

An Innovative Literacy-Supportive Education Pilot for Wound Self-Care

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Abstract

As the incidence of acute and chronic wound conditions rises and wound dressing protocols become more complex, uninsured patients lacking access to specialty wound care are challenged to manage their own wounds. Understanding multistep dressing change protocols may be inhibited by low health literacy. Low health literacy is associated with reduced disease knowledge and self-care. Little evidence of health literacy effects on wound patients is available nor are literacy-sensitive educational interventions that address wound knowledge and self-care. Improved outcomes occur in all health literacy levels in other diseases with the use of literacy-sensitive educational interventions that incorporate more than one literacy strategy over multiple sessions. To examine the effectiveness of a literacy-sensitive wound education intervention on wound knowledge and self-care, an evidence-based pilot project was conducted in an urban wound clinic. A convenience sample of 21 patients received a literacy-sensitive wound education intervention consisting of spoken and written communication over several sessions. Instruments measured health literacy level, wound knowledge, dressing performance, and wound healing status. There was a significant increase in wound knowledge scores in all literacy groups from baseline to visit two ($p < .01$) and four ($p < .01$). Dressing performance scores remained consistently high through visit four in all literacy levels. All participant's wounds progressed toward wound healing significantly from baseline to visit two ($p < .01$) and four ($p < .01$). Incorporation of a literacy-sensitive education intervention with supportive literacy aids over several sessions supports improved wound knowledge and dressing self-care and can affect healing in patients of all health literacy levels.

Keywords: health literacy, wounds, dressings, self-care, knowledge

An Innovative Literacy-Supportive Education Pilot for Wound Self-Care

The incidence of acute and chronic wound conditions is growing rapidly in the United States. Advances in wound care add complexity to wound care protocols, including dressing changes. Uninsured patients who require wound care services typically perform multistep dressing changes by themselves at home. If they are performed improperly the patient is at risk for negative outcomes. Medical personnel are tasked with teaching dressing changes to patients in a manner that factors in the health literacy needs of the patient. Evidence is limited in the effect of health literacy on self-wound care, but research in other chronic diseases with similar multi-step treatment regimens report improvement in disease knowledge and self-care in all health literacy levels with literacy-sensitive educational interventions that incorporate mixed strategies over multiple sessions. The purpose of this manuscript is to review the results of an evidence-based pilot project aimed at improving wound knowledge and self-care with the implementation of a literacy-supportive educational intervention in clients with wounds treated in an outpatient clinic.

Background and Significance

The incidence of acute and chronic wound conditions is growing rapidly. This is due to an increasing incidence of predisposing factors: diabetes, obesity, and an aging population (Sen et al., 2009). According to the Centers for Disease Control and Prevention (CDC) (2014), 21 million people in the United States have been diagnosed with diabetes, and an estimated 8.1 million have not yet been diagnosed. An estimated 25% of people with diabetes will develop a diabetic foot ulcer, and 66% of these will recur (Singh, Armstrong, & Lipsky, 2005). Chronic wounds or wounds that fail to improve in a timely and orderly process affect 6.5 million people in the United States and cost over 25 billion dollars annually to treat (Sen et al., 2009). Acute

wounds arise from a variety of sources including surgical wounds, trauma, abrasions, bites, and burns (Sen et al., 2009). The National Center for Health Statistics reported 48 million inpatient surgical procedures were performed in 2009, up 8 million from 2000 (CDC, 2009). As the number of surgical procedures continues to rise, so will the number of resultant wounds.

With this increase, the wound care product market is one of the world's largest and fastest growing, costing 15.3 billion dollars in 2010 (Sen et al.). This has led to availability and variability of wound products. Currently, there are over 4,000 wound products on the market (Hettrick, 2014). Dressing application protocols vary based on product type and usually require multiple steps to apply and remove.

Patients with health insurance typically receive wound care and dressing changes in specialty clinics or through home health care. On the other hand, most uninsured patients manage their wounds at home themselves or with help from family members. Compared with insured patients, uninsured patients experience poorer health outcomes, reduced quality of life, and increased mortality (Institute of Medicine, 2009). They also generally lack access to regular screening and prevention services (Institute of Medicine, 2009). In 2015, 28.4 million Americans were reportedly uninsured (National Center for Health Statistics, 2016). Patients without insurance find it harder to obtain care than those with insurance (Pieper, 2005). Uninsured patients with a wound face challenges in seeking assistance due to costly specialty care and dressings, and a limited number of wound clinics providing charity services (Pieper, 2005). Also, uninsured patients with chronic wounds require long-term attention and frequent follow-up (Pieper, 2005). This lack of access to wound services makes chronic wound healing difficult to achieve.

Limited access to wound care is concerning in major metropolitan cities such as Phoenix, Arizona. There, the rate of uninsured patients is as high as 22.2%, compared with the national average of 10.5% (United States Census Bureau, 2015). Uninsured rates are reported to be even greater in minorities. Phoenix has a large Hispanic population (40.8%) compared to the entire United States (16.3%) (United States Census Bureau, 2010). Over 30% of Hispanics in Phoenix lack health insurance according to the 2012 Pew Hispanic Report (Motel & Patten, 2012). Phoenix also has the highest Hispanic poverty rate in the United States and the lowest median household income (Motel & Patten, 2012). Based on these demographics, Hispanic patients with chronic wounds are especially challenged to receive wound care services.

Internal Evidence

Several clinics in Phoenix provide primary care to uninsured populations at little to no cost. Few offer specialty care. Currently, one clinic provides charity wound care. This clinic conducted an internal review of its uninsured patient population. The detailed results are shown in Table 1. The majority of patients reported their country of origin as Mexico and their primary language as Spanish (Lee, 2016). Of those who answered, 54% reported their education as high school or GED, and 33% reported less than an eighth-grade education (Lee, 2016). These findings suggest educational and language barriers that may impact health literacy levels.

In the charity wound clinic, an adult nurse practitioner who is a certified wound specialist sees a full range of wound patients from acute post-op surgical wounds to chronic venous stasis ulcers. The wound clinic offers most available wound care products and follows current evidence-based wound care protocols. Presently, wound care and dressing instructions are given orally and then demonstrated. Wound instructions are communicated through a certified medical interpreter for patients who speak Spanish. Though some patients do well, others are

inconsistent or fail to carry out dressing instructions. Specific problems include improper dressing changes, skipping dressing changes, and using mixed methods of wound care. Complications of suboptimal wound care in the clinic include infections, delayed healing, increased clinic dressing costs, patient inconvenience, and hospitalizations. Underlying causes of unsuccessful dressing changes reported by patients include lack of understanding of instructions, language barriers, reliance on family members not present at the clinic visit to change the dressings, and challenges with the complexity of the dressing change protocol. These factors indicate that current educational practices are not meeting the needs of the population. No formal health literacy assessment has been conducted in this clinic's population, and with the noted variables of language, education, and dressing complexity, the current dressing education process may not be appropriate for all patients.

Health Literacy

Health literacy is the capacity to process, understand, and obtain basic health information and services and act on them (Agency for Healthcare Research and Quality, 2015). Limited health literacy affects people of all incomes, races, ages, and education levels, but it disproportionately affects those with a lower socioeconomic status and minority groups (Baur, 2010). In 2006, The United States Department of Education published its findings on the first national assessment of health literacy of English-speaking adults (Kutner, Greenberg, Jin, & Paulsen, 2006). The study noted that over one-third of participants had basic to below basic health literacy (Kutner et al., 2006). Hispanic adults had lower health literacy than any other group. Of the adults who did not complete high school, 49% scored in the below basic health literacy category (Kutner et al., 2006).

Literacy and health literacy are similar, but health literacy requires additional skills in understanding health contexts such as knowledge and language of the body, healthy behaviors, and workings of the healthcare system (Baur, 2010). Patients with low to moderate health literacy skills struggle with self-management, require more visits to their healthcare provider, lack necessary skills to seek services, and incur higher healthcare costs due to treatment errors and delays (Egbert & Nanna, 2009). Health literacy has been noted to be an important factor in cancer screening utilization, patient compliance, and chronic disease outcomes (Shaw, Huebner, Armin, Orzech, & Vivian, 2009). The associations among health literacy status, chronic disease outcomes, and self-care behaviors have been well studied. In a large systemic review conducted by DeWalt, Berkman, Sheridan, Lohr, and Pignone (2004), patients with low health literacy were three times more likely to experience a poor health outcome. Schillinger et al. (2002) noted worse glycemic control and higher rates of retinopathy in type two diabetics with inadequate health literacy. Similarly, Al Sayah et al. (2013) and Macabasco-O'Connell et al. (2011) noted that lower health literacy was associated with lower heart failure knowledge, self-efficacy, and self-care behaviors.

Health literacy research pertaining to wound outcomes is limited. A single prospective cohort study on a subset of enrollees from a cross-sectional study noted that patients with lower health literacy scores had larger and older wounds compared to patients with higher health literacy (Margolis, Hampton, Hoffstad, Malay, & Thom, 2015). The initial cross-sectional study reported that those with lower health literacy were less likely to enroll in an investigational study, raising concern for decreased study recruitment in this population (Margolis et al., 2015). Although this study included a small sample size and had limited generalization, its findings indicate that health literacy and wound outcomes (size, duration) may be correlated.

Health literacy initiatives. Since health literacy has a significant effect on public health, several government agencies have sought to address health literacy by providing education, assessments, research, and intervention strategies. The United States Department of Health and Human Services through the Office of Disease Prevention and Health Promotion included health literacy in its national initiative *Healthy People 2020* (Office of Disease Prevention and Health Promotion, 2014). Included is the *National Action Plan to Improve Health Literacy*, which contains seven goals for improving health literacy with associated strategies (Baur, 2010). The strategy document assists organizations and individuals with program planning and action steps for multisector efforts to improve health literacy (Office of Disease Prevention and Health Promotion, 2010). It is based on the principle that services should be delivered in ways that are beneficial and understandable to enhance longevity, health, and quality of life (Office of Disease Prevention and Health Promotion, 2010). The Affordable Care Act and the Joint Commission on Accreditation of Healthcare Organizations include several health literacy provisions for insurers, clinicians, and organizations. Health literacy is a national health care priority, and these agencies call for action in medical communities to address limited health literacy.

Problem Statement

Uninsured wound patients face several challenges managing their condition, including cost and access to dressing supplies, follow-up care with a health care professional, and proper performance of the multistep wound dressing regimens. Teaching these multistep regimens is a challenge for clinicians as barriers to effectively communicate may inhibit understanding (Pieper, 2009). One of those barriers is health literacy (Pieper, 2009). Health literacy includes the functional, interactive, critical, and numeracy skills needed to function well in healthcare environments (Al Sayah, Majumdar, Williams, Robertson, & Johnson, 2013). Low health

literacy is a barrier to improving clinical outcomes (Al Sayah et al., 2013). Understanding the health literacy of a patient and directing education accordingly should allow for more effective teaching and better outcomes.

Due to the limited health literacy research in wound populations, investigating other diseases that have comparable self-care practices is warranted. Three such conditions are diabetes mellitus, chronic obstructive pulmonary disease, and congestive heart failure. The results of health literacy research in these conditions may be transferrable to interventions for wound populations. This leads to the clinically relevant PICOT question: in patients with chronic diseases, how does a health literacy assessment, compared to no health literacy assessment, impact health outcomes?

Sources and Search Process

An exhaustive literature search was conducted to identify published articles relevant to the PICOT question. The six databases systematically searched included: Cumulative Index to Nursing and Allied Health Literature (CINAHL), Cochrane Library, Education Resources Information Center (ERIC), National Guideline Clearinghouse, PsycINFO, and PubMed. The following keywords were used: *health literacy*, *assessment*, *assessments*, *outcome*, and *outcomes*. The additional use of the Boolean operators “AND” and “OR” were applied in appropriate databases to focus and narrow the search. The search was limited to English-language studies published in scholarly journals between 2007 and 2017. After completion of this initial search, all articles identified underwent manual review by title and abstract for the inclusion of chronic diseases. No exclusion criteria were applied.

In the CINAHL database search, all keywords, Boolean operators and the initial inclusion criteria were applied. This search yielded 173 articles (Appendix A). After additional review,

seven articles were chosen for critical appraisal. The Cochrane Library was searched using the keyword *health literacy* resulting in 11 articles (Appendix B). No inclusion criteria were applied to maximize results. All articles underwent manual review, and none were selected for critical appraisal due to lack of direct PICOT relevance. The ERIC database search included the use of Boolean operators with all keywords and the initial inclusion criteria. This search yielded 26 articles (Appendix C). After further review, two articles were chosen for critical appraisal. The National Guideline Clearinghouse database was searched using the keyword *health literacy*. This database has a set date range from 2011 to 2016; therefore, the inclusion criteria date range was not performed in this database. As noted in Appendix D, this yielded 21 articles. After manual review, no articles relevant to the PICOT were found. Appendix E details the PsycINFO database search which included the use of all keywords, Boolean operators and the addition of the inclusion criteria resulting in 171 articles. After further evaluation, seven articles were selected for critical appraisal. The PubMed database was searched using all keywords, the Boolean operators, and the field limit of “Title/Abstract.” This initial search yielded 242 articles (Appendix F), and after setting the initial inclusion criteria, 147 articles were identified. After manual review, four articles related to the PICOT underwent critical appraisal. To conclude the search, a hand ancestry search of the 20 articles undergoing critical appraisal resulted in three PICOT relevant articles that were not present in the initial search process due to publication before 2006. All three articles underwent further critical appraisal.

The search process of six databases plus an ancestry search led to an initial yield of 552 articles that met the inclusion criteria and a final yield of 23 studies directly related to the PICOT that underwent further critical appraisal. Ten final studies were chosen from these 23 based on level of evidence, PICOT, and clinical relevance and are detailed in Appendix G.

Critical Appraisal and Synthesis of Evidence

The ten final studies chosen for critical appraisal were quantitative in design. The majority were in the top two levels of Melnyk and Fineout-Overholt's (2015) hierarchy of evidence rating system. Appendix G details four level I studies (meta-analysis and systemic reviews) that included comprehensive database searches and valid appraisal methods to determine the strength of evidence. Although the systemic reviews exhibited heterogeneity in the number and types of included studies, they reported consistent results in their evaluation of low health literacy effects and intervention outcomes, indicating acceptable quality and validity (Appendix H). The five level II studies (randomized controlled trials) used the independent variable of health literacy level and performed multivariate regression analysis among subgroups of the dependent variables (Appendix G). The dependent variables were numerous and were measured with valid and reliable instruments (Appendix G). The studies were conducted with high quality as evidenced by scripted interventions with appropriate controls and statistically significant results (Appendix G). The level IV prospective cohort study consisted of urban wound patients and employed valid and reliable health literacy and self-efficacy instruments (Appendix G). This fair quality though underpowered ($n = 22$) study, had statistically significant results and yielded relevant findings in wound patients with low health literacy (Appendix G).

Overall, the ten studies exhibited a large degree of heterogeneity in the number of subjects (31-23,889), sample demographics, instrumentation, and statistical analysis methods (Appendix G). The mean age of subjects ranged from 11.5 to 76 years (Appendix H). The majority of studies consisted of at least 48% females (Appendix H). Four studies reported fewer subjects with low health literacy (30.8-37.2 %) than adequate or high health literacy (Appendix H). The majority of studies were conducted in outpatient clinics and focused on three chronic

diseases: diabetes mellitus, pulmonary disease, and cardiovascular disease (Appendix H). Bias was minimal with one study reporting information bias in chart review processes and another reporting measurement bias due to the use of a tool the researcher owned (Appendix G). All studies used valid and reliable health literacy assessment tools (Appendix G). Data analyses for the studies were conducted based on design and included *t*-tests, Fischer's exact test, multivariate models, and random effects models (Appendix G). Most studies reported confidence intervals, means, standard deviations, and significant findings (Appendix G).

Some studies evaluated the effect of health literacy level on outcomes, while others evaluated the impact of health literacy-sensitive interventions (Appendix H). Some looked at both (Appendix H). Patients with low health literacy exhibited significantly reduced adherence, self-care behaviors, health status, and disease knowledge (Appendix H). The studies of literacy-sensitive interventions included single and multiple education sessions and mixed-strategies encompassing four domains (Appendix H). Although intervention designs were variable, all reported statistically significant improvements in all health literacy levels with a greater effect on lower health literacy patients (Appendix G and H).

Evidence Conclusion

The evidence indicates the presence of reduced disease knowledge, self-care, and adherence in low health literacy patients. All patients benefit from literacy-sensitive interventions regardless of baseline health literacy. Similar to other low health literacy patients with chronic diseases, wound patients with low health literacy enroll less often in studies and have worse disease status. Most literacy-sensitive interventions include spoken and written communication, but alternative methods also improve outcomes. The body of evidence supports educational intervention efficacy for all literacy levels, but those with lower levels benefit from

more intense interventions (mixed strategies, multiple sessions). The tools available to measure health literacy are valid and reliable for assessing health literacy to allow for assessment of intervention efficacy and outcomes across groups.

Purpose Statement

A practice change in the form of an evidence-based pilot project was implemented with the purpose of improving wound knowledge and self-care with a literacy-supportive wound educational intervention that incorporated mixed strategies and multiple sessions in an uninsured wound population.

Theory Contribution to Utility of Evidence

The Health Literacy Skills Conceptual Framework (Squiers, Peinado, Berkman, Boudewyns, & McCormack, 2012) was chosen for development and design of this pilot project and is detailed in Appendix I. It systematically illustrates the pathway and relationships of the development and moderators of health literacy skills, their applications, and resultant outcomes (Squiers et al., 2012). The framework is built upon existing health literacy models and focuses at the level of the individual (Squiers et al., 2012).

This framework initially evaluates factors that influence the development and use of health literacy skills. Consistent with the framework, the pilot project assessed each participant's demographics, capabilities, and prior knowledge. This was conducted with a patient questionnaire, a wound knowledge pre-test, and a three-question Brief Health Literacy Screen (Chew, Bradley, & Boyko, 2004). Next, a health-related stimulus in the form of a wound educational intervention reviewing general wound knowledge, dressing change steps and schedule placed a health-literacy demand on the participant, and they used their health literacy skills to comprehend the stimulus. Next, an assessment of comprehension of the stimulus was

conducted with a Wound Knowledge Post-test and a Wound Dressing Steps Performance Checklist. To address mediators, an immediate reteach of concepts missed on the post-test and performance checklist were addressed with participants. In congruence with the framework, the health-related behavior of wound self-care and the outcome of wound knowledge and healing was assessed through valid measures.

Evidence-Based Practice Model

Larrabee's (2009) Model for Evidence-Based Practice Change systematically guides the implementation of research into practice and was utilized to guide pilot project implementation. Appendix J presents the model's six-step process that includes a practice needs assessment, identification of evidence, critical analysis of high-level evidence, designing practice change, change implementation, and integration and maintenance of the change (Larrabee, 2009). This model was chosen due to its extensive use in nurse-led evidence-based practice projects and its application by nursing and non-nursing disciplines in diverse settings (Larrabee, 2009). In the application of the model to the pilot project, step one identified the problem of limited wound knowledge and understanding of multi-step dressing application processes in uninsured wound patients in an outpatient clinic. In step two, a comprehensive source and search process produced ten applicable studies that led to step three, critical analysis of the evidence. This analysis suggested an effective approach would be to design literacy-sensitive education materials that incorporated mixed strategies and were conducted over multiple sessions. Step four consisted of designing the practice change through the creation of a literacy-sensitive educational intervention focused on wound knowledge and dressing change instructions utilizing evidence-based health literacy strategies. In step five, the implementation of the practice change was conducted, and outcome evaluations and project conclusions were determined. The final

step of implementation included ongoing communication and use of the materials with patients, integration and use of the education program by the clinic's wound nurses, and monitoring of the practice change to ensure congruency with practice and project sustainability.

Project Methods

A correlational design was used to answer the following pilot project questions: In uninsured adult wound patients with adequate and inadequate health literacy, does wound knowledge improve after a literacy-sensitive educational intervention and remain improved over time? Does wound self-care improve after a literacy-sensitive educational intervention and remain improved over time? Do patients exhibit an improved wound status over time after a literacy-sensitive educational intervention that focuses on wound knowledge and self-care?

Ethics

Proper standards of conduct were instituted to ensure education material design, project recruitment and conduct, and instrument handling followed the highest ethical standards. All wound educational material content were obtained from valid and reliable wound education sources. To ensure congruency with clinical practice, all materials underwent additional validation by three wound experts. Cultural congruency of the education materials was evaluated before pilot implementation with a random sample of the clinic's patients that were ethnically diverse and included English and Spanish speakers. The education materials detailed in Appendix K were designed as literacy-supportive, and measures were taken to ensure support for low literacy populations. All educational materials, project instruments, consents, and the project recruitment script were graded for literacy based on two valid and reliable readability formulas (Flesch Reading Ease and Flesch-Kincaid Grade) with the goal of a fifth-grade reading level or less (Badarudeen & Sabharwal, 2010; Eckman et al., 2012). All materials met this goal.

The poster and pamphlet also included other literacy-supportive design elements including simple pictorials, limited words, and a layout design consist with current education materials that the clinic's population is familiar with (Badarudeen & Sabharwal, 2010).

All written materials were offered in English and Spanish and include the consent, project educational materials, the demographic questionnaire, wound knowledge test, and the recruitment script. All materials were initially written in English and confirmed literacy-supportive and congruent with a fifth-grade reading level or less. The Arizona State University Institutional Review Board (IRB) approved the English versions of all materials. Next, a certified Spanish medical interpreter translated the materials from English to Spanish. Then another certified Spanish medical interpreter back-translated the materials from Spanish to English. A final evaluation was conducted by a Spanish linguistics professor from Arizona State University who identified and clarified any discrepancies between the two translations and also ensured literacy-supportive readability in low-literacy Spanish language populations. Upon finalization of the Spanish materials, they were submitted along with a Translation Certification Form to the IRB and underwent approval for use.

Approvals. Site approval, detailed in Appendix L, was received from the medical director at the outpatient medical clinic where the wound clinic is operated. The site did not require an internal IRB process. Appendix M details the approval of this pilot project by the Arizona State University IRB including all project materials, methods, and data collection procedures. Appendix N contains the measurement tool approvals from Mary Chew for the use of the Brief Health Literacy Screen and Barbara Bates-Jensen for the use of the Bates-Jensen Wound Assessment Tool.

Project risks and benefits. No foreseeable risk was identified with the pilot project. Direct participant benefits included improved knowledge and skills in the ability to take care of their wound in the home, leading to appropriate wound self-care by cleaning and performing the dressing changes properly and observing for early infection or other wound concerns. No compensation or credit was provided to participants.

Recruitment and consent. Potential participants presenting for wound care at an urban charity outpatient medical clinic were invited orally to participate using a recruitment script (Appendix O). For Spanish speakers, a certified Spanish medical interpreter read the Spanish recruitment script (Appendix O). Participants who verbalized interest underwent verbal consent. Since participants included English and Spanish speakers, this author, an English speaker, obtained verbal consent from all English-speaking participants and utilized a certified medical interpreter for the Spanish-speaking participants. Appendix P details the English and Spanish verbal consents utilized in pilot project implementation.

Privacy and confidentiality. Verbal consent was conducted in the participant's exam room to ensure privacy and confidentiality. Project data was obtained, accessed, and stored solely by this author. All written materials were kept in a folder that was not in plain view when in use and when not in use was locked in a secure location. Information placed on the computer was password protected. Participant IDs were linked via an anonymous reproducible ID in which participants were instructed to pick the first three letters of their mother's name and the last three digits of their telephone number. This anonymous ID was used to collect and analyze the data. No participant identifying data was collected. All written data was promptly shredded at the conclusion of the project.

Setting and Organizational Culture

The setting for the pilot project took place at a wound clinic that operates within an urban charity outpatient medical clinic in South Phoenix. The medical clinic operates within a large 501(c)(3) nonprofit charity that not only provides free medical care to the uninsured and working poor in South Phoenix but also has additional departments that support the mission of the organization to provide aid in the form of food, shelter, clothing, healthcare, and financial support. The mission of the clinic is to “sustainably increase the health and well-being of the community, by empowering those who have the greatest need, yet the least resources” (SVDP, n.d.). The clinic leadership and staff are devoted to this mission. As a result, they expressed interest and enthusiasm about the pilot project, since project outcomes could improve health education and empower the population they serve to improve self-care. Support provided by the clinic included space, materials, Spanish medical interpreters, and adjustments to the wound schedule appointments to allow time for project recruitment and implementation.

Innovation Leadership and Collaboration

Applying an innovation leadership mindset to pilot projects supports the translation of research evidence into novel solutions, encourages diverse approaches and knowledge development, and guides integration of pilot projects into organizational systems. Evidence suggested that complex multi-step regimens can be effectively taught and designed to improve outcomes. Translating this evidence to wound care dressing regimens required innovation. Innovation was called for in this project due to the lack of available wound education materials that addressed the complexity of wound care regimens that varied with each patient. In the search for an answer, the discovery of a small sticker with a heart on an illiterate patient’s medication bottle led to its adaption, alteration, and application to the pilot. This sticker concept

was applied to the educational materials and met the needs of each patient's unique wound dressing regimen and provided literacy support for low-literacy and illiterate participants.

Team and interprofessional collaboration helped drive pilot project design through the sharing of diverse approaches and knowledge development. Throughout project development, the author brought together a diverse team to encourage sharing of wound education concepts, patient needs, and consultation on material design. The team consisted of point-of-service workers, knowledge workers, wound nurses, and clinic leadership, all stakeholders in this pilot project. The author encouraged idea-sharing and open communication. As a result, a diverse range of ideas, approaches, and new knowledge was created. In future collaborations, emergence occurred when the collaborative team prioritized their ideas on wound education and material design through consensus and sharing and co-created materials and an education process that were cohesive with the needs of the clinic and its patients. The author also collaborated interprofessionally to enhance the educational materials, validate the study instruments and materials, and appropriately translate all pilot materials. Collaboration was conducted with graphic designers, a photographer, several medical interpreters, patients, wound experts, and a Doctor of Nursing Practice project mentor. Through these diverse collaborations, the author was exposed to divergent methods for project design and recommendations that were culturally congruent with the population. As a result, project materials were successfully literacy-supportive and were reported by participants as having high usability and understanding.

Innovation leadership guided the pilot projects implementation into the clinic. Through a systems-based approach, the author focused on the medical assistants, who were at the point of interaction of multiple factors critical to the project: recruitment of patients, wound clinic flow, medical interpreting, and patient scheduling. These key point-of-service workers were integral

in supporting pilot project implementation. The author worked collaboratively with them to understand current wound clinic flows and co-created an integrated process that was cohesive with current workflows, provided time for pilot project institution, and the dedication of resources to support pilot institution. As a result, pilot project implementation was effectively integrated and resulted in the ongoing presence of medical interpreters, patient participation, and an appropriate allotment of time during clinic hours to conduct the pilot.

Participants

Adults with acute or chronic wounds were recruited for this pilot project. Inclusion criteria were: adults, age 18 years or older, Spanish or English speaking, and able to provide consent. Exclusion criteria included wounds that required Negative Pressure Wound Therapy or Profore Multi-layer Compression Banding system since both of these treatments do not require patients to perform a wound dressing change.

Procedures

A literacy-sensitive educational intervention focusing on wound knowledge and dressing change instructions was conducted with the use of the health literacy strategies supported by the evidence (spoken and written communication, teach-back method) over several sessions (Kim & Lee, 2016). A poster was designed in English and Spanish focusing on wound knowledge and included the stages of healing, signs of infection, and pictures of items that are “good” and “bad” for wounds (Appendix K). A corresponding pamphlet included the information from the poster, a wound dressing change schedule, and a ten-step dressing change process (Appendix K). These same steps were converted to stickers and placed on the wound products allowing for patients to match steps to the products (Appendix K).

After participants underwent verbal consent, and chose the English or Spanish pilot materials, their unique identifier was placed in the upper left-hand corner of the pilot materials. During visit one, the participant filled out the Wound Education Participant Questionnaire (Appendix Q) that included basic demographic questions and a three-question Brief Health Literacy Screen (Chew, Bradley, & Boyko, 2004). The participant then took the Wound Knowledge Pre-test (Appendix R). The author, a wound care nurse practitioner, recorded wound healing status using the Bates-Jensen Wound Assessment Tool (Appendix S) (Bates-Jensen, Vredevoe, & Brecht, 1992). Usual care for the wound visit was then performed. Next, an educational intervention was orally presented using the teach-back methodology with visual aids (poster and brochure (Appendix K)) that detailed basic wound knowledge, self-care, dressing change steps, and dressing change schedule. Since each patient received a unique dressing treatment and dressing cover based on wound diagnosis, a sticker with a picture of the prescribed treatment and dressing cover was placed on step six and seven of the wound dressing brochure (Appendix K) and the corresponding wound dressing material packages. The participant then took the Wound Knowledge Post-test (Visit 1) (Appendix T) and performed the dressing change steps on a wound model. While the participant performed the steps, the author observed each step and filled out the Wound Dressing Steps Performance Checklist (Visit 1) (Appendix U). For any missed questions or steps, education by the teach-back methodology was conducted utilizing the same visual aids (poster and brochure). At wound care visits two and four, the author assessed and recorded the wound healing status using the Bates-Jensen Wound Assessment Tool (Appendix S). Participants took the Wound Knowledge Post-test (Visit 2, 4) (Appendix T), and performed the dressing change steps on a wound model. The author observed each performance step and filled out the Wound Dressing Steps Performance Checklist (Visit 2, 4) (Appendix U).

For any missed questions or steps, education by the teach-back methodology was conducted utilizing the same visual aids as at visit 1 (poster and brochure) (Appendix K). The study activities took 15 minutes per visit for each of the three visits. Visit two was scheduled one to two weeks from visit one, and visit four was scheduled four to six weeks from visit one.

Outcome Measures

The outcomes measured in this pilot project included wound knowledge and self-care in adequate and inadequate health literacy participants. Health literacy was measured using Chew, Bradley, and Boyko's (2004) Brief Health Literacy Screen. The three-question screen detailed in Appendix V, asks about confidence in forms, reading hospital materials, and learning about medical conditions (Chew et al., 2004). Answers are assigned a number from one to five to create a summative scale with a possible score range of three to fifteen. A score of nine or higher is correlated with inadequate health literacy and scores eight or lower with adequate health literacy (Sarkar, Schillinger, Lopez, & Sudore, 2010). The screen has adequate validity when compared to two established health literacy screens (AUROC=0.87, $p<.05$, 95% CI [0.78-0.96], $p<.05$) and high internal consistency reliability ($\alpha = .80$) among clinic and hospital patients (Chew et al., 2004; Wallston et al., 2014).

The wound knowledge outcome was chosen due to internal evidence from the charity clinic reporting that the low health literacy demographic had limited understanding in these areas. Additionally, high-level evidence showed literacy-sensitive educational interventions focused on disease knowledge resulted in statistically significant improvement in knowledge and disease outcomes for all health literacy levels (Al Sayah et al., 2013; Hahn et al., 2015; Kim & Lee, 2016). The wound knowledge outcome was measured with a wound knowledge test created by the author from the intervention's educational materials (poster, brochure). The wound

educational materials were obtained from valid sources including clinical guidelines published by the Association for the Advancement of Wound Care (n.d.) and the publication *Chronic Wound Care: The Essentials* (Krasner, 2014). The test content included basic wound self-care activities and signs and symptoms of infection. The ten-item test, detailed in Appendix R and T, was constructed and scored based on the Diabetes Knowledge Questionnaire (DKQ) by Garcia, Villagomez, Brown, Kouzekanani, and Hanis (2001) due to its established use in health literacy studies, validity in Spanish-speaking patients, and adequate reliability ($\alpha = .78$). Similar to the DKQ, questions in the wound knowledge test were written in the form of “my” statements with the answer options “Yes,” “No,” or “Don’t know.” Three wound experts reviewed the test contents, and they were edited based on feedback. All were in agreement on the sufficiency of the test’s final form, lending adequate face validity to the test. The test did not undergo reliability testing.

The second outcome measured in the pilot project was wound self-care. This outcome was chosen due to internal evidence noting self-care impairments such as improper dressing change performance in the home and studies such as that of Kiser et al. (2012) reporting statistically significant improvement in self-care in all health literacy levels after a literacy-sensitive educational intervention that included a multi-step inhaler technique, similar to dressing changes in that it was a multi-step process. The areas of study for wound self-care included the performance of dressing steps, reporting of the dressing schedule, and measurement of wound healing. The performance of the dressing steps and reporting of the dressing schedule were measured with a Wound Dressing Steps Performance Checklist created by the author. Appendix U details the eleven-item checklist and includes the educational brochure steps and schedule. The dressing steps are based on clinical guidelines published by the Wound Healing Society

(n.d.). Checklist development and scoring were modeled from a literacy-sensitive educational intervention for patients using metered-dose inhalers, a process that requires a similar step-wise approach (Kiser et al., 2011). Face validity was deemed adequate by three wound experts who reviewed the checklist contents and provided no further feedback. The checklist did not undergo reliability testing. Wound healing status was measured with the Bates-Jensen Wound Assessment Tool (Bates-Jensen, Vredevoe, & Brecht, 1992). A wound professional conducted the assessment in which 13 items were scored (Bates-Jensen et al., 1992). The items, detailed in Appendix S, include parameters such as measurement and wound condition (Bates-Jensen et al., 1992). A total score is calculated with lower scores indicating wound improvement and higher scores indicating wound degeneration (Bates-Jensen et al., 1992). The tool was content validated by nine expert wound nurses (content validity index value=.91, $p=.05$) and the tool was deemed to have adequate reliability ($\alpha = 0.91$) in the assessment of wound status (Bates-Jensen, 1997).

Data Collection and Analysis Plan

Data were collected solely by the author and for each participant included demographic information (age, sex, language preference, race/ethnicity, visit type), a three-question Brief Health Literacy Screen (Chew et al., 2004), four Wound Knowledge Tests, three Wound Dressing Steps Performance Checklists, and three assessments of wound healing using the Bates-Jensen Wound Assessment Tool (Bates-Jensen et al., 1992). Data analysis began with the evaluation of missing data on the instruments. No missing answers or items were noted. Participants recorded all answers on paper. All variables were taken from paper and directly entered into SPSS 23 statistical software, followed by three checks for input accuracy. Descriptive statistics were used to analyze participant demographic characteristics, health literacy, wound knowledge, dressing performance, and wound healing. The independent-

samples *t* test was conducted to compare the means of each health literacy group (adequate versus inadequate) of the study variables (health literacy, wound knowledge, performance, healing). Wound knowledge, performance, and healing were evaluated using the paired-samples *t* test to compare means from visit one, visit two, and visit four. These underwent further subgroup analysis by health literacy status (adequate versus inadequate). A value of $p < .05$ was used to establish statistical significance.

Budget

The budget for the pilot project (Appendix W) including materials and resources for pilot development and implementation totaled \$319.10. Many of the project costs were one-time incurrences related to educational material development. The education brochures and corresponding stickers were purchased in bulk and were expected to last an additional year.

Project Results

Demographic Data

A convenience sample of 21 participants completed the pilot project. Table 2 details the characteristics of the participants. The mean age of the participants was 46.5 (SD = 14.8) years with a wide range of ages reported (20 to 85 years). Roughly half were male (57%), the majority spoke Spanish (67%), and identified their race as Hispanic (81%). Other races participating included White, non-Hispanics (5%), Black or African Americans (10%), and one participant identified as Asian. Nearly half of the participants were new patients of the wound clinic (43%).

Health Literacy

The participant sample self-reported both adequate ($n=12$) and inadequate ($n=9$) literacy levels based on scores from the Brief Health Literacy Screen (Chew et al., 2004). Further subgroup analysis of the adequate versus inadequate health literacy groups demonstrated that

they were well matched demographically (Table 2). Both subgroups contained the same number of Spanish speaking participants. Although the age range for the participants was wide, there was no statistically significant difference in mean age ($t(19) = -2.03, p = .057$) between the subgroups. One notable difference was the low number of female participants reporting inadequate health literacy ($n=2$). An independent-samples t test comparing the mean health literacy scores of the inadequate and adequate health literacy groups found a significant difference ($t(19) = -5.08, p < .001$). The mean score of the adequate health literacy group was significantly lower ($M = 5.92, SD = 2.07$) than the mean score of the inadequate health literacy group ($M = 9.78, SD = 1.093$). This was an expected finding and allows for the comparison of educational intervention effects in both literacy groups.

Wound Knowledge

Baseline wound knowledge in participants was adequate with more than half of the questions answered correctly ($M = 7.71, SD = 1.52$) on the Wound Knowledge Pre-test (Table 3). There was no significant difference in baseline wound knowledge between those with adequate health literacy ($M = 7.58, SD = 1.62$) and those with inadequate health literacy ($M = 7.89, SD = 1.45$), $t(19) = .45, p = .66$. This trend continued in all three post-tests in which no significant difference in mean knowledge scores was appreciated between the adequate and inadequate health literacy participants. After the educational intervention wound knowledge scores increased on the post-test at visit one in all participants ($M = 9.57, SD = .87$) and remained increased at visits two and four (Table 3). A paired-samples t test was calculated to compare the mean Wound Knowledge Pre-test scores to the mean of all three post-tests (Table 4). A statistically significant increase in mean wound knowledge scores was found comparing the pre-test to the post-test at visit one ($t(20) = -5.15, p < .01$) suggesting an immediate positive

educational intervention effect on wound knowledge in the participants. This effect continued in future wound visits with statistically significant sustained increases in wound knowledge scores at visit two ($t(20) = -5.42, p < .01$) and visit four ($t(20) = -5.13, p < .01$) compared to pre-test scores.

Paired-samples *t* test calculations of the health literacy subgroup were calculated comparing the mean Wound Knowledge pre-test scores to the mean of all three post-tests. Both the adequate and inadequate health literacy participants showed similarly increased and sustained wound knowledge with statistically significant improvements in mean wound knowledge scores at visit one, two, and four (Table 4) suggesting a positive educational intervention effect on all literacy levels through the pilot.

Consistently missed questions included number five “letting my wound dry out helps wound healing” (32% missed) and number two “keeping my wound uncovered helps my wound heal” (18% missed). These findings were not surprising and were consistent with clinical practice in which patients reported frequent wound drying and uncovering practices prior to the pilot. Despite the educational intervention addressing recommendations to avoid drying and uncovering, participants did continue to miss these questions on the post-tests.

These pilot findings suggest improved wound knowledge after the literacy-supportive wound education intervention that remained improved over time in all health literacy levels.

Wound Self-care

Participants scored consistently well on the Wound Dressing Steps Performance Checklist across all visits (Table 5). As predicted, immediately after the initial educational intervention at visit one, participants scored high ($M = 10.38, SD = 1.12$) on the Wound Dressing Steps Performance Checklist. Wound dressing performance and schedule reporting scores

remained high and increased slightly from visit one to visit two ($M = 10.71$, $SD = .56$). This same trend continued at visit four with high wound dressing performance scores and an additional increase in the mean ($M = 10.86$, $SD = .36$). These increases were not found to be statistically significant with paired-samples t testing comparing the mean of visit one to visit two ($t(20) = -1.23$, $p = .232$) and visit four ($t(20) = -2.02$, $p = .056$). This was not unexpected since participants performed well initially, had supportive wound dressing educational materials, and continually repeated the dressing performance in the home. The small jumps in mean scores after each visit suggest increased and consistent proficiency in wound dressing changes over time. This is congruent with the author's observations during the pilot. By visit four, the participants had memorized the steps, performed them with confidence, and were eager to demonstrate their skills.

Subgroup analysis of those with adequate and inadequate health literacy showed improvement in the Wound Dressing Steps Performance Checklist scores with each progressive visit but participants with inadequate health literacy improved and then peaked at visit two. Those with adequate health literacy continued to improve through visit four (Table 5). At visit one, the adequate health literacy participants had slightly higher scores ($M = 10.58$, $SD = 1.17$) than those with inadequate health literacy ($M = 10.11$, $SD = 1.05$). At visit two, both groups continued to show small improvements in the dressing performance score (Table 5) but the inadequate health literacy groups remained at its visit two score mean through visit four ($M = 10.78$, $SD = .44$) unlike the adequate group, whose highest wound dressing performance scores were at visit four ($M = 10.92$, $SD = .29$). Comparison of subgroup findings on the independent-samples t test of mean scores at each visit and paired-samples t testing comparing the mean

subgroup's scores of visit one to visit two and visit four were as expected not statistically significant due to little variance.

The most frequently missed wound dressing performance steps included number five "applied skin protectant to periwound" (14% missed) and number two "put gloves on" (6% missed). The missed periwound skin protectant step was not surprising since applying protection to the periwound is a relatively new concept for patients. Participants recalled accurately their dressing schedule almost all of the time (97%).

These pilot findings suggest that self-care improved after a literacy-supportive educational intervention and remained improved over time in all health literacy groups.

Wound Healing

Initial wound healing measurements with the Bates-Jensen Wound Assessment Tool (Bates-Jensen et al., 1992) (Appendix S) were on average midway on the tool's wound status continuum between "healed" and "wound degeneration" ($M = 31.48$, $SD = 4.90$). Table 6 details score progression from visit one through visit four. Wound status progressed towards wound regeneration (healing) at visit two ($M = 27.05$, $SD = 6.17$) and more so by visit four ($M = 19.14$, $SD = 8.30$). Paired-samples t tests confirmed statistically significant improvements in mean wound healing scores from visit one to two ($t(20) = 4.86$, $p < .01$) and from visit one to four ($t(20) = 9.60$, $p < .01$) suggesting healing effect in all participants.

The adequate and inadequate health literacy participants were well matched regarding wound healing status which was surprising due to the wide variety of wound types and variable chronicity of the wounds enrolled in the pilot. Mean healing status scores were similar between the adequate and inadequate health literacy groups at visit one, two, and four with a consistent trend towards healing noted in all groups by visit four (Table 6). An independent-samples t test

was calculated comparing the mean score of adequate health literacy participants to the mean score of the inadequate health literacy participants at visit one, two and four. No significant differences between the means were found between the groups at visit one ($t(19) = .59, p = .559$), visit two ($t(19) = .75, p = .464$), and visit four ($t(19) = .40, p = .693$). Paired-samples t testing showed statistically significant improvements in mean wound healing scores from visit one to two for adequate health literacy participants ($t(11) = 3.80, p = .003$) and inadequate health literacy participants ($t(8) = 2.87, p = .021$). This healing effect continued in the comparison of means for visit one and four for adequate health literacy participants ($t(11) = 6.60, p < .01$) and inadequate health literacy participants ($t(8) = 6.91, p < .01$).

These pilot findings suggest that participants, regardless of health literacy level, exhibited improved wound status (healing) over time after a literacy-supportive educational intervention that focused on wound knowledge and self-care.

Discussion

In this pilot project, uninsured wound patients with various wound types and duration underwent a literacy-sensitive educational intervention that focused on general wound knowledge and self-care. Initial demographic data from the medical clinic suggested a low health literacy population, and when the author investigated studies on wounds and health literacy, a single cohort study reported patients with low health literacy had larger and older wounds compared with those of higher health literacy (Margolis et al., 2015). Internal evidence of the medical clinic suggested a need for wound knowledge support and dressing assistance. Evidence verified these clinical findings noting the association of reduced knowledge and self-care in low health literacy populations (Al Sayah et al., 2013; Egbert & Nanna, 2009). As a result of this information, pilot design focused on addressing wound knowledge and self-care,

with attention to all health literacy levels. High-level evidence suggested designing the educational intervention with the use of mixed literacy strategies over several sessions in order to improve knowledge and self-care outcomes (Berkman, Sheridan, Donahue, Halpern, & Crotty, 2011; Dewalt et al., 2012; Eckman et al., 2012; Kim & Lee, 2016). Based on this research, the author utilized oral and written communications over three clinic visits. Each patient's unique wound dressing treatment was innovatively addressed through the use of stickers and applying them not only to the multi-step wound brochure, but to product bags to facilitate matching products to the steps in the process. Several literacy-supportive strategies were employed to enhance learning. All written communications (materials) were designed according to current recommendations for literacy-sensitivity, which included the use of readability formulas, simple pictorials, and limited words (Badarudeen & Sabharwal, 2010). Also, the author utilized several medical interpreters to ensure readability in low literacy Spanish populations. Oral communications included simplified language and the teach-back methodology. Additionally, the use of wound models allowed participants to practice the wound dressing steps repeatedly and comfortably. The pilot results indicated the efficacy of the above. Increasing wound knowledge and dressing performance led to improved healing for all health literacy levels.

The pilot's demographic diversity supports applicability to wider wound populations. The pilot's demographics were representative of the wider medical clinic's population and consisted mostly of Spanish-speaking participants of Hispanic origin. Other ethnicities were represented. Both English and Spanish materials were utilized. The age range was wide. Both new and follow-up patients were represented. There was a large variety of wound types, including acute surgical wounds, venous ulcers, and chronic diabetic foot wounds. The pilot consisted of two health literacy groups (adequate, inadequate) that were well matched

demographically, thereby allowing for the comparison of education intervention efficacy between these groups. Similar to Kiser et al. (2011) in their trial of a literacy-sensitive intervention teaching a multi-step inhaler technique, health literacy levels were determined to provide an understanding of intervention benefits and determine if adjustments were needed. These demographics represent typical patients who present to outpatient wound clinics and therefore enhance project generalizability to other wound clinic populations.

In this pilot, wound knowledge improved in all participants. Wound knowledge significantly improved from baseline immediately after the literacy-sensitive education intervention and at visits two and four, reflecting immediate understanding and continued retention of the knowledge four to six weeks later. These same findings were present in both the adequate and inadequate health literacy groups suggesting efficacy at all literacy levels. These findings were expected, and were consistent with the results of Eckman et al. (2012) and Kim and Lee (2016), in which disease-specific knowledge increased for all literacy levels with an educational intervention that used mixed educational strategies. One aspect of the educational intervention was the immediate reteach of missed questions to address knowledge gaps right away. This likely assisted with continued knowledge proficiency. Surprisingly, no significant differences were present between the pre-test and post-test knowledge scores across all visits for both health literacy groups. Reasons for this finding may be that the literacy-sensitive design of the test, which measured low on the readability formulas, allowed improved understanding of the questions in both literacy groups. Other factors may have included knowledge test design, lack of power, and previous wound knowledge acquisition.

Certain areas of wound knowledge tied to cultural practices were difficult to change for some. Participants consistently scored incorrectly on wound care's biggest myths: letting

wounds dry out and leaving them uncovered is beneficial. This misconception goes back centuries and is considered an outdated practice. Despite repeated education on this missed question, four participants answered it incorrectly on the final post-test. This reflects the challenge of educating patients on stopping outdated practices, and is an important area to provide continued education at future wound visits.

Wound self-care improved after a literacy-sensitive educational intervention and remained improved over time. This was reflected in the dressing performance scores which remained consistently high throughout all visits, reflecting an understanding of the dressing steps and ongoing correct application. Nonsignificant small increases in mean dressing performance scores were noted from visit one to four suggesting that re-teaching missed steps at each visit may have contributed to future performance. Both literacy groups had similar mean performance scores with no significant difference between them throughout the study. This was likely due to the comprehensive educational program that used the teach-back methodology, practice on a wound model, and ongoing practice with visual aids. These findings were consistent with those of Kiser et al. (2012) in which the teach-back method, a visual aid, and oral communications were used in teaching multi-step inhaler techniques with noted improvements for all literacy levels. Similar to this pilot, their mean inhaler technique scores non-significantly improved in all literacy levels and both groups (low and higher literacy) had similar baseline and follow-up scores (Kiser et al., 2012).

Determination of consistently missed steps or technique direct future education design and teaching emphasis. Kiser et al. (2012) noted a consistently missed step in inhaler technique, breathing out completely before inhalation. This finding was similar to the literature and served as an area of consideration for education technique adjustment. The most frequently missed

wound dressing steps by patients has not been reported in the literature. In this pilot, patients primarily missed applying skin protectant to the periwound. This was not surprising since most were not familiar with periwound protection and the concept of protecting the intact skin around the wound. One solution could be to eliminate this step for low-exudating wounds. Perhaps a better approach would be to reteach the process in a different manner or at a different step to allow for improved comprehension. Checking in with patients on this step at future visits is critical since it is a new concept and likely to be missed.

Participants overall performed well reporting their wound dressing schedule accurately, an important step to prevent infection and prolonged contact of the wound with soiled dressings.

Participants significantly demonstrated an improved wound status (healing) with each visit, suggesting a healing effect after the intervention. These were surprising findings, considering the variety of wounds represented, and the multitude of factors that affect healing (e.g., diabetes). Unlike the study of Margolis et al. (2015), which noted larger and more prolonged wounds in low health literacy patients, this pilot showed no baseline differences in wound scores between those with adequate and inadequate health literacy. This trend continued through visit four, suggesting similar healing effects in both groups. These findings suggest that proper and consistent wound care performance by patients impacts healing and emphasizes the importance of effective literacy-supportive education of uninsured wound patients on specific knowledge and self-care dressing practices.

Impacts

Patient. The results of this pilot project and the innovative educational aids utilized have a direct patient impact. As a result of this literacy-sensitive education intervention, participants of all literacy levels gained wound knowledge, consistently demonstrated performance of their

wound dressing, and, as a result, continued to progress towards healing. Most notable was the confidence developed by visit four. Most, if not all, participants reported their dressing schedule and demonstrated their dressing change correctly. They learned the language of wound care, asked more informed questions, and were quick to identify early signs of infection. Since the materials were developed with patient input, patients easily understood the educational aids. The participant's knowledge retention is likely to have an impact on future wounding and the ability to note wound concerns and provide proper self-care early.

Most importantly, this pilot addressed the wound educational needs of the Hispanic and Spanish-speaking participants. This understudied group is the largest ethnic minority in the United States (United States Census Bureau, 2010). Due to lower health insurance rates, they are likely to perform their own wound care. This pilot addresses their educational needs.

Provider. This pilot enhances patient-provider communication. Due to the literacy-supportive design, participants of all health literacy levels gained an understanding of their wounds and the dressing process, and as a result, had improved dialogue and sharing with the author. The easily used educational intervention was integrated into the visit after the history and physical was performed, and after informing the patient of their wound diagnosis. Also, the innovative use of stickers addressed the complexity of unique dressing regimens in an easy and simplified form. Lastly, just about any medical personnel can perform the educational intervention including nurses, medical assistants, residents, and students.

System. The pilot project had direct system impacts on the urban wound clinic. Due to the design of the educational aids, the products were organized into bags containing seven days of supplies. Matching product stickers were placed on the bags. This allowed for an appropriate distribution of the products based on the patient's wound schedule and less waste. As a result of

less unused product being distributed, the clinic needed to order fewer supplies and saved money. With this new organizational system, the wound nurses were able to efficiently grab the needed materials. No longer were they spending time searching for materials in the clinic's wound supply closet. As participants progressed towards healing, fewer supplies and visits were needed. This allowed increased availability of products and clinic appointments for new patients.

Policy. Few clinics offer charity wound care for the uninsured. This pilot project lends feasibility to support policy for wound care for the uninsured. The pilot supports the use of an educational intervention that develops the needed wound knowledge and dressing application skills for this population, so they are able to perform proper self-care. Due to the organization of the materials, wound products can be distributed appropriately with reduced waste.

This project also supports health insurance policy changes that effect coverage of home health or wound specialty care. With reductions in covered services such as home health and wound specialty care, patients will be required to perform their own dressing changes. This education program addresses the needed teaching, and this teaching can be conducted in a variety of settings, including primary care.

Sustainability

Currently, the pilot's educational intervention and aids continue to be utilized by the wound clinic nurses, provider, and patients. Due to educational aid congruency with the needs of the clinic and patients, use in a variety of wounds, and the literacy-sensitive design, their use is likely to continue. The educational aids can be adjusted for changes in products. When the patient has a wound product change, a new brochure with the appropriate product sticker is placed. They also can be adjusted for future wound products, by taking pictures of the new

products and ordering the corresponding stickers online. The educational intervention is easily integrated into the clinic visit after the wound diagnosis is given and the education can be done quickly since the educational materials are already organized. Wound nurses and medical assistants can be trained in teaching the wound education and use of the teach-back methodology. Providers can work collaboratively with their wound care team, and each teaches a section of the education. Utilizing this team approach ensures education is covered from visit one and through future visits as well.

Project Strengths

This pilot project has several strengths. The project's educational methodology and aids were well developed and well translated to meet the educational needs of all health literacy levels. They can be utilized and distributed in all settings where wound care occurs at little cost, since the only purchases required are the poster, brochures, and stickers. The project met the needs of the urban wound clinic by providing an educational program to teach complex wound self-care in a simplified manner. As an added bonus, there was less material use and improved efficiency. Most notably, Spanish-speaking participants were provided literacy-sensitive education that met their needs. The pilot results supports the assertion that a wound educational intervention on general knowledge and self-care over several visits can increase wound knowledge, dressing application proficiency and dressing schedule reporting, and effect healing in all literacy levels of English and Spanish-speaking patients.

Project Limitations

There are notable limitations to this pilot project. A control group would have strengthened conclusions about the educational intervention effects, especially in the area of wound healing. Also, the sample size was too low to allow for valid Pearson's correlation

calculations. Also, the Wound Knowledge Test and Wound Dressing Steps Performance Checklist were only content validated. Efforts to determine further reliability and validity were not conducted. Finally, the pilot did not evaluate or control for comorbid conditions that can influence wound healing, therefore limiting the generalizability of the healing effects noted by the educational intervention.

Conclusion

Uninsured wound populations tasked with completing their own dressing changes require education on general wound information such as signs and symptoms of infection and instruction and skill development on how and when to apply their wound dressings. Low health literacy contributes to reduced disease knowledge and self-care ability. When coupled with dressing complexity, impairments in wound healing and other wound complications can occur. Findings from this pilot suggest that a literacy-sensitive educational intervention that utilizes mixed literacy strategies with repeated education for missed areas at future visits increases wound knowledge and self-care, and positively impacts wound healing. This project led to the development of innovative educational aids that simplified the dressing steps and matched steps with wound products. Also, the educational intervention streamlined an urban wound clinic's wound education into an organized process that could be conducted by all healthcare personnel, addressed the education needs of English as well as Spanish-speakers, and led to reduced wound product waste and cost. Findings from the pilot were congruent with previous research conducted in other chronic diseases with multi-step processes in that literacy-sensitive education improved outcomes for all health literacy levels. This pilot supports current health literacy initiatives calling for the delivery of healthcare services that are understandable over the full range of literacy levels. Although generalization to larger wound populations is limited, the pilot

supports efforts to develop and employ literacy-sensitive wound education in uninsured English and Spanish speaking populations.

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Table 1

Wound Clinic Demographics

Characteristic	%
Gender	
Male	48
Female	52
Country of Origin	
Mexico	73
United States of America	18
Other	9
Language	
English	28
Spanish	72
Other	1
Education	
Less than 8 th grade	33
High school or GED	54
2-year college	5
4-year college	6
Post graduate education	1
Race	
Black	4
Hispanic	79
Other	2
Native American/Asian	2
White	13

Note. Adapted from *Patient demographics last six months* [Data File], by M. Lee, retrieved

November 11, 2016 from <https://athenanet.athenahealth.com>

Table 2

Characteristics of the Participants

Characteristic	All Participants (<i>n</i> = 21)	Adequate Health Literacy (<i>n</i> = 12)	Inadequate Health Literacy (<i>n</i> = 9)
Age in years, <i>M</i> (<i>SD</i>)	46.5 (14.8)	41.2 (12.2)	53.6 (15.7)
Age range in years	20-85	20-67	39-85
Gender, <i>N</i> (%)			
Male	12 (57.1)	5 (41.7)	7 (77.8)
Female	9 (42.9)	9 (58.3)	2 (22.2)
Language Preference, <i>N</i> (%)			
English	7 (33.3)	5 (41.7)	2 (22.2)
Spanish	14 (66.7)	7 (58.3)	7 (77.8)
Race/Ethnicity, <i>N</i> (%)			
White, non-Hispanic	1 (4.8)	-	1 (11.1)
Hispanic	17 (80.9)	9 (75)	8 (88.9)
Black or African American	2 (9.5)	2 (16.7)	-
Asian	1 (4.8)	1 (8.3)	-
Visit Type, <i>N</i> (%)			
First visit	9 (42.9)	6 (50)	3 (33.3)
Follow-up visit	12 (57.1)	6 (50)	6 (66.7)
Health Literacy Score, <i>M</i> (<i>SD</i>)	7.57 (2.58)	5.92 (2.07)	9.78 (1.09)
Score range	3-12	3-8	9-12

Table 3

Wound Knowledge Test Scores

Tests	<i>M</i>	<i>SD</i>	Range
Pre-test			
All participants (<i>n</i> = 21)	7.71	1.52	4-10
Adequate health literacy (<i>n</i> = 12)	7.58	1.62	4-9
Inadequate health literacy (<i>n</i> = 9)	7.89	1.45	6-10
Post-test (Visit 1)			
All participants (<i>n</i> = 21)	9.57	.87	7-10
Adequate health literacy (<i>n</i> = 12)	9.92	.29	9-10
Inadequate health literacy (<i>n</i> = 9)	9.11	1.17	7-10
Post-test (Visit 2)			
All participants (<i>n</i> = 21)	9.24	1	7-10
Adequate health literacy (<i>n</i> = 12)	9.17	.94	7-10
Inadequate health literacy (<i>n</i> = 9)	9.33	1.12	7-10
Post-test (Visit 4)			
All participants (<i>n</i> = 21)	9.62	.81	7-10
Adequate health literacy (<i>n</i> = 12)	9.58	.67	8-10
Inadequate health literacy (<i>n</i> = 9)	9.67	1	7-10

Table 4

Comparison of Wound Knowledge Test Scores Over Time

Test Comparison	Paired-samples <i>t</i> test, <i>t</i>	<i>p</i> value
Pre-test vs. Post-test (Visit 1)		
All participants (<i>n</i> = 21)	-5.15	< .001*
Adequate health literacy (<i>n</i> = 12)	-4.84	.001*
Inadequate health literacy (<i>n</i> = 9)	-2.48	.038*
Pre-test vs. Post-test (Visit 2)		
All participants (<i>n</i> = 21)	-5.42	< .001*
Adequate health literacy (<i>n</i> = 12)	-4.42	.001*
Inadequate health literacy (<i>n</i> = 9)	-3.04	.016*
Pre-test vs. Post-test (Visit 4)		
All participants (<i>n</i> = 21)	-5.13	< .001*
Adequate health literacy (<i>n</i> = 12)	-4.06	.002*
Inadequate health literacy (<i>n</i> = 9)	-2.98	.017*

* statistically significant ($p < .05$)

Table 5

Wound Dressing Steps Performance Checklist Scores

Visit Checklist	<i>M</i>	<i>SD</i>	Range
Visit 1			
All participants (<i>n</i> = 21)	10.38	1.12	7-11
Adequate health literacy (<i>n</i> = 12)	10.58	1.17	7-11
Inadequate health literacy (<i>n</i> = 9)	10.11	1.05	8-11
Visit 2			
All participants (<i>n</i> = 21)	10.71	.56	9-11
Adequate health literacy (<i>n</i> = 12)	10.67	.65	9-11
Inadequate health literacy (<i>n</i> = 9)	10.78	.44	10-11
Visit 4			
All participants (<i>n</i> = 21)	10.86	.36	10-11
Adequate health literacy (<i>n</i> = 12)	10.92	.29	10-11
Inadequate health literacy (<i>n</i> = 9)	10.78	.44	10-11

Table 6

Bates-Jensen Wound Assessment Tool Scores

Tests	<i>M</i>	<i>SD</i>	Range
Visit 1			
All participants (<i>n</i> = 21)	31.48	4.90	25-45
Adequate health literacy (<i>n</i> = 12)	30.92	3.18	28-38
Inadequate health literacy (<i>n</i> = 9)	32.22	16.70	25-45
Visit 2			
All participants (<i>n</i> = 21)	27.05	6.17	14-42
Adequate health literacy (<i>n</i> = 12)	26.17	4.95	18-33
Inadequate health literacy (<i>n</i> = 9)	28.22	7.66	14-42
Visit 4			
All participants (<i>n</i> = 21)	19.14	8.30	9-35
Adequate health literacy (<i>n</i> = 12)	18.50	7.38	9-28
Inadequate health literacy (<i>n</i> = 9)	20	9.79	9-35

Appendix A

Search Strategy 1

CINAHL

The screenshot displays the EBSCOhost search interface. At the top, there are navigation tabs: "New Search", "Publications", "CINAHL Headings", "Evidence-Based Care Sheets", and "More". On the right, there are links for "Sign In", "Folder", "Preferences", "Languages", "Ask a Librarian", and "Help". The main search area includes the EBSCOhost logo, a search bar with "Searching: CINAHL Plus with Full Text" and "Choose Databases", and a "Suggest Subject Terms" dropdown. Below the search bar are three input fields for search terms, each with a "Select a Field (option...)" dropdown and a "Search" button. There are also "AND" dropdowns between the fields and a "Clear" button. Below the search area are links for "Basic Search", "Advanced Search", and "Search History".

The "Search History/Alerts" section is active, showing a table of search history entries. The table has columns for "Search ID", "Search Terms", "Search Options", and "Actions". The entries are as follows:

Search ID	Search Terms	Search Options	Actions
S6	S1 AND S2 AND S3	Limiters - Published Date: 20070101-20171231 Narrow by Language: - english Search modes - Boolean/Phrase	View Results (179) View Details Edit
S5	S1 AND S2 AND S3	Limiters - Published Date: 20070101-20171231 Search modes - Boolean/Phrase	View Results (191) View Details Edit
S4	S1 AND S2 AND S3	Search modes - Boolean/Phrase	View Results (211) View Details Edit
S3	outcome or outcomes	Search modes - Boolean/Phrase	View Results (552,396) View Details Edit
S2	assessment or assessments	Search modes - Boolean/Phrase	View Results (425,286) View Details Edit
S1	health literacy	Search modes - Boolean/Phrase	View Results (3,750) View Details Edit

Appendix B

Search Strategy 2

Cochrane Library

The screenshot shows the Cochrane Library search interface. At the top, the Cochrane Library logo is displayed with the tagline "Trusted evidence. Informed decisions. Better health." and a "Log in / Register" link. Below the logo is a search bar with the text "health literacy" entered. The search results are categorized by type, with "All" selected. The results list includes several entries with their titles, authors, and online publication dates. Each entry has a "Review" button next to it.

Wiley Online Library
Cochrane Library Trusted evidence. Informed decisions. Better health. [Log in / Register](#)

Search: Title, Abstract, Keywords | health literacy | [Go](#) [Save](#)
[Search Limits](#) [Search Help](#) (Word variations have been searched) [Add to Search Manager](#)

All Results (859)
 Cochrane Reviews (11)
 All
 Review
 Protocol
 Other Reviews (13)
 Trials (807)
 Methods Studies (20)
 Technology Assessments (7)
 Economic Evaluations (1)
 Cochrane Groups (0)

All
 Current Issue

Methodology
 Diagnostic
 Overview
 Prognosis
 Qualitative
 Conclusions changed
 New search
 Major change
 Update
 Withdrawn
 Comment

Cochrane Database of Systematic Reviews : Issue 3 of 12, March 2017
 Issue **updated daily** throughout month
 There are 11 results from 9760 records for your search on 'health literacy' in Title, Abstract, Keywords in Cochrane Reviews
 Sort by | Relevance: high to low

Select all | Export all | Export selected

- Interventions for enhancing consumers' online health literacy
 Josip Car, Britta Lang, Anthea Colledge, Chuin Ung and Azeem Majeed
 Online Publication Date: June 2011 [Review](#)
- Self-management education programmes for osteoarthritis
 Feline PB Koop, Lennart RA van der Burg, Rachelle Buchbinder, Richard H Osborne, Renea V Johnston and Veronica Pitt
 Online Publication Date: January 2014 [Review](#)
- Teaching critical appraisal skills in healthcare settings
 Tanja Horsley, Chris Hyde, Nancy Sarlesso, Julie Parkes, Ruairidh Milne and Ruth Stewart
 Online Publication Date: November 2011 [No](#) [Review](#)
- Decision aids for people facing health treatment or screening decisions
 Dawn Stacey, France Légaré, Nananda F Col, Carol L Bennett, Michael J Barry, Karen B Eden, Margaret Holmes-Rovner, Hilary Llewellyn-Thomas, Anne Lyddiatt, Richard Thomson, Lyndal Trevena and Julie HC Wu
 Online Publication Date: January 2014 [Review](#)
- Interventions for preventing eating disorders in children and adolescents
 Belinda M Pratt and Susan Woolfenden
 Online Publication Date: April 2002 [Review](#)

Appendix C

Search Strategy 3

ERIC

ProQuest
All databases > Social Sciences databases > ERIC | Change databases

ERIC
Basic Search Advanced Search About

(health literacy) AND (assessment OR assessments) AND (outcome OR outcomes)

Peer reviewed Modify search Recent searches Save search/alert

Related searches literacy literacy AND learning literacy AND reading View all >

26 results Search within Cite Email Print Save

Relevance Sort Select 1-20 0 Selected items Brief view Detailed view

Narrow results Applied filters Clear all filters

Source type: Scholarly Journals x
Publication date: 2007-2016 x
Language: English x

Peer reviewed
Source type
Scholarly Journals (26) x
Publication date

1 Why is **Health Literacy** Related to **Health**? An Exploration among U.S. National **Assessment** of Adult **Literacy** Participants 40 Years of Age and Older
Quinley, Raymond L., Waldrop-Vahedi, Drenna, Taha, Jessica. *Educational Gerontology* 38.11 (2012): 776-787.
Health literacy has emerged as an important factor related to **health** in older **literacy** to self-reported **health** status and explore the impact of these
Cited by (8) References (43)
Abstract/Details Link to full text Get it! (Q&A) Preview

2 Investigating the Association of **Health Literacy** with **Health** Knowledge and **Health** Behavior **Outcomes** in a Sample of Urban Community College Undergraduates
Hansen, Haidaye Ramsarong, Shneyderman, Yuliy, Belcastro, Philip A. *American Journal of Health Education* 46.5 (2015): 274-282.
health literacy and positive **health outcomes** Discussion: There was no ...There is a paucity of evidence associating **health literacy** metrics with adults ...responded to (1) Short Test Functional **Health Literacy** in Adults, (2) **Health**
References (32)
Abstract/Details Link to full text Get it! (Q&A) Preview

3 **Health Literacy Assessment** of the STOPFLA: Paper versus Electronic Administration Continuation Study
Phonon, Anon P., Ganes, Murali, Siddi, M. S. M., ...
Journal of Health, Behavior, and Society, 2014, 12(4), 1-10

Appendix D

Search Strategy 4

National Guideline Clearinghouse

The screenshot shows the National Guideline Clearinghouse search interface. At the top, there is a header with the U.S. Department of Health and Human Services logo and the Agency for Healthcare Research and Quality (AHRQ) logo. Below this is a navigation bar with links for HOME, NEW THIS WEEK, GUIDELINE SUMMARIES, GUIDELINE SYNTHESSES, EXPERT COMMENTARIES, MATRIX TOOL, SUBMIT GUIDELINES, and HELP & ABOUT. A search bar is located in the center of the navigation bar, and a 'Log into My NGC' link is on the right.

The main content area displays the search results for "health literacy". It shows 1-20 of 21 results. On the left, there is a 'NARROW RESULTS' sidebar with filters for 'Meets 2013 Inclusion Criteria (10)', 'U.S.-based Organizations (14)', and 'Addresses Multiple Chronic Conditions (5)'. Below this are filters for 'Publication Date' (From: 2011, To: 2016) and 'Target Population Characteristics' (Age: Aged, 80 and over (10); Aged (65 to 79 years) (12); Middle Age (45 to 64 years) (10)).

The search results are sorted by Relevance | Date. The first result is 'Facilitating client centred learning.' by Registered Nurses' Association of Ontario, published in 2012. The second result is 'Occupational therapy practice guidelines for mental health promotion, prevention, and intervention for children and youth.' by American Occupational Therapy Association, Inc., published in 2013. The third result is 'Occupational therapy practice guidelines for mental health promotion, prevention, and intervention for children and youth.' by American Occupational Therapy Association, Inc., published in 2016.

Appendix E

Search Strategy 5

PsycINFO

ProQuest
All databases > Social Sciences databases > PsycINFO | Change databases

PsycINFO
Basic Search Advanced Search About

(health literacy) AND (outcome OR outcomes) AND (assessment OR assessments)

Peer reviewed Modify search Recent searches Save search/alert

Related searches health literacy health literacy AND middle aged health literacy AND health knowledge, attitudes, practice View all >

171 results Search within Cite Email Print Save

Select 1-20 0 Selected items Brief view Detailed view

Relevance Sort

Narrow results

Applied filters Clear all filters

Source type: Scholarly Journals

Publication date: 2007-2017

Age group: Adulthood (18 yrs & older)

Language: English

Peer reviewed

Source type

Scholarly Journals (171)

1 The Mini Mental Status Exam as a surrogate measure of health literacy
DeHke, Allison R.; Curtis, Laura M.; Federman, Alex D.; Wolf, Michael S. Journal of General Internal Medicine 29.4 (Apr 2014): 615-620.
...to the three most commonly used health literacy assessments and education.
...validity of the MMSE with assessments of health literacy and education. Receiver
...Studies have documented strong associations between cognitive function, health
Cited by (2) References (31)
Abstract/Details Link to full text

2 The demographic assessment for health literacy (DAHL): A new tool for estimating associations between health literacy and outcomes in national surveys
Hanchate, Amresh D.; Ash, Arlene S.; Gazmararian, Julie A.; Wolf, Michael S.; Paasche-Orlow, Michael K. Journal of General Internal Medicine 23.10 (Oct 2008): 1561-1566.
...inadequate literacy, the National Health Interview Survey has no such
...data to derive a Demographic Assessment for Health Literacy (DAHL) score, and
...outcomes examined. Conclusions: A few population surveys measure health
Cited by (31) References (23)
Abstract/Details Link to full text

Appendix F
Search Strategy 6

PubMed

The screenshot shows the PubMed Advanced Search Builder interface. At the top, there are navigation links for 'PubMed Home', 'More Resources', and 'Help'. The main heading is 'PubMed Advanced Search Builder' with a 'YouTube Tutorial' link. A status bar indicates 'Filters activated: published in the last 10 years, Humans, English. Clear all'. Below this is a search input field with the text 'Use the builder below to create your search' and 'Edit' and 'Clear' buttons. The 'Builder' section contains two search boxes, both set to 'All Fields', with 'AND' between them. There are 'Show index list' links for each box. Below the builder is a 'Search' button and a link to 'Add to history'. The 'History' section contains a table with columns for 'Search', 'Add to builder', 'Query', 'Items found', and 'Time'. The table lists four previous searches (#1 to #4) with their respective queries and results.

Search	Add to builder	Query	Items found	Time
#4	Add	Search ((health literacy[Title/Abstract]) AND (assessment[Title/Abstract] OR assessments[Title/Abstract])) AND (outcome[Title/Abstract] OR outcomes[Title/Abstract]) Filters: published in the last 10 years; Humans; English	147	23:53:56
#3	Add	Search ((health literacy[Title/Abstract]) AND (assessment[Title/Abstract] OR assessments[Title/Abstract])) AND (outcome[Title/Abstract] OR outcomes[Title/Abstract]) Filters: published in the last 10 years; Humans	150	23:53:53
#2	Add	Search ((health literacy[Title/Abstract]) AND (assessment[Title/Abstract] OR assessments[Title/Abstract])) AND (outcome[Title/Abstract] OR outcomes[Title/Abstract]) Filters: published in the last 10 years	228	23:53:44
#1	Add	Search ((health literacy[Title/Abstract]) AND (assessment[Title/Abstract] OR assessments[Title/Abstract])) AND (outcome[Title/Abstract] OR outcomes[Title/Abstract])	242	23:53:34

Appendix G

Table 1

Evaluation Table

Citation	Theory/Conceptual Framework	Design/Purpose	Sample/Setting	Variables & Definitions	Measurement/Instrumentation	Data Analysis	Findings/Results	Level/Quality Application
<p>Aboumatar et al. (2013)</p> <p>The impact of health literacy on desire for participation in healthcare, medical visit communication, and patient reported outcomes.</p> <p>Country: USA</p> <p>Funding: National Heart, Lung, and Blood Institute</p> <p>Conflict/Bias: Conflict of interest and measurement bias-Author is copyright holder of the RIAS coding software and is</p>	<p>Communication accommodation theory</p> <p>Pre-visit coaching model</p>	<p>Design: Quantitative, RCT, cross-sectionally analyzed</p> <p>Purpose: To determine how HL influences patients' healthcare participation, visit communication, and self-reported outcomes.</p>	<p>N=329 n=279 patients Groups: Minimal patient/minimal physician (control)=55 Intense patient/minimal physician=57 Minimal patient/intensive physician=84 Intensive patient/intensive physician=83 n=50 physicians ATT: 4% Patients=1.4% (LTF, illness, withdrew) Physicians=18% (illness, withdrew)</p> <p>Demographics: Patients: M age=61.2 Females=181 (65.8) CR=101 (36.7) HS degree=189 (69) HI=249 (90.2) LHL: n=86</p>	<p>IV: HL status (LHL: score less than or equal to 60, AHL: score greater than 60)</p> <p>DV1: Patients' desire for involvement in medical decision making</p> <p>DV2: PPC behaviors</p> <p>DV3: Patient care ratings (post-visit physician PDM style, physician trust, visit satisfaction)</p> <p>DV4: Blood pressure</p>	<p>IV: REALM ($\alpha=.80-.91$)</p> <p>DV1: Single item question with 4 options. Answer #3 or #4, positive desire for involvement in care (CVR NR)</p> <p>DV2: RIAS ($\alpha=.82$)</p> <p>DV3: 3-item PDM scale (0-100) (CVR NR)</p> <p>DV4: Sphygmomanometer</p>	<p>SAS (versions 9.22 and 9.3)</p> <p>Fischer's exact test: to compare categorical data</p> <p>Jonckheere-Terpstra test: to compare ordinal responses</p> <p>Two samples <i>t</i>-test: to compare the distributions of the outcome measures</p> <p>Generalized linear models regression analysis with generalized estimating equations: to assess the effect of literacy status on outcomes</p>	<p>DV1: LHL: n=73 (71.6) AHL: n=119 (68.8) p=.32</p> <p>DV2: Medical question asking: LHL: M=4.46 95% CI [3.37, 5.89] AHL: M=6.82 95% CI [5.90, 7.89] p=.02 All other RIAS measures <i>ns</i> between LHL and AHL Intensive patient/intensive physician: LHL: M=3.85 95% CI [2.84, 5.22] AHL: M=6.42 95% CI [5.15, 8.0] p=.002 All other groups <i>ns</i></p> <p>DV3: <i>ns</i> between LHL and AHL groups Intensive patient/minimal physician: LHL: M=58.3 95% CI [45, 71.6] AHL: M=73.6 95% CI [67.6, 79.6]</p>	<p>Level II Strengths: Appropriate control, multiple settings, 12-month study, narrow CI, measurement tools CVR, theoretical framework discussed.</p> <p>Weaknesses: Participants awareness of being audiotaped, small <i>n</i> of LHL in each group, lack of masking.</p> <p>Conclusions: LHL and AHL similar desire to participate in care. LHL less medical question asking. LHL lower PDM scores than AHL most significant in intensive</p>

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the co-owner of the company that provided the RIAS coding service.			AHL: n=147 Physicians: M age=43 Female=22 (53.6) CR=18 (43.9) IM=33 (80.5) M PE=11.9 years Setting: 14 PC clinics Time: 12-month study IC: Patients: Age≥18, HTN, contact information Physicians: 20 hours per week direct patient care EC: Patients: Acutely ill, disoriented, unresponsive to assessment, MC that limit participation. Physicians: Planning to leave practice ≤ one year.				p=.04 All other groups <i>ns</i> DV4: LHL n=40 (39.6%) AHL n=92 (54.1%) p=.02 (AHL higher BP control)	patient/minimal physician intervention group. Worse BP control in LHL. Feasibility: For physician communication interventions, LHL may be less responsive and beneficial. Consider in LHL patients their reduced question asking and perception of PDM in determining interventions.
Al Sayah et al. (2013) Health literacy and health outcomes in diabetes: A systemic review. Country: Canada	Not directly stated, cited model noted: Nutbeam’s Health Literacy Model (2000)	Design: Quantitative, SR, AHRQ evidence-based practice center method Purpose: To systematically review research evidence on the relationships between HL or numeracy and	Databases=6 Citations=723 Met IC=34 articles (24 studies) CSS=29 Longitudinal=5 Demographics: RG=31-17,795 participants per study M age RG=45.8-67.2 Females RG=42.7-79.4% CR RG=2-65%	IV1: HL level (low, high) DV1: CO (Glycemic control, hypoglycemia, BP, DM complications, LDL) DV2: Behavioral indicators (DK,	IV1: REALM, REALM-R, TOFHLA, STOFHLA (α=.73-.98) DV1: HbA1C, self-reported hypoglycemia, sphygmomano-meter, self-reported retinopathy, nephropathy,	Cohen’s Kappa: used to assess inter-rater reliability in rating the strength of evidence between the two reviewers Fixed and random effects models: to perform meta-	Eligible articles: Inter-rater agreement=88% Cohen’s kappa=.70 95% CI [.59, .84] Quality rating: Inter-rater agreement=97% Cohen’s kappa=.91 95% CI [.76, .98] I ² =80-90% (large heterogeneity) Data reported qualitatively DV1: Glycemic control, DM complications:	Level I Strengths: Appropriate search methods and number of studies, SOE rating method CVR, IV and DV appropriate and included CVR HL measurements. Weaknesses: Heterogeneity

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<p>Funding: Alliance for Canadian Health Outcomes Research in Diabetes, Canadian Institute for Health Research, Institute of Nutrition, Metabolism and Diabetes</p> <p>Conflict/Bias: None reported or appreciated.</p>		health outcomes in patients with diabetes.	<p>HS degree=variable reporting</p> <p>Setting: PC clinic, GM clinic, MCO, hospital, DM clinic</p> <p>IC: Studies assessing HL or numeracy and HO in DM patients, valid HL or numeracy measure, at least 1 HO, written in English.</p> <p>EC: Review and conceptual articles, lack of outcomes of interest reported, studies not including diabetes, studies including gestational diabetes, studies of HL in caregivers of individuals with DM.</p>	<p>SE, SC, SMBG)</p> <p>DV3: Patient-provider interaction indicators (PPC, patient trust, information exchange and involvement in decision-making, use of computers and internet, other)</p>	<p>CAD, stroke, amputation), LDL level</p> <p>DV2: DK questionnaire, Summary of diabetes SC activities, Morisky score, DM SE scale, Diabetes Care Profile, Other (CVR NR)</p> <p>DV3: Wake Forest Physicians Trust Scale, Facilitation of Patient Involvement, Healthcare Relationship Trust Scale, Other (CVR NR)</p>	analysis to quantitatively summarize the evidence for outcomes	<p>INSUFF Hypoglycemia, BP: low SOE LDL: no association</p> <p>DV2: DK: high SOE, high HL better DK SE: INSUFF SC: moderate SOE, no association SMBG: low SOE</p> <p>DV3: PPC: low SOE Trust, Information: INSUFF Computers, Other: low SOE</p>	<p>across studies, studies lacked power, methodological issues, no interventions described, majority CSS.</p> <p>Conclusions: Moderate to High SOE for HL level and DK (direct relationship) and no difference between HL and SC behaviors. Studies in HL and clinical outcomes weak with low SOE.</p> <p>Feasibility: High SOE between LHL and poorer knowledge. The link to outcomes is INSUFF therefore HL screening to improve outcomes may be premature.</p>
<p>Berkman et al. (2011)</p> <p>Low health literacy and health outcomes: An updated systemic review.</p>	Integrative theory from an integrated model of behavioral theory	<p>Design: Quantitative, SR, PRISMA, AHRQ evidence-based practice center method</p> <p>Purpose: To update a 2004</p>	<p>Databases=5 Citations=3,911 Met IC=111 articles (86 studies) CSS=91 Other=10</p> <p>Demographics: HL: 89 articles</p>	<p>IV1: HL level (low, high)</p> <p>DV1: Outcomes (emergency care and hospitalization, preventative services)</p>	<p>IV1: REALM, REALM-R, TOFHLA, STOFHLA ($\alpha=.73-.98$)</p> <p>DV1: Total emergency room and</p>	Studies rated on quality (internal validity and risk of bias) using predefined criteria from four established sources	<p>DV1: All moderate SOE, Emergency/hospitalization s: increased use in LHL Preventative services: decreased use in LHL</p> <p>DV2: Taking medications appropriately: Moderate SOE, reduced in LHL Interpreting labels and</p>	<p>Level I Strengths: Appropriate search methods, large number of studies, SOE rating CVR, IV and DV appropriate and included CVR</p>

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<p>Country: USA</p> <p>Funding: Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services</p> <p>Conflict/Bias: None reported or appreciated.</p>		<p>SR and determine if low HL is associated with poorer use of healthcare, outcomes, cost, and disparities in health outcomes in people of all ages.</p>	<p>RG=50-23,889 participants per study <i>M</i> age RG=11.5-76 Females RG=0-91% CR RG=0-97.4% HS degree=variable reporting Numeracy: 22 articles RG=62-1,436 participants per study <i>M</i> age RG=37-68 Females RG=2-100% CR RG=4.8-96% HS degree=variable reporting</p> <p>Setting: PC clinic, GM clinic, endocrinology clinics, MCO, hospitals, academic medical centers, medical schools, schools, HIV clinics, DM clinics, residents in U.S. cities.</p> <p>IC: HL articles 2003-2/22/2011, numeracy articles 1966-2/22/11, English language, all ages, HL of patients or caregivers directly measured. Comparison to outcomes, health care access, HO, and costs of care. For numeracy studies includes knowledge.</p>	<p>DV2: Health care-related skills (taking medications, interpreting labels and messages) DV3: Disease prevalence and severity (MH outcomes, HIV infection) DV4: Global health status of elderly DV5: Death DV6: Interventions (single-strategies, mixed strategies)</p>	<p>hospitalization visits, frequency of mammography screening and influenza immunization DV2: Direct medication observations, self-reports, measurement of medication blood test (CVR NR) DV3: CES-D scale, HIV viral load, HIV symptom reporting (CVR NR) DV4: Self-report of overall health status, 12- and 36 Item Short Form Health Survey (All CVR) DV5: Evaluation of Prudential Medicare sample DV6: AHRQ method (SOE)</p>	<p>Due to heterogeneity across studies in approaches to measuring health literacy, numeracy, interventions and outcomes meta-analysis not possible and findings qualitatively presented</p>	<p>messages: Moderate SOE, reduced in SOE</p> <p>DV3: MH outcomes: Low SOE HIV severity and symptoms: INSUFF</p> <p>DV4: Global health status of elderly: Moderate SOE, poor health status in LHL</p> <p>DV5: Death: High SOE, higher mortality with LHL</p> <p>DV6: Single strategy: all rated low SOE or INSUFF Mixed strategy: Moderate SOE mixed strategies for adherence and SC Moderate SOE for disease management interventions. Moderate SOE studies included simple language, simple organization, pictures, teach back and repetition</p>	<p>HL measurements, appropriate IC and EC. Weaknesses: Heterogeneity, measurements and instrumentation used for DV with limited descriptions and reporting of validity and reliability. Conclusions: High to Moderate SOE in LHL associated with several outcomes. Interventions with mixed strategies moderate SOE focusing on adherence, self-management, and disease management. Feasibility: Supports LHL association with health outcomes and interventions focusing on self-management with simple techniques.</p>

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DeWalt et al. (2012) Multisite Randomized Trial of a single-session versus multisection literacy-sensitive self-care intervention for patients with heart failure. Country: USA Funding: National Heart, Lung, and Blood Institute Conflict/Bias: No reported conflicts. Information bias risk in medical record review process.	Social cognitive theory	Design: Quantitative, RCT Purpose: To compare the effects of two different amounts of HF self-care training on the incidence of all-cause hospitalization or death and HF-related hospitalization and quality of life.	EC: Self-reported HL, outcomes concerning attitudes, social norms, or patient-provider relationships. N=605 n=302 (single session) n=303 (multisection) ATT: 27.8% Single session=30.8% (died, missed 6 and 12-month interview) Multisection=28.1% (died, withdrew, missed 6 and 12-month interview) Demographics: Single session: M age=60.3 Females=146 (48) CR=122 (40) HS degree=86 (28) HI=260 (86) Multisection: M age=61.1 Females=145 (48) CR=111 (37) HS degree=91 (30) HI=266 (87.8) Setting: General IM and cardiology clinics from 4 sites. Time: 12-month study IC: Age 20 or older, diagnosis of HF, NYHA class II-IV symptoms in past 6 months, current use of	IV1: HL intervention (single session) IV2: HL intervention (multisection) IV3: HL level (LHL: 0-22 answers correct HHL: 23-36 answers correct) DV1: Hospitalization or death (all-cause) DV2: HF-related hospitalizations DV3: Emergency department visits DV4: HFQOL	IV3: STOFHLA ($\alpha=.90$) DV1: admission and discharge summary review, medical-record confirmed events, national death index DV2: admission and discharge summary review DV3: Emergency department visit record review DV4: Improving Chronic Illness Care Evaluation Heart Failure Symptom Scale ($\alpha=.88$)	Negative binomial regression: to compare differences in the incidence rates between the two study groups Wald test on the coefficient of the interaction term was used to test health literacy effectiveness between the two groups Generalized estimating equations: to determine the change in HFQOL associated with the intervention	DV1: Unadjusted IRR=1.01, 95% CI [0.83, 1.22], no difference between intervention groups LHL: Unadjusted IRR=0.75 95% CI [0.45, 1.25], favoring the multisection group (lower incidence) HHL: Unadjusted IRR=1.22 95% CI [0.99, 1.50], favoring the single-session group (lower incidence) Interaction $P=.048$ for multisection literacy level differences DV2: (95% CI) Unadjusted IRR=0.92, 95% CI [0.77, 1.11], favoring the multisection group LHL: Unadjusted IRR=0.53 95% CI [0.25, 1.12], favoring the multisection group (lower incidence) HHL: Unadjusted IRR=1.32 95% CI [0.92, 1.88] Adjusted IRR=1.34 95% CI [0.87, 2.07], favoring the single-session group (lower incidence)	Level II Strengths: Large N, low risk intervention, multi-site, 12-month study, CVR HL measurement tool, significant findings with narrow CI. Weaknesses: Lack of concurrent control group not exposed to the intervention, lower number of LHL participants. Conclusions: Intensive multisection interventions did not change clinical outcomes compared to the single-session but differed by literacy group. LHL participants in multisection intervention group benefitted more clinically. Feasibility: Multisection

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			loop diuretic, absence of cognitive impairment, working phone, speaks English or Spanish. EC: Inadequate vision, on dialysis, severe vascular disease, using oxygen for COPD, life expectancy <1 year, unable to pass mini cog screener, lives in a nursing facility or other place without medication control.				Interaction $P=.005$ for multisession literacy level differences DV3: Unadjusted IRR=0.82, 95% CI [0.42, 1.64] Adjusted IRR=0.79 95% CI [0.47, 1.31] no difference between groups, interaction probability value <i>ns</i> DV4: HFQOL improvement: (Favoring multisession) 1-month $p<0.001$ 6-month $p=0.003$ 12-month $p=0.08$ (<i>ns</i>) Intervention effects on HFQOL did not differ by literacy	interventions benefits LHL participants and improves clinical outcomes and is a design consideration for HL interventions.
Eckman et al. (2012) Impact of health literacy on outcomes and effectiveness of an educational intervention in patients with chronic diseases. Country: USA Funding: Foundation for Informed	Not directly stated, cited model noted: Schillinger Functional Health Literacy Model (2001)	Design: Quantitative, RCT Purpose: To study the impact of HL on an educational intervention for patients with coronary artery disease.	$N=187$ $n=83$ (VHS/DVD plus booklet) $n=87$ (booklet (control)) ATT: 9% (deaths, withdraws) Demographics: M age=59.9 (34-85) Females= 104 (61.2) CR=61 (35.9) HS degree=100 (58.8) HI=170 (100) LHL: $n=68$ HHL: $n=101$ Setting: 3 IM practices	IV1: Pre-intervention CAD knowledge assessment (control) IV2: HL level (LHL: score less than or equal to 60, HHL: score greater than 60) IV3: Clinical co-morbidities DV1: CAD knowledge DV2: Health behaviors (smoking	IV1: CAD knowledge assessment (12-item test made by researchers, pilot tested prior, no CVR). IV2: REALM ($\alpha=.91$) IV3: Checklist of other diagnosis (NR) DV1: CAD knowledge assessment (12-item test made by researchers, pilot	Descriptive statistics of baseline assessments Fisher's Exact test: to compare the patient characteristics by intervention group t -test: to compare means of the continuous variables Paired t -test: to compare baseline	DV1: LHL: Before intervention: $M=7.66$, $SD=2.20$ Final follow-up: $M=9.34$, $SD=1.17$ $p<.001$ HHL: Before intervention: $M=8.46$, $SD=1.68$ Final follow-up: $M=9.71$, $SD=0.93$ $p<.001$ LHL: coefficient -0.03 (.01), $p=0.03$ (larger improvement in CAD scores from baseline) DV2: MEDFACTS: LHL: Before intervention: $M=47.71$, $SD=25.17$	Level II Strengths: Low risk intervention, multi-site, 6-month study, CVR HL measurement tool, significant results, all steps of interventions scripted. Weaknesses: Lower number of LHL participants, a priori power analysis supported 100 per group, n below this, lack of

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<p>Medical Decision Making</p> <p>Conflict/Bias: None reported or appreciated</p>			<p>Time: 6-month study</p> <p>IC: Age ≥21, speak and understand English, CAD.</p> <p>EC: Cognitive dysfunction, visual problems.</p>	<p>status, self-reported exercise and dietary habits), HO (weight, BP)</p>	<p>tested prior, no CVR).</p> <p>DV2: MEDFACTS scale, 12-item Physical Scale for the Elderly, ($\alpha>.70$)</p> <p>DV3: Scale, Sphygmomano-meter</p>	<p>and post-intervention assessments</p> <p>Multivariate models: to predict change in knowledge scores, health behaviors, and clinical outcomes</p>	<p>Final follow-up: $M=40.50$, $SD=22.75$ $p<.001$</p> <p>HHL: Before intervention: $M=49.38$, $SD=23.27$</p> <p>Final follow-up: $M=41.16$, $SD=19.10$ $p<.001$</p> <p>Physical scale for Elderly: LHL <i>ns</i> HHL $p=.01$</p> <p>Cigarette smoking: <i>ns</i> all literacy groups Average number of cigarettes: LHL: $p<.001$, HHL $p=.01$</p> <p>LHL: intervention predicting weight change: coefficient $-0.47 (.24)$, $p=0.05$ (greater impact on weight loss)</p> <p>Subgroups analysis run for each DV between HHL and LHL and results <i>ns</i></p> <p>DV4: Weight, BP <i>ns</i> all literacy groups</p>	<p>concurrent control group not exposed to intervention.</p> <p>Conclusions: CAD knowledge scores and health behaviors improved all groups, dual intervention group showed significant improvement.</p> <p>Feasibility: Mixed intervention strategies to improve chronic disease knowledge and behaviors benefit both LHL and HHL patients and improve outcomes.</p>
<p>Hahn et al. (2015)</p> <p>Health literacy and patient-reported outcomes: A cross-sectional study of underserved English- and Spanish-speaking patients with type 2 diabetes.</p>	<p>Behavioral model for vulnerable populations</p>	<p>Design: Quantitative, RCT, cross-sectionally analyzed</p> <p>Purpose: To examine the association between patient characteristics, health behaviors, and health outcomes and</p>	<p>$N=308$ $n=146$ (English) $n=149$ (Spanish) ATT: English=5.2% Spanish=3.9% (LTF, illness, withdrew)</p> <p>Demographics: English: M age=54.8 Females= 68 (46) CR=31 (21) HS degree=46 (32) HI=59 (40)</p>	<p>IV1: HL score IV2: SE IV3: Health beliefs IV4: Clinical characteristics</p> <p>DV1: DM SC DV2: Health status DV3: Satisfaction with communication</p>	<p>IV1: Health LiTT (14-items) ($\alpha=70-.78$) IV2: DM SE (8-items) ($\alpha=84-.85$) IV3: Health beliefs (20-items) ($\alpha=67-.94$) Diabetes Knowledge (24-items) ($\alpha=85-.87$) IV4: self-reported medication use,</p>	<p>SAS (version 9.3) and Mplus (version 6.11)</p> <p><i>t</i>-test, Chi-square test, Fisher's exact test: to compare the characteristics between English and Spanish – speaking participants</p>	<p>Health LiTT: English T score $M=52.1$, $SD=10.6$ Spanish T score $M=47.8$, $SD=8.9$ $p=.001$</p> <p>DM SE English: $M=75.7$, $SD=19.4$ Spanish: $M=82.4$, $SD=18.3$ $p=.01$</p> <p>Health beliefs</p>	<p>Level II Strengths: Measurement tools CVR, theoretical framework discussed, adequate N, low risk, appropriate IC and EC.</p> <p>Weaknesses: Single setting, demographical differences,</p>

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<p>Country: USA</p> <p>Funding: Agency for Healthcare Research and Quality</p> <p>Conflict/Bias: None reported or appreciated.</p>		<p>explore the role of HL as a mediator of outcomes.</p>	<p>Spanish: M age=54.5 Females= 91 (61) CR=0 HS degree=17 (11) HI=28 (19)</p> <p>Setting: General medical clinic</p> <p>IC: Age ≥18, males or nonpregnant females, speak English or Spanish, DMII on oral medication or insulin, sufficient cognitive function and manual dexterity.</p> <p>EC: Pregnant women.</p>		<p>body mass index, HbA1C</p> <p>DV1: DM SC-past 7 days (8-items) (CVR NR)</p> <p>DV2: Health status (10-items) (α=.70-.80)</p> <p>DV3: Satisfaction with communication (7-items) (α=.85-.91) Decision-making preference (Single item question with 4 options to choose from (CVR NR)</p>	<p>Multivariate regression analyses: to determine the statistical interaction of language with health behavior and outcome</p>	<p>Diet and medication barriers, Social support for diet: $p<.001$ (English lower score=less barriers and support)</p> <p>DK: English: $M=15$, $SD=4.1$ Spanish: $M=13$, $SD=3.9$ $p<.001$</p> <p>Information sources: Pamphlets ($p<.001$), internet ($p=.009$), healthcare professionals ($p=.005$), (English- higher use of sources)</p> <p>DV1: DM SC <i>ns</i> between groups</p> <p>DV2: Physical health English: T score $M=41.6$, $SD=7.8$ Spanish: T score $M=39.5$, $SD=8.9$ $p=.03$ (English better physical health) Mental health T score <i>ns</i></p> <p>DV3: English: $M=14.9$, $SD=3.8$ Spanish: $M=13.4$, $SD=4.2$ $p=.001$ (English more satisfaction with communication)</p>	<p>cross-sectional design.</p> <p>Conclusions: Spanish speakers had lower HL and worse physical, mental and overall health than English speakers. LHL associated with low DK, barriers and limitations in communication.</p> <p>Feasibility: Multimedia assessments feasible in all HL levels and speakers. Study includes similar population to wound clinic. Supports LHL in Spanish-speakers and limitations in knowledge and communication.</p>
<p>Kim & Lee (2016)</p> <p>Health-literacy-sensitive</p>	<p>Framework of health literacy and its associations with diabetes mechanisms and</p>	<p>Design: Quantitative, SR and MA, PRISMA,</p>	<p>Databases=3 Citations=490 Met IC=13 All but 1 USA studies RCT w/ control=6</p>	<p>IV1: HL level (low, high) IV2: HL interventions (written</p>	<p>IV1: STOFHLA, REALM, (α=.90-.91)</p>	<p>Comprehensive Meta-Analysis software (version 2.2)</p>	<p>DV 1, 2: Mixed Methods Appraisal Tool Quality rating 100%: Study 1: Cultural competency training,</p>	<p>Level I Strengths: Appropriate search methods, SOE rating</p>

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<p>diabetes self-management interventions: A systemic review and meta-analysis.</p> <p>Country: Korea</p> <p>Funding: National Research Foundation of Korea</p> <p>Conflict/Bias: None reported or appreciated.</p>	<p>outcomes (Bailey et al., 2014)</p>	<p>Mixed Methods Appraisal Tool</p> <p>Purpose: To review health-literacy-sensitive diabetes management interventions focusing on strategies for accommodating patients with low HL and to examine the efficacy of the interventions to improve health outcomes.</p>	<p>RCT 2 intervention groups=3 RCT 1 group pre/posttest=4</p> <p>Demographics: N=2,543 RG=46-339 participants per study M age RG=NR Females RG=NR CR RG=NR AA RG=20.6-100% HS degree=NR</p> <p>Setting: NR</p> <p>IC: January 2000-January 2015, described intervention adapted for patients with low HL, patient with DMII, measured HL levels, experimental design used, peer-reviewed, published in English, measured outcomes.</p> <p>EC: Studies aimed to develop or validate instruments.</p>	<p>communication, spoken communication, empowerment, tailoring communication to patients' language or cultural practices and beliefs)</p> <p>DV1: Cognitive or psychological outcomes (knowledge, self-efficacy, activation, perceived susceptibility)</p> <p>DV2: SC outcomes (SC behavior, diet, exercise, medication, problem solving, glucose testing, foot care)</p> <p>DV3: HO (HbA1C)</p>	<p>IV2: Two authors reviewed separately and categorized into previously developed inclusive list of HL intervention types (CVR NR) Mixed Methods Appraisal Tool Quality score (CVR)</p> <p>DV1: NR DV2: NR DV3: HbA1C</p>	<p>Random effects model: to calculate effects sizes and standardized mean differences in HbA1C between groups</p>	<p>communication tailored to population, motivational interviewing=Significant difference in medication adherence Study 2: Simplified internet program=significant differences in DK at end of sessions at 2, 3, 4 weeks. (All p NR)</p> <p>Mixed Methods Appraisal Tool Quality rating 75%: Study 1: Communication training, easy-to-read materials=significant difference in SE at 6 months Study 2: Easy-to-read materials with pictorial images, teach-back method with clear communication=significant differences in DK, adherence to diet and medication in both groups versus control Study 3: Provider communication training, teach-back, communication tailored to culture, conversation maps=significant improvement in HbA1C, DK, SE, SC, foot care, exercise, both HHL and LHL DK improvement. Study 4: Telephone follow-up, easy-to-read education materials,</p>	<p>method CVR, CVR HL measurements, appropriate IC and EC. Theoretical framework discussed. All RCT.</p> <p>Weaknesses: Heterogeneity, limited statistical analysis, measurements and instrumentation used for DV NR, limited demographics.</p> <p>Conclusions: Multiple LHL interventions in DM led to positive health outcomes, most included a spoken communication domain which was found to be an important factor in DM self-management. HL-sensitive interventions produced a moderate effect on HbA1c in LHL patients.</p> <p>Feasibility: Several interventions</p>

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							<p>counseling focusing on action plans=significant improvements in participants' activation, SE, diabetes-related stress, behaviors, DK at 3 months, similar improvements with HHL and LHL (All <i>p</i> NR)</p> <p>DV3: Intervention effects on HbA1C overall: ES=-0.18, 95% CI [-0.36, -0.004] (small effect) <i>p</i>=.04</p> <p>Intervention effects on HbA1C for LHL: ES=-0.51, 95% CI [-0.97, -0.04] (moderate effect) <i>p</i>=.03</p> <p>Intervention effects on HbA1C for HHL: ES=-0.13, 95% CI [-0.80, 0.54] (small effects) <i>p</i>=.70 (<i>ns</i>)</p>	discussed and their associated communication domains can be applied to the wound clinic population depending on the outcome goal.
<p>Kiser et al. (2012)</p> <p>A randomized controlled trial of a literacy-sensitive self-management intervention for chronic obstructive pulmonary</p>	<p>Not directly stated, cited model noted: Baker's Health Literacy Conceptual Model (2006)</p>	<p>Design: Quantitative, RCT</p> <p>Purpose: To examine the impact of a literacy-sensitive intervention on inhaler technique and determine if</p>	<p><i>N</i>=99 <i>n</i>=67 (education intervention) <i>n</i>=32 (usual care (control)) ATT: Intervention=20.9% Usual care=25% (LTF)</p> <p>Demographics: Intervention: <i>M</i> age=63 (43-84)</p>	<p>IV: HL level (LHL: score - 22, AHL: score 23-36)</p> <p>DV: Inhaler technique assessment</p>	<p>IV: STOFHLA (α=.90)</p> <p>DV: Researcher designed eight-item inhaler technique checklist (CRV)</p>	<p><i>t</i>-test: to compare mean change in scores between groups</p>	<p>MDI overall: Control: Baseline Score: <i>M</i>=5.6 Follow-up score: <i>M</i>=5.2 Intervention: Baseline Score: <i>M</i>=5.2 Follow-up score: <i>M</i>=6.7 <i>M</i> change= 2.1 95% CI [1.1, 3.0], <i>p</i><.001 (mean 2.1 point improvement from control)</p> <p>LHL:</p>	<p>Level II Strengths: Appropriate control group, low risk intervention with appropriate follow-up measurement, CVR HL measurement tool, several findings</p>

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disease patients. Country: USA Funding: not reported Conflict/Bias: None reported or appreciated.		effects differ by literacy in COPD patients.	Females= 64% CR=67% HS degree=30% HI=91% Low HL: 37% Usual Care: M age=63 (44-83) Females=66% CR=72% HS degree=28% HI=97% Low HL: 33% Setting: General IM clinic Time: 8-week study IC: Active prescription for an inhaled medication, order for inhaled medication on the inpatient service, age≥18, English speaking, diagnosis of COPD, chronic bronchitis, or emphysema. EC: NR				Control: Baseline Score: <i>M</i> =5.2 Follow-up score: <i>M</i> =4.0 Intervention: Baseline Score: <i>M</i> =4.8 Follow-up score: <i>M</i> =6.3 <i>M</i> change=2.8 95% CI [0.6, 4.9], <i>p</i> =.015 (mean 2.8 point improvement from control) HHL: Control: Baseline Score: <i>M</i> =5.8 Follow-up score: <i>M</i> =5.5 Intervention: Baseline Score: <i>M</i> =5.4 Follow-up score: <i>M</i> =6.9 <i>M</i> change=1.8 95% CI [0.7, 2.9], <i>p</i> =.001 (mean 1.8 point improvement from control) 7 or greater score on MDI technique: Control: baseline= 29.6% Follow-up=23.5% Intervention: baseline= 21.4%, Follow-up=66.7% <i>p</i> =.002	significant, intervention scripted and consistent. Weaknesses: Single site, unmatched number in both groups, lower number of LHL participants, no masking. Conclusions: Intervention group had greater improvement in technique and score. Both LHL and HHL showed improvements. Feasibility: Multi-strategy intervention (spoken communication and literacy-sensitive written communication) benefitted both literacy levels with improvement in SC.
Margolis et al. (2015) Health literacy and diabetic foot ulcer healing.	Not directly stated, cited model noted: Health literacy causal conceptual model (Paasche-Orlow & Wolf, 2007)	Design: Quantitative, Prospective cohort study taken from a subset enrolled in a CSS	<i>N</i> =41 CSS <i>n</i> =22 subjects for Cohort study (enrolled from CSS) AR: 0% Demographics: Cohort study:	IV1: HL score IV2: DM HL and numeracy IV3: DM SE DV: Wound outcomes (size,	IV1: STOFHLA (α =.90) IV2: Diabetes literacy and numeracy (α =.95) IV3: Perceived Diabetes Self-	Stata (version 13.1) Descriptive statistics of all variables	STOFHLA: Enrolled: <i>M</i> = 33.8, <i>SD</i> =2.3 Not enrolled: <i>M</i> = 27.3, <i>SD</i> = 9.6 <i>p</i> =.009 DM numeracy:	Level IV Strengths: CVR HL measurement tool and log healing rate CVR, 12-week study appropriate.

Key: α - Cronbach's alpha, AA – African-American, AHL – adequate health literacy, AHRQ – Agency for Healthcare Research and Quality, ATT – attrition rate, BP – blood pressure, CAD – coronary artery disease, CES-D – Center for Epidemiologic Studies Depression Scale, CI – confidence interval, CR – Caucasian race, CSS – cross-sectional study, CO – clinical outcomes, COPD – chronic obstructive pulmonary disease, CVR – confirmed valid and reliable, DK – diabetes knowledge, DM – diabetes mellitus, DV – dependent variable, EC – exclusion criteria, GM – general medical, HbA1C – hemoglobin A1c, HF – heart failure, HFQOL – heart failure quality of life, HHL – high health literacy, HI – health insurance, HIV – Human immunodeficiency virus, HL – health literacy, HMO – Health Maintenance Organization, HO – health outcomes, HRQOL – health-related quality of life, HS – high school, HTN – hypertension, IC – inclusion criteria, IM – internal medicine, INSUFF – insufficient evidence, IRR – incidence rate ratio, IV – independent variable, LDL – low-density lipoprotein, LHL – low health literacy, LTF – loss to follow-up, *M* – mean, MA – meta-analysis, MC – medical condition, MCO – managed care organization, MDI – metered dose inhaler, *Mdn* – median, MEDFACTS – meat, eggs, dairy, fried foods, fat in baked goods, convenience foods, fats added at the table, and snacks MH – mental health, *N* – number of participants, *n* – number of subgroup, NR – not reported, *ns* – not significant, NYHA – New York Heart Association, OS – observational study, PC – primary care, PDM – participatory decision-making, PE – practice experience, PPC – patient-provider communication, PRISMA – Preferred Reporting Items for Systematic Reviews and Meta-Analyses, RCT – randomized controlled trial, REALM – Rapid Estimate of Adult Literacy in Medicine, REALM-r – Rapid Estimate of Adult Literacy in Medicine revised, RIAS – Roter Interaction Analysis System, RG – range, SAS – Statistical Analysis Software, SC – self-care, *SD* – standard deviation, SDC – sociodemographic characteristics, SE – self-efficacy, SMBG – self-monitoring of blood glucose, SOE – strength of evidence, SOR – standardized odds ratio, SPSS – Statistical Package for Social Sciences, SR – systematic review, SRR – standardized relative risk, STOFHLA – Short Test of Functional Health Literacy, TOFHLA – Test of Functional Health Literacy in Adults; UMC – University Medical Center, VA – Veteran's Affairs

Citation	Theory/Conceptual Framework	Design/Purpose	Sample/Setting	Variables & Definitions	Measurement/Instrumentation	Data Analysis	Findings/Results	Level/Quality Application
<p>Country: USA</p> <p>Funding: National Institutes of Health</p> <p>Conflict/Bias: None reported or appreciated</p>		<p>Purpose: To understand how a patient’s HL affects management decisions of their foot ulcers.</p>	<p><i>M</i> age=53.5 (47-61.5) Females=37% CR=NR AA=75% HS degree=NR HI=NR STOFHLA CSS: 31.1 STOFHLA Cohort: 33.8 STOFHLA Not enrolled in cohort: 27.3 (low)</p> <p>Setting: Urban wound care setting Time: 12 weeks</p> <p>IC: NR EC: NR</p>	<p>duration of wound)</p>	<p>Management Scale ($\alpha=.83$)</p> <p>DV: Wound ruler</p>	<p>Chi-square, <i>t</i>-test, linear regression: to compare literacy assessments between groups</p>	<p>Enrolled: <i>M</i>= 0.71, <i>SD</i>= 0.26 Not enrolled: <i>M</i>= 0.55, <i>SD</i>=0.32 <i>p</i>=.02 DM SE and DM HL mean scores <i>ns</i> between groups</p> <p>DV: Enrolled: <i>M</i> wound=4.5cm² <i>SD</i>=7.1 <i>Mdn</i>=2.3 cm² Range= 0.48-3.8 cm² <i>M</i> duration (months)=13.2, <i>SD</i>=14.1 <i>Mdn</i> (months)=7 Range (months)= 3-24 Week 4: 59.1% (<i>n</i>=13) increased in size, log healing rate =0.09 cm²/week, <i>SD</i>=0.29 Week 12: 27.3% (<i>n</i>=6) healed. LHL had larger (<i>p</i>=.04) and older (<i>p</i>=.125) wounds.</p>	<p>Weaknesses: Study design, low <i>N</i> and <i>n</i>, single site, IC and EC NR, lower number of LHL participants than AHL in cohort.</p> <p>Conclusions: LHL less likely to enroll in study and had larger and older wounds.</p> <p>Feasibility: Consider challenges of study recruitment and LHL wound patient presentation with larger and longer wounds.</p>
<p>Miller (2016)</p> <p>Health literacy and adherence to medical treatment in chronic and acute illness: A meta-analysis.</p> <p>Country: USA</p> <p>Funding: Robert Wood Johnson Investigator</p>	<p>Not directly stated, cited model noted: Framework of health literacy and health action (von Wagner, Steptoe, Wolf, & Wardle, 2009)</p>	<p>Design: Quantitative, MA, PRISMA</p> <p>Purpose: To assess effect sizes in studies of (a) the correlation between HL and medication and non-medication adherence, and (b) the effects of HL</p>	<p>Databases=2 Citations=8,463 Met IC=220 CSS=48 Experimental studies=172</p> <p>Demographics: NR</p> <p>HL and adherence= 48 studies HL interventions on improving HL= 71 studies</p>	<p>IV1: HL level (low, high) IV2: HL interventions</p> <p>DV1: Treatment adherence DV2: Improving HL level DV3: Patient adherence</p>	<p>IV1: TOFHLA, REALM, Other ($\alpha=.73-.91$) IV2: HL interventions (details NR)</p> <p>DV1, DV3: Self-reports, patient diaries, pill counts, physical examination, electronic assessments, Medication Event</p>	<p>SPSS (version 12.0)</p> <p><i>t</i>-test: to compare moderators in correlational and experimental studies</p> <p>Random effects model: to compute and combine effect size statistics and allow for generalization</p>	<p>DV1: Unweighted mean <i>r</i>=0.14, 95% CI [0.08, 0.19], <i>p</i><.001 (14% higher risk of nonadherence among LHL than of HHL patients. SRR= 1.33 95% CI [1.17, 1.47] SOR= 1.76 95% CI [1.38, 2.16] Moderator Variable: Treatment regimen: <i>t</i> (46)=-2.443, <i>p</i>=.018, <i>r</i>=.34 Patient illness: <i>t</i> (46)=2.564, <i>p</i>=.014, <i>r</i>=.35</p>	<p>Level I Strengths: Appropriate search methods, MA method CVR, CVR HL measurements, appropriate IC and EC, multiple sites, large amount of included studies.</p> <p>Weaknesses: Theoretical framework not discussed,</p>

Key: α - Cronbach’s alpha, AA – African-American, AHL – adequate health literacy, AHRQ – Agency for Healthcare Research and Quality, ATT – attrition rate, BP – blood pressure, CAD – coronary artery disease, CES-D – Center for Epidemiologic Studies Depression Scale, CI – confidence interval, CR – Caucasian race, CSS – cross-sectional study, CO – clinical outcomes, COPD – chronic obstructive pulmonary disease, CVR – confirmed valid and reliable, DK – diabetes knowledge, DM – diabetes mellitus, DV – dependent variable, EC – exclusion criteria, GM – general medical, HbA1C – hemoglobin A1c, HF – heart failure, HFQOL – heart failure quality of life, HHL – high health literacy, HI – health insurance, HIV – Human immunodeficiency virus, HL – health literacy, HMO – Health Maintenance Organization, HO – health outcomes, HRQOL – health-related quality of life, HS – high school, HTN – hypertension, IC – inclusion criteria, IM – internal medicine, INSUFF – insufficient evidence, IRR – incidence rate ratio, IV – independent variable, LDL – low-density lipoprotein, LHL – low health literacy, LTF – loss to follow-up, *M* – mean, MA – meta-analysis, MC – medical condition, MCO – managed care organization, MDI – metered dose inhaler, *Mdn* – median, MEDFACTS – meat, eggs, dairy, fried foods, fat in baked goods, convenience foods, fats added at the table, and snacks MH – mental health, *N* – number of subgroup, NR – not reported, *ns* – not significant, NYHA – New York Heart Association, OS – observational study, PC – primary care, PDM – participatory decision-making, PE – practice experience, PPC – patient-provider communication, PRISMA – Preferred Reporting Items for Systematic Reviews and Meta-Analyses, RCT – randomized controlled trial, REALM – Rapid Estimate of Adult Literacy in Medicine, REALM-r – Rapid Estimate of Adult Literacy in Medicine revised, RIAS – Roter Interaction Analysis System, RG – range, SAS – Statistical Analysis Software, SC – self-care, *SD* – standard deviation, SDC – sociodemographic characteristics, SE – self-efficacy, SMBG – self-monitoring of blood glucose, SOE – strength of evidence, SOR – standardized odds ratio, SPSS – Statistical Package for Social Sciences, SR – systemic review, SRR – standardized relative risk, STOFHLA – Short Test of Functional Health Literacy, TOFHLA – Test of Functional Health Literacy in Adults; UMC – University Medical Center, VA – Veteran’s Affairs

Citation	Theory/Conceptual Framework	Design/Purpose	Sample/Setting	Variables & Definitions	Measurement/Instrumentation	Data Analysis	Findings/Results	Level/Quality Application
<p>Award in Health Policy, National Institutes of Health</p> <p>Conflict/Bias: None reported or appreciated.</p>		<p>interventions on improvement of HL and adherence.</p>	<p>HL interventions on improving adherence=101 studies</p> <p>Setting: 3 HMO's, 4 VA hospitals, 41 UMC's, 6 private practices, 39 clinics, 49 hospitals, 6 patient homes, 99 other settings, 24 in multiple categories.</p> <p>IC: 1948-2012, peer-reviewed, English, HL and adherence measurement.</p> <p>EC: Not an empirical study, qualitative reviews, mental illness articles, no HL intervention aimed at improving adherence, no quantitative data to calculate an <i>r</i> effect size.</p>		<p>Monitoring System, pharmacy refill assessments, appointment logs, other (CVR NR)</p> <p>DV2: NR</p>	<p>Fixed effects model: to calculate weighted mean analysis and test for heterogeneity</p> <p>Binominal effect size display: to estimate the effect size in changes in success rates that are attributable to a specific treatment and calculate the standardized odds ratio and standardized relative risk</p>	<p>DV2: Unweighted mean $r=0.22$, 95% CI [0.18, 0.25], $p<.001$ SRR= 1.56 95% CI [1.44, 1.67] SOR= 2.45 95% CI [2.07, 2.78] Moderator Variable: HL assessment: $t(69)=3.992$, $p<.001$, $r=.43$ Context of Care: $t(69)=-2.17$, $p=.033$, $r=.25$ Patient income: $t(69)=-2.345$, $p=.022$, $r=.27$</p> <p>DV3: Unweighted mean $r=0.16$, 95% CI [0.14, 0.19], $p<.001$ SRR= 1.38 95% CI [1.32, 1.47] SOR= 1.91 95% CI [1.76, 2.16] Moderator Variable: Adherence: $t(99)=4.578$, $p<.001$, $r=.42$ Ethnicity: $t(99)=-2.06$, $p=.043$, $r=.2$</p>	<p>measurements and instrumentation used for DV limited reporting and CVR NR. Demographics NR.</p> <p>Conclusions: HL positively related to adherence and was higher in non-medication regimens. HL interventions had a greater effect on low income and minority patients.</p> <p>Feasibility: Supports effectiveness of HL interventions for non-medication regimens in adherence and support in vulnerable populations.</p>

Key: α - Cronbach's alpha, AA – African-American, AHL – adequate health literacy, AHRQ – Agency for Healthcare Research and Quality, ATT – attrition rate, BP – blood pressure, CAD – coronary artery disease, CES-D – Center for Epidemiologic Studies Depression Scale, CI – confidence interval, CR – Caucasian race, CSS – cross-sectional study, CO – clinical outcomes, COPD – chronic obstructive pulmonary disease, CVR – confirmed valid and reliable, DK – diabetes knowledge, DM – diabetes mellitus, DV – dependent variable, EC – exclusion criteria, GM – general medical, HbA1C – hemoglobin A1c, HF – heart failure, HFQOL – heart failure quality of life, HHL – high health literacy, HI – health insurance, HIV – Human immunodeficiency virus, HL – health literacy, HMO – Health Maintenance Organization, HO – health outcomes, HRQOL – health-related quality of life, HS – high school, HTN – hypertension, IC – inclusion criteria, IM – internal medicine, INSUFF – insufficient evidence, IRR – incidence rate ratio, IV – independent variable, LDL – low-density lipoprotein, LHL – low health literacy, LTF – loss to follow-up, M – mean, MA – meta-analysis, MC – medical condition, MCO – managed care organization, MDI – metered dose inhaler, Mdn – median, MEDFACTS – meat, eggs, dairy, fried foods, fat in baked goods, convenience foods, fats added at the table, and snacks MH – mental health, N – number of participants, n – number of subgroup, NR – not reported, ns – not significant, NYHA – New York Heart Association, OS – observational study, PC – primary care, PDM – participatory decision-making, PE – practice experience, PPC – patient-provider communication, PRISMA – Preferred Reporting Items for Systematic Reviews and Meta-Analyses, RCT – randomized controlled trial, REALM – Rapid Estimate of Adult Literacy in Medicine, REALM-r – Rapid Estimate of Adult Literacy in Medicine revised, RIAS – Roter Interaction Analysis System, RG – range, SAS – Statistical Analysis Software, SC – self-care, SD – standard deviation, SDC – sociodemographic characteristics, SE – self-efficacy, SMBG – self-monitoring of blood glucose, SOE – strength of evidence, SOR – standardized odds ratio, SPSS – Statistical Package for Social Sciences, SR – systematic review, SRR – standardized relative risk, STOFHLA – Short Test of Functional Health Literacy, TOFHLA – Test of Functional Health Literacy in Adults; UMC – University Medical Center, VA – Veteran's Affairs

Appendix H

Table 1

Synthesis Table

Studies	Aboumatar	Al Sayah	Berkman	DeWalt	Eckman	Hahn	Kim	Kiser	Margolis	Miller
Year	2013	2013	2011	2012	2012	2015	2016	2012	2015	2016
Design	CSS of RCT	SR	SR	RCT	RCT	CSS of RCT	SR and MA	RCT	CS	MA
LOE	II	I	I	II	II	II	I	II	IV	I
Number of Subjects	329	31-17,795	50-23,889	605	187	308	46-339	99	41	
Demographics										
Mean age	61.2	45.8-67.2	11.5-76	60.7	59.5	54.7		63	53.5	
% Females	65.8	42.7-79.4	0-100	48	61.2	51.6		65	37	
% Low HL	30.8			37.2	36			36		
% High/adequate HL	69.2			62.8	54			64		
Chronic Disease										
DM		X	X			X	X			X
Pulmonary			X					X		X
Cardiac	X		X	X	X					X
Wound									X	
Other			X							X
Setting										
PC/GM/IM Clinic	X	X	X	X	X	X		X		X
Specialty Clinic		X	X	X					X	X
Other		X	X							X
HL Instruments										
REALM/REALM-r	X	X	X		X		X			X
TOFHLA/STOFHLA		X	X	X			X	X	X	X
Other			X			X				X
PRE Intervention LHL Effects										
Adherence			↓				↓			
Self-care/self-management		↓	↓				↓			
Self-efficacy							↓			
Interpreting print materials			↓			↓				
Blood pressure control	↓	↓								
Emergency/Hospitalization use			↑							
HbA1C control							↓			
Preventative services			↓							
Health status			↓			↓			↓	
Patient-Physician Communication		↓				↓				
Disease knowledge		↓				↓	↓			

Key: ↑ – significant improvement, ↓ – significant reduction, ↔ – no change, CS – cohort study, CSS – cross-sectional study, DM – diabetes mellitus, GM – general medical, HbA1C – hemoglobin A1c, HL – health literacy, IM – internal medicine, LHL – low health literacy, LOE – level of evidence, MA – meta-analysis, PC – primary care, RCT – randomized controlled trial, REALM – Rapid Estimate of Adult Literacy in Medicine, REALM-r – Rapid Estimate of Adult Literacy in Medicine revised, SR – systemic review, STOFHLA – Short Test of Functional Health Literacy, TOFHLA – Test of Functional Health Literacy

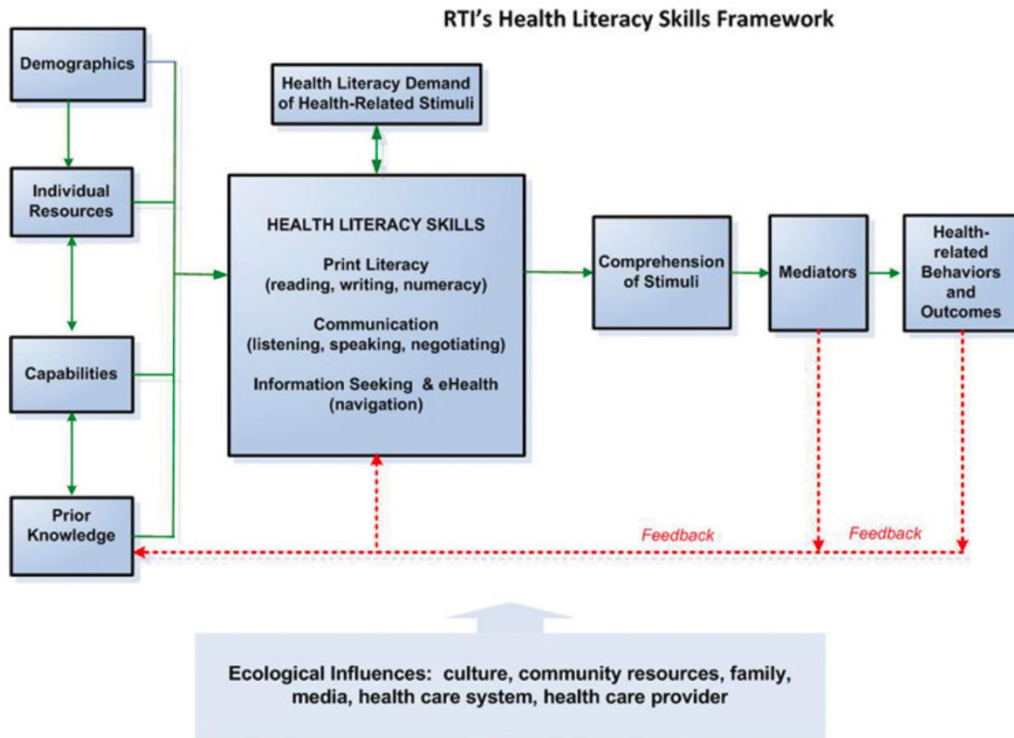
Studies	Aboumatar	Al Sayah	Berkman	DeWalt	Eckman	Hahn	Kim	Kiser	Margolis	Miller
HL Intervention Strategy										
Single session			X	X	X		X	X		
Multiple sessions	X		X	X			X			
Provider Communication	X		X				X			
Spoken Communication	X		X	X			X	X		
Written Communication	X		X	X	X		X	X		
Video/DVD/Computer	X		X		X		X			
HL Intervention Outcomes										
Behavioral:										
Adherence			↑				↑			↑
Disease management			↑							
Self-care/self-management			↑			↑	↑	↑		
Self-efficacy			↑				↑			
Clinical:										
Blood pressure	↔					↔				
Weight						↑				
HbA1C							↑			
Quality of Life			↔	↑						
Communication:										
Participatory decision making	↑									
Medical question asking	↑									
Knowledge:										
Disease knowledge			↑		↑		↑			

Key: ↑ – significant improvement, ↓ – significant reduction, ↔ – no change, **CS** – cohort study, **CSS** – cross-sectional study, **DM** – diabetes mellitus, **GM** – general medical, **HbA1C** – hemoglobin A1c, **HL** – health literacy, **IM** – internal medicine, **LHL** – low health literacy, **LOE** – level of evidence, **MA** – meta-analysis, **PC** – primary care, **RCT** – randomized controlled trial, **REALM** – Rapid Estimate of Adult Literacy in Medicine, **REALM-r** – Rapid Estimate of Adult Literacy in Medicine revised, **SR** – systemic review, **STOFHLA** – Short Test of Functional Health Literacy, **TOFHLA** – Test of Functional Health Literacy

Appendix I

Theoretical Framework

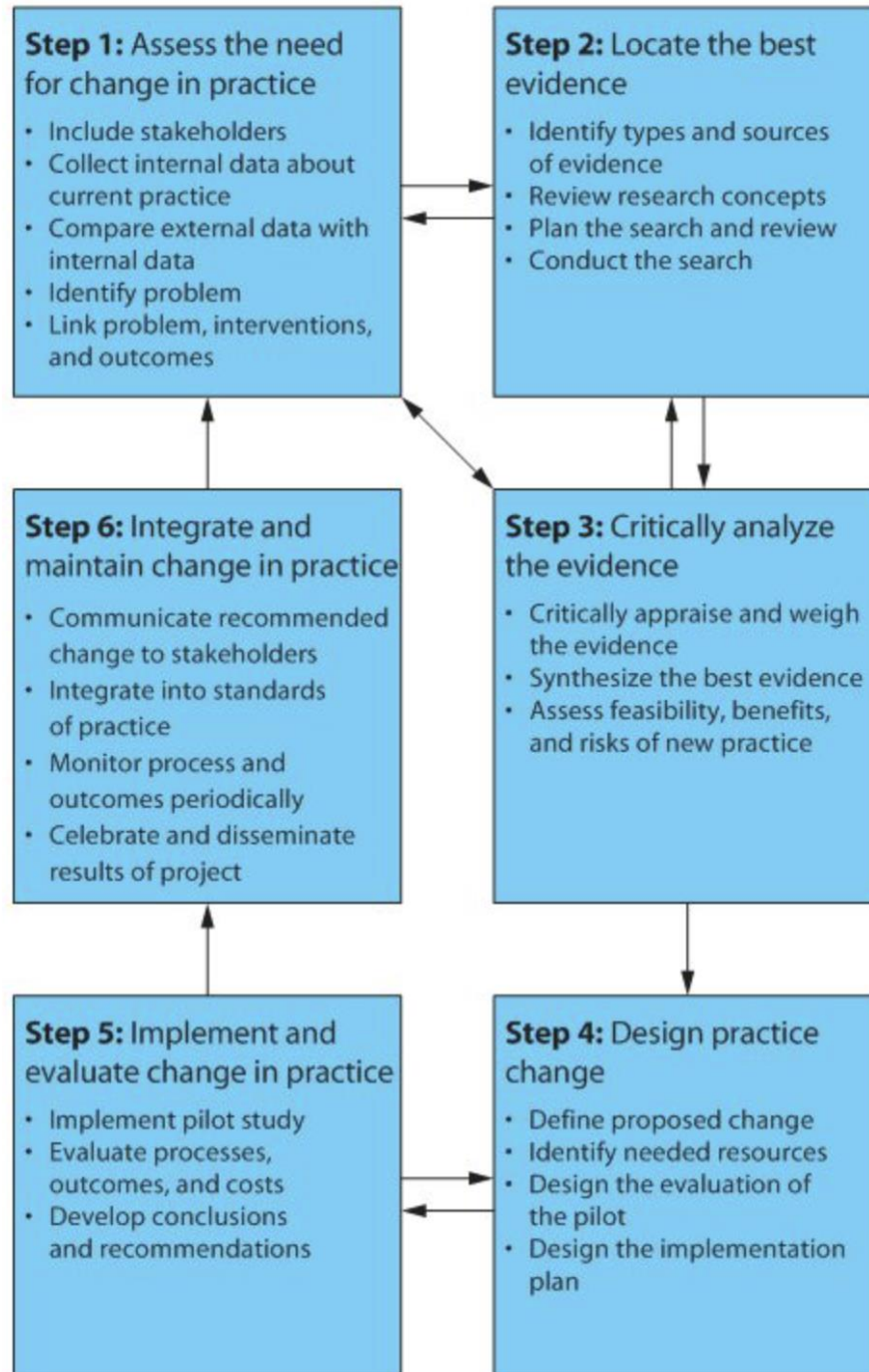
Health Literacy Skills Conceptual Framework (Squiers et al., 2012)



Appendix J

Evidence Based Practice Model

Model for Evidence-Based Practice Change (Larrabee, 2009)




Appendix K

Education Materials

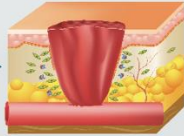
Wound Poster

WHEN IS MY WOUND GOING TO HEAL? ¿Cuándo sanará mi herida?

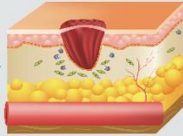
STAGES | Etapas



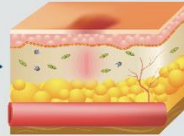
Injury
Herida



Inflammation
Inflamación




Tissue Growth
Crecimiento
de Tejido






Healed
Sanado

SIGNS OF INFECTION Señales de infección




- Increased Pain | Aumento del dolor
- Increased Redness | Aumento del enrojecimiento
- Increased Warmth | Aumento del calentamiento
- Increased Swelling | Aumento de la hinchazón
- Increased Drainage | Aumento del desecho
- Increased Odor | Aumento del olor



GOOD | Bien →

BAD | Malo →

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Wound Brochure English

What can help my wound?

- **WASH YOUR HANDS.** With soap and water before and after changing your dressing to prevent infection.
- **KEEP IT COVERED.** Keep your wound covered with a clean dressing.
- **BE CAREFUL.** Protect your wound from injury by avoiding objects or clothing that can irritate it.
- **EAT RIGHT.** Eat a well-balanced diet to help your body heal.

What is bad for my wound?

- **HIGH BLOOD SUGARS.** Watch your blood sugars and keep them controlled.
- **SMOKING.** Smoking reduces the supply of oxygen to heal the wound.
- **INFECTION.** Bacteria can infect the wound and lead to serious problems.
- **DRYNESS.** Do not leave your wound open to air to dry out. Wounds heal faster when kept moist.

What are the signs of infection?

Check for infection at every dressing change and seek immediate care for:

- Fevers, chills, nausea or vomiting
- Increased wound pain
- Increased redness and warmth in and around the wound
- Increased swelling around the wound
- Increased wound drainage or odor

DRESSING CHANGE SCHEDULE

mark box when complete

	Week 1	Week 2	Week 3	Week 4
MON				
TUES				
WED				
THURS				
FRI				
SAT				
SUN				

HOW TO CARE FOR YOUR WOUND



INSTRUCTIONS
for patients and caregivers

Questions or Concerns?
Contact us at 602-261-6868

Virginia G. Piper
St. Vincent de Paul Medical Clinic
420 W. Watkins Rd. Phoenix, AZ 85002

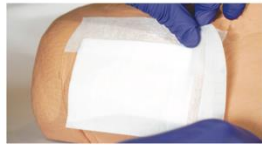



THE SOCIETY OF ST. VINCENT DE PAUL
FEEL. CARE. HOPE. HEAL.

WOUND DRESSING STEPS

- 1 Wash your hands with soap and water.
 
- 2 Put on gloves if available.
 
- 3 Remove the old dressing by lifting the tape across the skin gently as shown.
 

- 4 Wet the washing sponge with water then gently clean the wound with circular motions starting at the center of the wound then to the outer edge then pat dry with a soft, clean towel.
 
- 5 Apply the skin protection pad to the skin around the wound.
 
- 6 Apply the wound treatment as directed.
 

- 7 Place the dressing cover over the wound.
 
- 8 Secure the dressing in place with tape.
 

ADDITIONAL INSTRUCTIONS

- 9 Discard the old dressing and used washing sponge.
- 10 Wash hands again when dressing change is complete.

OTHER _____

Wound Brochure Spanish

¿Qué puede ayudar a mi herida?

- **LÁVESE LAS MANOS.** Con jabón y agua antes y después de cambiar vendaje para prevenir infección.
- **MANTÉNGALO CUBIERTO.** Mantenga su herida cubierta con un vendaje limpio.
- **CUIDADO.** Proteja su herida de lesiones evitando objetos o ropa que puedan irritarla.
- **COMA BIEN.** Coma una dieta balanceada para ayudar a su cuerpo a sanar.

Qué es malo para su herida?

- **AZÚCAR ALTA EN LA SANGRE.** Revise su azúcar en la sangre y manténgalo bajo control.
- **FUMAR.** Fumar reduce el nivel de oxígeno para sanar la herida.
- **INFECCIÓN.** Las bacterias pueden infectar la herida y causar graves problemas.
- **RESEQUEDAD.** No deje la herida abierta al aire para que se seque. Las heridas se curan más rápido cuando se mantienen húmedas.

¿Cuáles son los signos de infección?

Revise si hay infección en cada cambio de vendaje y busque atención inmediata para:

- Fiebre, escalofríos, náusea o vómito
- Aumento del dolor en la herida
- Aumento del enrojecimiento o se siente caliente en y alrededor de la herida
- Aumento de hinchazón alrededor de la herida
- Aumento del drenaje o olor en la herida

CAMBIO DE VENDAJE HORARIO

Cuando se haya completado marque el cuadro

	Semana 1	Semana 2	Semana 3	Semana 4
LUNES				
MARTES				
MIÉRCOLES				
JUEVES				
VIERNES				
SÁBADO				
DOMINGO				

¿Preguntas o Inquietudes?
602-261-6868

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St. Vincent de Paul Medical Clinic
420 W. Watkins Rd. Phoenix, AZ 85002



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FEEL. CLARITY. MOVE. REAL.

CÓMO CUIDAR SU HERIDA



INSTRUCCIONES para el paciente y el cuidador del paciente

PASOS PARA CAMBIAR EL VENDAJE DE HERIDAS

- 1 Lávese las manos con jabón y agua.
 
- 2 Póngase guantes si tiene disponible.
 
- 3 Retire el vendaje viejo despegando la cinta de la piel suavemente como se muestra.
 

- 4 Humedezca la esponja de lavado con agua y luego limpie suavemente la herida con movimientos circulares comenzando en el centro de la herida y luego hacia el borde externo, luego seque con una toalla suave y limpia.
 
- 5 Aplique el protector de la piel alrededor de la herida.
 
- 6 Aplique el tratamiento de la herida según como se indicó.
 

- 7 Coloque la cubierta del vendaje sobre la herida.
 
- 8 Asegure que el vendaje quede en posición con cinta adhesiva.
 

INSTRUCCIONES ADICIONALES

- 9 Deseche el vendaje viejo y la esponja de lavado usada.
- 10 Lávese las manos de nuevo cuando termine el cambio de vendaje.

OTRO _____

Wound Stickers



Appendix L

Site Approval



July 13, 2017

To Whom It May Concern:

On behalf of the Society of St. Vincent de Paul Virginia G. Piper Medical and Dental Clinic, I am pleased to support the evidence-based practice study entitled "Literacy-Sensitive Education for Wound Self-Care in the Uninsured" as proposed by Erin Tharalson, ANP-BC and Lynda Rout, DNP.

In doing so, our practice agrees to serve as a research site for this project for data collection with the provision that all practice, patient, and physician specific identifying information be removed from any and all publications arising from this research.

Please feel free to contact me at 602-261-6867 with any questions or if you require additional information.

Sincerely,

Maurice Lee MD, MPH, FAAFP
O: 602-261-6867
F: 602-261-6816
Medical Director
Virginia G Piper St. Vincent de Paul Medical & Dental Clinic

The Society of St. Vincent de Paul
P.O. Box 13600 Phoenix, AZ 85002

420 W. Watkins Rd, Phoenix, AZ 85002
www.stvincentsofpaul.net
602.254.3336

FEED. CLOTHRE. HOUSE. HEAL.

Appendix M

Institutional Review Board Approvals

Modification approval



APPROVAL: EXPEDITED REVIEW

Lynda Root
 CONHI - DNP
 602/496-0810
 Lynda.Root@asu.edu

Dear Lynda Root:

On 8/9/2017 the ASU IRB reviewed the following protocol:

Type of Review:	Modification
Title:	An Innovative Literacy-Supportive Education Pilot for Wound Self-Care
Investigator:	Lynda Root
IRB ID:	STUDY00006445
Category of review:	(mm) Minor modification
Funding:	None
Grant Title:	None
Grant ID:	None
Documents Reviewed:	<ul style="list-style-type: none"> • Wound Knowledge Test English, Category: Measures (Survey questions/Interview questions /interview guides/focus group questions); • Spanish recruitment script, Category: Recruitment Materials; • Site approval letter, Category: Off-site authorizations (school permission, other IRB approvals, Tribal permission etc); • Informed Consent, Category: Consent Form; • Wound Knowledge Test Spanish, Category: Translations; • IRB Protocol Revision, Category: IRB Protocol; • Wound Performance Checklist, Category: Other (to reflect anything not captured above); • Wound education brochure Spanish, Category: Translations; • Erin Tharalson CITI Training Verification, Category: Other (to reflect anything not captured

	<p>above);</p> <ul style="list-style-type: none"> • Spanish informed consent, Category: Consent Form; • St.pdf, Category: Other (to reflect anything not captured above); • Bates Jensen Wound Assessment Tool, Category: Other (to reflect anything not captured above); • Brief Health Literacy Screen Permission, Category: Other (to reflect anything not captured above); • Participant Questionnaire English, Category: Measures (Survey questions/Interview questions /interview guides/focus group questions); • Recruitment script, Category: Recruitment Materials; • Translation Certification Form, Category: Translations; • Photos for brochure, Category: Other (to reflect anything not captured above); • Participant Questionnaire Spanish, Category: Translations; • Wound education brochure, Category: Other (to reflect anything not captured above); • English and Spanish Wound education poster, Category: Other (to reflect anything not captured above); • Bates-Jensen Wound Assessment Tool Permission, Category: Other (to reflect anything not captured above);
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The IRB approved the protocol from 7/22/2017 to 7/21/2018 inclusive. Three weeks before 7/21/2018 you are to submit a completed Continuing Review application and required attachments to request continuing approval or closure.

If continuing review approval is not granted before the expiration date of 7/21/2018 approval of this protocol expires on that date. When consent is appropriate, you must use final, watermarked versions available under the “Documents” tab in ERA-IRB.

In conducting this protocol you are required to follow the requirements listed in the INVESTIGATOR MANUAL (HRP-103).

Sincerely,

IRB Administrator

cc: Erin Tharalson

Initial approval



APPROVAL: EXPEDITED REVIEW

Lynda Root
 CONHI - DNP
 602/496-0810
 Lynda.Root@asu.edu

Dear Lynda Root:

On 7/22/2017 the ASU IRB reviewed the following protocol:

Type of Review:	Initial Study
Title:	An Innovative Literacy-Supportive Education Pilot for Wound Self-Care
Investigator:	Lynda Root
IRB ID:	STUDY00006445
Category of review:	(4) Noninvasive procedures, (7)(a) Behavioral research
Funding:	None
Grant Title:	None
Grant ID:	None
Documents Reviewed:	<ul style="list-style-type: none"> • Erin Tharalson CITI Training Verification, Category: Other (to reflect anything not captured above); • Wound education poster, Category: Other (to reflect anything not captured above); • Bates Jensen Wound Assessment Tool, Category: Other (to reflect anything not captured above); • Wound Performance Checklist, Category: Other (to reflect anything not captured above); • Informed Consent, Category: Consent Form; • Recruitment script, Category: Recruitment Materials; • IRB Protocol Revision, Category: IRB Protocol; • Wound education brochure, Category: Other (to reflect anything not captured above); • Site approval letter, Category: Off-site authorizations (school permission, other IRB approvals, Tribal

	<p>permission etc);</p> <ul style="list-style-type: none"> • Participant Questionnaire English, Category: Measures (Survey questions/Interview questions /interview guides/focus group questions); • Brief Health Literacy Screen Permission, Category: Other (to reflect anything not captured above); • Wound Knowledge Test English, Category: Measures (Survey questions/Interview questions /interview guides/focus group questions); • Photos for brochure, Category: Other (to reflect anything not captured above); • St.pdf, Category: Other (to reflect anything not captured above); • Bates-Jensen Wound Assessment Tool Permission, Category: Other (to reflect anything not captured above);
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The IRB approved the protocol from 7/22/2017 to 7/21/2018 inclusive. Three weeks before 7/21/2018 you are to submit a completed Continuing Review application and required attachments to request continuing approval or closure.

If continuing review approval is not granted before the expiration date of 7/21/2018 approval of this protocol expires on that date. When consent is appropriate, you must use final, watermarked versions available under the “Documents” tab in ERA-IRB.

In conducting this protocol you are required to follow the requirements listed in the INVESTIGATOR MANUAL (HRP-103).

Sincerely,

IRB Administrator

cc: Erin Tharalson
Erin Tharalson

Appendix N

Measurement Tool Approval

Brief Health Literacy Screen

Lisa Chew
 RE: Three health literacy screening questions
 To: Erin Tharalson, Cc: Lynda Root

Dissertation May 26, 2017 at 3:16 PM
 Details LC

Yes, please feel free to use the screen.

Thanks,
 Lisa

The above email may contain patient identifiable or confidential information. Because email is not secure, please be aware of associated risks of email transmission. If you are a patient, communicating to a UW Medicine Provider via email implies your agreement to email communication; see <http://www.uwmedicine.org/Global/Compliance/EmailRisk.htm>

The information is intended for the individual named above. If you are not the intended recipient, any disclosure, copying, distribution or use of the contents of this information is prohibited. Please notify the sender by reply email, and then destroy all copies of the message and any attachments. See our Notice of Privacy Practices at www.uwmedicine.org.

From: Erin Tharalson [<mailto:ertharals@asu.edu>]
Sent: Friday, May 26, 2017 2:56 PM
To: lchew@u.washington.edu
Cc: Lynda Root
Subject: Three health literacy screening questions

Hi Dr. Chew,

My name is Erin Tharalson and I am an adult nurse practitioner and certified wound specialist practicing in Phoenix, Arizona. I am also student at Arizona State University working towards a clinic al doctorate in nursing practice (DNP). My capstone project titled "Literacy-sensitive education for wound self-care in the uninsured" will be conducted at a charity clinic in South Phoenix that services the uninsured and working poor receiving wound management. At the clinic we have numerous low health literacy, mostly Spanish-speaking patients, in need of literacy-sensitive education that supports wound knowledge and dressing instructions. I would like written permission to use your three question health literacy screen (see below) to stratify patients. Those who score as "inadequate" will be stratified to a more intense education intervention. The outcomes of the study will be measurement of wound knowledge and self-care.

I have included my professor guiding my project as well on this email. Please let me know if I have permission to use the screen. Also if you have any scoring suggestions or recommendations that is much appreciated.

Sincerely,
 Erin Tharalson, MSN, RN, ANP-BC, CWS
ertharals@asu.edu
 480-206-8076

Bates-Jensen Wound Assessment Tool

Bates-Jensen, Barbara @
 Re: Use of the Bates-Jensen Wound Assessment Tool
 To: Erin Tharalson

Inbox - iCloud 11:30 AM BB

New contact info found in this email: Barbara Bates-Jensen batesjen@sonnet.ucla.edu [add...](#)

Hi Erin,
 I am happy to give you permission to use the Bates-Jensen Wound Assessment Tool (BWAT) in your practice and your study. I am attaching the most recent version of the tool for your use.
 Please let me know if I can be of any assistance to you!
 Sincerely,
 Barbara Bates-Jensen

Barbara M. Bates-Jensen PhD, RN, FAAN
 Professor of Nursing and Medicine
 School of Nursing and David Geffen School of Medicine
 University of California, Los Angeles
 5-234 Factor Bldg.
 700 Tiverton Ave
 Los Angeles, CA 90095-6919
 Cell: 626-437-8543 (preferred)
 Email: bbatesjensen@sonnet.ucla.edu
 Wound Reach Foundation
www.woundreach.org
www.ouchrace.com

From: Erin Tharalson <ertharals@asu.edu>
Date: Wednesday, June 14, 2017 at 9:50 PM
To: Barbara Bates-Jensen <batesjen@sonnet.ucla.edu>
Subject: Re: Use of the Bates-Jensen Wound Assessment Tool

Hi Dr. Bates-Jensen,

My name is Erin Tharalson and I am an adult nurse practitioner and certified wound specialist practicing in Phoenix, Arizona. I am also student at Arizona State University working towards a clinic al doctorate in nursing practice (DNP). My capstone project titled "Literacy-sensitive education for wound self-care in the uninsured" will be conducted at a charity clinic in South Phoenix that services the uninsured and working poor receiving wound management. At the clinic we have numerous low health literacy, mostly Spanish-speaking patients, in need of literacy-sensitive education that supports wound knowledge and dressing instructions. I would like written permission to use your Bates-Jensen Wound Assessment Tool to measure wound status over 4 weeks as part of the outcome of self-care.

Please let me know if I have permission to use the tool.

Sincerely,
 Erin Tharalson, MSN, RN, ANP-BC, CWS
ertharals@asu.edu
 480-206-8076



Mail Attachment

Appendix O

Recruitment Script

English

RECRUITMENT SCRIPT

I am a graduate student under the direction of Dr. Lynda Root from the College of Nursing and Health Innovation at Arizona State University.

I am conducting a study to evaluate a wound educational program that may improve your wound knowledge and ability to care for your wound.

I am recruiting individuals who would like to learn more about their wound and dressing changes. Participants will answer 10 questions before and after a brief 10-minute education session and perform their dressing change on a wound model. The total time each visit is approximately 15 minutes and will occur at your next three clinic visits.

In order to participate, you must be 18 years or older, able to speak English or Spanish, and your wound must not require a wound vac or multi-layer compression. Your participation in this study is voluntary. If you choose not to participate in this study or withdraw at any time it will not impact your care or treatment at the clinic.

Spanish

RECRUITMENT SCRIPT-Spanish

Soy una estudiante de postgrado bajo la dirección de la Dr. Lynda Root de la escuela de enfermería y innovación de salud en la Universidad Estatal de Arizona. Estoy llevando a cabo un estudio para evaluar un programa educativo sobre heridas, el cual puede mejorar su conocimiento y cuidado sobre su herida.

Estoy reclutando a personas que deseen aprender más sobre su herida y cambio de vendaje. Los participantes responderán 10 preguntas antes y después de una sesión educativa breve de 10 minutos y realizarán su cambio de vendaje en un modelo de herida. El tiempo total de cada visita es de aproximadamente 15 minutos y ocurrirá en sus tres próximas visitas en la clínica.

Para participar, usted debe tener más de 18 años, hablar inglés o español, y la herida no debe requerir un terapia de presión negativa o múltiples capas de compresión. Su participación en este estudio es voluntaria. Su atención o tratamiento en la clínica no se verá afectado en caso de que usted decida no participar o retirarse de este estudio.

Appendix P

Informed Consent

Informed consent in English

Informed Consent**An Innovative Literacy-Supportive Education Pilot for Wound Self-Care**

To Whom It May Concern:

I am a doctoral student under the direction of Professor Lynda Root, DNP, RN in the Doctor of Nursing Practice Program in the College of Nursing and Health Innovation at Arizona State University. I am conducting a study to educate you in basic wound knowledge and care of your wound.

Why am I being invited to take part in a study?

We are inviting you to take part in this study because you have a wound, you are at least 18 years old, and you speak English or Spanish.

Why is this study being done?

Patients struggle with caring for their wound and changing their dressings. When this is done incorrectly, it can slow wound healing. This study is being done to find out if a formal education program in basic wound care and dressing steps improves wound knowledge, the ability to care for your own wound, and wound healing.

How long will the study last?

We expect that individuals will spend 15 minutes at each visit participating in the proposed activities. The study includes a total of 3 visits.

How many people will be studied?

We expect about 30 people will participate in this study. Your participation in this study is voluntary. If you choose to not participate or withdraw from the study at any time, there will be no penalty.

What happens if I say yes, I want to be in this study?

You will be asked to fill out a basic form about yourself and a wound knowledge test. The study nurse practitioner will look at your wound and fill out a wound status form. You will then receive education in basic wound care and dressing steps. Next, you will complete the knowledge test again and perform the dressing steps for your wound on a wound model. If you miss any steps or test questions, those areas will be reviewed. At your second and fourth wound visit, the study nurse practitioner will look at your wound and fill out a wound status form; you will be asked to fill out the knowledge test again and perform the dressing steps on a wound model. You are free to decide whether you wish to participate in this study.

What happens if I say yes, but I change my mind later?

You can leave the study at any time it will not be held against you and will not impact your care or treatment at the clinic. You have the right to not answer any questions, and to stop participation at any time. Refusal to participate in this study will have no effect on the care you receive at this clinic.

Will being in this study help me in any way?

Possible benefits include improved knowledge and skills in the ability to take care of your wound in the home.

What happens to the information collected for the study?

The information collected for the study will be anonymous and names or identifying information will not be recorded in any study materials. If you consent to share your results they could be used in papers, presentations, or publications, but your name will not be reported. Any reporting of results will be in aggregate form only. The pre and post assessments will be linked in group form and not at the individual level.

Who can I talk to?

If you have questions, concerns, or complaints, contact the study team: Lynda Root, the Primary Investigator at (602) 496-0810 or Erin Tharalson at (602) 261-6868.

This study has been reviewed and approved by the Social Behavioral IRB. You may talk to them at (480) 965-6788 or by email at research.integrity@asu.edu if:

- Your questions, concerns, or complaints are not being answered by the study team.
- You cannot reach the study team.
- You want to talk to someone besides the study team.
- You have questions about your rights as a study participant.
- You want to get information or provide input about this study.

Please let me know if you would like to participate in the study.

Informed consent in Spanish

Consentimiento Informado

Estudio piloto de educación innovadora en apoyo a la enseñanza del autocuidado de las heridas

A quien corresponda:

Soy estudiante de doctorado bajo la dirección de la Profesora Lynda Root, DNP, RN, en el Programa de Doctorado en Enfermería de la Escuela de Enfermería e Innovación y Salud de la Universidad Estatal de Arizona. Estoy realizando un estudio para educar en el conocimiento básico de las heridas y el cuidado de las mismas.

¿Por qué le estoy invitado a participar en este estudio?

Le invitamos a participar en este estudio porque tiene una herida, tiene por lo menos 18 años y habla inglés o español.

¿Por qué se está realizando este estudio?

Los pacientes luchan con el cuidado de sus heridas y el cambio de sus vendajes. Cuando esto se hace de manera incorrecta, puede retrasar la sanación de las heridas. Este estudio se está llevando a cabo para averiguar si un programa de educación formal en el cuidado básico de heridas y los pasos para el vendaje mejoran el conocimiento sobre las heridas, la capacidad de cuidar su propia herida y la sanación.

¿Cuánto tiempo durará el estudio?

Esperamos que los individuos pasen 15 minutos en cada visita participando en las actividades propuestas. El estudio incluye un total de 3 visitas.

¿Cuántas personas serán estudiadas?

Esperamos que aproximadamente 30 personas participen en este estudio. Su participación en este estudio es voluntaria. Si decide no participar o retirarse en cualquier momento, no habrá penalidad.

¿Qué sucede si digo que sí quiero participar en este estudio?

Se le pedirá que llene un formulario básico sobre usted y una prueba de conocimiento acerca de las heridas. La practicante de enfermería del estudio examinará su herida y llenará un formulario del estado de esta. A continuación, recibirá educación sobre el cuidado básico de las heridas y los pasos de vendaje. A continuación, completará la prueba de conocimiento nuevamente y realizará los pasos del vendaje para su herida en un modelo. Si falla en alguno de los pasos o en alguna pregunta, esas áreas serán revisadas. En su segunda y cuarta visita, la practicante de enfermería del estudio examinará su herida y llenará un formulario describiendo el estado de la herida; se le pedirá que llene la prueba de conocimiento nuevamente y realice los pasos de vendaje en un modelo de la herida. Usted es libre de decidir si desea participar en este estudio.

¿Qué pasa si digo que sí, pero luego cambio de opinión?

Usted puede abandonar el estudio en cualquier momento sin repercusiones en su contra y no afectará su atención o tratamiento en la clínica. Tiene el derecho de no contestar cualquier pregunta y de dejar de participar en cualquier momento. Negarse a participar en este estudio no tendrá ningún efecto sobre el cuidado que usted recibe en esta clínica.

¿Participar en el estudio me ayudará de alguna manera?

Los posibles beneficios incluyen un mayor conocimiento y habilidades en la capacidad de cuidar de su herida en el hogar.

¿Qué sucede con la información recolectada para el estudio?

La información recolectada para el estudio será anónima y los nombres o información de identificación no serán registrados en ningún material de estudio. Si usted da su consentimiento para compartir sus resultados, estos se podrían utilizar en documentos, presentaciones o publicaciones, pero su nombre no será informado. Cualquier reporte de resultados será en forma agregada solamente. Las pre y post evaluaciones estarán vinculadas en forma de grupo y no a nivel individual.

¿Con quién puedo comunicarme?

Si tiene preguntas, inquietudes o quejas, contacte por teléfono al equipo de estudio: Lynda Root, el investigador principal (602) 496-0810 o Erin Tharalson (602) 261-6868.

Este estudio ha sido revisado y aprobado por el Instituto de Comportamiento Social IRB. Puede comunicarse con ellos en el teléfono (480) 965-6788 o por correo electrónico en: research.integrity@asu.edu si:

- Sus preguntas, dudas o quejas no son respondidas por el equipo de estudio.
- No puede comunicarse con el equipo del estudio.
- Quiere hablar con alguien diferente al equipo de estudio.
- Tiene preguntas sobre sus derechos como participante en el estudio.
- Desea obtener información o proporcionar información sobre este estudio.

Por favor, déjeme saber si le gustaría participar en el estudio.

Appendix Q

Wound Education Participant Questionnaire

English

ID _____

Date _____

Wound Education Participant Questionnaire

Instructions: Mark your answer with an "X" in the box or write in the space provided.

Age: _____

Sex: Male
 Female

Language preference:

-
- English
-
-
- Spanish

Race/Ethnicity:

-
- White, non-Hispanic
-
-
- Hispanic
-
-
- Black or African American
-
-
- Asian
-
-
- Other

Visit type:

-
- This is my first visit to the wound clinic
-
-
- This is a follow-up visit to the wound clinic

How confident are you in filling out medical forms by yourself?

-
- Extremely
-
-
- Quite a bit
-
-
- Somewhat
-
-
- A little bit
-
-
- Not at all

How often do you have someone (like a family member, friend, hospital/clinic worker or caregiver) help you read hospital materials?

-
- Always
-
-
- Often
-
-
- Sometimes
-
-
- Rarely
-
-
- Never

How often do you have problems learning about your medical condition because of difficulty understanding written materials?

-
- Always
-
-
- Often
-
-
- Sometimes
-
-
- Rarely
-
-
- Never

Spanish

ID _____

Date _____

Cuestionario de participantes de Educación de la herida

Instrucciones: Marque su respuesta con una "X" en la caja o escriba en el espacio proveído.

Edad: _____

Sexo: Hombre
 Mujer

Preferencia de idioma:

 Inglés
 Español

Raza/Etnia:

 Blanco, no es de origen hispano, latino o español
 Hispano, latino o español
 Negro o Afroamericano
 Asiático
 Otra

Tipo de visita:

 Esta es mi primera visita a la clínica de heridas
 Es visita de seguimiento a la clínica de heridas

¿Qué tan seguro(a) se siente al llenar formas usted solo(a)?

 Extremadamente
 Bastante
 Algo
 Un poco
 Para nada

¿Qué tan seguido tiene used, un familiar, un amigo(a), un empleado(a) del hospital o la clinica u otra persona que le ayude a leer materiales del hospital?

 Siempre
 A menudo
 A veces
 Rara vez
 Nunca

¿Qué tan seguido tiene problemas aprendiendo sobre su condición médica porque es difícil entender información escrita?

 Siempre
 A menudo
 A veces
 Rara vez
 Nunca

Appendix R

Wound Knowledge Pre-test

English

ID _____

Date _____

Wound Knowledge**Pre-test**

Instructions: Mark your answer with an "X" in the box.

	Questions	Yes	No	Don't Know
1	Eating healthy foods can help my wound heal.			
2	Keeping my wound uncovered helps my wound heal.			
3	Washing my hands with soap and water before and after I change my dressing prevents infection.			
4	Cigarette smoking can slow my wound healing.			
5	Letting my wound dry out helps wound healing.			
6	Clothing or objects can irritate or injure my wound.			
7	If I have diabetes, high blood sugars can make my wound worse.			
8	Increased wound redness and warmth is normal.			
9	Increased wound odor is a sign of infection.			
10	If I think I have a wound infection I should wait for my next wound clinic appointment to report it.			

Spanish

ID _____

Date _____

Conocimiento de la herida**Pre-test**

Las instrucciones: Marque su respuesta con una "X" en el cuadro.

	Las Preguntas	Sí	No	No sé
1	Comer alimentos saludables puede ayudar con la sanación de mi herida			
2	Mantener mi herida descubierta ayuda a la sanación de mi herida.			
3	Lavarme las manos con agua y jabón antes y después de cambiar el vendaje previene la infección.			
4	Fumar cigarrillos puede retrasar la sanación de mis heridas.			
5	Dejar mi herida secar ayuda a la sanación de mi herida.			
6	Ropa y objetos pueden irritar o lesionar mi herida.			
7	Si tengo diabetes, la azúcar alta en la sangre puede empeorar mi herida.			
8	Si tiene aumento de enrojecimiento o siente la herida caliente es normal.			
9	El aumento de olor en la herida es una señal de infección.			
10	Si pienso que tengo una infección en la herida debo esperar a mi próxima cita para reportarla.			

Appendix S

Wound Healing Status

Bates-Jensen Wound Assessment Tool (Bates-Jensen et al., 1992)

BATES-JENSEN WOUND ASSESSMENT TOOL

Complete the rating sheet to assess wound status. Evaluate each item by picking the response that best describes the wound and entering the score in the item score column for the appropriate date. If the wound has healed/resolved, score items 1,2,3, & 4 as =0.

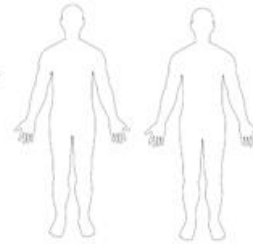
Location: Anatomic site. Circle, identify right (R) or left (L) and use "X" to mark site on body diagrams:

- Sacrum & coccyx
- Trochanter
- Ischial tuberosity
- Buttock
- Lateral ankle
- Medial ankle
- Heel
- Other site: _____

Shape: Overall wound pattern; assess by observing perimeter and depth.

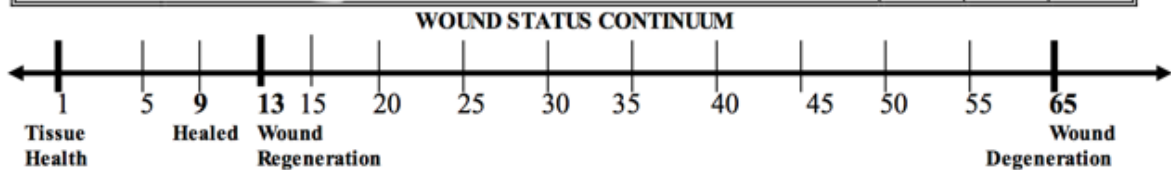
Circle and date appropriate description:

- Irregular
- Round/oval
- Square/rectangle
- Linear or elongated
- Bowl/boat
- Butterfly
- Other Shape



Item	Assessment	Date Score	Date Score	Date Score
1. Size*	*0 = Healed, resolved wound 1 = Length x width <4 sq cm 2 = Length x width 4-≤16 sq cm 3 = Length x width 16.1-≤36 sq cm 4 = Length x width 36.1-≤80 sq cm 5 = Length x width >80 sq cm			
2. Depth*	*0 = Healed, resolved wound 1 = Non-blanchable erythema on intact skin 2 = Partial thickness skin loss involving epidermis &/or dermis 3 = Full thickness skin loss involving damage or necrosis of subcutaneous tissue; may extend down to but not through underlying fascia; &/or mixed partial & full thickness &/or tissue layers obscured by granulation tissue 4 = Obscured by necrosis 5 = Full thickness skin loss with extensive destruction, tissue necrosis or damage to muscle, bone or supporting structures			
3. Edges*	*0 = Healed, resolved wound 1 = Indistinct, diffuse, none clearly visible 2 = Distinct, outline clearly visible, attached, even with wound base 3 = Well-defined, not attached to wound base 4 = Well-defined, not attached to base, rolled under, thickened 5 = Well-defined, fibrotic, scarred or hyperkeratotic			
4. Undermining*	*0 = Healed, resolved wound 1 = None present 2 = Undermining < 2 cm in any area 3 = Undermining 2-4 cm involving < 50% wound margins 4 = Undermining 2-4 cm involving > 50% wound margins 5 = Undermining > 4 cm or Tunneling in any area			
5. Necrotic Tissue Type	1 = None visible 2 = White/grey non-viable tissue &/or non-adherent yellow slough 3 = Loosely adherent yellow slough 4 = Adherent, soft, black eschar 5 = Firmly adherent, hard, black eschar			
6. Necrotic Tissue Amount	1 = None visible 2 = < 25% of wound bed covered 3 = 25% to 50% of wound covered 4 = > 50% and < 75% of wound covered 5 = 75% to 100% of wound covered			
7. Exudate Type	1 = None 2 = Bloody 3 = Serosanguineous: thin, watery, pale red/pink 4 = Serous: thin, watery, clear			

Item	Assessment	Date Score	Date Score	Date Score
	5 = Purulent: thin or thick, opaque, tan/yellow, with or without odor			
8. Exudate Amount	1 = None, dry wound 2 = Scant, wound moist but no observable exudate 3 = Small 4 = Moderate 5 = Large			
9. Skin Color Surrounding Wound	1 = Pink or normal for ethnic group 2 = Bright red &/or blanches to touch 3 = White or grey pallor or hypopigmented 4 = Dark red or purple &/or non-blanchable 5 = Black or hyperpigmented			
10. Peripheral Tissue Edema	1 = No swelling or edema 2 = Non-pitting edema extends <4 cm around wound 3 = Non-pitting edema extends >4 cm around wound 4 = Pitting edema extends <4 cm around wound 5 = Crepitus and/or pitting edema extends >4 cm around wound			
11. Peripheral Tissue Induration	1 = None present 2 = Induration, < 2 cm around wound 3 = Induration 2-4 cm extending < 50% around wound 4 = Induration 2-4 cm extending > 50% around wound 5 = Induration > 4 cm in any area around wound			
12. Granulation Tissue	1 = Skin intact or partial thickness wound 2 = Bright, beefy red; 75% to 100% of wound filled &/or tissue overgrowth 3 = Bright, beefy red; < 75% & > 25% of wound filled 4 = Pink, &/or dull, dusky red &/or fills ≤ 25% of wound 5 = No granulation tissue present			
13. Epithelialization	1 = 100% wound covered, surface intact 2 = 75% to <100% wound covered &/or epithelial tissue extends >0.5cm into wound bed 3 = 50% to <75% wound covered &/or epithelial tissue extends to <0.5cm into wound bed 4 = 25% to < 50% wound covered 5 = < 25% wound covered			
TOTAL SCORE				



Plot the total score on the Wound Status Continuum by putting an "X" on the line and the date beneath the line. Plot multiple scores with their dates to see-at-a-glance regeneration or degeneration of the wound.

Appendix T

Wound Knowledge

English

Post-test (Visit 1)

ID _____

Date _____

Wound Knowledge**Post-test (Visit 1)**

Instructions: Mark your answer with an "X" in the box.

	Questions	Yes	No	Don't Know
1	Eating healthy foods can help my wound heal.			
2	Keeping my wound uncovered helps my wound heal.			
3	Washing my hands with soap and water before and after I change my dressing prevents infection.			
4	Cigarette smoking can slow my wound healing.			
5	Letting my wound dry out helps wound healing.			
6	Clothing or objects can irritate or injure my wound.			
7	If I have diabetes, high blood sugars can make my wound worse.			
8	Increased wound redness and warmth is normal.			
9	Increased wound odor is a sign of infection.			
10	If I think I have a wound infection I should wait for my next wound clinic appointment to report it.			

Post-test (Visit 2)

ID _____

Date _____

Wound Knowledge**Post-test (Visit 2)**

Instructions: Mark your answer with an "X" in the box.

	Questions	Yes	No	Don't Know
1	Eating healthy foods can help my wound heal.			
2	Keeping my wound uncovered helps my wound heal.			
3	Washing my hands with soap and water before and after I change my dressing prevents infection.			
4	Cigarette smoking can slow my wound healing.			
5	Letting my wound dry out helps wound healing.			
6	Clothing or objects can irritate or injure my wound.			
7	If I have diabetes, high blood sugars can make my wound worse.			
8	Increased wound redness and warmth is normal.			
9	Increased wound odor is a sign of infection.			
10	If I think I have a wound infection I should wait for my next wound clinic appointment to report it.			

Post-test (Visit 4)

ID _____

Date _____

Wound Knowledge**Post-test (Visit 4)**

Instructions: Mark your answer with an "X" in the box.

	Questions	Yes	No	Don't Know
1	Eating healthy foods can help my wound heal.			
2	Keeping my wound uncovered helps my wound heal.			
3	Washing my hands with soap and water before and after I change my dressing prevents infection.			
4	Cigarette smoking can slow my wound healing.			
5	Letting my wound dry out helps wound healing.			
6	Clothing or objects can irritate or injure my wound.			
7	If I have diabetes, high blood sugars can make my wound worse.			
8	Increased wound redness and warmth is normal.			
9	Increased wound odor is a sign of infection.			
10	If I think I have a wound infection I should wait for my next wound clinic appointment to report it.			

Spanish

Post-test (Visit 1)

ID _____

Date _____

Conocimiento de la herida**Post-test (Visit 1)**

Las instrucciones: Marque su respuesta con una "X" en el cuadro.

	Las Preguntas	Sí	No	No sé
1	Comer alimentos saludables puede ayudar con la sanación de mi herida			
2	Mantener mi herida descubierta ayuda a la sanación de mi herida.			
3	Lavarme las manos con agua y jabón antes y después de cambiar el vendaje previene la infección.			
4	Fumar cigarrillos puede retrasar la sanación de mis heridas.			
5	Dejar mi herida secar ayuda a la sanación de mi herida.			
6	Ropa y objetos pueden irritar o lesionar mi herida.			
7	Si tengo diabetes, la azúcar alta en la sangre puede empeorar mi herida.			
8	Si tiene aumento de enrojecimiento o siente la herida caliente es normal.			
9	El aumento de olor en la herida es una señal de infección.			
10	Si pienso que tengo una infección en la herida debo esperar a mi próxima cita para reportarla.			

Post-test (Visit 2)

ID _____

Date _____

Conocimiento de la herida**Post-test (Visit 2)**

Las instrucciones: Marque su respuesta con una "X" en el cuadro.

	Las Preguntas	Sí	No	No sé
1	Comer alimentos saludables puede ayudar con la sanación de mi herida			
2	Mantener mi herida descubierta ayuda a la sanación de mi herida.			
3	Lavarme las manos con agua y jabón antes y después de cambiar el vendaje previene la infección.			
4	Fumar cigarrillos puede retrasar la sanación de mis heridas.			
5	Dejar mi herida secar ayuda a la sanación de mi herida.			
6	Ropa y objetos pueden irritar o lesionar mi herida.			
7	Si tengo diabetes, la azúcar alta en la sangre puede empeorar mi herida.			
8	Si tiene aumento de enrojecimiento o siente la herida caliente es normal.			
9	El aumento de olor en la herida es una señal de infección.			
10	Si pienso que tengo una infección en la herida debo esperar a mi próxima cita para reportarla.			

Post-test (Visit 4)

ID _____

Date _____

Conocimiento de la herida**Post-test (Visit 4)**

Las instrucciones: Marque su respuesta con una "X" en el cuadro.

	Las Preguntas	Sí	No	No sé
1	Comer alimentos saludables puede ayudar con la sanación de mi herida			
2	Mantener mi herida descubierta ayuda a la sanación de mi herida.			
3	Lavarme las manos con agua y jabón antes y después de cambiar el vendaje previene la infección.			
4	Fumar cigarrillos puede retrasar la sanación de mis heridas.			
5	Dejar mi herida secar ayuda a la sanación de mi herida.			
6	Ropa y objetos pueden irritar o lesionar mi herida.			
7	Si tengo diabetes, la azúcar alta en la sangre puede empeorar mi herida.			
8	Si tiene aumento de enrojecimiento o siente la herida caliente es normal.			
9	El aumento de olor en la herida es una señal de infección.			
10	Si pienso que tengo una infección en la herida debo esperar a mi próxima cita para reportarla.			

Appendix U

Wound Dressing Steps

Performance Checklist (Visit 1)

ID _____

Date _____

Wound Dressing Steps**Performance Checklist (Visit 1)**

Instructions: Mark an "X" based on observation.

	Steps	Yes	No
1	Washed hands with soap and water prior to dressing change.		
2	Put gloves on.		
3	Removed old dressing by lifting the tape across the skin.		
4	Wet the washing sponge with water then gently cleaned the wound with circular motions from the center to the outer wound edge.		
5	Applied skin protectant to the periwound.		
6	Applied the wound treatment.		
7	Placed the dressing cover over the wound.		
8	Secured the dressing in place.		
9	Threw out old dressing and contaminated washing sponge.		
10	Washed hands with soap and water.		
11	Identified correct days to change the dressing.		

Performance Checklist (Visit 2)

ID _____

Date _____

Wound Dressing Steps**Performance Checklist (Visit 2)**

Instructions: Mark an "X" based on observation.

	Steps	Yes	No
1	Washed hands with soap and water prior to dressing change.		
2	Put gloves on.		
3	Removed old dressing by lifting the tape across the skin.		
4	Wet the washing sponge with water then gently cleaned the wound with circular motions from the center to the outer wound edge.		
5	Applied skin protectant to the periwound.		
6	Applied the wound treatment.		
7	Placed the dressing cover over the wound.		
8	Secured the dressing in place.		
9	Threw out old dressing and contaminated washing sponge.		
10	Washed hands with soap and water.		
11	Identified correct days to change the dressing.		

Performance Checklist (Visit 4)

ID _____

Date _____

Wound Dressing Steps**Performance Checklist (Visit 4)**

Instructions: Mark an "X" based on observation.

	Steps	Yes	No
1	Washed hands with soap and water prior to dressing change.		
2	Put gloves on.		
3	Removed old dressing by lifting the tape across the skin.		
4	Wet the washing sponge with water then gently cleaned the wound with circular motions from the center to the outer wound edge.		
5	Applied skin protectant to the periwound.		
6	Applied the wound treatment.		
7	Placed the dressing cover over the wound.		
8	Secured the dressing in place.		
9	Threw out old dressing and contaminated washing sponge.		
10	Washed hands with soap and water.		
11	Identified correct days to change the dressing.		

Appendix V

Health Literacy Tool

Brief Health Literacy Screen (Chew et al., 2004)

How confident are you in filling out medical forms by yourself?

- Extremely
- Quite a bit
- Somewhat
- A little bit
- Not at all

How often do you have someone (like a family member, friend, hospital/clinic worker or caregiver) help you read hospital materials?

- Always
- Often
- Sometimes
- Rarely
- Never

How often do you have problems learning about your medical condition because of difficulty understanding written materials?

- Always
- Often
- Sometimes
- Rarely
- Never

Appendix W

Budget

GOODS & SERVICES	COST
Graphic designer	\$100.00
Photography copyrights	\$29.99
English Brochures	\$38.50
Spanish Brochures	\$38.50
Stickers	\$78.90
Study instrument photocopying	\$8.72
Plastic bags for products	\$11.70
Posters	\$12.79
DONATED SERVICES	
Interpreter Services	\$0.00
Wound Model	\$0.00
Photographer	\$0.00
Illustrator	\$0.00
TOTAL	\$319.10