Impact of a Talking Prescription Digital Audio Label on Blood Pressure and Self-Efficacy in Low Health Literate Patients with Chronic Hypertension

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Abstract

Background: Low health literacy (LHL) can lead to low patient self-efficacy for medication administration contributing to millions of adverse drug events a year. This in turn, can lead to exacerbation of chronic medical conditions such as hypertension, and it is possible that talking prescription labels can be an effective intervention to bridge the LHL gap in understanding medication information in the hypertensive population.

Purpose: Evaluate a talking prescription Digital Audio Label (DAL) to decrease blood pressure and increase self-efficacy for prescription medication administration in patients with LHL and chronic hypertension as well as evaluate the patient perception of usability and ease of use of the DAL to deliver verbal prescription medication information.

Method: A quasi-experimental, two group, pretest-posttest study conducted at a free outpatient medical clinic via randomized convenience sampling of chronic hypertension patients with an intervention group who received the DAL and a control group who received usual verbal prescription information.

Results: A total of 84 patients were evaluated, 52 chose to participate and 26 used the DAL. The majority were > 50 years old with an approximate even distribution of males versus females and Caucasians versus African Americans. There were no statistically significant differences found between the groups for demographics, blood pressure changes or improvements in self-efficacy scores.

Conclusion: Blood pressure decreased and self-efficacy scores increased after using the DAL inferring a possible positive impact. The DAL was rated as very useful and easy to use. Ongoing research is needed to explore the DAL use in patients with new onset hypertension with a larger sample size and longer duration to eliminate the effect of established medication regimes.

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Background

Low literacy levels in the United States (U.S) are at a critical level. According to the latest update to data collected in 2014 for the U.S Program for the International Assessment of Adult Competencies (PIAAC), low literacy was estimated at affecting approximately 43 million Americans (Rampey et al., 2016). The PIAAC report revealed that LHL is still at a critical level compared to the prior National Assessment of Adult Literacy conducted in 2003 and impacts all racial/ethnic/age groups, with African American, Hispanics, elderly, those with less than a high school education and those on Medicaid having the lowest literacy levels (Rampey et al., 2016; Berkman, Sheridan, Donahue, Halpern & Crotty, 2011). These demographics are largely similar to those individuals with a high incidence of hypertension, which is one of the most serious chronic public health problems in the U.S and is anticipated to have a 60% increase in the population by the year 2025 (Mendes et al., 2016).

Poor understanding and lack of reading ability is directly correlated with poor medication self-efficacy and poor patient outcomes, such as outcomes related to hypertension (Mendes et al., 2016). Reportedly, there are nearly 187 million people who do not take medications as prescribed primarily because of confusion or poor understanding of their medicines (Herrier, Apgar, Boyce, & Foster, 2015). Pharmacy Health Literacy is defined as “the degree to which patients are able to obtain, process, and understand basic health, medication information and pharmacy services needed to make appropriate health decisions” (Agency for Healthcare Research and Quality [AHRQ], 2017). On the literacy scale, from below level 1 equating to functionally illiterate, to a 5 being the most proficient, the PIAAC reported the U.S had

approximately 16.6 million adults ranking at below level 1, which is considered functionally illiterate, and 26.5 million adults at a level 1, which is basic literacy (Rampey et al., 2016). Tasks specifically related to the ability to interpret a prescription medication label require literacy levels of intermediate and above. This infers the approximately 43 million U.S adults may not be able to adequately interpret prescription medication labels, and with over 4 billion prescriptions filled so far in 2019, the inability to read prescriptions could significantly contribute to elevated adverse patient outcomes, increased doctor visits, increased admission rates and increased overall health care and prescription related costs in the U.S.

Adverse drug events (ADEs) are defined by AHRQ (2019) as harm experienced by a patient as a result of exposure to a medication. Wilson indicated in a study on low English proficiency that 42% of adults reported difficulty interpreting prescription container labels and had confusion about how to take prescription medications, resulting in 16% of those adults experiencing an ADE related to instruction misinterpretation (as cited in National Council for Prescription Drug Programs, 2013, p. 14). The increased chance of LHL patients taking the wrong medication, taking the wrong dose, or missing doses of medication used to treat their medical condition can lead to exacerbation of the medical condition or even death. Preventable ADEs are more likely to be life threatening (54%) or cause death (30%) (Devine, 2010). This can lead to an annual increase in emergency room visits (700,000), increased admission rates (100,000) and results in increased overall health care and prescription related costs (AHRQ, 2019). Rasu, Bawa, Suminski, Snella and Warady (2015) reported that adults with LHL had increased healthcare visits and prescription related expenditures equating to approximately $92 billion in healthcare costs with the potential to reach $172 billion.

To overcome literacy barriers, studies have indicated adults with difficulty reading prescription medication labels often had to depend on external sources and methods to identify prescription medications, such as eliciting the help of someone else to read the prescription medication bottle to them (42%) or using alternative identification techniques, such as placing a rubber band on the prescription bottle or placing medication is varying container sizes or shapes to help differentiate the medications (McMahon & Curtis, 2009; Government Accountability Office [GAO], 2016). LHL leading to dependent behavior such as this can decrease one's sense of empowerment related to managing their own health and self-efficacy related to appropriate medication use. Self-efficacy is defined as a patient's belief that they can successfully perform a specific behavior to achieve a desired outcome (Lamarche, Tejpal & Mangin, 2018). This loss of empowerment leads to medication non-adherence related to feelings of lack of control over the management of their medical condition, resulting in decreased motivation to demonstrate the behaviors necessary to adhere to their medication regime (World Health Organization, 2013; Herrier et al., 2015). If health care providers or pharmacists can provide an intervention that overcomes LHL barriers to reading medication prescription labels, it could be hypothesized that doing so would increase patient independence and control, and therefore increase personal self-efficacy that could lead to improved behaviors necessary to adhere to an appropriate medication regime and even aid in controlling chronic health conditions such as hypertension.

Significance and Implications for Practice

There have been several policy initiatives attempting to address findings in various national literacy assessments. Interventions such as the Department of Health and Human Services' 2010 National Action Plan to Improve Health Literacy, the Plain Writing Act of 2010, implementation of the Joint Commission Patient-Centered Communication Standard

PC.02.01.21 and the Healthy People 2020 goal of improving health literacy. Financial incentives were also adjusted in Value Based Purchasing (VBP) regulations to include an evaluation of communication patients receive regarding their prescribed medications. This measure is one of eight measures in the Person and Community Engagement quality domain of the VBP program and accounts for 25% of a hospital's Total Performance Score as measured by the Hospital Consumer Assessment of Healthcare Providers and Systems Survey (Centers for Medicare & Medicaid Services, 2017). These efforts draw attention to the problem of LHL, but there is a lack of integrating a systematic approach by organizations and health care providers to properly integrate literacy standards of care into their practice and organizational clinical practice guidelines.

Despite the known national endemic of LHL and policy attempts to intervene, there are still many barriers to ensuring patient understanding of health care information provided that result in proper interventions aligned with patient literacy needs. Examples of barriers are provider perception of negative connotation associated with assessment questions for LHL, false responses to inquiries on behalf of the patient to avoid embarrassment, lack of awareness of published prescription drug label best practices by pharmacies for accessible prescription drug labels, increased cost of innovative labeling systems, and failure of the law, such as the Americans with Disabilities Act (ADA) of 1990, to recognize and include patients who are LHL in statutes of protection (Herrier et al., 2015; AccessaMed, 2014; GAO, 2016). The ADA prohibits discrimination and ensures equal opportunity for persons with disabilities, such as blindness, but does not address the LHL population.

In addition, Section 904 of the 2012 Food and Drug Administration (FDA) Safety and Innovation Act (S.3187) authorized a work group to develop best practices surrounding making

prescription drug container labels. The National Council on Disability was tasked with the responsibility to educate the public, pharmacies, and other entities on these best practices. Three years later, the GAO-17-115 report, following up on the status of these actions, found minimal efforts had been made to raise awareness about these best practices, because they are not mandated (AccessaMed, 2014; GAO, 2016). Amongst the many best practices published was audible drug container labels (United States Access Board, 2013; AccessaMed, 2013; GAO 2016). These are small devices that affix to a prescription drug container that are activated by the patient by pushing a button, resulting in a verbal message description of the prescription drug information. This type of device, a talking prescription DAL, was used for the intervention in this study.

Problem Statement

Little is known about talking prescription devices as an intervention in the LHL population to control chronic health conditions, specifically hypertension, increase self-efficacy for taking medications, and the end user's perception of device usability. Literature indicates that there are approximately 43 million American adults with LHL and there were over 4 billion prescriptions filled in 2019 that require an intermediate literacy level to read the prescription label (Rampey et al., 2016). Lack of intermediate literacy skills leads to the LHL population being three times more likely to misinterpret prescription labels which leads the patient to alternative prescription medication identification techniques or dependency on others to read the labels to them and can result in medication related ADEs (McMahon & Curtis, 2009; GAO, 2016; Lam et al., 2017). This directly impacts self-efficacy for appropriate prescription medication use and contributes to increased national health care costs related to exacerbation of medical conditions.

Purpose

The primary purpose of this Doctor of Nursing Practice (DNP) study is to evaluate if the talking prescription DAL is an effective intervention to decrease blood pressure and increase self-efficacy for prescription medication administration in patients with LHL and chronic hypertension. The secondary purpose is to evaluate the usability of the DAL to deliver verbal prescription medication information.

Clinical PICOT Question

The population, intervention, comparison, outcome, time (PICOT) question is: in adults patients, aged 18-64 years old, with chronic hypertension and LHL scores >2 on the Single Item Literacy Screener (SILS) in a free outpatient medical clinic (P), does using a talking prescription DAL to provide verbal prescription drug container information (I) compared to usual clinic care (C) improve blood pressure and medication self-efficacy scores on the Self-efficacy for Appropriate Medication use Scale (SEAMS) (O) after using the device for 30 days (T)?

Research Questions

The primary research measures to be answered are:

- Is there a statistically significant difference between groups in the mean blood pressure levels before and after the intervention at 30 days?
- Is there a statistically significant difference between groups in the mean SEAMS scores before and after the intervention at 30 days?

The secondary research measure is:

- Do LHL hypertensive patients score the DAL useable for verbal delivery of prescription medication?

Strengths, Weaknesses, Opportunities, Threats Analysis

Historically, the primary foci in research has been on provider or system failures rather than errors that are commonly derived from the patient's misunderstanding of medications (Wolf et al., 2016). For these reasons a Strengths, Weaknesses, Opportunities, Threats (SWOT) analysis was conducted at a free outpatient medical clinic to determine if they service a patient population, such as LHL patients, who are said to have a high incidence of medication misinterpretation (Lam et al., 2017). The free medical clinic provides healthcare and prescriptions to low income, underinsured and uninsured adults. The free medical clinic's patient population was reported of consisting of 48.5% Caucasian, 37.4% African American, 1.6% Hispanic, 2.3% Asian, 10.2% other/unknown, which contains a large percentage of the demographic type that are reported to have LHL levels per the PIAAC (Rampey et al., 2016). The free medical clinic can provide services via volunteer healthcare providers and are funded 100% by donations and grants. During the analysis it was noted that the free medical clinic does not implement measures to accommodate patients with LHL and chronic hypertension to overcome barriers to understanding their prescription drug regime. There was no assessment for LHL in their patients and they did not implement any pharmacy best practices for prescription drug labeling, but reported they have a high incidence of patients that are LHL. See Appendix A for SWOT analysis results. These results suggested this organization as an optimal location to investigate the clinical questions for this study.

Literature Review

Literature Search Methods

Given the technology of talking prescription labels and the capability of reading prescription labels via technological mechanisms is innovative, it has historically been associated with high costs. The literature surrounding these types of technological interventions was

difficult to locate based on terminology references for talking prescription labels or were outdated beyond the 10 year literature inclusion time frame. Most literature surrounding any type of technology related medication devices related to providing talking prescription information was geared toward patients with visual impairments and altering the print of the physical label itself, with minimal acknowledgement of addressing patients preferred learning methods, and medication prescription label needs for patients with LHL.

Databases such as PubMed, Cumulative Index to Nursing and Allied Health Literature (CINAHL), ScienceDirect, Cochrane, and Google Scholar were searched. Search terms were modified from the original PICOT question and ultimately resulted in being: impact, verbal, patient, education, literacy, outcomes and talking pill bottle. A total of 164 articles were identified. Limiters were studies within a 10-year time frame, English language, humans, and full text. Inclusion criteria were studies that included assessments on outcomes related to patients receiving to verbal health education information and those evaluating the use of an automated verbal prescription label. For those articles that met the inclusion criteria, references of those articles were also reviewed for potential inclusion. See Appendix B for a diagram on the original literature search approach taken. An additional search was performed to include the terms of verbal prescription label and talking pill bottle resulting in three additional relevant articles located to support the innovative measurement portion of the PICOT and were included in the literature review.

Literature Supporting Verbal Education

The relevant articles identified, positively associated verbal education and technological interventions for improving medication health literacy and are summarized below. See Appendix C for the Literature Review Summary Matrix.

Wali, Hudani, Wali, Mercer, and Grindrod (2016) performed a level I evidence systematic review of interventions to improve medication information for LHL populations. This article's specific aim was to review evidence on interventions for improving medication knowledge in LHL populations. The review included six different types of interventions for providing medication information; 1) written information 2) visual information 3) verbal information 4) label/medication bottle 5) reminder systems and 6) educational programs and services. The review found one of the most common types interventions for providing medication instructions was verbal information. There were 36 studies out of the total of 47 studies in the review that focused on an audible intervention as a mode to provide medication information. Of those 36 studies, there were 27 studies that analyzed knowledge improvement regarding prescription medication. Overall 81% of the 27 studies demonstrated statistically significant improvement of knowledge regarding prescribed medication. There were 21 studies reviewed to assess reports of medication adherence with verbal instructions and 17 of those reported an increase in medication adherence. In addition, this review indicated that LHL patients who received a combination of written and verbal instructions regarding health information had an increase in understanding ($p < 0.0001$). This article supports this study's PICOT population by substantiating the fact that those with LHL need to have a better understanding of prescription information and have a higher prevalence of poor outcomes when they do not. This study also acknowledged that effective interventions for increasing medication knowledge are those that can be sent home with the patient for real time, at the point of use, access to the pharmacist's medication instructions. The DAL used in this study is an intervention that provides such access.

Harrington and Valerio (2014) offered evidence to substantiate this study's PICO topic by indicating that patients with LHL have a higher prevalence of poor health outcomes. The study also indicates that LHL contributes to increased health care costs (Harrington & Valerio, 2014). In the literature, a large percent of patients were shown to have a preference for verbal information although there are many other modes of delivering health care information. The design was a mixed method approach with the author combining level I evidence via a systematic review of literature to identify and categorize current influences on verbal information in health care, identifies existing theories, models and definitions, and conducts qualitative data collection on providers and patient focus groups. From this information the authors derive the Verbal Exchange Health Literacy (VEHL) definition and model. VEHL is specific to oral exchange of health information. The authors suggest that to improve health outcomes, it is important to acknowledge the verbal mode of interpreting health information which is the mode by which this study's intervention provided medication information in the LHL population.

Marcus (2014) performed a mixed method study incorporating a systematic review of studies regarding verbal education best practices and a qualitative staff survey to evaluate verbal education barriers to learning. A synthesis of this data facilitated the development of the EDUCATE model of verbal education. It is significant to assess the needs of the learner and implement the mode of education that is preferred by the learner. The author notes that patients retain approximately half of information given by the many health care providers on the multidisciplinary team, regardless of the mode of delivery, and that repetition of information is helpful to aid in patient retention of the health information provided. Other aspects of the EDUCATE model, besides repetition, that specifically support this DNP study are to present the most important information first, emphasize one to three key points, and use concrete

instructions. These components are noted as strategies in creating applications as well as in developing health literacy educational tools (Broderick et al., 2014). These aspects support this DNP study given the DAL intervention is a talking technology tool that provides verbal delivery of prescription medication information that is repeatable for up to 400 times with a 60 second message.

Literature Supporting Related Technology Intervention and Measures

The study that most mirrors this DNP study design is a study by Lam et al. (2017) on LHL patients and the impact of Talking Pill Bottles on medication self-efficacy, medication adherence, knowledge about antihypertensive prescription medications, blood pressure changes after using the Talking Pill Bottle and patients' acceptance of the Talking Pill Bottle after 90 days. This study acknowledges the significant impact LHL has on the potential for patient medication ADEs related to misinterpretation of prescription labels and the importance of patients to be able to access medication at home when the patient feels they need it, more so at the time of medication administration. Results of this study did not report a significant difference in medication knowledge scores and SEAMS scores between the control and intervention groups at 90 days. Within group knowledge scores did statistically improve over the study period for both groups, p <0.001 whereas within-group SEAMS scores from baseline to 90 days were not statistically significant, p =0. 425 and p = 0.544 respectively. Medication adherence scores were measured using the Morisky Medication Adherence Scale (MMAS-8) and the Cumulative Medication Gap (CMG). There was no significant difference in the MMAS scores between groups at 90 days, but scores did significantly improve from baseline to 90 days, in both the control and the intervention groups, p = 0.012 and p = 0.003 respectively. CMG scores, which measure adherence via prescription refills, increased, demonstrating clinical significance, but not

statistical significance. The clinical outcome measurement of blood pressure differences was not significant between the groups nor within the control group but were significant within the intervention group from baseline to 90 days, systolic blood pressure (SBP) $p = 0.036$ and diastolic blood pressure (DBP) $p = 0.027$. To evaluate the patients' acceptance of the Talking Pill Bottle the Technology Acceptance Model (TAM) was applied and consists of 2 measurement scales, the Perceived Ease of Use (PEOU) and the Perceived Usefulness (PU) subscale. The majority of the patients (98%) found the Talking Pill Bottles easy to use and that the system helped them understand their medications quickly (77%), improving their ability to take their medications correctly (74%).

Kamal et al. (2018) completed a randomized controlled trial (RCT) over 7 months to evaluate changes in medication adherence and acceptability of a talking prescription in 197 resource constrained Pakistani participants with a diagnosis of a cerebrovascular accident (CVA) or coronary artery disease (CAD) who take anti-platelet and statin medication. There were 99 participants in the intervention group and 98 in the usual care group. The intervention was the Talking Rx consisting of tailored, evidence based information to remind a patient to take their medication and remind them of the significance of adhering to the medication regime. Outcome measures included the MMAS-8 scale to compare the difference in medication adherence between the intervention and control groups at 90 days. Although there was an increase in the MMAS-8 scores in the intervention group who received the Talking Rx, the difference was not statistically significant, $p = 0.40$, compared to the control group. The study also compared the mean differences on MMAS-8 scores for participants with CVA versus CAD. Scores increased in the both the CVA and CAD intervention groups, but were not statistically significant, $p = 0.15$ and $p = 0.69$ respectively. Finally, there was a User Interface Experience analysis conducted on

participants in the intervention group. The study reported that >80% of the participants they contacted for the exit interview (n = 84) felt satisfied with the Talking Rx and that it was an excellent method for receiving information regarding their prescription medications. This study is one of few studies that support this DNP study because it is current, there is a similar population, technology intervention, comparable groups as well as the design and outcome measures used.

A six-month pilot study implementing a Meducation® calendar for medication education and reminders was conducted on 23 Veterans to assess medication adherence by Zullig, McCant, Melnyk, Danus, and Bosworth (2014). This technological intervention was geared for the LHL population or those with limited English proficiency. Medication outcomes were measured via a seven question self-reported questionnaire at baseline and three months. Clinical outcomes of blood pressure, heart rate, body weight, low-density lipoproteins, high-density lipoproteins, total cholesterol and creatinine were also measured at baseline and six months using a 95% confidence interval (CI). At three months, the patient-reported medication non-adherence regarding forgetting to take medications decreased by 45%, with a 58% decrease in reported carelessness about taking medications. At six months there was a 3.2% increase in prescription refills, but this was not statistically significant (p = 0.73). Patient creatinine was the only clinical characteristic with statistical significance (p = 0.05). Although the results were not statistically significant for the other clinical outcome measurements, there was an overall decrease in the values, except for total cholesterol, which conveys clinical importance that technology intervention may have an impact on altering behaviors required to properly adhere to the prescribed medication regime. This study is relevant to this DNP study because it has similar LHL population, design, blood pressure outcome measurement and suggests the Meducation®

technology could have a positive impact on medication health literacy and health related outcomes.

Lertwiriyaprapa and Fakkheow (2015) evaluated an Audio Prescription Labeling (APL) system developed for use in the visually impaired, low income Thai population. The system offered two languages, inferring the capability for integrating other languages, and had reported capability to relay important information such as the patient's name, drug name, dosage, general instructions, warnings, prescription number, the doctor's name and telephone number. Five providers and 70 elderly and blind Thai end users evaluated the efficacy of this system. The majority of providers (92%) agreed this device helped patients to self-medicate and improve the quality of life of visually-impaired people. Qualitative survey results from patients that are relevant to this DNP study's focus were the satisfaction with degree of complete information the system provided (92%), suitability for use (92%), accuracy and completeness of labeling (92%), usefulness for the study population (92%), and the system's overall ease of use (84%). Although this article focused its APL system for use in a visually impaired, this article was incorporated into this literature review because the study intervention was similar to that of this study and the results confer improved self-efficacy, device usefulness in an adult population that are low income and have LHL, which mirror characteristics of this study's intervention and population.

A seminal article by Allnatt, Engelhardt, Gao, & Mariano (2001) was included, despite its age, for relevance to the PICOT question given its purpose was to evaluate the usability and ease of use of a Voice Prescription Label (VPL). A VPL was developed to provide audio prescription label information to Veterans who were considered visually impaired. Information provided to patients from the device were: 1) name of drug and dose; 2) directions for use; 3) special instructions; 4) issuing physician's name; 5) date issued; 6) number of refills remaining;

7) prescription number; and 8) the pharmacy's name, address, and telephone number. The data provided herein supports this DNP study by demonstrating that 80% of patient with visual impairments strongly agreed that they preferred the VPL to their previous methods of interpreting prescription labels, and 92% would recommend the use of the VPL. An increase in health literacy is conferred, most importantly because the patients felt they could easily identify the name of the medication due to having audible prescription information in real time. Having this information regarding prescription medications can lead to a decrease in preventable ADEs within the broader population.

Critical Appraisal of Evidence

To overcome barriers to understanding prescription medications, LHL patients report receiving verbal information about their prescription medications was a preferred method of receiving information. This mode of delivery has reported increase in medication adherence, and self-efficacy for appropriate medication administration adherence in LHL populations. The relevant literature included for this study vary from levels I-VI. Given there was limited research regarding the use of talking prescription devices as a method to deliver verbal prescription medication information to the general public, specifically to the LHL population, research supporting preferred methods of learning, and satisfaction with other technological devices were included.

Three studies included in the review are a systematic review and mixed method design, indicate that LHL patients prefer verbal delivery of health care information. This method contributes to increased retention of health care information, improved health literacy and patient outcomes (Wali et al., 2016; Harrington et al., 2014; Marcus, 2014). A pilot study by Zullig et al. (2014) was included because the study included a technology device that, although did not

demonstrate a statistically significant change in physiological outcomes such as, blood pressure, they were clinically significant with a decrease of 0.5 mmHg. Two studies that are cohort, level III studies are a seminal study by Allnatt et al. (2001) and another by Lertwiriyaprapa & Fakkheow (2015) that indicated patients were satisfied with the usability of a talking prescription label and that the device increased quality of life, which is related to improved self-efficacy. The last two studies, that are most relevant to this study are randomized controlled trials by Lam et al. (2017) and Kamal et al. (2018). Lam et al. (2017) indicated there was a clinically significant improvement of self-efficacy related to taking medications, a statistically significant decrease in blood pressure and positive rating of the talking pill bottle's usability in the LHL population. Kamal et al. (2018) reported similar results with an increase in participant MMAS-8 scores between the control and intervention groups, as well as within the groups with a diagnosis of CVA ad CAD who used the Talking Rx, although not statistically significant. The study participants also rated the Talking Rx as excellent for providing prescription information.

Significant relevant literature is readily available regarding patient preferred methods of learning, changes in medication adherence and self-efficacy by means of other interventions and efficacy of interventions for the blind. Literature is lacking related to using talking prescription labels and other innovative technology for LHL population. More research is needed to compare usability and patient satisfaction with talking prescription labels, evaluate provider perceptions related to workflow interruptions while integrating a talking prescription label into practice and studies need to have a longer duration.

Nursing Framework

Bandura's social cognitive theory of self-efficacy is applied as a guide in developing this study. It is believed that self-efficacy is one of the most significant predictors of behavior change

with self-efficacy defined as “one’s belief that they can successfully perform a specific behavior to achieve a desired outcome” (Lamarche et al., 2018). Desired outcomes for this study are improved blood pressure and self-efficacy for taking prescription medications in the LHL population through the application of a literacy sensitive process designed for this study. The ability to read and understand health related information contributes to patients taking a more active role in management of their health and disease processes (Herrier et al., 2015). Application of this theory assumes the DAL has potential, as an assistive device, to contribute to sufficient understanding of prescription medications. For patients who have difficulty reading prescription drug labels, this could mean increasing self-control and decreasing dependence on others to properly take their prescription medications which could ultimately have an impact on control of blood pressure and medication adherence.

Institutional Review Board and Human Subject Protection

This DNP study was designed as a minimal risk study to the voluntary participant. Permission was granted by the Chief Executive Officer of Stripes Global Incorporated to use the device in this study with no monetary gain on behalf of the study site, the primary investigator or the donating company and therefore there are no conflicts of interest to disclose. See Appendix D for email confirmation regarding no conflicts of interest.

Safety

The DAL was not manufactured with the requirement to have fail safe performance, meaning if the device failed to function properly it would not lead directly to personal injury, severe physical damage or lead directly to death (Stripes Global, 2018). The DAL did not replace or disrupt the integrity of the required pharmacy placed label placed on the prescription bottle that the patient would be sent home with from the pharmacy clinic. The DAL was placed in

addition to the original pharmacy label and was to be used as an assistive device. An assistive device is defined as “any item, piece of equipment, or product system, whether acquired commercially off the shelf, modified, or customized, that is used to increase, maintain or improve the functional capabilities of patients with disabilities” (Ruffin, 2012, p. 99). For additional added safety, a double checking procedure with another nurse was implemented to verify the pharmacy information was entered correctly into the text to speech software for device programming.

Liability

A consent was uniquely designed for both the intervention and control groups in the study using the Graceland University consent template and was modified in accordance with this study and Graceland University Proposal Review Committee and Institutional Review Board recommendations as applicable. The consents included a release of liability statement and contact information for replacement in case the device malfunctioned (See Appendix E for intervention group consent and Appendix F for control group consent). In addition, it was confirmed that the free medical clinic is a nonprofit volunteer entity that is covered by Ohio Revised Code 2305.38 - Uncompensated Volunteers of Nonprofit Charitable Organizations No Liability. This means that volunteers providing services within this clinic are “not liable in damages in a civil action for injury, death, or loss to person or property that arises from the actions or omissions of any of the officers, employees, trustees, or other volunteers of the charitable organization for which the volunteer performs services” (LAWriter, 2019). For patients to receive volunteer care at the free medical clinic patients had also signed a Record Release for Treatments and Examinations (Appendix G), a Confidentiality of Records form that allows sharing of patient information, specifically for research purposes (Appendix H), as well as

a Voluntary Care Informed Consent and Waiver that serves as a release of liability for persons and organizations associated with the clinic (Appendix I). The free medical clinic is also a Health Insurance Portability and Accountability Act (HIPAA) covered entity, so an additional HIPAA release form was not required for this study.

Privacy and Data Retention

The free medical clinic provided the use of a private office for patient interviews that had locking drawers and a locking door for safe keeping and storage of patient related paperwork for three years. In addition, unique login and passwords were required to unlock the computer as well as login into SurveyMonkey for data entry. Patient privacy, identity and contact information was protected via data cleaning procedures and use of the patient's drawing ticket number as their unique patient identifier. Privacy protection was emphasized in the consent designed by the primary investigator indicating that the individual would not be identified in the reporting of results and their individual identity would remain confidential.

Method

Design

This study was a quasi-experimental, two group, pretest-posttest study to evaluate the talking prescription DAL as an effective intervention to decrease blood pressure and increase self-efficacy for prescription medication administration in patients with LHL and chronic hypertension as well as evaluate the usability of the DAL to deliver verbal prescription medication information. The study was conducted from May through mid-August at a free medical clinic with volunteer participants in an intervention group who received the talking prescription DAL and a control group who received usual care of verbal prescription information from pharmacy staff. Pre and post surveys were implemented to evaluate blood pressure changes

and changes in self-efficacy for appropriate medication use before and 30 days after using the DAL. Post-intervention phone interviews also evaluated the usability of the talking prescription DAL in the intervention group.

Setting

The setting was a free medical clinic in Akron, Ohio that provides free medical care and prescriptions to low income, underinsured and uninsured adults. Via donations and grants, the free clinic was able to serve over 3000 patients last year. Services offered are in areas such as Internal Medicine, Nephrology, Ophthalmology, Women's Health, Cardiovascular, Urology, Acupuncture, Mental Health, Dental, and even Chiropractic care, but all services vary based on the availability of the volunteer staff. The clinic has three paid staff, a full-time nurse manager, a full-time clinical coordinator, and a part time secretary, who were the primary points of contact and study champions. Other healthcare providers consist of approximately 70 volunteer doctors and nurses that rotate during various day and evening clinic hours. There is a pharmacy on site, also with varying hours based on provider availability that were subject to last minute cancellation by the clinic. Day clinics were reported to see approximately 15 to 20 patients a clinic and evening clinics approximately 30 patients.

Participants

Patients were between the ages of 18 to 64 years old, of any socioeconomic or demographic background with a diagnosis of chronic hypertension, on at least one blood pressure medication with LHL as identified by a score of > 2 on the SILS. Additional inclusion criteria were that the patient had to be able understand spoken English and fill at least one prescription with a minimum of a 30-day supply. Exclusion criteria were cognitive impairment, inability to understand English, hearing impairment, SILS score of < 2, indicating the patient

never needs help reading printed health material, age >64 years old due to SILS survey age parameters, and filling a current prescription of <30-day supply.

Sample

Previous literature using talking prescription devices as an intervention demonstrated a wide variability in the sample size to use as a comparison. To estimate a minimum sample size, an a priori power analysis was completed based on using an independent samples *t*-test with a large Cohen's *d* for an anticipated effect size of 0.80, $\alpha = 0.05$, power of 0.80 and results indicated a total sample size of a minimum of 52 patients were needed. To account for a potential 20% attrition rate, a need for an additional 10 patients was estimated, for a total of 62 patients. The goal was to have even numbers in the intervention and control groups with 31 patients in each group. Due to a lower than anticipated LHL rate, several cancelled clinics due to lack of providers, high number of no call no shows and time constraints from the required use of the DAL in the study, it was decided by the primary investigator to cease the acquisition of participants at a total of 52, with 26 randomly assigned to each group.

Recruitment

The target population for this study was acquired by the primary investigator via a convenience sampling of scheduled patients at each schedule clinic. A reliable recruitment process was performed throughout the study following the inclusion and exclusion criteria. Recruitment occurred during both day and evening clinics that had a higher volume of patients to attempt to achieve the desired number of participants. The primary investigator was present during all recruitment to conduct participant interviews and data collection and minimize the concern for interrater reliability. The potential to win a $100 gift card was offered as an incentive to complete all requirements of the study as outlined Phase 0-3 in the Data Collection section.

Tools

Patient reported outcome measures (PROMs) and patient reported experience measures (PREMs) were used in this study. Patient reported outcomes via PROMs and PREMs carry increased credibility and are being recognized for their potential ability to transform healthcare by contributing to robust research through a patient-centered approach (Weldring & Smith, 2013). To implement a patient centered approach, accommodate the needs of the sample population and minimize literacy burden, data gathered for the measurement tools was done via verbal interviews which are a primary method of gathering subjective data (Herrier et al., 2015).

Pre-intervention tools.

Single Item Literacy Screener (SILS).

To determine a patient's health literacy level and inclusion into the study population, the SILS was used. This is a patient's self-report of health literacy for printed health materials with a reported 54% sensitivity of detecting limited reading ability (95% CI: 47%, 61%) and a specificity of 83% (95% CI: 81%, 86%) with an area under the Receiver Operating Characteristics Curve (ROC) of 0.73 (95% CI: 0.69, 0.78) (Morris, MacLean, Chew & Littenberg, 2006). The tool consists of one Likert scale question with scores of 1=Never, 2=Rarely, 3=Sometimes, 4=Often and 5=Always. Scores > 2 are considered inadequate health literacy, indicating the patient has some difficulty with reading printed health related material (Morris et al., 2006). Permission to use this screener was requested by the author via the Health Literacy Tool Shed and permission has been granted to use this item for non-commercial use. See Appendix J for SILS tool and permission to use email.

Pre and post intervention patient reported outcome measures.

Self-efficacy for appropriate medication use scale (SEAMS).

The SEAMS scale is a 13 question PROM that correlates the patient's behavior with self-management of their prescribed medication regime (Lamarche et al., 2018). It was a 3-point Likert scale questionnaire modified to a 5-point scale ranging from a score of 1 indicating not having any confidence in adhering to the medication regime, to a 5 being very confident (See Appendix K). A 5-point Likert scale is recommended to acquire more precise data that is easily understood and allows for a more thorough analysis and correlation if the interval level of measurement is used (Oracle, 2012). This modification provides the minimum score 13 and a maximum score of 65. This is a reliable and valid self-report instrument that measures medication self-efficacy and is appropriate for use in patients across a range of literacy skills with a reported criterion related validity to the Morisky Medication Adherence scale of a Spearmen's $p = 0.051$, $p = 0.0001$, and internal consistency reliability via the Cronbach's alpha of 0.90 (Lamarche et al., 2018). Patient reported self-efficacy was assessed at baseline and reevaluated after 30 days of using the DAL. Data was compared between the intervention and control groups to answer the question regarding mean differences in self-efficacy after using the DAL for 30 days. This type of indirect PROM is preferred for this type of study given direct measures, such as pill counting are costly, and impractical unless the patient is under direct observation for the duration of the study to monitor for pill dumping or pill sharing (Lam & Fresco, 2015). This tool is an open source tool and did not require permission to use.

Post intervention patient reported experience measure.

Digital audio label (DAL) usability questionnaire.

The DAL usability questionnaire is a 10- item PREM adapted from the 10-item questionnaire used in the VPL study by Allnatt et al. (2001) (See Appendix L). This was implemented 30 days post use of DAL in the intervention group and scored as a 5-point Likert scale ranging from a score of 1 = strongly disagree to a 5 = strongly agree on perceived ease of use and perceived usability of the device. This PREM incorporates the elements of the TAM which was tested as a valid and reliable PREM of perceived usefulness (PU) and perceived ease of use (PEOU) with a Cronbach alpha for PU of 0.97 and for PEOU of 0.091 (Davis, 1989; Lam et al., 2017). Concepts measured in the DAL usability questionnaire were derived from two definitions of usability per the International Organization for Standardization: 1)"the extent to which a product can be used by specified users to achieve specified goals with effectiveness; 2) usability compliance is one of five product quality categories" (Yen & Bakken, 2012). Modifications to the Allnatt et al. (2001) questionnaire were chosen since it was specifically designed to evaluate the concepts of interest to the primary investigator related to the talking prescription device. The modifications made were grammatical to indicate the questions being asked were for face to face interviews, rather than that of the participant reading the questions to themselves. The modified tool was tested for reliability using a Cronbach alpha test. Results indicated the tool was highly reliable (10 items; $\alpha = 0.99$).

Indicators on the post intervention usability PREM were used to answer the research question regarding perceptions of usability and ease of use for the DAL, and may be a predictor of participant acceptance of the innovative device as an aid to increase medication self-efficacy and possibly improve blood pressure.

Intervention

Study Device Description

The intervention for this study is the DAL that is compliant with the ADA and FDA Safety and Innovation Act for accessibility as an assistive device (See Appendix M for a picture of the device). This small, electronic, patient centered device affixes to a prescription drug container and is activated by pushing a button, resulting in a verbal message description of the prescription drug information. According to AccessaMed Inc. (2018) the DAL device:

- Is two inches tall by one inch wide and adheres to any surface.
- Is simple to use via the push of a button, the user hears a clear audio description of the information recorded such as 1) patient name; 2) name of drug and dose; 3) instructions; 4) prescription number; 5) fill date; 6) number of refills; 7) quantity filled; 8) description of drug; 9) expiration date; 10) physician's name; 11) drug manufacturer; 12) pharmacy name; 13) pharmacy telephone number; and 14) any additional warnings necessary.
- Is fully self-contained and requires no additional equipment by the patient to operate.
- Has a battery life that lasts a minimum of 400 pushes with a 60 second recording.

The DAL was selected because it is a small, self-contained, patient centered device. It does not take up extra space in a standard medicine cabinet, is inexpensive for pharmacies or patients, and is easy to program. The product is available to pharmacies and patients or families as startup kits. The home kit retail price is $125 and includes a docking station with Text-to-Speech software, the Universal Serial Bus (USB) cable and 10 DALs, additional DALs are available for purchase on their website at $40 for 10 DALs. The Text-To-Speech software is an application where a patient simply fills in the blanks of required prescription information (See Appendix N for Data Entry Screen). This minimizes human error during programming regardless

of whether pharmacies or patients do the programming of prescription information, thus making this device an optimal option for this DNP Study. After device evaluation, the manufacturer was contacted resulting in a donation of a docking station with Text-to-Speech software, the USB cable and 100 devices for use in this DNP study. Consideration was given to the fact more than 100 devices may be needed dependent upon the number of prescriptions the intervention sample population may be prescribed. Additional devices did not have to be purchased by the primary investigator. See Appendix O for the study budget.

Comparison of Similar Devices

Similar devices that were still being manufactured were evaluated for this DNP study. ScriptTalk is a similar device that uses a radio frequency identification device tag that is affixed to the bottom of the prescription bottle. The bottle has to be placed over another separate battery-operated reading device that has multiple navigation buttons that must be manipulated to play the voice output information. Although it is portable, having to carry and unite two separate pieces of equipment to read a prescription medication lacks convenience. The price for the reader and two thousand labels for a pharmacy is approximately $657 with the ScripTalk printer costing $2060 and there is not an option for patients if they would like to implement this on their own at home. This was not selected for this DNP study due to the multiple pieces required for use and the high cost.

Talking Rx is similar to the DAL. It runs on a replaceable battery, but the device adheres to the bottom of the prescription bottle, rather than the side of the bottle like DAL, making the bottle taller than normal and storage difficult in standard sized medicine cabinets. Talking Rx also indicates the patient can transfer medication from the pharmaceutical bottle to the bottle that “fits” on the device, which infers only one device size is offered as compared to the DAL, that

fits any size bottle and offers varying adhesive structures to adhere to other sizes and shapes of medication containers. Transfer of prescribed medications from bottle to bottle is an unsafe practice that can lead to inadvertent medication related ADEs by transferring a medication to the wrong container. The cost of this device is $26 and can become expensive when patients are on more than one medication. This device was not selected due to the possibilities of transfer errors that could occur with the device as well as cost.

Data Collection

Phase 0 (Pre-Intervention)

The data collection process was designed to ensure minimal workflow interruption in the clinic providers and for the patients and was approved via a signed site agreement by the nurse manager. Preliminary education for the volunteer staff on the study process and plan was provided via a PowerPoint emailed to the clinic volunteer providers 1 week before implementation. This method of education was selected due to the clinic's unique staffing model of using volunteers only, who had varied hours scheduled for volunteering as well as the clinic's wide-ranging clinic hours of operation. See Appendix P for the clinic's scheduled days and hours. Part of the education plan was for the primary investigator to be on site at all clinics when the study sample and data were being acquired, to ensure the volunteer staff scheduled to provide patient care during a clinic, received reinforced education on the study plan, process and requirements and had an opportunity to pose any questions related to the study if they arose.

Prior to each clinic, charts were reviewed by the primary investigator or clinic staff to identify patients who met inclusion criteria and develop a preliminary list of potential participants. During the clinic hours multiple patients would arrive at once, forming a line outside of the clinic. Once the patients signed in for their appointment, they waited in the lobby

to be called for their initial intake assessment and were seen by clinic providers in the order in which they signed in on a paper sign in sheet. To minimize the potential of the patient being called for their intake assessment while they were being interviewed by the primary the investigator, the patients were selected for interviewing based on the preliminary list starting from the bottom of the sign in sheet moving upward.

Phase 1 (Verbal Interviews)

In a private room, using the script in Appendix Q, the patient was assessed to verify qualifications for inclusion according to the inclusion and exclusion criteria. If the SILS score was >2 and the answers were yes to the chronic hypertension diagnosis and being on blood pressure medication, the explanation continued per the script depending on the allocation to the intervention or the control group and then the patient was asked a first time if they wanted to volunteer to participate. If the answer was yes, study participation requirements were verbally explained as described on the consent that coincided with the participant's allocation to either the intervention group who received the DAL or the control group who received usual care of verbal prescription information from pharmacy staff. Allocation to the intervention or control group was randomized as every other person being allocated to one group or the other. If the patient did not meet the criteria for inclusion or refused to participate, they were asked to return to the waiting area to be seen by their providers.

For those who volunteered to participate, the teach-back educational method was implemented for the study participation requirements. Using this teaching method is part of the AHRQ Health Literacy Universal Precautions Toolkit and is a research-based health literacy intervention that promotes adherence to teaching and patient safety (AHRQ, 2015). The teach-back method required the participants to explain in their own words the education they received

to ensure understanding of participation requirements in the study. Once confirmation was made that the participant understood the requirements, the participant was asked a second time if they would still like to participate. If the participant chose to participate, the consent was signed with a copy provided, and verbal questioning continued with data entered into the SurveyMonkey with the participant name, drawing ticket number to be used to identify the participant, demographics per Appendix R for age, sex, education level, ethnicity and baseline PROM SEAMS scores. SurveyMonkey was selected because the survey results can be directly uploaded to the Statistical Package for the Social Sciences (SPSS) version 26. SurveyMonkey was also chosen because it allows for edits to the surveys after data has been entered allowing for there to be one record per participant to include both the pre and post intervention data.

Phase 2 (Device Programming)

Upon completion of the interview the participants in both groups were returned to the waiting area to be seen for their appointment with the requirement of returning to the investigator after obtaining their prescription medication for either programming of a DAL for each prescription received for those in the intervention group or to verify receipt of prescriptions in participants in the control group. Upon returning to the primary investigator the baseline blood pressures were collected from the patient's chart, recorded in SurveyMonkey and the participants were given their drawing ticket for entry into the drawing to win the $100 gift card for study participation and completion. To program the DAL, the primary investigator entered the prescription as printed on the prescription bottle label into the text to speech software and programming was verified for accuracy with another nurse or provider. All patients were required to make a follow up appointment before they left the clinic. The primary investigator

notified the front desk receptionist of the participants who volunteered in the study so that their next appointment was set for 30 days to perform a blood pressure check.

Phase 3 (Post-Intervention)

After 30 days, if the primary investigator was not present for the participant follow up appointment that occurred within 14 days after the 30 day time frame of their initial face to face interaction, phone calls were made to reevaluate the PROM SEAMS scores and gather additional survey data from the intervention group only, regarding the PREM of usability of the DAL via the DAL Usability Survey. All responses and post-intervention blood pressures acquired from the participant's chart from their follow up nursing blood pressure appointment were updated in the SurveyMonkey record. Once all participants were contacted for follow up data collection, the drawing was held to select a winner for the $100 gift card. All participants were notified via email or phone at the end of the study by the primary investigator if they did not win the drawing. The winner of the gift card was notified, the mailing address was confirmed, and the gift card was mailed via certified mail to ensure receipt of delivery by the primary investigator.

Data Analysis

Data collected in SurveyMonkey was imported into SPSS. The data set was cleansed to remove participant identifiable information, unnecessary columns or rows, identify data omissions, ensure headings were properly labeled and levels of measurement were properly allocated. The independent variables were grouped by 1 = intervention group and 2 = control group, coded in SPSS as a nominal level of measurement. Descriptive statistics were applied with frequency distributions for each demographic category of age, gender, education and ethnicity. Demographic data was collected on a numerical scale with the level of measurement in SPSS categorized as nominal to describe the demographics of the participants between groups.

For the two primary outcome measures, of if there is a statistically significant difference between groups in the mean blood pressure levels before and after the intervention at 30 days and if there is a statistically significant difference between groups in the mean SEAMS scores before and after the intervention at 30 days, independent *t*-tests were used. A *p* value of 0.05 was set for statistical significance. Blood Pressure, although a ratio level of measurement was coded as scale for SPSS. SEAMS scores were a 1-5 Likert scale and coded in SPSS as scale despite it being an interval level of measurement. The DAL data was also a 1-5 Likert scale with an interval level of measurement coded as scale with descriptive statistics and frequencies used to evaluate DAL ease of use and usability.

Results

Demographics

A total of 84 patients were screened. A total of 52 patients met the inclusion criteria in addition to scoring > 2 on the SILS question indicating they had inadequate health literacy and some difficulty with reading printed health related material. A total of 12 participants met criteria for inclusion but refused to participate, 19 patients did not score as LHL on the SILS and one patient spoke Spanish, but the device programming did not support audible information to be converted to Spanish. Approximately half of the patients were either African American (42%) or Caucasian (52%). The majority of the patients (83%) were between the ages of 50-64 years old and female (58%). Despite scoring as low health literate on the SILS, over half (58%) of the patients possessed either a high school degree/General Education Diploma or some level of college education. Income data was not collected given the study was conducted at free medical clinic and required the patient to be at or below poverty level to qualify for care. No statistical

differences in the demographic variables were noted between the two groups, see Appendix S for the results.

Primary Outcome Measure 1 - Blood Pressure Differences

Overall changes in mean blood pressure differences were evaluated between the intervention and control group. To answer the question if there was a statistically significant difference between the SBP and DBP in the intervention and control groups before and after the intervention at 30 days, an independent samples *t* test was calculated. A decrease in SBP or DBP of ≥ 2 mmHg was considered clinically significant (Lam et al., 2017). The table in Appendix T represents the comparison of mean SBP and DBP of both groups pre and post intervention after 30 days and the table in Appendix U represents the changes in mean blood pressures between the groups. At baseline the intervention group's SBP and DBP blood pressure readings (SBP: M = 135.54, sd = 20.754; DBP: M = 81.27, sd = 8.884) were lower compared to the control group (SBP: M = 142.69, sd 24.838; DBP: M = 87.65, sd = 11.440). SBP was not statistically significant, but DBP was found to be significantly lower in the intervention group compared to the control (SBP: (t(50) = -1.127, p = 0.265; DBP: (t(50) = -2.248, p = 0.029). After 30 days, blood pressures between patients in the intervention group who received the DAL (SBP: M = 133.88, sd = 17.075; DBP: M = 80.85, sd = 9.739) were compared to the control group who received usual care (SBP: M = 134.46, sd = 17.505; DBP: M = 82.15, sd = 10.661). The between group mean SBP and DBP post intervention was slightly higher in the non-intervention group, but the difference was not statistically significant (SBP: (t(50) = -0.120, p = .905; DBP: (t(50) = -0.462, p =0.646).

Primary Outcome Measure 2 - SEAMS Scores

The SEAMS tool was used to measure medication self-efficacy in patients. To answer the question of if there was a statistically significant difference between groups in the mean SEAMS scores before and after the intervention at 30 days post intervention an independent samples *t* test was calculated to compare patient responses to SEAMS scores. A 1 point increase was considered clinically significant (Kamal et al., 2018). The table in Appendix V illustrates the mean SEAMS scores of both groups at baseline and after 30 days and the table in Appendix W represents the mean differences in SEAMS scores between the groups. At baseline the intervention group's SEAMS scores ($M = 3.86$, $sd = 0.853$) were lower compared to the control group ($M = 4.11$, sd 0.820). This reflects less confidence in the ability of the patient in the control group to correctly adhere their prescribed medication regime. Despite this, there was no statistically significant difference between groups on SEAMS scores ($t(50) = -1.083$, $p = 0.284$). After 30 days, SEAMS scores between patients in the intervention group who received the DAL ($M = 4.207$, $sd = 0.737$) were compared to the control group who received usual care ($M = 4.18$, $sd = 0.638$) and did not reflect statistical significance ($t(50) = 0.142$, $p = 0.888$) indicating there was not an increase in medication self-efficacy in patients who used the DAL.

Secondary Outcome Measure 3 - DAL Usability

To answer the question of if LHL hypertensive patients score the DAL useable for verbal delivery of prescription medication the DAL usability questionnaire, a PREM of PU and PEOU, was implemented 30 days post use of the DAL in the intervention group. Results are displayed in the table in Appendix X. Few patients (11.5%) disagreed or strongly disagreed that the DAL was usable and easy to use. The majority of the participants had an overall high PU and PEOU for the DAL with an average response of strongly agreed (77.7%) on the 10 questions. Over half

(61.5%) of the participants agreed and strongly agreed they would prefer this method of reading prescription labels over their previous methods. Participants who answered neither (26.9%), disagree (3.9%) and strongly disagree (7.7%) to preferring the use of this device over other methods gave the reason that they already had their method and routine established for taking their medications. All, but one participant (96%), indicated they would highly recommend this device to those with difficulty reading prescription labels.

Discussion

This study examined the effect of the DAL on decreasing blood pressure, increasing medication self-efficacy and participant satisfaction with use of the DAL in a sample population that was LHL with chronic hypertension. The goal of 62 participants was not met despite attending both day clinics and evening clinics that had a higher volume of patients. The study design facilitated ease of participation by 52 total participants, which was the minimum sample size estimated for a power of 0.80. All participants were LHL and of low income despite over half of them possessing a high school diploma, GED or some college education. The majority of the participants were older Caucasian or African American adults, which is similar to the characteristics of individuals with low literacy levels reported in the latest update of the PIAAC.

The intervention group's mean SBP and DBP was lower than the control group at baseline as well as after 30 days of using the DAL but had a larger difference between the groups prior to use of the DAL. Statistical significance between the groups was found only in the DBP and was prior to the intervention period, suggesting the control group had poorer blood pressure management at baseline compared to the intervention group. Although there was a decrease of 1.6 mmHg in the SBP and a decrease of 0.42 mmHg in the DBP of the intervention group after using the DAL for 30 days, it is difficult to infer clinical significance because the set threshold of

a decrease in blood pressure by ≥ 2 mmHg was not met. The baseline blood pressures differ from findings in the study conducted by Lam et al., (2017) given the baseline blood pressures in the control group were slightly lower compared to the intervention group. The SEAMS scores in the intervention group were also lower compared to the control group prior to the intervention. There was no statistical difference in scores between the groups, but the lower scores in the intervention group at baseline could infer the intervention group had a greater need for the capabilities of the DAL. There was an increase in the SEAMS scores of the intervention group compared to the control group after the intervention as well as an increase in the SEAMS scores within the intervention group alone by 0.34, but the between group difference was not statistically significant. This is consistent with the findings by Lam et al., (2017). Although there was an increase in SEAMS scores, it is difficult to speculate clinical significance given the threshold of an increase of 1 point in the scores was not met.

Findings surrounding the use of the DAL to provide prescription medication information in a community setting with a LHL population suggest it is easy to use, useful and the capabilities it provides has the potential to have a positive impact on chronic health conditions such as hypertension. Participant responses on the follow up questionnaire regarding the DAL demonstrated a high acceptance of the device with high scores for usability to deliver prescription medication information and ease of use. These findings were also consistent with the outcomes reported by Lam et al. (2017) and Kamal et al. (2018). Recurring theme reported by participants was that the DAL would have improved usefulness if it had an alert as a reminder to take their medications, indicated a specific time of day to take the medication and a way to know when the battery was low. Some participants reported that it would be useful for their older parents and that when they went for follow up care at a location other than the free medical clinic

that external providers were astonished at the functionality of the device and that a device as such was available in the market.

Limitations

There were several limitations that could have impacted this study. It should not be assumed that low income equates to LHL since patients at the low income free medical clinic were excluded from the study because they did not score as LHL on the SILS question. The Post hoc power and effect (0.80) of the study results were impacted by the sample size and the inequality between the intervention and control groups at baseline measurements. Generalizability is limited due to isolation to participants who only spoke English and the unique free medical clinic setting in which this study was performed. Transference is excluded to larger hospital settings or clinics with a larger consumer base that provide care to individuals that are not low income, not LHL or do not speak English. The short study duration may not have been suitable to allow for participants to fully integrate the use of the DAL into their long term medication regime and in turn have a clinical and statistically significant influence on blood pressure. In addition, the fact that the participants were not newly diagnosed with hypertension and were already on existing antihypertensive medications, participants already had established routines for taking their medications. This could have had a confounding effect on the post intervention SEAMS scores as well as blood pressure in the intervention group. Finally, the answers to the SEAMS questions could have been confounded by participants altering their answers to avoid disapproval from the primary investigator about medication consumption habits.

Study implications for Practice, Nursing, Future Research

This study surfaces the need for nursing leaders to advocate provision of interventions that overcome LHL barriers to reading medication prescription labels. One of many goals in nursing should be to ultimately increase an individual's sense of empowerment related to managing their own health and self-efficacy related to appropriate medication use. We know empowerment can lead to medication adherence and increase feelings control over the management of their medical condition, resulting in increased motivation to demonstrate the behaviors necessary to adhere to their medication regime (World Health Organization, 2013; Herrier et al., 2015). Attention needs to be directed toward acute care settings as well as free standing community pharmacies in an effort to mitigate the rippling effect that ADEs can have on increased doctor visits, increased admission rates and increased overall health care and prescription related costs in the U.S. LHL, although a national problem, is not one that is being addressed via pharmacy label best practice recommendations such as audible drug container labels. Initially nursing leaders can engage in the development of a systematic approach for organizations and health care providers to properly integrate literacy standards of care into their practice and organizational clinical practice guidelines. On a larger scale, nursing leaders can begin to educate policy makers about this wide spread patient safety issue to get mandates for LHL assessments and get innovative technology, such as the DAL, covered under government sponsored health plans such as Medicare and Medicaid.

There has been minimal research related to this type of innovative technology for prescription delivery information. Ongoing research could focus on comparing talking prescription label device functionality within independent study groups as well as the long term long-term impacts that talking prescription devices can have on decreasing medication errors, decreasing exacerbation of chronic health conditions and ultimately decrease national health care

expenditures. Achieving this would require a larger sample population and a longer study duration. Implications of level of education, age, and gender could also be evaluated. Participant comments about their already established medication regime during recruitment imply additional areas of exploration such as those for participants with a new diagnosis requiring a new prescription, given they are less likely to have established medication routines. It is also important to consider research surrounding provider perspectives on device PU and PEOU as well as the impact of device programming and dispensing of the device being integrated into the daily workflows. Avoiding negative impact on provider workflows is becoming increasingly critical with the implementation of innovative technology (Dobre, Carter, Herout, & Cournoyer, 2018).

Study Sustainability

There was unanimous support from the clinical supervisor, the nurse manager and volunteer staff at the free medical clinic to sustain the implementation of the DAL for LHL patients. It was recommended that an assessment of health literacy be implemented during the patient intake assessment via integration of literacy questioning into their intake assessment forms to identify patients who could benefit from having DALs for use on their prescriptions. The software, docking station used for programming, 34 left over DALs and the DAL displays for the lobby and pharmacy were donated to the clinic, however there were limitations identified of the clinic's ability to maintain sustainment of offering the DAL. Given this clinic is 100% funded by donations and grants, the ability of the clinic to purchase additional devices will be based on prioritization of clinic funding allocations. Consideration was being given to applying for a grant to help fund the purchase of additions DALs.

DNP Essentials

It is important to apply the essentials while planning and conducting the DNP study to demonstrate that the DNP graduate received the preparation necessary to be able to transition into a leader. The DNP Essentials prepare the graduate to look at health care delivery through a new lens, enabling the graduate to leverage essential skills acquired while conducting the DNP study and transpose those skills into identifying forward-thinking and evidence based health care delivery approaches. There are eight DNP Essentials according to the American Association of Colleges of Nursing (2016) and development of this study links to all DNP essentials in many ways. The DAL intervention selected for this study was an innovative technology evaluated for appropriateness to deliver verbal prescription drug information to a LHL population (Essential I, IV). A device such as this was not commonly used in practice and had minimal comparative research to evaluate the device usability and efficacy as an intervention to improve patient's blood pressure and medication self-efficacy in LHL populations specifically, therefore identifying a gap in evidence for practice (Essential III). To gain approval for the plan to implement the DAL in practice, alternative literature was appraised and communicated to the IRB committee in the realms of LHL and the impact on diminished medication self-efficacy, patient preferred learning methods, other technology-based interventions to provide verbal prescription label information, and the significance a device like the DAL could have in the long term future for population health and chronic conditions (Essential II, III, VI, VII, VIII).

Research was conducted as to the feasibility of this study and a detailed process and data analysis plan was designed and presented to the IRB committee for review and approval (Essential VI). Significant attention was given to developing a script, consent, method of questioning and proper patient safety precautions to demonstrate sensitivity to the selected population and technology intervention being used (Essential II, IV, V, VIII). The data

collection, analysis and evaluation plans were implemented by the primary investigator alone for the purpose of knowledge growth and skill acquisition to be able to repeat this or a similar process in future studies (Essential IV). The outcome metric data can be translated into useful information 1) to develop relevant clinical practice guidelines for organizations and, 2) for insurance providers or local and national policy makers to guide decision making surrounding the prudence of covering the cost of technology devices such as the DAL for the nation's prescription needs (Essential V, VI, VII).

Dissemination

To disseminate the results of this study, the clinic site of implementation, was provided with an executive summary of the study and the final results. Due to the study receiving a research grant for $100 from the Phi Gamm Chapter of Sigma Theta Tau, results are required to be presented on Wednesday, December 11th, 2019 to the Chapter during the International Nursing Research Exposition (iNurse). Additional dissemination of the study has been initiated via submission of the study manuscript to the Computers ,Informatics, Nursing Journal, see Appendix Y. Permission was obtained from the DAL manufacturer to publish data and outcomes of the study and asked that the device be referred to as either the OptaPHONIC^{TM} Digital Audio Label or Digital Audio Label (DAL).

Conclusion

There are millions of people who do not take medication as prescribed primarily because of confusion or poor understanding of their medicines (Herrier et al., 2015). Innovative technologies such as talking prescription drug labels have been reported as being efficacious by patients because health information was relayed in a clear method, improved recollection of prescription information, increased medication knowledge, adherence and medication self-

efficacy, but there are minimal studies that exist related to the use of a talking prescription label. There are also minimal studies on this type of intervention specifically for the LHL, hypertensive population and there are no comparison studies supporting the efficacy of one device over another or comparing outcomes by literacy level (Lertwiriyaprapa & Fakkheow, 2015; Wali et.al., 2016; McMahon & Curtis, 2009; Mullen et al., 2018).

This study implemented an existing talking prescription assistive technology device to provide verbal prescription medication information for patients who were LHL with chronic hypertension. Although there were no statistically significant decreases in blood pressure or improvements in self-efficacy scores between the intervention and control groups, patients in the intervention group reported the DAL as having high PU and PEOU for delivery of verbal prescription label information. This study adds to the literature demonstrating that talking prescription labels are an easy to use and usable intervention. Studies of a longer duration, with a larger sample population have the potential to demonstrate increased self-efficacy for prescription medication administration and possibly decrease blood pressure on patients with LHL with a new diagnosis of hypertension. Information such as this can inform organizations, pharmacies and policy makers when considering and justifying changes to prescription labeling practices that can potentially have a nationwide impact on decreasing ADEs and healthcare costs related to exacerbations of chronic health conditions.

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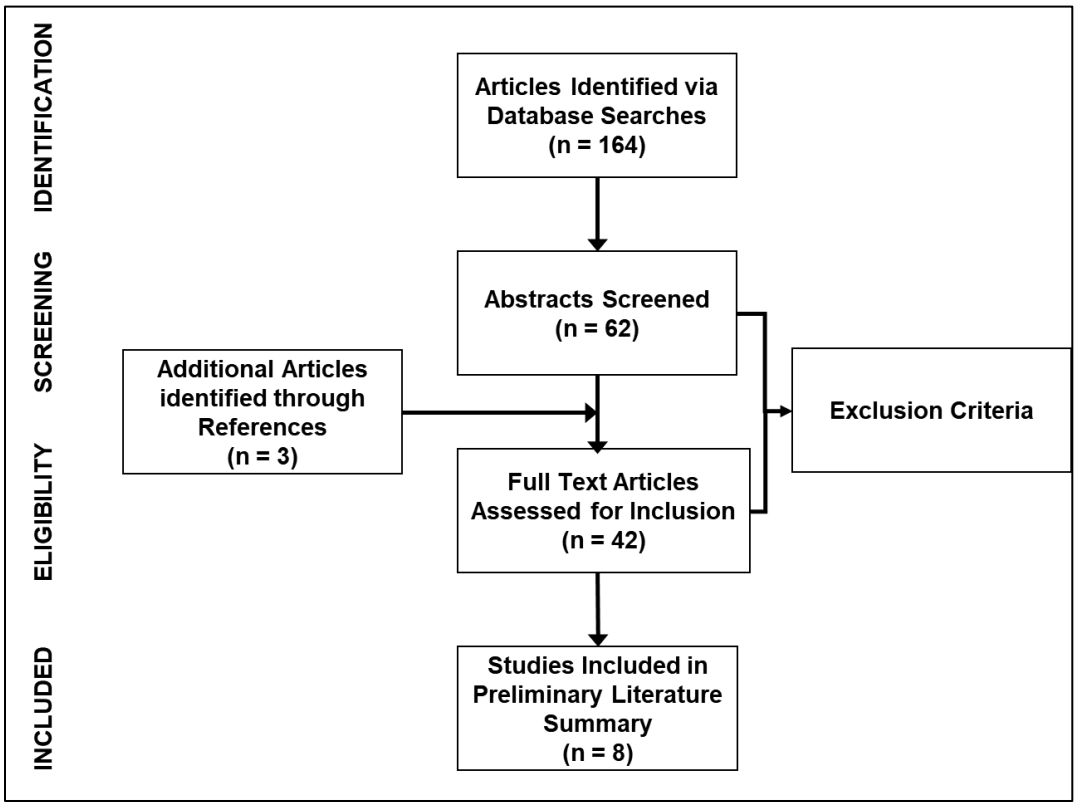
Appendix A

SWOT Analysis

SWOT Analysis	
Strengths	Weaknesses
• Patient population demographics match those indicated as LHL in the research. • Volunteer staff support of helping the LHL population understand medications prescribed. • The study supports the National Action Plan to Improve Health Literacy by exploring methods such as the DAL to deliver easy to understand prescription medications information	• Does not print paper medication instructions. • Does not print braille. • Does not print large font labels upon request. • Does not have a language line. • Do not currently have a practice guideline in place for assessing LHL. • No government oversight, donations & grants only. • Do not currently offer the DAL or similar device.
Opportunities	Threats
• Obtain grant funding for the DAL to become a product offered by the clinic for the LHL population • Potential for device to increase medication self-efficacy in the LHL chronic hypertension population for prescription medication administration. • Potential for implementation of new practice guideline to assess patients for LHL in regular workflows. • Potential decrease in strain on clinic resources r/t unnecessary patient care provided.	• Sporadic clinic times. • Costs of the device & funding constraints. • Lack of laws mandating pharmacy best practices for audio prescription devices for LHL patients. • Intake staff do not feel comfortable asking SILS question and may resist practice change. • Programming of device may have a perceived negative impact on staff workflows.

Appendix B

Pharmacy Health Literacy Search Chart



Appendix C

Literature Review Summary Matrix

PICOT question: In adults patients, ages 18-64 years old, with chronic hypertension and LHL scores >2 on the Single Item Literacy Screener (SILS) in a free outpatient medical clinic (P), does using the talking prescription DAL to provide verbal prescription drug container information (I) compared to usual clinic care (C) improve blood pressure and medication self-efficacy scores on the Self-efficacy for Appropriate Medication use Scale (O) after using the device for 30 days (T)?

Author, Year, Title, Design & Level of Evidence	**Study Purpose**	**Population/Sample/Setting**	**Independent/Dependent Variables (I/V and D/V)**	**Findings**
Study #1 Wali et al., 2016 "A systematic review of interventions to improve medication information for low health literate populations" **Designs Included:** A systematic review of RCTs, non-RCTs and uncontrolled trials (UCT). Level I	Review evidence on interventions for improving medication knowledge in LHL literate populations.	**Population/Sample:** LHL population. Included 47 articles specifying outcome measures for knowledge and/or adherence, focused on medication information, were written in English and were available in full text. **Setting:** N/A	**IV:** 1. Written information 2. Visual information 3. Verbal information 4. Label/medication bottle 5. Reminder systems 6. Educational programs and services **DV:** Patient medication knowledge and adherence	The most common interventions are written interventions, but other effective strategies include visual information, verbal information, specialized labels, reminder systems and education programs. Overall 81% of 27 studies demonstrated statistically significant improvement of knowledge regarding prescribed medication when information was provided verbally.
Study#2 Harrington et al., 2014 "A conceptual model of Verbal Exchange Health Literacy"	Emphasize consideration of verbal and aural relay of health information	**Population and Sample:** Providers (n=6) Patients in Focus Groups (n=49) • 73% female • 69% African American • 8% Latino • 23% White **Setting:** Primary care	**IV:** Providers and Patient Focus Groups **DV:** Outcomes of interviews	Verbal Exchange Health Literacy is one of several constructs contributing to the patient's health literacy and ability to acquire and use health information. This combined with reading, writing and numeracy skills may facilitate better health

Author, Year, Title, Design & Level of Evidence	Study Purpose	Population/Sample/Setting	Independent/Dependent Variables (I/V and D/V)	Findings
Designs Included: Mixed Methods Level I & Level VI				decisions, equating to improved patient outcomes.
Study#3 Marcus, C. 2014 "Strategies for improving the quality of verbal patient and family education: A review of the literature and creation of the EDUCATE model" **Designs Included:** Mixed Methods Level I & Level VI	To study verbal instruction as a component of patient and family education and make recommendations for best practices for healthcare providers who use this method.	**Population/Sample:** Nursing Staff (n=46) **Setting:** The Brigham and Women's Faulkner Hospital, a 150-bed non-profit, community teaching hospital located in Jamaica Plain, Massachusetts	**IV:** Nurses **DV:** Outcomes of online surveys regarding patient education practices	Identified verbal education models, best practices, barriers and needs to synthesize the EDUCATE Model.
Study #4 Lam, et al., 2017 "Addressing low health literacy with "Talking Pill Bottles": A pilot study in a community pharmacy setting" **Designs Included:** RCT Level II	Evaluate the impact of Talking Pill Bottles on medication self-efficacy, medication adherence, knowledge about antihypertensive prescription medications, blood pressure (blood pressure) changes after using the Talking Pill Bottle and patients' acceptance of the Talking Pill Bottle.	**Population/Sample:** LHL patients filling prescriptions for hypertension (n=134) **Setting:** Two community Pharmacies	**IV:** Talking Pill Bottles **DV:** Outcome measures of SEAMS, MMAS-8, CMG, blood pressure, PEOU and PU.	There were statistically significant within group results for improved knowledge and medication adherence in both the control and intervention groups and increased overall refills. blood pressure readings decreased and were statistically significant in the control group indicating the Talking Pill Bottles may contribute to blood pressure control.
Study #5 Kamal et al., 2018 "Making prescriptions "talk" to stroke and heart attack survivors to improve	Evaluate changes in medication adherence, and acceptability of a talking prescription device and SMS reminders in the Pakistani population with CVA and CAD taking anti-	**Population/Sample:** Pakistani population with CVA and CAD taking anti-platelet and statin medication (n=197) **Setting:** Cardiology and Neurology outpatient clinics	**IV:** 1) Daily Interactive Voice Response call services 2) Daily tailored medication reminders and 3) Weekly lifestyle modification messages for a period of 3 months. **DV:** Outcome measures of MMAS-8 between intervention and control	There was an increase in participant MMAS-8 scores between the control and intervention groups, as well as within the groups with a diagnosis of CVA ad CAD who used the Talking Rx, although not statistically significant. The study

Author, Year, Title, Design & Level of Evidence	Study Purpose	Population/Sample/Setting	Independent/Dependent Variables (I/V and D/V)	Findings
adherence: Results of a randomized clinical trial (The Talking Rx Study)" **Designs Included:** RCT Level II	platelet and statin medication.		groups and within CVA and CAD groups; User Interface Experience analysis conducted on participants in the intervention group.	participants also rated the Talking Rx as excellent for providing prescription information.
Study #6 Zullig et al., 2014 "A health literacy pilot intervention to improve medication adherence using Meducation® technology" **Designs Included:** Pilot Study Level VI	Evaluate the effectiveness of an innovative health literacy tool called Meducation® on cardiovascular medication adherence.	**Population/Sample:** Veterans with Cardiovascular risk factors (n=23) **Setting:** VA Medical Center	**IV:** Meducation® calendar with reminders and education **DV:** Medication adherence evaluated via scores of self-reported medication adherence questionnaire and medication prescription refills Clinical outcomes of blood pressure, heart rate, body weight, low-density lipoproteins (LDL), high-density lipoproteins (HDL), total cholesterol and creatinine	Self-reports of medication adherence at three months after the intervention overall demonstrated a decrease in medication non-adherence. There was an increase in prescription refills. Overall improvement in clinical outcomes were statistically insignificant.
Study #7 Allnatt et al., 2001 "An evaluation of the functionality and acceptability of the voice prescription label" **Designs included:** Cohort Level III	Meet the need for providing information on prescription labels that is readily accessible to people who are visually impaired.	**Population/Sample:** Stratified random sample of 25 visually impaired Veterans **Setting:** Outpatients in a Veterans Affairs Medical Center	**IV**: Voice Prescription Label **DV:** Veteran patient survey results	100% of the patient strongly agreed they were able to find their bottle of medication and the VPL was easy to turn off and on; 80% preferred the VPL to their previous assistive devices for taking medication & 92% said they would recommend the device to others suggesting the VPL may be an advance in the health care of people who are visually impaired
Study #8 Lertwiriyaprapa et al., 2015 "A low-cost audio prescription	Overall objective was to prevent deaths and injuries, related to medication errors, while developing a usable APL that	**Population/Sample:** 70 visually impaired, low income Thai end users and 5 experts **Setting:** Skills Development Center for the Blind, Nonthaburi, Thailand and	**IV:** Audio Prescription Labeling System **DV:** Satisfaction Questionnaire from Thai patients and experts	Qualitative survey results from both populations that are relevant to this DNP study's focus indicated satisfaction with the degree of complete information

Author, Year, Title, Design & Level of Evidence	Study Purpose	Population/Sample/Setting	Independent/Dependent Variables (I/V and D/V)	Findings
labeling system using RFID for Thai visually impaired people” **Designs included:** Cohort Level III	is cost effective for low income, visually impaired population.	the Bang Kruai Hospital, Nonthaburi, Thailand		the system provided, clarity of the audio information, and the system’s ease of use. Overall the APL system can be effectively used for helping visually-impaired people in terms of self-medication.

Appendix D

No Conflict of Interest Email

Tyson Schultz
to me

I agee,

Tyson F. Schultz
CEO and Founder
STRIPES GLOBAL INC.
C: 206-910-2804
F: 206-504-2045
tyson@stripes-corp.com

STRIPES GLOBAL
AMERICA'S BEST FOR AMERICA'S GREATEST

SDVOSB
HUBZone
Historically Underutilized Business Zone

From: Melonia Lillie <melonia.lillie@gmail.com>
Sent: Tuesday, March 19, 2019 11:57 AM
To: Tyson Schultz <tyson@stripesglobal.com>
Subject: Fwd: Mel Lillie Doctorate project

Hi Tyson to make it easier for you. Could you just respond to this email saying "I agree" that:

1. There are no conflicts of interest.
2. There are no expectations with the DNP student using the device.
3. The DNP student has permission to use the device and publish data and outcomes of the project and will refer to the device as either the optaPHONIC ™ Digital Audio Label or Digital Audio Label (DAL).

Thank you,

Melonia Lillie MSN, RN-BC, CCRN, CPAN, PMP, CPHIMS
Nurse Informaticist/Health System Analyst
Cell: 951-315-3980

Appendix E

Consent Form Intervention Group

Informed Consent for Participants 18 years of Age or Older v.I

You are being invited to participate in a Practice Improvement Project. The project aim is to learn more about individual's difficulty with reading prescription labels, usability of a talking prescription label called optaPHONIC™ Digital Audio Label, its impact on blood pressure, self-efficacy (confidence) for appropriate medication use.

This is 100% voluntary and if you agree, you will be asked you to:

1. Verbally answer baseline survey questions related to your demographics (age, education, race) and current self-efficacy (confidence) for medication administration. (There are no right or wrong answers, you may skip any question you do not want to answer).
2. Use the free optaPHONIC™ Digital Audio Label affixed to your prescription medication bottle for a minimum of 30 days.
3. Return to the clinic in 30 days for a nurse visit to check your blood pressure.
4. Provide contact information for a follow up phone interview after 30 days of using the device to verbally answer the survey questions related to your self-efficacy for medication administration and usability of the optaPHONIC™ Digital Audio Label.
5. Grant the investigator permission to review your medical record held at OPEN M for a review of your blood pressure readings.

DURATION:
The 1st interview and device programming will take approximately 15 minutes depending on how many prescriptions you have.

The follow up interview will take approximately 10 minutes via a phone call.

BENEFITS:
Possible benefits are that the device may help improve your pharmacy health literacy. Other possible benefits to society are providing information on the use of talking prescription labels and their potential role in helping people manage their own health by taking their medications independently, correctly and avoiding medication errors.

RISKS:
There is a chance that:

- The survey questions could make you sad or upset.
- Someone could find out that you were in the Practice Improvement Project and learn something about you that you did not want them to know.
- The device could inadvertently stop working. If this happens, email the investigator and a new device (s) will be provided.
- You may be subject to risks that have not yet been identified.

COMPENSATION:
Upon completion of the surveys, you will be entered into a raffle for a chance to win a $100 gift card.

LIABILITY
The investigator makes no warranty that the device will be error free or free from interruptions or other failures and you agree to release the investigator and other persons and organizations

1

associated with this project from any and all liabilities resulting from any perceived injury directly or indirectly caused by the device malfunction.

Your decision to participate in this project will have no effect on your relationship with the investigator, the care you receive at OPEN M or Graceland University. You may withdraw at any time without penalty.

You will not be identified in the reporting of results. Your individual identity will remain confidential.

Your participation in the project indicates your understanding of the project and agreement to participate to the best of your ability. Please ask the investigator any questions you may have. If you choose to participate, sign and date this form as indicated below. If you choose not to participate, return this form to the investigator.

Primary Investigator
Contact for questions related to optaPHONIC™ Digital Audio Label or project participation

Melonia Lillie (Mel)
Email: mel4@stling.graceland.edu

OPEN M Medical Clinic
Contact for questions related to medical care or medications

941 Princeton Street
Akron, OH 44311
Phone: (330) 434-0110

_____ _____
(Signature of Participant) (Printed Name of Participant) (Date)

By signing, you are stating that you are willing to participate in this Practice Improvement Project and that you have received a copy of the consent form.

_____ _____
(Signature of Investigator) (Printed Name of Investigator) (Date)

I certify that I have explained the project expectations, risks and benefits and answered any questions raised.

2

Appendix F

Consent Form Control Group

Informed Consent for Participants 18 years of Age or Older vC

You are being invited to participate in a Practice Improvement Project. The project aim is to learn more about if individual's have difficulty with reading prescription labels, how confident you are taking prescription medications and how that impacts your blood pressure.

This is 100% voluntary and if you agree, you will be asked you to:

1. Verbally answer baseline survey questions related to your demographics (age, education, race) and current self-efficacy (confidence) for medication administration. (There are no right or wrong answers, you may skip any question you do not want to answer).
2. Return to the clinic in 30 days for a nurse visit to check your blood pressure.
3. Provide contact information for a follow up phone interview after 30 days to verbally answer the survey questions related to your self-efficacy (confidence) for medication administration.
4. Grant the investigator permission to review your medical record held at OPEN M for a review of your blood pressure readings.

DURATION:
The 1st interview will take approximately 15 minutes.

The follow up interview will take approximately 10 minutes via a phone call.

BENEFITS:
There are no specific benefits to you as an individual for participating in this Practice Improvement Project. Possible benefits to society are providing information on how self-efficacy (confidence) in taking your medications can impact blood pressure in hypertension patients.

RISKS:
There is a chance that:

- The survey questions could make you sad or upset.
- Someone could find out that you were in the Practice Improvement Project and learn something about you that you did not want them to know.
- You may be subject to risks that have not yet been identified.

COMPENSATION:
Upon completion of the surveys, all participants will be entered into a raffle for a chance to win a $100 gift card.

LIABILITY
You agree to release the investigator and other persons and organizations associated with this project from any and all liabilities resulting from any perceived injury directly or indirectly caused by participating in the project.

Your decision to participate in this project will have no effect on your relationship with the investigator, the care you receive at OPEN M or Graceland University. You may withdraw at any time without penalty.

You will not be identified in the reporting of results. Your individual identity will remain confidential.

1

Your participation in the project indicates your understanding of the project and agreement to participate to the best of your ability. Please ask the investigator any questions you may have. If you choose to participate, sign and date this form as indicated below. If you choose not to participate, return this form to the investigator.

Primary Investigator	**OPEN M Medical Clinic**
Contact for questions related to optaPHONIC™ Digital Audio Label or project participation	Contact for questions related to medical care or medications
Melonia Lillie (Mel) Email: mel4@sting.graceland.edu	941 Princeton Street Akron, OH 44311 Phone: (330) 434-0110

_____ _____ _____
(Signature of Participant) (Printed Name of Participant) (Date)

By signing, you are stating that you are willing to participate in this Practice Improvement Project and that you have received a copy of the consent form.

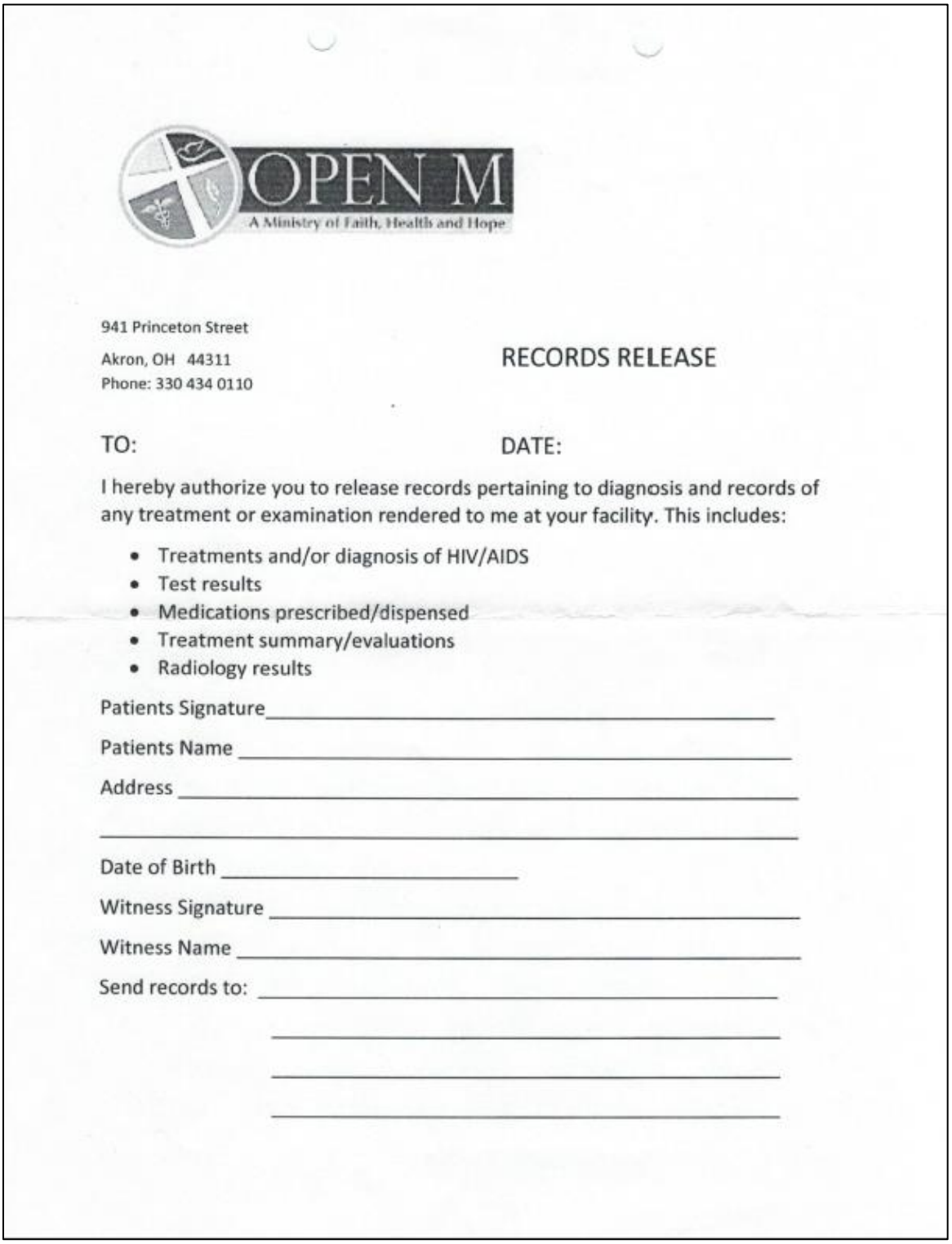
_____ _____ _____
(Signature of Investigator) (Printed Name of Investigator) (Date)

I certify that I have explained the project expectations, risks and benefits and answered any questions raised.

2

Appendix G

OPEN M Records Release



OPEN M
A Ministry of Faith, Health and Hope

941 Princeton Street
Akron, OH 44311
Phone: 330 434 0110

RECORDS RELEASE

TO: DATE:

I hereby authorize you to release records pertaining to diagnosis and records of any treatment or examination rendered to me at your facility. This includes:

- Treatments and/or diagnosis of HIV/AIDS
- Test results
- Medications prescribed/dispensed
- Treatment summary/evaluations
- Radiology results

Patients Signature_____

Patients Name _____

Address _____

_____

Date of Birth _____

Witness Signature _____

Witness Name _____

Send records to: _____

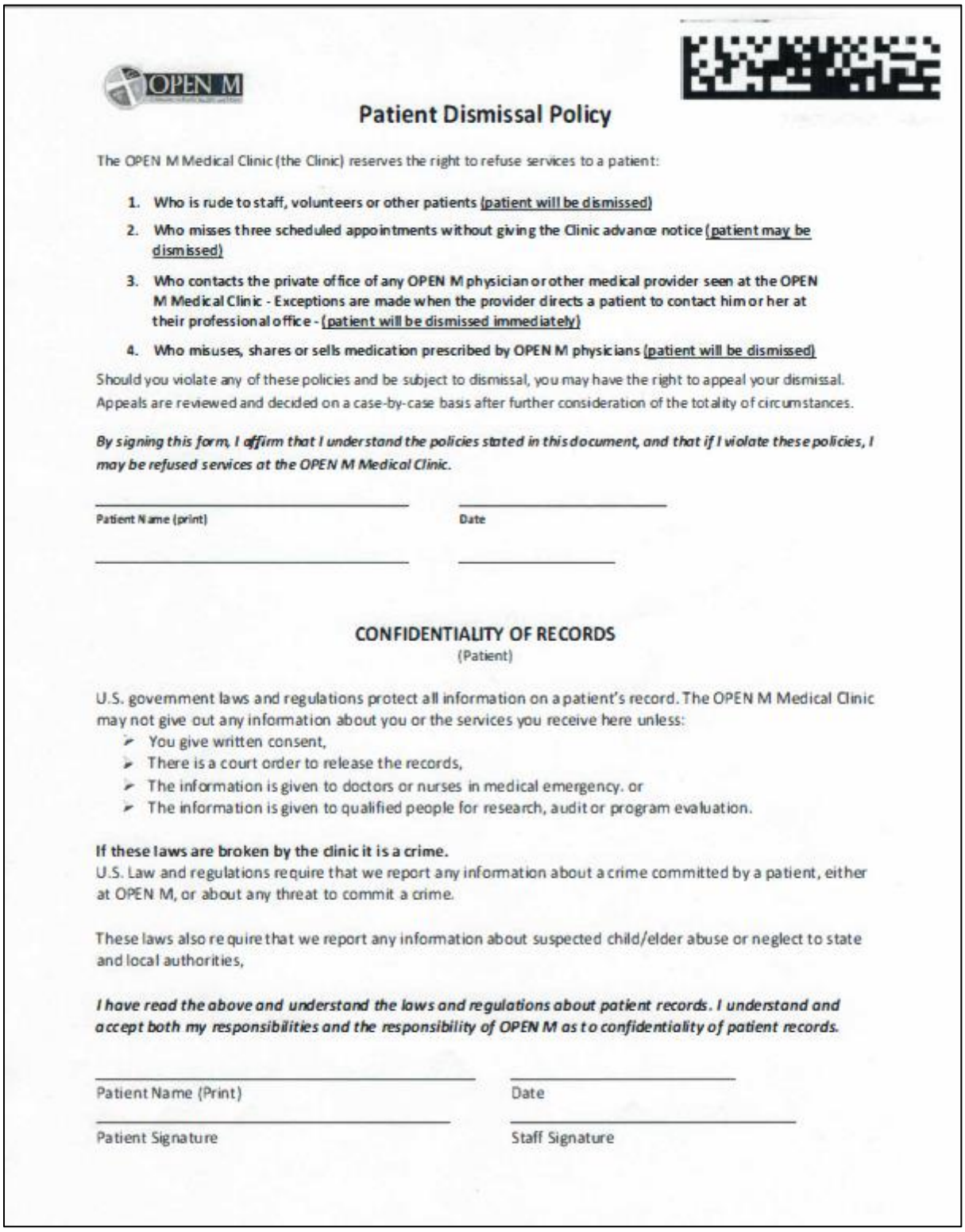
_____

_____

_____

Appendix H

OPEN M Patient Dismissal-Confidentiality of Records



OPEN M

Patient Dismissal Policy

The OPEN M Medical Clinic (the Clinic) reserves the right to refuse services to a patient:

1. Who is rude to staff, volunteers or other patients (patient will be dismissed)
2. Who misses three scheduled appointments without giving the Clinic advance notice (patient may be dismissed)
3. Who contacts the private office of any OPEN M physician or other medical provider seen at the OPEN M Medical Clinic - Exceptions are made when the provider directs a patient to contact him or her at their professional office - (patient will be dismissed immediately)
4. Who misuses, shares or sells medication prescribed by OPEN M physicians (patient will be dismissed)

Should you violate any of these policies and be subject to dismissal, you may have the right to appeal your dismissal. Appeals are reviewed and decided on a case-by-case basis after further consideration of the totality of circumstances.

By signing this form, I affirm that I understand the policies stated in this document, and that if I violate these policies, I may be refused services at the OPEN M Medical Clinic.

Patient Name (print) Date

CONFIDENTIALITY OF RECORDS

(Patient)

U.S. government laws and regulations protect all information on a patient's record. The OPEN M Medical Clinic may not give out any information about you or the services you receive here unless:

- You give written consent,
- There is a court order to release the records,
- The information is given to doctors or nurses in medical emergency. or
- The information is given to qualified people for research, audit or program evaluation.

If these laws are broken by the clinic it is a crime.
U.S. Law and regulations require that we report any information about a crime committed by a patient, either at OPEN M, or about any threat to commit a crime.

These laws also require that we report any information about suspected child/elder abuse or neglect to state and local authorities,

I have read the above and understand the laws and regulations about patient records. I understand and accept both my responsibilities and the responsibility of OPEN M as to confidentiality of patient records.

Patient Name (Print) Date

Patient Signature Staff Signature

Appendix I

Voluntary Care Informed Consent and Waiver

Voluntary Care Informed Consent and Waiver

I have been informed and I understand that the medical personnel of this clinic, in exchange for providing freecare, cannot be sued or held liable unless their action, failure to act, or omission, constitutes willful misconduct.

I hereby release the treating practitioners, clinic health care workers, and other persons or organizations associated with this clinic from any and all liabilities resulting from:

- Any injury directly or indirectly caused by the medical care and treatment provided to me.
- Any injury that may directly or indirectly result from my failure to arrange or delay in arranging for a consultation recommended by the professional personnel of this clinic.

I hereby give permission and consent to all diagnostic and medical procedures determined to be necessary for me. I acknowledge that the professional personnel of this clinic have informed me of the nature and purpose of medical care and treatment to be provided to me, and I have carefully considered this. This includes finger sticks for blood for diagnostic or screening purposes. I have been advised that finger sticks may cause bruising.

I give consent to release of my medical records to a subsequently treating practitioner, managed care plan, third party payer or Medicaid/Medicare authority, when requested, to ensure continuity of care, to establish statistical data (without disclosing my identity) or to facilitate reimbursement, if any, for the above services.

I certify that I have read and fully understand the above paragraphs and that explanations provided to me were clear and understandable. I have been able to ask further questions regarding these matters, and have no further questions at this time. I certify that I am mentally competent to give this informed consent.

PLEASE MARK ALL LISTED BELOW THAT APPLY

____ I sign this form of my own free will and without being subject to any undue influence.
___ I certify that I am either indigent, an uninsured person and/or underserved.
___ I attest that I am at or below 200% of the federal poverty guidelines.

_____
Print Patient Name

_____ _____
Sign Patient/Parent/Guardian/Legal Rep. Print Parent/Guardian/Legal Rep.

_____
Sign Witness

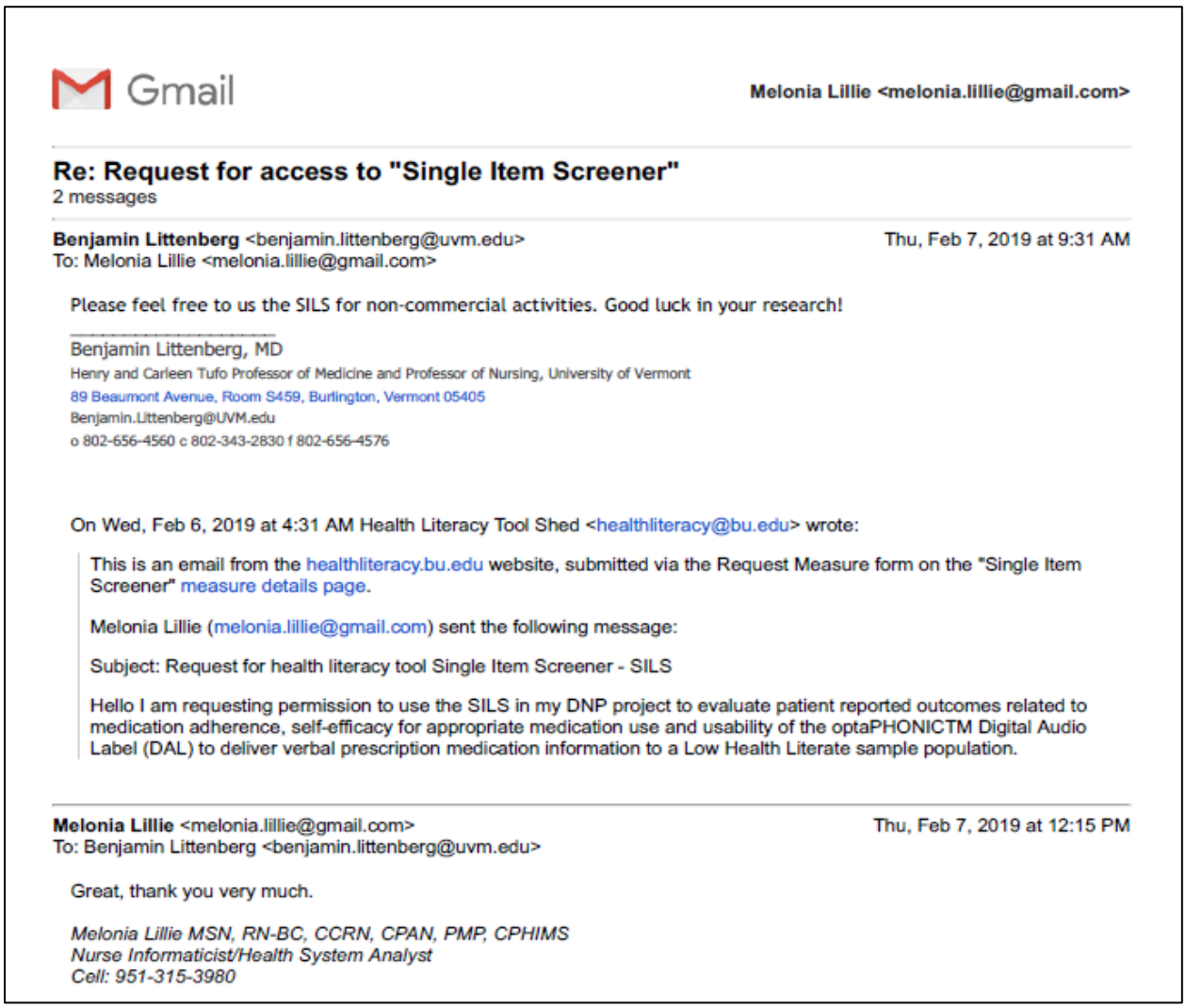
_____
Date

Appendix J

Single Item Literacy Screen and Permission for Use

	Never	Rarely	Sometimes	Often	Always
"How often do you need to have someone help you when you read instructions, pamphlets, or other written material from your doctor or pharmacy?"	1	2	3	4	5

Note: Scores > 2 are considered inadequate health literacy, indicating the patient has some difficulty with reading printed health related material.



Gmail **Melonia Lillie <melonia.lillie@gmail.com>**

Re: Request for access to "Single Item Screener"
2 messages

Benjamin Littenberg <benjamin.littenberg@uvm.edu> Thu, Feb 7, 2019 at 9:31 AM
To: Melonia Lillie <melonia.lillie@gmail.com>

Please feel free to us the SILS for non-commercial activities. Good luck in your research!

Benjamin Littenberg, MD
Henry and Carleen Tufo Professor of Medicine and Professor of Nursing, University of Vermont
89 Beaumont Avenue, Room S459, Burlington, Vermont 05405
Benjamin.Littenberg@UVM.edu
o 802-656-4560 c 802-343-2830 f 802-656-4576

On Wed, Feb 6, 2019 at 4:31 AM Health Literacy Tool Shed <healthliteracy@bu.edu> wrote:

> This is an email from the healthliteracy.bu.edu website, submitted via the Request Measure form on the "Single Item Screener" measure details page.
>
> Melonia Lillie (melonia.lillie@gmail.com) sent the following message:
>
> Subject: Request for health literacy tool Single Item Screener - SILS
>
> Hello I am requesting permission to use the SILS in my DNP project to evaluate patient reported outcomes related to medication adherence, self-efficacy for appropriate medication use and usability of the optaPHONICTM Digital Audio Label (DAL) to deliver verbal prescription medication information to a Low Health Literate sample population.

Melonia Lillie <melonia.lillie@gmail.com> Thu, Feb 7, 2019 at 12:15 PM
To: Benjamin Littenberg <benjamin.littenberg@uvm.edu>

Great, thank you very much.

Melonia Lillie MSN, RN-BC, CCRN, CPAN, PMP, CPHIMS
Nurse Informaticist/Health System Analyst
Cell: 951-315-3980

Appendix K

Self-Efficacy for Appropriate Medication Use Scale (Pre & Post)

How confident are you that you can take your medicines correctly:	Not at all confident	Not very confident	Neither	Fairly Confident	Very Confident
1. If you take several different medicines each day?	1	2	3	4	5
2. If you take medicines more than once a day?	1	2	3	4	5
3. If you are away from home?	1	2	3	4	5
4. If you have a busy day planned?	1	2	3	4	5
5. If they cause some side effects?	1	2	3	4	5
6. If no one reminds you to take the medicine?	1	2	3	4	5
7. If the schedule to take the medicine is not convenient?	1	2	3	4	5
8. If your normal routine gets messed up?	1	2	3	4	5
9. If you are not sure how to take the medicine?	1	2	3	4	5
10. If you are not sure what time of the day to take your medicine?	1	2	3	4	5
11. If you are feeling sick?	1	2	3	4	5
12. If you get a refill of your old medicines and some of the pills look different than usual?	1	2	3	4	5
13. If a doctor changes your medicines?	1	2	3	4	5

Appendix L

Digital Audio Label Questionnaire

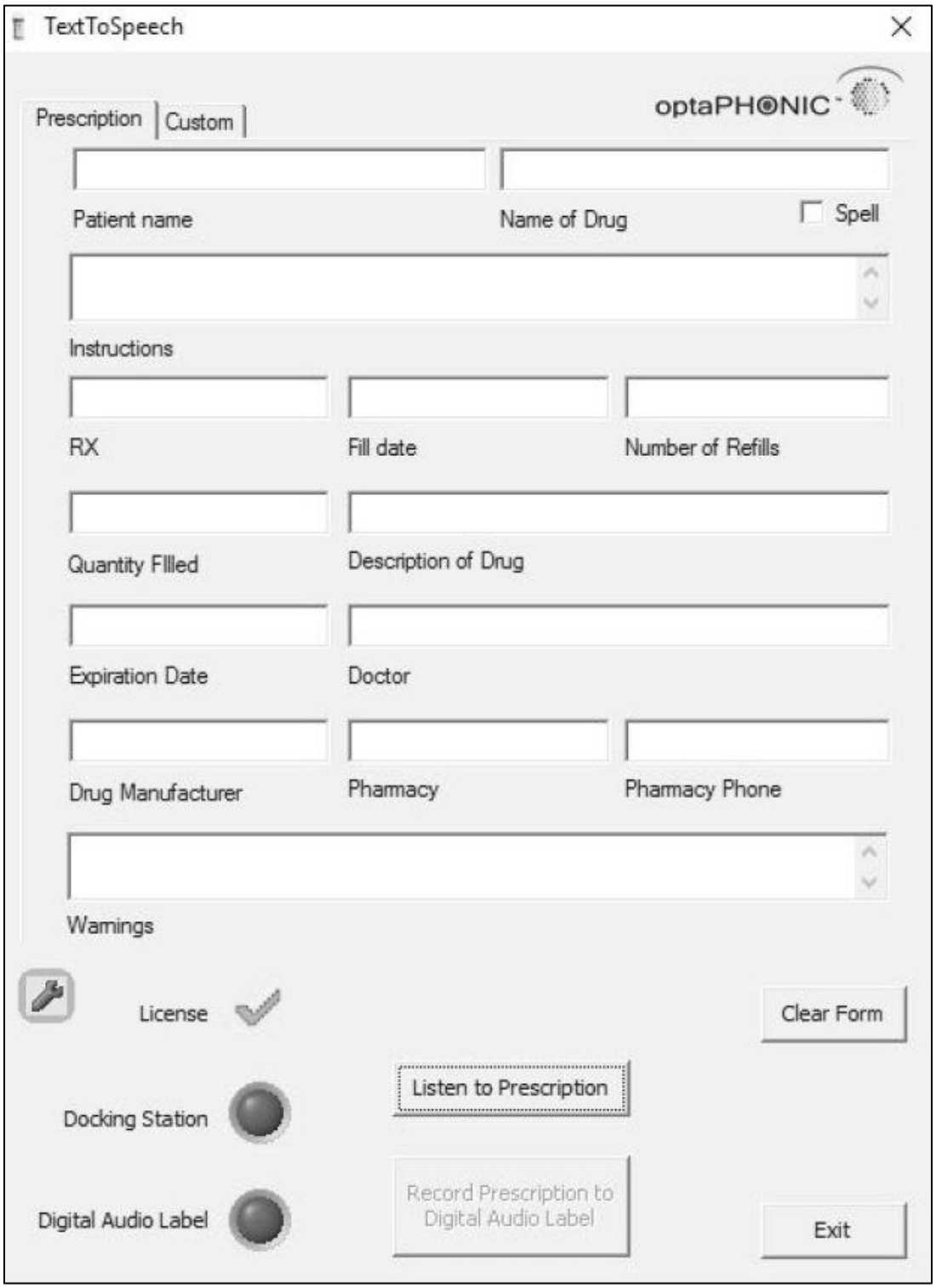
		Strongly Disagree	Disagree	Neither	Agree	Strongly Agree
1.	The instructions for using the digital audio label were easy to understand?	1	2	3	4	5
2.	Were you able to locate the medication bottle with the digital audio label whenever you needed to take your prescription?	1	2	3	4	5
3.	Were you able to easily turn on the digital audio label for audio playback?	1	2	3	4	5
4.	Were you able to easily turn off the digital audio label for audio playback?	1	2	3	4	5
5.	The voice you heard speaking your prescriptive information through the digital audio label was clear and easy to understand?	1	2	3	4	5
6.	Were you able to easily identify the name of your medication through using the DAL?	1	2	3	4	5
7.	Were you able to easily obtain all directions for taking your medication using the digital audio label?	1	2	3	4	5
8.	Were you able to easily obtain all physician and pharmacy information you needed from the DAL?	1	2	3	4	5
9.	Overall, would you prefer to use the digital audio label over your previous methods of reading your prescription labels?	1	2	3	4	5
10.	Would you highly recommend use of the DAL to others with difficulty reading prescription labels?	1	2	3	4	5

Appendix M

Digital Audio Label

Appendix N

Text to Speech Data Entry Screen



Appendix O

Budget

Description	Potential Cost	Actual Cost
Printing brochure/flyer for DAL	$40.00	$40.00
DAL Starter Kit (software, docking station and 10 DALs) – Retail	$125.00	$0[1]
Additional 90 DALs-Retail	$400.00	$0[1]
Plastic tabletop brochure and device display	$5.00	$5.00
Gift card for participant drawing x1 ($100)	$100.00	$0.00[2]
Snack contribution for volunteers	$60.00	$60.00
Postage (certified mail)	$6.00	$6.00
SurveyMonkey	$250.00	$0.00[3]
SPSS software	$53.00	$53.00
Total Budget	**$1039.00**	**$166.00**

[1] Wholesale price per DAL = $2.26; starter kit and 100 DALs were donated by the manufacturer.
[2] Received research grant from Sigma Theta Tau for $100.00.
[3] SurveyMonkey membership borrowed from mentor.

Appendix P

Clinic Scheduled Days and Times

Mondays	2nd Monday of the month @ 9am
Tuesdays	1st and 3rd Tuesday of the month @ 5pm 4th Tuesday of the month @ 9 am
Wednesdays	1st Wednesday of the month @ 1:30 pm 3rd Wednesday of the month @ 1pm
Thursdays	1st, 2Nd & 4th Thursday of the month @ 5pm 3rd Thursday of the month @ 9am

Appendix Q

Interview Script

Script for Face to Face Interview

"Hello, my name is Mel Lillie. I am a graduate nursing student at Graceland University. I am conducting a project to assess individuals between the ages of 18-64 who may have difficulty with reading prescription labels, and your self-efficacy or confidence related to taking prescription medications and the relationship these have on blood pressure. Are you between the ages of 18 and 64, do you have a diagnosis of high blood pressure and on at least 1 blood pressure medication? Ok, and how often do you need to have someone help you when you read instructions, pamphlets, or other written material from your doctor or pharmacy

1=Never, 2=Rarely, 3=Sometimes, 4=Often and 5=Always

>>If age requirement is not met, answer is no to HTN and BP med and score is 2 or < on SILS= not qualified and return to waiting room.

>>If age requirement is met and yes to HTN and BP med, and score is >2 on SILS proceed.

Intervention group - I am inviting you to participate in my project and in doing so you will receive a free talking prescription label called the optaPHONIC™ Digital Audio Label (point to display). This device speaks the information on your prescription label and may help you with taking your medications if you have difficulty reading prescription labels and maybe even help with your blood pressure. All participants will also be entered into a drawing after completing all of the project requirements for a $100 gift card. Are you interested in participating thus far?

Control group - I am inviting you to participate in my project and in doing so you will be entered into a drawing after completing all of the project requirements for a $100 gift card. Are you interested in participating thus far?

>>If answer is yes,

"Great, I am going to read the consent to you that explains the requirements. Please stop me if you have questions or need me to clarify anything I have read."

>>Read consent

Do you still want to participate in this project?

>>If answer is yes = Teach Back-Ask patient to state in their own words their understanding of the project expectations.

>>Correct understanding → Acquire the consent signature→ provide copy to the patient

>>Incorrect understanding → reinforce information → correct understanding → acquire the consent →provide copy to the patient

1

All Participants: Now I am going to ask you some questions and I am going to enter your answers into my computer about how often you need help reading health information you are given, your demographics (age, education, race) and current self-efficacy or confidence you have when taking your medications and I will get your blood pressure from your chart after your visit, ok?

Intervention Group - now what you do is wait in the waiting room and see your providers. Once you receive your prescription(s), come see me before you leave for me to program your free device and give you your raffle ticket for the drawing. Keep in mind if you leave today without at least one prescription for 30 days, you will unfortunate not qualify to participate in the project.

>>Patient return after receiving prescriptions

>>Program the device(s) according to the prescription label and adhere device(s) to the prescription bottle(s).

>>Provide demonstration.

"Now all you have to do is press this red button to hear what medication is in this bottle. It lasts about 400 pushed or several months. Do you have any questions? Nice to meet you, thank you for participating and please contact me via if you have any questions about this device or the project, my contact information is on the copy of your consent. Contact OPEN M for questions about your medical care or prescriptions you received."

Control Group - now what you do is wait in the waiting room and see your providers. Once you receive your prescription(s) you can go home and I will contact you in 30 days to ask you the follow up survey questions. Keep in mind if you leave here today without at least one prescription for 30 days, you will unfortunate not qualify to participate in the project.

Declining participants: "Ok, that is fine, just have a seat in the waiting room to be called by your providers.

2

Appendix R

Demographic Data Collected

Age	1. 25-34 2. 35-49 3. 50-64
Gender	1. Female 2. Male
Education	1. No high school degree 2. High school degree/GED 3. Some college-did not graduate 4. College degree 5. Prefer not to answer
Ethnicity	1. Asian 2. Native American 3. African American/]Black 4. Caucasian/White 5. Hispanic/Latino 6. Pacific Islander 7. Other_____ 8. Prefer not to answer

Appendix S

Demographics of Study Participants

		Intervention *n=26*	Control *n*=26	Sig. (2-tailed)
Age	25-34	0	1	0.538
	35-49	4	4	
	50-64	22	21	
Gender				
	Female	15	15	1.000
	Male	11	11	
Education				
	No high school degree	2	3	0.086
	High school degree/GED	11	3	
	Some college-did not graduate	8	8	
	College degree	2	7	
	Prefer not to answer	3	5	
Ethnicity				
	Asian	1	0	0.451
	African American	12	10	
	Caucasian	12	15	
	Other	1	1	

Note. $p = .05$

Appendix T

Comparison of Mean Blood Pressures Between Groups at Baseline and at 30 days Post Intervention

Measurement	Group	*n*	Mean	SD	Standard Error Mean
Pre SBP	Intervention	26	135.54	20.754	4.070
	Control	26	142.69	24.838	4.871
Pre DBP	Intervention	26	81.27	8.884	1.742
	Control	26	87.65	11.440	2.244
Post SBP	Intervention	26	133.88	17.075	3.349
	Control	26	134.46	17.505	3.433
Post DBP	Intervention	26	80.85	9.739	1.910
	Control	26	82.15	10.661	2.091

Appendix U

Comparison of Changes in Mean Blood Pressure Between Intervention and Control Groups

Measurement	t	Df	Sig. (2-tailed)	Mean Difference	Standard Error Difference	95% Confidence Interval of the Difference Lower	Upper
Pre SBP	-1.127	50	.265	-7.154	6.348	-19.904	5.596
Pre DBP	-2.248	50	.029*	-6.385	2.841	-12.090	-.679
Post SBP	-.120	50	.905	-.577	4.796	-10.209	9.056
Post DBP	-.462	50	.646	-1.308	2.832	-6.996	4.380

Note. *p = .05

Appendix V

Comparison of Mean SEAMS Scores Pre and Post Intervention

Measurement	Group	*n*	Mean	SD	Standard. Error Mean
Pre-SEAMS Score Means	Intervention	26	3.8609	.85326	.16734
	Control	26	4.1124	.82052	.16092
Post-SEAMS Score Means	Intervention	26	4.2071	.73775	.14468
	Control	26	4.1800	.63898	.12531

Appendix W

Comparison of Changes in Mean SEAMS Scores Between Groups

Measurement	t	df	Sig. (2-tailed)	Mean Difference	Standard Error Difference	95% Confidence Interval of the Difference Lower	Upper
Pre-SEAMS Scores Means	-1.083	50	.284	-.25148	.23216	-.71778	.21482
Post-SEAMS Scores Means	.142	50	.888	.02712	.19141	-.35733	.41157

Note. $p = .05$

Appendix X

Responses to the DAL Questionnaire

		Strongly Disagree	Disagree	Neither	Agree	Strongly Agree
1.	The instructions for using the digital audio label were easy to understand?	0	0	1 (3.8)	5 (19.2)	20 (76.9)
2.	Were you able to locate the medication bottle with the digital audio label whenever you needed to take your prescription?	0	0	1 (3.8)	4 (15.4)	21 (80.8)
3.	Were you able to easily turn on the digital audio label for audio playback?	0	0	1 (3.8)	4 (15.4)	21 (80.8)
4.	Were you able to easily turn off the digital audio label for audio playback?	0	0	2 (7.7)	4 (15.4)	20 (76.9)
5.	The voice you heard speaking your prescriptive information through the digital audio label was clear and easy to understand?	0	0	1 (3.8)	4 (15.4)	21 (80.8)
6.	Were you able to easily identify the name of your medication through using the DAL?	0	0	1 (3.8)	4 (15.4)	21 (80.8)
7.	Were you able to easily obtain all directions for taking your medication using the digital audio label?	0	0	1 (3.8)	4 (15.4)	21 (80.8)
8.	Were you able to easily obtain all physician and pharmacy information you needed from the DAL?	0	0	1 (3.8)	5 (19.2)	20 (76.9)
9.	Overall, would you prefer to use the digital audio label over your previous methods of reading your prescription labels?	2 (7.7)	1 (3.9)	7 (26.9)	4 (15.4)	12 (46.2)
10.	Would you highly recommend use of the DAL to others with difficulty reading prescription labels?	0	0	1 (3.9)	0	25 (96.2)

Note. *n* = 26. ( ) = %. One patient's device stopped working and score was counted as neither for all questions.

Appendix Y

Computers Informatics Nursing Journal Submission

CIN Submission Received for Impact of a Talking Prescription Digital Audio Label on Blood Pressure and Self-Efficacy in Low Health Literate Patients with Hypertension - - Important Information Enclosed - [EMID:dbed3928d0efac26]

1 message

CIN <em@editorialmanager.com> Sun, Oct 27, 2019 at 9:08 PM
Reply-To: CIN <edit@medesk.com>
To: MELONIA LILLIE <melonia.lillie@gmail.com>

Oct 28, 2019

Dear Mrs. LILLIE,

Your manuscript, "Impact of a Talking Prescription Digital Audio Label on Blood Pressure and Self-Efficacy in Low Health Literate Patients with Hypertension," has been received by the CIN editorial office. Within 4 to 6 weeks it will be reviewed for technical requirements, receive a manuscript number, and go on to peer review.

* Please do not e-mail the editorial office requesting status before you receive a manuscript number. * Status will remain 'submitted to journal' during the technical review period.

MANUSCRIPT STATUS is automatically updated at the Editorial Manager Web site. When an editor evaluates the manuscript, status changes to "With Editor"; when reviewers are invited or assignments have been accepted, status will change to "reviewer invited" or "under review," respectively.

When the required number of reviews (2) is received, status changes to "required reviews complete." The manuscript is then queued for editorial review which can take up to 4 weeks.

REVIEW TIMES: Initial submission to editorial decision averages about 16 weeks. It may take longer around the beginning or end of an academic year, during the holidays, or school breaks. Reviewer availability also depends on academic schedules.

Please note that the editorial office cannot provide status updates for individual manuscripts. It is quicker to log in and check your manuscript directly.

You can check on the status of your article at any time by logging on to the CIN Editorial Manager Web site as an author.

https://www.editorialmanager.com/cin/

Please note that manuscripts will not be sent on to review until each coauthor has confirmed status and completed the online copyright transfer/financial disclosure questionnaire. Additional Information

Appendix Z

Acronyms

Acronym	Definition
ADA	Americans with Disabilities Act
ADE	Adverse Drug Event
APL	Audio Prescription Labeling
CAD	Coronary Artery Disease
CI	Confidence Interval
CINAHL	Cumulative Index to Nursing and Allied Health Literature
CMG	Cumulative Medication Gap
CVA	Cerebrovascular Accident
DAL	Digital Audio Label
DBP	Diastolic Blood Pressure
DNP	Doctor of Nursing Practice
FDA	Food and Drug Administration
IRB	Institutional Review Board
LHL	Low Health Literacy
MMAS	Morisky Medication Adherence Scale
PEOU	Patient Ease of Use
PHL	Pharmacy Health Literacy
PIAAC	Program for the International Assessment of Adult Competencies
PREM	Patient Reported Experience Measure
PROM	Patient Reported Outcome Measure
PU	Perceived Usefulness
RCT	Randomized Controlled Trial
SBP	Systolic Blood Pressure
SEAMS	Self-efficacy for Appropriate Medication use Scale
SILS	Single Item Literacy Screen
SMS	Short Message Service
SWOT	Strengths, Weaknesses, Opportunities, Threats
TAM	Technology Acceptance Model
TOFHLA	Test of Functional Health Literacy in Adults
U.S	United States
USB	Universal Serial Bus
VBP	Value Based Purchasing
VPL	Voice Prescription Label