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Implementation Of A Medication Adherence Protocol In A Large Urban Safety Net Hospital

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IMPLEMENTATION OF A MEDICATION ADHERENCE PROTOCOL IN A LARGE URBAN SAFETY NET HOSPITAL

Submitted to the Faculty
Yale University School of Nursing

In Partial Fulfillment
of the Requirements for the Degree
Doctor of Nursing Practice

Carlie Moraza Martinez, MSN, BBA, NP-C

May 22, 2022

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This DNP Project is accepted in partial fulfillment of the requirements for the degree Doctor of Nursing Practice.

Joan Kearney, PhD, APRN, FAAN

Date: _____

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May 22, 2022

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Abstract

Medication nonadherence has a deleterious effect on patients with chronic health conditions, as it contributes to poorer health outcomes and increased healthcare spending. This Doctor of Nursing Practice project sought to improve medication adherence in at-risk patients by enhancing patient-provider communication and improving health literacy in a large, urban, safety net hospital. Utilizing a multi-prong approach, patients were provided with a visual aid – a pill card, in conjunction with the teach-back method, to improve systolic blood pressure (SBP), diastolic blood pressure (DPB) and Hemoglobin A1c (HbA1c) over a 6-month period. Twenty-three patients participated in the project. Participant demographics, attitudes towards the intervention, and clinical indicators were analyzed. The project was well received by all who participated. Key findings included patients finding the pill card easy to use and the teach-back method helpful in learning more about their medications. All target clinical indices decreased: SBP; DBP; A1C, in keeping with current positive findings on the use of triangulated methods conducted with larger samples. This data demonstrates the need for future larger scale projects to evaluate outcomes using these methods. This protocol has the potential to be utilized as a foundational program for other safety net hospitals.

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Chapter 1

Introduction

Medication nonadherence is a common and expensive problem, affecting upwards of 50% of patients with chronic health conditions and is responsible for over 100,000 preventable deaths and $100 billion in annual health care costs (Kleinsinger, 2018). This costly phenomenon contributes to poorer chronic disease prevention and management, worse population health outcomes and rising health care costs (Kleinsinger, 2018). Medication use and health care costs have seen substantial increases over the past decade (Kleinsinger, 2018). In the US, approximately seventy five percent of hospital outpatient clinic visits involve some form of pharmaceutical (Watanabe, Mcinnis, &; Hirsch, 2018). This high prevalence of pharmacotherapy as a means of chronic disease management necessitates a solution to the problem of non-adherence.

The World Health Organization (WHO) defines medication adherence as "the extent to which a person's behavior corresponds with agreed recommendations from a health care provider." (Sabaté, 2003). However; this is an oversimplified definition, as focus is implied solely on the patient's actions, when in reality adherence is not a one-dimensional problem. Factors including the complexity of a medication regimen, timing of doses, side effects, individual behaviors, costs of treatment, health literacy, and social factors must be taken into account when developing an intervention (Costa et al., 2015). Medication adherence interventions are often unifactorial, and as a result can fall short of remedy and sustainability.

When evaluating ways to effect change, a population level view of prescription use can help inform clinical practice and guide interventions. In a National Health and Nutrition Examination Survey analysis of prescription drug use from 2015-2016, nearly half of the US

population had used at least one prescription drug in the past 30 days, and 85% of adults greater than 60 use prescription drugs (Centers for Disease Control and Prevention, 2019). Twenty four percent of US patients reported using three or more prescription drugs in the past 30 days and 12.6% had used five or more (Centers for Disease Control and Prevention, 2019). Highest prescription use was found in non-Hispanic whites followed by non-Hispanic blacks and use was lowest among non-Hispanic Asian and Hispanic patients (Centers for Disease Control and Prevention, 2019). In total, 5.8 billion prescription drugs were ordered or provided to patients in 2018 and over two thirds of those prescriptions were for chronic diseases such as diabetes and hypertension (IQVIA, 2019). However, despite initial prescribing, nearly 30% of new prescriptions go unfilled and 50% of the time medications are taken incorrectly. Further, after six months of being prescribed a medication for a chronic disease, a majority of patients fail to take the recommended amount prescribed or stop treatment altogether (Center for Drug Evaluation and Research, 2016).

Problem Statement

The problem of medication nonadherence is multifaceted, with suboptimal medication adherence leading to higher rates of health care utilization alongside the development of new secondary medical problems, resulting in further healthcare spending (Watanabe, Mcinnis, & Hirsch, 2018).

Despite many available interventions, problems with adherence continue to persist. No disease, type of drug, or type of therapy, whether chronic or acute, is immune to medication nonadherence (Costa et al., 2015) WHO attributes medication non-adherence to five dimensions: "social and economic factors, health care team and system related factors, condition related factors, therapy related factors, and patient related factors" (Sabaté, 2003). It is a complex

problem that in addition to behavioral factors, is related to "the disease itself, complexity and duration of the treatment, possible adverse drug reactions, cost of treatment, and social factors (Costa et al., 2015)." Multifactorial interventions are most effective, including those targeting provider and systems level processes in addition to patient behaviors (Kleinsinger, 2018).

In order to develop an effective solution, a proper understanding of the complex nature of the problem must occur and multiple dimensions should be targeted. The intervention should consider the fact that many patients receiving care in safety net hospitals typically come from lower socioeconomic status, have diverse cultural backgrounds which influence their health beliefs, may lack English proficiency, and have lower health literacy (Agency for Healthcare Research and Quality, 2018). This Doctor of Nursing Practice project developed and implemented a multidimensional approach to improving medication adherence rates in at-risk patients in a busy Internal Medicine (IM) practice within a large urban safety net hospital, with a goal of improving health outcomes and decreasing costs.

Significance

Medication non-adherence incurs tremendous financial burden on the U.S. healthcare system and negatively impacts health outcomes. Estimates of annual adjusted cost per person to the U.S. economy for disease specific non-adherence vary widely; from $949 to $44,190 per person, while all-cause non-adherence is $5271 to $52,341 (Cutler, Fernandez-Llimos, Frommer, Benrimoj, & Garcia-Cardenas, 2018) Non-adherence is also directly linked to clinical outcomes, contributing to 33-69% of hospital admissions, higher risk of adverse events and increased mortality (Centers for Disease Control and Prevention, 2017). Medication adherence is an essential component of chronic disease management, specifically for conditions such as hypertension and diabetes. (Chisholm-Burns & Spivey, 2012)

Chapter 2

Review of the Literature

Search Strategy

This review of the literature examines the factors contributing to medication non-adherence and strategies to improve adherence. An electronic search was conducted using PubMed, CINAHL and EBSCO. Relevant search terms included "medication adherence" OR "medication non-adherence" OR "medication compliance" AND "interventions" OR "strategies" OR "protocol" AND "primary care" OR "internal medicine" AND "adult" AND "health literacy" AND "safety-net" OR "Medicaid" OR "urban." The search yielded 122 results. After removing duplicates and screening records for exclusions, 23 full text articles were assessed for relevance which yielded a total of 13 quantitative studies and 1 qualitative study ranging in dates of publication from 1997-2020 (see Appendix A).

Literature Findings

The Institute of Medicine (IOM) Health Literacy report states "efforts to improve quality, reduce costs, and reduce disparities cannot succeed without simultaneous improvements in health literacy" (Nielsen-Bohlman,Panzer & Kindig, 2004 pp.xiii-xiv) This is especially true when considering interventions to improve medication adherence (Nielsen-Bohlman, Panzer & Kindig, 2004). The report found that approximately ninety million Americans have inadequate literacy skills to navigate the U.S. healthcare system (Nielsen-Bohlman, Panzer & Kindig, 2004). These patients are more likely to have difficulty taking medications correctly, understanding medication labels and instructions, and are at greater risk of worse clinical outcomes than those with higher levels of health literacy (Bennett, 2008) This is particularly true for patients who also lack English proficiency; research indicates that patients with lower English proficiency typically

have worse health outcomes (Office of Disease Prevention and Health Promotion, 2020) Low health literacy is common among patients with chronic conditions such as hypertension and diabetes and is exacerbated by the complex medication regimens that typically accompany such conditions (Rudd, 2007).

When assessing potential interventions to improve adherence for patients with low health literacy, it is imperative to understand subtle preferences in knowledge acquisition. Psychology and marketing research reveal that humans typically prefer pictures over text (Sansgiry, Cady & Adamcik,1997) One approach for patients with low health literacy is the use of a visual aid that they can refer to after their visit (Negarandeh, Mahmoodi, Noktehdan, Heshmat, & Shakibazadeh, 2013). Studies show that pictorial aids are especially helpful for relaying importance of therapy, medication administration timing, and side effects. (Sansgiry, Cady & Adamcik,1997) Further, the use of pictures in combination with written and verbal information seems to enhance retention of information (Katz, Kripalani & Weiss, 2006). Dowse and Ehlers (2004) demonstrated this phenomenon in their randomized controlled trial of text only versus text plus pictogram study design for a low-literate, mostly female population. The pictogram group achieved an average of 95% understanding versus 70% for the control group ($p<0.01$). More importantly, adherence improved significantly, by 90% in the text plus pictogram group and 72% in the control group ($p<0.01$) (Katz, Kripalani & Weiss, 2006).

Kripalani et al., 2007 conducted a randomized controlled trial to develop, implement and evaluate a "pill card"; a single page display of a patient's daily medications that includes images of pills and highly simplistic administration instructions. Researchers found that at 3 months 60% of patients were still using the pill card. Regular pill card use was significantly higher among those with lower literacy skills, lower education levels, or patients who were cognitively

impaired ($p < 0.05$). Further, 92% of participants understood how to use the tool, and 94% reported the tool helped them remember information about their medications (Kripalani, et. al, 2007). A randomized controlled trial conducted by Negarandeh, Mahmoodi, Noktehdan, Heshmat, & Shakibazadeh (2013), showed similar findings. Researchers paired 127 patients with type II diabetes and low health literacy with a pictorial image alongside a teach back method to improve adherence to medication and diet. Significant improvements in medication knowledge and adherence were found in the intervention groups but not in control groups ($p<0.001$).

The Agency for Healthcare Research and Quality (AHRQ) supports the use of pill cards in clinical practice, arguing that pill cards are a simple way to visually demonstrate a patient's daily medication regimen. Via the use of pictures or icons, together with short phrases, patients can easily see each medication, its indication, the amount to take, and frequency of doses. AHRQ argues that this format is far easier for patients to comprehend than the typical complex and lengthy instructions provided with prescriptions (Agency for Healthcare Research and Quality, 2018). Kripalani et. al, 2007 recommends grouping dosing instructions into the following four time periods: morning, noon, evening and bedtime. The full medication schedule can be displayed in table format including pictures of pills or icons, how many pills to take, and what time of day the pills should be taken (Kripalani et al., 2007). Label formats can be enhanced by clear headers, lists, and white space for ease of readability, with large print, and simple language that avoids the use of medical jargon (Shrank, Avorn, Rolon, & Shekelle, 2007).

The evidence is promising for visual based aids and is even more compelling if a more than one approach is used. In a systematic review of the literature conducted by Costa et. al, 2015, interventions relying on a single element were found unlikely to improve adherence. For

example, interventions targeting patient education alone improved overall knowledge but demonstrated no significant increase in adherence. However, when interventions incorporated more than one element, adherence and clinical outcomes were more likely to improve (Costa et. al, 2015). Additionally, the notion that adherence is influenced by the level of risk patients associate with a particular medication was a common theme among studies included in the review. Findings support the importance of communication by healthcare providers in order for patients to make informed decisions. Milosavljevic, Aspden & Harrison, 2018, had similar conclusions, the most effective interventions were multifaceted, focused and personalized, and had a combined emphasis on regimen simplification and communication between patient and provider.

Patient and provider communication is especially important if a patient overestimates the risk of taking a particular medication. One method to improve accuracy of communication relayed between patient and provider is the teach back method. Using this method, patients are asked to repeat back what they understood from the instructions provided by their health care practitioner and the intervention is well suited for patients with lower health literacy (Agency for Healthcare Research and Quality, 2017 & Bickmore, Pfeifer & Paasche-Orlow, 2009). Via this approach, health care providers can individualize teaching and reassess the patient's level of comprehension. This method is well studied, its effects well documented, and is recommended as a "top patient safety practice" by the National Quality Forum (2010).

Experts recommend treating all patients as though they could have trouble understanding instructions, as only twelve percent of patients have a level of health literacy adequate to interpret medical information, and even these patients' amount of comprehension can be adversely affected by illness or stress (Agency for Healthcare Research and Quality, 2020).

AHRQ recommends a "universal precautions" approach to health literacy for every patient, as it would be unrealistic to evaluate each individual's level of comprehension at any given time (2020). Approaches to universal precautions should include simplified language, confirmation of comprehension and positive reinforcement of the patient's motivation to change their behavior (Agency for Healthcare Research and Quality, 2020).

Interventions that are multifaceted, pictorially based, and emphasize communication between patient and provider show clear benefit. Medication adherence lowers health care costs, reduces length of inpatient hospital stays, and reduces emergency department utilization (Roebuck, Liberman, Gemmill-Toyama, & Brennan, 2011). Using claims data over a three-year period extracted from one of the largest pharmacy benefits managers, researchers measured health services use of 135,008 patients and compared that information with the same patients' level of medication adherence (Roebuck, Liberman, Gemmill-Toyama, & Brennan, 2011). The study demonstrated a significantly lower length of stay for inpatient hospitalizations in the adherent group. Emergency department utilization was also lower in the adherent group with 0.01-0.04 visits less than non-adherent patients. Adherence also demonstrated significant reductions in total healthcare spending, with annual savings per patient in the amount of "$7,823 for heart failure, $3908 for hypertension, $3756 for diabetes and $1258 for dyslipidemia" (Roebuck, Liberman, Gemmill-Toyama, & Brennan, 2011).

While adherence can increase medication expenditures, it lowers overall medical costs. For every dollar spent on medications, the return on investment (ROI) ranges from $1.25 to $37 depending on the type of medication (Roebuck, Liberman, Gemmill-Toyama, & Brennan, 2011). One study's findings demonstrated that for every $177 spent on diabetes pharmaceuticals, there was a $1251 savings in disease-related costs, netting a per patient savings of $1074,

averaging a ROI of 7.1:1; while for hypertension and hypercholesterolemia, the average ROI for the same percentage increase in pharmaceutical use was 4.0:1 and 5.1:1, respectively (Sokol, Mcguigan, Verbrugge, & Epstein, 2005). Results of health outcomes studies also back these figures, for example, in a study examining risk of fracture in osteoporotic patients, those who were at least 80% adherent to their medications had a 26% reduction in fracture risk (Siris et al., 2006). Improved medication adherence has also been forecasted to result in $1000-$7000 in annual per-patient savings depending on the patient's disease state (Roebuck, Liberman, Gemmill-Toyama, & Brennan, 2011).

Disease related cost reduction must also be acknowledged, as increased medication adherence has an inverse relationship to disease related medical expenses. In a retrospective cohort study using claims data from 137,277 patients, statistically significant ($p<0.05$) associations were found between higher levels of adherence and lower disease related medical costs in patients with hypercholesterolemia and diabetes (Sokol, Mcguigan, Verbrugge, & Epstein, 2005). For both conditions, total healthcare costs also decreased with higher levels of adherence, with the most reduction in costs seen for patients with 80-100% adherence (Sokol, Mcguigan, Verbrugge, & Epstein, 2005). In the same study, statistically significant decreases in hospitalization risk were found in the adherent group ($p <0.05$), and all-cause costs were reduced, despite increased drug costs (Sokol, Mcguigan, Verbrugge, & Epstein, 2005).

Cost of the intervention itself must also be taken into consideration. The aforementioned interventions are implementation friendly as they are relatively simple, inexpensive, and require few resources. For interventions such as the use of a pill card, AHRQ offers a free template; all that's needed is a computer, a printer, and the medication information to be included on the final product (Agency for Healthcare Research and Quality, 2020). As the literature suggests, the

final intervention should address more than one dimension. A teach back strategy could be combined with pill card use to improve success of the intervention. The teach back method is simple and should not add a significant amount of time to patient encounters (Merck, 2014). The medication is explained, the patient is asked to repeat back how they will perform the treatment or take the prescribed medication, and then an assessment is made of the patient's level of understanding (Agency for Healthcare Research and Quality, 2017). In addition to the pill card template, AHRQ offers a teach-back "quick start" guide for clinicians and has free resources for both patients, clinicians, and practice staff to support implementation (2020).

Project Model

Incorporation of an evidence-based practice model of implementation helped define the clinical question, select and evaluate the evidence, translate the evidence into practice, and evaluate outcomes (Parkosewich, 2006). Rosswurm and Larrabee outline a six-step process to help users synthesize empirical and contextual evidence with a goal of guiding implementation of evidence-based interventions (Rosswurm & Larrabee, 1999). Steps included: "1) assessing the need for change 2) Linking the problem with interventions and identifying the outcomes 3) synthesizing evidence from the literature 4) developing a practice change 5) implementing and evaluating the practice change, and 6) integrating and maintaining the practice change" (Rosswurm & Larrabee, 1999). The model also encourages users to consider that clinical data is not the sole metric guiding changes in practice, that clinicians should consider patient satisfaction and preferences when identifying areas needing improvement
(See Appendix C) (Parkosewich, 2006).

Supporting Theoretical Framework

A theoretical framework can help identify key factors that can either hinder or facilitate adoption of an intervention (Amico, Mugavero, Krousel-Wood, Bosworth, & Merlin, 2017). For purposes of this project, the Health Belief model provided relevant constructs, including "the level of accurate information about or knowledge of the disease; the role of treatment and the specifics about following the treatment recommended; awareness or some sense of need for the treatment; motivation to adhere; and a skill set needed to execute adherence behavior across diverse situations and settings" (Amico, Mugavero, Krousel-Wood, Bosworth, & Merlin, 2017). The Health Belief Model suggests that patient behaviors are influenced by the simultaneous occurrence of patient's (1) adequate concern about their condition (2) belief that they are susceptible to poor health outcomes related to their condition (perceived threat) and (3) the belief that following a particular recommendation could mitigate the perceived threat at an acceptable social or financial cost (Rosenstock, Strecher & Becker, 1988) Assessing educational needs can fortify implementation planning and should take into consideration the extent to which patients believe they can adequately execute a recommended action (Rosenstock, Strecher & Becker, 1988).

Project Goal

The goal of this project was to develop and implement a multidimensional approach to improving medication adherence in high-risk patients at a busy IM practice within a large urban safety net hospital, and aimed to reduce health disparities, improve health outcomes, and decrease costs.

Project Aims:

1) To develop a medication adherence protocol to reduce levels of Hemoglobin A1c (HbA1c), systolic blood pressure (SBP) and diastolic blood pressure (DBP) each by 25% over a 6-month period in at-risk patients enrolled in an IM practice in a large urban safety net hospital using universal precautions for health literacy.
2) To implement the medication adherence protocol and evaluate.
3) To make recommendations for scaling and sustainability throughout the rest of primary care with a goal of using the protocol as a model for other safety net hospitals.

Chapter 3

Methods

Description and Approach to Aims

This quality improvement project sought to develop and implement a multidimensional approach to improving medication adherence rates in at-risk patients in a busy IM practice within a large urban safety net hospital, with a goal of reducing health disparities, improving health outcomes and decreasing costs. The project utilized a medication visual aid in conjunction with the teach back method in order to reduce HbA1c, SBP, and DBP. Information gleaned from this project will be used to help guide future clinic practices. The project aims and methods are described in this chapter.

The aims are as follows:

1. To develop a medication adherence protocol to reduce levels of HbA1c, SBP and DBP by 25% over a 6-month period in at-risk patients enrolled in a general internal medicine practice in a large urban safety net hospital using universal precautions for health literacy.
2. To implement the medication adherence protocol and evaluate outcomes.
3. To make recommendations for scaling and sustainability throughout the rest of primary care with a goal of using the protocol as a model for other safety net hospitals.

Aim 1

To develop a medication adherence protocol to reduce levels of HbA1c, SBP and DBP by 25% over a 6-month period in at-risk patients enrolled in an IM practice in a large urban safety net hospital using universal precautions for health literacy.

- The Agency for Healthcare Research and Quality's (AHRQ) quick start teach-back and pill card templates were adapted for use at the safety net hospital's IM practice.
    - The teach-back tool provided an easy-to-use framework to facilitate adoption of the teach-back method. Leadership was approached including the IM director and pharmacy lead to solicit buy-in and teach-back champions were identified to provide much needed support and enthusiasm for the project and to encourage colleagues' continuity with the protocol. The AHRQ pill card template offers a framework to provide patients with a visual aid of what medications they are taking and when they are taking them, allowing them to have all the information they need in a one page easy to read format.
- Criteria were created for the target audience.
    - Eligible patients had a HbA1c >8 if over age 65, or a HbA1c >7 if under age 65 and/or a blood pressure reading of >150/90 mm Hg if over age 60 without a diagnosis of diabetes or chronic kidney disease, and/or a blood pressure reading of >140/90 mm Hg if over age 60 with a diagnosis of diabetes or chronic kidney disease (CKD) or any patient aged 18-59 with no known major comorbidities. This eligibility criteria are consistent with goals set out by the American Diabetes Association, the American Heart Association and the American College of Cardiology, to prevent complications that arise from poorly controlled blood pressure and blood glucose (American Heart Association, 2020 & Journal of the American College of Cardiology, 2018 & American Diabetes Association, 2018).
- Information was gathered from key stakeholders.

    - The director of IM and pharmacy lead were asked to identify what has worked in the past to combat medication non-adherence, what has not worked, and why, in order to avoid redundancy in project efforts and to proactively infer potential barriers to project adoption.
- The medication visual aid was created.
    - Suggested columns from the AHRQ pill card template were used to create the visual aid. Columns included: name of medication and dose, what the medication is used for, instructions on how to take the medication, and timing of dose delineated as morning, afternoon, evening, and nighttime. The information was displayed in chart format with a check mark under the corresponding dose timing for each medication (see Appendix E).
- AHRQ's one page teach-back handout describing how to perform teach-back with patients was printed in anticipation of use by IM providers, nurses, and pharmacy liaisons (see appendix F).

Aim 2

To implement the medication adherence protocol and evaluate outcomes.

- At-risk patients were identified using a practice-wide report generated by the EMR that displays data based on filtered results to capture any patient with a HbA1c >8 if over age 65, or a HbA1c >7 if under age 65 and/or a blood pressure reading of >150/90 mm Hg in any patient over age 60 without a diagnosis of diabetes or chronic kidney disease, and/or a blood pressure reading of >140/90 mm Hg in any patient over age 60 with a diagnosis of diabetes or chronic kidney disease (CKD) or any patient aged 18-59 with no known major comorbidities.

- A plan was made to prepare and train staff. Due to Covid constraints this protocol was followed by one provider and not multiple providers as originally planned. The training and protocol were as follows:
    - Medical assistants would receive a one-page handout detailing how to review the patient's chart for an "intervention eligible" flag at the beginning of an encounter. A hands-on activity would be employed utilizing steps detailed in the one-page handout, including having the medical assistant open a test patient's chart to evaluate the patient's "chart review tab" within the EMR to see if an updated medication visual aid was currently in use. If not in use, the medical assistant would notify the provider using a color-coded reminder on the door of the patient's room for the provider and RN to see, so they could begin use of the new medication visual aid and teach back protocol.
    - Medical providers, pharmacy liaisons and RNs would receive the AHRQ one page teach-back handout detailing how to perform teach-back with patients, along with a blank medication visual aid to fill out in real time. Teach back training would be performed for all providers and staff using real time demonstration with role play between patient and provider. Standardized scripts would be used for each training session (see Appendix G).
- Implement the intervention.
    - Key Steps of the implementation process included:
        1. The provider identifying patients in need of a medication visual aid
        2. The Provider filling out the medication visual aid and performing teach back with the patient.

3. The provider verifying the patient's home address and mailing the pill card to the patient.

There were weekly audits of charts by the provider to ensure patients had not had any adjustments to their medications by another provider since receipt of their last pill card. If changes had been made, the patient was contacted to re-perform teach back and a revised pill card was mailed to the patient's home.

- At the end of 6 months, data from the EMR was used to identify patients who had received the medication visual aid. Pre and post HbA1c, SBP and DBPs on patients who received the visual aid and teach-back protocol were compared and documented (as HbA1c is part of a patient's routine screening every three months, no labs were ordered or drawn for this protocol). Patients were contacted via patient portal "Mychart" accounts or by phone call (for those who did not have access to a computer, smartphone or Mychart) to complete a post intervention survey in the form of a Likert scale (see appendix H).
    - Data was recorded into tables for BP, HbA1c, age, gender and ethnicity.

Univariate analysis was used to show the number of patients with a BP and/or HbA1c out of goal. Paired t tests were used to determine if a statistically significant difference existed pre and post- intervention. Alpha was set at 0.05.

Aim 3

To make recommendations for scaling and sustainability.

a. Results and recommendations were disseminated to senior leadership, highlighting the benefits of the protocol in the IM rollout.

b. Implementation of staff training and protocol were recommended for geriatrics and family medicine departments.
c. To encourage continued use and sustainability, it was recommended to incorporate the protocol into provider dashboards (dashboards are routinely used to follow provider compliance with population health-related activities and are their use is commonplace in hospital outpatient clinics).

Implications

Medication adherence directly affects chronic disease treatment success. Implications of this project on adherence rates were wide ranging from the effects on patient outcomes such as reductions in mortality and morbidity to benefits to the health care system (Jimmy & Jose, 2011). A combination of team-based care, patient education, reduced barriers, and use of a visual aid to enhance patient/provider communication during and after the encounter provided a framework for success (Neiman et al., 2018). Further, offering cost effective solutions which can be applied to a wide variety of patients and settings, along with an understanding of the root causes of the problem was also vital to the intervention's effectiveness and its long-term impact. (Neiman et al., 2018). The project predicted that patients who received the new medication visual aid and teach back would have improved BP and HbA1c measurements. The goal was to have a user-friendly protocol that added minimal time to the patient encounter while simultaneously creating a culture shift normalizing the new workflow. The project provided a useful framework for other clinics and/or safety net hospitals to improve their rates of adherence.

IRB Considerations

The Yale University IRB guidelines deemed this a Quality Improvement Project. Participant information was de-identified, and the project was designed to maximize benefit and minimize risk.

Project Timeline

Week 1: Identify at risk patients using practice dashboards

Weeks 2-3: Prepare for patient contact

Weeks 4-27: Go-live/Implementation

Week 28: Send out post intervention patient surveys

Week 29: Evaluate Pre and post HbA1c and BP on patients who received the intervention and use descriptive statistics to describe population using tables

Weeks 30-31: Statistical analysis in consultation with a statistician

Return on Investment

The business case for this project was supported via an evaluation of the return on investment (ROI). The project recommended use of a medication visual aid alongside an increase of provider, nurse and pharmacy teach-back during patient encounters. The intervention involved staff training on the incorporation of the Agency for Healthcare and Research Quality's free quick start teach-back guide and pill card templates. Training was scheduled to occur during regularly scheduled, weekly, hour-long practice meetings, so no loss in revenue for the hour would occur. Further, participant's time did not need to be accounted for, as the hour-long weekly meeting is a standing meeting, already built into staff schedules. Total costs for the project were under $300, allowing for a low cost/high yield intervention.

This project served as a pilot for a long-term goal of reduced 30-day readmissions for all diabetic patients. Readmissions for hypertension are not included in the analysis as national data

on incidence of 30-day readmission rates for hypertension is lacking (Kumar et al., 2019). For purposes of this ROI evaluation, a diabetic readmission will include inpatient adults > 18 years of age with a primary or secondary diagnosis of diabetes. Given the safety net's annual 30-day diabetes readmission rate of 1947 patients, multiplied by the average cost of a 30-day readmission ($15,200), amounts to $29,594,400 in wasteful spending annually (Agency for Healthcare Research and Quality, 2021).

Data will be reviewed at the end of 1 year to evaluate whether or not patients had decreased readmissions for diabetes. Direct savings will include a conservative target reduction of 1% of the safety-net's annual 30-day readmissions for diabetes, totaling $295,944. Indirect benefits such as the potential for fewer complications, and patient and provider satisfaction should also be noted, though they are not included in the ROI breakdown. This project will enhance quality while lowering cost, achieving the IHI Triple aim of "improving the patient experience of care, including quality and satisfaction, improving the health of populations, and reducing the per capita cost of health care" (Institute for Healthcare Improvement, 2021).

Chapter 4

Results

A total of twenty-three patients with blood pressure and/or blood sugar measurements above goal were enrolled in the project. Fifteen patients completed the project. With a total sample size of $n = 15$, the average age was 54.6 yrs. (SD = 15.2). (Table 1). Gender breakdown was 53.3% Male and 46.7% Female (Table 2). Race and ethnicity of participants comprised: 33% White, 20% Hispanic, 13% African, 27% African American, and 7% Portuguese (Figure 1). This ethnic breakdown mirrors that of the safety-net's overall population.

Statistical analysis was conducted in conjunction with a statistician. Descriptive and frequency statistics were used to describe the demographics of the sample. Normality of continuous variables was assessed using Shapiro-Wilk tests. Analyses were performed using SPSS Version 28 (Armonk, NY: IBM Corp.,date).

Statistical Results

Normality was met for the BP observations and could not be computed for the A1c analysis. SBP and DBP observations were normally distributed, so paired t-tests were used (Table 3). Means and standard deviations for each observation of each outcome can be seen in Table 4. There were no significant changes in systolic BP, $t(12) = 2.03$, $p = 0.07$, diastolic BP, $t(12) = 1.06$, $p = 0.31$, or A1c, $t(1) = 0.85$, $p = 0.55$ (Table 5).

Findings on Clinical trends and Program evaluation

Despite a lack of statistically significant changes in any of the outcome measures, other data endpoints support the use of this protocol. Most importantly, all target clinical indices (SBP, DBP and HbA1c) decreased (Table 5).

Additionally, patients received a post-intervention survey in the form of a Likert scale, where respondents were asked to rate the intervention in 5 different domains on a scale of 1-5 with 1 = Agree strongly 2 = Agree, 3 = Unsure, 4 = Disagree, 5 = Disagree Strongly. Questions included:

- Did you find the program useful?
- Did you like using the pill card?
- Did you like having your medication instructions relayed back?
- Did the program help you understand what conditions your medications are for?
- Did the program help you understand how to take your medications correctly?

Survey results demonstrated a majority of patients found the intervention useful, liked the pill card and teachback methods, felt the program helped them understand their medical conditions and how to correctly take their medications (Figure 2)

Chapter 5

Discussion and Conclusion

This quality improvement project successfully implemented a health literacy forward medication adherence intervention in a large inner city safety net hospital resulting in decreased levels of SBP, DBP and HbA1c over a 6-month period. Key findings included decreases in all target clinical indices and an overall positive reaction from participants. Improvement in self-efficacy and knowledge of one's disease state must also be noted. Elements crucial to the intervention's success included user-friendly, easy to comprehend materials that were tailored to each patient. Overall, the two approaches to medication adherence used in this project had positive effects, though not statistically significant. Future work should include a robust sample size, longer follow-up period, and allow for adequate resources to be allocated to the implementation to ensure fidelity to the intervention.

Impact of the Covid-19 Pandemic

The medication adherence protocol initially involved preparing and training staff and developing an implementation team. Due to unforeseen circumstances resulting from the covid-19 pandemic the ability of the proposal to be executed as planned was limited.

Limitations

The protocol was unable to be carried out as proposed due to limitations resulting from the pandemic including: staff furloughing, turnover, scarcity of resources and decreased access to in-person encounters with many visits turning virtual. This presented challenges in data collection and patient outreach as actions were carried out by a sole provider. Executing a quality improvement process of this magnitude with one provider is not practical in most clinical

settings. Given the multiple competing priorities typically encountered by staff in a safety-net hospital it would not be feasible to replicate a similar approach to implementation in other settings. Other limitations included having a small sample size which likely influenced statistical significance. Additionally, some of the safety net's populations including Asian, Hawaiian/Pacific Islander, American Indian/Native American, and Middle Eastern, were not represented in the sample limiting generalizability of findings. Having the same provider who performed teach back also administer the post-intervention survey could have influenced patient's survey responses.

Future Research

Data from this project highlights the need for future quality improvement work in medication adherence initiatives. Future work should focus on larger samples and leverage use of the EMR and ancillary staff for a hybrid, interdisciplinary approach to the intervention to account for workforce limitations typical to the safety net environment. Interventions should be iterative and utilize a universal precautions approach to health literacy. It would be beneficial to examine effects of the teach back method and pill card use on other outcomes including hospitalizations, health related quality of life, and knowledge retention in addition to those examined in this project.

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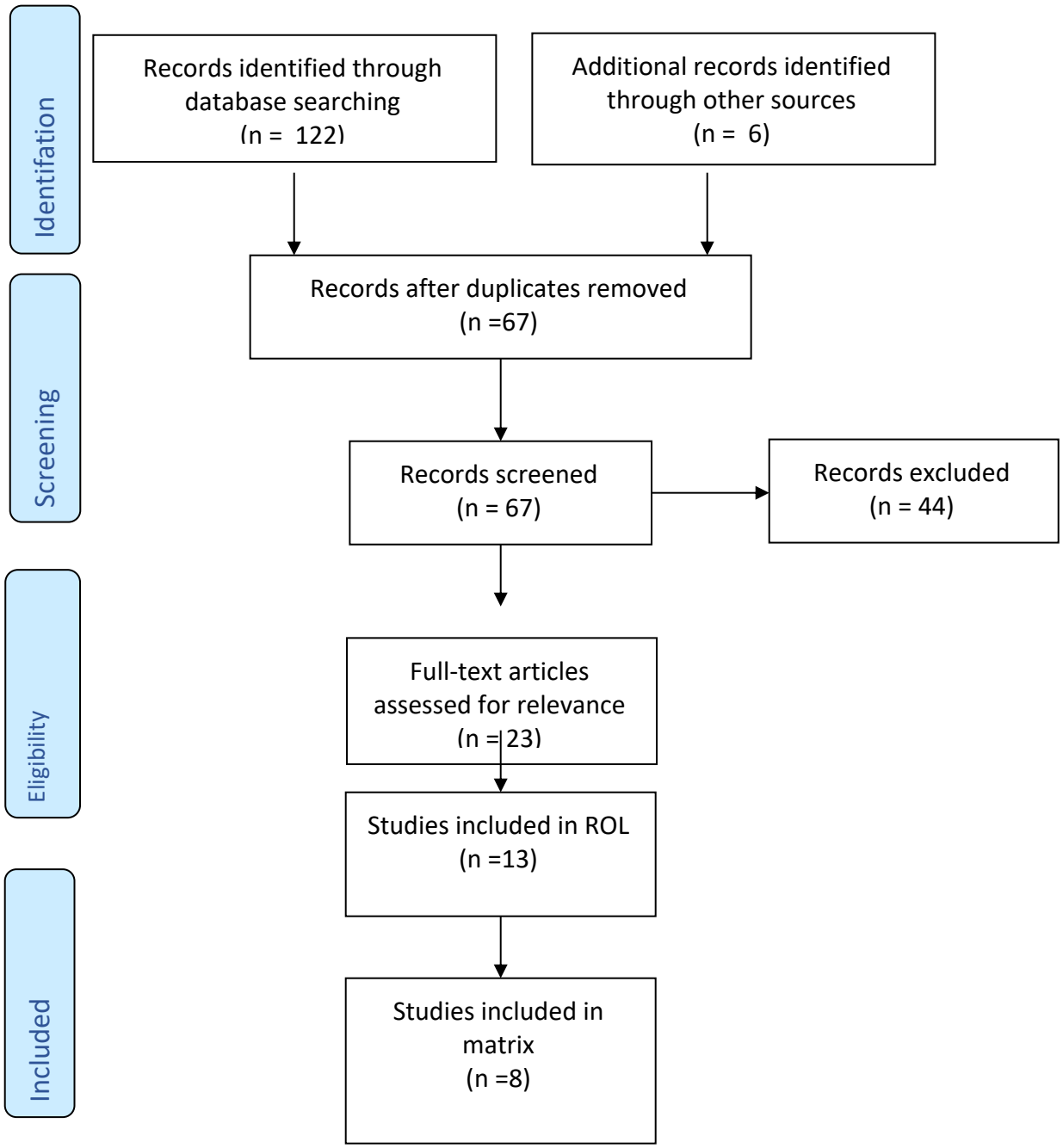
Appendix A:

Adapted PRISMA Flow Diagram for DNP Project ROL

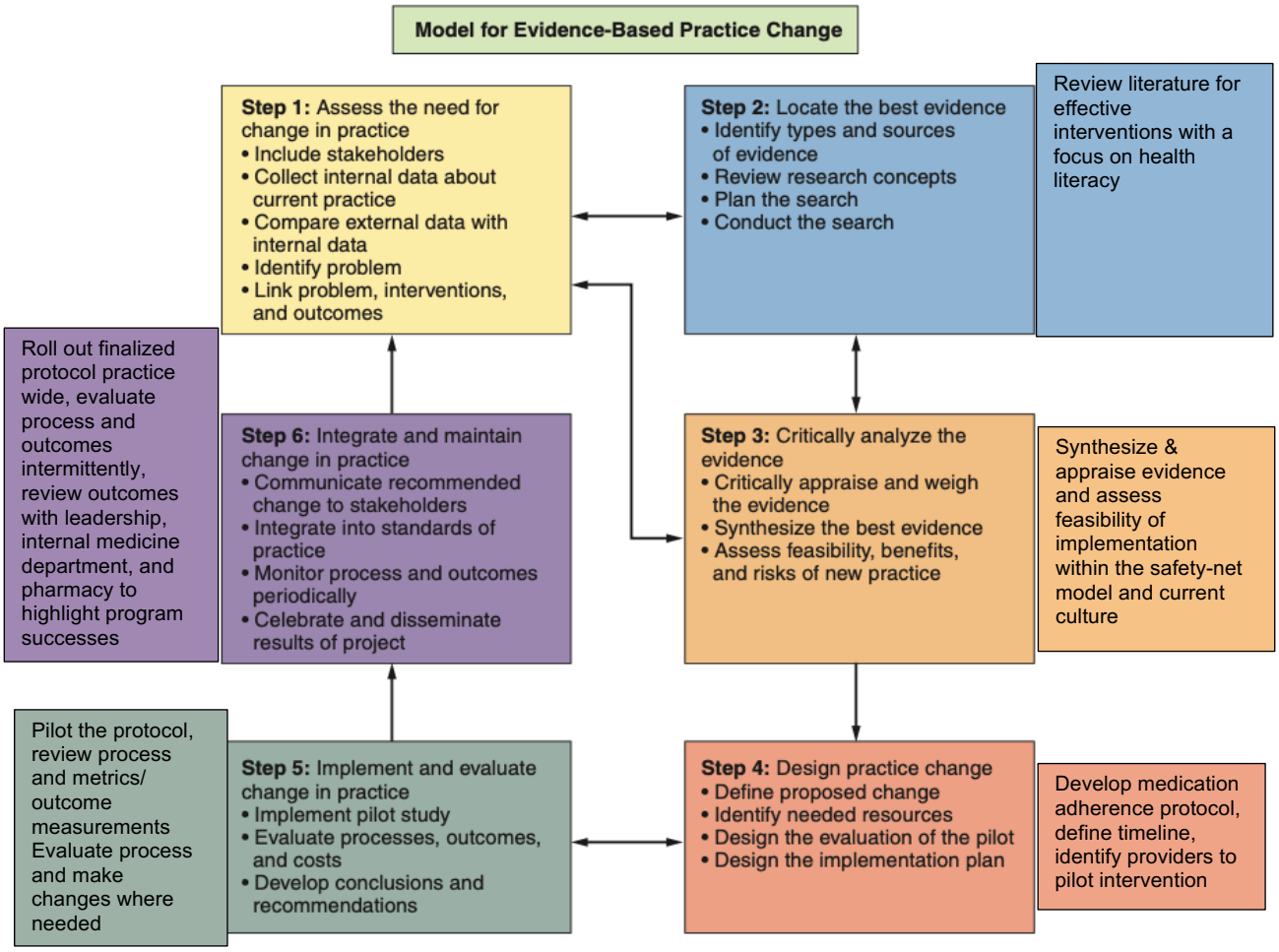


From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). *P*referred *R*eporting *I*tems for *S*ystematic Reviews and *M*eta-*A*nalyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit www.prisma-statemen

YSN

Appendix B:
Project Model



A model of Evidence Based Practice Change. Larrabee, J.H., (2009) Nurse to Nurse Evidence Based Practice. New York, McGraw-Hill

Appendix C: Medication Visual Aid

Name: Sarah Smith **Date Created: July 5, 2021**
Pharmacy phone number: 123-456-7890

Name	Used For	Instructions	Morning 	Afternoon 	Evening 	Night 
Simvastatin 20mg	Cholesterol	Take 1 pill at night				✓
Furosemide 20mg	Fluid	Take 2 pills in the morning and 2 pills in the evening	✓		✓	
Insulin 70/30	Diabetes (Sugar)	Inject 24 units before breakfast and 12 units before dinner	✓		✓	

(Agency for Healthcare Research and Quality, 2020)

Appendix D: Provider, RN and Pharmacy Liaison Teach-back Handout

Teach-Back Quick Guide

→ Use teach-back for ALL patients.
→ Start with most important message.
→ Limit to 2-4 key points.
→ Use plain language.
→ Rephrase message until patient demonstrates clear understanding.

Examples of Teach-Back Starters

→ "Just to be safe, I want to make sure we are on the same page. Can you tell me…"
→ "I want to make sure that I explained things clearly. Can you explain to me…"
→ "Can you show me how you would use your inhaler at home?"

Use Plain Language

Use these words	Avoid these words	Use these words	Avoid these words
reduces swelling	anti-inflammatory	heart doctor	cardiologist
blood thinner	anticoagulant	skin doctor	dermatologist
take before meals	take on an empty stomach	doctor who treats diabetes	endocrinologist
take after meals	take on a full stomach	stomach doctor; doctor for digestion problems	gastroenterologist
high (low) blood sugar	hyper(hypo-)glycemic	doctor for women	gynecologist
high (low) blood pressure	hyper(hypo-)tension	doctor for the brain, spine, and nervous system	neurologist
fats	lipids	cancer doctor	oncologist
overweight	obese	eye doctor	ophthalmologist
weak bone disease	osteoporosis	lung doctor	pulmonologist
not cancer	benign	joint, bone, and immune system doctor	rheumatologist

Learning Objectives:

- Staff understands the goal of using the teach-back method and how the teach-back process is to be conducted.
- Staff will be able to perform a live demonstration of a teach back interaction

https://www.ahrq.gov/sites/default/files/wysiwyg/professionals/quality-patient-safety/patient-family-engagement/pfeprimarycare/TeachBack-QuickGuide-card.pdf

Teach-Back

Role Play Scenario 1

Facilitator Instructions

1. As facilitator, play the role of the patient.
2. Request a volunteer to play the role of the clinician. The clinician will engage in teach-back with the patient.
3. Provide the volunteer and the training group with information about the scenario. Page 2 contains the basic patient information.
4. Read silently the additional patient information (page 3) to be able to respond to the volunteer during the role play.
5. Role play the scenario with the volunteer. Assume that the clinician has told the patient the plan of care and the visit is now ending. Ask the volunteer to engage in teach-back to ensure the patient understands.
6. As the patient, react to the clinician's tone, message, and body language in the same way you might if you were the patient.
7. Using the discussion prompts (page 3), engage the training group in a learning discussion on what went well and what could be improved.

For All

Purpose

The clinician has told the patient the plan of care and the visit is now ending. The clinician will engage in teach-back to ensure the patient understands.

Basic Patient Information

A 78-year-old male patient with uncontrolled hypertension, Mr. Thomas, has come in for a scheduled visit with his primary care clinician for knee pain. Mr. Thomas is a fit and active man who is frustrated that his knee pain is preventing him from exercising.

Mr. Thomas takes hydrochlorothiazide 50 mg – 1 tablet PO QD, atorvastatin 20 mg – 1 tablet PO QD, and low-dose adult aspirin 81 mg – 1 tablet PO QD. Mr. Thomas reports he's taking his hydrochlorothiazide about 3 to 4 times a week because the full dose causes him to pee a lot and disrupts his normal activities and sleep. The clinician has decided to change his blood pressure medicine to lisinopril.

Mr. Thomas's PHQ 9 depression screening was positive, and after talking with him, the clinician has decided to prescribe an antidepressant.

The plan of care for Mr. Thomas includes the following:

- Stop the hydrochlorothiazide and start lisinopril (20 mg PO QD).
- Start fluoxetine (20 mg PO QD).
- Follow up with an orthopedist for a possible knee replacement.
- Continue the atorvastatin (20 mg PO QD).
- Continue the low-dose adult aspirin (81 mg PO QD).

For Facilitator Only

Additional Patient Information

- Mr. Thomas is having a hard time keeping the new information straight. He is a very capable man but admits he feels like his thoughts and words are slower than normal.
- Mr. Thomas is earnest and kind. He respects his clinician's expertise and help.
- Mr. Thomas is surprised that he is "depressed" but is willing to use the new medicine.
- Mr. Thomas traveled by bus to his appointment so he doesn't have a pen or paper to write down any new information.
- Mr. Thomas gets flustered when the clinician first tries to use teach-back. He struggles to remember the important messages and feels like he is being rushed to "spit back" information.

Discussion Prompts

- What do you think was done well?
- What could have been done better?
- Was anything missing?

Things To Look For

- Did the clinician use teach-back starter phrases such as "I want to make sure that I explained things clearly, can you tell me…"
- Did the clinician use plain language (not medical jargon)?
- If the patient did not teach back correctly, did the clinician rephrase the message until the patient demonstrated a clear understanding?
- Did the patient feel like he was being quizzed?

Teach-Back

Role Play Scenario 2

Facilitator Instructions

1. As facilitator, play the role of the patient.
2. Request a volunteer to play the role of the clinician. The clinician will engage in teach-back with the patient.
3. Provide the volunteer and the training group with information about the scenario. Page 2 contains the basic patient information.
4. Read silently the additional patient information (page 3) to be able to respond to the volunteer during the role play.
5. Role play the scenario with the volunteer. Assume that the clinician has told the patient the plan of care and the visit is now ending. Ask the volunteer to engage in teach-back to ensure the patient understands.
6. As the patient, react to the clinician's tone, message, and body language in the same way you might if you were the patient.
7. Using the discussion prompts (page 3), engage the training group in a learning discussion on what went well and what could be improved.

For All

Purpose

The clinician has told the patient the plan of care and the visit is now ending. The clinician will engage in teach-back to ensure the patient understands.

Basic Patient Information

A 32-year-old male patient, Mr. Penny, has come in for a persistent cough and low-grade fever for the last 3 days. Mr. Penny's temperature is 38.1 degrees Celsius, his BP is 128/82, and his weight is 179, down from 186 a year ago. Mr. Penny states he's been more tired than usual, he gets short of breath walking up stairs, and his chest hurts sometimes when he breathes deeply. Given the current information and decreased breath sounds on the right lower lobe and audible rales, his clinician suspects bacterial pneumonia.

Mr. Penny had blood collected in the office and is being sent to radiology for a chest x ray. Mr. Penny has been prescribed azithromycin, 500 mg PO today and 250 mg PO the next 4 days and advised to drink lots of fluids and to take acetaminophen or ibuprofen as needed for discomfort.

The clinician will follow up with Mr. Penny by telephone after diagnostic test results are available. Mr. Penny is requested to return to the practice in one week and to call the office if fevers continue or his condition does not improve.

For Facilitator Only

Additional Patient Information

- Mr. Penny hasn't been sleeping well and is uncomfortable. Normally he is quite agreeable but today he is impatient and irritable.
- When the clinician starts to do teach-back, he feels like his clinician is talking down to him and that he is being tested. Mr. Penny doesn't like this.
- Mr. Penny works in construction and is concerned about taking too much time off of work. He wants to know when he will be well because his job doesn't pay him when he's not at work, and he can't afford to be sick.

Discussion Prompts

- What do you think was done well?
- What could have been done better?
- Was anything missing?

Things To Look For

- Did the clinician use teach-back starter phrases such as "I want to make sure that I explained things clearly, can you tell me…"
- Did the clinician use plain language (not medical jargon)?
- If the patient did not teach back correctly, did the clinician rephrase the message until the patient demonstrated a clear understanding?
- Did the patient feel like he was being quizzed?

Teach-Back

Role Play Scenario 3

Facilitator Instructions

1. As facilitator, play the role of the patient.
2. Request a volunteer to play the role of the clinician. The clinician will engage in teach-back with the patient.
3. Provide the volunteer and the training group with information about the scenario. Page 2 contains the basic patient information.
4. Read silently the additional patient information (page 3) to be able to respond to the volunteer during the role play.
5. Role play the scenario with the volunteer. Assume that the clinician has told the patient the plan of care and the visit is now ending. Ask the volunteer to engage in teach-back to ensure the patient understands.
6. As the patient, react to the clinician's tone, message, and body language in the same way you might if you were the patient.
7. Using the discussion prompts (page 3), engage the training group in a learning discussion on what went well and what could be improved.

For Facilitator Only

Additional Patient Information

- Ms. Santiago has a supportive husband and family, but she is at the appointment alone today.
- Ms. Santiago feels very grateful to the hospital team who saved her life.
- Ms. Santiago wants to know how to properly pronounce each of her medicines and to know its purpose because she believes this will help her make these medicines a part of her new routine.
- Ms. Santiago is unaware of systems to organize medicines such as pill boxes or blister packs from pharmacies because she has never had the need to know about them.

Discussion Prompts

- What do you think was done well?
- What could have been done better?
- Was anything missing?

Things To Look For

- Did the clinician use teach-back starter phrases such as "I want to make sure that I explained things clearly, can you tell me…"
- Did the clinician use plain language (not medical jargon)?
- If the patient did not teach back correctly, did the clinician rephrase the message until the patient demonstrated a clear understanding?
- Did the patient feel like she was being quizzed?

For All

Purpose

The clinician has told the patient the plan of care and the visit is now ending. The clinician will engage in teach-back to ensure the patient understands.

Basic Patient Information

A 46-year-old female patient, Ms. Santiago, is here for a scheduled followup visit. Ms. Santiago was discharged from the hospital 4 days ago after a myocardial infarction and the placement of a drug-eluting stent in the right coronary artery through angioplasty. Before the MI, Ms. Santiago had an unremarkable medical history and was taking vitamin D 1,000 mg PO QD. She is married with three children ages 9, 12, and 15 and works full time as an elementary school teacher.

Today Ms. Santiago is feeling overwhelmed by her current health status and her new medicines. She can't pronounce any of the medicines and doesn't know what they do. She can't keep anything straight and has already missed a few doses. She is sure that she has taken some of them twice because she forgot she had taken them already.

Ms. Santiago is scheduled to see her cardiologist in 10 days. The plan of care today for Ms. Santiago includes:

- Follow up with her cardiologist as planned.
- Return to the primary care practice in two months for Prevnar 13® vaccine.
- Continue taking her prescribed medications:
  - Ticagrelor 90 mg – 1 tablet PO BID (morning and evening)
  - Metoprolol 75 mg (25 mg/tablet) – 3 tablets PO QD (morning)
  - Lisinopril 10 mg – 1 tablet PO QD (morning)
  - Low-dose adult aspirin (81 mg/tablet) – 1 tablet PO QD (morning)
  - Atorvostatin 80 mg – 1 tablet PO QD (evening)
  - Vitamin D 1,000 mg – 1 tablet PO QD

https://www.ahrq.gov/sites/default/files/wysiwyg/professionals/quality-patient-safety/patient-family-engagement/pfeprimarycare/teach-back-role-play-final508.pdf

Appendix F

Patient Post Intervention Survey

Please place a check mark in the column that corresponds best with your answer for each question

	Agree Strongly	Agree	Unsure	Disagree	Disagree Strongly
I found this program useful					
This program helped me understand which health conditions my medications are for					
This program helped me understand how to take my medications correctly					

Tables

Table 1. Age (n = 15)

	N Statistic	Mean Statistic
Age	15	54.60
Valid N (listwise)	15	

Table 2. Gender

	Frequency	*Percent*
Male	8	*53.3*
Female	7	*46.7*
Total	15	100.0

Table 3. Paired Samples Test

		t	df	Significance Two-Sided p
Pair 1	Pre SBP - Post SBP	2.028	12	.065
Pair 2	Pre DBP - Post DBP	1.062	12	.309
Pair 3	Pre A1c - Post A1c	.849	1	.552

Table 4. Means and Standard Deviations

Outcomes	Pre-intervention *M* (SD)	Post-intervention *M* (SD)	*p*-value
Systolic BP	148.23 (13.36)	136.62 (15.68)	0.65
Diastolic BP	87.38 (13.94)	83.08 (12.51)	0.31
A1c	10.90 (4.38)	8.65 (0.64)	0.55

Table 5. Decrease in Clinical Indices

Outcomes	Pre-intervention *M* (SD)	Post-intervention *M* (SD)
Systolic BP	148.23 (13.36)	136.62 (15.68)
Diastolic BP	87.38 (13.94)	83.08 (12.51)
A1c	10.90 (4.38)	8.65 (0.64)

Figures

Figure 1. Race/Ethnic Breakdown

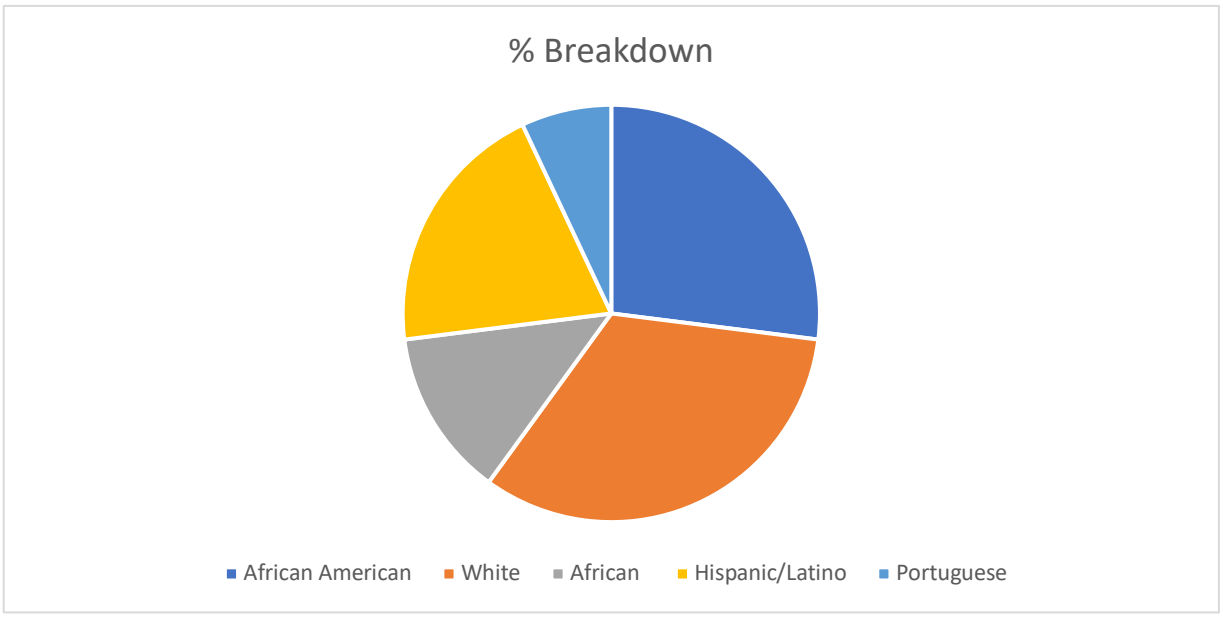


Figure 2. Post Intervention Survey