula and teaching interventions. After the initial curricula and case study was created, the focus group consisting of two nursing faculty members and four junior nursing student volunteers shared their perspectives about HL-related concepts seen in their clinical experiences and taught during nursing courses. Descriptions of low health literacy patient behavior cues and identification of nursing expectations for low literate patients behaviors and health outcomes were incorporated into the research team training. The standardized patients and teacher were trained in the simulation case study and patient representations in the functional and multidimensional curricula and case studies using cues and prompts from focus group data. Additional intervention refinements to health literacy curricula, training content and educational activities will take place based on more in-depth analysis of the focus group discussions, recorded teaching sessions and individual participant audiovisual recordings. Teacher, standardized patient and participant feedback will be solicited when possible, and appraised for feasibility and relevancy of the content and activities through additional surveys.

The third aim was to examine effects of traditional compared to expanded health literacy teaching interventions signaling effects on HL-related knowledge and HL-related behaviors (Melnyk & Morrison-Beedy, 2012). The nine participants reported "rarely" or "sometimes" observing or using health literacy practices (M = 1.89, range 1.44 -2.67) such as conducting patient literacy screening, using various written and audiovisual media in patient education or confirming understanding with teach back. The most commonly reported HL intervention used was giving patients written materials (M = 2.87). This suggests that functional interventions

"*sometimes*" or "*frequently*" continue to be the most commonly practiced and role-modeled HL behavior used by nurses. These findings underscored the current and ongoing lack of exposure and limited application of health literacy evidence and competencies similar to those initially reported by Cormier & Kotrlik (2009). Determining the amount of HL knowledge a nurse has may be difficult to estimate solely from their prior nursing ore educational experiences due to the lack of relationship noted among prior nursing or educational experience and HL knowledge gains (Manuscript 3, Table 3).

Although the teaching interventions did not result in HL knowledge increases for participants as a whole over half (55.9%) of participants did improve their knowledge about HL concepts (Manuscript 3, Table 3). Increases in knowledge were somewhat higher for the multidimensional compared to the functional group. The Web-based module and teaching interventions were not designed to increase discrete HL knowledge facts but instead focused more on participant's application of HL knowledge and HL-related behaviors to enhance patient-provider communication during the simulated patient interactions. This finding suggests that cognitive knowledge gains were not a necessary precursor for HL-related behaviors seen in HLP-NICE scores increased for participants in both groups (Manuscript 3, Table 3).

Communication competencies evaluated by KEECC-A ratings also increased significantly for both groups although the functional control group demonstrated slightly more significant gains than the multidimensional (Manuscript 3, table 3). These differences in communication competencies may have occurred because the text-based and task-oriented functional group experiences and competencies may have been more familiar and customary to participants. Because functional participants had used written materials more frequently in their nursing practice, refining their analysis and use of written materials to highlight key textual

points did not involve new or more extensive HL-related behavior changes required for patient-centered interactions and teach back techniques.

Multidimensional teaching interventions introduced patient-centered concepts that may have been less habitual or familiar to the participants. Competencies such as assessing patient preferences, using teach-back and surveying for additional needs with open-ended questions may have needed additional time or rehearsal to be fully integrated into their nursing practice. Focus group participants spent one-third more time discussing the functional curriculum and experiences compared to discussions about the multidimensional approach, inferring that they were more familiar with using functional approaches or had seen the functional approach used more often in their practice and nursing education.

Short-term improvements were seen in increased HL-related behaviors after participants viewed the web-based module, participated in teaching groups and the standardized patient interactions. Sustained development of health literacy competencies was not built into this research or evaluated at this time. Additional enhancements to the HL curricula and teaching activities will occur based on more in-depth analysis of the focus group discussions, audiovisual teaching session and participant recordings using teacher and participant feedback regarding the feasibility and relevancy of the activities to current nursing educational and clinical practice as part of the fourth aim.

Research Limitations

The purpose of a feasibility study includes analysis of intervention time and resource constraints to maximize accuracy and resource utilization for hypothesis testing in full-scale trials (Bowen et al., 2009, Thabane, 2010). Feasibility results may be reproducible, yet trying to base evidence on feasibility study outcomes without adequate sample sizes, psychometric

soundness or statistical power may lead to poorly-supported claims of evidence (Melnyk & Beedy-Morrison, 2012, Thabane, 2010). While the feasibility findings may signal potential improvements in how to teach HL competencies, a larger study with a more diverse sample size and a more psychometrically-robust HLP-NICE should be conducted to identify better linkages between the interventions and documented HL-related behavior changes. When evaluating the feasibility focus are of acceptability, the study was limited both in participant numbers and makeup of the final sample due to failed recruitment efforts as proposed in the original study plan. The target number of 30 to 40 participants seemed reasonable given a graduating class of 54, yet fewer were willing to volunteer due to stated time conflicts in preparing for the NCLEX exam, getting RN licensure to practice, starting new jobs or moving to other areas. In addition, several graduates indicated that being recorded during the interactions was their primary barrier to participation. This nursing program does not use recordings in simulation or for self-evaluation of other competencies, so that performance anxiety may have been an unanticipated barrier to participation.

After the initial recruitment attempt did not meet target numbers, additional recruitment strategies included mailing invitations to recent graduates from the previous two years (Appendix FF) and verbal and written invitations to the nursing and adjunct faculty (Appendix GG). After IRB amendments were approved and the strategies carried out, eleven participants started the study with nine completing the interventions. One male participant was lost to contact, and one female was not able to complete due to time and family conflicts. The lessons learned from this situation would be to include multiple recruitment strategies in the initial study proposal, by consulting with nursing research and statistical experts regarding estimations of suitable sample sizes, and by offering to reduce potential participant anxiety by having recording

practice time before interventions occur. An additional strategy to diversify the recruitment pool for participant and stakeholder should include partnering with other interested schools of nursing for participant acceptability, access, resources and longitudinal research efforts.

The HLP-NICE observational checklist was created to bridge measurement gaps due to a lack of available health literacy or nursing communication tools. Although initially examined in this study, the HLP-NICE signaled strong affinity for the communication competencies found in the psychometrically supported KEECC-A (r_s =.953**,** r^2 = .9082, p = .00). These findings should be viewed cautiously, due to the limited participant numbers, homogeneous sample demographics and nascent curricular frameworks and teaching interventions.

Supporting signals for continuing development and testing of the HLP-NICE included expert relevancy ratings approaching significance (CVI 88.9%), trends toward internal consistency (pre intervention Cronbach's α .29; post-intervention Cronbach's α .59), HLP-NICE (Cohen's κ .52) and KEECC-A (Cohen's κ .56) inter-rater reliability between one of the standardized patients and the researcher and convergent validity for KEECC-A communication and HLP-NICE HL-related competencies (r_s =.953**,** r^2 = .9082, p = .008). Improvements in wording, design, conceptual consistency and psychometric evaluation with larger and more diverse samples should take place before claims of reliability and validity can be supported. While nursing HL and communication competencies trended towards improvement in short-term measurement, these results should be viewed cautiously, and not generalized to other populations or setting until further research has taken place.

Theoretical Framework

Nurses communicate essential health information when interacting with patients, and are influenced by the knowledge, attitudes and skills they were first exposed to in undergraduate

nursing educational exposures. These HL competencies are shaped by the extent a particular concept is included in the nursing educational curriculum, course content and clinical experiences Signals from this feasibility study can inform the preparation of nurses by integrating HL and communication competencies targeting "the wide range of skills, and competencies that people develop to seek out, comprehend, evaluate and use health information and concepts to make informed choices, reduce health risks and improve quality of life" (Zarcadoolas, Pleasant & Greer, 2006, p. 55). Just as patients need more than text-based interventions such as literacy screenings or simplified information to engage in shared-decision making, nurses need more than functional nursing interventions and expertise in creating and simplifying text-based information to communicate effectively in patient-centered interactions.

Nurses and other health professionals may follow a non-linear process structured after the Health Literacy Pathway Model or HLPM stages (Edwards, Woods, Davies & Edwards, 2012) when acquiring, appraising and applying HL knowledge, skills and behaviors in health-promoting interactions with patients of diverse literacy levels and life circumstances. Stage 1 occurred when participants were educated in HL cognitive knowledge, skills and attitudes to interact meaningfully with patients through the web-based HL knowledge module and face-to-face teaching content. The assumption was that nursing competency development required a basic level of HL knowledge before HL-related behaviors were taught or transferred into practice. Changes in the first dependent variable, HLK HL knowledge percentages, indicated that HL-related behaviors may not depend on the amount of HL knowledge initially taught, but more on linking and rehearsing core HL knowledge to simulated or real-life clinical situations.

Stage 2 occurred when the acquired HL knowledge was paired with specific HL skills related to fundamental, scientific, cultural and civic dimensions. Comparisons of the functional

and multidimensional-specific knowledge and skills, the matching case study teaching plan outlines and teaching scripts used to develop each approach –specific strategies and cues. Stage 3 occurred when HL knowledge, skills and actions taught in the intervention sessions were practiced with the teacher-interventionist and peers, and assessed by SPs as part of the educational interventions. This stage incorporated deliberative HL intervention practice with teacher and peer feedback to improve performance of HL competencies as part of each teaching intervention.

Stage 4 occurred if the standardized patient and nurse identified and evaluated potential barriers and facilitators when creating a patient-directed plan of care filtered through patient's perspectives, needs and preferences. Stage 5 occurred if the standardized patient and nurse reached agreement on a course of action or planned care. While these stages were not directly evaluated for this study, HLP-NICE items (Appendix Q) such as the nurse identifying if patient concerns or barriers were elicited and addressed in a mutually agreed-upon action plan. Health literacy-related behavior changes, the second dependent variable, was measured in Stages 3, 4 and 5 through comparisons of the KEECC-A communication competency and HLP-NICE checklist scores based on pre- and post-intervention recorded SP-nurse interactions. While the potential moderating variables affecting participant HL knowledge gains evaluated were age, gender, prior time with patient care experience, past educational attainments and prior exposure to HL concepts in nursing educational experiences, none of these variables were associated with retention or gains in HL knowledge for this particular sample and tool. The anticipated mediating variable in stages 3, 4 and 5 was the effect of HL knowledge levels on HL-related behavior changes. The lack of association between knowledge and practice suggested that the

level of HL knowledge gains did not have a significant mediating effect on observed HLP-NICE HL – related behavior or KEECC-A communication changes.

The over-emphasis of nursing educational research on cognitive knowledge facts such as limited health literacy prevalence, patient screening, written material interventions and health system impact may not be the single best educational approach to develop nursing competencies in patient interactions. More than half of participants gained HL knowledge, but there were no significant differences in HLK knowledge pre- and post-intervention scores. All participants did have significant increases in HL-related behaviors which were not dependent on cognitive knowledge gains. Participants, however, were exposed to standardized levels of functional and multidimensional knowledge through the web-based one hour module to ensure a similar level of general knowledge before attending their specific teaching session.

The teaching interventions were designed to emphasize communication and HL competencies using teacher- and peer- facilitated interactions, rather than comprehension of discrete HL knowledge facts. The use of active communication-based learning strategies and evaluation of SP interactions for effects on communication in this study differed significantly from previous nursing educational research. Past research did not include evaluating patient interaction outcomes, but surveyed cognitive knowledge levels (Cormier & Kotrlik, 2009; Jukkala, Deupree & Graham, 2009), taught HL knowledge facts (Sand-Jecklin et al., 2010: McCleary-Jones, 2012) or functional text-based competencies (Shieh & Hosei, 2008). These study outcomes signal that shifts from teaching functional HL cognitive concepts to applying and synthesizing multidimensional HL concepts in educational curriculum and practice may better prepare nurses for more effective communication practices with patients at all literacy levels.

According to Zarcadoolas, Pleasant and Greer (2006) multidimensional HL starts with fundamental literacy and communication proficiencies in written, verbal, non-verbal and numeracy concepts but adds additional HL-related dimensions including scientific and technology comprehension, cultural perspectives and civic advocacy skills for patients and providers. HL-related actions based on these dimensions involve more than reading skills or textual simplification for patient-provider collaborations to access, navigate and act on complex and increasingly technology-derived health information sources. Recent graduates and experienced nursing faculty significantly increased their HLP-NICE HL and KEECC-A communication competencies, which suggested that multidimensional HL concepts continue to be under-represented and inconsistently utilized in nursing educational curricula, didactic content and clinical experiences.

Main threats to internal design validity were controlled for by strategic randomization, researcher blinding to initial assignments and similar time on task for both groups. External design validity threats from the HLKES pre-test and pre-intervention SP interaction, however, may have stimulated more knowledge recall and retention which was then carried out in HL-related behavior changes. This explanation seems unlikely due to the lack of support for significant HL knowledge gains for participants as a group, yet caution must be used before concluding that either intervention was the sole driver of improvements in competencies.

Research trajectory

The next research steps involves dissemination of the findings and locating grant funding to continue refinements of the health literacy curriculum and HLP-NICE instrument. A peer-reviewed poster of the feasibility study findings was presented at the Nurse Education Research Conference April 2016. The health literacy curriculum and teaching interventions will be

evaluated for potential content relevance, feasibility and improvements. Integration of these modifications will be undertaken through comparisons of multidimensional teaching interventions to the teaching script, qualitative analysis of the recorded teaching interventions and review of participant feedback. Instead of comparing separate approaches, combining fundamental health literacy concepts with added multidimensional scientific- technological, cultural and civic components may support a stronger alternative than either approach alone. The U.S. healthcare system remains heavily dependent on written information in multiple media formats to supplement and reinforce verbal health information. Most technological advances still require a textual or numeric component, which means that nurses will need diverse, flexible and patient-focused HL and communication competencies to effectively meet patient's health information needs.

The HLP-NICE instrument will be evaluated for quality improvements based on expert feedback and more-in-depth analysis of the cognitive interviews in preparation for more psychometric appraisal. An abstract reporting the HLP-NICE initial testing and updated iteration will be submitted June, 2016 for presentation in October, 2016 at the annual Health Literacy Research Conference (HARC). The expectation is that the modifications to the teaching intervention and HLP-NICE will be built into the next structured efficacy study. During July and August, 2016, preliminary preparations will occur through querying other undergraduate nursing and allied health schools and faculty for potential partnerships.

Documentation of a new study plan and partnerships for the NLN nursing education grant will be prepared for October, 2016 submission, and if not funded will be resubmitted for the American Nurses Foundation Grants funding cycle May 1st, 2017. Submitting and completing an intermediate grant will give this novice researcher opportunities to develop additional

research relationships and grant administration expertise before submitting an NIH AREA or HRSA grant to support extended interdisciplinary research in undergraduate health care provider competencies. As a professional development for future work with the HLP-NICE, additional training opportunities in instrument development will be looked for within the next year. The researcher's home academic university is a teaching institution with nursing, allied health and pre-professional programs which might serve as an appropriate venue to explore the effects of HL competency development with health providers before and as starting their professional practices. The scholarship of teaching remains underappreciated and underfunded (Forbes & Hickey, 2009; Benner et al., 2010), but more robust HL teaching curricula, relevant HL course emphasis, deliberative HL clinical practice and interdisciplinary inclusion shows potential to foster safer and more effective communication practices for future health care providers.

Nursing and interdisciplinary implications

HL Knowledge and HL-related behaviors together characterize HL competencies used by nurses and health providers practicing within health care systems. The concept of "practice" may have multiple meanings used to characterize how one responds to professional challenges, dilemmas or new situations. One definition of practice revolves around the culmination of knowledge, attitudes and skills routinely used by providers in health care environments, or practice as what one does as part of one's professional responsibilities. A more nuanced theoretical relationship between practices and "habitus" outlined by Bourdieu (1977) suggests that one's personal or professional practices are more complex than rigidly structured automatic responses to changes or new situations. Habitus is shaped by deeply rooted prior knowledge and formative social interactions used within a contextual field, or environment. When someone is faced with choices or dilemmas, they may consciously or unconsciously revert to acts or

behaviors that aligns with previous choices or perceived socially-sanctioned actions. The choices revering to one's habitus are not prescriptive, but may be reinforced or strengthened by perceptions of advantage or self gain in social capital rather than consideration of potential consequences or risks. Once crystallized, there may be strong internal or external resistance to changing one's habitus despite robust evidence to the contrary (Bourdieu, 1977; Swartz, 2002).

Nursing HL practices may form a professional class habitus which shapes communication in patient-nurse interactions within the social and cultural context of the health system field. Interviews of 26 paraplegic patients and 26 nurses based on discourse analysis of 155 interactions over a 20 month time period noted that understanding- oriented interactions were infrequent, with limited patient-nurse collaborations or negotiations between nurse and patient attempted or solicited unless the nurse determined no other conflicts with nursing responsibilities or tasks existed (Sieger, Fritz & Them, 2012). The current textual and task-focused nursing communication class habitus may not allow patients to fully engage in dialogue to make health decisions or manage their own health (Nutbeam, 2008; Swartz, 2002; Sieger et al., 2012). To change the current task-oriented nursing communication habitus, more deliberative practice of effective and evidence based nursing communication and HL competencies should occur throughout the nursing educational process rather than once or twice during a nurse's educational process.

Concerns exist about current nursing educational preparation to effectively develop outcome-based competencies for increasingly complex and diverse health care environments (Benner et al, 2010). Patients need understandable and actionable health information if they are to follow health instructions, use health resources effectively, avoid preventable safety errors and reduce costly readmissions. Incorporating Universal Health Literacy Precautions successfully

will take health providers who are educated in evidence-based multifaceted health literacy strategies and are sensitive to life contexts beyond formal health care environments. This study addressed some of these concerns through use of a more robust research design and innovative instructional strategies to prepare nurses to consistently perform HL competencies. The research also supported *The National Health Literacy Action Plan* goals for health professional education through evaluations of a standardized instrument designed to benchmark core HL competencies (US DHHS, ODHD, 2010).

Prior nursing educational research has infrequently demonstrated or evaluated the effects of communication or HL-related competencies in patient outcomes except for descriptions of self-reported effectiveness or observed incongruences. Student's use of HL practices such as return demonstration, eliciting patient context, translating medical terminology for patient understanding or providing language-appropriate materials was reported as evidence of HL competency. Limited additional corroboration of recipient effectiveness or changes in health outcomes was offered as proof of student communication effectiveness (Sand- Jecklin et al, 2010; Shieh et al., 2013; Shieh & Hosei, 2008: Scheckel, Emery & Nosek, 2010; Zanchetta et al., 2013). In contrast, the outcomes from this feasibility study may signal more substantive approaches to implementing and integrating multidimensional HL competencies in nursing education curricula, didactic content and clinical experiences. Refining and re-evaluating combinations of technology-assisted knowledge acquisition, face-to-face interactive learning strategies and theoretically based objective evaluations offers potential to improve the existing nursing "habitus" through adoption of Universal Health Literacy Precautions in baccalaureate nursing education.

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MUSC
MEDICAL UNIVERSITY of SOUTH CAROLINA

Institutional Review Board for Human Research (IRB)
Office of Research Integrity (ORI)
Medical University of South Carolina

Harborview Office Tower
19 Hagood Ave., Suite 601, MSC857
Charleston, SC 29425-8570
Federal Wide Assurance # 1888

APPROVAL:
This is to certify that the research proposal Pro00035215 entitled:
Effects of multidimensional vs. functional health literacy educational interventions on baccalaureate nurse-standardized patient interactions: Experimental pilot study

Submitted by: **Kempa French**
Department: **Medical University of South Carolina**
Sponsor: **Sigma Theta Tau, Sigma Theta Tau full title: Sigma Theta Tau International Honor Society of Nursing Assessment Technologies Institute (ATI)**

For consideration has been reviewed by **IRB-I - Medical University of South Carolina** and approved with respect to the study of human subjects as adequately protecting the rights and welfare of the individuals involved, employing adequately methods of securing informed consent from these individuals and not involving undue risk in the light of potential benefits to be derived therefrom. Additionally, the Institutional Review Board for Human Research (IRB) recommends approval of the investigator's request for Waiver of Signed Consent in accordance with 45 CFR 46.117(c)(1),(2) because the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality and/or because the research presents no more than minimal risk and involves no procedures for which written consent is normally required outside of the research context. No IRB member who has a conflicting interest was involved in the review or approval of this study, except to provide information as requested by the IRB.

Original Approval Date: **1/14/2015**
Approval Expiration: **1/13/2016**

Type: **Expedited**

Chairman, **IRB-I - Medical University of South Carolina**
Susan Newman*

Statement of Principal Investigator:

As previously signed and certified, I understand that approval of this research involving human subjects is contingent upon my agreement:

1. To report to the Institutional Review Board for Human Research (IRB) any adverse events or research related injuries which might occur in relation to the human research. I have read and will comply with IRB reporting requirements for adverse events.
2. To submit in writing for prior IRB approval any alterations to the plan of human research.
3. To submit timely continuing review reports of this research as requested by the IRB.
4. To maintain copies of all pertinent information related to the research activities in this project, including copies of informed consent agreements obtained from all participants.
5. To notify the IRB immediately upon the termination of this project, and/or the departure of the principal investigator from this Institution and the project.

* ***Electronic Signature****: This document has been electronically signed by the IRB Chairman through the HSSC eIRB Submission System authorizing IRB approval for this study as described in this letter.*

Institutional Review Board for Human Research (IRB)
Office of Research Integrity (ORI)
Medical University of South Carolina

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Effects of multidimensional vs. functional health literacy educational interventions on baccalaureate nurse-standardized patient interactions: Experimental pilot study

submitted by: **Kempa French**
Department: **Medical University of South Carolina**
Sponsor: **Sigma Theta Tau**

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PLEASE NOTE, YOUR CONSENT FORM(S) HAVE BEEN RE-STAMPED WITH THE NEW APPROVAL DATE. PLEASE MAKE SURE TO USE THE NEW STAMPED VERSIONS FOR CONSENTING SUBJECTS FROM THIS POINT FORWARD

Continuing Review Approval Date: **12/27/2015**
Approval Expiration: **12/26/2016**

Type: **Expedited**

Vice Chairman, IRB-I - Medical University of South Carolina
*** Susan Newman, PhD, RN, CRRN**

Statement of Principal Investigator:

As previously signed and certified, I understand that approval of this research involving human subjects is contingent upon my agreement:

1. To report to the Institutional Review Board for Human Research (IRB) any adverse events or research related injuries which might occur in relation to the human research. I have read and will comply with IRB reporting requirements for adverse events.
2. To submit in writing for prior IRB approval any alterations to the plan of human research.
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* *Electronic Signature: This document has been electronically signed by the IRB Chairman through the HSSC eIRB Submission System authorizing IRB approval for this study as described in this letter.*

AUSTIN PEAY STATE UNIVERSITY
INSTITUTIONAL REVIEW BOARD

Date: 2/10/2015

RE: Your application regarding study number: 15-010 Effects of multidimensional vs. functional health literacy educational interventions on standardized patient-nursing interactions: an experimental pilot study

Dear Kempa (Kim) French,

We appreciate your cooperation with the human research review process. Study 15-010 has been reviewed on an expedited level. It is my pleasure to inform you that the study has been approved.

This approval is subject to APSU Policies and Procedures governing human subject research. The full IRB reserves the right to withdraw approval if unresolved issues are raised during the review. This approval is for one calendar year and will expire on February 10, 2016. You are required to submit a closed study report at the completion of the study. If you require additional time to complete the study you must submit a request for continuing review form by February 10, 2016. Any changes to the approved protocol must be submitted to IRB for approval and the study must be postponed until such changes are reviewed and approved by IRB.

You are free to conduct your study as approved by APIRB. If you have any questions or require further information, you can contact me by phone (931-221-6106) or email (shepherdo@apsu.edu).

Sincerely,

Omie Shepherd

Omie Shepherd, Ph. D. Chair, APIRB

Cc: Dr. Charlene Pope

AUSTIN PEAY STATE UNIVERSITY
INSTITUTIONAL REVIEW BOARD

Date: 2/11/2016

Re 15-010: Effects of Multidimensional vs. Functional Health Literacy Educational Interventions

Dear Dr. Pope and Ms. French,

The IRB appreciates your cooperation with the human research review process. Continuation of study 15-010 has been reviewed on an expedited level. It is my pleasure to inform you the study has been approved for the purpose of completing data analysis only and no other data will be collected during the continued review time period.

This approval is subject to APSU Policies and Procedures governing human subject research. The full IRB may still review this protocol and reserves the right to withdraw approval if unresolved issues are raised during the review. Your study continuation expires on 2/11/2017 , unless closed before that date. Please submit the appropriate form (Closed Study or Request for Continuing Review) prior to 2/11/2017 .

Please note that any changes to or deviations from the approved study protocol must be promptly reported to the IRB and approved before continuing with the study. Some changes may be approved by expedited review; others require full board review. If you have any questions or require further information, you can contact me by phone (931-221-7506) or email (butterfieldj@apsu.edu).

Sincerely,

Jonniann Butterfield, Ph.D., Chair
Austin Peay Institutional Review Board

 Medical University of South Carolina and Austin Peay State University
CONSENT TO BE A RESEARCH SUBJECT

Effects of multidimensional vs. functional educational interventions on baccalaureate nurse-standardized patient interactions: Consent as a recent baccalaureate graduate participating in an experimental pilot study.

INTRODUCTION

The Medical University of South Carolina College of Nursing and Austin Peay State University School of Nursing support the practice of protection for human subjects participating in research. The following information is provided to help you decide whether you wish to participate in the present research study. You keep the right to refuse to sign this form and not participate in this study. You should be aware that even if you consent to participate in this study, you may withdraw from this study at any time without consequence to your academic standing or grades. If you choose to withdraw from this study, it will not affect your relationship with the APSU School of Nursing, the services it has provided to you, or with either the Medical University of South Carolina or Austin Peay State University.

A. PURPOSE AND BACKGROUND

You are being asked to volunteer for a research study. This research is sponsored by joint grant funding from Sigma Theta Tau International Nursing Honor Society (STTI) and Assessment Technologies Inc. (ATI). Academic sponsors include the Medical University of South Carolina and Austin Peay State University. The first purpose of this pilot study is to evaluate the effectiveness of a researcher-created observational health literacy checklist to assess the participant's health literacy competencies. The second purpose is to compare effects of multidimensional and functional health literacy educational interventions on a nurse's use of health literacy practices when interacting with standardized patient actors. You are being asked to participate in this study because as a recently graduated baccalaureate nursing student you can represent competencies of nurses completing their curriculum, course content and clinical experiences as they enter nursing clinical practice. The investigator in charge of this study is Kempa (Kim) S. French MSN, FNP-BC. The study is being done at Austin Peay State University and will involve approximately 40 volunteers.

B. PROCEDURES

If you agree to participate in the study, the following will happen:
1. You will be randomized into one of two groups to receive one of two different health literacy teaching interventions.
2. You will be given a patient scenario about giving discharge or medication instructions, and then video recorded in this scenario with the standardized patient actor at the University simulation lab.
3. After this first simulation is completed, you will be asked to complete an online survey at the University computer lab made up of a demographic survey and both sections of the Health Literacy Knowledge and Experiences Survey, or HL-KES to complete the pre-intervention (1 hour estimated time).
4. You will be asked to complete an interactive online case study consisting of health literacy knowledge and a 5 multiple choice post-test at your convenience using a provided online link before the educational interventions (1 hour estimated time).
5. You will be asked to attend a face-to-face educational session during the following two weeks which will consist of a single two- hour long intervention with your assigned group at the University classroom and facilities (2 hours).

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IRB Number: Pro00035215
Date Approved 8/13/2015
Expiration Date: 1/13/2016

6. After completing your educational intervention session, you will be asked to return for a post-intervention evaluation in the following week to complete the second recorded standardized patient interaction and repeat the HL-Knowledge section of the HL-KES (1 hour).
7. You may be withdrawn from the study without your consent if the researchers believe it is in your best interest or if you fail to follow study procedures.

C. DURATION

If you agree to be in the study, the approximate time required for completion is five (5) hours over a 4 week period of time. Participation in the study will take 3 visits during that 4 week period of time.

D. RISKS

There are no anticipated physical risks from participating in this study. You will be assigned to an educational intervention by chance. The educational intervention you are randomly assigned to may prove to be less effective in fostering health literacy competencies development than the alternative educational intervention or approaches. The possibility of psychological distress to you may exist because audiovisual recording, evaluation and outcomes assessments are part of measuring the intervention effectiveness. If you feel that you are distressed or need additional counseling resulting from the study, you may contact Dr. Kevin Harris at harrisk@apsu.edu or (931) 221-6505.

E. BENEFITS

The benefits of this research are building knowledge for the nursing discipline and advancement of nursing education, nursing communication and clinical practice; however, no direct personal benefit or economic gain other than professional satisfaction in research participation is anticipated. It is hoped that the information gained from this study will help inform future baccalaureate nursing educational practice to help the researcher learn more about effective development of undergraduate nursing health literacy nursing competencies.

F. COSTS

You will not be charged for any of the study educational interventions or procedures. All costs for the research administration and interventions will be covered by the study.

G. PAYMENT TO PARTICIPANTS

In return for your time and effort, a ten dollar gas card will be offered to you after the pre-intervention session ($10), teaching session ($10) and post-intervention sessions ($10) to help with travel costs for a potential total of $30. If you do not complete the study, you will be offered the $10 gas card for each session of participation. Three (3) hours of continuing education units (CEUs) will be given for finishing the 1 hour asynchronous online module and 2 hour face-to-face intervention sessions to support your practice and to meet state-recommended continuing educational requirements as part of your professional development. Payments that you receive from MUSC for participating in a research study are considered taxable income per IRS regulations. Payment types may include, but are not limited to: checks, cash, gift certificates/cards, personal property, and other items of value. If the total amount of payment you received from MUSC reached or exceeded $600.00 in a calendar year, you would have been issued a Form 1099.

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IRB Number: Pro00035215
Date Approved 8/13/2015
Expiration Date: 1/13/2016

H. ALTERNATIVES

If you choose not to participate in this study, you could receive other educational interventions to build your health literacy competencies. The standard intervention to educate nurses about health literacy competencies are through classroom lectures or online health provider modules.

I. STUDENT PARTICIPATION

Your participation or discontinuance will not constitute an element of your academic performance nor will it be a part of your academic record at Austin Peay State University or the Medical University of South Carolina.

J. PARTICIPANT CONFIDENTIALITY

You will be asked to create your own "nurse alias" name to use when interacting with the standardized patient actors in video-recorded pre-and post-intervention sessions. These self-determined names will not be recorded on any code-book or log to protect your confidentiality. The PI will not have access to specific participant identities, scores or results until after all data has been collected and recorded. All data results will be reported as aggregate or group results so that no individual can be identified from any reported findings.

At the completion of the study, your cell phone numbers will be deleted from the dedicated cell-phone, with the study phone sim card removed and destroyed to prevent any data loss. The mini-DVD cassettes will be retained in the fireproof locked box for potential future transcription and qualitative analysis. There is additional protection on all portable recording devices and the dedicated research laptop to limit access, delete personal data or assist in device retrieval if the device is lost or stolen. The participant's "nurse alias" initials will be used as identifiers when recorded interactions are transcribed in future analysis, and will not be linked to participants real names or research ID's.

K. REFUSAL TO SIGN CONSENT

You are not required to sign this consent form and you may refuse to do so without affecting your right to participate in any programs or events of the Medical University of South Carolina or Austin Peay State University or any services you are receiving or may receive from MUSC or APSU. If you refuse to sign, however, you cannot participate in this study.

L. CANCELLING THIS CONSENT

You may withdraw your consent to participate in this study at any time. If you choose to withdraw from the study before data collection is completed, any collected data will be destroyed and not used.

M. QUESTIONS ABOUT PARTICIPATION

If you have any questions about the procedures, you may direct them to the principal investigator, Kim (Kempa) S. French, MSN, FNP-BC. Ms. French may be contacted at frenchk@apsu.edu , (931) 221-7528, or the McCord Building, Rm 303.

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 Medical University of South Carolina and Austin Peay State University
CONSENT TO BE A RESEARCH SUBJECT

Effects of multidimensional vs. functional educational interventions on baccalaureate nurse-standardized patient interactions: Consent as a recent baccalaureate graduate participating in an experimental pilot study.

Results of this research will be used for the purposes described in this study. This information may be published, but you will not be identified. Information that is obtained concerning this research that can be identified with you will remain confidential to the extent possible within State and Federal law. The investigators associated with this study, the sponsor, and the MUSC Institutional Review Board for Human Research will have access to identifying information. All records in South Carolina and Tennessee are subject to subpoena by a court of law.

In the event that you are injured as a result of participation in this study, you should immediately go to the emergency room of the Medical University Hospital, or in case of an emergency go to the nearest hospital, and tell the physician on call that you are in a research study. They will call your study doctor who will make arrangements for your treatment. If the study sponsor does not pay for your treatment, the Medical University Hospital and the physicians who render treatment to you will bill your insurance company. If your insurance company denies coverage or insurance is not available, you will be responsible for payment for all services rendered to you.

Your participation in this study is voluntary. You may refuse to take part in or stop taking part in this study at any time. You should call the investigator in charge of this study if you decide to do this. Your decision not to take part in the study will not affect your current or future medical care or any benefits to which you are entitled.

The investigators and/or the sponsor may stop your participation in this study at any time if they decide it is in your best interest. They may also do this if you do not follow the investigator's i

Volunteers Statement

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have any more questions about my participation in this study or study related injury, I can contact Kim French at (931) 221-7528 or frenchk@apsu.edu. I may also contact the Medical University of SC Hospital Medical Director (843) 792-9537 concerning medical treatment.

If I have any questions, problems, or concerns, desire further information or wish to offer input, I may contact the Medical University of SC Institutional Review Board for Human Research IRB Manager or the Office of Research Integrity Director at (843) 792-4148. I may also contact the APSU IRB committee chair Dr. Omie Shepherd at shepherdo@apsu.edu or (931) 221- 6106. This includes any questions about my rights as a research subject in this study.

I agree to participate in this study. I have been given a copy of this form for my own records.
If you wish to participate, you should sign below.

Signature of person obtaining consent	**Date**	**Participant Signature**	**Date**

Printed Participant Name

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 Medical University of South Carolina and Austin Peay State University
CONSENT TO BE A RESEARCH SUBJECT

Effects of multidimensional vs. functional educational interventions on baccalaureate nurse-standardized patient interactions: Consent as a nursing faculty members participating in an experimental pilot study.

INTRODUCTION

The Medical University of South Carolina College of Nursing and Austin Peay State University School of Nursing support the practice of protection for human subjects participating in research. The following information is provided to help you decide whether you wish to participate in the present research study. You keep the right to refuse to sign this form and not participate in this study. You should be aware that even if you consent to participate in this study, you may withdraw from this study at any time without consequence to your academic or employment standing or grades. If you choose to withdraw from this study, it will not affect your relationship with the APSU School of Nursing, the services it has provided to you, or with either the Medical University of South Carolina or Austin Peay State University.

A. PURPOSE AND BACKGROUND

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B. PROCEDURES

If you agree to participate in the study, the following will happen:

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7. You may be withdrawn from the study without your consent if the researchers believe it is in your best interest or if you fail to follow study procedures.

C. DURATION

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D. RISKS

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H. ALTERNATIVES

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I. FACULTY PARTICIPATION

Your participation or discontinuance will not constitute an element of your employment or academic performance nor will it be a part of your employment or academic record at Austin Peay State University or the Medical University of South Carolina.

J. PARTICIPANT CONFIDENTIALITY

You will be asked to create your own "nurse alias" name to use when interacting with the standardized patient actors in video-recorded pre-and post-intervention sessions. These self-determined names will not be recorded on any code-book or log to protect your confidentiality. The PI will not have access to specific participant identities, scores or results until after all data has been collected and recorded. All data results will be reported as aggregate or group results so that no individual can be identified from any reported findings.

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K. REFUSAL TO SIGN CONSENT

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L. CANCELLING THIS CONSENT

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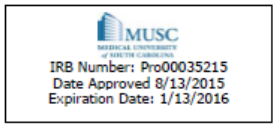

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Effects of multidimensional vs. functional educational interventions on baccalaureate nurse-standardized patient interactions: Consent as a nursing faculty member participating in an experimental pilot study.

Results of this research will be used for the purposes described in this study. This information may be published, but you will not be identified. Information that is obtained concerning this research that can be identified with you will remain confidential to the extent possible within State and Federal law. The investigators associated with this study, the sponsor, and the MUSC Institutional Review Board for Human Research will have access to identifying information. All records in South Carolina and Tennessee are subject to subpoena by a court of law.

In the event that you are injured as a result of participation in this study, you should immediately go to the emergency room of the Medical University Hospital, or in case of an emergency go to the nearest hospital, and tell the physician on call that you are in a research study. They will call your study doctor who will make arrangements for your treatment. If the study sponsor does not pay for your treatment, the Medical University Hospital and the physicians who render treatment to you will bill your insurance company. If your insurance company denies coverage or insurance is not available, you will be responsible for payment for all services rendered to you.

Your participation in this study is voluntary. You may refuse to take part in or stop taking part in this study at any time. You should call the investigator in charge of this study if you decide to do this. Your decision not to take part in the study will not affect your current or future medical care or any benefits to which you are entitled.

The investigators and/or the sponsor may stop your participation in this study at any time if they decide it is in your best interest. They may also do this if you do not follow the investigator's instructions.

Volunteers Statement

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have any more questions about my participation in this study or study related injury, I can contact Kim French at (931) 221-7528 or frenchk@apsu.edu. I may also contact the Medical University of SC Hospital Medical Director (843) 792-9537 concerning medical treatment.

If I have any questions, problems, or concerns, desire further information or wish to offer input, I may contact the Medical University of SC Institutional Review Board for Human Research IRB Manager or the Office of Research Integrity Director at (843) 792-4148. I may also contact the APSU IRB committee chair Dr. Omie Shepherd at shepherdo@apsu.edu or (931) 221- 6106. This includes any questions about my rights as a research subject in this study.

I agree to participate in this study. I have been given a copy of this form for my own records.
If you wish to participate, you should sign below.

Signature of person obtaining consent	**Date**	**Participant Signature**	**Date**

MUSC
MEDICAL UNIVERSITY of SOUTH CAROLINA
IRB Number: Pro00035215
Date Approved 8/13/2015
Expiration Date: 1/13/2016

_____
Printed Participant Name

SIGMA THETA TAU INTERNATIONAL FOUNDATION FOR NURSING
helping nurses
AROUND THE WORLD HEAL, LEAD AND LEARN

550 WEST NORTH STREET | INDIANAPOLIS, INDIANA 46202, U.S.A. | E-MAIL: FOUNDATION@STTI.IUPUI.EDU | TOLL-FREE: 888.634.7575 | WWW.NURSINGSOCIETY.ORG

17 February 2015

Kempa S. French
Nursing
Austin Peay State University
P.P Box, 601 College Street
Clarksville, TN 37044
USA

Kempa:

Your initial disbursement for your 2013 Sigma Theta Tau International/ATI Educational Assessment Nursing Research Grant is set to mail 27 February 2015. As a reminder, your grant received and extension. Completion of your project, including final summary and expenditure reports are due by 31 August 2015. As a reminder the following are allowable expenses. Transferring funds is allowed as long as the funds continue to be allowable expenses.

Expenditures:
Sigma Theta Tau International does not fund indirect costs nor costs related to completing an education program (e.g. tuition). Please include your budget amounts for the following items:

- *Personnel (Requests for Investigator salaries may be included. Include hourly rate for personnel in justification section.)*
- *Secretarial staff*
- *Typing costs (Must be those directly related to the research. Typing of dissertations will not be funded.)*
- *Research Assistants*
- *Consultants (Limit to $50 per hour)*
- *Supplies*
- *Equipment*
- *Computer costs (software only)*
- *Travel Expenses (data collection only)*
- *Other*

The final disbursement of $500 for this grant, will be paid, if owed, once all items have been received and all guidelines have been met according to our page at http://www.nursingsociety.org/Research/Grants/Pages/grant_finalreport.aspx. Unused funds are expected to be returned to the society.

Please notify all necessary offices that should be contacted in the handling of your grant. .If you have any questions, please do not hesitate to contact me.

Cordially,
Tonna M. Thomas, MS
Grants Coordinator

SIGMA THETA TAU INTERNATIONAL FOUNDATION FOR NURSING
helping nurses
AROUND THE WORLD HEAL, LEAD AND LEARN

550 WEST NORTH STREET | INDIANAPOLIS, INDIANA 46202, U.S.A. | E-MAIL: FOUNDATION@STTI.IUPUI.EDU | TOLL-FREE: 888.634.7575 | WWW.NURSINGSOCIETY.ORG

April 21, 2016

Kempa S. (Kim) French, MSN, FNP-BC
Associate Professor of Nursing
Austin Peay State University
Clarksville TN 37044

Kempa,

Permission has been granted for an extension of your 2013 Sigma Theta Tau International/ATI Educational Assessment Nursing Research grant entitled, "*Assessment of Multidimensional and Functional Health Literacy Educational Interventions with BSN graduates: A Randomized Controlled Trial*". Completion of your project, including final summary and expenditure report is expected by 31 January 2016. As this is the second request for an extension, additional requests will not be granted.

As a reminder the following are allowable expenses. Transferring funds is allowed as long as the funds continue to be allowable expenses.

Expenditures:
Sigma Theta Tau International does not fund indirect costs nor costs related to completing an education program (e.g. tuition). Please include your budget amounts for the following items:

- *Personnel (Requests for Investigator salaries may be included. Include hourly rate for personnel in justification section.)*
- *Secretarial staff*
- *Typing costs (Must be those directly related to the research. Typing of dissertations will not be funded.)*
- *Research Assistants*
- *Consultants (Limit to $50 per hour)*
- *Supplies*
- *Equipment*
- *Computer costs (software only)*
- *Travel Expenses (data collection only)*
- *Other*

The final disbursement of $500 for this grant, will be paid, if owed, once all items have been received and all guidelines have been met according to our page at http://www.nursingsociety.org/advance-elevate/research/research-grants/guidelines-for-preparing-the-grant-final-report-for-the-honor-society-of-nursing-sigma-theta-tau-international. If the study is not completed, or there are unused funds, they are expected to be returned to the society.

Please notify all necessary offices that should be contacted in the handling of your grant. .If you have any questions, please do not hesitate to contact me.

Cordially,
Tonna M. Thomas, MS
Grants Coordinator

MUSC
MEDICAL UNIVERSITY
of SOUTH CAROLINA

Office of Research Integrity
19 Hagood Ave, Suite 601
(843) 792-4148
Fax (843) 792-7457

Off Campus Study Site Form

PRO/HR # 0035215

STUDY TITLE: Assessment of multidimensional vs. functional health literacy educational interventions with BSN graduates: an experimental pilot study

PRINCIPAL INVESTIGATOR: Kempa S. French, MSN, FNP-BC

ADDRESS OF OFF-SITE FACILITY:
Austin Peay State University
School of Nursing, P.O. Box 4658
601 College Street
Clarksville, TN 37044
**complete a new form for each off site facility*

NAME OF NON-MUSC INVESTIGATOR/ INSTITUTIONAL OFFICIAL: Kevin Harris, PhD

SECTION I.

A. Is the off-campus site "engaged" in human subject's research pertaining to this study?

To make this determination you will need to consult the OHRP website to assist in determining if the off campus site's role in this study makes the site "engaged." In general, an institution is considered *engaged* in a particular non-exempt human subjects research project when its employees or agents for the purposes of the research project obtain: (1) data about the subjects of the research through intervention or interaction with them; (2) identifiable private information about the subjects of the research; or (3) the informed consent of human subjects for the research. See the following link for categories and guidance:
http://www.hhs.gov/ohrp/policy/engage08.html

1. Check either A or B below: (Completion of A or B is required)

☒ (A) Activities at the off-campus site are consistent with examples under Category A; the site is engaged in human subject's research

If you checked this section, please identify the specific type of activity or activities to be done at this off site campus by providing the number of the example from the OHRP website. For example: A1, A2, A3, etc.
A2, A3, A4, A5, A6

☐ (B) Activities at the off-campus site are consistent with examples under category B; the site is not engaged in human subjects' research

If you checked this section, please identify the specific type of activity or activities to be done at this off site campus by providing the number of the example from the OHRP website. For example: B1, B2, B3, etc.

2. Does the off-campus site have a Federal Wide Assurance (FWA)?

☒ Yes If yes, what is their FWA? FWA00005669, expires 02/20/2018
☐ No

3. Does the off-campus site have an Institutional Review Board for Human Research?

☒ Yes ☐ No

If Yes, the individual or site must contact that IRB and provide MUSC with documentation on whether IRB approval is required.

Please provide the name, address and phone number of the IRB:
Dr. Omie Shepherd, APSU IRB Committee Chair
Professor, Health and Human Performance
P.O. Box 4445
Austin Peay State University
Clarksville, TN 37044
shepherdo@apsu.edu
931-221- 6106

If Yes, has the off-campus site's IRB approved this study?

☒ Yes ☐ No

If the off-campus site's IRB has not approved this study, will review by that IRB be required?

☐ Yes ☐ No: IRB approval will be sought when MUSC IRB approval has be completed

If no, please explain.

SECTION II. *(Complete this section if you selected Section I.A(1)(A)).*
A. List all community individuals that will be engaged in the study.

Individuals are "engaged" if they will: (1) obtain data about research participants through intervention or interaction with them; or (2) obtain identifiable private information or identifiable specimens about the participants of the research – even if they do not directly interact with them

or (3) the informed consent of human subjects for the research. More information pertaining to what constitutes engagement can be found in the OHRP guidance on engagement at: http://www.hhs.gov/ohrp/policy/engage08.html

Individual's Name *Use full legal name*	**Individual's Credentials and/or Position** *(e.g., M.D., Executive Director., recruitment specialist)*	**Individual's Role on the study** *(e.g. ,consent, deliver interventions, data analysis)*
Dustin Thede	Research assistant	Study recruitment, consent for study inclusion, collect and enter data in Phase 2
Mary Lynne Capps	Standardized patient #1	Deliver and rate pre- and post-intervention social interactions/interventions in Phase 2
Teresa Cunningham	Standardized patient #2	Deliver and rate pre- and post-intervention social interactions/interventions in Phase 2
Amy Black, MSN, FNP-C	Teacher-interventionist, MSN, Nurse educator	Deliver teaching interventions in Phase 2
Dr. Kevin Harris	PhD, External committee mentor and interdisciplinary collaborator for PI	Collaborate with PI to recruit and train research assistant and standardized patients from APSU Psychology Department
Dr. Jessica Hatz	PhD, Phase 1 Focus group mentor	Lead a focus group as part of Phase 1 evaluation activities

To expand table, move to the end of the last row and press the tab key.
***Any community individual "engaged" in research will need to complete the CITI MIAMI training course and be listed on the eIRB personnel list.*

** If any community individual member of a facility is considered "engaged" in research, the site is then considered "engaged in research under section I(A)(1) of this form.

B. For each individual listed above who will be involved in the informed consent process, please complete the information below.

Name: Dr. Kevin Harris
Current Position/Role at the Facility: Associate Professor of Psychology
Human Subjects Education/Training: CITI per APSU protocols

Until IRB approval is completed, grant funding will not be available to recruit and compensate the team members. CITI training will be a part of the team training, and the specific individual's names, positions, credentials and proof of their research training will be submitted as a protocol addendum.

***For those individuals and/or sites that do not have their own IRB, MUSC may consider taking on the role of IRB of Record. Please review the guidance provided by SCTR (pg2) on how to apply for a Federal Wide Assurance (FWA) / Institutional Authorization Agreement (IAA). Contact your MUSC IRB administrator if you have questions.

**MUSC may assume IRB responsibilities for non-affiliated institutions and investigators only under certain conditions (i.e., such as when an approved IRB Authorization Agreement exists designating the MUSC IRB to serve as the IRB of Record and the facility applies for and receives and FWA from OHRP).

**If the MUSC IRB takes on the role of IRB of Record, individuals must complete an IRB approved education program (CITI MIAMI) for the protection of human research participants prior to conducting this, or any other, research involving human participants.

04-25-2016

Dear Kim,

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Best of luck with your dissertation and best regards,

Laura

Laura Stingelin

Permissions Helpdesk Associate

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Effects of multidimensional vs. functional educational interventions on baccalaureate nurse-standardized patient interactions: Demographic survey of recently graduated BSN students

Thank you for participating in this pilot health literacy study conducted by Kim French at Austin Peay State University. The information collected by this short survey will be used only to assess group characteristics. This form and information will be kept securely by Ms. French. Your responses will not be used for any other purpose, and will not affect past or future services offered by Austin Peay State University, the Medical University of South Carolina, or their associated nursing departments.

1. Age (in years) _____

2. Gender (mark one with an **X**)

   Female _____ Male _____

3. Ethnicity (mark one with an **X**)

Hispanic or Latino _____ Not Hispanic or Latino _____

Prefer not to reply _____

4. Race: Mark with an **X** your primary choice or if you choose not to reply.
You may use **+** mark/s for additional groups that you consider part of your racial background.

   American Indian or Alaska Native _____

   Asian _____

   Black or African American _____

   Native Hawaiian or Other Pacific Islander _____

   White _____

   Prefer not to reply _____

5. Past health care work experience outside of nursing school? (Mark one with an **X**)

   No _____ Yes _____

6. Length of time in past health care work experiences (In years and months, or months if less than 1 year)

   _____ Years _____ Months

7. Grade point average (GPA) at graduation (Mark one with an **X**)

   2.5 – 2.99 _____

   3.0 – 3.49 _____

3.5 - 4.0 _____

Prefer not to reply _____

If you are **nursing faculty**, please answer the 3 questions on the next page.

Only answer the following questions if you are **nursing faculty**

8. Length of time as nursing faculty, whether full or part-time? (In years)

_____ Years

9. Primary teaching concentration? (Mark with an X)

_____ Medical-Surgical (Fundamentals or AH1)

_____ Psych/Mental Health

_____ Critical Care (AH2)

_____ Maternal- Child

_____ Community Heath

_____Leadership/Administration

10. Highest educational level achieved?

_____BSN

_____MSN

_____Master's, other discipline _____

_____DNP

_____EdD

_____PhD

_____Prefer not to reply

Study ID _____

Introduction: Health Literacy is the ability to read, understand and make informed decisions about health care. One purpose of this study is to assess the knowledge and experiences of BSN nursing graduates from Austin Peay State University. If you choose to participate I encourage you to answer all questions but you have the right to refuse to answer any question on the survey. Your responses will be kept anonymous and in no way affect your past grades in any nursing course or any future services provided to you by APSU. Thank you for your participation

Part 1: Health Literacy Knowledge

Directions: Questions 1-29 are multiple-choice questions. Choose the best answer and record only one response for each question on the document provided.

___1. Low health literacy levels are most prevalent among which of the following age groups?

a. 16 to 24 years of age.
b. 25 to 34 years of age.
c. 35 to 44 years of age.
d. 45 to 54 years of age.
e. 65 years of age and older.

___2. Low health literacy levels are common among:

a. African Americans.
b. Hispanic Americans.
c. White Americans.
d. All ethnic groups.

___3. The research on health literacy indicates that:

a. the last grade completed is an accurate reflection of an individual's reading ability.
b. most individual's read three to five grade levels lower than the last year of school completed.
c. if an individual has completed high school they will be functionally literate.
d. if an individual has completed grammar school they will be functionally literate.

___4. What is the likelihood that a nurse working in a public health clinic, primarily serving low- income minority patients, will encounter a patient with low health literacy skills?

a. almost never.
b. occasionally
c. often
d. very often

___5. The best predictor of healthcare status is:

a. socioeconomic status.
b. literacy.
c. gender.
d. educational level.

___6. Patients with low health literacy skills:

a. rate their health status higher than those with adequate literacy skills.
b. experience fewer hospitalizations than those with adequate health literacy skills.
c. are often prescribed less complicated medication regimes than those with adequate health literacy skills.
d. are often diagnosed late and have fewer treatment options than those with adequate health literacy skills.

___7. Health behaviors common among patients with low health literacy skills include:

a. lack of participation in preventative healthcare.
b. disinterest in learning about healthcare problems.
c. an unwillingness to make lifestyle changes necessary to improve health.
d. the inability to learn how to correctly take prescribed medications.

___8. Patients cope with low health literacy skills by:

a. asking multiple questions about healthcare instructions they do not understand.
b. exploring treatment options before signing surgical consent forms.
c. relying heavily on written healthcare instructions.
d. pretending to read information given to them by healthcare providers.

___9. The nurse should keep in mind that individuals with low health literacy levels:

a. can understand written healthcare information if they are able to read it.
b. will not be able to learn about their healthcare needs.
c. have lower intelligence scores than average readers.
d. have difficulty applying healthcare information to their health situation

___10. Which statement best describes the instrument, The Rapid Estimate of Adult Literacy in Medicine?

a. This instrument determines the reading level of written healthcare information.
e. This instrument assesses the math skills of an individual required for medication administration.
c. This instrument evaluates the overall quality of written health care information.
d. This instrument assesses the ability of an individual to read common medical terms.
e. I do not know.

___11. When working with individuals who have low health literacy skills the nurse should keep in mind that these individuals:

a. may not admit that they have difficulty reading.

b. will readily share that they need assistance with written information.

c. will frequently ask questions about information they do not understand.

d. should not be expected to manage their healthcare since they cannot read.

___12. Which of the following questions would provide the nurse with the **best** estimate of reading skills of the patient?

a. "What is the last grade you completed in school?"

b. "Do you have difficulty reading?"

c. "Would you read the label on this medication bottle for me?"

d. "Do you need eye glasses to read?"

___13. Which statement best describes the Test of Functional Health Literacy?

a. This instrument is used to assess the reading comprehension and numerical skills of an individual.

b. This instrument is only available in English and therefore has limited use with immigrants.

c. This instrument is an effective tool for assessing the reading level of individuals.

d. This instrument is recommended for determining the reading level of written healthcare materials.

e. I do not know.

___14. What is the strongest advantage to conducting health literacy screenings? Health literacy screenings:

a. provide nurses with a good estimate of the educational level of individuals.

b. will help nurses to be more effective when providing healthcare teaching.

c. can be used to diagnose learning difficulties that serve as barriers to patient teaching.

d. assist healthcare agencies to comply with educational standards established by the Joint Commission on Accreditation of Health Organizations.

___15. Which of the following statements, made by the nurse, would be the best approach to initiating a health literacy screening with a patient?

a. "It is necessary for me to assess your reading level; this will take a few minutes and it is very important."

b. "I need to conduct a test to see if you can read, please read these words for me."

c. "I want to make sure that I explain things in a way that is easy for you to understand; will you help me by reading some words for me."

d. "I need to administer a reading test to you, if you cooperate this will not take long."

___16. After providing written healthcare information to a patient he states, " Let me take this information home to read." This may be a clue to the nurse that the patient:

a. is in a hurry and does not have time for instruction.
b. is not interested in learning the information.
c. is noncompliant with healthcare treatments.
d. may not be able to read the materials.

___17. An individual with functional health literacy will be able to:

a. follow verbal instructions but not written healthcare instructions.
b. read healthcare information but have difficulty managing basic healthcare needs.
c. read and comprehend healthcare information.
d. read, comprehend, and actively participate in decisions concerning healthcare.

___18. Which of the following is true with regards to written healthcare information?

a. Most healthcare information is written at an appropriate reading level for patients.
b. Illustrations can improve a patient's understanding of written information.
c. Patients are usually provided with information that they think is important to know about their healthcare status.
d. Overall patients comprehend written information better than verbal instructions.

___19. The recommended reading level for written healthcare information is:

a. 5^{th} grade.
b. 8^{th} grade.
c. 10^{th} grade.
d. 12^{th} grade.

___20. The first step in developing written healthcare information is to:

a. outline the content.
b. list the learning objectives.
c. find out what the audience needs to know.
d. research the content area.

___21. Which of the following statements best describes the Fry Method?

a. This formula is used to calculate word difficulty in a written document.
b. This method calculates the readability level of a written document by counting selected syllables and sentences within the document.
c. It is an effective tool used for measuring how well a patient understands

healthcare information.

d. This instrument is used to evaluate the cultural appropriateness of written healthcare instructions.

e. I do not know.

___22. Recommendations for developing written healthcare materials include:

a. use dark colored papers for printing.

b. presenting information in the form of a conversation.

c. including abbreviations when possible to save space.

d. printing words in fancy script.

___23. When listing side effects for a handout on chemotherapy the oncology nurse should limit the list to:

a. 2-3 items.

b. 5-6 items.

c. 10- 12 items.

d. 15-20 items.

___24. Written healthcare information provided to a patient related to a specific disease should include:

a. only three or four main ideas about the disease.

b. all treatment options available to manage the disease.

c. a detailed explanation of the pathophysiology of the disease.

d. statistics on the incidence of the disease.

___25. Which of the following would be the most effective wording for a heading in a brochure on hypertension?

a. HYPERTENSION: THE SILENT KILLER

b. *Symptoms of high blood pressure*

c. How do I know that I have high blood pressure?

d. What factors contribute to hypertension?

___26. The **best** way to ensure that a breast cancer prevention brochure is culturally appropriate is to:

a. review research on the community's culture.

b. obtain input from nurses who have worked in the community.

c. explore the types of materials currently available.

d. include community members in the design of the brochure.

___27. Which of the following instructions on the management of diabetes would be best understood by an individual with low health literacy skills?

a. Check your blood sugar every morning.

b. Insulin should be taken as directed by your physician.

c. Diabetes is a disease of energy metabolism.

d. Complications associated with insulin include hypoglycemic reactions.

___28. Which of the following approaches to patient education provides minimal opportunity for the patient to actively engage in learning?

a. Incorporating short answer questions periodically throughout written healthcare materials and providing space for the patient to write responses.

b. Instructing the patient to watch a video after providing written healthcare instructions.

c. Planning a question answer session in small groups after completing a learning activity.

d. Providing pictures for the patient to circle in response to questions asked in a healthcare brochure.

___29. The most effective way for a nurse to determine how well a patient with low health literacy skills understands healthcare information is to**:**

a. Utilize a pre-test before instruction and a post-test following instruction.

b. Ask the question, "Do you understand the information I just gave you?"

c. Have the patient teach back the information to the nurse.

d. Verbally asking the patient a series of questions following instructions.

Thank you for completing the survey. The original was developed by Dr. Catherine Cormier (Cormier & Kotrlik, 2009).

Study ID _____

Directions: Questions 30-38 ask you to describe the following: How often you have incorporated health literacy interventions in your nursing practice while in nursing school. Choose the response that best describes your health literacy experiences while in nursing school class or clinicals and record your answer on the form.

____30. How frequently was health literacy emphasized in your nursing curriculum?
a = Never b = Sometimes c = Frequently d = Always

____31. How often did you use a health literacy screening tool to assess the health literacy skills of an individual?
a = Never b = Sometimes c = Frequently d = Always

____32. How often did you evaluate the reading level of written healthcare materials before using them for patient teaching?
a = Never b = Sometimes c = Frequently d = Always

____33. How often did you evaluate the cultural appropriateness of healthcare materials, including written handouts, videos, audiotapes, before using them for patient teaching?
a = Never b = Sometimes c = Frequently d = Always

____34. How often did you evaluate the use of illustrations in written healthcare materials before using them for patient teaching?
a = Never b = Sometimes c = Frequently d = Always

____35. How often did you use written materials to provide healthcare information to an individual or community group?
a = Never b = Sometimes c = Frequently d = Always

____36. How often did you use audiotapes to provide healthcare information to an individual or community group?
a = Never b = Sometimes c = Frequently d = Always

____37. How often did you use videotapes to provide healthcare information to an individual or community group?
a = Never b = Sometimes c = Frequently d = Always

____38. How often did you use computer software to provide healthcare information to an individual or community group?
a = Never b = Sometimes c = Frequently d = Always

Thank you for completing the HLK-ES. This survey was developed by Dr. Catherine Cormier.

Kemp

I apologize for the delay. Things have been somewhat hectic for me this summer. Your project sounds very exciting and I give you permission to use the HL-KES tool. I have attached a copy of the survey and key for the knowledge section. I wold love to hear back from you regarding the results of your study. If there is anything I can do to help please feel free to contact me. Hopefully next time it will not take so long to respond!

Best of Luck

Cathy

-----Original Message-----

From: French, Kempa S. [mailto:frenchk@apsu.edu]

Sent: Thu 6/21/2012 4:29 PM

To: Catherine Cormier

Subject: Request to use the Health Literacy Knowledge and Experiences Survey (HL-KES)

Hello Dr. Cormier. I am a doctoral nursing student from the Medical University of South Carolina and a Community Health nursing faculty member at Austin Peay State University in Tennessee . In reviewing the literature about health literacy and nursing education, I was impressed by your work documenting the creation and development of the Health Literacy Knowledge and Experiences Survey(HLK-ES). As part of my doctoral research, I would like to use the HL-KES to benchmark the integration of health literacy principles in undergraduate nursing education. I have attached a copy of my abstract to give you an idea of how the survey would be used, although at this point the dissertation is still a work in progress. I would also be glad to call or e-mail you with additional information if you have other questions,

Sincerely,

Kempa S. (Kim) French, PhD-c, MSN, FNP-BC
Kempa S. French
Associate Professor of Nursing
Austin Peay State University
Clarksville TN 37044
931-221-7528
frenchk@apsu.edu<mailto:frenchk@apsu.edu>

Kalamazoo Essential Elements Communication Checklist – Adapted *

How well does the learner do the following:

	1 Poor	2 Fair	3 Good	4 Very Good	5 Excellent
A. Builds a Relationship (includes the following):	○	○	○	○	○
• Greets and shows interest in patient as a person					
• Uses words that show care and concern throughout the interview					
• Uses tone, pace, eye contact, and posture that show care and concern					
	1 Poor	2 Fair	3 Good	4 Very Good	5 Excellent
B. Opens the Discussion (includes the following):	○	○	○	○	○
• Allows patient to complete opening statement without interruption					
• Asks "Is there anything else?" to elicit full set of concerns					
• Explains and/or negotiates an agenda for the visit					
	1 Poor	2 Fair	3 Good	4 Very Good	5 Excellent
C. Gathers Information (includes the following):	○	○	○	○	○
• Begins with patient's story using open-ended questions (e.g."tell me about…")					
• Clarifies details as necessary with more specific or "yes/no" questions					
• Summarizes and gives patient opportunity to correct or add information					
• Transitions effectively to additional questions					
	1 Poor	2 Fair	3 Good	4 Very Good	5 Excellent
D. Understands the Patient's Perspective (includes the following):	○	○	○	○	○
• Asks about life events, circumstances, other people that might affect health					
• Elicits patient's beliefs, concerns, and expectations about illness and treatment					
• Responds explicitly to patient's statements about ideas and feelings					
	1 Poor	2 Fair	3 Good	4 Very Good	5 Excellent
E. Shares Information (includes the following):	○	○	○	○	○
• Assesses patient's understanding of problem and desire for more information					
• Explains using words that patient can understand					
• Checks for mutual understanding of treatment plan					
• Asks if patient has any questions					
	1 Poor	2 Fair	3 Good	4 Very Good	5 Excellent
F. Reaches Agreement (if new/changed plan) (includes the following):	○	○	○	○	○
• Includes patient in choices and decisions to the extent s/he desires					
• Asks about patients ability to follow diagnostic and/or treatment plans					
• Identifies additional resources as appropriate					
	1 Poor	2 Fair	3 Good	4 Very Good	5 Excellent
G. Provides Closure (includes the following):	○	○	○	○	○
• Asks if patient has questions, concerns or other issues					
• Summarizes / asks patient to summarize plans until next visit					
• Clarifies follow-up or contact arrangements					
• Acknowledges patient and closes interview					

*Adapted from Essential Elements: The Communication Checklist, ©Bayer-Fetzer Group on Physician-Patient Communication in Medical Education, May 2001, and from: Rider EA. Interpersonal and Communication Skills. In: Rider EA, Nawotniak RH. *A Practical Guide to Teaching and Assessing the ACGME Core Competencies, 2nd edition.* Marblehead, MA: HCPro, Inc., 2010. Copyright © 2010 HCPro, Inc.

Contact: Elizabeth A. Rider, MSW, MD – elizabeth_rider@hms.harvard.edu (member, Kalamazoo Consensus Group)

Hi Kim,
You are most welcome! I appreciate your note.
Beth

From: French, Kim [frenchk@apsu.edu]
Sent: Thursday, April 11, 2013 11:16 AM
To: Rider, Elizabeth Ann
Subject: RE: Request to use KEECC-A in doctoral study

Dr. Rider, thank you so much for your generosity and willingness in allowing me to use the KEECC-A as part of my dissertation work. I will make sure that the correct citation/copyright statement is used both with the tool and in referencing the instrument in my research. In addition, I will do everything possible to use the KEECC-A responsibly and appropriately. When I (finally) get through my dissertation, I will share feedback and experiences with you and your group on how the instrument works with nursing students and our standardized human actors. I am also grateful for the additional references and materials you have provided for my consideration- the additional insights can only help to strengthen my research argument-that all disciplines can be educated to provide more patient-centered communication.
With all due regards,
Kim French
frenchk@apsu.edu

From: Rider, Elizabeth Ann [elizabeth_rider@hms.harvard.edu]
Sent: Wednesday, April 10, 2013 11:37 AM
To: French, Kim
Subject: RE: Request to use KEECC-A in doctoral study

Dear Kim,

I am delighted to hear about your wanting to use the KEECC-A for your dissertation research.

Our Kalamazoo Consensus Statement Group has worked out a citation/copyright statement for the use and/or adaptation of our assessment tool. Yes, you may use the "Kalamazoo Essential Elements Communication Checklist-Adapted"---as long as the following citation remains in its entirety on the form/tool:

*Adapted from Essential Elements: The Communication Checklist, ©Bayer-Fetzer Group on Physician-Patient Communication in Medical Education, May 2001, and from: Rider EA. Interpersonal

Assessing the ACGME Core Competencies, Second Edition.
Marblehead, MA: HCPro, Inc., 2010 (394 pages)

The book includes the evidence-base, best practices, models and tools to help teach, assess, and document the core competencies in medical education. We included actual tools for each of the 6 competencies. You'll find many suggestions for teaching, curriculum, and assessment in all chapters--and many communication skills assessment tools in that chapter. (I'm really not trying to sell the book; it just includes information and evaluation tools that others have found useful.)

If you are interested in the book, it is available from the publisher, Amazon.com, Barnes and Noble.com and other book sellers. Amazon currently has the best price (it changes!).
Amazon site: http://www.amazon.com/Practical-Guide-Teaching-Assessing-Competencies/dp/1601467400/ref=sr_1_1?ie=UTF8&qid=1351123578&sr=8-1&keywords=acgme

Your hospital, nursing school, or medical school library may have a copy as well.

Good to hear from you! Please let me know if you have any questions or if I can provide any further information.

Sincerely,

Beth

Elizabeth A. Rider, MSW, MD
Director of Academic Programs
Institute for Professionalism and Ethical Practice, Boston Children's Hospital/Harvard Medical School
Director, Faculty Education Fellowship in Medical Humanism and Professionalism, Boston Children's Hospital
Director of Programs for Communication Skills
The John D. Stoeckle Center for Primary Care Innovation, Massachusetts General Hospital
Harvard Medical School
Co-Chair, Medicine Academy, National Academies of Practice
Co-Author, A Practical Guide to Teaching and Assessing the ACGME Core Competencies
elizabeth_rider@hms.harvard.edu

From: French, Kim [frenchk@apsu.edu]
Sent: Wednesday, April 10, 2013 11:36 AM
To: Rider, Elizabeth Ann
Subject: Request to use KEECC-A in doctoral study

Hello Dr. Rider. I am Kim French, a nursing PhD student at the Medical University of South Carolina and faculty at Austin Peay State University in Clarksville, TN. Dr. Barbara Joyce indicated that you were the copyright holder of the KEECC-A instrument when I had contacted her about using the tool as part of my dissertation. I am interested in comparing the health literacy-related communication competencies of the KEECC-A with a health literacy competency observational checklist that I am developing for nurses and nursing students. I have attached my abstract for your review, but I would be glad to call and discuss if you have any additional questions. Also, I would like to know if there are any costs associated with the KEECC-A so that I could build that into my research budget. I appreciate your consideration of my request.
Sincerely,
Kempa (Kim) S. French MSN, FNP-BC
Associate professor of nursing
frenchk@apsu.edu
(931) 221-7528 (Office)
(931) 221-7737 (School of Nursing)

HLP-NICE is an observational checklist designed to assess the health literacy competencies of nurses when interacting with patients.

The quality of the nursing interaction is evaluated by circling one of the following indicators:
0 = Not observed 1 = Poor 2 = Fair 3 = Good 4 = Excellent N/A = Not applicable

If the objective is not relevant for the situation, then the Not Applicable (N/A) indicator should be circled.
If N/A is circled, then a brief explanation or rationale should be recorded in the comments section.

Observed strengths and/or suggestions for improvement can also be written in the comments section.

Health Literacy Objective	**Interaction Quality**	**Comments**
Engages, assesses and reassesses patient needs		
At the **beginning** of the encounter		
1. Nurse greets the patient appropriately	0 1 2 3 4 N/A	
2. Nurse introduces self, and identifies a shared purpose for the interaction	0 1 2 3 4 N/A	
3. Nurse addresses patient's main health concern and context - patient understanding of main concern - barriers to self-management of concern - available support systems	0 1 2 3 4 N/A	
4. Nurse assesses patient preferences for communication and learning needs	0 1 2 3 4 N/A	
At the **end** of the encounter: **5.** Nurse asks open ended questions such as "What other questions or	0 1 2 3 4 N/A	

Health Literacy Objective	**Interaction Quality**	**Comments**
concerns do you have?"		
Health Literacy Objective	**Interaction Quality**	**Comments**
Explains information clearly in plain language		
6. Nurse vocal tone is appropriately paced with an acceptable volume and pitch	0 1 2 3 4 N/A	
7. Nurse posture indicates active listening	0 1 2 3 4 N/A	
8. Nurse's medical language matches the patient's level of language and understanding	0 1 2 3 4 N/A	
9. Nurse uses everyday language instead of medical jargon or medicalized terms	0 1 2 3 4 N/A	
10. Nurse uses words which indicate caring or concern and matches the patient's feelings or level of understanding	0 1 2 3 4 N/A	
Prompts effective participation in visit: Focus on 3 or fewer key messages		
11. Nurse's initial teaching statement indicates the provider's responsibility for ensuring patient	0 1 2 3 4 N/A	

Health Literacy Objective	**Interaction Quality**	**Comments**
comprehension		
Health Literacy Objective	**Interaction Quality**	**Comments**
12. Nurse emphasizes 3 or fewer key points during interaction	0 1 2 3 4 N/A	
13. Nurse repeats and reviews each key point with patient during interaction	0 1 2 3 4 N/A	
14. Nurse gets specific feedback from patient for each key point (Teach Back)	0 1 2 3 4 N/A	
15. Nurse gets patient agreement for correctly repeated information, or reteaches misunderstood information until information is correctly restated	0 1 2 3 4 N/A	
16. Nurse refrains from interruptions that may disrupt patient explanations or misses patient cues	0 1 2 3 4 N/A	
Uses patient-friendly explanations, materials and drawings		

Health Literacy Objective	**Interaction Quality**	**Comments**
17. Nurse puts health information in context by defining new or unfamiliar terms during explanations	0 1 2 3 4 N/A	
Health Literacy Objective	**Interaction Quality**	**Comments**
18. Nurse puts health information in context by using common analogies during explanations	0 1 2 3 4 N/A	
19. Nurse selects appropriate educational materials or drawings to match assessed learning needs and preferences	0 1 2 3 4 N/A	
20. Nurse writes down key verbal points or highlights key points in printed materials	0 1 2 3 4 N/A	

Medical University of South Carolina Protocol

PI Name: Kempa S. French, MSN, FNP-BC

Study Title: Effects of multidimensional vs. functional health literacy educational interventions on baccalaureate nurse-standardized patient interactions: An experimental pilot study.

TABLE OF CONTENTS

A. SPECIFIC AIMS

Purpose. Patients with limited health literacy are more likely to have poorer health outcomes, higher emergency room use and hospitalization rates, and greater morbidity and mortality rates than those with adequate literacy levels (Berkman et al., 2011; Sudore et al., 2010). The risks to health and well-being, the influences on morbidity and mortality markers and economic impact for patients, communities and health systems argue for robust preparation of health providers, including nurses, in evidence-based health literacy competencies. Early health literacy research in the US emphasized patient literacy screenings and intervening for those with low or limited literacy levels. The majority of interventions used in this functional literacy approach emphasized written health literacy measures and patient abilities to read text. This approach is the one most commonly used in the US (Barry et al., 2013), yet omits patient comprehension and the provider's contribution to health-related interactions and explanations. As an alternative, the multidimensional health literacy approach includes patient competencies beyond text literacy, including their participation in speaking, cultural beliefs and ways of seeking understanding (Shaw et al., 2012). This expanded approach may require the development of additional health literacy competencies from health care providers and related attributes from health institutions beyond textual modification alone (Brach et al., 2012). A recent consensus study proposes health literacy educational competencies and health literacy-related practices for health professionals (Coleman et al., 2013), which are potentially useful for evaluation of differing theoretical and pedagogical strategies for nursing education practice. The first purpose of this experimental pilot study is to compare the effects of multidimensional and functional health literacy skills-based nursing educational interventions on the uptake of health literacy practices. A second complementary purpose is to lay the groundwork for psychometric evaluation of an observational health literacy competency checklist incorporating select consensus-based constructs to assess the health literacy competencies of 10 recently graduated baccalaureate (BSN) nurses and 10 nursing educators who are faculty members from the same BSN program.

Research Question: In a sample of 10 recently graduated baccalaureate nurses and 10 nursing educators, does the use of multidimensional versus functional health literacy educational strategies lead to significantly different outcomes of health literacy knowledge and health-literacy related behaviors observed in recorded nurse-patient interactions?

Specific Aims. To answer this question, four aims will be addressed.

Aim 1. Develop and assess the Health Literacy Patient-Nurse Interaction Competencies Evaluation or HLP-NICE tool for psychometric trending of multidimensional and functional health literacy competencies seen in:

a. interrater reliability levels for Cohen's kappa (κ) of 0.4 or greater for ratings by the 2 standardized patients (SP) when using the HLP-NICE,
b. internal reliability using Cronbach's alpha (α) of 0.60 or greater,
c. content and construct validity from health literacy and nursing education stakeholder opinions, and
d. pre- and post-intervention concurrent validity comparison with the Kalamazoo Essentials Evaluation Communication Competencies-Adapted or KEECC-A Instrument (Rider & Nawotniak, 2010).

Hypothesis for Aim 1. The HLP-NICE observational checklist will show no preliminary trends towards psychometric properties of interrater and internal reliability, and content, construct and concurrent validity.

Aim 2. Develop and refine two health literacy curriculum interventions exemplifying multidimensional versus functional theoretical perspectives with pre-intervention assessments from external stakeholders and post-intervention process evaluation modifications from the teacher-interventionist and external stakeholders.

Aim 3. Assess the effects of multidimensional versus functional health literacy teaching curriculum interventions on two randomly assigned groups consisting of 10 recently graduated baccalaureate nursing students and 10 nurse educators by comparing graduate nurse and faculty pre-intervention recall of prior health literacy experiences using the Health Literacy Experiences Survey (Cormier & Kotrlik, 2009) and post-intervention changes in:

a. health literacy knowledge scores using the Health Literacy Knowledge Survey (Cormier & Kotrlik, 2009) from nurse-participant self-report,
b. communication competency scores using the Kalamazoo Essentials Evaluation of Communication Competencies-Adapted or KEECC-A Instrument (Rider & Nawotniak, 2010) from standardized-actor ratings of nurse participants, and
c. health literacy-related behavior scores using the newly-developed Health Literacy Patient-Nurse Interaction Competencies Evaluation or HLP-NICE observational checklist supporting select consensus-based health literacy participant competencies as rated by standardized patient-actors. .

Hypothesis for Aim 3. There are no differences in health literacy knowledge and health literacy-related behavior changes between the multidimensional and functional health literacy groups exemplifying the two differing theoretical and pedagogical health literacy approaches.

Aim 4. Identify what further development and testing the HLP-NICE observational checklist needs through analysis of quantitative observations of participant health literacy-related competencies and qualitative cognitive interviews with standardized patients and external stakeholders.

These four aims will be addressed through a two-phase four group experimental pilot study designed to identify the signal effects of health literacy educational interventions with 10 recently graduated BSN's and 10 nurse educators when observed in standardized patient simulations and initial testing of health literacy competencies measurement. The outcomes will contribute to more rigorous evidence for the inclusion of health literacy (HL) knowledge and HL-related behaviors in nursing curricula, course content and simulated or actual clinical experiences.

B. BACKGROUND AND SIGNIFICANCE

BACKGROUND

Health Literacy Perspectives. Traditional functional health literacy perspectives have focused on meeting the health information needs of the 36 percent of the American population estimated to have basic or below basic health literacy. Past efforts have researched patient literacy screening and written material simplification for those with limited health literacy. This literacy-based approach overlooks the health information needs and skills of the sixty-four percent of patients with adequate literacy levels. In observations of 57 recorded provider-patient interactions assessed for the question type and quantity using Roter's Interaction Analysis System, Katz and colleagues (2007) noted that health providers were unlikely to modify their communication style or use of jargon despite significant differences between the amount and quality of questions asked by patients with higher and lower literacy levels. Semi-structured interviews of patients with high and low literacy levels also explored the diverse needs and uses of information gathering and comprehension beyond health care settings (Smith, Dixon, Trevena, Nutbeam, & McCaffrey, 2009). While higher and lower literacy patients shared similar needs for accessible and actionable health information, other considerations of autonomy levels and information use varied. Those patients with higher education and literacy levels tended to be more actively engaged in gathering information and the decision-making process. These differences suggest that there is no "one-size fits all" health literacy approach, and that health literacy should be evaluated as multiple levels of knowledge, skills and behaviors in a progression from basic to increasingly enlightened, engaged and empowered patient-provider collaborations. The expanded multidimensional health literacies perspective offers alternative health-promoting approaches to the current illness-focused models.

Addressing the health knowledge needs of all patients will take providers who are educated in evidence-based health literacy strategies and are sensitive to life contexts beyond formal health care environments. These collaborative interactions may lead to greater individual, community and population empowerment, but may not be achieved without further research and action on the part of all stakeholders within clinical, research, academic, and political environments. The National Health Literacy Action Plan has been proposed to facilitate health literacy clinical practices in response to greater calls for patient-centered care (U.S. Department of Health and Human Services [DHHS], 2010). Expectations of improvement may not be fully realized, however, because there are no defined economic, social or political incentives to implement the Health Literacy Action Plan recommendationsNo timelines or clear benchmarks are given to evaluate the seven goals outlined in the plan's recommendations. There is also limited curricular guidance for health provider faculty to use when teaching and role-modelling health literacy competencies for students (Coleman, 2011). These problems, while not insurmountable, may contribute to the ongoing minimal uptake of health literacy evidence in health care professional education and clinical practice.

Existing Educational Interventions. One educational approach favored by health systems to increase health literacy knowledge awareness and practice includes web-based training modules such as the CDC's *Health literacy for public health professionals* (CDC, n.d.), HRSA's *Effective communication tools for healthcare professionals* (HRSA, n.d.) and AHRQ's *Health Literacy Universal Precautions Toolkit for healthcare systems* (AHRQ, n.d.). These educational approaches support both current health literacy evidence and the Health Literacy Action Plan goals, but have not been mandated for use by the current educational or health care systems. The information is targeted to practicing professionals and may require significant amounts of time or facility collaboration to implement. Nurses and other allied health professionals begin professional practice after completing undergraduate studies, and may receive only minimal health literacy exposure throughout their curriculum, course content or clinical assignments (Coleman, 2011; Coleman et al., 2013). Health literacy definitions and measurement are of relatively recent origin, which creates additional barriers reducing the quantity and quality of health literacy evidence integrated in provider education and practice. Reaching consensus concerning the need for additional health literacy content in nursing education may be challenging given competing curricular priorities (Coleman, 2011) and nursing curriculum demands, course content and external pressures regarding NCLEX testing (Forbes and Hickey, 2009).

THEORETICAL CONTEXT

Theoretical/conceptual frameworks: Functional Health Literacy Health literacy has been defined as *"…the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make health decisions"* (Nielsen-Bohlman, Panzer, & Kindig, 2004, p. 31-32). This definition has been used to guide past health literacy research, but may not account for the use of health information outside of formal health care settings, or fully explain how people use this knowledge to reach informed decisions

regarding their health and well-being. Health provider interventions have emphasized patient health literacy status as a pathology marker, which neglects provider, health system and environmental impact when appropriate medication advice is not discussed with stakeholders (Lemer et al., 2009). Structured interviews with 283 primary care patients explored patient-reported shame and embarrassment about lack of comprehension or limited reading abilities (Wolf et al. 2007). Half of those with literacy levels measured at 3rd grade or less were more likely to report these negative feelings about their literacy abilities, but those with borderline literacy levels indicated that it would be helpful for providers to have knowledge of their literacy level to better meet their needs. Bass and colleagues (2002) illustrated limitations that health professionals in training may have with accurately detecting or intervening for patients with lower literacy based on communication, behavioral cues or educational status alone. The 45 medical residents who participated identified 10% (n=18) of the patients as having low health literacy levels when 36% (n=59) scored a six or less on the REALM-R literacy screening instrument [(1df) =13.18, p <.001]. The residents also misidentified 1.3 % (n=3) of patients as having inadequate literacy although the patient's REALM-R score was above six. Comparisons between self-reported provider effectiveness and patient perceptions of the same interaction between 19 physicians and 145 patients at a NY internal medicine ambulatory clinic suggested that low competency providers tended to overestimate both the effects of their patient education on patient comprehension of health information [OR 0.33 CI (0.18, 0.62), p<0.001] and their own effectiveness as communicators [OR 2.71, CI (1.90, 3.88), p <0.001] (Lukoschek, Fazzini, & Marantz, 2003). Patient literacy screening instruments such as the Single Literacy Question were intended to foster a better match of patient literacy level and patient learning needs using easy–to-administer tools (Morris et al., 2006). Identifying limited literacy levels, however, may not account for the impact of provider communication barriers and the limitations of written materials used to supplement patient education. Castro and colleagues (2007) noted when assessing observations of 74 diabetic patients with low literacy and their providers, that 81 % of visits included providers' use of medical jargon without additional explanations. Jargon was used an average of four times per visit and particularly when making recommendations (37%) or providing patient instructions (29%). Comprehension of identified medical jargon terms evaluated through telephone surveys indicated that the 19 contacted patients had difficulty grasping the meaning of medical jargon at best regardless if the words were presented with or without contextual cues (Castro et.al, 2007, p. S90).

Schwartzenberg and colleagues (2007) surveyed the health literacy practices of 168 physicians, nurses and pharmacists. Those providers who participated reported the recent use of plain language, handing out written materials, and speaking slowly more often than recommended health literacy standards such as ensuring patient comprehension through teach-back and tailoring written materials to the patient. Other interventions such as simplifying written health information may not fully alleviate knowledge gaps for patients, who may struggle to comprehend and apply unfamiliar and complex health concepts. During two years of mammogram screening follow-up in a RCT of 445 women with lower literacy, Davis and colleagues (1998) noted that only those who got personalized information were more likely to adhere to screening recommendations than those receiving standardized advice, simplified information or combinations of these three interventions. Coyne and colleagues (2003) reported outcomes from a RCT designed to assess self-reported anxiety level, comprehension and willingness to participate in clinical cancer trials with 207 clients from 44 cancer clinics. While short-term anxiety levels and perceived satisfaction were improved with the simplified consent forms, there was no corresponding increase in patient comprehension of key information or agreement for trial participation. These results suggest that additional factors beyond easing written material literacy requirements should be considered when interacting with patients and families.

Theoretical/conceptual frameworks: Multidimensional Health Literacy To address these limitations, the traditional definition of health literacy has broadened to include "the wide range of skills, and competencies that people develop to seek out, comprehend, evaluate and use health information and concepts to make informed choices, reduce health risks and improve quality of life" (Zarcadoolas, Pleasant & Greer, 2006, p. 55-57). This more holistic definition expands patient health literacy skills to include scientific, cultural and civic attributes beyond discrete and unconnected reading abilities. From the multidimensional perspective, patient health literacy levels are not a single incidental finding, but are flexible characteristics which may vary based on perceived needs, resources and health conditions (Nutbeam, 2008).

The most recent multidimensional health literacy model proposed by Sørensen and colleagues (2012) synthesizes 17 current medical and public health definitions of health literacy to provide a more comprehensive definition to be used by medical and public health professionals. Health literacy includes elements of basic literacy abilities, but should also include the knowledge, skills and motivation for patients and populations to act

appropriately on health information within many contexts to maintain or improve the overall quality of life (Sørensen et al., p. 5). If this definition of health literacy is applicable, then emphasis on screening and interventions based on functional literacy skills alone may not fully characterize patient and population use of health information to improve individual quality of life, community health circumstances, or health system manageability.

The multidimensional emphasis moves beyond discrete literacy-based interventions to include patient perspectives of their risk level, cultural filters and comfort with level of control. When evaluated longitudinally, 18 patients with chronic disease reported both positive and negative coping and information-seeking skills. These multilayered strategies were related to their personal skills and their level of control over their health decisions, thus influencing their readiness for additional health information (Edwards, Wood, Davies & Edwards, 2012). Patients with lower literacy levels indicated preference for final confirmation of health decisions after discussions of alternatives (Smith et al, 2009). When asked who they would turn to if they had health questions, patients stated they were more likely to seek help from non-healthcare providers such as family members rather than health professionals (Sand-Jecklin, Murray, Summers & Watson, 2010). Multidimensional approaches show promise to improve provider HL competencies , but this approach requires different educational strategies to prepare providers to clearly explain technical and scientific concepts, incorporate cultural perspectives or collaborate in civic actions. These findings suggest that discrete functional interventions to simplify the literacy burden of written materials may be less likely to improve long-term health outcomes without accounting for additional health provider or health system factors.

NURSING EDUCATION CONTEXT

Nursing Education Literature Review. Nursing education research has focused on traditional functional literacy skills such as assessing nurse health literacy knowledge levels (Cormier & Kotrlik, 2009; Jukkala, Deupree & Graham, 2008; McCleary-Jones, 2012; Scheckel, Emery & Nosek, 2010), evaluating written materials (Shieh & Hosei, 2008) or conducting patient health literacy screenings (Sand-Jecklin et al., 2010). To ascertain the current status of health literacy integration in nursing education, a systematic search was updated most recently in July 2015, using 8 academic electronic databases including *Cochrane Reviews, Medline-Ovid, PubMed, CINAHL, and ERIC*. Additional strategies included hand searching, targeted searching of relevant nursing journals and expert recommendations. From the 8 peer-reviewed available nursing educational reports reported in English, a synthesis revealed that the majority of nursing education research used lower level descriptive designs such as surveys (Cormier & Kotrlik, 2009; Jukkala et al., 2008) or single site case studies (McCleary-Jones, 2012; Sand-Jecklin et al, 2010, Scheckel et al., 2010; Shieh & Hosei, 2008, Shieh et al. 2013). Short-term student knowledge gains occurred after brief learning interventions (McCleary-Jones, 2012; Sand-Jecklin et al, 2010; Shieh & Hosei, 2008) but sustained learning retention or direct observation of health literacy practices in patient-student interactions was not evaluated. Factors affecting reported outcomes include limited reliability and absence of validity testing (Jukkala et al., 2009; McCleary-Jones, 2012; Sand-Jecklin et al., 2010; Shieh & Hosei, 2008), researcher selection bias (Scheckel et al., 2010) and an overdependence on self-reporting without corroboration from additional sources (Cormier & Kotrlik, 2009; Scheckel et al., 2010, Shieh et al., 2013, Zanchetta et al., 2013).Additional searches did not locate any health literacy research regarding measurement of nurse educator competencies or how educator health literacy competencies might influence nursing student outcomes and practice.

None of the previous studies identified a theoretical framework, tested long-term knowledge retention, evaluated the impact of student learning on observed nurse-patient outcomes or assessed the health literacy knowledge, skills and attitudes of those teaching health literacy competencies to health professionals, including nurses This pilot study will address these gaps by comparing educational outcomes of recently graduated nurses with nurse educators from their School of Nursing based on functional versus multidimensional health literacy theoretical definitions, models and practices (Edwards, Wood, Davies & Wood, 2010; Nutbeam, 2008, Zarcadoolas et al., 2006). The use of the validated Health Literacy Knowledge Survey (Cormier & Kotrlik, 2009) will provide a benchmark for cognitive knowledge changes, and allows further exploration of the effects of health literacy knowledge in the development of health literacy competencies. The validated KEECC-A (Joyce, Steenburgh & Scher, 2010; Rider & Nawotniak, 2010) will provide a benchmark for medical communication competency changes, and in conjunction with the newly-developed HLP-NICE will add further insights into the impact of health literacy-related behaviors in the development of nursing communication and health literacy competencies. This project will be one of the first studies to assess the effects of differing health literacy approaches on the

quantity and quality of health literacy practices directly observed in nurse-patient interactions. This project will also be one of the first studies to assess levels of health literacy knowledge and health-literacy related behaviors of the nurse educators who are responsible for developing and role-modelling professional nursing competencies of future professionals.

SIGNIFICANCE

Significance of the Study. Patients need understandable and actionable health information if they are to follow health instructions, use health resources effectively and avoid preventable safety errors and costly rehospitalizations. This study is significant for health care systems because of the undue physical, emotional, and financially negative influences that poorly communicated or misunderstood health information has on health outcomes for patients, their families, communities and health systems. This study is significant for all health care professionals because the information and interventions to improve health literacy competencies of nursing students and educators could be modified for use by other health disciplines in ongoing professional or clinical education, and in clinical practice. After the HL observational checklist has been formally validated, the checklist could be used by other health professionals, including practicing nurses, to identify existing HL competencies, benchmark progress or teach for greater health literacy mastery over time. Nurses are the largest group of health care professionals in the US healthcare system, and are assumed to communicate accessible and actionable patient health information regardless of literacy level or health condition. The preparation of nurses to deliver essential health information reflects on the influence of nurse educators as they teach and role model competencies, including health literacy concepts and practices. This study is significant for nurse educators because knowledge gained regarding nurse educator competencies may point to more effective strategies to teach and role-model safe and effective nursing communication and HL competencies. The resulting trends signaled by this study's more robust approach may then be used to identify additional research gaps, stimulate curricular review or support curricular, course content or clinical modifications to build stronger health literacy nursing competencies.

C. PRELIMINARY STUDIES

This pilot study is the first study undertaken by the principal investigator (PI) in fulfillment of doctoral dissertation requirements to assess feasibility of a nursing educational intervention using standardized patients. This study proposes to develop a model for educating nurses in health literacy competencies as measured by a health literacy competencies observational checklist. The PI has had three years of experience in working with a team of nurse practitioners (NP), community clinic staff and undergraduate BSN nursing students in a community foundation-funded pilot study to improve diabetic and hypertensive health outcomes through telephone follow-up and health coaching of high risk chronic disease patients by the BSN students working with NP's. The PI has been involved in creating, developing and modifying standardized telephone scripts and the informed consent form, facilitating student calls and patient follow-up using electronic and hard copy records, selecting and training students, and facilitating patient care between faculty and clinic NP s, staff, and BSN students.

In preparation for creating SP roles and performance fidelity, the PI attended an immersion workshop June, 2013 that detailed the National Association of Standardized Patient Educator Core Curriculum modules. Relevant practice standards and core curriculum guidelines will be incorporated into the standardized patient training and evaluation components of this research project. The PI has also completed basic training in the administrative computer system of the home academic institution to follow institutional financial procedures and policies. The PI will consult with colleagues at a nearby academic medical center with an existing SP program for additional support of training and evaluation procedures. The PI has also completed initial and refresher CITI training, and CCRT at MUSC.

D. RESEARCH DESIGN AND METHODS (including data analysis)

RESEARCH OVERVIEW

Research Approaches. This study uses a two phase mixed-methods experimental approach to meet the study aims assessing HL knowledge and HL-related behavior changes after an educational intervention.

Phase 1: Health Literacy Checklist and Intervention Development. Phase 1 focuses on preliminary HL checklist and HL curriculum development using quantitative and qualitative feedback from appropriate stakeholders. As part of Aim 1, a panel composed of 2 nursing education experts, the PI's Doctoral Advisor and 3 health literacy experts will evaluate the HLP-NICE instrument for content validity (Di Iorio, 2006). For Aim 2, a purposive sampling of at least 2 nursing faculty who are experienced nurses and 4 student volunteers will participate in a 2 hour focus group session totaling 6 - 8 members to assess each HL curriculum for relevance, accuracy and realism. The PI will use the focus group feedback to train the standardized patient-actors and teacher-interventionist and optimize resource management before the interventions are attempted. Feedback from expert content and practicing reviewers will be used to refine the HLP-NICE instrument for future educational interventions.

Phase 2: Pre- and Post-intervention comparison of 2 Health Literacy Curricular Approaches. Phase 2 uses a quantitative between-subjects design to compare changes between pre- and post-intervention HL knowledge and HL-related behaviors for Aim 3. A convenience sample of up to 10 recently graduated baccalaureate nurses and 10 nurse educators will be recruited and then randomly assigned to the experimental and control groups. Intervention effects will be assessed by interactions with standardized patients (SP) reflected in KEECC-A and HLP-NICE ratings by the SP's. The PI will not be directly involved in delivering the interventions; therefore she will be blinded to specific intervention assignments from the time that informed consent has been given until after the completion of data collection.

From their clinical experiences, nursing students have reported discrepancies between their knowledge of health literacy evidence and use in practice (Cormier & Kotrlik, 2009; Scheckel et al., 2010). Although students have demonstrated improvements in short-term HL knowledge (Sand-Jecklin et al., 2010; McCleary-Jones, 2012), they indicate less confidence in their ability use HL knowledge to clinically intervene with patients or health systems (Hosei, Belcher & Habermann, 2013). The quantitative analysis of changes in participant knowledge and behaviors should support more effective educational strategies fostering the HL competencies of nurses and other health providers (Coleman, 2011; Coleman et al., 2013) for the quantitative component of Aim 4. The qualitative component of Aim 4 will be addressed by re-interviewing the 2 standardized patients, 2 nursing faculty and practicing nurse and student nurse post-intervention regarding the most recent version of the HLP-NICE checklist by repeating the I cognitive interviewing process (Willis, 2005). The teacher-interventionist will be surveyed post–intervention by the PI to give feedback regarding the educational process and teaching strategies for process improvement and additional refinements in the curriculum or teaching strategies. APPENDIX A (Figure 1) outlines the study flow for study enrollment, assignment, interventions, follow-up and analysis using a flow chart modified from CONSORT 2010 guidelines (Schulz, Altman & Moher for the CONSORT Group, 2010).

STUDY FLOW PLAN

Phase 1: Preliminary Study Development

Phase 1 checklist preliminary development/evaluation. A first step in evaluating the psychometric foundation of the HLP-NICE checklist is an appraisal of content validity. Expert content validity of the checklist will be measured when 3 health literacy expert reviewers, the PI's Doctoral Advisor and 2 nursing faculty reviewers perform a content review and provide suggestions for improvement as needed. In consultation with the Doctoral Advisor, the PI will identify the potential reviewers to be contacted to serve as the 6 members of the expert reviewer panel. A query e-mail with a request for collaboration and study information sheet will be sent to potential reviewers. The e-mail will include the PI's contact information to answer questions or requests for additional information. Because no identifying information will be collected or used, agreement to participate will be used in place of signed consent for this minimal risk activity. The approximate time required for review completion is three (3) hours for the initial evaluation with a possible additional two (2) hour session if the checklist needs significant content revision based on feedback from the initial content review. After agreeing to the review, the volunteers will receive the following written materials: the Health Literacy Patient-Nurse Interaction Competencies Evaluation (HLP-NICE) instrument, written instructions on how to evaluate the HLP-NICE, a theoretical definition and overview of the underlying constructs, HLP-NICE description and an evaluation form for rating the HLP-NICE. Agreement of 90% by the expert reviewers will support content validity before checklist use in simulation with the standardized patients. For reviewer time and inconvenience in the review process, a $10 donation reviewer's choice of a cause will be offered. The information sheet for the expert content reviewers is located in APPENDIX D1.

A second step in evaluating the HLP-NICE items is an appraisal of item wording, clarity and error reduction through cognitive interviewing (Willis, 2005). The Cognitive Aspects of Survey Methodology (CASM) approach described by Willis uses qualitative cognitive interviewing by stakeholders to improve questionnaire items (Willis, 2005). The use of cognitive interviewing supports stronger data for questionnaire developers and researchers to use when considering whether to include, modify or exclude survey items. Evaluation of the checklist aligns with the study's first and fourth aims, which structures the assessment the HLP-NICE for content validity, comprehensibility and feasibility through stakeholder feedback. The HLP-NICE items will first be reviewed by the researcher following a modified format of the Question Appraisal System checklist provided by Willis (2005).

After this first PI review, stakeholders who would use the checklist in practice should then be interviewed, preferably in more than 1 round (Willis, 2005, p. 145 – 146). Up to 6 total stakeholders, including the 2 standardized patient-actors once recruited, 2 nursing faculty at APSU who are involved with nursing simulations and a practicing nurse and a junior-level nursing student from the local area will be enlisted to review the HLP-NICE checklist for clarity and coherence in individual pre- and post- intervention interviews led by the PI. This strategy will allow the input of all potential stakeholders who might use the checklist for formative or summative evaluations of health literacy competencies mastery. A query e-mail with a request for collaboration will be sent with PI contact information for questions or additional information. In recognition of reviewer time and effort through the interview process, a $10 donation to the charity or cause of the reviewer's choice will be offered prior to participation in the review. For transcription purposes, identifiers such as SP1, T1 or N1 will be used without any names or additional personal identifiers to provide confidentiality. No personally identifying information will be collected. The information sheet for reviewers is located in APPENDIX D2.

Verbal probing strategies with participant responses will be audio-recorded for initial review and later transcription to create descriptive summaries. From these summaries, provisional coding schemes will be generated and then organized into interpretive tables of user responses to examine codes for problem areas to address before the educational interventions occur (Knafl et al., 2007, Willis, 2005). The second post-intervention round will repeat this process with the same participants to support existing items or improve clarity of the instrument. After final modifications are completed, the amended HLP-NICE will be submitted for IRB review and approval if any use will occur with the modified instrument in Phase 2 interventions.

Phase 1 health literacy curriculum preliminary development/evaluation. Preparation for the delivery of the educational interventions will involve evaluating standardized teaching plans in relationship to current nursing educational evidence, health literacy theoretical underpinnings and existing nursing clinical practice. The unfolding case study scenario, the health literacy curriculum teaching plans and associated activities will be reviewed by a focus group of up to 8 total reviewers: 2 nursing faculty, 4 junior level baccalaureate students and if available, 2 practicing nurses from APSU and the local area to assess accuracy, relevancy and realism. Once participants agree to participate they will be given a package consisting of the unfolding case study (APPENDIX H1), teaching objectives and activities for each approach (APPENDIX H2, H3) to be reviewed during the focus group session.

The session will be set up for a 2 hour period of time convenient to the participants. A break including refreshments between the first and second hour will occur to separate assessment of the functional and multidimensional approaches. The focus group will open with an ice-breaking activity to build group cohesion, followed by orientation activities regarding group communication and confidentiality. The PI will ask a colleague in a related social science discipline outside the nursing department (education, sociology or psychology) to serve as moderator to facilitate the discussion, and to provide an objective and unbiased outlook as facilitator (Barbour, 2008). The PI will listen to the focus group as a silent observer to make written field notes of individual and group interactions but will not participate in the focus group discussions. The focus group will be audio recorded for additional review and transcription by the PI. Before starting the focus group activities, a $10 campus bookstore gift certificate will be offered to participants for their time and inconvenience of focus group participation. Feedback from the teaching objectives, activities and case study details will facilitate refinement of the HLP-NICE instrument and training of the standardized patient-actors and teacher-interventionist in preparation for Phase 2. APPENDIX G provides the detailed focus group script outline. If changes are made to the HLP-NICE checklist based on these activities, the amendment will be submitted for IRB review before use in Phase 2 interventions.

Phase 1 study procedures development. Preparation for the implementation of the study procedures will involve developing basic role descriptions, training protocols and timelines for task completion for the research assistant, the data consultant, the two standardized human patient actors/designated raters of the pre- and post-intervention recorded interactions (Wallace, 2007), the teaching interventionist and the PI as suggested for best practices in behavior change interventions (Bellg et al., 2004). The initial role descriptions will be created by the PI and then modified into the final form with input from specific team members once they are recruited. The initial training protocols and task completion benchmarks will be created by the PI, and then modified into the final form with team input after initial recruitment. The protocol will be reviewed at key points throughout the study, both for individual and team evaluation of fidelity and feasibility. Role descriptions, training protocols and the task completion timeline will be collated into a single electronic study protocol document which is password accessible for team members, with paper copies created for each specific team member, and an electronically stored version on CD in the researcher's office. The paper copies and electronically stored version will be reviewed and updated after team meetings and after any interim changes by the PI. At the conclusion of the study, the team members will be asked to evaluate their role descriptions, training protocols and the timeline for feasibility, accuracy and relevancy

Phase 1: Research personnel enlistment, training and retention plans

Phase 1 research personnel enlistment. The research team will consist of the PI/primary researcher, two standardized patient-actors, a research assistant, and a teaching interventionist. The PI's intent is to enroll 2 graduate psychology students to train as standardized patient-actors and who are able to meet the time commitment, interested in participating in the research and willing to take on the responsibilities involved in assuring research fidelity. This enlistment and training will occur in consultation with Dr. Kevin Harris, the external research mentor who is a member of the PI's dissertation committee and a cognitive behavioral psychologist colleague at the researcher's institution. Using psychology students should reduce the risk of selection bias, because students from an outside discipline would not be familiar with the nursing students or program and could bring additional objectivity when scoring nursing student interactions. An undergraduate psychology student will be engaged to serve as research assistant for similar reasons. A nurse with a background in computer sciences and data management will be engaged to consult with the PI in setting up the databases, ensuring data entry accuracy and data security. A colleague of the PI who teaches health promotion, community health and therapeutic communication techniques and practices in undergraduate senior cohort will be enlisted and trained to deliver the multidimensional and functional educational interventions.

The PI has been awarded a $5591 Sigma Theta Tau International Nursing Honor Society (STTI)/ Assessment Technologies Institute (ATI) Educational Assessment Grant for Phase 1 personnel costs and Phase 2 intervention support contingent upon final IRB approval. No funding will be given for any pre-award activities, which means that personnel could not be recruited or trained until after IRB review and approval is granted. Because of the pre-award funding limitation, the specific names and training certification information will not be available before the IRB review process although role descriptions are given, specific personnel names are not available at this time. When specific personnel for those designated roles and CITI training is completed, the IRB protocol will be amended and updated to include that information.

The PI's home institution was part of the original grant review for funding purposes according to institutional policy, but the MUSC grant office was notified when the initial grant notification was received. As discussed and approved by MUSC's grant office, the PI's home institution grant office will receive and administer the grant funds. The PI has taken additional training in the home institution's administrative computer system to create the personnel payment tracking system. Electronically–saved and hard copy records of the grant accounts and disbursements will be maintained in a locked file in the PI's office, and in secured databases on REDCap and the PI's academic home so that if an audit is requested the information can be accessed in a timely manner.

Phase 1 research personnel training. Many nursing programs are not affiliated with an academic medical center and may or may not have readily available access to professional standardized patient (SP) actors. Kripalani and colleagues (2006) note that those newer to the role of standardized patients performed as well as more experienced standardized patients in discussing their preparations as actors in a medical student health literacy workshop. They attributed this to shared life experiences of navigating the health system, which indicates a degree of support for training people who are not professional actors for use in educational settings. In preparation for creating SP roles and performance fidelity, the PI has attended an immersion workshop June,

2013 that detailed the National Association of Standardized Patient Educator Core Curriculum modules. Relevant practice standards and core curriculum guidelines will be incorporated into the standardized patient training and evaluation components of the research. The researcher will consult as needed with colleagues at a nearby academic medical center with an existing SP program for additional verification of training and evaluation procedures. As recommended by Wallace (2007), the researcher will create a training manual which includes the following: the letter of agreement to participate, consent form for release of recorded images for simulated actors, the teacher-interventionist and for any subsequent participants who agree to participate, case materials such as the unfolding case study and online module outline, checklist, general study information and guidelines for what will be on the pre-and post-intervention interactions. SP's will be encouraged to review the training protocols, scenario and study information before the initial team meeting and write down questions or points for consideration (Wallace, 2007, p.160).

The graduate students-actors will receive training in limited health literacy attributes, related behavioral cues and potential student responses during planned training sessions. Part of this training will be based on information and feedback taken from the Phase 1 focus group sessions related to differences between functional and multidimensional health literacy cues and patient characteristics. They will be video recorded in interactive simulations with the researcher and teacher-interventionist for feedback and practice. To ensure inter-rater reliability, a Cohen's κ will be calculated based on comparisons of scores from selected pre-intervention practice videos (Di Iorio, 2005, p.202). Agreement of at least 0.4 to 0.75 will suggest adequate intra-rater agreement, with agreement less than 0.4 needing additional review of the checklist and SP practice to meet an adequate level. To ensure the consistency and quality of performances during the research, intermittent monitoring and "debriefing" feedback from the external mentor will be given to the SP's during the pre-and post-intervention interaction periods, based on a process evaluation checklist developed with SP input. If the Cohen's κ agreement is less than 0.4 (Di Iorio, 2005, p.200) then PI evaluation, additional training or protocol reviews will be implemented to maintain intra-rater reliability (Wallace, 2007, p.240).

Once the intervention modifications have been addressed through the nursing faculty/health literacy experts and nursing student focus groups previously described, the researcher will script the scenarios and teaching plans into standardized training protocols for the student-actors and teacher-interventionist. The standardized patients will take a leading role in cognitive interviews regarding the wording, interpretation and clarity of the HLP-NICE items after appropriate training (Knafl et al., 2007). The teacher-interventionist will be video-recorded during preliminary and educational interventions, and then review the recordings using a process evaluation tool created from the teaching plans as part of the teacher training protocol. This review should increase intervention reliability and reduce the risks of intervention variability and bias due to significant differences in intervention delivery (Melnyk & Morrison-Beedy, 2012).

Phase 1 research data collection orientation plan. The research assistant and PI will train for data collection consistency. The researcher will develop comprehensive training protocols before the assistant is enlisted, but will modify protocols considering the feedback from those individuals during training. Tasks such as obtaining participant consent, coding the demographic and survey information, assigning participants to each cohort and recording the interactions will occur before the intervention starts. The researcher assistant will complete a process evaluation checklist for each data entry checkpoint to ensure standardization of data collection.

Phase 1 research personnel retention. Building and maintaining a strong research team is essential to recruit and retain qualified participants (Melnyk & Morrison-Beedy, 2012). The PI has had three years of experience in working with a team of nurse practitioners, community clinic staff and undergraduate BSN nursing students in a pilot study to improve diabetic and hypertensive health outcomes through telephone follow-up and health coaching of high risk NP patients by the BSN students. The researcher has been involved in creating, developing and modifying standardized telephone scripts and the informed consent form, facilitating student calls and follow-up records, selecting and training students and acting as liaison between the NP's and BSN students. The selection of the research assistant and graduate student-actors will be made with the guidance of the external mentor from the psychology department, and include consideration of existing standardized patient guidelines (Wallace, 2007).

The teacher-interventionist is a colleague of the researcher who has expertise in nursing education, health promotion and therapeutic communication techniques. Clearly defined role descriptions and detailed study protocols and training manuals should strengthen accountability and promote reasonable expectations for

research completion. Because of the time needed to conduct the research, the researcher will need to be sensitive to competing demands between study training and interventions, and the student and educator school and work schedules. Team cohesion should be enhanced by scheduling team meetings at convenient times for all members, and collaborating through ongoing review of existing protocols, new idea contributions or suggestions for process improvement. The intervention should be scheduled for times which are less likely to conflict with the research team school or work schedules. The research assistant, graduate student-actors and data consultant will be compensated based on national reimbursement rate averages. The researcher will also acknowledge the doctoral advisor, individual member, team, volunteer and institutional support and contributions in future presentations and publications. Article authorship roles and assignments will be discussed and agreed upon during the first team meeting. General guidelines may be for the PI to be first author for submissions detailing the development of the research methodology, HLP-NICE and teaching interventions. The standardized patients and teacher-interventionist should receive first authorship for submissions which focus on their roles within this process, with the external mentor receiving first authorship for submissions dealing with interdisciplinary collaborations.

Phase 2: Participant Recruitment, Retention, Intervention and Data Collection Strategies

Phase 2 participant recruitment. General interest written information about the upcoming study will be posted two weeks before graduation to stimulate potential student interest in participation and ensure researcher availability to answer potential participant queries. The poster template (APPENDIX B), a scripted verbal announcement by the research assistant, and the written announcement on the School of Nursing Facebook page (APPENDIX C2) are included in the IRB applications for review and approval. General information will be included regarding incentives to reduce potential coercion or ethical conflicts.
The first recruitment and enrollment strategy will occur during attendance at a NCLEX review course offered two to three weeks after graduation from the program. At this point in time, final grades will have been entered and graduation recorded so that the researcher could not change or modify grades or graduation status. If graduates do not choose to participate, then the non-participant numbers and brief reasons will be collected and analyzed after study completion to identify potential barriers in future recruitment attempts.

The second recruitment strategy will be to invite nursing program graduates from within the last 2 years and full-time nursing faculty to participate in the study if target enrollment is not met by the first approach. Recruitment would occur by reposting the flyer and announcement to the School of Nursing Facebook page and sending query letters modified for post-graduation and faculty. The graduate query invitation letter would include the PI's contact information, participation invitation (APPENDIX C2)and the flyer(APPENDIX C1) If no response had been received within 2 weeks, a second mailing to nonresponders would be made by the PI to assess interest in participation if the first volunteer numbers have not reached the recruitment target goal Nurse educators would be invited to attend through a query e-mail sent to the 21 full-time nursing faculty from the graduate's nursing school (APPENDIX C3). This e-mail will include the PI's contact information and a brief description of the research involvement,

Phase 2 participant retention. Although this pilot study takes place during the relatively short period of a month, strategies to maintain participant retention are recommended to reduce potential attrition (Melnyk & Morrison-Beedy, 2012). Timing the interventions to occur shortly after graduation while graduates are waiting to sit for the NCLEX examination should lessen participant school and time conflicts between the demands of faculty teaching load, nursing school and new employment. The asynchronous web-based format for the initial HL Knowledge exposure allows participants to complete health knowledge information at their own pace and convenience. Additional attendance reminders will be sent 1 week prior to the post-evaluation session using the participant's preferred contact e-mail address.

A ten dollar gas card will be offered to participants before the pre-intervention session, teaching session and post-intervention sessions to assist with travel costs for a potential total of $30. Three hours of continuing education contact hours will be requested from the state nurse's association for the 1 hour asynchronous online module and 2 hour face-to-face intervention sessions. These hours will support state-recommended continuing educational development for the participants who complete the research, and for research team members who are nurses. Receiving contact hour credits should reinforce the desire to maintain professional credentialing and increase awareness of additional learning opportunities through research participation.

Phase 2 participant randomization. After IRB approval is obtained, consenting participants will be randomized into two structurally equivalent groups using the following process for assignment and blinding based on a counterbalancing strategy. Participants will select an umarked envelope from a manila envelope maintained by the research assistant. Each envelope will contain identical slips of paper inside the larger manila envelope . The first person scheduled will choose one of the envelopes, with the next person assigned to the opposite cohort. The third would again select an envelope with the next person again being assigned to the opposite cohort until all participants have been assigned. The research assistant will also designate study ID numbers from F01 or M01 up to F10 and M10 in a random pattern to assure anonymity and confidentiality. All written, electronic or recorded documentation including transcription data will be coded with this study number and will not include any names or other identifying informaiton. Participants may choose to create and maintain a "nursing alias" to use during their recorded patient interactions, which should also provide added confidentiality when the simulated patient recordings are viewed or transcribed. A second electronic log will be kept separately from the participant demographic information codebook to record the results of electronically collected data and analyses performed with only the participant code number as the identifier. All pertinent data will be entered by the standardized patients or research assistant and verified by the research assistant for accuracy and completeness. These actions should ensure that the PI will be blinded to the results and reduce potential selection or observation bias.

Phase 2 intervention overview. After the information is reviewed and agreement to participate is noted, (APPENDIX D2), participants will be recorded in a semi-structured interaction with the standardized patient using a simulation based on ensuring adherence to discharge instructions at the University simulation lab. Participants will then complete a survey at the University computer lab composed of the demographic data survey (APPENDIX E) and both sections of the Health Literacy Knowledge and Experiences Survey, or HL-KES (Cormier & Kotrlik, 2009) as part of the pre-intervention. After the first session and prior to the facilitated session, participants will be asked to complete an online module consisting of basic health literacy knowledge regarding prevalence of limited literacy, health literacy skills and attitudes using an encrypted online link. This 1 hour module will use an unfolding patient case study approach with interactive activities and a 5 multiple choice question quiz to assess content mastery and module completion. At a convenient point during the following two weeks, the face-to-face intervention sessions for each approach will be conducted. Each intervention will consist of a two- hour long researcher-facilitated educational session conducted with each cohort at the University classroom and simulation lab. The educational sessions will occur at two separate times to reduce intervention contamination. After the educational intervention sessions are completed, both groups will return for the post-intervention evaluation during thefollowing week to complete the second recorded standardized patient interaction and repeat the HL-Knowledge section of the HL-KES (APPENDIX I).

Phase 2 data collection. The research assistant will be responsible for collecting and recording the results using databases set up to be analyzed with the SPSS statistical program available through the researcher's home institution. Results stored in the online password-protected and firewalled server maintained for research purposes in the MUSC College of Nursing. The assistant will collect and record the demographic data, the HL-KES pre-and post-survey scores, the 5 point online quiz scores which checks for quiz completion, and HLP-NICE and KEECC-A scores. The standardized patients will rate the videotaped patient interactions of the other standardized patient pre-and post-intervention to provide greater objectivity and reduce the possibility of intervention or performance bias or halo effects. Data entered by the standardized patients will be checked by the research assistant for accuracy and completeness. The researcher will be available during the collection and intervention times to answer team member questions to avoid missing data, but will not have access to the specific participant assignment and nurse alias identities, scores or results until after all data has been collected and recorded. The diffusion of shared information between participants during the four week collection of data might contaminate the findings and limit the individual impact of the educational interventions. During the initial recruitment meeting, the research assistant and teacher- interventionist will request that participants do not discuss questionnaire answers or intervention information until after the four week study time has been completed. This request will be repeated during each contact with the participants as a reminder, and the scheduling of a feedback session should allow participants from both cohorts to discuss their ideas and share input after the completion of data collection.

Phase 2 Intervention content: delivery, receipt and enactment

Functional intervention. The functional teaching session will focus on assessing patient literacy levels as outlined in APPENDIX H2. The Single Item Literacy Screening or SILS (Morris et al., 2006) for patient literacy

screening, the Simplified Measure of Gobbledygook (SMOG) as a readability formula and Suitability Assessment Measurement (SAM) written material evaluation checklist (Shieh & Hosei, 2008) will exemplify functional intervention practices. . Participants will work in small groups using the SILS, SMOG and SAM to evaluate patient literacy levels and written material effectiveness. Students will write a final reflection outlining key functional learning points and how they might use them in practice. For the second recorded interaction, the functional group will be instructed to create or use the rated pamphlet focusing on congestive heart failure control using SILS, SMOG and SAM principles. The use of SAM, an observational checklist of written health materials, characterizes current functional health literacy practices and promotes a similar time on task between the experimental and attention control groups.

Multidimensional intervention. The multidimensional interactive teaching session will include this information, but will also integrate multidimensional health literacy principles such as using plain language, Teach-Back techniques and writing or highlighting key learning points (APPENDIX H3). Activities designed to foster patient self-empowerment and informed decision-making will culminate in small groups of students practicing and critiquing peer interactions using a student-produced checklist as a process guide and cues for evaluation Students will write a final reflection outlining key learning points and how they might use multidimensional health literacy knowledge in practice. Multidimensional participants will also be instructed to use the existing pamphlets on heart failure control, and plan to teach the information for the second simulation using techniques practiced during the intervention session.

OUTCOME VARIABLES AND INSTRUMENTS

Outcome Variables

Independent Variable. The independent variable is random assignment to one of two nursing education intervention groups: the multidimensional health literacy experimental or the functional health literacy attention control group.

Dependent Variables. There are two dependent variables: health literacy knowledge and health provider communication competencies as part of health literacy-related behaviors. Health literacy knowledge changes will be measured by comparing pre- and post-intervention Health Literacy-Knowledge (HL- K) Test component scores from the Health Literacy Knowledge and Experiences Survey or HL- KES (Cormier & Kotrlik, 2009). Health literacy-related behavior changes will be measured through pre- and post-intervention health literacy competency instrument scores of the recorded nurse-patient interactions. These scores will be taken from a standardized medical communication competencies checklist Kalamazoo Essential Elements of Communication Competencies-Adapted or KEECC-A (Joyce et al. 2010; Rider & Nawotniak, 2010) and the researcher-created health literacy competencies checklist Health Literacy Patient-Nurse Interaction Competencies Evaluation or HLP-NICE.

Study Instruments

Health Knowledge and Experiences Instrument. Participants will complete the Health Literacy- Knowledge and Experiences Survey or HL-KES (Cormier & Kotrlik, 2009) pre-intervention with the Health Literacy-Knowledge section only repeated post-intervention (APPENDIX I). The HL-KES is a 38 item questionnaire which contains two sections: Multiple choice questions of basic health literacy knowledge (HL- K) and self-reported observations of clinical health literacy experiences (HL- ES). The Health Literacy Knowledge section contains 29 multiple choice questions that tests general health literacy knowledge in 5 content areas: Basic health literacy facts (6), limited health literacy information (4), patient literacy screening (6), written material guidelines (11), and intervention evaluation (2). These five content areas were derived from a literature review and the number of questions were weighted in each section according to the emphasis in the literature. The results are scored as correct or incorrect, with the percentage correct as an indicator of health literacy knowledge. For this study, the focus will be on pre- and post-intervention changes in overall percentage correct, but without further analysis of each content area results. The Health literacy Experiences section contains 9 questions for participant recall of the amount and frequency of health literacy promotion practices seen in practice as part of the six question subscale of core health literacy experiences (CHLE) or the three question subscale of technology health literacy experiences (THLE). The four point Likert scaled responses for the Experiences section are: 1 = *never*, 2 = *sometimes*, 3 = *frequently*, 4 = *always*. The HL-KES can be administered and completed within 20 to 30 minutes and could be

given either using paper-based or web-based format, adding to the ease of administration and feasibility of the instrument. The pre-intervention administration of the HL-KES is estimated to take 30 minutes, with the post-intervention administration of the HL- K section taking 20 minutes.

The HL-KES focuses more on functional health literacy skills and knowledge, and limits recall of health literacy practices to self-reported recall of experiences, with little additional verification of patient response or outcome effects. The HL-KES has advantages over other health literacy knowledge instruments such as Limited Literacy Impact Measurement (Jukkala, Deupree & Graham, 2009), or the McCleary-Jones (2012) multiple choice test due to more robust evidence for reliability and validity. Content validity was supported by a calculated content validity index of 98% when reviewed by a panel of 5 experts in nursing education, HL and research. Construct validity was inferred to be good using results from a principal component analysis with Varimax rotation with 57.15% of the results loading on the 2 constructs at 0.50. Internal reliability was suggested by Cronbach's α of 0.89 on the HL-ES, and 0.79 and 0.76 on the 2 subscales of the HL-ES. The pre-intervention administration of this instrument includes both the 29 multiple choice Health Literacy Knowledge items and 9 Likert-scaled Health Experiences items to capture baseline knowledge and self-reported observations of health literacy experiences while in nursing school. The post-intervention administration will only include the 29 multiple choice Health Literacy Knowledge items to document knowledge changes from the baseline. Appendix I contains the HL-KES forms and key for the multiple choice questions.

Communication Competencies Instrument: KEECC-A. The standardized patient-actors will evaluate the other actor's recorded pre- and post-intervention patient-student interactions using the second instrument, the Kalamazoo Essential Elements Communication Checklist (Adapted) or KEECC-A (Joyce, Steenburgh & Scher, 2010). The KEECC-A is an eight item rating scale which characterizes provider communication competencies based on the Kalamazoo I and II consensus statements. The seven provider communication competencies were modified from 23 original communication sub dimensions and are characterized as follows: Builds relationships, opens the discussion, gathers information, understands the patient's perspective, shares information, reaches agreement and provides closure. The eighth item is a global dimension question that assesses the overall rater impression of communication competency. (APPENDIX J). The authors noted that estimated time for raters to complete the KEECC-A averaged 7 (± 2.7) minutes, which is a significant time reduction from the 30 minutes of the original KEECC (Joyce et al., 2010, p. 166).

In a comparative review of 15 existing physician-patient communication rating instruments, Schirmer and colleagues (2005) did not recommend one single instrument as the gold standard for evaluating physician communication competencies. The use of a checklist rather than a rating scale was found to be more user friendly for less-experienced faculty raters. The instruments that were evaluated shared strong inter-rater reliability (Cronbach's α = 0.79) with greater consistency in approximating the Kalamazoo Consensus Statement or KCS (SD = 0.73) and family interviewing skills (SD= 0.60). When the KEECC-A was used by 28 faculty, 15 SP's and 135 residents in post-intervention rating of communication competency training, trends of inter-rater reliability and construct validity were noted (Joyce et al., 2010). Inter-rater reliability was suggested by the moderately strong correlations between trained faculty and standardized patient ratings ($r132 = .31$, $p < .001$). Evidence existed for internal reliability for all 3 groups with Cronbach's α as follow: Participants/Group 1 (.94), faculty/group 3 (.89) and standardized patients/Group 2 (.90). The authors inferred a degree of test-retest reliability by noting the similar internal reliability ratings between these results and prior evaluations of the original KEECC and piloting of the KEECC-A (Joyce et al., 2010, p. 166). Content validity was also suggested through discussion of expert content review and empirical research supporting the Kalamazoo consensus statements, but no content validity index percentage was reported.

Health Literacy Competencies Instrument: HLP-NICE. The standardized patients will evaluate the recorded patient-nurse interactions from recorded pre-and post-interventions using a researcher-developed checklist (HLP-NICE) and results will be compared with the KEECC-A pre- and post-intervention HL-related scores. A review of the literature did not locate an existing instrument to assess nursing or health care use of HL practices with patients, or the effects of HL competency development and effects on patient-nurse interactions. A supplementary instrument, a process evaluation checklist, was developed by the researcher to fill this gap. The paper-based observation checklist has been developed to record the quantity and quality of health literacy practice use observed in patient-nurse interactions as one marker for levels of health literacy verbal and written competencies. Four categories of the checklist were structured after those used in an educational intervention to

improve health literacy competencies of medical students (Kripalani et al., 2006) but the addition of patient engagement and assessment was necessary to capture initiating and concluding an interaction.

HLP-NICE Development. The 20 items of the Health Literacy Patient-Nurse Interaction and Communication Evaluation (HLP-NICE) were synthesized from two complementary sources designed to increase health literacy knowledge, skills and behaviors of health care providers. The first source identified key health literacy-related concepts and practice standards commonly used throughout existing literature through educational programs designed to educate health providers. Health literacy education principles were drawn from the Health Research Services Administration (HRSA, nd), Centers for Disease Control and Prevention (CDC, nd), Ohio State University Health Literacy Center (OSU, nd) and Teaching Patients with Low Literacy Skills 2nd ed. (Doak, Doak and Root, 1996). The second source identified health literacy-related principles integrated through health professional interpersonal communications and shared-decision making principles collated from items of the KEECC-A (Joyce et al., 2010), Rochester Participatory and Shared-Decision making or RPAD scale (Shields, Franks, Fiscella, Meldrum, & Epstein, 2005), Quality and Safety Education for Nurses or QSEN recommendations (Cronenwett et al., 2007) and select health literacy consensus statements from an interdisciplinary panel of academic health professionals (Coleman et al., 2013).

For each patient-nurse interaction checklist item, the frequency of observed health literacy practices is identified by selecting one of the following 6 point Likert-scaled descriptors as follows: *4 = Excellent, 3 = Good, 2 = Fair, 1 = Poor, 0 = Not observed, N/A = Not applicable*. If the N/A designation is used, then the participant would not be penalized for items which may not apply or be relevant in a given situation. If N/A is selected, then brief rationale should be stated in the comments section to ensure that an appropriate reason was used to exclude the item. The comments could also be used to improve interaction recall and support rater debriefing or individual self-reflection when the section is reviewed after completion of the interaction. The ratings would be summed, and range from 0 (no competencies observed throughout the interaction) to 80 (the highest level of competencies observed) if all 20 items are scored. The raw score would be converted into a percentage based on the summed score divided by 20 items total. If fewer than 20 items were evaluated the final result would be based on the summed score divided by the total number of items evaluated for a percentage. Potential percentage ranges suggesting health literacy competencies could be as follows: *excellent* (70 – 100%), based on a mean 3.5 / 4, *good* (50 – 69) based on a mean 2.5 / 4, and *fair* (30 – 49%) based on a mean of 1.5 / 4 or *poor* (less than 30 %). Further evaluation of the checklist in the preliminary phase or initial use may refine the percentages corresponding to levels or competencies. These outcomes could provide comparisons of a participant's individual competencies levels or changes in mastery levels across time.

Greater use of health literacy competencies in patient-provider interactions are represented by the increased frequency and quality of health literacy behaviors observed by the rater. Students, nursing educators and programs, practicing nurses and health care facilities could use ratings and aggregate scores to guide individual and program feedback regarding strengths, areas for improvement or additional learning needs at diverse levels and across time. APPENDIX K provides the actual HLP- NICE observational checklist.

STATISTICAL METHODOLOGY: DATA ANALYSES

Demographic data. To characterize the sample, descriptive statistics will be tabulated from participant completion of the demographic survey and the Health Literacy Experiences section of Cormier and Kotrlik' s (2009) HLK-ES using appropriate univariate statistics. A frequency table will be generated to summarize the ranges, means, medians and standard deviations of baseline demographic characteristics of graduates and nurse educators. Self-reported age, gender and race/ethnicities will be reported as percentages for comparison with national nursing student statistical percentages. Self-reported grade point averages (GPA) will be reported as a reflection of knowledge levels, and considered as a possible covariate if significant differences exist in comparisons of multidimensional and functional cohort GPA's. Prior health care experience time as a nursing assistant, medic or practical nurse will be reported as a reflection of nursing experience levels, and considered as a possible covariate if significant differences exist in comparisons of the four groups. The nurse educators will also be surveyed for length of time in years for their nursing faculty role and identification of primary teaching concentration (medical-surgical or community health for example) The distributional characteristics of the sample will be evaluated for skewness, outliers, and missing data. The sample should be normally distributed due to the random assignment process. If significantly abnormal distributions are identified, then appropriate transformations will be performed to bring the data to normality. If data are missing, then a careful evaluation will determine the

advisability of balancing gaps in data completion with the risks of potentially compromised outcomes (Kellar & Kelvin, 2013). The demographic data form to be used with the sample is included for review in Appendix E. The Health Literacy Experiences Survey (Cormier & Kotrlik, 2009) is located in Appendix I.

Aim 1. Aim 1 explores the psychometric properties of a process evaluation tool characterizing health literacy competencies of nurses. The HLP-NICE observational checklist has been developed for this research project to bridge gaps in identifying and fostering health literacy competencies used by nurses when interacting with patients. This checklist is in the early phases of scale development; therefore, initial content validity, reliability and validity assessments will be performed either pre-intervention or as part of the intervention. The preliminary development section discusses establishment of face and content validity prior to the educational interventions.

Reliability of the HLP-NICE will be assessed in the following areas: inter-rater reliability of the instrument when used by the standardized patients and internal reliability between pre- and post-intervention scores of the HLPNICE. Inter-rater reliability will be assessed by the calculation of inter-rater percentage agreement pre-intervention targeted to a Cohen's κ of 0.4 as the minimum acceptable inter-rater reliability level. Inter-rater agreement will also be evaluated with evaluation of the recorded interactions to ensure ongoing inter-rater fidelity. Internal reliability of the HLP-NICE items will be assessed using a Cronbach's α co-efficient approaching an expected cutoff of 0.60 or better used as evidence supporting the item correlation to each other and the primary health literacy constructs (Di Iorio, 2006). Test-retest reliability will not be evaluated because the health literacy-related behavior variable is expected to change due to the teaching interventions.

Validity of the HLP-NICE will be assessed in the following areas: Content and construct validity prior to the interventions, and concurrent criterion validity. Content validity will be supported by pre-intervention feedback from health literacy and nursing education experts with a content validity index of 90% or greater. Construct validity will be assessed using validity co-efficient results to explore the relationship between the KEECC-A and HLP-NICE instruments, and the ANOVA to explore group differences with a known groups approach (Di Iorio, 2006, p. 232). The results can be used to indicate whether the hypotheses underlying the development of nursing health literacy competencies is sound, or if modifications to the HLP-NICE instrument are necessary, based on alternative explanations for the findings. Concurrent criterion validity will be evaluated by examining the association between HLP-NICE scores with the KEECC-A scores using a Pearson product moment correlation or validity co-efficient (Di Iorio, 2006, p. 146 – 147, 225 - 226). This preliminary work would not support prediction of future results but could be used to estimate the variability of outcome measures as input for calculation of sample size in subsequent studies (Leon, Davis & Kraemer, 2011).

Aim 2. Aim 2 explores the feasibility of the multidimensional and functional educational approaches in their initial use as a means to formulate and improve intervention quality. The accuracy, relevance and realism of the educational approaches and activities will be assessed in Phase 1 pre-intervention by creating provisional and final coding schemes based on transcriptions of focus group response summaries and the PI's observations and field notes. This data will be explored using a framework analysis approach (Green & Thorogood, 2014; Knafl et al., 2007). After familiarizing herself with the focus group transcriptions and field notes, the PI will explore the data by generating a provisional coding scheme from the data, then indexing the coding labels into tables. The data tables will then be used for comparison between codes and within the tables to map and interpret potential relationships between codes and theoretical concepts. For the feasibility of the educational approaches after implementation, the PI will conduct a post-intervention interview with the teacher-interventionist to provide feedback to pinpoint intervention strengths and limitations for potential changes in curricular interventions.

Aim 3. Aim 3 investigates the signal effects of the health literacy educational interventions on health literacy knowledge and health literacy-related provider behaviors supporting health literacy competencies in patient-provider interactions. Completion of the online health literacy knowledge information will be documented by percentages correct when participants complete a researcher-developed 5 item multiple choice quiz. The first dependent variable of health literacy knowledge changes will be measured by comparing pre- and post-intervention Health Literacy-Knowledge Survey (Cormier & Kotrlik, 2009) component scores. The participant pre- and post- intervention HL-Knowledge scores from the cognitive multiple choice questions will be assessed for changes in percentage correct pre- and post-intervention. These continuous variables will be measured using independent t-tests with an *alpha* of .05 as the level of significance (Kellar & Kelvin, 2013). An analysis of covariance (ANCOVA) will be assessed if the four groups are significantly different in baseline demographic

variables such as age, gender, race/ethnicity, grade point average, history of prior patient care or health literacy clinical experiences (Kellar & Kelvin, 2013).

The second dependent variable of health literacy-related behavior changes due to the educational interventions will be measured through comparisons of pre- and post-intervention experimental and attention-control groups HLP-NICE and KEECC-A scores of the recorded nurse-standardized patient interactions. These continuous group variables will be measured using the Mann-Whitney with an alpha of .05 as the level of significance (Pett, 1997). An analysis of covariance (ANCOVA) will be assessed if the groups are significantly different in baseline demographic variables (Kellar & Kelvin, 2013). Signal trends will suggest promising concepts or how innovative teaching strategies may best be implemented for future development and research. Process improvements may also be elucidated from the research, although the small sample size would not power statistically significant results.

Aim 4. Aim 4 examines the feasibility of the HLP-NICE observational checklist to reflect health literacy competencies. Based on findings from the first three aims, analysis of relationships between the intervention outcomes, HLP-NICE scores and psychometric trends should occur post-intervention as a means to improve the quality of the instrument. For HLP-NICE feasibility, the second semi-structured cognitive interview of the standardized patients and the initial interviewees will be conducted post-intervention to evaluate the quality of HLP-NICE after field use (Willis, 2005). Based on findings from the post-intervention feedback, the fourth aim will identify additional development and testing parameters to position the HLP-NICE observational checklist for additional refinements in future research.

E. PROTECTION OF HUMAN SUBJECTS

RISKS TO THE SUBJECTS

Sample: Characteristics, size, selection.

Phase 1: Human subjects of the preliminary phase focus group are participants who will be older than 18 and able to consent as adults. Phase 1 HL curriculum evaluation participants will involve purposive sampling of a total of 8 focus group volunteers (Barbour, 2008). To provide greater diversity in the discussions, the PI will specifically invite at least 1 male nurse, 1 male faculty member and 1 male student to participate in the focus group as contrasting minority perspectives to balance the preponderance of women in nursing. Students may feel intimidated and less likely to speak in the presence of those who are perceived to be more clinically experienced or have academic influence as faculty. To reduce this potential perceived inequity, a greater number of students will be recruited than faculty. The final sample will be made up of 2 nursing faculty who are not currently teaching at the junior level and 4 junior nursing students who have had some clinical or life experiences to balance the work, academic and educational perspectives of the group.

Phase 2: Human subjects of the intervention phase are nursing school graduates who are older than 18 and able to consent as adults. A convenience sample of 10 recently graduated nurses and 10 nursing educators will be recruited from an estimated 150 students and 21 full-time nursing faculty. The sample of nurses who have graduated from the PI's baccalaureate nursing program within the last 2 years will include the 47 graduates from May, 2015 The subjects range in age from 20 to 66 and are in good physical health to meet the physical and psychological demands of the nursing profession. The nursing program is located at a Southeastern four year public liberal arts university.
For October 2010, the last year that aggregate demographic data were available, the total student enrollment for the prelicensure program was 236 students, with self-reported gender rates of 214 (90%) females and 22 (10%) males (APSU SON Self Study Report, 2011). These percentages were similar to the NLN 2011 national BSN gender rates reported from 2010 surveys (NLN, nd) as 87% female and 13% male. The university students self-identified their ethnicity as primarily non-Hispanic White (171 students, 72%), followed by non-Hispanic Black (23, 10%), Hispanic or Latino (12, 5%), Asian or Pacific Islander (11 students, 5%), American Indian or Alaskan Indian (6 students, 3 %) and 13 students (5%) who reported *other* or who did not choose a designation (APSU SON, Table 3.1a, p.66). These self-reported percentages share some similarity to the national BSN percentages from NLN 2011 annual surveys as reflected in the following demographics: 67 % non-Hispanic Whites, 12% non-Hispanic Blacks, 6 % Hispanic or Latino, 8% Asian or Pacific Islander , 0.2% American or Alaskan Indian and 6% choosing other (NLN, nd). These similarities would indicate that the sample is fairly representative in gender and

ethnicity for the BSN nursing student population as a whole, and would be less likely to skew the results through significant under- or over-representation based on gender or ethnicity. The current nursing faculty is comprised of 1 administator and 20 full-time nurse educators who teach generic and on-line RN-BSN courses and master's level courses through the Regent's Online Course Consortium (ROCC) program. The faculty demographic makeup is 20 females (95%) and 1 male (5%), with a racial/ethnic identification as primarily non-hispanic White (17, 81%), non Hispanic Black (2, 9 %), Hispanic (1, 5%) and American Indian (1, 5%). These numbers are also somewhat similar to national nursing faculty percentages from NLN 2009 national survey demographic results which are as follows: female (95%), male (5%), non-hispanic White (72.4%), non-Hispanic Black (7%), Hispanic or Latino (3%), Asian or Pacific Islander (2%), American Indian (0.6%) (NLN, nd).

Phase 2 Sample size considerations. The sample size for pilot studies should balance the resources available to the researcher, the study aims and the potential use of outcomes in facilitating future research (Thabane et al., 2010; Hertzog, 2008). The aims for this pilot study includes evaluating the use of standardized patient actors and diverse teaching strategies, exploring which theoretical approach best advances nursing health literacy competencies and comparing health literacy concepts between the HLP-NICE and KEECC-A. The sample size, however, is constrained by the number of students who agree to participate and who have graduated May, 2015. The nursing program graduates an average of 45 students in fall or spring semesters with a smaller class in the fall. All students of the graduating class will be invited to participate but preparing for at least 10 participants will allow for inability to participate due to refusal, moving for work or relocation to a military duty station after graduation. The 10 participants per group will be adequate to assess feasibility, determine administrative burden and evaluate if group differences exist. The sample size will not be adequate to power an exploratory factor analysis for HLP-NICE criterion validation (Di Iorio, 2006, p.238). The outcomes, however, will provide insight into improving feasibility and be a consideration in estimating more precise sample size and power estimates for ongoing health literacy research (Hertzog, 2008; Melnyk & Morrison-Beedy, 2012; Thabane et al., 2010). A careful evaluation and interpretation of the statistical information will occur with the assistance of an experienced statistician to assure that results will not be misinterpreted or overstated.

Targeted/Planned Enrollment Table

Total Planned Enrollment Phase 1 and 2: 26

TARGETED/PLANNED ENROLLMENT RANGES: Number of Participants			
	Sex/Gender		
Ethnic Category	Females	Males	Total
Hispanic or Latino	3	1	4
Not Hispanic or Latino	19	3	22
Ethnic Category: Total of All Subjects*	26		
Racial Categories			
American Indian/Alaska Native	1	1	2
Asian	1	1	2
Native Hawaiian or Other Pacific Islander	1	1	2
Black or African American	5	1	6
White	10	4	14
Racial Categories: Total of All Subjects*	18	8	26

**The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects".*

Inclusion and exclusion criteria. Inclusion criteria for Phase 1 participation are as follows: Nursing faculty, junior-level nursing students and practicing nurses over the age of 18 and able to consent as adults. Exclusion criteria for the focus group nursing faculty would be junior-level faculty members to reduce perceived or actual coercion or conflicts of interest between students and faculty. Inclusion criteria for Phase 2 participation are as follows: Nursing students over the age of 18, able to consent as adults and have completed all course and clinical requirements for graduation with recent graduation from a generic baccalaureate nursing program. Exclusion criteria are: Non-baccalaureate degree nursing program graduates or RN-BSN completer program graduates. Baccalaureate nursing programs are more likely to integrate health literacy and patient education through Community nursing courses, which may not be offered in associate degree or hospital diploma programs

(Cormier & Kotrlik, 2009; Shieh & Hosei, 2008; Shieh et al., 2013). These programs are not available for access to the PI at this University. Graduates from online RN-BSN completer programs may not be locally accessible to physically participate during the intervention time period. RN-BSN students may have experience in nursing interactions through other nursing programs which would act as a confounder to the interventions. During recruitment every effort will be made to encourage as diverse a group as possible to participate, but the makeup of this nursing school and nursing faculty population mirrors the national preponderance of women enrolled as students in nursing programs.

Sources of Materials. Participant written material sources includes collections of demographic data, survey and quiz computerized scores and written intervention documents such as the readability and suitability instruments and post-intervention reflections. Audiovisual material sources include audio-recordings of focus group interviews and audio-visual recordings of simulated patient-nurse interactions. For the focus group, focus group observations and transcriptions will use alternate identifiers such as S1 – S4 for students and T1 – T2 for faculty to reduce the risk of accidental identification and protect participant confidentiality. The electronic demographic data log and electronic scale result codebooks will be set up with consultation as needed by the RedCap technical team and piloted during preliminary testing to evaluate ease of use and potential data loss or security issues. The student's predetermined research identifier (F01, M01) and "nursing alias"initials or name initials will be used as identifiers for AV recording evaluation. Data will be reported in aggregate or thematic form only and no personal identifiers will be included on any written data.

Participant considerations of potential risk. There are no identifiable physical risks to participants from involvement in the research, but attention will be paid to maintaining research personnel safety with adequate training for safe use of electrical/recording equipment. There is a possibility of psychological distress to Phase 2 participants because testing and evaluation of outcomes are part of assessing intervention effectiveness. There are no negative educational, social or legal consequences should someone choose to withdraw or not complete the study because participation is voluntary. The refreshments provided for Phase 1 focus group participants will provide a natural break between evaluating the 2 health literacy curricula and support recruitment efforts without unduly influencing the desire to participate. The ten dollar bookstore certificate for Phase 1 focus group participation and thirty dollars for Phase 2 travel costs is minimal assistance to reduce potential economic barriers and support participation during the time before graduates may be gainfully employed. This limited amount, however, is unlikely to be a large enough inducement to coerce participation.

ADEQUACY OF PROTECTION AGAINST RISKS

Phase 1 participation and waiver of informed consent. Pre-intervention participation involves those queried for interest in participating in the expert content checklist review, checklist clarifications, and focus group evaluation of the two health literacy curricula for accuracy, relevance and realism. For these phase 1 activities, the feedback will be to give the PI additional direction on how to train the standardized patient-actors and teacher-interventionist in the use of the HLP-NICE during the interventions. The waiver of signed consent documentation is being pursued for the focus group as a low risk non-invasive and de-identified activity. The PI would need to be sensitive to potential ethical conflicts or bias due to the involvement of students in the focus group while in nursing school, but no names will be collected or attached to any of the Phase 1 information results.
The PI will send general information through e-mail queries to potential HLP-NICE expert content and usability reviewers. The The PI will introduce the focus group request to nursing faculty at a nursing faculty meeting, and then meet with individual faculty to review details and answer questions (APPENDIX C1). The PI will attend a meeting of the Student Nursing Association to introduce the focus group purpose and requirements and enlist junior level student's participation (APPENDIX C1). Announcements will also be posted around the SON and on Facebook to encourage additional interest for students and former students who are practicing nurses (APPENDIX C1). Junior level students will not be eligible to participate in Phase 2 interventions due to study timing. This would also reduce the risk of contamination or confounding influences on Phase 2 results from dual participation of these students. The PI does not teach any junior level courses, so that focus group contact would be unlikely to result in coercion or add to the risk of bias. The PI will distribute focus group information (APPENDIX C1) and offer to meet with students, faculty or practicing nurses who indicate interest in participation. The focus group time will be set up in consideration of student, faculty and nursing staff to reduce potential attrition or conflicts by those who have consented to attend. The preparatory group information will be given to participants immediately before the focus group takes place.

Phase 2 recruitment and informed consent. This study provides adequate protection against the risks of coercion or selection or observation bias through avoidance of direct PI involvement both before and during the Phase 2 recruitment and intervention process. The research assistant will make general interest information announcements to graduating seniors three weeks before graduation, and will post hard copies around the nursing school and on the School of Nursing Facebook page to stimulate potential interest in participation and ensure PI availability to answer potential queries. The recruitment poster and the amended scripted announcement used both verbally, for mailings and for the School of Nursing Facebook page are included in the appendices for IRB review and approval prior to use (APPENDIX B, APPENDIX C2). Limited information will be included regarding specific incentives or continuing education credits to avoid any potential perceptions of coercion or ethical conflicts.

Formal recruitment, enrollment and obtaining participant consent for the first recruitment attempt will occur during attendance at a NCLEX review course offered two to three weeks after graduation from the program. The research assistant will make a more detailed invitation for recruitment at the beginning of each review session and be available during the five review days to review the research benefits and potential risks. The research assistant or the PI will obtain written individual consent once the participants indicate informed and voluntary consent (APPENDIX D4). Prior to starting the intervention, the research assistant will have the participant select an envelope to determine randomized assignment. The research assistant will enter each participant's research ID number and give specific written directions as to intervention dates, times and processes after consent has been obtained. The PI will be available either in person or by telephone or e-mail to answer questions, address concerns or gain consent if the research assistant is not available.

The second recruitmentattempt will occur through mail contact with program graduates from the last 2 years to complete recruitment target goals. A query letter (APPENDIX C-2), the flyer (APPENDIX C-I) and the PI contact card will be mailed to area recent program graduates as an invitiation to participate in the study. The names will be accessed from old rolls of students during their graduation semester. This list will be used to document phone call attempts, but will be shredded immediately after the recruitment effort is completed If the PI has not heard from the mail recipients within the 2 weeks after the invitation has been sent, a follow-up letter to assess interest will be sent using the query script listed in the appendix materials (C2). Reasons such as non-response to both mailings and numbers of those unable to participate will be added into to the nonparticipant data log. For those contacts who agree to participate, a meeting time prior to study inclusion will be determined to review the study procedures, answer questions about participation and complete the informed consent process. Faculty will be invited to participate with 2 query e-mails at least 1 week apart (APPENDIX C3)and the recruitment poster and PI contact information if further information is desired.

Ethical considerations. The Phase 1 and Phase 2 human subjects of this pilot study involve nursing faculty, practicing nurses and nursing graduates who are older than 18, able to consent as adults, and who speak and read English. Participation in either phase of this study is voluntary, and every effort will be made to protect the ethical rights and confidentiality of each participant which includes protection of the accompanying written and recorded documentation. In preparation for this research responsibility, the PI completed the online MUSC Core Researcher Training in June 2011, the online CITI Basic Subjects: Social and Behavioral Research training June 2011, and the online CITI Social and Behavioral Refresher course September 2014. The associated documents are available upon request. These documents will be kept on file electronically and in hard copy format in the PI protocol files. The research team will also need to complete CITI Basic Subjects training before any involvement with the participants. Certification hard copies of all team members will be filed with the standardized protocols.

Protection against potential risks. The PI has planned how to reduce potential risks to ethical breaches and confidentiality through diverse protective measures. For Phase 1, the researcher will purposely recruit junior level students from the BSN research course who will not have additional contact with the PI who teaches senior level students. The PI also does not have any grading responsibilities with this level of students which should reduce risks of coercion. No visual record or actual names will be recorded or used from participants, or be included with the focus group data to reduce researcher bias or breaks in confidentiality. The PI will enlist and train a willing colleague to facilitate the group interview, and will take on the role of silent observer while making field notes for later review. Students at the junior level are not at a point in the educational process where they could also participate in the Phase 2 interventions. For Phase 2 when formal recruitment begins, final grades will have been entered and graduation recorded so that the PI could not change or modify grades or graduation status without detection. There would be no impact on University services or link to faculty SON information or human resource records for those nurse educators who choose to participate in the research. For the mailed recruitment effort,

past graduate addresses and telephone numbers will only be accessed through the online directory available to faculty such as the PI through the encrypted and password-protected University website. This information will not be recorded in the research documentation and will be kept separate from any study data or database. The graduate roll list will be used to track contact attempts, but will be shredded immediately after the recruitment attempt is completed If graduates do not choose to participate, then research assistant or PI will collect the non-participant numbers and stated reasons (such as no response to 2 letters) to analyze after study completion for the sole purpose of identifying potential barriers in future recruitment attempts (APPENDIX F).
The research assistant will be responsible for collecting and recording written and electronic results using *REDCap* electronic databases set up with SPSS statistical program. The assistant will collect and record the written demographic data and the HL-KES pre-and post-survey paper scores. The research assistant will then record the results into an electronic database using the predetermined participant identifiers (F01, M03). Using de-identified information and not linking the codebook information with demographic data collection logs should reduce potential breaks in confidentiality. The 5 point online quiz scores which checks for quiz completion, and HLP-NICE and KEECC-A scores will be electronically documented and associated with the participant identifiers but not with specific names or student or faculty information. All data will be stored on the online password-protected firewalled server maintained for research purposes in the MUSC College of Nursing.

Simulated nurse-patient interactions will involve recording the participant's pre- and post-intervention interactions involving observed health literacy competencies of participants. The standardized patient actors (SP's) will rate the video-recorded patient interactions of the other standardized patient after all interactions have been completed. The SP's will record the results of the KEECC-A and HLP-NICE checklists into electronic databases as they review the recorded interactions. Data entered by the SP's will be checked by the research assistant for accuracy and completeness. Participants may choose to create their own "nurse alias" name to use when interacting with the standardized patient actors in video-recorded pre-and post-intervention sessions. These self-determined names will not be recorded on any code-book or log to protect the confidentiality of the participants. The researcher will be available during the collection and intervention times to answer team member or participant questions to avoid missing data, but will not have access to specific participant assignments, scores or results until after all data has been collected and recorded.

The PI will purchase a basic LoJack subscription for protection of the portable research devices which includes access lockout, personal data deletion and assistance with device recovery if devices are lost or stolen. The devices to be covered include the dedicated research laptop computer, cellphone, and portable external hard-drive used for data backup. A fireproof safety box will be purchased to lock the cell phone and recorded audio media and mini-DVD cassettes for safety and data protection. This box will be kept in a locked cabinet in the researcher's office, accessible only to the PI and external mentor in the PI's office in room 303 of the McCord Building, APSU, Clarksville, TN 37044. The School of Nursing has DVD recording units which will be used by the research assistant to record the standardized patient-nurse pre- and post-intervention interactions. The PI will provide audio-recording units for the focus group. The audio-recording media and mini DVD cassettes will be purchased by the researcher and inventoried and kept on file with other data for SP viewing and interaction preservation, and PI transcription. The PI will keep a log of audio media and DVD cassette check-out and check-in times by each SP or the PI during the rating process to track DVD cassette or audiotape usage. The PI will not have access to any Phase 2 data or recordings until after all data is collected and recorded. The audio-recordings and mini-DVD cassettes will be retained in the fireproof locked box for potential future transcription and qualitative analysis. The participant's "nurse alias" initials will be used as identifiers if recorded interactions are transcribed in future analysis, and will not be linked to participants real names or research ID's. The informed consent form will include specific consent for future transcription for full and fair disclosure and transparency in the consent process.

POTENTIAL BENEFITS OF THE PROPOSED RESEARCH TO THE SUBJECTS AND OTHERS

The benefits of this research are knowledge building for the nursing discipline and advancement of nursing education and clinical practice; however, no substantial personal benefit or economic gain other than professional satisfaction in research participation is anticipated. The ten dollar gas card offered after the pre-intervention, intervention, and post-intervention sessions for travel costs is minimal assistance to compensate for time and inconvenience of participation and to reduce potential economic barriers and support participation during the time before graduates may be gainfully employed. This limited amount, however, is unlikely to be a large enough inducement to coerce participation. All participants will be invited to attend a post-study informational session

when final results are available, and asked for feedback regarding intervention feasibility and improvements for future studies. An alternative to these interactive educational strategies would be to provide health literacy didactic content alone to build clinical knowledge. While a didactic approach is less resource intensive, the long-term benefits of knowledge alone have not resulted in greater application of health literacy practices by health providers (Coleman, 2011). The demands of the nursing profession include a rigorous content-laden curriculum which ends in the high-stakes NCLEX cognitive testing before licensure is granted. In comparison to this arduous educational process, the risks of being recorded in well-defined simulations and interactive learning activities and completing a brief 5 point quiz are minimal and should be acceptable to the participants.

Importance of knowledge to be gained. The proposed research will provide a stronger foundation for integrating health literacy competencies to better prepare nurses for patient- centered health care. The strengths of this research study include using a more rigorous research design than previous nursing education health literacy studies. This novel study uses diverse educational strategies to promote health literacy uptake; the study includes initial work in evaluating the health literacy competencies of nurses with a structured process evaluation instrument and direct observations of standardized patient-nurse interactions. Although gains in health literacy knowledge have been noted as an interventional outcome (McCleary-Jones, 2012; Sand-Jecklin et al., 2010), the use of lower level designs and lack of a control group does not account for confounders such as the participant's inherent cognitive abilities and test-taking skills. The use of an interactive web-based case study to deliver core health literacy knowledge and standardized patient-actors from the psychology department in moderate to high-level simulation aligns with educational and disciplinary recommendations for the deliberative inclusion of technology, simulation, observed competencies and interdisciplinary collaboration in undergraduate nursing education (Forbes & Hickey, 2009; The Future of Nursing, 2010).

SUBJECT SAFETY AND MINIMIZING RISKS

Participant considerations. The possibility of psychological distress to participants exists because testing and evaluation of outcomes are part of assessing intervention effectiveness. Participants will be offered an external contact for counseling or assistance if participant concerns or distress occurs. This information will be incorporated on the study consent form for participant reference, and in the standardized training protocols for team reference. Student group interactions will be facilitated by an experienced faculty member with extensive background in mental health nursing and psychology to ensure appropriate individual and group interactions and identification of unwarranted stress due to the interventions. The teacher-interventionist will have the external contact information available during the interventions, and will monitor participant responses during the 2 hour interventions to determine if high stress levels are occurring due to the intervention. During the standardized patient interactions, the interactions will be monitored the SP's in conjunction with the research assistant. If a participant appears to be psychologically distressed or overly agitated, the SP will have a prescripted response to cue the end of the interaction, including the cessation of AV recording. SP's and the research assistant will also have the external contact information available to offer should an early termination of the interaction occur. Participation is voluntary, and there are no negative consequences should someone choose to withdraw or not complete the study. The endpoint of the study is completion of the post-intervention interaction and second Health Literacy-Knowledge Survey component (Cormier & Kotrlik, 2009).

F. REFERENCES/LITERATURE CITATIONS

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G. CONSULTANTS

Where applicable, attach electronic versions of appropriate letters from all individuals confirming their roles in the project. Go to the application under "additional uploads" to attach this information.

The statistician for the researcher's dissertation committee, Dr. Bonnie Dumas, has been providing statistical consultation and guidance throughout the study development process and is a member of the PI's dissertation committee. Dr. Ida Spruill, MUSC nursing faculty member with expertise in diabetes care, genetic influences and health-literacy related research in African-American populations, has agreed to serve as a content consultant to ensure relevant and culturally-diverse health literacy interventions. Dr. Kevin Harris, a colleague of the PI in the Psychology Department who is a cognitive behavioral psychologist with background and professional contacts in simulation methodology and deliberative practice, will assist with selection and training of the graduate and undergraduate psychology students and the simulation research development.

H. FACILITES AVAILABLE

Facilities/resources

The setting is a Carnegie Master's level 4 year public liberal arts university accredited by the Southern Association of Colleges and Schools Commission on Colleges. The five semester baccalaureate program is accredited by the National League of Nursing Accrediting Commission and the state Board of Nursing until 2019. The School of Nursing has the facilities and physical resources to support the research. Nursing faculty has private keyed offices with lockable cabinets, laptop computers with docking stations and access to 3 printing areas. The PI has a personal printer in her office which will be used to make paper copies or scan information for research purposes. Physical resources includes a 31 unit nursing computer lab room, six prioritized classrooms capable of accommodating 25 - 75 students with audiovisual (AV), internet and SMART Board capability and one similarly-equipped conference room. Five clinical laboratories with recording equipment are accessible and include web- and DVD cameras, computers, speakers, and AV/internet resources. During January, there are fewer nursing classes so that this research should not interfere with regularly scheduled student classes or simulation laboratories. The Grant resource for the PI includes the University Grants and Sponsored Research Director Andrew Shephard-Smith, who has the experience and the expertise to facilitate the grant process. Mr. Shepherd-Smith can be contacted at shepardsmitha@apsu.edu, at the Grant office local address. Austin Peay State University
P.O. Box 4517

Clarksville TN 37044
(931) 221-7881 - office
(931) 221-7304 - fax

a. INVESTIGATOR BROCHURE

If applicable, attach the electronic version of the investigator brochure. Go to the application under "additional uploads" to attach this information.

There is no investigator brochure.

b. APPENDIX

Attach any additional information pertinent to the application, such as surveys or questionnaires, diaries or logs, etc. Go to the application under "additional uploads" to attach this information.

Research Assistant Guidelines

Qualifications:

1. Undergraduate junior or senior psychology student
2. Strong computer data entry and writing competencies
3. Able or willing to learn how to set up and use DVD/ AV recording equipment
4. Detail-oriented, reliable and self-motivated to successfully monitor assigned research activities

Requirements:

1. Willing to complete CITI research ethics online training
2. Available for the following research activities (target dates):
    a. basic team training April –early May (4 hours),
    b. intensive team training 2nd week of May (4 hours) – create a data collection process checklist with data manager
    c. recruitment & initial simulation recording 4th week of May and 1st week of June (28 hours)
    d. follow-up and final simulation recording 4th week of June (20 hours)
    e. final research data entry end of June with data manager (4 hours)

Compensation: $10 / hour, no additional monetary or health insurance benefits but will receive acknowledgment in publications and presentations

Phase 1 and 2 Research Assistant Detailed Information:

Phase 1 research data collection orientation plan. The research assistant, data manager and PI will train for data collection consistency. The researcher will develop comprehensive training protocols before the assistant and manager are enlisted, but will modify protocols considering the feedback from those individuals during training. *Tasks such as obtaining participant consent, coding the demographic and survey information, assigning participants to each cohort and recording the interactions will occur before the intervention starts. The researcher assistant and data manager will complete a process evaluation checklist for each data entry checkpoint to ensure standardization of data collection.*

Phase 2 participant recruitment. General interest written information about the upcoming study will be posted two weeks before graduation to stimulate potential student interest in participation and ensure researcher availability to answer potential participant queries. The poster template (APPENDIX B), a *scripted verbal announcement by the research assistant,* and the written announcement on the School of Nursing Facebook page (APPENDIX C2) are included in the IRB applications for review and approval. General information will be included regarding incentives to reduce potential coercion or ethical conflicts. *Recruitment, enrollment and obtaining participant consent will occur during attendance at a NCLEX review course offered two to three weeks after graduation from the program. At this point in time, final grades will have been entered and graduation recorded so that the researcher could not change or modify grades or graduation status.* If graduates do not choose to participate, then the non-participant numbers and brief reasons will be collected and analyzed after study completion to identify potential barriers in future recruitment attempts.

Phase 2 recruitment and informed consent. This study provides adequate protection against the risks of coercion or selection bias through avoidance of direct PI involvement both before and during the Phase 2 recruitment and intervention process. *The research assistant will make general interest information*

announcements to graduating seniors three weeks before graduation, and will post hard copies around the nursing school and on the School of Nursing Facebook page to stimulate potential interest in participation and ensure PI availability to answer potential queries. The recruitment poster and the scripted announcement used both verbally and for the School of Nursing Facebook page are included in the appendices for IRB review and approval prior to use (APPENDIX B, APPENDIX C2). Limited information will be included regarding specific incentives or continuing education credits to avoid any potential perceptions of coercion or ethical conflicts.

Formal recruitment, enrollment and obtaining participant consent will occur during attendance at a NCLEX review course offered two to three weeks after graduation from the program. The research assistant will make a more detailed invitation for recruitment at the beginning of each review session and be available during the five review days to review the research benefits and potential risks. The research assistant will obtain written individual consent once the participants indicate informed and voluntary consent (APPENDIX D4) and will then have the participant select the envelope to determine randomized assignment. The research assistant will enter each participant's research ID number and give specific written directions as to intervention dates, times and processes after consent has been obtained. The data manager consultant will be available two hours each day during the recruitment period to assist with demographic data entry and verification of initial results entry. The PI will be available either in person or by telephone or e-mail to answer questions or address concerns. At the end of each daily session, the research assistant and data manager will complete a process evaluation instrument to assure the standardization and quality of data collection is maintained.

Phase 2 participant retention. Although this pilot study takes place during the relatively short period of a month, strategies to maintain participant retention are recommended to reduce potential attrition (Melnyk & Morrison-Beedy, 2012). Timing the interventions to occur shortly after graduation while graduates are waiting to sit for the NCLEX examination should lessen participant school and time conflicts between the demands of nursing school and new employment. The asynchronous web-based format for the initial HL Knowledge exposure allows participants to complete health knowledge information at their own pace and convenience. *The research assistant will send module completion reminders 1 week prior to the face-to-face session by participant self-identified preference of text or e-mail. Additional attendance reminders will be sent 1 week prior to the post-evaluation session.*

Phase 2 participant randomization. After IRB approval is obtained, consenting participants will be randomized into two structurally equivalent groups using the following process for assignment and blinding. Participants will select from a manila envelope distributed by the research assistant labeled from 1 – 40 or with the final number of participants. Each envelope will contain a pre-randomized assignment to one of the interventions previously selected by using numbers from a randomization table. *The research assistant will code the demographic information into a paper-based code book starting with either F01 or M01 to assure anonymity and confidentiality. All written, electronic or recorded documentation including transcription data will be coded with this number and will not include any names.* Students will create and maintain a "nursing alias" to use during their recorded patient interactions, which should also provide added confidentiality when the simulated patient recordings are viewed or transcribed. A second electronic log will be kept separately from the participant demographic information codebook to record the results of electronically collected data and analyses performed with only the student code number as the identifier. *All data will be entered by the research assistant, and verified by the data manager for accuracy and completeness.* These actions should ensure that the researcher will be blinded to the results and reduce potential selection bias.

Phase 2 data collection. *The research assistant will be responsible for collecting and recording the results using databases set up with SAS statistical program available through the researcher's home institution.* Results stored in the online password-protected and firewalled server maintained for research purposes in the MUSC College of Nursing. *The assistant will collect and record the demographic data, the HL-KES pre-and post-survey scores, the 5 point online quiz scores which checks for quiz completion, and HLP-NICE and KEECC-A scores.* The standardized patients will rate the videotaped patient interactions of the other standardized patient pre-and post-intervention to provide greater objectivity and reduce the possibility of intervention bias or halo effects. *Data entered by the research assistant will be checked by the data manager consultant for accuracy and completeness.* The researcher will be available during the collection and intervention times to answer team member or participant questions to avoid missing data, but will not have access to the specific participant identities, scores or results until after all data has been collected and recorded. The diffusion of shared information between participants during the four week collection of data might contaminate the findings and limit the individual impact of the educational interventions. *During the initial recruitment meeting, the research assistant and teacher-interventionist will request that participants do not discuss questionnaire answers or intervention information until after the four week study time has been completed. This request will be repeated during each contact with the participants as a reminder, and the scheduling of a feedback session should allow participants from both cohorts to discuss their ideas and share input after the completion of data collection.*

Research Assistant Training Protocol

Task	Steps	Resources: Team Folder, Dividers, Notebook, pens
Reimbursement Documentation	1. Provide ID Temp Help form (may need to go to HR to provide I9, W-4 and direct deposit) 2. Time sheet completion each pay period	Pink Temp Help forms, A# or SS#. White and pink time sheet
CITI Human Subjects Training	1. Documentation of completion copy for research binder and IRB	CITI training pdf CITI Completion certificate
Study Purpose & Flow		Copy of Study Consort Flow Copy of APSU IRB
Research Assistant Specific Activity List		Research Assistant Personnel Guidelines
Participant Recruitment and Retention	1. Informed consent – develop consent checklist card 2. Participant group allocation 3. Collect contact information and non-participation log data 4. Send reminder e-mail/texts	Informed Consent forms, Index cards Participant folders Study flow summary & cohort-specific instructions Computerized randomization table, envelopes Cohort-specific log Contact information list for reminders
Data Collection	1. Ensure distribution of demographic surveys and pre-HL-KES and post HL-K	Demographic data form HL-KES form and key
Video-recording SP and teacher interactions	1. Equipment check for usability and quality 2. Ensure physical set up for each interaction	Equipment and physical setup index card checklist
Data entry verification	1. Recheck SP data entry for correctness & missing data	Data entry checklist /Index Card
Debriefing	1. Give feedback on the process for improvement	

Standardized Patient Training Protocol

Task	Steps	Resources : Team folder, dividers, notebook, pens
Reimbursement Documentation	1. Provide ID Temp Help form (may need to go to HR to provide I9, W-4 and direct deposit) 2. Time Sheet Completion each pay period	Pink Temp Help forms, A# or SS# White and pink copy of time sheet
CITI Human Subjects Training	1. Documentation of completion copy for research binder and IRB	1. CITI training pdf 2. CITI Completion certificate
Study Purpose & Flow		Copy of Study Consort Flow Copy of APSU IRB
Standardized patient Consent	1. Read through consent 2. Summarize key points 3. Review questions or concerns 4. Sign consent and make copy for self	Research personnel consent form White Board/ Dry Erase Markers
SP Specific Activity List		SP Personnel Guidelines
Basic HL Knowledge	1. Watch video, discuss self or family situations where unsure about health information (examples from real life)	IOM Health Literacy Video (Extended Version)
SP Role Training	1. Read through case study information individually 2. Highlight or mark cues which indicate limited literacy 3. Practice with each other with peer feedback 4. Practice being videotaped during an interaction with AB or myself as nurses	Case study information and fundamental/multidimensional scripts Index cards- cues Prop lists
SP Rater Training (Wednesday)	1. Read through KEECC-A form and ratings manual 2. Practice rating a YouTube interaction using KEECC-A 3. Read through HLP-NICE form and CVI scoring information	KEECC-A form HLP-NICE form Rating process checklist/ index card
SP Data Collection	1. Process index card Consistent data collection	
Debriefing	Give feedback on the process for improvement	

Teacher- Interventionist Training Protocol

Task	Steps	Resources: Team notebook, Dividers, Notebook, Pens
Reimbursement Documentation	1. Provide ID Temp Help form (may need to go to HR to provide I9, W-4 and direct deposit)	Pink Temp Help forms, A# or SS#
CITI Human Subjects Training	1. Documentation of completion copy for research binder and IRB	CITI training pdf CITI Completion certificate
Study Purpose & Flow	1. Briefly present the order of the study and how each person's role will fit	Copy of Study Consort Flow Copy of APSU IRB
Teacher- Interventionist Consent	1. Read through guidelines and consent 2. Summarize key points 3. Review questions or concerns 4. Sign consent and make copy for self	Teacher-Interventionist Guidelines Teach
Basic HL Training	1. Watch video and discuss	IOM Health Literacy Video (Extended Version)
Teacher Training: Fundamental Activities	1. Review case study, script and fundamental teaching activities 2. Practice teaching presentation /key points while being videotaped 3. Review teaching video with key points for modification/ correction	Fundamental case study, script and Teaching Activities SILS. SMOG & SAM handouts, Room, recording equipment and whiteboard availability
Teacher Training: Multidimensional Activities	1. Review case study, script and fundamental teaching activities 2. Practice teaching presentation /key points while being videotaped 3. Review teaching video with key points for modification/ correction	Multidimensional case study, script and Teaching Activities; Room, recording equipment and whiteboard availability Highlighters
Debriefing	Give feedback on the process for improvement	

Training resources:

IOM extended version HL: Rx to end confusion

https://www.youtube.com/watch?v=iBy3I7YKCQQ

Rating Criteria for each approach to SP Interaction

KEECC-Adapted; How well does the learner do the following (throughout the interaction)?

- Poor = rarely or none of the time
- Fair = some of the time, not consistently
- Good = at least half of the time
- Very good = most of the time, more often than not
- Excellent = all the time

A. Builds a Relationship (includes the following):

• Greets and shows interest in patient as a person
• Uses words that show care and concern throughout the interview
• Uses tone, pace, eye contact, and posture that show care and concern

For both functional and multidimensional approaches, the nurse should greet the patient by name, introduce themselves and their role, and use active listening techniques consistently throughout the interaction.

B. Opens the Discussion (includes the following):

• Allows patient to complete opening statement without interruption
• Asks "Is there anything else?" to elicit full set of concerns
• Explains and/or negotiates an agenda for the visit

In this simulation, Mrs. Smith is being discharged home from the hospital with new medications to take, and to follow-up with her health provider in 1 week. For both approaches, the nurse may indicate that the shared purpose is to prepare Mrs. Smith to self-manage her congestive heart failure when she gets home.
***Functional or multidimensional** approach "We need to go through these discharge papers before you go home from the hospital. You should understand what you need to do to take care of yourself to keep from coming back to the hospital again"*

C. Gathers Information (includes the following):

• Begins with patient's story using open-ended questions (e.g. "tell me about…")
• Clarifies details as necessary with more specific or "yes/no" questions
• Summarizes and gives patient opportunity to correct or add information
• Transitions effectively to additional questions

***Functional** approach (screen for patient literacy level) "Tell me how often someone helps you fill out medical forms or paperwork" (May elaborate on how her daughter might help her with remembering this information)*
***Multidimensional** approach "Tell me about your main concern today." (May elaborate on how Mrs. Smith has handled this in the past- barriers or what worked to improve her health)*

D. Understands the Patient's Perspective (includes the following):

• Asks about life events, circumstances, other people that might affect health
• Elicits patient's beliefs, concerns, and expectations about illness and treatment

• Responds explicitly to patient's statements about ideas and feelings

Functional approach *(screen the pamphlet for readability estimate or SMOG score and suitability estimate or SAM score) "Would you prefer to read information in English or Spanish?"*

Multidimensional approach *(screen the patient for learning and language or cultural preferences) What do you know about taking your medications and your follow-up appointment?*
What has worked for you in the past (or has been difficult for you?) How do you like to learn new information - by reading, listening to the radio or watching TV, or just listening to someone else explain new information? What language do you prefer to learn new information in?

E. Shares Information (includes the following):

• Assesses patient's understanding of problem and desire for more information
• Explains using words that patient can understand
• Checks for mutual understanding of treatment plan (*new medications, follow-up appointment*)
• Asks if patient has any questions

Functional approach *(Teach main points by going over discharge papers or pamphlet). The nurse goes over the main points of taking medication, and the provider's follow-up phone number. The nurse may ask if the patient has any questions about what the nurse has gone over.*
Multidimensional approach *(Teach 3 Teach Back) The nurse should indicate responsibility for ensuring mutual understanding, then teach 3 main or key points (how will you take your medicine, when will you follow up with your provider, and what will you do if you have a problem before your appointment?).*

F. Reaches Agreement (if new/changed plan) (includes the following):

• Includes patient in choices and decisions to the extent s/he desires
• Asks about patient's ability to follow diagnostic and/or treatment plans *(ability to take new medications and follow-up with health care provider)*
• Identifies additional resources as appropriate
Functional approach- *"Do you think you will have any problems with taking your new medicines when you get home? Do you want any other information about your medicines or heart condition?"*

Multidimensional approach- *"Just to make sure I was clear, tell me how you will take your new medications when you get home (or what will you tell your daughter about taking your new medications?) What might keep you from taking your medications or keeping your follow-up appointment?*

G. Provides Closure (includes the following):

• Asks if patient has questions, concerns or other issues
• Summarizes / asks patient to summarize plans until next visit
• Clarifies follow-up or contact arrangements
• Acknowledges patient and closes interview

Functional approach *"Here is the provider's phone number (on discharge paper) and your medication instructions (May underline, highlight or point to the number.) Read this over with your daughter when you get home. You or your daughter can call your provider if you have any questions or problems before your next appointment. Do you have any other questions for today?"*

Multidimensional approach *"We have talked about a lot of information today. What other questions do you have for me today? Just keep in mind that you or your daughter can call your provider at this phone number if you think of any other questions or need to be seen before your appointment (either point to, read, or highlight the phone number).*

Both approaches- Thank you for your time and attention, Mrs. Smith. As soon as your daughter gets here everything will be ready for you to go home,

- *Poor = rarely or none of the time*
- *Fair = some of the time, not consistently*
- *Good = at least half of the time*
- *Very good = most of the time*

Excellent = all the time

HLP-NICE Observational Checklist

The quality of the nursing interaction is evaluated by circling one of the following indicators:
0 Not observed = should have been done but wasn't
1 Poor = rarely or not observed
2 Fair = sometimes observed
3 Good = observed most of the time
4 Excellent = observed all of the time
N/A Not applicable = may not apply to that particular situation or context

*If the objective is not relevant for the situation, then the Not Applicable (N/A) indicator should be circled. If N/A is circled, then a brief explanation or rationale should be recorded in the comments section * may not be applicable for the given situation**
Observed strengths and/or suggestions for improvement can also be written in the comments section.
At the **beginning** of the encounter

1. Nurse greets the patient appropriately
-Nurse greets the patient by their name and title, not just first name or nickname
2. Nurse introduces self, and identifies a shared purpose for the interaction
- Nurse should state name, position and ask if patient shares reason for interaction- what does the patient want to get from the interaction (patient goal)

3. Nurse addresses patient's main health concern and context
- patient understanding of main concern
- barriers to self-management of concern
- available support systems

Multidimensional: What is your main concern today? What might keep you from feeling better, or what has worked for you in the past?

4. Nurse assesses patient preferences for communication and learning needs
Functional: How often do you need help with medical or hospital forms?

Multidimensional: How do you prefer to learn new information? Reading, hearing, or talking it over with someone else?
At the **end** of the encounter:
5. Nurse asks open ended questions such as "What other questions or concerns do you have?"
For either Functional or Multidimensional, open ended questions should be used to address other learning needs or to finalize closure of the communication loop. Asking closed ended yes or no responses such as "Do you have any other questions?" lessens patient sharing in closure.

Explains information clearly in plain language
6. Nurse vocal tone is appropriately paced with an acceptable volume and pitch

7. Nurse posture indicates active listening

8. Nurse's medical language matches the patient's level of language and understanding

9. Nurse uses everyday language instead of medical jargon or medicalized terms

10. Nurse uses words which indicate caring or concern and matches the patient's feelings or level of understanding

Prompts effective participation in visit: Focus on 3 or fewer key messages

11. Nurse's initial teaching statement indicates the provider's responsibility for ensuring patient comprehension *(Shame-free environment)*

12. Nurse emphasizes 3 or fewer key points during interaction *(Teach 3)*

13. Nurse repeats and reviews each key point with patient during interaction *(Chunk and check)*

14. Nurse gets specific feedback from patient for each key point *(Teach Back)*

15. Nurse gets patient agreement for correctly repeated information, or reteaches misunderstood information until information is correctly restated *(Teach Back)*

16. Nurse refrains from interruptions that may disrupt patient explanations or misses patient cues *(Active listening)*

Uses patient-friendly explanations, materials and drawings

17. Nurse puts health information in context by defining new or unfamiliar terms during explanations *(* May be N/A if no new or unfamiliar terms or health information is shared during the interaction*)*

18. Nurse puts health information in context by using common analogies during explanations *(*may be N/A if no analogies are needed to help patients understand or clarify health information*)*

19. Nurse selects appropriate educational materials or drawings to match assessed learning needs and preferences
- Based on what has occurred during the interaction, the nurse should be able to match the appropriate supplemental written or audio or audiovisual materials to the patient. For example, written materials with

pictures may be more appropriate for someone with hearing limitations, compared to verbal instructions alone. **May be N/A if an interaction occurs without any written material being shared*)*

20. Nurse writes down key verbal points or highlights key points in printed materials. **May be N/A if an interaction occurs without any written material being shared *.*

Instructions for the Content Experts

Thank you for agreeing to review and evaluate the scale I have developed for my study, the Health Literacy Patient-Nurse Interaction Competencies Evaluation (HLP-NICE). You were selected for this task because of your expertise in health literacy and/or nursing education and practice and interest in scale development to assess the competencies of nurses using health literacy practices when observed in patient interactions. At this time your assistance is needed in assessing the content validity of this newly developed scale to identify the health literacy competencies of nurses when observed in simulated or real-time interactions with patients. This task involves rating the relevancy of each HLP-NICE item to health literacy-related knowledge, behaviors and attitudes of nurses in fostering patient-centered collaboration.

The following information is included for your review:

1. Description of the conceptual framework for HLP-NICE scale development
2. Description of the HLP-NICE instrument
3. Form for rating item-relevancy
4. HLP-NICE instrument

The procedure for this review is:

1. Read the description of the theoretical basis of scale development and
2. Using the rating form, rate each item as to its degree of relevance in measuring nursing competencies in patient interactions.
3. Note whether items are appropriate to measure nursing health literacy competencies.
4. Make any suggestions you may have for the addition or deletion of items or for changes in the wording of items on the HLP-NICE form.
5. Evaluate the instructions for the scale on the HLP-NICE form.
6. Evaluate the format of the scale on the HLP-NICE form.

Conceptual Framework for HLP-NICE Scale Development

Zarcadoolas, Pleasant and Greer (2006) expanded the traditional definition of health literacy from a functional literacy-based focus to multiple dimensions which encompass "the wide range of skills, and competencies that people develop to seek out, comprehend, evaluate and use health information and concepts to make informed choices, reduce health risks and improve quality of life" (p. 196-197). While it is essential for providers to meet the health information needs of the estimated 36% of the US population with limited or lower literacy skills (Kutner et al., 2003), restricting health literacy practices to those with lower reading abilities may neglect the health information needs of the 64% of the population with adequate or more developed literacy abilities (Nutbeam, 2008). Screening for patient literacy levels or simplifying written materials overlooks provider influences in effective patient interactions such as observed overuse of medical jargon (Castro et al. 2007) and self-reported underuse of evidence-based health literacy practices (Schwartzenberg et al., 2007). Health care providers may need additional preparation and training to become more competent in using patient-centered communication in their daily interactions. The HLP-NICE scale is one tool that could be used to develop and benchmark these competencies in nursing education and clinical practice.

In reflecting the multidimensional health literacy theoretical approach advocated by Zarcadoolas and colleagues (2006), the HLP-NICE scale does not differentiate provider actions or behaviors based on identifying patient literacy levels. The scale focus is on observing and rating provider competencies in verbal and non-verbal patient interactions, regardless of patient literacy abilities. This approach is aligned with calls for greater inclusion of health literacy practices by all health stakeholders using a universal precautions approach similar to universal infection control recommendations (Paasche-Orlow, Schillinger, Greene & Wagner, 2007).

The HLP-NICE items were synthesized from two complementary sources designed to increase health literacy knowledge, skills and behaviors of health care providers, including nurses. The first source identified key health literacy-related concepts and practice standards commonly used throughout existing literature in educational programs designed to educate health providers. Health literacy education principles were drawn from the Health Research Services Administration (HRSA, nd), Centers for Disease Control and Prevention (CDC, nd), Ohio State University Health Literacy Center (OSU, nd), Teaching Patients with Low Literacy Skills 2nd ed. (Doak, Doak and Root, 1996) and a curriculum for training medical students (Kripalani et al., 2006). The second source identified health literacy-related principles integrated through health professional interpersonal communication and shared-decision making concepts collated from items of the KEECC-A (Rider, 2010), Rochester Participatory and Shared-Decision making or RPAD scale (Shields, Franks, Fiscella, Meldrum, & Epstein, 2005), Quality and Safety Education for Nurses or QSEN recommendations (Cronenwett et al., 2007) and selected health literacy consensus statements regarding key health literacy educational principles identified by an interdisciplinary panel of academic health professionals (Coleman, Hudson & Maine, 2013).

Description of the HLP-NICE instrument

The HLP-NICE consists of 20 items. Each item rates the quality of observed health literacy practices using a six point scale as follows: *0 = Not observed, 1 = Poor, 2 = Fair, 3 = Good, 4 = Excellent, N/A = Not applicable*. If *N/A* is selected, then brief rationale should be stated in the comments section to ensure that an appropriate reason was used to exclude the item. If the *N/A* designation is appropriate, then the participant would not be penalized for items which may not apply or be relevant in an interaction. The comments recorded in this section could also be used to improve interaction recall and support rater debriefing or individual self-reflection when reviewed after completion of the interaction.

Responses to each item when summed yield a total score. Total scores range from 0 (no competencies observed throughout the interaction) to 80 (the highest level of competencies observed) if all 20 items are scored. The total raw score would be converted into a percentage based on the summed score divided by 20 items total. If fewer than 20 items were evaluated the final result would be based on the summed score divided by the total number of items evaluated for a percentage. Potential percentage ranges suggesting levels of health literacy competencies are as follows: *excellent* (70 – 100%), based on a mean 3.5 / 4, *good* (50 – 69%) based on a mean 2.5 / 4, *fair* (30 – 49%) based on a mean of 1.5 / 4 or *poor* (less than 30 %).

The higher the percentage level corresponds to greater use of health literacy competencies by providers during observed or recorded patient interactions. It would be expected that nursing students just starting out would have fewer health literacy competencies than those students or nurses who were further along

in their professional development. Competency levels may also be influenced by the quantity, quality and consistency of health literacy content and practices taught in nursing curriculum, course content and clinical experiences. The observed outcomes, however, could provide benchmarks of a participant's individual competencies levels at a single point in time, or comparisons of changes in a nurse's health literacy competencies over time.

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Instructions for the Relevancy Rating Form

Please use the form on the following 2 pages to rate the relevancy of each item to your understanding of the health literacy definition proposed by Zarcadoolas, Pleasant and Greer (2005). Consider how nurses might use multiple health literacy competencies to collaborate in patient-centered interactions. Please read each item carefully. Rate each item using the four-point scale below based on how relevant you believe it is in measuring the concept of nursing health literacy competencies.

1 = not relevant

2 = somewhat relevant

3 = quite relevant

4 = very relevant

HLP-NICE Relevancy Rating Scale

1 = not relevant

2 = somewhat relevant

3 = quite relevant

4 = very relevant

(**Engages, assesses and reassesses patient needs)**

At the **beginning** of the encounter

1. Nurse greets the patient appropriately	1 2 3 4
2. Nurse introduces self, and identifies a shared purpose for the interaction	1 2 3 4
3. Nurse addresses patient's main health concern and context - patient understanding of main concern - barriers to self-management of concern - available support systems	1 2 3 4
4. Nurse assesses patient preferences for communication and learning needs	1 2 3 4

At the **end** of the encounter

5. Nurse asks open ended questions such as "What other questions or concerns do you have?"	1 2 3 4

(Explains information clearly in plain language)

6. Nurse vocal tone is appropriately paced with an acceptable volume and pitch	1 2 3 4
7. Nurse posture indicates active listening	1 2 3 4
8. Nurse's medical language matches the patient's level of language and understanding	1 2 3 4
9. Nurse uses everyday language instead of medical jargon or medicalized terms	1 2 3 4
10. Nurse uses words which indicate caring or concern and matches the patient's feelings or level of understanding	1 2 3 4

(Prompts effective participation in visit: Focus on 3 or fewer key messages)

11. Nurse's initial teaching statement indicates the provider's responsibility for ensuring patient comprehension	1 2 3 4
12. Nurse emphasizes 3 or fewer key points during interaction	1 2 3 4
13. Nurse repeats and reviews each key point with patient during interaction	1 2 3 4
14. Nurse gets specific feedback from patient for each key point (Teach Back)	1 2 3 4
15. Nurse gets patient agreement for correctly repeated information, or reteaches misunderstood information until information is correctly restated	1 2 3 4
16. Nurse refrains from interruptions that may disrupt patient explanations or misses patient cues	1 2 3 4

(Uses patient-friendly explanations, materials and drawings)

17. Nurse puts health information in context by defining new or unfamiliar terms during explanations	1 2 3 4
18. Nurse puts health information in context by using common analogies during explanations	1 2 3 4
19. Nurse selects appropriate educational materials or drawings to match assessed learning needs and preferences	1 2 3 4
20. Nurse writes down key verbal points or highlights key points in printed materials	1 2 3 4

Relevancy rating scale

1 = not relevant

2 = somewhat relevant

3 = quite relevant

4 = very relevant

Cognitive Interview Script

A. Instructions for Cognitive Interviewer (Read through before starting each interview)
   1. Review HLP-NICE to make sure you can get through it and determine probes to ask
   2. Read the INSTRUCTIONS TO SUBJECT either verbatim or paraphrased to start the interview
   3. Make sure to enter the START TIME on the HLP-NICE form when the interview begins
   4. Go for up to one hour. If you don't get done, just mark where you ended. If something is difficult to administer, or if you can't figure out how to read a question, make a comment about the item being a problem and ask it the best you can.
   5. Use the suggested probes that are written in and other probes that you think of. Don't feel you have to probe every question extensively.
   6. Enter comments in the HLP-NICE comment section about problems or issues that come up. Try to make sure they are readable so that they can be usable for analysis.
   7. Make sure to enter the END TIME on the HLP-NICE form when you are done.
   8. After the interview, look back over the questionnaire and add any additional comments or thoughts that come to mind.

B. Instructions Read To Subject

   Note to Interviewer (not read to subject)

   a. *Either read these instructions completely or paraphrase them, but be sure to include the key elements 1 – 7.*
   b. *For the initial interview, the think aloud practice question should be used. For the follow-up interview with the same subjects, the think aloud practice question may be omitted.*

Thanks for coming in. Let me tell you a little more about what we'll be doing today.

1. I am testing a health literacy observational checklist with the help of practicing nurses, nursing educators, standardized patient-actors and nursing students.
2. The checklist can be used to assess the health literacy competencies of nurses interacting with patients in a variety of situations. This could include nurse peer evaluations, faculty or standardized patient evaluations of nursing students or self-evaluation of either live or recorded patient- nurse interactions.
3. I will ask you to read through a part of the checklist and take a minute to think about a section or individual question and potential responses. I'll then ask you questions and you can answer them just like a regular survey.
4. Our goal today, however, is to get a better idea of how the questions are working. After reading the section or question 1 time, I would like you to *think aloud* as I ask the question again - just tell me everything you are thinking about as you reflect on what the question means to you.

B. Instructions Read to Subject (cont. from page 1)

5. Please keep in mind that I really want to hear all your opinions and reactions. There are no right or wrong answers. Don't hesitate to speak up whenever something seems unclear, is hard to answer, or doesn't seem to apply to you.
6. Finally, we will do this for an hour or so unless we run out of things to be asked.
7. What other questions do you have before we start?
8. *(Optional think aloud practice question)* Let's begin with a practice question. Remember to try to think aloud as you answer.

   How difficult was it for you to get here to do the interview today:

   very difficult, somewhat difficult, a little difficult, or not at all difficult?

   (Probe as necessary) Tell me more about that? What do you mean by (answer)? Could you share other details about (answer)?

C. Possible probe questions to use: write the probe question/s asked in the comment section

Instructions- Are these instructions for checklist use clear, or are there some areas that appear confusing or hard to understand?

Tell me more about that response.
In your own words, what is this question asking?
Can you elaborate on what that response means to you?
How did you arrive at that response?
What time period are you thinking of?
What does the term *"word or phrase"* mean to you in this question?
How sure are you of your answer?
What other words or phrases might you use in this question?
Can you think of anything else about this question?

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APPENDIX Y: **Phase 1 Focus group script outline**

Welcome (5 minutes):

Thank you for taking the time and effort to participate in this focus group to review the functional and multidimensional health literacy educational outline and activities. Today's discussion will involve getting your perspective on these two different educational approaches to foster the health literacy competencies of nurses. During the first hour, I will start by asking you about the fundamental health literacy approach and teaching strategy you have reviewed, and then during the second hour after the break I will ask the same questions about the multidimensional health literacy approach and teaching strategy. Your different backgrounds and perspectives are essential to providing feedback to ensure that the educational interventions are as accurate, realistic and relevant to nurses as possible. Everyone's observations are important to this process. I am asking that no personal names be used in our discussion so that everyone will feel comfortable in expressing their perspectives and opinions. Use the alternate ID on the card which you have been given to identify and address each other during the discussion to protect everyone's privacy and confidentiality.

Ice-breaker activity (10 minutes):

Take 1 minute to share a health communication interaction that you have seen either as a nursing student or teacher, or as a patient or with a family member that involved health literacy and understanding [*Pause for reflection.*] Explain the lesson learned in that situation, whether positive or negative.

Functional Health Literacy Introduction (5 minutes):

Health literacy has been defined in 2004 Institute of Medicine recommendations and the 2010 National Action Plan to Improve Health Literacy as " the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions". Nursing interventions based on functional health literacy may include screening patients for their literacy levels, or modifying written, audiovisual or web-based materials such as pamphlets, web-sites or health environments to improve patient access and use of health information.

As the patient introduced in the first case scenario, Mrs. Smith needs to get, use and understand health information to manage her lifestyle choices and medications related to her newly-diagnosed congestive heart failure.

Take 1 or 2 minutes and read through the first case scenario to reflect on aspects of acquiring, sharing and using health information [*Pause for reading*]

Acquiring health information (15 minutes)

In the first scenario, the nurse might assess the patient's literacy level by asking, ""How often do you have someone help you fill out medical or hospital forms?"(*Assess patient literacy level and preferred language)*

1. What are your thoughts about how these questions affect Mrs. Smith's ability to get needed health information?
2. Tell us about patient responses when you have heard or seen this question used before?

At some point, the nurse may review the chart for patient's language preference, and look at SMOG readability and SAM suitability scores of pamphlets if evaluated. The nurse could also ask Mrs. Smith "Which language would you prefer for reading health information?" to ensure that any pamphlets or educational material given matches the patient's literacy level and language preference. *(Compare identified literacy level with available written resources)*

3. Share your experiences of asking similar types of questions or reviewing patient charts for this information.
4. How did the patient responses or chart information influence your actions?

Sharing health information (10 minutes)

After the nurse points out or highlight key information in the written material, they might state, "Many times we go through this information very quickly, so make sure and read through this important information about your health condition" *(Teach pertinent health information using the most suitable written resources)*

5. If you have heard similar statements or questions like this, what was the impact on health information sharing between patients and providers?

Using health information (5 minutes)

In finishing up, the nurse may then ask, "After you read this health information, let me know if you have any other questions" *(Survey for additional questions about health information)*

6. What insights into Mrs. Smith's potential use of health information could be gained from her responses?

Functional Health Literacy Conclusion (15 minutes)

7. Based on our discussion of the scenario so far, what changes would you make to the scenario, or how these questions are asked?

Take 1 or 2 minutes and briefly review the planned teaching strategies using this scenario to teach functional health literacy practices.

8. Based on your review of the teaching strategies planned for this approach, what recommendations would you make, based on your prior educational or clinical experiences?
9. Would you make any changes to the planned teaching strategies for this approach?

We will take a 15 minute break for refreshments. When we return, we will consider the second scenario and teaching strategies for nurses using this scenario, and how the interactions between the nurse and Mrs. Smith reflect acquiring, sharing and potential use of health information.

Multidimensional Health Literacy Introduction (5 minutes):

An expanded definition of health literacy was characterized in 2006 by Zarcadoolas, Pleasant and Greer as "the wide range of skills, and competencies that people develop to seek out, comprehend, evaluate and use health information and concepts to make informed choices, reduce health risks and improve quality of life". Nursing interventions based on multidimensional health literacies may include functional literacy skills but also includes provider use of plain language, verifying patient understanding of health information, and using shared decision-making principles during health interactions.

As part of the second scenario, Mrs. Smith needs to look for, understand, weigh options and use health information to make choices about her lifestyle and medications, reduce her risks for readmission, and maintain or enhance her quality of life.

Take 1 or 2 minutes and read through the second case scenario to reflect on aspects of acquiring, sharing and using health information [*Pause for reading*]

Acquiring health information (20 minutes)

To facilitate the patient acquiring needed health information, the nurse may ask, "What is your main concern today?" or "Tell me what you already know about your health condition" *(Assess patient concerns and knowledge levels)*

1. What are your thoughts about how these questions may impact Mrs. Smith's ability to get needed health information?
2. Tell us about patient responses when you have heard or seen these questions used before?

At some point in time, the nurse may review the patient charts for health resources and pertinent information. The nurse asks "Tell me what might keep you from taking care of your health" or "What has worked best for you to stay healthy in the past?" (*Collaborate to identify barriers and resources for self-care)*

3. Share your experiences of asking similar types of questions or reviewing patient charts for this type of information.
4. How did the patient responses or chart information influence your actions?

Sharing health information (10 minutes)

As part of sharing health information the nurse may state, "Many times we go through this information very quickly, and I want to make sure that I was clear. Could you tell me 2 or 3 main points of what we have discussed?" or "What 2 or 3 main points will you tell your family when you get home?" (*Teach 3, Teach back)*

5. If you have heard similar statements or questions like this, what was the impact on health information sharing between patients and providers?

Using health information (5 minutes)

In finishing up, the nurse may ask "What other questions or concerns do you have? (*Survey for additional questions about health information)*

6. What insights into Mrs. Smith's potential use of health information could be gained from her responses?

Multidimensional Health Literacy Conclusion (15 minutes)

7. Based on our discussion of the scenario so far, what changes would you make to this scenario, or how these questions are asked?

Take 1 or 2 minutes and briefly review the planned teaching strategies to teach multidimensional health literacy practices.

8. Based on your review of the teaching strategies planned for this approach, what recommendations would you make, based on your prior educational or clinical experiences?

9. Would you make any changes to the planned teaching strategies for this approach?

Conclusion (10 minutes).

"Thank you for your insights, observations and participation in today's discussion to evaluate functional and multidimensional health literacy nursing scenarios."

Ask each participant in turn, "Is there anything else that you want to add?"

After everyone has had the opportunity to respond, ask the entire group "What other questions do you have about this study?" If there are no more questions, ask participants to pick up their campus bookstore certificate and complete a brief demographic survey before leaving today.

Appendix Z. Health Literacy Teaching Intervention Outlines & Scripts

Functional Teaching Script and Activities

Outline	Teaching Script & Activities/ *Cue or evaluation questions*
Introduction (10 minutes)	Resources: Set-up of the nurse's station, whiteboard/ dry eraser, Participant folders with index cards, 1 copy of each pamphlet, 1 copy of SILS/SMOG/SAM forms, writing paper, pencils, highlighters, appointment list, video-recording set-up & gift cards , teacher folder with copy of script, assessment forms and supporting articles 1. Have ppt of nurse and Mrs. Smith visible (ppt #1) - Start with cue question #1 2. Cue #1- *Have you ever taken care of a patient like Mrs. Smith? How did their ability to read written materials such as consent forms or instructions affect their ability to care for themselves? What are some of Mrs. Smith's characteristics that may be typical of those who have difficulty reading?* 3. Discussion- Aging population, multiple chronic health conditions, language other than English, lower educational and socioeconomic status *The purpose of today's presentation is to review and practice nursing health literacy competencies so that we can better match patient reading abilities to the learning resources and medical forms that are used daily* 4. *As you watch the following video, consider what you have learned so far regarding patient reading abilities and typical characteristics of most health materials. How does this compare to what we know about people with low literacy levels and health so far?* 5. Show Tales of a Medicine Cup YouTube Video https://www.youtube.com/watch?v=7QIN2nU8B_k Evaluation: After watching the video ask the following: 6. *From this video, we can see that even those who have adequate reading abilities may be challenged or confused by what they read and how to apply it to their health situations. We also get insight to some of the safety and health problems that can occur if written health instructions aren't clearly understood.* *People are bombarded with written health information but are expected to access, use and apply that information to promote their health. Nurses as patient educators can be effective information "translators" using consistent patient-centered health literacy ACTS with each person.* Competencies using some of the health literacy ACTS are to **assess** the patient and written materials for literacy levels, **compare** patient and material levels to choose suitable materials, highlight and **teach** key information and then **survey** for additional resources which might help Mrs. Smith. 7. Discussion- *Have you seen any of these HL competencies used in practice? From your experiences, what barriers might exist to greater implementation of health literacy practices in healthcare system*? (time. lack of training, legal risks, lack of interest or accountability) *Nursing competencies used in this process include assessing and comparing patient literacy levels and material readability, teaching key points by highlighting crucial information, and then surveying for additional resources to meet their patient's stated needs. By the time we are done today, we will have practiced each of the ACTS and created our own checklist to remember the key competencies as we learn and practice.*
Written Materials Screening & Patient literacy	**Assess** for patient reading level *For nurses, the first step in patient care is to assess where the patient baseline is, and this is true for health literacy.* 1. *The first HL ACTS that nurses should perform is Assessing their patient's literacy level. While there are formal health literacy tests, we are going to use an informal screening*

Outline	Teaching Script & Activities/ *Cue or evaluation questions*
Screening Content (20 minutes) (Unfolding case study lecture presentation- new information regarding Mrs. Smith, 2nd power point SIL, SMOG, SAM & criteria)	*tool, the Single Item Literacy Screening question, known as SILS. Can you recall what some advantages of using the SILS versus more formal tests such as the TOFHLA (Test of Functional Health Literacy) might be?* Discussion- easier to use in clinical practice, less time to learn and administer, may not be as precise but still gives nurses an approximate idea of their patient's reading abilities 2. The nurse should first introduce themselves, and identify their purpose by saying that they are going to help Mrs. Smith get ready for discharge by reviewing some important health information. *The nurse may state, "I need to ask you some questions so I know which resources will help you learn about your medicines and congestive heart failure before you go home".* *The nurse then asks, "Could you share with me how often you have someone help you fill out medical or hospital forms? rarely, sometimes, frequently or always"* *When thinking about SILS, possible literacy screening results are adequate literacy if the patient needs rarely or sometimes needs assistance with hospital forms, and low or limited literacy if they frequently or always need assistance to complete medical or hospital forms.* *Mrs. Smith may say, "I often have my daughter help me read and fill out hospital forms, but I doesn't like to ask too often. My daughter has enough to keep her busy with her work and taking care of my grandchildren. She does help me fill my pill bottles each week, and keeps up with my prescriptions. I don't want to bother her any more than I have to, or ask my doctor too many silly questions."* 3. Discussion- From her response, what would you consider her literacy level to be- adequate or **limited**? How might her response be different if she had adequate reading abilities? What other sources of information might you use to assess her abilities and preferences? (medical record, interactions with other people or health providers, asking her about her preferred language) *4. While identifying Mrs. Smith's literacy level may help us know about her greater health risk, this still doesn't address her potential difficulties in understanding written materials. This is why health materials should also be screened based on what we know about the reading level and information characteristics found in most health materials and resources.*
Written Materials Screening & Patient literacy Screening Practice (20 minutes)	**Assess material readability** - SMOG (Simplified Measure of Gobbledygook) readability assessment- grade reading level formula 1. The first health material evaluation is to assess the grade reading level it takes to read and understand written materials. Two of the more commonly used reading formulas are the Frye and Simplified Measure of Gobbledygook known as SMOG. The SMOG formula is based on 100% comprehension, is easy to use, and uses syllable counts in a mathematical formula to estimate reading level. The more polysyllabic words a person has to read, the longer time it takes to read and the higher a reading level is needed. Keep in mind that many people who have difficulty reading will either take longer or have less understanding of pamphlets using long or complex words. However, even if the material is easy to read, if the words are crammed together, or has multiple fonts, pictures without explanations or does not match the target population background, even low level reading materials may not deliver the health message in an understandable manner. - SAM (Suitable Assessment of Materials) is another instrument which nurses can use to evaluate the appropriateness of written or audiovisual materials for patients with limited or low literacy. These materials may be rated superior (70 – 100%), adequate (40 – 69%) or not suitable (less than 40%) by scoring 6 material factors measured by 22 criteria. The major factors are material content, literacy demand, graphics, layout & typography,

Outline	Teaching Script & Activities/ *Cue or evaluation questions*
	learning stimulation & motivation, and cultural appropriateness. **Compare** patient literacy screening results with available materials *Based on Mrs. Smith's response and risk factors for limited literacy noted from her chart (age, country of origin, educational level, and multiple health conditions), the nurse identifies that Mrs. Smith is at risk for limited literacy. The nurse would then choose the most suitable brochure available based on the nurse's identification of Mrs. Smith's limited literacy. This comparison should help the nurse better match Mrs. Smith's abilities with adequate or superior health materials more suitable for her identified literacy level and need for control.* *The nurse may ask, "It sounds like you want to be fairly independent when it comes to taking care of your health. In which language do you prefer to read health information?" Mrs. Smith may respond, "English is muy bien, thank you."* Discussion- *With Mrs. Smith's response to her preferences, and your current knowledge, which of the 3 pamphlets would you choose to match her literacy level? How might your choices be different if she were blind or deaf? Or spoke in a foreign language?* All of these factors may need to be considered by the nurse when selecting appropriate health information. (Teacher Demonstration with participant return demonstration using SIL, SMOG and SAM.) Have each participant pick one of the 3 pamphlets, and then discuss the following (no real right or wrong) Discussion: *Why did you choose your pamphlet or why didn't you pick one of the other pamphlets?* (Too wordy, not enough pictures. hard to read….)
Creation of functional teaching and evaluation methods (50 minutes)	**Teach** written materials highlighting Ask Me 3 questions **1.** *Nurses can help patient's navigate through the 'Nice-to know" versus essential "need-to know" information. A National Patient Safety Foundation initiative called* ***Ask Me 3*** *identifies 3 basic questions that patients should ask their health providers to get and understand key information about their health. Nurses can also find and benchmark answers to these questions in written materials as a starting point for prioritizing what the patient should learn and understand* **2.** The Ask Me 3 Questions are- *1. What is my problem?* (this makes the problem personal to them, individualizes the information) *2. What actions do I need to take to fix the problem?*(to take action, people need to know what to do, not just what they need to know) *3. Why is it important for me to do this?* (people need to tie their actions to the motivation which can improve their health…consequences of inaction or benefits of actions) **3.** Teacher Demonstration with participant return demonstration using SIL, SMOG and SAM (already identified on each of the 3 pamphlets distributed) & highlighting Ask Me 3 questions on pamphlet and discharge paper) ***3.*** *Find and highlight the following 3 important pieces of information using Ask Me 3 (3rd PowerPoint)* **4.** *When finished teaching the highlighted key points, the nurse may then state "Many times we go through this information very quickly and it is important for you to take your new medicines and follow up with your health care provider. Make sure and read through this information before your follow-up appointment. I have underlined/highlighted the most important information about your health condition, the phone numbers of your provider and the 24 hour hospital help-line to call for problems on the discharge form" Mrs. Smith may state, "I don't know if I can read this too well without my reading glasses*

Outline	Teaching Script & Activities/ *Cue or evaluation questions*
	because of those tiny letters. I will look at the brochure just as soon as I get home." Discussion: What might be your concern with Mrs. Smith at this point, and how might you address these issues? (Unable to read/possible shame or stigma vs material difficult to read, may need alternative or additional health information sources….) **5.** The nurse will need to conclude the interaction by addressing these additional learning needs or concerns, leading to the last ACT which is to- **Survey** for additional written resources or needs 6. Group discussion and creation of a checklist with functional HL principles (Whiteboard/dry eraser/index cards) **6.** *The nurse may conclude by stating, "What other questions do you have? While it sounds like you want to be fairly independent in taking care of yourself, it is also helpful to have family members working with you to stay healthy. Why don't you and your daughter read about your health condition more closely when you get home? You can also call your provider or the help line at these phone numbers if you have any of those problems that we talked about today."* *To complete the interaction, The nurse may also survey for additional learning needs- "What other information would you like to have?"* Nurses can then consider the patient's literacy level & background to find additional resources to meet patient requests. *We are going to create our own checklist to use to aid our memory when it comes to using these health literacy ACTS in practice, then we will put it all together and pair up to practice taking turns with 1 person as the nurse, the other as Mrs. Smith. You can evaluate each other with your checklist, and then we can try it out with the group as a whole* Participant pairs role play with chosen pamphlet with Ask Me 3 highlighted and using checklist for self- evaluation and group evaluation
Summary Activity (10 minutes)	4th PowerPoint- ACTS/ pictures of Mrs. Smith Teacher-facilitated small group discussion summarizing principles & peer-created evaluation (Self- reflection- Write down key points from today's session, and how you might use SIL, SAM & SMOG and your checklist in your clinical practice) After the practice session winds up, finish with- Now that we have talked about HL ACTS, *Let's take a few minutes and think about how you might use this information in your clinical practice. Take your piece of paper, and write down your thoughts – we'll share them after a few minutes*
Next steps (10 minutes)	Schedule next interaction with Mrs. Smith for Sunday, Sept 27th between 1 pm – 6 pm using appointment list. Remind not to discuss with others. Repeat HL Knowledge test and discharge interaction with Mrs. Smith at this time (est. 45 minutes) What other questions do you have? Thank you for taking the time to participate in this teaching session

Medical University of South Carolina and Austin Peay State University
Phase 1 Expert Content Reviewer Information Sheet

Effects of multidimensional vs. functional educational interventions on baccalaureate nurse-standardized patient interactions: Health literacy content reviewer request

For Health Literacy Observational Checklist Reviewers,

As a content expert in the fields of nursing education and/or health literacy, you are being invited to review an observational checklist which characterizes health literacy competencies nurses may use when interacting with patients. Your voluntary participation is vital to the success of this project, so I hope that you will consider participating by reviewing the Health Literacy Patient-Nurse Interaction Checklist Evaluation or HLP-NICE instrument for content validity. The approximate time required for review completion is three (3) hours for the initial evaluation with a possible additional two (2) hour session if the checklist needs significant content revision based on feedback from the initial content review. After you agree to participate, you will receive the following written materials: the Health Literacy Patient-Nurse Interaction Competencies Evaluation (HLP-NICE) instrument, written instructions on how to evaluate the HLP-NICE, a theoretical definition and overview of the underlying constructs, HLP-NICE description and an evaluation form for assessing the content validity of HLP-NICE.

I have estimated that the time needed for your participation will range from a minimum of 3 hours up to a maximum of 5 hours total to complete the content validity index. This evaluation has been designed to ensure complete security and confidentiality of any written information that you provide. Your responses regarding the content validity of the checklist will not be linked to any personally identifiable information.

In recognition for your time and any inconvenience associated with the review, a $10 donation will be made to the charity or cause of your choice. I can be reached through e-mail at frenchk@apsu.edu, in person at 931-221-7528 or at my office at 303 McCord building at Austin Peay State University, Clarksville TN if you would like be a reviewer or need additional information or other questions about reviewing the checklist.

MUSC
IRB Number: Pro00035215
Date Approved 1/14/2015

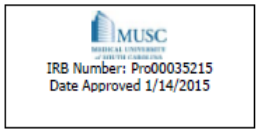
Medical University of South Carolina and Austin Peay State University
Phase 1 & 2 Reviewer Information Sheet

Effects of multidimensional vs. functional educational interventions on baccalaureate nurse-standardized patient interactions: Health literacy checklist assessment request

For Health Literacy Checklist Pre- and post- intervention checklist reviewers,

As a content expert in the fields of nursing education and/or nursing practice, you are being invited to participate in the preliminary assessment of the usability of a researcher-developed Health Literacy Patient-Nurse Interaction Checklist Evaluation or HLP-NICE instrument. This assessment will occur before and after the educational interventions take place. This instrument will be used in Phase 2 of a health literacy educational pilot study to evaluate the effects of two different educational approaches on the health literacy competencies of undergraduate nursing students. Your voluntary participation is vital to the success of this project, so I hope that you will consider taking part. If you agree to participate in this assessment, you will be given the HLP-NICE checklist to review for content and clarity with the PI. A 1 hour pre- and post-intervention semi-structured interview will be conducted and audio-recorded by the principal investigator to identify strengths and areas for improvement based on interview feedback. The estimated time needed for your participation will be a minimum of 2 hours and a maximum of 3 hours. The study has been designed to ensure complete security and confidentiality of written or recorded information collected by the PI. Your responses will not be linked to any personally identifiable information.

In recognition of the time and inconvenience associated with your participation in this assessment, you will be offered a $10 donation to the cause or charity of your choice. There is no compensation available, however, for any study-related injuries if they occur. I can be reached through my e-mail at frenchk@apsu.edu, in person at 931-221-7528 or at my office at 303 McCord building at Austin Peay State University, Clarksville TN if you would like additional information or have other questions about this study.



Appendix CC: Focus group invitation script

Phase 1 health literacy curriculum preliminary development/evaluation. Preparation for the delivery of the educational interventions will involve evaluating standardized teaching plans in relationship to current nursing educational evidence, health literacy theoretical underpinnings and existing nursing clinical practice. The unfolding case study scenario, the health literacy curriculum teaching plans and associated activities will be reviewed by a focus group consisting of 8 total reviewers: 2 nursing faculty, 4 junior level baccalaureate students and 2 practicing nurses from APSU and the local area to assess accuracy, relevancy and realism. Once participants agree to participate they will be given a package consisting of the unfolding case study (APPENDIX H1), teaching objectives and activities for each approach (APPENDIX H2, H3) to be reviewed during the focus group session.

The session will be set up for a 2 hour period of time convenient to the participants. A break including refreshments between the first and second hour will occur to separate assessment of the functional and multidimensional approaches. The focus group will open with an ice-breaking activity to build group cohesion, followed by orientation activities regarding group communication and confidentiality. *The PI will ask a colleague in a related social science discipline outside the nursing department (education, sociology or psychology) to serve as moderator to facilitate the discussion, and to provide an objective and unbiased outlook as facilitator (Barbour, 2008).* The PI will listen to the focus group as a silent observer to make written field notes of individual and group interactions but will not participate in the focus group discussions. The focus group will be audio recorded for additional review and transcription by the PI. Before starting the focus group activities, a $10 campus bookstore gift certificate will be offered to participants for their time and inconvenience of focus group participation. Feedback from the teaching objectives, activities and case study details will facilitate refinement of the HLP-NICE instrument and training of the standardized patient-actors and teacher-interventionist in preparation for Phase 2. APPENDIX G provides the detailed focus group script outline.

Medical University of South Carolina &
Austin Peay State University Nursing Departments

40 Participants Needed For Research in Health

Literacy Interventions in Nursing Education

I am looking for up to 40 recent nursing graduates over the age of 18 to volunteer for this educational research.

As a participant in this study, you will be randomly assigned to one of two different health literacy educational strategies to explore how these approaches influence the health literacy practices of nurses.

Your participation would involve 4 sessions during a 4 week time span.
(5 hours total)
These 4 sessions include:
1 pre- and 1 post-intervention session of a brief survey and simulation with a standardized patient (1 hour each),
1 online health literacy module (1 hour),
and
1 educational intervention session (2 hours).

In appreciation for your participation, you will be offered compensation for your time and inconvenience.
There is no compensation or coverage available for any study-related injuries.

For more information about volunteering for this study, please contact:
Kim French
APSU School of Nursing
931-221-7528
Email: *frenchk@apsu.edu*

This study has been reviewed by and received ethics clearance through the Austin Peay State University and Medical University of South Carolina Institutional Review Board Committees

MUSC
IRB Number: Pro00035215
Date Approved 1/14/2015

Medical University of South Carolina and Austin Peay State University

SCRIPT FOR RECRUITMENT TO BE A RESEARCH SUBJECT (C2- Amendment)

Effects of multidimensional vs. functional educational interventions on baccalaureate nurse-standardized patient interactions: Health literacy participants for an experimental pilot study.

You are being invited to participate in the Health Literacy Inclusion in Nursing Education Research Study due to your recent graduation from the APSU School of Nursing and your nursing experiences in a variety of health settings. This pilot study is designed to evaluate the effects of two different educational approaches used to build the health literacy competencies of undergraduate nursing students. Your voluntary participation is vital to the success of this project, so I hope that you will consider taking part. I have estimated that the time needed for your participation will be 4 to 5 hours total over the course of 4 weeks in late June through July. The flyer included gives more detail about the activities and associated time involvement. The study has been designed to ensure complete security and confidentiality of written and recorded information that you provide. Your actions and responses will not be linked to any personally identifiable information. The results of this study will not affect any current or future services provided to you by the APSU nursing program or the University.

In recognition for the time and inconvenience associated with your participation in this research study, compensation will be provided. There is no compensation available, however, for any study-related injuries if they occur. I can be reached through my e-mail at frenchk@apsu.edu, my work phone at 931-221-7528 or my office at 303 McCord building at Austin Peay if you would like additional information or have other questions about this study.

Sincerely,

Kim French MSN, FNP-BC

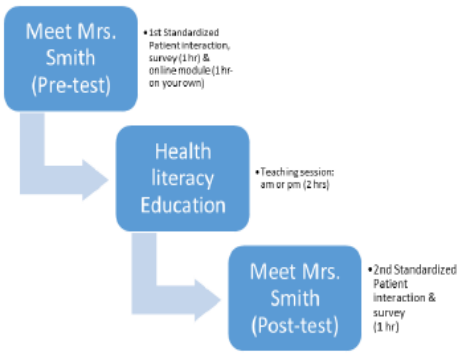
MUSC
IRB Number: «ID»
Date Approved «ApprovalDate»
Expiration Date: «ExpirationDate»

Health literacy participants needed for an experimental pilot study: Effects of multidimensional vs. functional educational interventions on baccalaureate nurse-standardized patient interactions.

You are being invited to participate in the Health Literacy Inclusion in Nursing Education Research Study due to your recent graduation from the APSU School of Nursing and your nursing experiences in a variety of health settings. This pilot study is designed to evaluate the effects of two different educational approaches used to build the health literacy competencies of undergraduate nursing students. Your voluntary participation is vital to the success of this project, so I hope that you will consider taking part. I have estimated that the time needed for your participation will be 4.5 to 5 hours total over the course of 3 weeks in July and early August. The flyer included gives more detail about the activities and associated time involvement. The study has been designed to ensure complete security and confidentiality of written and recorded information that you provide. Your actions and responses will not be linked to any personally identifiable information. The results of this study will not affect any current or future services provided to you by the APSU nursing program or the University. While this study may not provide any personal benefits, your participation in this research may add evidence to support a the practice of nursing through evaluation of how best to teach health literacy practices to future students.

In recognition for the time and inconvenience associated with your participation in this research study, compensation will be provided. There is no compensation available, however, for any study-related injuries if they occur. I can be reached through my e-mail at frenchk@apsu.edu, my work phone at 931-221-7528 or my office at 303 McCord building at Austin Peay if you would like additional information or have other questions about this study.

Sincerely,
Kim French MSN, FNP-BC



MUSC
IRB Number: «ID»
Date Approved «ApprovalDate»

Medical University of South Carolina and Austin Peay State University
SCRIPT FOR RECRUITMENT TO BE A RESEARCH SUBJECT

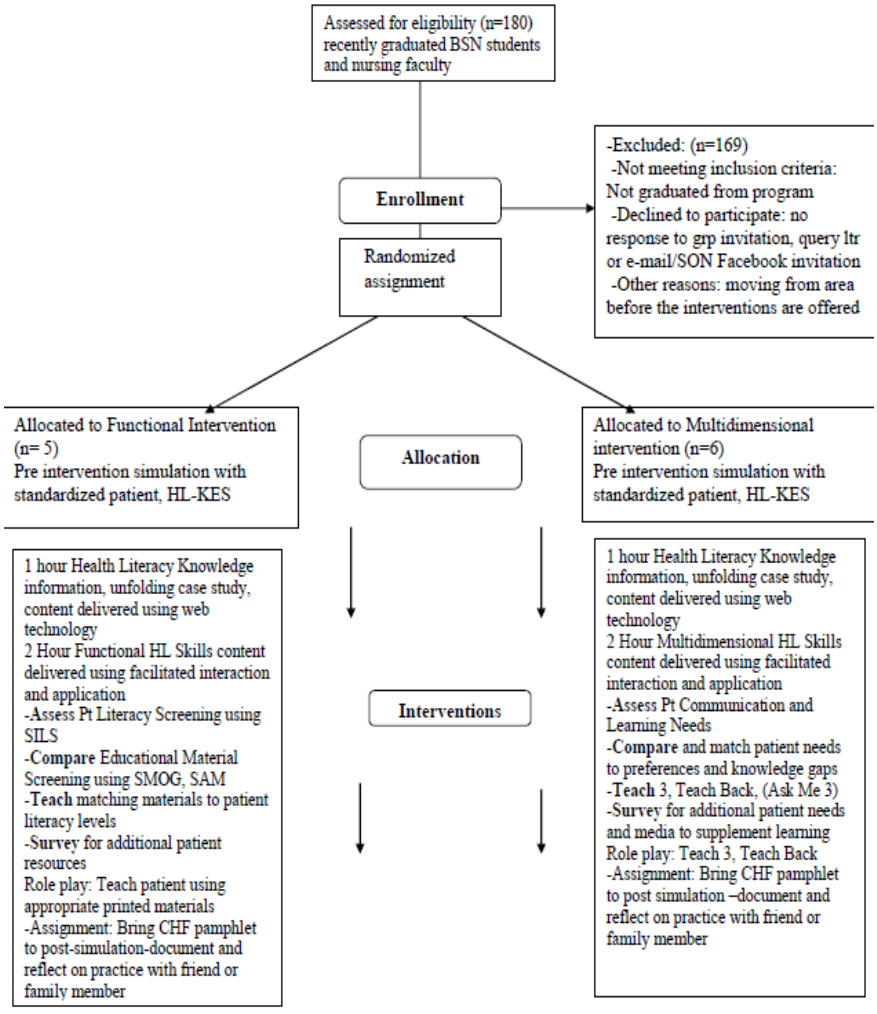
Effects of multidimensional vs. functional educational interventions on baccalaureate nurse-standardized patient interactions: Health literacy participants for an experimental pilot study.

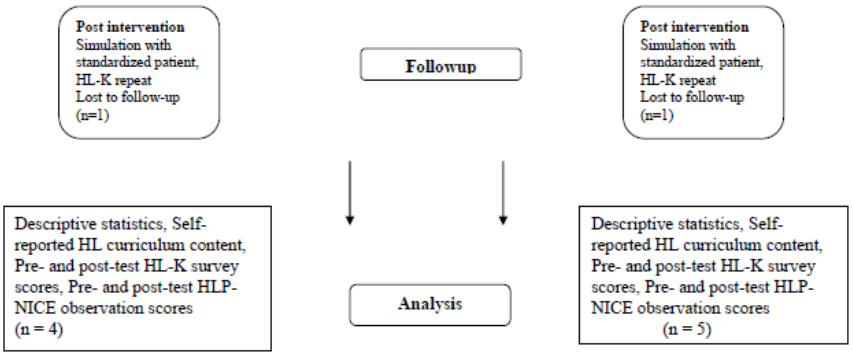
You are being invited to participate in the Health Literacy Inclusion in Nursing Education Research Study due to your expertise as full-time faculty member of the APSU School of Nursing, and your experiences as a nurse from a variety of health settings. This pilot study is designed to evaluate the effects of two different educational approaches used to build the health literacy competencies of undergraduate nursing students. Your voluntary participation is vital to the success of this project, so I hope that you will consider taking part. I have estimated that the time needed for your participation will be 4 to 5 hours total over the course of 4 weeks in late August and September. The flyer included gives more detail about the activities and associated time involvement. The study has been designed to ensure complete security and confidentiality of written and recorded information that you provide. Your actions and responses will not be linked to any personally identifiable information. The results of this study will not affect any current or future services provided to you by the APSU nursing program or the University.

In recognition for the time and inconvenience associated with your participation in this research study, compensation will be provided. There is no compensation available, however, for any study-related injuries if they occur. I can be reached through my e-mail at frenchk@apsu.edu, my work phone at 931-221-7528 or my office at 303 McCord building at Austin Peay if you would like additional information or have other questions about this study.

Sincerely,
Kim French MSN, FNP-BC

Figure 1. Functional vs, Multidimensional HL Educational Interventions: Consort 2010 Flow Diagram





Reference

Schulz, K.F., Altman, D.G., Moher, D., for the CONSORT Group. (2010). CONSORT 2010 Statement: Updated guidelines for reporting parallel group randomised trials. *BMJ*. 340: 698 – 702, doi: 10.1136/bmj.c332

APPENDIX II. Health Literacy Web-based Module Unfolding Case Study

An unfolding case study used throughout the web-based and face-to face modules

Introduction to the patient: You are a nurse who has been assigned to care for Mrs. Marika Smith, a 69 year old widow with HTN (high blood pressure), arthritis, and CHF (congestive heart failure). Mrs. Smith will be discharged shortly from a 5 day hospitalization for her initial diagnosis and treatment of CHF. The physician was concerned about the addition of new medications to her existing drugs, and wants to keep her from returning to the hospital with further complications or worsening of the CHF. As part of your patient education plan for discharge, you are to teach and reinforce her medication knowledge, and evaluate her abilities to correctly use and maintain her medications, monitor her new onset CHF and follow up with her primary care provider. The teaching information that you use or share will be evaluated on the dimensions of content accuracy, applicability and her comprehension of the information during the time you will be discharging Mrs. Smith.

Additional information as case study unfolds: Mrs. Smith has multiple factors affecting her health status. The health literacy web-based module will supply additional information for the students to identify and use in the performance of their assigned tasks. Ms. Smith is an older person who immigrated to this country from the Dominican Republic when she was 12 years old. She is now widowed, but finished the 11th grade before getting married, and worked primarily as a homemaker. She now lives with her daughter, son-in-law, and 2 grandchildren in a 3 bedroom apartment in a large city. She has Medicare and her pre-hospital medications included Lasix (Furosemide) 40 mg 1 tablet daily, KChlor (Potassium) 20 mEq 1 tablet daily, and Tylenol (Acetaminophen) 650 mg 1 tablet every 4 hours for arthritis. Her new medications include Zestril (Lisinopril) 20 mg 1 tablet 2 times daily and Lanoxin (Digoxin) 0.125 mg 1 tablet 2 times daily. She also takes herbal medications for her arthritis but is not sure of what is in the "arthritis" pills and massage cream. She skips her potassium supplement sometimes because of the "bad taste" and doesn't always recall if she is supposed to take 1 or 2 Tylenol when her joints really hurt. She has minor visual difficulties and wears reading glasses, but otherwise no other cognitive or health impairments. She is scheduled to follow-up with her primary care provider in 3 weeks time. Mrs. Smith states that she often has difficulty understanding the written information that she got on discharge and doesn't want to bother the doctor by asking "silly questions" about her medications or health. She often has her daughter help her read her health information, but states that she doesn't like to ask too often since her daughter has enough to keep her busy with work and the grandchildren.

Scenario Introduction Script: You have been assigned to discharge Mrs. Smith home to her family today. Your task is to ensure that she is educated about how to take her new medications and any changes in her congestive heart failure symptoms, and to keep her follow-up appointment in 3 weeks with her health care provider. You have reviewed her medical record and note that she lives with her daughter, son-in-law and grandchildren, has finished the 11th grade and that English is her primary language. The three pamphlets about congestive heart failure available on your unit have a SMOG readability estimate of 5th, 9th and 11th grades with inadequate, adequate and very adequate SAM suitability percentage score.

Meet Mrs. Smith: Health Literacy Competencies for Nurses

You are a nurse who has been assigned to care for Mrs. Marika Smith, a 69 year old widow with HTN (high blood pressure), arthritis, and CHF (congestive heart failure). Mrs. Smith will be discharged shortly from a 5 day hospitalization for her initial diagnosis and treatment of the CHF. The physician was concerned about the addition of new medications to her existing drugs, and wants to keep her from returning to the hospital with further complications or worsening of the CHF. As part of your patient education plan for discharge, you are to teach and reinforce her medication knowledge, and evaluate her abilities to correctly use and maintain her medications, monitor her new onset CHF and follow up with her primary care provider. The teaching information that you use or share will be evaluated on applicability to her situation, accuracy and her comprehension during the time you will be discharging Mrs. Smith.

Mrs. Smith now lives with her daughter, son-in-law, and 2 grandchildren in a 3 bedroom apartment in a large city. She has Medicare and her pre-hospital medications included Lasix (Furosemide) 40 mg 1 tablet daily, KChlor (Potassium) 20 mEq 5 ml daily, and Tylenol (Acetaminophen) 650 mg 1 tablet every 4 hours for arthritis. Her new medications include Zestril (Lisinopril) 20 mg 1 tablet daily and Lanoxin (Digoxin) 0.125 mg 1 tablet daily. She also takes herbal medications for her arthritis but is not sure of what is in the "arthritis" pills and massage cream. She skips her potassium supplement sometimes because of the "bad taste" and doesn't always recall if she is supposed to take 1 or 2 Tylenol when her joints really hurt. She has minor visual difficulties and wears reading glasses, but otherwise no other cognitive or health impairments. She is scheduled to follow-up with her primary care provider in 3 weeks' time. She is waiting for her daughter to pick her up after she is discharged from the hospital.

For your assignment, you will have a choice of several different pamphlets about congestive heart failure, a clipboard, and Mrs. Smith's discharge orders. Her medical record will also be at the hallway nurse's station. Feel free to wear whatever you feel most comfortable in as the nurse, but Flo's Closet is also available as well if you prefer. Think about your "nurse alias" or name that you will use for your work with Mrs. Smith.

Many thanks for participating in this study to evaluate the effectiveness of 2 different teaching strategies for health literacy, and feel free to e-mail or call me with any other questions.
Sincerely,
Kim French
frenchk@apsu.edu
931-221-7528

Appendix KK Health literacy Teaching Plan for Web-based Module

Purpose: After completing a web-based health literacy module, recently graduated nurses will recall core knowledge of literacy and health literacy and the impact this has on individuals, communities, health providers and the American health care system

Goal: Recently graduated nurses will demonstrate core health literacy knowledge regarding limited literacy effects and health literacy knowledge

After viewing the web-based module and completing the module activities, study participants will be able to:

Learning Objectives	Content Outline	Instruction Methods	Time allotted	Resources	Evaluation Method
1. Describe the prevalence, high risk populations and the effects of limited literacy for individuals, communities, health providers and the US health care system	1. Define literacy & health literacy, 2. 1992 NALS, 2003 NAALS study 3.National Health Literacy Action Plan & Universal HL precautions	Introduction to case study- Ms. Smith Voice-enhanced web-based power point presentation	5 minutes	Computer/internet access Piece of paper, pencil or pen	1 minute reflection response
2. Describe 4 patient , 3 provider and 3 health system factors which affect patient abilities to obtain health information or make health decisions	1. Literacy & Health literacy vs health literacies- fundamental, cultural, scientific & civic 2. Patient communication risk factors for limited literacy: age, diverse ethnicity or limited English proficiency, cognitive and sensory changes, lower SES 3. Health provider communication competencies: Patient preferences, plain language, cultural or cognitive sensitivity verify understanding of health information 4. Health system	Voice-enhanced web-based power point presentation, Reflection about factors affecting Mrs. Smith's ability to make decisions or participate in her health care, negative & positive pt & provider influences	10 minutes	Computer /internet access	Cue question 1 response

Learning Objectives	Content Outline	Instruction Methods	Time allotted	Resources	Evaluation Method
	communication competencies: Shame-free environment, medical terminology, benefits and barriers of advancing communication technologies				
3. Relate techniques to assess health material capacity to provide understandable and actionable health information	1. Readability formulas 2. Suitability instruments 3. Decision aids 4. Audio-visual aids	Voice-enhanced web-based power point presentation; Reflection question	15 minutes	Computer/ internet access	Cue question 2 response
4. Discuss techniques to assess patient capacity to obtain, process, interpret and understand basic health information	Patient Literacy Screening- 1.TOFHLA/REALM, 2. NVS 3. SIL	Voice-enhanced web-based power point presentation Reflection question	10 minutes	Computer/ .internet access	Cue question 3 response
5. Describe use of 5 health literacy practices to optimize patient-provider health communications	Health material evaluation, patient literacy screening, active listening, plain language, teach 3 teach back method	Voice-enhanced web-based power point presentation,	15 minutes	Computer/ internet access	Cue question 4 response
Learning Objectives	**Content Outline**	**Instruction Methods**	**Time allotted**	**Resources**	**Evaluation Method**
6. Summarize guiding principles of health literacy -		Voice-enhanced web-based power point presentation, Reflection question	5 minutes	Computer/ internet access Piece of paper, pencil or pen	80% or better on 5 question quiz (HLK question topics) 1 minute reflection response:

Starting Reflection response 1: Take 1 or 2 minutes and write a paragraph or two responding to the following questions.

Have you observed a situation in which you or someone you knew had difficulty understanding health care information or instructions given by a health care provider? What were the most important factors that led to this situation? Were you aware of any health- related consequences in this situation?

Cue 1: How will the nurse assess Ms. Smith's current knowledge and information needs? What does the nurse need to do next? Is there any other information you as the nurse would want to know?

The nurse has asked Ms. Smith "How often do you have someone help you fill out medical or hospital forms?" and Ms. Smith replies, "My daughter has to help me most of the time, but if she isn't available, I just leave the form blank or bring it home so she can help me."

Cue 2: From this information, what would the nurse learn about Ms. Smith's current abilities to navigate the health system? What does the nurse need to do next? What additional information would the nurse need based on Ms. Smith's response to the Single Item Literacy Screening question? (Chew, Boyko & Bradley, 2004)
How the nurse's information gathering might needs differ if Ms. Smith's response to the Single Item Literacy Screening question was "I don't need any help, I understand most health information and fill out forms without any difficulties as long as I have my reading glasses on."
How might the nurse's information needs differ if Ms. Smith was 59 and did not have any health insurance?
Would the nurse's information needs differ if Ms. Smith was deaf, or if she did not speak English fluently?

Ms. Smith will state" I can read this information a little bit better, but it is still hard for me to make out all the words. There are so many words that are squeezed close together, and the pictures don't make any sense. Are these people all happy that their hearts are in bad shape? And just look at them, they look so skinny and unhealthy. They must not be like me."

Cue 3: What other factors need to be considered for suitable written health information? Which factors need to be considered for information discussed verbally by the provider? What other resources or materials do you think Ms. Smith or her daughter might need to follow treatment and medication recommendations, based on her responses?

When you talk to Ms. Smith, she states she will take her medicine just like it says on each bottle, but when she looks at a bottle of her Digoxin, she states " I need to get my reading glasses for those tiny words- I will just do that later when you are gone."

Cue 4: How can the nurse assess that Ms. Smith understands the information that has been discussed with her without making her feel ashamed or stigmatized?

Ending reflection response #2: Take 1 or 2 minutes and write three or four sentences responding to the following question.

Based on what you first wrote, what would you do differently in that situation or as the health provider in the future?

References:

Ask Me 3

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Health Literacy: A Prescription to End Confusion

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QSEN, Cronenwett et al., 2010)
Doak, Doak & Root, 1996; AHRQ Health Literacy Tool Kit, 2015

French (2014)

(NAALS, Kutner & al. 2004)

(AHRQ, Berkman et al.,2010)

National HL Action Plan

PEMAT/AHRQ (2013);

HC system Factors Health Literacy Action Plan (2010); Brach et al. (2013); The Joint Commission (2010); Health Grades; https://www.hospitals.healthgrades.com/CPM/assets/File/HealthGradesPatientSafetySatisfactionReport2012.pdf
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Smith, S. K., Dixon, A., Trevena, L., Nutbeam, D., & McCaffrey, K. J. (2009). Exploring patient involvement in healthcare decision making across different educational and functional health literacy groups. *Social Science and Medicine, 69,* 1805-1812. DOI:10.1016/j.socscimed.2009.09.056

Teach 3 Teach Back

Additional resources:

APPENDIX LL. Educational Intervention: Functional Health Literacy

Purpose: To provide recently graduated nurses participating in a health literacy education intervention with the knowledge, skills and attitudes used to foster functional health literacy competencies
Goal: Participants will incorporate functional health literacy competencies when observed in a health-related interaction with a standardized patient

Health Literacy Pathway Stage Objective	Content Outline	Instruction Methods	Time allotted	Resources	Participant competencies: Participants will	Evaluation Method
1. Build health literacy knowledge	Review Scope of Limited Literacy & Health literacy functional principles	AMA Health Literacy Short YouTube video, Review of case scenario prompts for common information misperceptions, concerns about HL and patient screening	10 minutes	(HL online module/quiz questions completed prior to teaching intervention) Case Scenario Review- Power-point Slide with Patient Picture and Case Scenario information Internet Access	1a. Identify percentage of Americans affected by limited literacy and 2 effects of literacy on health outcomes 1b. Discuss 2 common misperceptions regarding patient literacy levels 1c.Discuss 2 barriers to consistent use of screening and health information evaluation	Teacher prompts with evaluation and correction of participant responses during discussion of initial case study elements identifying literacy effects on health outcomes, health care provider perceptions of limited literacy patients and health system barriers to consistent evaluation of patient literacy and written material suitability
2. Develop functional health literacy skills and practices	Assess Patient & Health Materials Levels: Patient literacy screening: Single Literacy Question or SIL (Morris et al., 2006) Health Materials: Readability: SMOG formula (McGlaughlin, 1969)	Unfolding case study lecture presentation- new information regarding Mrs. Smith	20 minutes	Power-point slide with new information targeted to functional competencies Handout with SIL, Chew research study Computer access, Handouts with SMOG formula and SAM criteria and checklist	2a. Describe correct use of SIL to screen patients for literacy levels 2b. Describe and use SMOG to evaluate health information reading levels 2c. Describe correct use of SAM to evaluate health information	Teacher prompts with evaluation and correction of participant responses to teacher prompt cues and questions about SIL, SMOG and SAM use with patients

Health Literacy Pathway Stage Objective	Content Outline	Instruction Methods	Time allotted	Resources	Participant competencies: Participants will	Evaluation Method
	Suitability: SAM instrument (Doak et al, 1996)				suitability for low literacy patients	
Health Literacy Pathway Stage Objectives	Content Outline	Instruction Methods	Time allotted	Resources	Participant objectives: Participants will:	Evaluation Method
3. Develop functional health literacy actions	Provide essential CHF information –screen MS. Smith using SIL, Health information written at 5th -6th grade level, suitable for patients with limited literacy levels	Teacher Demonstration with participant return demonstration using SIL, SMOG and SAM, Group discussion and creation of a checklist with functional HL principles	30 minutes	Computer access, Handouts with SMOG and SAM criteria and checklist 5 CHF patient educational materials at varied reading and suitability levels	3a.Correctly identify Ms. Smith's (teacher's) literacy level with use of SIL questions 3b. Choose a pamphlet which most closely matches Ms. Smith's identified literacy level 3c. Create a checklist based on SIL. SMOG and SAM use with patient	Teacher observation and correction of participant return demonstration of use of SIL, SMOG & SAM when participants identify the Ms. Smith's (teacher's) literacy level (adequate, borderline or inadequate literacy) and pamphlet at 5th grade reading level suitable for low literacy patients from 5 available pamphlets at varying levels
4. Collaborate to produce informed options using functional health literacy knowledge and actions	Screen Mrs. Smith using SIL, Health information written at 5th -6th grade level using SMOG, Suitable for patients with limited literacy levels using SAM	Participant pairs role-play different assigned tasks (CHF sx, medication use, DASH diet…) using SIL, SMOG & SAM	30 minutes	Task sheets, Whiteboard, dry erase markers and note cards (for group task assignment and result documentation)	4a. Demonstrate correct use of SIL, SMOG & SAM in role-play 4b. Constructively analyze peer practice and give appropriate feedback to peers about functional health literacy principles	Teacher and Peer analysis and critiques of pair role-play using the created checklist to benchmark and evaluate peer performances

Health Literacy Pathway Stage Objective	Content Outline	Instruction Methods	Time allotted	Resources	Participant competencies: Participants will	Evaluation Method
5. Collaborate to make an informed decision using functional health literacy knowledge and actions	Ensure that Mrs. Smith has materials which match her screened literacy levels, and that she reads the information	Teacher-facilitated small group discussion summarizing principles, peer-created evaluation and self- reflection-write down key points and how participant can use SIL, SAM & SMOG checklist in clinical practice	30 minutes	Whiteboard for summary of results, blank notecards and pencils for self-reflection Copy-machine availability to make copies of evaluation checklist	5a. Summarize correct application of SIL questions, SMOG and SAM evaluation in clinical practice 5b. Discuss and document 2 advantages, 2 barriers and 3 key points to use of SIL, SMOG & SAM in practice	Teacher evaluation of functional HL principles and participant self-analysis through written reflection on note-card

Assignment for last session with standardized patient: Bring or create a pamphlet suited for Mrs. Smith's situation to use in discharge teaching with standardized patient

References.

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Educational Intervention: Multidimensional Health Literacy (Appendix MM)
Presenter: Amy Black, RN, MSN, FNP- C
Purpose: To provide recently graduated nurses participating in a health literacy educational intervention with the knowledge, skills and attitudes used to foster multidimensional health literacy competencies
Goal: Participants will incorporate multidimensional health literacy competencies when observed in a health-related verbal interaction with a standardized patient

Health Literacy Pathway Stage Objectives	**Content Outline**	**Instruction Methods**	**Time Frame**	**Resources**	**Participant Competencies** Participants will:	**Evaluation Method**
1. Build multidimensional health literacy knowledge	Review Literacy/Health literacy knowledge from previously completed HL online module	Palo Alto VA Teach Back video, Teacher-facilitated reflection question review	10 minutes	(HL online module and cue questions) Computer/internet access-video viewing capabilities	1a. Identify percentage of Americans affected by limited literacy and 2 effects of literacy on health outcomes 1b. Discuss 2 common misperceptions regarding patient literacy levels 1c.Discuss 2 barriers to consistent use of teach back and patient-centered learning preferences in clinical practice	Teacher prompts with evaluation and correction of participant responses during discussion of initial case study elements identifying literacy effects on health outcomes, health care provider perceptions of limited literacy patients and health system barriers to consistent use of teach-back and patient-centered health literacy practices
2. Develop multidimensional health literacy skills and practices	Identify pt needs, cultural background and learning preferences- Learn Multidimensional principles such as Active listening, Teach 3-Teach back, Highlight	Unfolding case study lecture presentation- cue questions and prompts, additional information regarding Mrs. Smith	20 minutes	Copy of Cornett and Speros articles Case study information on PowerPoint slides	2a. Describe assessment questions to identify patient learning preferences 2b. Describe 3 active listening principles to use in patient interactions 2c. Explain Teach 3 – Teach back principles for verification of patient understanding	Teacher prompts with evaluation and correction of participant responses to prompt cues and additional questions about identifying patient preferences, active listening, Teach3-Teach Back,

Health Literacy Pathway Stage Objectives	**Content Outline**	**Instruction Methods**	**Time Frame**	**Resources**	**Participant Competencies** Participants will:	**Evaluation Method**
	written material priorities using Ask-Me- 3				2d. Identify 3 priority messages to highlight or emphasize in health information using Ask Me 3	and Ask Me 3
Health Literacy Pathway Stage Objectives	**Content Outline**	**Instruction Methods**	**Time**	**Resources**	**Participants competencies** Participants will:	**Evaluation**
3. Develop multidimensional health literacy actions	Assess and intervene to match pt needs, cultural background and learning preferences practicing with Active listening, Teach 3 teach back, & Ask Me 3 highlighted key points in written health materials	Teacher Demonstration/participant return demonstration Group discussion and creation of a checklist based on multidimensional principles	30 minutes	Whiteboard/dry erase markers, Notecards and pencils, Highlighters 3 CHF written educational materials at similar levels of readability and suitability	3a.Correctly identify Ms. Smith's (teacher's) learning preferences based on stated needs, cultural background and medical history 3b. Differentiate between correct and incorrect active listening principles by Ms. Smith 3c. Create a checklist of nursing actions to correctly perform active listening, Teach3 Teach Back & Ask Me 3 highlighted health materials	Teacher observation and correction of participant return demonstration when participants discuss patient learning preferences, Teach3 Teach Back, and Ask Me 3 responses and teacher evaluation of individual checklist
4. Collaborate to produce informed options using multidimensional health literacy knowledge and actions	Identify barriers and benefits for options and use patient's preferences in care plan, teach to goal and negotiation techniques, Reassess for	Participant pairs role play with assigned teaching tasks (medication, diet, exercise, symptoms) using checklist for evaluation	30 minutes	Role Play Task sheets	4a. Demonstrate correct use of active listening, Teach-3 Teach-Back, Ask Me 3 and reassessing through open ended questions in role-play 4b. Constructively analyze peer practice and give appropriate feedback to	Teacher and peer analysis and feedback of pair role-play using the created checklist to benchmark and evaluate peer performances of role-play

Health Literacy Pathway Stage Objectives	**Content Outline**	**Instruction Methods**	**Time Frame**	**Resources**	**Participant Competencies** Participants will:	**Evaluation Method**
	additional information needs				peers about multidimensional health literacy principle	
5. Collaborate to make an informed decision using multidimensional health literacy (5. Continued) knowledge and actions	Verify patient comprehension of final decision, Use open-ended questions to reassess for additional needs or resources	Teacher-facilitated small group discussion summarizing principles, peer-created evaluation and self- reflection- Participants write down key points and how active listening, teach-back and highlighting key information can be used in their practice	30 minutes	Whiteboard for summary of results, notecards and pencils for self-reflection Copy-machine availability to make copies of evaluation checklist	5a. Summarize correct application of patient learning preference assessment, active listening, Teach3 Teach-back and Ask Me 3 5b. Discuss and document 2 advantages, 2 barriers and 3 key points to use of multidimensional health literacy principles in clinical practice	Teacher evaluation of multidimensional HL principles and participant self-analysis through written reflection on note-card

Assignment for last session: Bring or create a pamphlet suited for Mrs. Smith's situation to use in discharge teaching with standardized patient

References

Bastable, S. B. (Ed.). (2008). *Nurse as educator: Principles of teaching and learning for nursing practice* (3rd ed.). Sudbury, MA: Jones and Bartlett.

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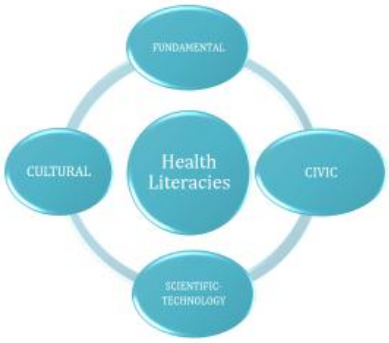

Theoretical Framework: Multiple literacy dimensions Zarcadoolas, Pleasant & Greer 2005, 2006

HL Multiple Dimensions:

Fundamental
- Verbal, non-verbal and media

Scientific/Technological
- Scientific rationale & risk, technology proficiency

Cultural
– Preferences, values, beliefs and ways of knowing

Civic
- Advocacy, empowerment, engagement

S

EDWARDS MICHELLE. [Michelle.Edwards@swansea.ac.uk]

Thank you so much for allowing me to build on your work. I will also be glad to share my results with you when I get done...but as you know, this will take a while. I am also looking forward to reading your most recent research on "distributed health literacy" and how our patients use their social capital and resources to build their own health literacies.
Sincerely,

Kempa S. (Kim) French, MSN, FNP-BC
Associate Professor of Nursing
Austin Peay State University
Clarksville TN 37044
931-221-7528
frenchk@apsu.edu

Friday, July 05, 2013 12:28 AM EDWARDS MICHELLE. [Michelle.Edwards@swansea.ac.uk]

Actions

To:

M

French, Kim

You replied on 7/5/2013 10:50 AM.

Dear Kim,

I am happy for you to use the model. Your work looks interesting, good luck with it.

Best wishes
Michelle

Dr Michelle Edwards
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Appendix PP. STTI-ATI Project Budget Table

Categories	Amount Requested	Total Budget Amount
Personnel		
-Standardized patients (2 APSU grad students)	15 per hour for 60 hours = 900/ 1800 + 138 (7.65 %)	1938
Fringe benefits (Summer, no class)		394
-Teacher/interventionist (1)	20 per hour for 16 hours = 320 + 74 extra comp fringe (23% of amount)	
Fringe benefits		320
		Total personnel: 2652
- Data manager (1 non APSU)	20 per hour for 16 hours = 320	
Secretarial staff	N/A	
Typing costs	N/A	
Research Assistant (1)	10 per hour for 60 hours = 600 + 46 (7.65%)	**Total Research Assistant:** 646
Fringe benefits (Summer, No class)		
Consultants		
-Statistician (1 non APSU)	50 per hour for 8 hours = 400	400
		Total Consultants: 400
Supplies		
-Cell phone minutes	20 per month for 3 months	60
- Fireproof safety file box	130	130
- White, 3 hole punch paper reams (5)	10 per ream = 50	50
-Binders (6) and dividers (6)	10 per set = 60	60
-HP copier toners (4)	40 per toner = 160	160
-40 pencils	3 per 10 pack = 12	16
-40 black pens	5 per 10 pack = 20	20
-MiniDVD's for AV recording (7 packs)	14 per pack for 7 packs = 98	98
		Total supplies: 594
Computer costs		
-Database storage fees (REDCap)	500	500
-Online module hosting fees	100 per year for 2 years = 200	200
		Total computer costs: 700
Travel costs	N/A	
Other		
-Participant gift cards (40)	15 per participant for 40 = 600	**Total other costs:** 600
Total budget amount		5592

Justification:
Personnel

The two peer student standardized patients will be paid $15 per hour, which is the national average for standardized patient wages according to the Association of Standardized Patient Educators website (http://www.aspeducators.org/). The 60 hours of estimated work time includes allowances for 12 – 16 hours of training time and HLP-NICE cognitive interviewing, 4 hours of team meetings and protocol

updates, 20 hours of recorded participant interviews and 20 hours of evaluating the interviews using KEECC-A and HLP-NICE instruments.

The teacher –interventionist will be reimbursed for her time at a rate of $20 per hour to attend 4 hours of team meetings and protocol updates, 4 hours of training time and 8 hours of intervention preparation, implementation and evaluation.

The data manager will be paid $20 per hour for 16 hours to assist in database set-up, data security review and data information completion in tandem with the research assistant.

Research assistant

The student research assistant will be paid $10 per hour, which is the national standard for a fair living wage. The 50 hours of work will include 4 hours of training time, 4 hours of team meeting and protocol updates, 16 hours of recruitment and research initial recording time and 24 hours of research intervention assistance and followup time.

Consultants

The statistical consultant will be paid $50 per hour for 8 hours to review the raw data, data analysis plan and provide guidance for the layout and interpretation of results.

Supplies

3 months worth of basic cell phone minutes will be purchased to provide an inexpensive dedicated telephone/text phone with cell minutes to contact participants for participation reminders. When not in use, the phone will be locked in the researcher's office. At the completion of the study, the participant cell phone numbers will be deleted and sim card removed and destroyed to prevent any data loss.

A fireproof safety box will be purchased to lock the cell phone and recorded mini-DVD tapes for safety and data protection. The box will be kept in a locked cabinet in the researcher's office, accessible only to the researcher and those who need access as determined by the researcher.

The School of Nursing has DVD recording units which will be used by the research assistant to capture the standardized patient-nurse pre- and post-intervention interactions. The mini DVD tapes will be purchased by the researcher to keep on file with other data for SP viewing and interaction preservation.

The binders, dividers, paper and toner will be used to create research team folders and generate other paper-based forms. The researcher has an HP OfficeJet desk printer available in her office to use for this purpose. Pencils and pens will be purchased to ensure that any paper-based forms such as scantrons or rating forms can be completed by the research team or participants.

Computer

REDCap or Research Electronic Data Capture (www. project-redcap.org) is a software toolset and workflow method for electronic collection and management of research data to facilitate data entry, edit checks and statistical analysis. Both REDCap and REDCap Survey systems offer an automated export mechanism to common statistical packages such as SAS using institutionally sanctioned secure servers. The underlying database is hosted at the researcher's academic Datacenter. REDCap database will be used to store and retrieve researcher-created spreadsheets documenting electronic demographic codebooks and HL-KES, KEECC-A and HLP-NICE pre- and post-intervention result databases.

The fee to host the online health literacy knowledge module at the researcher's home institution for 2 years will ensure that participants and the researcher team have time to adequately access the information. With feedback from research team members and participants, the additional time will to be used to modify and improve the modules for future use.

Other

The participants will be offered a $5 gas card after each face to face session (pre-intervention, intervention and post-intervention) to offset travel costs. Participants will be waiting to sit for the NCLEX national certification exam, and the assistance would help to reduce economic transportation costs which might be a barrier to study participation.

STTI - ATI Project Summary

Kempa S. French, April 2016

People with limited or low literacy are more likely to suffer harm and negative health consequences than those with intermediate or high reading proficiencies (Berkman et al., 2010). Nurses are expected to meet the health information needs for patients of all literacy levels, yet evidence-based health literacy (HL) interventions and concepts remain under-represented in undergraduate nursing education (Coleman, 2011; Toronto & Weatherford, 2015). In response to identified gaps between patient information needs and nursing educational preparation, this research was undertaken to evaluate the effects of two different HL theoretical approaches on the HL knowledge, nursing communication and HL-related behaviors of nurses participating in this study.

Project aim summary.

This feasibility study incorporated four aims to assess the uptake of HL knowledge and behaviors by participants. The first aim was to create and assess preliminary psychometric evidence for an observational HL checklist, which was achieved with the Health Literacy Patient-Nurse Interaction Competencies Checklist or HLP-NICE (DeVellis, 2010; Waltz, Strickland & Lentz, 2010). In preparation for the third aim, the second aim was used to create then review traditional functional versus expanded multidimensional health literacy curricula and teaching strategies for realism and relevance in building nursing HL competencies. The third aim evaluated the feasibility of the teaching interventions reflected in HL knowledge and HL-related behavior changes of study participants. The fourth aim is still in progress and will entail in-depth review and analysis of qualitative and quantitative study data to modify both the HLP-NICE tool and teaching interventions for use in future research.

Theoretical/conceptual framework

Traditional functional health literacy definition and interventions have emphasized text-based approaches such as screening patients for literacy levels and modifying written materials (Nielsen-Bohlman, Panzer & Kindig, 2004). This approach, however, may not fully account for the influences of patient learning or cultural preferences (Friedman, Corwin, Dominick & Rose, 2009), provider use of jargon (Castro et al., 2007), or lack of provider evaluation of patient comprehension (Schillinger et al., 2002). Zarcadoolas, Pleasant and Greer's (2006, p.55) multidimensional health literacy definition was derived to address these deficiencies in portraying health literacy as "the wide range of skills, and competencies that people develop to seek out, comprehend, evaluate and use health information and concepts to make informed choices, reduce health risks and improve quality of life".

Nurses who use this multifaceted approach would need to cultivate scientific – technological, cultural and civic competencies in addition to written, verbal and media-related proficiencies to effectively communicate health information in patient-centered care. The Health Literacy Pathway Model (HLPM), a 5 stage competency developmental model incorporating multidimensional HL concepts, was structured after reporting a non-linear pathway that patients followed to develop their own health literacy skills when interacting with providers (Edwards, Woods, Davies & Edwards, 2012). The expected outcome for nurses educated using the HLPM developmental approach would be that they would communicate health information more effectively with patients, resulting in better patient comprehension and more patient-centered collaborations in health-enhancing interactions.

Methods, procedures and sampling

This mixed methods feasibility study used sequential qualitative case study and quantitative two group between subjects approaches to meet the four stated aims. The first two aims were met using instrumental case study methodology collected from multiple data sources as part of determining feasibility focus areas for the third aim. Content validity feedback from a panel of four HL, nursing education or linguistic experts was used to determine a content validity index percentage of agreement (di Iorio, 2005). HLP-NICE quality improvement feedback was obtained through my own quality analysis and cognitive interviews with five representative checklist users (Willis, 2005). \

The third aim was met through collection of baseline demographic data, Health Literacy Knowledge and Experiences Survey or HLKES scores (Cormier & Kotrlik, 2009) and ratings of pre--intervention recorded interactions with a standardized patient rated using the HLP-NICE with an existing validated tool, the Kalamazoo Essential Elements Communication Competencies – Adapted or KEECC-A (Rider, 2010). Both groups then completed a web-based interactive case study "*Meet Mrs. Smith: Building health literacy competencies of nurses through ACTS."* which detailed health literacy knowledge and practices to align with recommended Universal Health Literacy Precautions (US DHHS ODPHP, 2010). During their scheduled theoretically-specific teaching intervention, the multidimensional group was instructed in active listening, plain language use and teach-back techniques to assess patient concerns. The functional group was instructed in patient literacy screening using Single Literacy Question, with SMOG readability formula and SAM suitability checklists to assess written material quality. The functional group then addressing identified patient literacy levels through highlighting key written information. The HL-Knowledge Survey section and post-intervention recorded

interactions were re-evaluated at one to two weeks after the teaching sessions and then rated using the HLP-NICE and KEECC-A. The fourth aim will continue as collected quantitative and qualitative data is reviewed more intensively to provide a strong foundation for the next research steps.

Institutional review board approval was received from both the researcher's academic institution and research site institution before any intervention took place. After the initial recruitment strategy did not garner an adequate number of participants, a secondary strategy was implemented after IRB approval to recruit more recently graduated nurses and nursing faculty. Former students from the previous 2 years and nursing faculty were invited to participate by word of mouth, informational hard-copy and online poster announcements and mail queries during a school break after graduation. The final convenience sample initially consisted of eleven recently graduated baccalaureate nurses or nursing faculty recruited from the Southeastern public liberal arts baccalaureate nursing program. Respondents were formally consented into the study by the research assistant, then randomly assigned to each cohort using a systematic randomization strategy (Waltz, Strickland & Lenz, 2010). Two of the nursing graduates (1 male, 1 female) completed the first interaction, but not the teaching interventions or second interaction, leading to exclusion of their data from the final analysis.

The remaining 9 participants included 3 recent graduates and 6 nursing faculty. The sample were all female and were somewhat racially (2 Black, 22.2%; 7 White, 77. 8%) if not ethnically diverse (no Hispanic or Latino participants). Ages ranged from 22 – 69 (M = 44.89) with health care work experience outside of nursing school ranging from 0 – 45 years (M = 16.89). Of the 6 faculty participants, teaching experience ranged from 1 – 23 years (M = 7.67) with medical-surgical teaching concentration primarily represented (83.33%) with one pediatric

specialty faculty member. All levels of academic preparation at and above the baccalaureate level were represented with three BSN graduates, and with two MSN, four doctorally prepared (two DNP, one EdD, one DSN) faculty members.

Summary of findings

The HLP-NICE tool received expert feedback with the content validity index of 88.9%, approaching the 90% agreement level recommended for acceptance (di Iorio, 2005). Information from both the researcher's tool quality analysis and representative user cognitive interviews will be used to further improve the HLP-NICE tool before a second round of evaluation takes place. Information from the focus group transcripts sharing nursing clinical and teaching HL experiences for the two teaching approaches was used to train the standardized patients and teacher regarding basic HL knowledge and behavioral cues suggesting the patient may have low or limited literacy.

Recall of health literacy experiences using Health Literacy Experiences survey items indicated that participants saw or used core and technology health literacy practices *"rarely"* to *"sometimes"* (M = 1.89, range 1.44 -2.67). Health literacy knowledge changes did not appear to be associated with past health literacy experiences or years of nursing experience (KW -.07, p =.43), educational achievement (KW 1.38, df 1, p =.24) or GPA (KW 4.8, df 4, p = .31). Health literacy knowledge overall did not increase significantly for participants (Wilcoxon SR, p =.31), although 5 of 9 participants (55.56%) demonstrated knowledge gains. The multidimensional gained more HL knowledge compared to the functional group (U 2.000, p = 03). HLK internal reliability evaluation using Cronbach's α was .67 pre-intervention and .42 post-intervention.

Increases in communication (KEECC-A Wilcoxon SR, p =.008) and HL-related behavior competencies (HLP Wilcoxon SR, p =.01) were demonstrated by all participants. The functional

group appeared to gain more communication proficiency (KEECC-A U .500; p = .02), but neither group were significantly different in HL-related behavior changes (HLP U 6.000, p = .18). KEECC-A reliability using Cronbach's α was .77 pre-intervention and .82 post-intervention. HLP-NICE Cronbach's α was .29 pre-intervention and .59 post-intervention. There was a very strong positive association noted between the post-intervention KEECC-A communication and HLP-NICE HL-related behaviors (r_s =.953, r^2 = .9082, p = .00). While concurrent validity for associated communication competencies between the KEECC-A and HLP-NICE were signaled, neither sample size nor the reliability results could fully support validity.

Recommendations

This study points to shifts in how HL competencies have been traditionally taught to more interactive strategies and outcome-based benchmarks to inform HL inclusion in nursing curricula, didactic content and clinical exposures. The lack of relationship between cognitive knowledge gains and behavior-related changes suggest that improving HL competencies is not fully dependent on mastery of discrete HL knowledge facts. While prior HL research has provided insight into the quality and quantity of HL competencies seen or used in educational practice, none of the past nursing research had linked increasing HL knowledge to observed changes in student HL practices or patient learning outcomes. The HLP-NICE tool was easy to use during evaluation of recorded ratings and took an average of 10 minutes to complete. The HLP-NICE offers a promising beginning to assessing the HL competencies of nurses and nursing students, but could not be recommended as a reliable or valid instrument without additional modifications and testing.

The innovative and diverse teaching strategies were effective in improving short-term communication and HL-related competencies of the participants. The total time for pre-and post-interaction evaluations and the online and face-to-face interventions took approximately 4 hours, which was not perceived as overly time-consuming by participants. Cognitive qualitative interview data provided by nursing faculty, practicing nurses and students and suggestions by the expert reviewers from the preparatory phase will be used to improve the quality of tool wording and process before further testing and additional psychometric analysis occurs.

This study addressed existing gaps in current HL educational practices to provide more robust evidence for diverse interactive strategies to advance nursing health literacy competencies. All patients, regardless of literacy or language abilities, need understandable and actionable health information if they are to follow health instructions, use health resources effectively and avoid preventable safety errors and costly rehospitalizations. The health literacy competencies for adoption in patient-centered education should be synthesized throughout the nursing curriculum, practiced in simulated educational and real-life patient clinical interactions, and promoted to current nurses through continuing education. The next research step will be to refine the tool and teaching strategies to be tested with a larger and more diverse sample in real-world educational settings.

Financial summary

The total amount of the approved budget was $5591, with the primary financial expense for this study covering employment costs for the two standardized patients, teacher and research assistant ($3, 513). Gift cards used to reimburse participants for time and inconvenience associated with study participation totaled $400, with an additional $433 spent on office and data recording supplies. Because of the reduced participant numbers, data manager, statistical

consultant and database storage services were not sought or used. The final budget total expenditures were approximately $4346, with the $745 overage to be returned to Sigma Theta Tau International.

Grant assistance benefits

Nursing communication is intricately tied to patient safety and high quality care, but little evidence has informed nursing educational practice to improve well- documented deficits in effective nursing communication based on HL evidence. Without this financial support, it would have been very difficult for me to afford to train the research team or offer compensation for participants, thus reducing the opportunity to conduct more rigorous educational research. The data collected from multiple sources will also be used to inform future research in this area, and can be used as a basis for my research trajectory. A poster of the findings was presented at the Nursing Education Research Conference in April 2016, and has been placed in the Virginia Henderson repository for future dissemination. I am honored to be associated with Sigma Theta Tau International Honor Society, and will always gratefully acknowledge the role that the STTI and ATI educational assessment grant played in successfully starting my nursing educational research trajectory.

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Assessing health literacy competencies: A randomized pilot comparing two teaching approaches at the BSN level

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INTRODUCTION

- Patients with limited literacy have poorer health outcomes, higher emergency room use & hospitalization rates and higher illness rates than those with adequate literacy (Berkman et al., 2011).
- **Universal Health Literacy Precautions** approach recommended using evidence-based communication practices with all patients, regardless of literacy level (DHHS-ODPHP, 2010)
- Nurses should be prepared during their education to intervene with patients at all literacy levels to promote patient-centered collaborations (Coleman et al. 2012; Zarcadoolas, Pleasant & Greer, 2006)

AIMS , PARTICIPANTS, STUDY FLOW

Two phase, two group experimental pilot study aiming to:

- **Compare** theoretical HL teaching strategies
  - **Functional**: Pt. & material literacy screening, Written material simplification
  - **Multidimensional (MDM)**: Pt. preferences, Plain talk, Active listening, Teach Back
- **Create** HL competencies tool
- **Evaluate** tool reliability and validity trends with expert & stakeholder feedback, ratings and instrument validity comparisons

- 8 Participants recruited after IRB approval, Systematic randomization to 2 groups
  - :- 3 recent BSN graduates, 6 nursing faculty
  - 22.8 % Black/African-American, 77.2% White; all female
- Work experience: 0 – 45 years
- Nursing degrees: BSN to DSN/ EdD

METHODS

- Pre-intervention **HL experiences**: Health Literacy Experiences Survey (HLE-S; Cormier & Kotrlik, 2009); 9 Likert scaled item (1- 4): *rarely = 1 to always = 4*
- Pre-and post-intervention **HL knowledge** levels: HL Knowledge Survey (HLK-S; Cormier & Kotrlik, 2009): 29 multiple choice items: *% correct (0 – 100)*
- Pre-and post-intervention **Communication** ratings Kalamazoo Essential Elements Communication Competencies-Adapted (KEECC-A; Rider & Nawotniak, 2010): 7 Likert-scaled items (1- 5): *poor=1 to excellent=5*
- Pre-and post-intervention **HL– related behavior** ratings: Health Literacy Patient-Nurse Interaction Competencies Evaluation (HLP-NICE), 20 Likert-scaled items (0 – 4); *0 = not observed to 4= excellent+ N/A*

RESULTS

- Participant recall of past HL **Experiences**: pt. literacy screening, material evaluations or teach back use occurred "*rarely*" to "*sometimes*" (M =1.889, 1.44 -2.67) with no association noted between HL experiences & HL knowledge gains (r_s -,072, p = .427)
- HL **Knowledge** did not significantly change (WSR, p = .312). HL Knowledge Incr. for 5 of the 9 participants (55.56%). MDM grp knowledge incr. more than Functional (U 2.000, p= .032).
- **Communication** and **HL competencies** incr. for all participants (WSR, p = .008). No sig. differences were noted between HL-related competences of both grps (U 6.000, p = .183), but Functional grp did incr more in communication competencies U .500, p = 0,016.).

CONCLUSIONS

- Recall of HL-related clinical experiences is similar to past reports (Cormier & Kotrlik, 2009) suggesting inconsistent and limited use of HL evidence in clinical practice
- **HL-related behaviors** can be improved short-term without over-focusing on HL knowledge gains
- **Strengths**: Experimental design, innovative & diverse teaching strategies (online module, Assess- Compare-Teach-Survey framework, standardized patients at non-medical center academic site).
- **Limitations**- Restricted generalizability due to small size and homogeneous sample
- Educating nurses in HL competencies is feasible, cost effective and timely, with ongoing research needed to implement Universal Health Literacy Precautions (USDHHS- ODPHP, 2010) recommendations.

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