

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

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## Background/ Significance

- HTN = 60% increase in the population by the year 2025.
- Low Health Literacy (LHL) = 43 million Americans.
- Poor understanding of medications = Alternative methods to ID prescription medications = Loss of empowerment = diminished self-efficacy.
- Adverse Drug Events (ADE) = \$92 billion in preventable healthcare costs with the potential to reach \$172 billion.

(Rampey et al., 2016; Herrier, Apgar, Boyce & Foster, 2015; Devine, 2010; Rasu, Bawa, Suminski, Snella & Warady, 2015; Mendes et al., 2016; Government Accountability Office [GAO], 2016).



## Background/ Significance

- Failure of the law, such as the Americans with Disabilities Act or the Food and Drug Administration Safety and Innovation Act to recognize and include individuals who are LHL in statutes of protection.
- Policy initiatives do not mandate standard LHL assessments.
- Negative connotation associated with assessment questions = false responses to inquiries to avoid embarrassment.
- Lack of awareness of audible prescription drug labels as a best practice by pharmacies.
- Patients highly rate audible prescription labels as easy to use and useful for medication information.

(Herrier, et al., 2015; Accessamed, 2014; GAO, 2016).



## Background/ Significance

- Pharmacy best practices for prescription drug labeling:
  - Large print labels
  - Braille labels
  - **Audible labels**
    - ❖ The intervention for this study.
    - ❖ Few similar interventions in production and studies available for data comparison.
    - ❖ Present data positively relates audible prescription labels as an assistive device in overcoming barriers to understanding prescription medication, increase medication self-efficacy and positive patient experience using the label.

(United States Access Board, 2013; AccessaMed, 2013; GAO, 2016)

# SWOT

## Strengths

- 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

## Opportunities

- Obtain grant funding for the DAL to become a product offered by the clinic for the LHL population.
- Potential to increase medication self-efficacy in the LHL chronic hypertensive population.
- 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.

## Weaknesses

- Does not print paper medication instructions, braille or 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 talking prescription Digital Audio Label (DAL)

## Threats

- 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.

# Problem Statement

*Little is known about talking prescription devices as an intervention in the LHL population to control blood pressure, increase self-efficacy for taking medications, and the end user perception of device usability.*

**SOLUTION:**

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- Improve patient outcomes and reduce patient costs
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- Meets all ADA and FDA requirements
- Reinforce your value based mission by promoting safety and independence
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- Press the button for medication information

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# PICOT

- *In adults ages 18-64 years old, with 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 receiving usual verbal prescription information (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)?*

# Primary Purpose & Research Questions

- Evaluate if a talking prescription DAL is an effective intervention to decrease blood pressure and increase self-efficacy for prescription medication administration in patients with LHL and hypertension.
  - Is there a statistically significant **between** group difference in the mean **blood pressure** levels before and after the intervention at 30 days?
  - Is there a statistically significant **between** group difference in the mean **SEAMS** scores before and after the intervention at 30 days?



# Secondary Purpose & Research Questions

- Evaluate the ease of use and usability of the talking prescription DAL to deliver verbal prescription medication information.
  - Do LHL patients with chronic hypertension score the DAL system useable for verbal delivery of prescription medication?

# Theoretical Framework

- Bandura's Social Cognitive Theory of Self-Efficacy
  - Assumes that self-efficacy beliefs determine action, with the caveat that the person must have the appropriate skills and adequate incentives for performance.
  - Self-efficacy is one of the most significant predictors of behavior change.

(Dennis 1997, p. 6; Lamarche, Tejpal & Mangin, 2018; Herrier et al., 2015).

Author, Year, Title, Design & Level of Evidence	Study Purpose	Population/Sample/ Setting	Independent/Dependent Variables (I/V and D/V)	Findings
<p><b>Study #1</b></p> <p>Wali et al., 2016</p> <p>“A systematic review of interventions to improve medication information for low health literate populations”</p> <p>Designs Included: A systematic review of RCTs, non-RCTs and uncontrolled trials (UCT). Level I</p>	<p>Review evidence on <b>interventions for improving medication knowledge in LHL literate populations.</b></p>	<p>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.</p> <p>Setting: N/A</p>	<p>IV:</p> <ol style="list-style-type: none"> <li>1. Written information</li> <li>2. Visual information</li> <li>3. <b>Verbal information</b></li> <li>4. <b>Label/medication bottle</b></li> <li>5. Reminder systems</li> <li>6. Educational programs and services</li> </ol> <p>DV: Patient medication knowledge and adherence</p>	<p>The most common interventions are written interventions, but other <b>effective strategies</b> include visual information, <b>verbal information, specialized labels</b>, reminder systems and education programs. Overall 81% of 27 studies demonstrated statistically significant improvement of knowledge regarding prescribed medication when information was provided verbally.</p>
<p><b>Study#2</b></p> <p>Harrington et al., 2014</p> <p>“A conceptual model of Verbal Exchange Health Literacy”</p> <p>Designs Included: Mixed Methods Level I &amp; Level VI</p>	<p><b>Emphasize consideration of verbal and aural relay of health information.</b></p>	<p>Population and Sample: Providers (n=6)</p> <p>Patients in Focus Groups (n=49)</p> <ul style="list-style-type: none"> <li>• 73% female</li> <li>• 69% African American</li> <li>• 8% Latino</li> <li>• 23% White</li> </ul> <p>Setting: Primary care</p>	<p>IV: Providers and Patient Focus Groups</p> <p>DV: Outcomes of interviews</p>	<p><b>Verbal Exchange Health Literacy is one of several constructs contributing to the patient's health literacy and ability to acquire and use health information.</b> This combined with reading, writing and numeracy skills <b>may facilitate better health decisions, equating to improved patient outcomes.</b></p>

# Integrated Review of Literature

*(Supporting Verbal Information)*

Author, Year, Title, Design & Level of Evidence	Study Purpose	Population/Sample/ Setting	Independent/Dependent Variables (I/V and D/V)	Findings
<p>Study#3</p> <p>Marcus, C. 2014</p> <p>“Strategies for improving the quality of verbal patient and family education: A review of the literature and creation of the EDUCATE model”</p> <p>Designs Included: Mixed Methods Level I &amp; Level VI</p>	<p>To study <b>verbal instruction</b> as a component of patient and family education and make recommendations for best practices for healthcare providers who use this method.</p>	<p>Population/Sample: Nursing Staff (n=46)</p> <p>Setting: The Brigham and Women’s Faulkner Hospital, a 150-bed non-profit, community teaching hospital located in Jamaica Plain, Massachusetts</p>	<p>IV: Nurses</p> <p>DV: Outcomes of <b>online surveys</b> regarding patient education practices.</p>	<p>It is significant to <b>assess the needs of the learner</b> and <b>implement the mode of education that is preferred by the learner</b></p> <p><b>Repetition of information is helpful to aid in patient retention of the health information provided</b></p>

# Integrated Review of Literature

*(Supporting Verbal Information)*

Author, Year, Title, Design & Level of Evidence	Study Purpose	Population/Sample/ Setting	Independent/ Dependent Variables (I/V and D/V)	Findings
<p><b>Study #4</b></p> <p>Lam, et al., 2017</p> <p>“Addressing low health literacy with “Talking Pill Bottles”: A pilot study in a community pharmacy setting”</p> <p>Designs Included: RCT; Level II</p>	<p>Evaluate the <b>impact of Talking Pill Bottles on medication self-efficacy, medication adherence, knowledge about antihypertensive prescription medications, blood pressure (BP) changes after using the Talking Pill Bottle and patients’ acceptance of the Talking Pill Bottle.</b></p>	<p>Population/Sample: <b>LHL patients</b> filling prescriptions for hypertension (n=134)</p> <p>Setting: Two community Pharmacies</p>	<p><b>IV: Talking Pill Bottles</b></p> <p>DV: Outcome measures of internally developed medication knowledge test, <b>SEAMS</b>, MMAS-8, CMG (medication adherence), <b>BP</b>, <b>PEOU</b> and <b>PU</b>.</p>	<p>Knowledge test scores improved within the control and intervention groups from baseline to 90 days <math>p &lt; 0.001</math>, but not significant between groups.</p> <p>Medication adherence (MMAS) improved within groups, Standard arm <math>p = 0.012</math> and treatment arm <math>p = 0.003</math>, but not significant between groups. Refill adherence (CMG) was higher in the treatment arm, but was not statistically significant <math>p = 0.197</math>.</p> <p><b>SEAMS scores</b> within groups were not statistically significant, standard arm <math>p = 0.425</math>, treatment arm <math>p = 0.544</math>. Between groups were not significant <math>p = 0.838</math>.</p> <p><b>PEOU</b> = Approximately 93% found the talking pill bottle easy to use; 89% found the device easy to control; 89% said it was easy to become skillful with the device.</p> <p><b>PU</b>=70% reported device as useful; 77% said device helped them understand their medications more quickly and 74% said the device improved their ability to take medications correctly and on time. <b>BP readings decreased</b> and were statistically significant in the control group (SBP <math>p = 0.036</math> &amp; DBP <math>p = 0.027</math>) indicating the Talking Pill Bottles may contribute to BP control.</p>

# Integrated Review of Literature

*(Supporting Technology Intervention and Measures)*

Author, Year, Title, Study Purpose Design & Level of Evidence	Population/Sample/ Setting	Independent/Dependent Variables (I/V and D/V)	Findings
<p><b>Study #5</b> Kamal, et al., 2018 "Making prescriptions "talk" to stroke and heart attack survivors to improve adherence: Results of a randomized clinical trial (The Talking Rx Study)" Designs Included: RCT; Level II</p>	<p>Evaluate changes in medication adherence, health literacy, and acceptability of a talking prescription device and SMS reminders in the Pakistani population with CVA and CAD taking anti-platelet and statin medication.</p> <p>Population/Sample: Pakistani population with CVA and CAD taking anti-platelet and statin medication (n=197)</p> <p>Setting: Cardiology and Neurology outpatient clinics</p>	<p>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.</p> <p>DV: Outcome measures of MMAS-8 between intervention and control groups and within CVA and CAD groups; User Interface Experience analysis conducted on participants in the intervention group.</p>	<p>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 participants also rated the Talking Rx as excellent for providing prescription information.</p>
<p><b>Study #6</b> Zullig et al., 2014 "A health literacy pilot intervention to improve medication adherence using Meducation® technology" Designs Included: Pilot Study; Level VI</p>	<p>Evaluate the effectiveness of an innovative health literacy tool called Meducation® on cardiovascular medication adherence.</p> <p>Population/Sample: Veterans with Cardiovascular risk factors (n=23)</p> <p>Setting: VA Medical Center</p>	<p>IV: Meducation® calendar with reminders and education</p> <p>DV: Medication adherence evaluated via scores of self-reported medication adherence questionnaire (Morisky Green Levine tool) and medication prescription refills (MPR).</p> <p>Clinical outcomes of blood pressure, heart rate, body weight, low-density lipoproteins (LDL), high-density lipoproteins (HDL), total cholesterol and creatinine</p>	<p>Self-reports of medication adherence at three months post - intervention demonstrated a decrease in medication non-adherence. There was an increase in prescription refills. Overall improvement in clinical outcomes were statistically insignificant.</p> <ul style="list-style-type: none"> <li>•Systolic BP p=0.87</li> <li>•Diastolic BP p=0.53</li> <li>•Clinic pulse p=0.40</li> <li>•Clinic weight p=0.08</li> <li>•LDL p= 0.30</li> <li>•HDL p=0.52</li> <li>•Total cholesterol p=0.07</li> <li>•Creatinine p=0.05</li> <li>•MPR p=0.73</li> </ul>

# Integrated Review of Literature

*(Supporting Technology Intervention and Measures)*

Author, Year, Title, Design & Level of Evidence	Study Purpose	Population/Sample/ Setting	Independent/Dependent Variables (I/V and D/V)	Findings
<p><b>Study #7</b> Allnatt et al., 2001 "An evaluation of the functionality and acceptability of the voice prescription label (VPL)" Designs included: Cohort Level III</p>	<p>Meet the need for <b>providing information on prescription labels that is readily accessible</b> to people who are visually impaired.</p>	<p>Population/Sample: Stratified random sample of 25 visually impaired Veterans Setting: Outpatients in a Veterans Affairs Medical Center</p>	<p><b>IV: Voice Prescription Label</b>  DV: Veteran patient survey results on 10-item VPL Questionnaire</p>	<p><b>100%</b> of the participants strongly agreed they were able to find their bottle of medication and the VPL was easy to turn off and on; <b>80%</b> preferred the VPL to their previous assistive devices for taking medication &amp; <b>92%</b> 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.</p>
<p><b>Study #8</b> Lertwiryaprapa et al., 2015 "A low-cost audio prescription labeling (APL) system using RFID for Thai visually impaired people" Designs included: Cohort Level III</p>	<p>Overall objective was to <b>prevent deaths and injuries, related to medication errors, while developing a usable APL</b> that is cost effective for <b>low income</b>, visually impaired population.</p>	<p>Population/Sample: 70 visually impaired, low income Thai end users and 5 experts Setting: Skills Development Center for the Blind, Nonthaburi, Thailand and the Bang Kruai Hospital, Nonthaburi, Thailand</p>	<p><b>IV: Audio Prescription Labeling System</b>  DV: <b>Satisfaction Questionnaire</b> from Thai patients and experts</p>	<p>Qualitative survey results indicate overall that the <b>APL system can be effectively used</b> for helping visually-impaired people in terms of <b>self-medication</b>. <b>92%</b> of providers agreed this device can <b>help patients to self-medicate and improve the quality of life</b> of visually-impaired people. There was satisfaction with degree of complete information the system provided (<b>92%</b>), suitability for use (<b>92%</b>), accuracy and completeness of labeling (<b>92%</b>), <b>usefulness</b> for the study population (<b>92%</b>), and the system's overall <b>ease of use</b> (<b>84%</b>).</p>

# Integrated Review of Literature

*(Supporting Technology Intervention and Measures)*

# Literature Critical Appraisal

- Research included supporting:
  - Other types of technology interventions
  - Patient preferred methods of learning
  - Measures/tools used.
- Three studies (Wali et al., 2016; Harrington et al., 2014; Marcus, 2014):
  - 1) systematic review Level I and 2) mixed method designs Level VI.
  - Indicate that LHL patients prefer verbal delivery of health care information = contributed to increased retention of health care information, improved health literacy and patient outcomes.



# Literature Critical Appraisal

- Two studies (Allnatt et al., 2001; Lertwiriya-prapa & Fakkheow, 2015):
  - Cohort - Level III studies.
  - Satisfaction with the usability of a talking prescription label = increased quality of life, which is related to improved self-efficacy.
- One Study (Zullig et al., 2014):
  - Pilot study - Level VI
  - Clinically significant blood pressure decrease of 0.5 mmHg.
  - Statistically significant decrease in weight, cholesterol and creatinine.
- Two studies (Lam et al., 2017; Kamal et al., 2018):
  - Randomized controlled trials - Level II.
  - Clinically significant improvement of medication self-efficacy.
  - Statistically significant decrease in blood pressure.
  - Positive rating of the talking pill bottle's usability in LHL
  - Talking Rx rated as excellent for providing prescription information.

# Literature Critical Appraisal

- Significant relevant literature is readily available regarding:
  - Patient preferred methods of learning.
  - Changes in medication adherence and self-efficacy by means of other interventions.
  - Efficacy of interventions for the blind.
- Literature is lacking using talking prescription labels & other innovative technology for LHL population.
  - More research is needed:
    - ❖ Comparing similar devices.
    - ❖ Evaluating provider perceptions of device and feelings of workflow interruption to program the DAL.
    - ❖ Of a longer duration of >6 months.

# Synthesis of Literature

- LHL patients prefer to receive verbal information about their prescription medications.
- Limited literature using talking prescription devices.
- Talking prescription devices have the potential for a positive impact on chronic health conditions.

# Institutional Review Board

- Minimal risk study with no conflicts of interest to disclose.
- A private office for patient interviews was used to maintain privacy and store paper related information.
- Patients were provided a copy of their signed consent.
- The DAL is an ASSISTIVE device and did not replace or disrupt the integrity of the required pharmacy placed label.
- DAL programming verified by a second provider for patient safety.
- Data sets were cleansed of patient identifiable information.
- Computer used for data collection survey required a passcode for unlocking.

## Methods (Design)

- Conducted from May through mid-August 2019.
- Quasi-experimental, two group, pre-post test design with a control and intervention group.
- Evaluate the DAL impact on blood pressure and self-efficacy.
- Evaluate usability and ease of use of the DAL.

## Methods (Setting)

- Free medical clinic in an urban midwestern city of Ohio.
- Services offered:
  - Internal Medicine, Nephrology, Ophthalmology, Women's Health, Cardiovascular, Urology, Acupuncture, Mental Health, Dental and even Chiropractic care.
- Volunteer only staff.
- Funded by donations and grants only.

# Methods (Participants)

- 52 Adults aged 18 to 64 years old, of any socioeconomic or demographic background, with chronic hypertension, on at least one blood pressure medication with LHL as identified by a score of  $> 2$  on the SILS.
- Inclusion Criteria
  - SILS score of  $> 2$
  - Adults aged 18 to 64 years old
  - Diagnosis of hypertension
  - On at least 1 blood pressure medication
  - Filling 30-day prescription.
  - Not hearing impaired
  - Understands English or has interpreter

# Methods (Sample)

- Participants - large Cohen's  $d$  0.80,  $\alpha = 0.05$ , power of 0.80,  $n=52$  accounting for 20% attrition,  $n=62$  patients.
- Convenience sample.
- Even distribution intervention and control groups
- Ceased the acquisition of participants at a total of 52, with 26 randomly assigned to each group.



# Methods (Recruitment)

- Target population acquired by the primary investigator.
  - Minimize the concern for interrater reliability.
- Convenience sampling of scheduled clinic patients.
- Followed the inclusion and exclusion criteria.
- Day and evening clinics.
- \$100 gift card was offered as an incentive to complete all study requirements.

# Methods (Tools)

## Patient Reported Outcome Measures (PROMs)

- Single Item Literacy Screener
- Self-Efficacy for Appropriate Medication use Scale.

## Patient Reported Experience Measure (PREM)

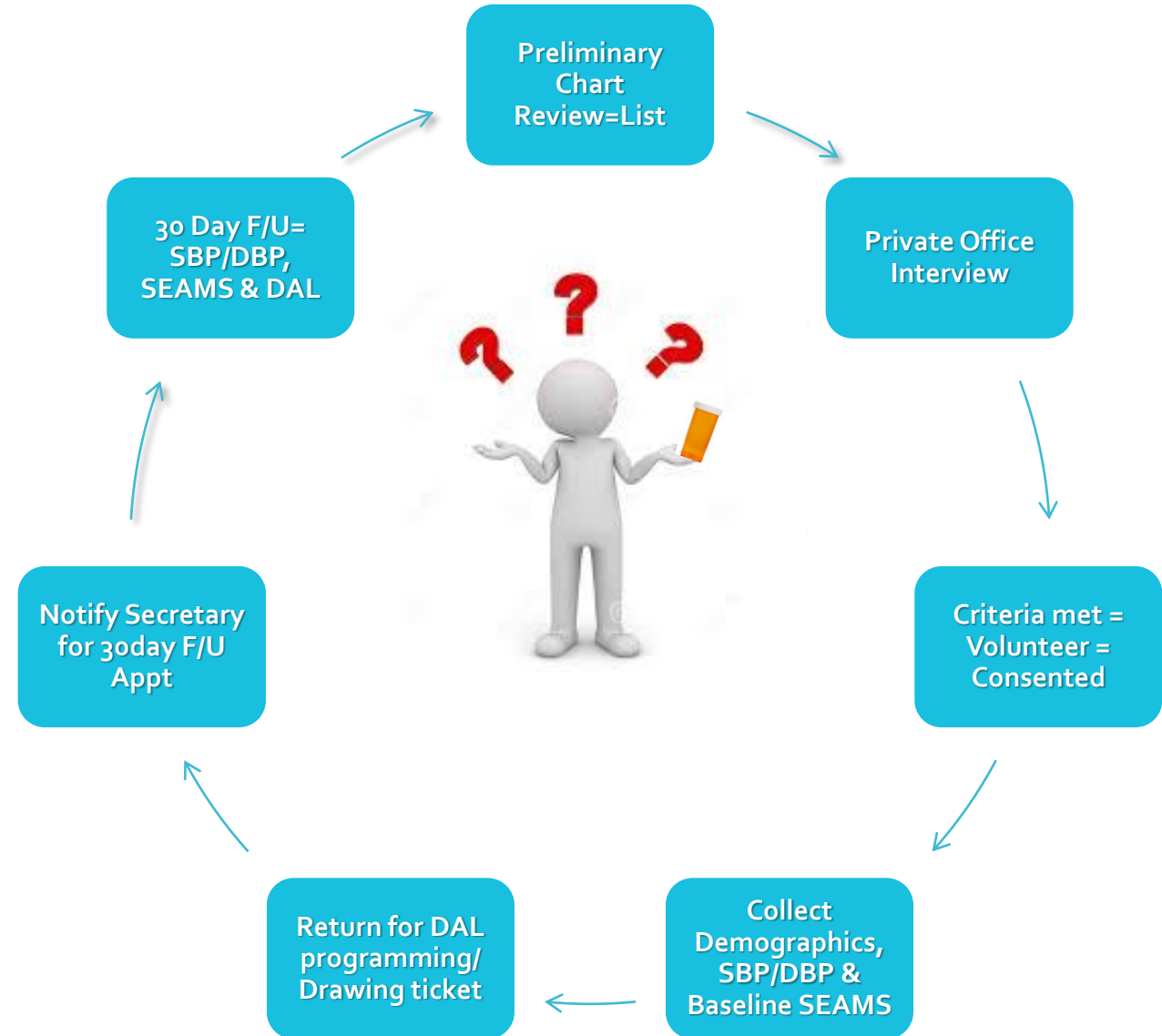
- Digital Audio Label Usability Questionnaire

# Methods (Intervention)

## Talking Prescription Digital Audio Label



# Methods (Data Collection)



# Methods (Analysis)

- SurveyMonkey data uploaded into SPSS
- Data cleansed
- Variables and Levels of Measurement
  - Independent variables were:
    1. Intervention Group – Received DAL (Nominal #1)
    2. Control Group - Usual Care (Nominal#2)
  - Dependent variables were:
    1. Demographics (Nominal; Numerical Likert)
    2. Blood pressure (Ratio; Scale in SPSS; SBP/DBP)
    3. SEAMS survey scores (Interval; Scale in SPSS; 1-5 Likert)
    4. DAL survey scores (Interval; Scale in SPSS; 1-5 Likert)

# Methods (Analysis)

- Statistics:
  - Descriptive Statistics-Frequencies
    - ❖ Demographics
    - ❖ DAL Scores
  - Independent samples *t*-tests
    - ❖ Q1: Difference in the mean blood pressure levels (SBP/DBP)
    - ❖ Q2: Difference in mean SEAMS scores
    - ❖  $p = 0.05$

# Results (Demographics)

## Demographics of Study Participants

		Intervention <i>n</i> =26	Control <i>n</i> =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

# Results: Research Question #1

Is there a statistically significant **between** group difference in the mean blood pressure levels before and after the intervention at 30 days?

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

Measurement	Group	<i>n</i>	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



# Results: Research Question #1

Is there a statistically significant **between** group difference in the mean blood pressure levels before and after the intervention at 30 days?

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. \* $p = .05$

# Results: Research Question #2

Is there a statistically significant **between** group difference in the mean SEAMS scores before and after the intervention at 30 days?

Comparison of Mean SEAMS Scores Pre and Post Intervention

Measurement	Group	<i>n</i>	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

# Results: Research Question #2

Is there a statistically significant **between** group difference in the mean SEAMS scores before and after the intervention at 30 days?

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.  $p = .05$

# Results: Research Question #3

Do LHL patients with hypertension score the DAL system useable for verbal delivery of prescription medication?

## 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)

## Discussion (Blood Pressure)

- 52 participants, LHL
- Majority = Caucasian and African American.
- Lower blood pressure in Intervention group pre & post
  - Largest difference pre-intervention.
- Statistical significance in the DBP prior to the intervention ( $p=.029$ ).
- Decrease of 1.6 mmHg in the SBP post-intervention.
- Decrease of 0.42 mmHg in the DBP post-intervention.
- ?? clinical significance - threshold of a decrease in blood pressure by  $\geq 2$  mmHg was not met.

## Discussion (SEAMS)

- Pre-intervention = SEAMS scores in the intervention group were lower compared to the control group.
  - No statistical difference ( $p=0.28$ )
  - Could infer the intervention group had a greater need for the capabilities of the DAL to receive medication information.
- Post-intervention = SEAMS scores in the intervention group were higher compared to the control group.
- Increase in the SEAMS scores within the intervention group alone by 0.34.
  - ?? clinical significance given the threshold of an increase of 1 point in the scores was not met.

# Discussion (DAL)

- Easy to use and useful.
- Potential for the DAL on to have a positive impact on chronic health conditions such as hypertension.
- Participant responses = high acceptance
  - High scores for usability and ease of use.
- Recurring themes of improved usefulness:
  - Alert as a reminder to take their medications.
  - Recorded message indicated time of day to take the medication.
  - Low battery alert.
  - Useful for their older parents.

# Limitations/ Confounding Factors

- Generalizability is limited:
  - Small sample size.
  - Isolation to the English language.
  - Free medical clinic setting in which this study was performed.
  - Transference excludes:
    - ❖ Larger hospital settings or clinics.
    - ❖ Those that are not low income, not LHL or do not speak English.
- Confounders:
  - Short study duration.
  - Participants were not newly diagnosed with hypertension = set routines.
  - Participant avoidance of disapproval from the primary investigator about medication consumption habits.



# Sustainment

- Unanimous staff support.
- Recommended assessment of health literacy be implemented during the patient intake assessment.
- Donated software, docking station used for programming, 34 DALs & DAL lobby displays.
- Requires clinic funding allocations.
  - Consideration was being given to applying for a grant.

# Doctor of Nursing Practice Essentials

DNP Essential	Study Activity
I. Scientific Underpinnings for Practice	<ul style="list-style-type: none"> <li>• Identification of LHL problem and its impact on health care outcomes, medication ADEs and high healthcare costs.</li> </ul>
II. Organizational and Systems Leadership for Quality Improvement and Systems Thinking	<ul style="list-style-type: none"> <li>• Planned the study implementation in an organization.</li> <li>• Projected the project schedule, risks and budget.</li> </ul>
III. Clinical Scholarship and Analytical Methods for Evidence-Based Practice	<ul style="list-style-type: none"> <li>• Implemented the study literature review and synthesis.</li> <li>• Developed the goals, objectives and measures to evaluate the study outcomes.</li> <li>• Selected validated measurement tools for application in the study.</li> <li>• Developed a script, consent, method of questioning and proper patient safety precautions to demonstrate sensitivity to the selected population.</li> </ul>
IV. Information Systems/Technology and Patient Care Technology for the Improvement and Transformation of Health Care	<ul style="list-style-type: none"> <li>• Identified a technological intervention as a potential aid to address health literacy related to understanding prescription medication.</li> <li>• Data collection, analysis and evaluation plans conducted by primary investigator for knowledge growth.</li> </ul>
V. Health Care Policy for Advocacy in Health Care	<ul style="list-style-type: none"> <li>• Recommendations made to study site to include health literacy assessment and consideration of implementing DALs into usual workflow.</li> </ul>
VI. Interprofessional Collaboration for Improving Patient and Population Health Outcomes	<ul style="list-style-type: none"> <li>• Collaborated with faculty to develop accurate study plan to gain IRB approval.</li> <li>• Collaborated with site staff to employ study.</li> <li>• Study facilitates recognition of talking prescription labels.</li> </ul>
VII. Clinical Prevention and Population Health for Improving the Nation's Health	<ul style="list-style-type: none"> <li>• Provided literature to support argument that LHL is a diverse public health problem and that the study intervention could have an impact on public health outcomes.</li> </ul>
VIII. Advanced Nursing Practice	<ul style="list-style-type: none"> <li>• Practice and knowledge gap identified.</li> <li>• Topic adds to lacking existing literature on the efficacy of talking prescription labels.</li> </ul>

# Dissemination

- Provided Executive Summary to study site.
- Presentation on Wednesday, December 11th, 2019 during the International Nursing Research Exposition (iNurse).
- Submission of manuscript to the Computers, Informatics, Nursing, Journal.

# 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 <sup>1</sup>
Additional 90 DALs-Retail	\$400.00	\$0 <sup>1</sup>
Plastic tabletop brochure and device display	\$5.00	\$5.00
Gift card for participant drawing x1 (\$100)	\$100.00	\$0.00 <sup>2</sup>
Snack contribution for volunteers	\$60.00	\$60.00
Postage (certified mail)	\$6.00	\$6.00
SurveyMonkey	\$250.00	\$0.00 <sup>3</sup>
SPSS software	\$53.00	\$53.00
<b>Total Budget</b>	<b>\$1039.00</b>	<b>\$166.00</b>

<sup>1</sup> Wholesale price per DAL = \$2.26; starter kit and 100 DALs were donated by the manufacturer.

<sup>2</sup> Received research grant from Sigma Theta Tau for \$100.00.

<sup>3</sup> SurveyMonkey membership borrowed from mentor.

# Conclusion

## **Break the Cycle!!**

- 1<sup>st</sup> → Acknowledge that LHL is a problem.
- 2<sup>nd</sup> → Recognize medication information needs to be delivered in a way that is most helpful for the patient.
- 3<sup>rd</sup> → Get rid of the stigma & Implement Standards of Care to increase self-efficacy.
- 4<sup>th</sup> → Implement future research on the provider perspectives on device ease of use and integration into their workflow.

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