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User-Centered Design of Nutri, A Novel Goal Setting Clinical Decision Support Technology to Improve the Equity of Data-Driven Dietary Behavior Change Interventions in Primary Care

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User-Centered Design of Nutri, A Novel Goal Setting Clinical Decision Support Technology to Improve the Equity of Data-Driven Dietary Behavior Change Interventions in Primary Care

by

Jacqueline May Henning

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Dedication

To my lovely parents, whose love and encouragement
support me through all my endeavors.

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They say graduate school is challenging, at times defeating, and sometimes downright exhausting. Although I’ve experience these at various times throughout the past two years, my experience has been filled primarily with joy, excitement, and exhilaration. I owe this to the support of multiple mentors, peers, friends, and family members.

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Abstract

User-Centered Design of Nutri, A Novel Goal Setting Clinical Decision Support Technology to Improve the Equity of Data-Driven Dietary Behavior Change Interventions in Primary Care

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Interventions for dietary management of chronic disease increasingly leverage smartphone applications with the promise that data-driven personalization will improve effectiveness. However, since these interventions require users to collect, synthesize, and interpret data, users with more resources are more likely to benefit, thereby exacerbating existing health disparities. Multilevel interventions that distribute responsibility for dietary behavior change between patients and providers may improve equity; however, primary care providers (PCPs) lack time and training to elicit, synthesize, and interpret diet data. We hypothesize these limitations can be overcome with clinical decision support (CDS) technology that captures and synthesizes patient diet data into knowledge for PCPs to engage patients in collaborative diet goal setting, an effective behavior change technique.

The aim of this study is to identify system requirements that would motivate providers to use a collaborative diet goal setting CDS and evaluate implementation design choices with the CDS prototype.

We performed a 2-phase qualitative study with English and Spanish-speaking adult patients and PCPs from a federally qualified health center and an academic clinic in 30 to 60-minute semi-structured generative and usability interviews. We used an iterative design process involving user-experience designers, software engineers, and providers to develop the final CDS prototype.

Using inductive thematic analysis, eight PCP and patient themes emerged. From PCP interviews we identified that: (1) Time constraints and patient characteristics influence if PCPs use personalized or generic goal setting, (2) Subjective and non-standardized processes guide personalized goal setting, (3) PCPs regard patient-generated data as an inaccurate and non-holistic representation of the patient's diet, (4) Current clinical workflows make diet goal setting and monitoring cumbersome. For patients we found that: (1) PCP is seen as an authority figure, (2) Listening and dialog are facilitators for shared decision-making, (3) patients regard diet data as a source of truth, and (4) Goal achievement is distinct from goal setting. These themes, along with refinements identified in usability interviews, guided the iterative design of "Nutri," a workflow-compatible CDS that synthesizes patient diet data from 24-hour recalls via a series of computational rules and presents diet goals for PCPs to discuss with patients through collaborative goal setting.

The results from this study demonstrate the potential of a data-driven CDS for collaborative diet goal setting in primary care. The 2-phase user-centered iterative design process we used to design Nutri demonstrates how usability interviews can refine the operationalization of insights generated from traditional qualitative approaches. Follow-up studies will test Nutri in a clinic setting.

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Chapter 1: Introduction and Review of Literature

CHRONIC DISEASE, DIET, AND DISPARITIES

In the U.S., seven out of every ten deaths are due to chronic disease.[1] This equates to a loss of $1.3 trillion annually on lost productivity and treatment costs.[2] Understanding the relationship between disease and diet is crucial to prevent and manage this widespread health crisis which affects more than 109 million Americans.[2]

Chronic diseases are more prevalent among Hispanic/Latinx,[3] Black,[4] and other minority groups[4–105–7] as well as low-income Americans.[7] These health inequalities relay a large economic burden on the U.S. In fact, the percent excess direct medical care expenditures for African Americans, Asians, and Hispanics that were due to health inequalities was 30.6% in 2009.[8] Nevertheless, management of chronic disease incidence in minority populations has not improved. By 2042, minority/ethnic groups are expected to comprise the majority of the U.S. population.[9] If these trends continue, the shift in population demographics will have drastic effects on the dynamics of population-level chronic disease risk.

Diet is a major contributor to several chronic diseases ranging from type 2 diabetes (T2D),[10–12] cardiovascular disease,[12,13] chronic kidney disease,[5,14] and cancer.[15,16] Furthermore, diet is linked to several risk factors; such as metabolic syndrome[17], hypertension[18], and obesity[19]. Dietary improvement and accompanying weight loss is associated with diabetes remission,[20] improved blood pressure,[21] normalized blood lipid profiles,[22] and improved cardiovascular health.[23] Thus, effective and accessible dietary behavior change interventions could improve the health of millions of Americans, including those disproportionately affected by chronic disease.

Prevention and Management of Diet Related Chronic Disease

Traditionally, diet has been addressed through a variety of individual-based strategies. In recent decades, the advent of mobile phone technology has perpetuated the development of a vast number of health-related smartphone applications (apps) with the intention to address a wide variety of diet related ailments.[24] Apps range from calorie counting or food diary approaches to informational or educational regarding different diets, food sources, and nutrition guidelines.[24,25]

Several studies have found promising clinical outcomes using smartphones. A review of seven interventions with overweight participants found that smartphone interventions had a beneficial effect on sugar-sweetened beverage intake and a statistically significant impact on weight reduction.[26] Furthermore, Turner-McGrievey et al. found that participants using a mobile diet app for self-monitoring of food intake consumed fewer calories than those using a website or paper-journal, suggesting that mobile app use improved adherence to self-monitoring and diet changes in comparison to traditional paper-based approaches.[27]

Mobile phones have evolved rapidly mainly with information processing, design elements, and features. Because of this, several investigators have taken dietary self-management a step further by leveraging patient-generated data to personalize nutritional interventions in order to deliver tailored health conveniently to patients.[28–31] Known as "precision health", collecting diet and other health data through mobile health-based self-management tools to inform individualized analysis may allow for a more precise or accurate prediction to improve chronic disease prevention and management strategies.[32,33]

However, because personalized nutrition interventions are highly data-driven, they require extensive patient-generated data. Individual-based interventions rely on patients to collect, synthesize, and interpret their data, all of which are burdensome and cognitively challenging tasks. This makes these interventions less accessible and user-friendly for the minority and low-income populations who are most affected by chronic disease, thereby exacerbating existing health disparities.[34,35] Therefore, it is important to note that although patient-generated data opens doors for self-knowledge and self-awareness, to take advantage of data, low-resource patients need to be able to analyze it and identify appropriate self-management behaviors in order to fully benefit.

Coordinating Support from the Health Care System

Several individual-based interventions reported participants' struggle to translate patient-generated data to actionable self-management behaviors.[36] Desai et al. reported that community members using smartphones perceived personalized blood glucose predictions novel and informative, but desired more guidance to identify strategies for undesirable forecasts.[37] In addition, Turchioe et al. found that medically underserved patients relied on health care providers to transform their diet and other health data into behavior change goals.[38]

In accordance with these results, it is imperative to incorporate support from experts within the healthcare system to help patients translate insights into actionable self-management strategies. PCPs are well positioned to do this given primary care is the setting where most patients' chronic disease risk is addressed.[39] This benefit is amplified for low-resource patients who are less likely to seek out specialist care (e.g., dietitians) due to a lack of resources and/or time. Therefore, transferring the burden from the individual to the healthcare system by including PCPs in multilevel dietary change intervention has the potential to positively impact those affected by diet-related chronic disease with benefits for health equity by increasing access to those typically underserved in the healthcare system.

PRIMARY CARE AND DIETARY BEHAVIOR CHANGE STRATEGIES

PCPs are uniquely positioned to promote dietary behavior change through high impact and data-driven collaborative diet goal setting. This strategy has been linked to specific modifiable precursors to dietary behavior change: behavioral intention[40,41] and self-efficacy;[42] and is a key element of the American Diabetes Association's self-management education guidelines.[43]

Collaborative Diet Goal Setting

Collaborative goal setting is based on shared decision-making principles: the patient and provider discuss and agree on a health goal during the treatment decision process.[44] Shared decision-making rivals the outdated paternalistic and informed patient-provider communication style which operate largely in a one way flow of information from the provider to patient or patient to provider respectively.[45,46] In contrast, with shared decision-making there is a two-way exchange of medical and personal information with active patient participation to arrive at the best treatment decision.[46]

Collaborative goal setting has three distinct phases: selecting a health behavior to focus on (e.g. increasing vegetable intake), setting a measurable goal for the chosen behavior (e.g. five servings per day), and creating an action plan to achieve the goal (e.g. meal planning).[44] The positive effect of collaborative-goal setting in primary care encounters on behavioral intention and self-efficacy is described in the following sections.

Behavioral Intention

Behavioral intention is one of the variables from the Theory of Planned Behavior (TPB)[47] which is extended from the Theory of Reasoned Action (TRA)[48] and is a commonly used theory to predict behavior. According to the TPB, intentions are an indication of the amount of effort an individual is willing to commit to executing a given behavior and is the most proximal determinant of an individual's adherence to a dietary pattern.[49]

Collaborative goal setting has been shown to be an effective method of reaching treatment agreement[40] and lead to higher levels of behavioral intention.[50] In a descriptive action plan study with over 200 patients with chronic disease risk, 83% of participants discussed and agreed on a behavioral goal with their primary care provider, with 53% of those reported to making a behavior change consistent with that action plan 3-weeks later.[40] Another behavioral goal intervention with nearly 200 adults in primary care found that patients who set goals to reduce their dietary fat intake or increase their fruit and vegetable intake had, on average, reduced their dietary fat by 22% and increased their fruit and vegetable intake by 1.66 servings after the 4-month intervention compared to those who did not target these goals.[41] It is clear that collaborative diet goal setting is an effective method to increase a patients behavioral intention to commit to a dietary action.

Self-Efficacy

Self-efficacy has its roots in social cognitive theory and is the belief that one is able to successfully perform an action.[51] Individuals who have a strong sense of self-efficacy will enhance accomplishments and personal well-being by approaching difficult tasks as obstacles able to be conquered as opposed to threats to be avoided.[52] Thus, self-efficacy is an important predecessor to effective self-management of disease behaviors and clinical outcomes.

Self-efficacy can be developed through several sources of influence. One way is through social persuasion to strengthen an individual's sense that they have what is needed to succeed.[52] Thus, collaborative goal setting is a pathway for PCPs to boost a patient's perceived self-efficacy by persuading verbally that they possess the knowledge and capabilities needed to achieve a goal. This is demonstrated in a cohort study with over 1000 survey responses from patients with diabetes where the collaborative goal setting factor was positively associated with a greater likelihood of average or high self-efficacy.[42] Built over several appointments, this type of positive social persuasion could lead to sustained dietary behaviors that positively impact the patient's chronic disease prevention and management efforts. Therefore, collaboratively setting a diet goal with a PCP may positively impact a patient's perceived self-efficacy leading to enhanced goal achievement.

Primary Care Providers and Diet Counseling

Despite the clear potential for PCPs to contribute to dietary improvement through collaborative diet goal setting,[53] the vast majority of dietary behavior change interventions focus solely on self-management outside of the healthcare system. This missed opportunity is attributed to PCPs' limited training in nutrition.[54,55] Aggarwal et al. found that 35% of polled physicians reported receiving nutrition education through a single lecture or section of a lecture while in medical school.[55] In addition, they found that 73% of physicians recalled receiving no or minimal nutrition education during residency training.[55] Therefore, although PCPs may recognize the importance of nutrition, they may lack the knowledge and confidence needed to effectively provide diet counseling in practice.

Other challenges that prevent PCPs from participating in collaborative diet goal setting include the lack of patient diet data as well as a systematic process to efficiently analyze the data to identify and prioritize the patient's dietary problems. Finally, PCPs are limited by the amount of time they have in an appointment. Given these challenges, a solution that enables PCPs to participate in quick and effective collaborative diet goal setting while leveraging patient diet data is necessary to support dietary changes for chronic disease management and prevention efforts.

Clinical Decision Support Technology

Clinical decision support (CDS) technology may enable PCPs to participate in quick and effective collaborative diet goal setting. CDS technologies are electronic systems designed to aid clinicians in step-by-step clinical decision making through patient-specific recommendations which are presented to the clinician for consideration.[56] These systems are designed to improve healthcare delivery through enhanced medical decisions by utilizing pertinent clinical knowledge and patient health information[57].

History

The first CDS systems were deployed in the 1970s and were poorly integrated to existing systems, required extensive time to use, and had limited use cases outside academia.[58] Since then, these systems have made significant strides, with the capability to integrate with several electronic health record (EHR) systems in the healthcare system. In fact, in 2013, an estimated 41% of U.S. hospitals with an EHR also had a CDS system.[59] Additionally, modern day CDS can be administered through desktops, tablets, and smartphones making them more accessible and convenient for providers and patients to use.

Health Information Technology

Delivering personalized medicine without assistance from technology is challenging due to the increasing amount[60] and diversity[61] of health data. Therefore, CDS systems are becoming increasingly popular due to their ability to leverage complicated data sets that may be otherwise challenging to obtain or interpret by a human.[62] Physicians recognize this benefit, with interest in using CDS growing from 28% in 2016 to 37% in 2019 as reported by the American Medical Association.[63]

Use Case

There are several use-cases for CDS in primary care. As demonstrated in several studies, one of the primary use cases for CDS is to improve prescribing behavior among physicians.[64–69] CDS has also been utilized in the detection and diagnosis of several chronic diseases such as hypertension,[70] cancers,[71,72] kidney disease.[73] A relatively new use case that has emerged for CDS is for behavioral interventions with an emphasis on shared decision making principles.[74–82] An example of the potential for this approach is a recent pilot study of a data-driven CDS for collaborative goal setting that was effective in improving physical activity among low-resource patients with pre-diabetes who set goals with their PCP.[74] Importantly, while the CDS leveraged patients' step counts for data-driven personalization of their physical activity goals, it relied on patients to simply choose their preference from a list of diet goals and ultimately was not effective in changing diet.[74] There is a gap in the literature pertaining to CDS studies that leverage patients' diet data to personalize diet goal recommendations; however, the Mann et al. study supports this approach based on their success using personalized physical activity goals.[74]

CDS for Collaborative Diet Goal Setting

A CDS system would provide three key elements needed for quick and effective collaborative diet goal setting in primary care. First, a CDS for collaborative diet goal setting could provide the diet data PCPs are lacking through an integration with the Automated Self-Administered 24-Hour Recall (ASA24), a validated dietary recall system developed by the National Cancer Institute.[83] Second, a CDS system for collaborative diet goal setting could automate the diet data analysis process through its computerized knowledge base,[84] saving PCPs the time and expertise needed to analyze complicated diet data. Lastly, a CDS system for collaborative diet goal setting could provide step-by-step guidance through the stages of collaborative goal setting to facilitate an effective exchange between the PCP and patient during the shared decision-making encounter.

Given these links, the limitations in PCPs ability to participate in effective dietary behavior change interventions can be overcome with a health information technology-based CDS to provide PCPs with data-driven guidance for personalized collaborative diet goal setting. This technology would enable patients to leave their primary care encounter with the behavioral intention and goal self-efficacy needed to initiate dietary self-management for improved chronic disease prevention and management efforts.

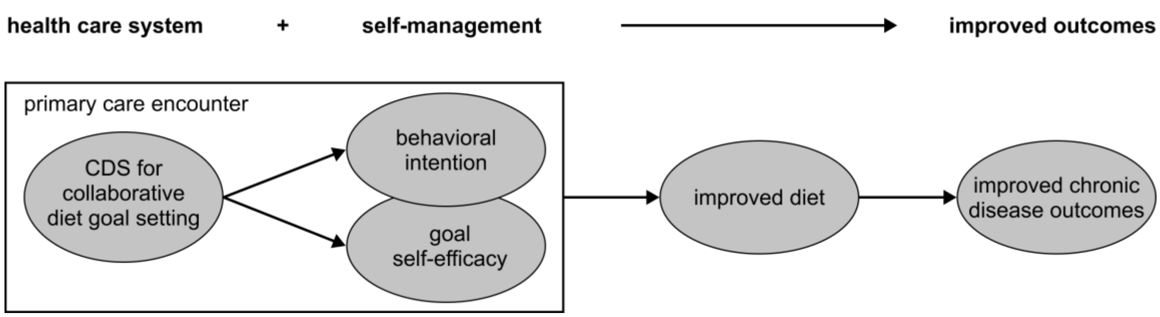

Figure 1: Conceptual Model of a CDS for Data-Driven Collaborative Diet Goal Setting in Primary Care

Challenges regarding CDS Adoption from Providers

Although CDS systems can provide benefits to providers and patients, the success of CDS implementation is varied. Kawamoto et al. reported in a systematic review of 70 CDS studies that only 68% significantly improved clinical practice through patient outcomes or process measures.[56] This disparity can be attributed in large part to the low adoption rate of new electronic tools among providers. According to a systematic review of 148 randomized controlled trials of CDS systems, nearly two-thirds of the studies revealed low adoption rates (50%).[85,86] Several challenges to CDS adoption that are recognized in the literature include a lack of workflow integration, ineffective alerts or recommendations, potential harm to the patient-provider relationship, and dependency on the PCPs' computer literacy. These challenges are described in more detail in the following sections.

Lack of Workflow Integration

A general lack of integration into the busy clinical workflow is a major barrier to CDS system adoption by providers.[56,62,62,87,88,88–91] Lugtenburg et. al found that 60% of general practitioners in a randomized trial testing of a CDS system for heart failure strongly agreed that a CDS system would be difficult to integrate into daily practice.[89] An interrupted workflow can lead to increased cognitive effort, more time needed to complete tasks, and less face-to-face interaction with the patient.[62] Therefore, a technology system that interrupts the natural clinical workflow will face resistance from physicians who have established time management habits. It is important to carefully identify the target user as some clinical workflows may better accommodate a CDS system than others. For example, a randomized controlled trial by Dexter et al. found that vaccination reminders presented to nurses were more effectively acted on than the same reminders presented to physicians.[92] If the ideal member of the clinical team is the provider, a CDS system should recommend actions unobtrusively with supporting key pieces of information or data that is incorporated seamlessly into their decision-making workflow.

Ineffective Alerts or Recommendations

Ineffective alerts or recommendations due to alert fatigue and general distrust has been cited as a barrier to provider adoption of CDS systems.[62,88,90,93,94] Alert fatigue is a phenomenon where too many alerts or insignificant recommendations are presented to providers to the point where they start to dismiss them regardless of significance.[62] Studies show that 33% to 96% of alerts are ignored, either because providers found them redundant, insignificant, or disagree with the alert altogether.[95] Decisions regarding non-interruptive (passive alerts that the clinician can choose to review) or interruptive alerts (non-passive alerts which the clinician must review) should be carefully considered based on nature of the CDS system and severity of the patient condition in order to support provider adoption.[88]

Harm to the Patient-Physician Relationship

Some providers have concerns that a CDS system may harm the patient-physician relationship.[89,90,96,97] Physicians in a focus group study described their concern that a CDS system may tie a physician more closely to their computer while the patient sits quietly behind their back.[90] This could be especially detrimental to the CDS system that is intended to support shared-decision making. Therefore, it is important to recognize that although CDS systems are powerful tools capable of much more than a human, they are not designed to completely replace a trained healthcare professional. A CDS system should not have the leading role in the encounter, but rather be used as a supporting tool to help facilitate an effective exchange between the patient and provider.

Dependency on Computer Literacy

Another barrier to CDS adoption is the amount of effort needed to successfully use the system, especially for older providers who do not have a high technological proficiency.[90,91,98,99] In the implementation of a CDS system by Trivedi et al., clinicians with lower computer literacy or confidence in technology were not willing to tolerate system error messages or lengthy system navigation processes.[91] Therefore, it is imperative that a CDS system is easy to use and intuitive for providers to navigate. Following these principles will also reduce the time needed to use the system which is another commonly cited barrier to CDS system adoption by providers.[87,88,90,97,99]

USER-CENTERED DESIGN

Although there is evidence to support the positive impact of CDS systems on healthcare delivery and patient outcomes, several challenges prevent their acceptance, adoption, and ultimately efficacy in practice. Deploying a user-centered design approach (also known as human-centered design) provides a way to identify and respond to these challenges effectively to design systems that are easy to learn; increase productivity, satisfaction and acceptance; and decrease errors and training time.[100]

User-centered design draws on cognitive science, psychology, and computer science to make technological systems more usable and helpful in practice.[100] The goal in user-centered design is to create systems that is aligned with the characteristics and needs of users by positioning the end user (i.e., the person who will be primarily using the product) in the center of the design process.[100,101] This approach has been applied to a variety of technological development processes. However in recent years, a particular relevance of user-centered design with CDS system development among researchers has emerged, the primary reason being that user-centered design provides a way to identify and address several of the key challenges associated with CDS systems.[102]

Incorporating user-centered design in the early phases of a project not only supports the development of effective CDS systems, but also saves time and money. It is estimated that solving a problem in the development phase costs 10 times more than solving the problem in the design phase. [100] In addition, solving a problem after the system is deployed costs 100 times more than if it were solved in the design phase.[100] Thus, user-centered design has immense benefits in regards to project operations as well.

Four Steps of User-Centered Design

User-centered design, as defined by the International Organization for Standardization, is based on four steps: 1. Identification of the end user and context of use; 2. Discovery and specification of user requirements; 3. Development of preliminary design solutions; 4. Evaluation of design solution against user requirements (Figure 2).[101,103] Steps 3 and 4 will oscillate back and forth as designs are iteratively improved throughout usability interviews.

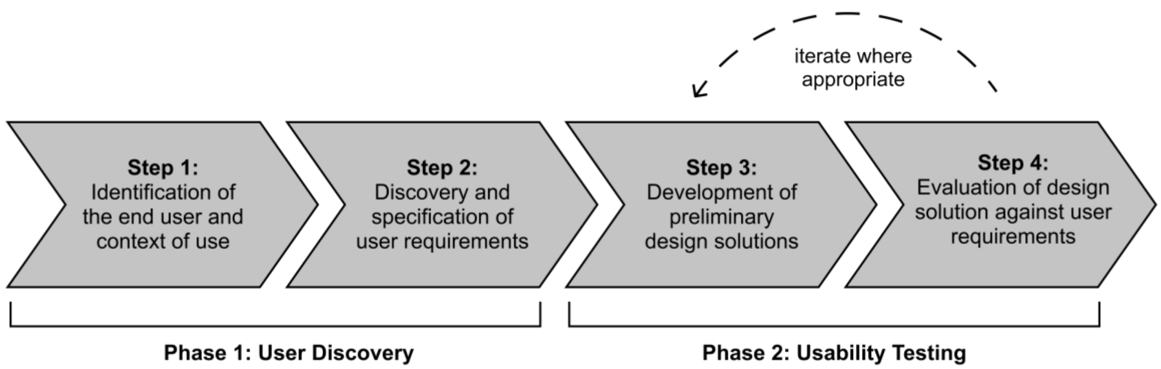

Figure 2: User-centered design process. Adapted from Harte et al. 2017 *JMIR Hum Factors*

Phase 1 – User Discovery

The primary goal in the first phase (steps 1 and 2) of the user-centered design process is to identify and understand the target user. This can be done through a variety of strategies including interviews,[76,78,104–109] focus groups,[77,78,80,105,110,111] and in-field observations.[108,110,112] This stage is crucial to test, validate, and refute any preconceptions that exist among study team regarding the target user. Themes identified from these interactions can inform user profiles, system requirements, and associated features needed to fulfill objectives. For example, Melnick et. al conducted focus groups and in-field observations to understand the decision-making around computer tomography (CT) for minor head injury and identified themes regarding the importance of acknowledging patient concerns, building trust, and managing patient uncertainty.[110] Utilizing these themes, Melnick et. al designed a feature where patients could share their concerns in the waiting room so that the provider would know what to address while concurrently establishing trust and managing uncertainty with their patient during the decision-making process.[113]

Phase 2 – Usability Testing

The primary goal in the second phase (steps 3 and 4) of the user-centered design process is to assess the prototype and associated design decisions through usability testing: the evaluation of a protype by participants who are representative of the target user group as they interact with the system. This phase helps assess the interaction between systems and users in their day-to-day operations.[114] "Think aloud" reports are a common testing technique utilized in several CDS studies[76,78,107,109,115–120] where participants are encouraged to vocalize their thoughts as they interact with the prototype through a series of tasks.[114] Iterative design refinements after testing sessions help ensure that the prototype does not take on the preconceptions of the designers and will conclude when observations indicate that the prototype has reached optimum functionality and usability.[114] When done correctly, up to 80% of usability problems can be identified in as few as 8-12 transcripts.[114] In contrast to the user discovery phase, the codes used in this phase are descriptive of general design principles. Typical codes may include usability, readability, workflow, content, understandability, and usefulness.[115] Other studies opt to use more general codes such as pros, areas of improvement, and use-cases.[82]

There is no established method for determining an optimally functioning system. This can make the transferability of knowledge challenging since researchers utilize different methods to assess the usability of their CDS systems (or no method at all). A popular quantitative choice includes the system usability scale (SUS) assessment, a ten-item questionnaire rated on a five-point Likert scale developed by Brooke in 1986.[76,106,121] After the CDS system is developed and launched, researchers may choose to report on adoption or acceptance rates from providers, which provides practical real-world justification of the system's functionality. Nevertheless, it is interesting to note that a good adoption or acceptance rate does not justify that the tool is scalable for widespread dissemination. Mann et. al reported that adoption rates for a CDS system to improve antibiotic prescription rates were 40-50% lower than anticipated based on the results from their pilot trial.[122] The disparity in adoption rate could be attributed to their selected participant pools, where the original study was conducted at a single hospital comprised of resident-level providers in contrast to the second study which was conducted at two larger health systems consisting of mostly attending-level providers.[122] Thus, research teams should carefully decide where to recruit participants and pilot their tool to develop and scale their prototype with maximum efficiency.

Successful CDS Features

There are several studies describing the development of CDS systems with shared decision-making principles.[76–80,82,109,113,115,123] Successful design features were initiated to improve navigation and efficiency, workflow compatibility, shared decision-making, and usability. Each of these categories and associated features are described in subsequent sections.

Navigation and Efficiency

Features that improve navigation and overall efficiency of CDS systems is imperative due to provider's limited time in an appointment. Several studies have incorporated a step-by-step "wizard" setup assistant that guides the provider through a series of steps in the decision-making process. This may spare providers, particularly those with lower tech literacy, the confusion of progressing through the steps independently.[76,113] For example, the Melnick et. al decision aid regarding computer tomography for head injury included a clearly delineated four-step process: (1) injury evaluation, (2) risk visualization, (3) risk discussion, and (4) considerations.[113] Other studies improve decision making efficiency by weighing or grouping options by priority or risk category to help providers quickly narrow down and identify the most beneficial topic to discuss with patients.[76,113,124]

Workflow Compatibility

Several studies have identified and incorporated features to improve CDS inclusion into the provider workflow.[78,109,113,115] For example, the Chrimes et. al CDS system for improving physical activity prompted the goal setting workflow too early in the patient encounter, making the CDS feel like a data-collection tool rather than a system for shared-decision making.[115] These results led to a design iteration where the tool was refined to prompt goal setting later in the workflow.[115] Other CDS systems have integrated with the EHR to alert the provider at the optimal time based their activity within the EHR.[104,124]

Facilitating Shared Decision-Making

To support effective decision-making, several features have been included in CDS systems to promote cross-communication between the provider and patient. For example, Henderson et. al incorporated open-ended question prompts throughout the CDS system to induce meaningful discussion.[80] Other studies included side by side cards for easy comparison across options[80,125] and easy to comprehend visuals or graphics for patients.[80,82,115,119] Mishuris et. al evolved their data visuals through an iterative 6-step process, beginning with a radar plot, evolving to a series of line graphs, before ultimately deciding on a speed dial design with hover details which was perceived most favorably by patients.[82] Other studies used risk pictorials to demonstrate how the patient's risk compared to others like them in order to assist in the decision-making conversation.[80,113]

Usability

Several features to support overall usability were included and described in several studies. Card view is a popular way to present patient information and is reminiscent of paper-decision aids that providers and patients may be familiar with.[80,113,125,126] A card view also enables the provider to see all the information on one screen which is preferred by providers.[78] Other design elements for improved usability include simplified and consistent language throughout,[80,119] color to identify important pieces of information and reduce cognitive load,[76,119] and a "quick view" with expansion boxes to drill down on specific details.

SUMMARY

Because of the strong link between chronic disease, diet, and disparities, effective dietary behavior change interventions are paramount to manage population level chronic disease risk. Interventions for dietary management of chronic disease increasingly leverage smartphone applications with the promise that data-driven personalization will improve effectiveness. However, since these interventions require users to collect, synthesize, and interpret data, users with more resources are more likely to benefit, thereby exacerbating existing health disparities. Medically underserved patients often rely heavily on health care providers to transform their data into behavior change goals. Therefore, shifting the burden from individuals to the healthcare system by including PCPs in multilevel diet goal setting interventions may support patients in adopting a healthy diet. Nevertheless, PCPs' lack of time and training in nutrition prevent them from participating in collaborative goal setting, an effective dietary behavior change technique. A health information technology-based CDS system could provide PCPs with data-driven guidance for collaborative diet goal setting so that patients can leave their primary care encounter with the goal commitment and self-efficacy necessary to initiate dietary self-management. However, there remains a gap in the literature regarding the ideal workflow and accompanying features to promote an effective user-experience to support adoption of a Data-Driven Collaborative Diet Goal Setting CDS in Primary Care.

SPECIFIC AIMS

The aims of this research are as follows: (1) To identify system requirements that would motivate PCPs and patients to use a collaborative diet goal setting CDS, and (2) To evaluate and refine implementation design choices.

Chapter 2: Manuscript

User-Centered Design of Nutri, A Novel Goal Setting Clinical Decision Support Technology to Improve the Equity of Data-Driven Dietary Behavior Change Interventions in Primary Care

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INTRODUCTION

Chronic diseases—including, cancer, diabetes, hypertension, stroke, and heart disease—are responsible for seven out of every ten deaths in the U.S.[1] This equates to 1.7 million American deaths per year.[1] Low income, racial/ethnic minority patients are 1.5 to 2.0 times more likely than white patients to be affected by chronic disease.[127] These health inequalities relay a large economic burden on the U.S. From 2003 to 2006, the percent excess direct medical care expenditures due to health inequalities as a percent of the total expenditures for racial minorities was nearly 31%.[8] Several studies have shown that dietary

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improvement is associated to positive chronic disease prevention and management outcomes.[17–23] Thus, effective and accessible dietary behavior change interventions have the potential to positively impact millions of Americans, including those disproportionately affected by chronic disease.

Interventions for dietary management of chronic disease increasingly leverage smartphone applications to personalize nutrition interventions through patient-generated data. Known as “precision health”, collecting diet and other health data through mobile health-based self-management tools to inform individualized analysis may allow for a more precise or accurate prediction to support prevention and treatment strategies.[32,33] However, these individual-based interventions require users to collect, synthesize, and interpret diet data, all of which are burdensome and cognitively challenging tasks. Therefore, users with more resources are more likely to benefit from these interventions, thereby exacerbating existing health disparities.[34,35] We previously found that many medically underserved patients rely on health care providers to transform their diet and health data into behavior change goals.[38] Additionally, Desai et al. reported that community members using smartphones perceived personalized blood glucose predictions novel and informative, but desired more guidance to identify strategies to avoid or mitigate undesirable forecasts.[37] Therefore, shifting the burden from individuals to the healthcare system by including PCPs in multilevel diet goal setting interventions may help patients adopt a healthy diet, with associated benefits for health equity by increasing access to quality nutrition care to underserved patients.

PCPs can promote dietary behavior change through data-driven collaborative diet goal setting; an effective behavior change technique. This strategy has been linked to specific modifiable precursors to dietary behavior change: behavioral intention[40,41] and self-efficacy;[42] and is a key element of the American Diabetes Association's self-management education guidelines.[43] Despite this potential, the vast majority of dietary behavior change interventions focus solely on self-management outside of the healthcare system. This missed opportunity is attributed to PCPs' limited training in nutrition[54,55] and time that they can spend with each patient. Given these limitations, a solution that enables PCPs to participate in quick and evidence-based collaborative diet goal setting while leveraging patient diet data is needed to support diet-related chronic disease management and prevention efforts in primary care.

PCPs' unfamiliarity with conducting behavioral nutrition or dietary behavior change interventions may be overcome with a health information technology-based clinical decision support (CDS) technology to provide PCPs with data-driven guidance for personalized collaborative diet goal setting. Clinical decision support systems are electronic systems designed to aid clinicians in step-by-step, clinical decision making through patient-specific recommendations which are presented to the clinician for consideration.[56] Nevertheless, the success of CDS implementation is varied. Kawamoto et al. reported in a systematic review of 70 CDS studies that only 68% significantly improved clinical practice through patient outcomes or process measures.[56] This disparity can be attributed, in large part, to the low adoption rate of new electronic tools among providers. According to a systematic review of 148 randomized controlled trials of CDS systems, nearly two-thirds of the studies revealed low adoption rates (50%).[85,86] Some of the barriers to adoption include a lack of workflow integration,[56,62,62,87,88,88–91] ineffective alerts or recommendations,[62,88,90,93,94] perceived harm to the patient-physician relationship,[89,90,96,97] and lack of computer literacy[90,91,98,99]. Deploying a user-centered design approach provides a way to identify and respond to these challenges effectively to design systems that are easy to learn; increase productivity, satisfaction and acceptance; and decrease errors and training time.[100]

We are developing the Nutri software to provide a streamlined diet goal-setting tool that coordinates with the EHR to help PCPs engage in time-efficient and evidence-based dietary counseling during primary care appointments to help patients improve dietary management of chronic disease. This paper describes the results of the iterative two-phase user-centered design process of Nutri.

METHODS

This qualitative observational study is the first part of a larger study focused on evaluating a CDS system for collaborative diet goal setting for low-resource patients and practitioners in primary care. We engaged with a multi-disciplinary core research team consisting of primary care physicians, dietitians, user-experience designers, biostatisticians, and software engineers. The study was conducted in two phases (Figure 3).

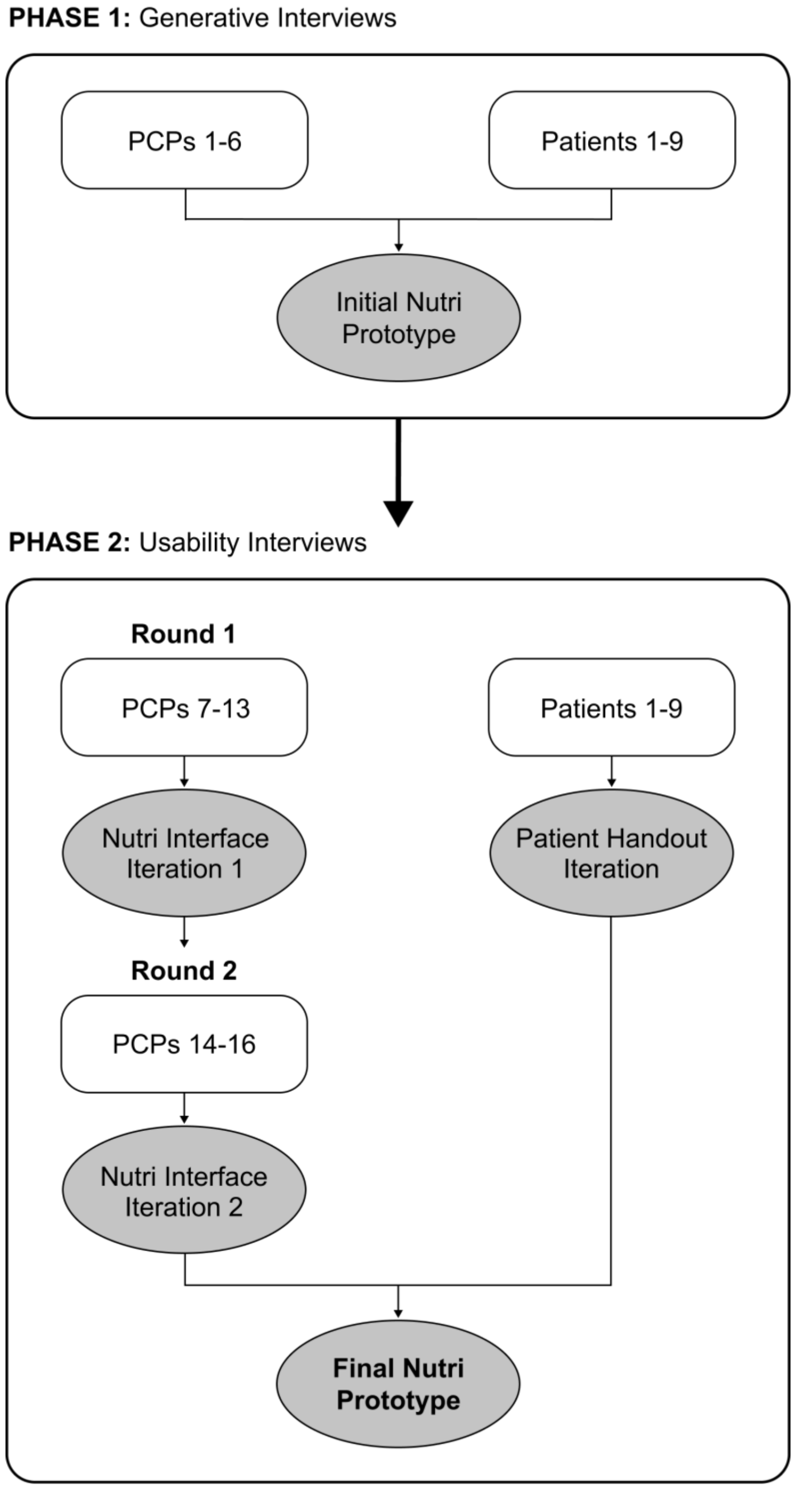


Figure 3: Development Process of Nutri

Phase 1 consisted of generative interviews to understand PCP and patient perceptions of and experiences with diet counseling. Phase 2 consisted of usability interviews with the Nutri prototype. Different PCPs completed the phases in separate interviews; however, the same patients completed both phases in one interview. We used an iterative design process to develop the final Nutri prototype design.

Phase I Methods: Generative Interviews

The first phase of the study involved understanding Nutri's user groups through generative interviews. We conducted one-hour qualitative interviews with PCPs to understand motivations and processes for diet counseling; explore experiences with goal setting and shared decision-making, including facilitators and barriers; and discuss the potential for a diet goal setting tool in primary care. The results from these interviews directed the Nutri workflow and initial prototype design. We conducted qualitative interviews with patients to learn about their perspectives on diet counseling and goal setting in primary care during the first half of their interview.

Participants

PCPs were recruited from a federally qualified health center network and a large academic health care center. Candidate PCPs were approached by the research team via email. Inclusion criteria for PCPs were: (1) primary care provider designation (i.e., physician, physician assistant, or nurse practitioner) and (2) age from 18 to 65. Resident trainees were excluded. Patients were recruited from the FQHC network through a referral from their PCP who identified them as a potential candidate and shared a study recruitment flyer with them. Inclusion criteria for patients were: (1) fluent in English or Spanish, (2) BMI $\geq$ 25 kg/m^2, (3) diagnosed with a diet-related comorbidity (e.g., hypertension, hypercholesterolemia, pre-diabetes, type 1 or 2 diabetes), (4) visited their PCP at least once in the last 24 months, and (5) age from 18 to 65. We obtained approval from the [blinded] Institutional Review Board.

Procedure

We used a semi-structured interview guide developed by a team of nutrition and user-experience researchers to conduct individual interviews with participants. The participant interview guide was divided into two sections to accommodate the generative and usability interview questions. PCP interviews were conducted in a private room at the provider's practice (when interviewing in-person), or through a video conferencing platform (when interviewing online). All patient interviews were conducted through a video conferencing platform. Interviews were audio recorded and transcribed verbatim by a member of the research team or the video conferencing transcription service.

Data Analysis

Transcripts were analyzed in NVivo12 using conventional content analysis.[128] Three coders (JH, DL, JL) collaboratively created a preliminary codebook after individually coding one transcript. After individually coding an additional transcript, the coders met again to edit and finalize the codebook. All remaining transcripts were independently coded using the final codebook. Coders met weekly to compare results and resolve discrepancies through discussion. The first author generated initial themes through inductive thematic analysis and presented them to the coding team for thematic congruence until the final themes were established. The results from this phase informed the Nutri workflow.

The user-experience team (EN, JL, KC) designed the initial Nutri prototype based on the generative results from phase 1, the Nutri workflow, and the body of literature surrounding successful CDS for shared decision-making features.

Phase II Methods: Usability Interviews

The second phase of the study involved usability interviews with the initial Nutri prototype. 30-minute to one-hour qualitative interviews with PCPs and patients were conducted using cognitive task analysis; participants were asked to "think aloud" as they saw and interacted with different components of the Nutri prototype.[114] PCPs were asked to complete a series of tasks with the prototype to progress through the major components of the collaborative goal setting experience. Patients were presented with an example of the Nutri patient education handout and asked a series of accompanying questions during the second half of their interview.

Participants

PCPs were recruited from the FQHC network and university-affiliated clinics for underserved patients via email and staff meetings. Inclusion criteria for PCPs were: (1) PCP designation (i.e., physicians, physician assistants, or nurse practitioners), (2) employed at the clinic $\geq$ 6 months, and (3) age from 18 to 65. Resident trainees were excluded. The patients in phase 2 were the same participants from phase 1. Given that previous research has demonstrated that up to 80% of usability problems can be identified with 8-12 participants,[114] we recruited at least 8 participants in each user group.

Procedure

A research team member, who was trained by a user-experience team leader (EN), conducted each PCP interview with a structured interview guide and two predetermined tasks (goal setting with (1) new patient and (2) return patient). We conducted two rounds of usability interviews based on our initial and subsequent iterations of the Nutri prototype. Throughout each task, PCPs were encouraged to "think aloud" as they progressed through each part of the CDS prototype. Interviews were conducted online via a video conferencing platform. The PCP was given remote control of the interviewer's screen so that they could interact with the prototype and their selection of goals was documented. Following the "think aloud" protocol, PCPs were asked a series of follow-up questions to assess their perception and satisfaction with the prototype, areas of weakness or opportunity, and suggestions to improve the collaborative diet goal setting process. In the second (usability) part of patient interviews, participants were presented with the Nutri handout and asked a series of questions using a semi-structured interview guide. All interviews were audio recorded and transcribed verbatim.

Data Analysis

A set of a priori codes were developed based on the results from Phase 1 and codebooks used in other usability studies.[114] The three categories for coding segments included: (a) Nutri CDS components, (b) valence as perceived by the coders (i.e., "positive", "negative", "neutral", or "suggestion"), and (c) heuristic criteria to assess usability issues as portrayed through participant verbalizations or actions. Three coders (JH, DL, JL) independently coded transcripts and resolved discrepancies as described in Phase 1.

The user-experience team led the iterative design process of Nutri through weekly meetings with the study team. Two Nutri prototype iterations were initiated based on PCP perceptions of and interactions with the Nutri prototype after two usability testing rounds. The user-experience team also led the redesign of the Nutri handout.

RESULTS

Phase I Results: Generative Interviews

Participants

Of the six provider interviews, four were with family medicine physicians and two were with pediatric physicians. Of the nine patients recruited, three were Spanish speakers. Clinic and sociodemographic information were collected prior to the interviews (Table 1).

Variable	
PCPs (n = 6)	mean (SD) or n (%)
Female Sex — no. (%)	5 (83.3%)
Provider Type — no. (%)	
Family Medicine	4 (66.6%)
Pediatric	2 (33.3%)
Clinic Type — no. (%)	
FQHC	3 (50%)
Academic primary care clinic	3 (50%)
Patients (n = 9)	
Age – yr.	50 ± 8.92
Female Sex — no. (%)	7 (77%)
Race	
Black or African American	2
American Indian or Alaska Native	1
White	5
Other	1
Hispanic or Latino — no. (%)	4 (44%)
Spanish Speaker — no. (%)	2 (22%)
Financial Stability	
More than enough to get by	1
Just enough to get by	7
Not enough to get by	1
Smartphone owner — no. (%)	9 (100%)
Computer/laptop user — no. (%)	7 (78%)

Table 1: Participant Clinic and Sociodemographic Characteristics (Phase 1)

Generative Themes from PCPs

We identified four common themes that represented PCPs' perspectives on diet counseling and collaborative goal setting in practice: (1) Time constraints and patient characteristics influence if a personalized or generic goal setting approach is used, (2) Subjective, non-standardized processes guide personalized goal setting, (3) Patient-generated data is regarded as an inaccurate and non-holistic representation of the patient's diet, and (4) Current clinical workflows make diet goal setting and monitoring cumbersome.

1: Time constraints and patient characteristics influence if a personalized or generic goal setting approach is used. Although PCPs uniformly described that nutrition is an important component of the primary care visit, they approached diet counseling differently. Some providers used a more personalized diet goal setting approach: "I try to... you know, ask them based on that [diet] conversation... what are some specific goals they can make" (PCP 4). Others reported choosing a more generic approach by recommending standardized goals that could be applicable to any patient: "If they're normal weight or they're sedentary, I'll just say, you know, 'try to work on, you know, ten thousand steps a day' and that'll be in my little, you know, blurb that they get as a printout... at the end" (PCP 3). When patient characteristics merited an in-depth discussion about diet (e.g., severe chronic condition, lab values, or BMI) or when PCPs had more time, they described engaging in a more personalized approach.

2: Subjective, non-standardized processes guide personalized goal setting. When PCPs chose a personalized diet counseling approach, they reported collecting diet data verbally during the appointment through a series of questions. Questions varied greatly among providers. Some asked targeted questions regarding a certain food category: "What kind of things are you drinking?" (PCP 1); whereas others preferred to inquire about the quantity of food intake "How many times a week do you eat at a fast-food restaurant?" (PCP 3). Some PCPs favored behavioral information in lieu of diet data: "I'll ask them... what their neighborhood might be like, um what sort of grocery stores they shop at." (PCP 4). Lastly, some providers opted for an open-ended approach and asked their patients to simply tell them what they ate. PCPs described diet recalls as taking a few minutes – just enough time to give the PCP an idea of what the patient may be consuming.

3: Patient-generated data are regarded as inaccurate and non-holistic representations of the patient's diet. Although PCPs reported occasionally receiving food logs or diaries from patients, they perceived this data to be an inaccurate and uncomprehensive representation of a patient's daily food intake. PCPs considered that the inaccuracies may be due to patient's purposeful omission of unhealthy components: "I think the information you're likely to get on that one day is the um – the salmon and steamed vegetables, and... unsweetened yogurt with blueberries and all that other stuff, and you'll miss the half of the pizza they had the night before" (PCP 2). Other PCPs considered it to be influenced by patient personality traits: "I worry, you know, that... let's say you're having a lazy day and you're not inputting stuff. Um, but that's the day you have tons of sugary drinks, you know?" (PCP 5).

4: Current clinical workflows make diet goal setting and monitoring cumbersome. All the PCPs interviewed shared that they conducted diet counseling to some degree; however, the current clinic workflow makes reporting, monitoring, and following up on diet goals cumbersome: "We don't really have the ability to check back and say, 'Work on losing 10 pounds.' 'That was a month ago. How are you doing?' 'What support might you need?' 'What barriers do you have?' There's really not infrastructure to follow up more closely on that type of thing" (PCP 3). Some PCPs indicated that they would document the diet conversation in the EHR note; however, they reported frustration with this strategy given patient forgetfulness that would require reeducation at a subsequent visit: “A lot of times, you know, I’ll look at my note from the previous visit, and we would have discussed the very thing, and I'd given them the very advice that I'm giving them today, and they just didn't remember” (PCP 2).

Generative Themes from Patients

We identified four common themes that represented patient’s perspectives on dietary counseling in primary care: (1) PCP as an authority figure, (2) Listening and dialog are facilitators for shared decision-making, (3), Diet data as a source of truth, and (4) Goal achievement is distinct from goal setting.

1: PCP as an authority figure. Patients expressed uniform interest in talking about nutrition with their PCP. In fact, some patients stated that their PCP would be the best person to share their diet history with and considered diet a standard component of primary care. PCPs were described as an authority figure whose opinion patients attributed higher value in comparison to other sources of insight: “just to be able to have someone else give their opinion of where you need to be versus just your own thoughts. And then, with it being your physician, his guidance would, you know, be influential” (Patient 2). More specifically, patients shared an interest in leveraging the expertise and guidance of their PCP when selecting a personalized diet goal: “I’d be much more confident in the steps that I’m taking the doctor was assisting me and choosing” (Patient 6).

2: Listening and dialog are facilitators for shared decision-making. Patients described a greater sense of satisfaction with their PCP if their provider took the time to listen to their concerns and engage in meaningful conversation. The polarity between an engaged PCP and a non-engaged PCP largely affected a patient’s perception of care: “I have a great doctor who listens, so it's easy to communicate with him. Versus like doctors

I've had in the past, who, you know, you're talking to a wall. They don't really listen" (Patient 2). Listening and dialog were described as especially important when it came to discussing nutrition and setting diet goals. Patients expressed dissatisfaction with PCPs who provided basic nutrition advice: "you go to the doctor a lot of times [and] the doctors um, just [tells] you 'You need to diet and exercise.'... and that's all you get" (Patient 4).

3: Diet data as a source of truth. Patients responded favorably to the idea of personalized diet goals based on their data. Some described diet data as a point of reference that could help them more clearly assess their progress between visits: "a lot of times you talk about goals and numbers are thrown at you, but to actually see a chart to see how far you are, you know, just puts things in perspective" (Patient 9). One Spanish-speaking patient shared that their diet data could help their PCP comprehend what she was eating more clearly and therefore provide her better care: "he can only understand if I can explain to him what I eat. Because when I don't tell him really what I eat... it is also difficult on his part to be able to explain to me" (Patient 3).

4: Goal achievement is distinct from goal setting. When asked what their PCP could do to help them understand and improve their diet, patients described a desire for a concrete diet plan that included specific foods to consume or diet guidelines to follow: "when a person has a heart attack, the doctor usually discusses like pretty much a diet regimen of you should eat more - you know, less fatty foods and, you know, increase this or that. Yeah. So pretty much like - kind of like a play by play [laugh]" (Patient 2). Others shared their interest in an educational program to further their understanding of their selected diet goal: "I'm one of those, that if I have a learning platform or some kind of program, it's very helpful. And then once we set the goals, using that program to help obtain those goals would be helpful" (Patient 3).

Nutri Workflow and Initial Prototype

Phase 1 interviews indicated that although providers and patients value diet conversations, providers lack the tools necessary to apply evidence-based strategies in collecting, synthesizing, and transforming data into impactful diet goals. Patients revealed they would seek counsel from their provider when choosing diet goals; however, PCPs did not report engaging in shared decision-making principles, such as collaborative goal setting. Goal setting varied from patient to patient with more personalized and in-depth approaches favored when certain patient characteristics were evident or when PCPs had more time. When a personalized approach was used, PCPs reported verbally collecting diet data during the appointment rather than using patient generated diet data which PCPs perceived as inaccurate. Although PCPs reported issuing basic nutrition handouts at the end of the visit, patients desired specific action plans or education materials to help them reach their goals. Lastly, patients perceived diet data as helpful in recording goal progress; however, current clinical workflow prevent PCPs from engaging in monitoring and follow-up of diet goals.

Based on these results and our literature review we identified 5 system requirements for an effective collaborative diet goal setting CDS for primary care: objective data collection/synthesis, workflow compatibility, easily identifiable high-impact goals, EHR integration, and patient education to support goal success. Therefore, we designed the initial Nutri prototype to be a 4-step cyclical diet goal setting and evaluation process: (1) personalized diet goal results, (2) shared decision making, (3) summary/notes, and (4) follow-up evaluation (Figure 4).

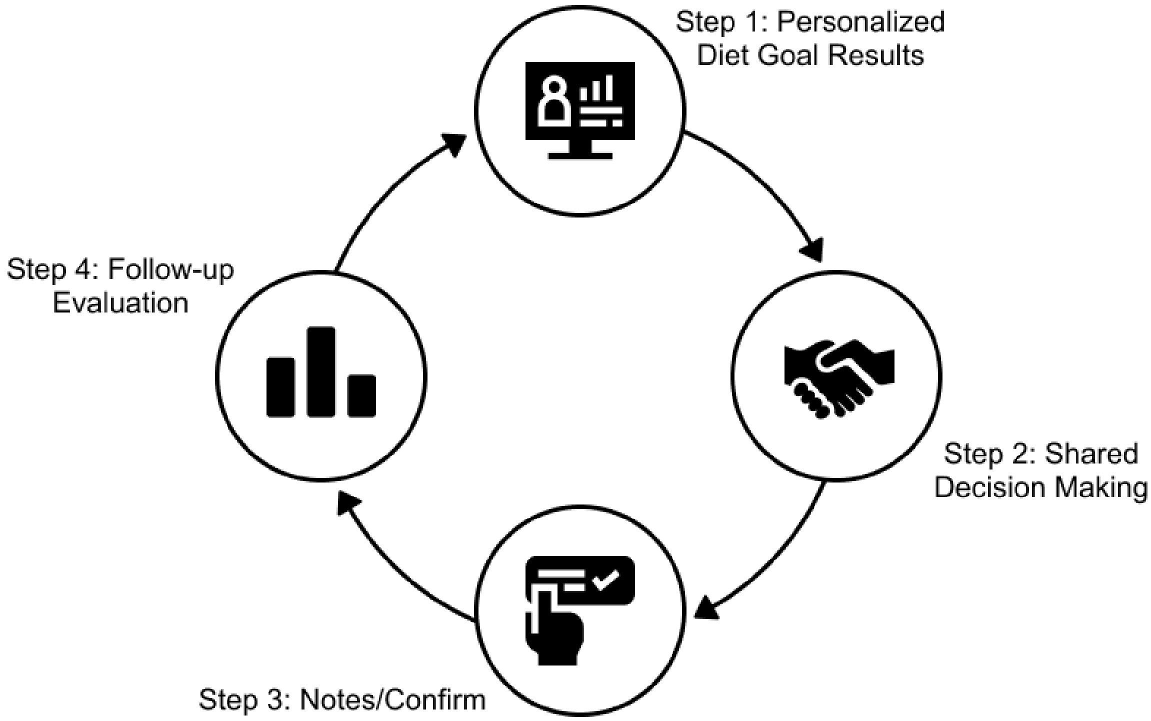


Figure 4: Nutri 4-Step Diet Goal Setting and Evaluation Process

The first step of the goal setting process includes an overview of personalized diet goals to help PCPs narrow down which goals to highlight with the patient. A patient's diet data captured from the Automated Self-Administered 24 Hour Recall (ASA24)[83] is automatically processed to return a prioritized list of goals with reference values based on Dietary Guidelines for Americans.[129] The nine diet goals are presented to the PCP for quick selection of up to three goals to discuss more with the patient.

The second step of the goal setting process promotes shared decision making between the PCP and patient to select the best goal for the patient to work on. Selected diet goals from the previous screen and associated data (intake values and food intake lists) are presented side-by-side for optimal collaborative goal setting between the PCP and patient. Patient confidence scale provides an opportunity to engage in brief motivational interviewing[130] to further narrow down choices.

The third step of the goal setting process is a place for final review and notetaking. The PCP can print the patient's diet goal handout which includes the selected diet goal, associated diet data, food currently in the diet that contribute to the goal, and confidence as recorded with the PCP during the appointment. The goal selected and associated data is automatically recorded in the note section and is intended to be automatically copied into the patient's electronic health record.

The fourth step of the goal setting process is goal evaluation. The PCP is prompted to compare a return patient's previous goal result to their most recent goal result to assess their progress since their last visit. Based on their progress, the PCP can choose to continue the goal or start the process again with a new goal.

The initial Nutri prototype (figure 5) and patient handout (figure 6) are depicted below.

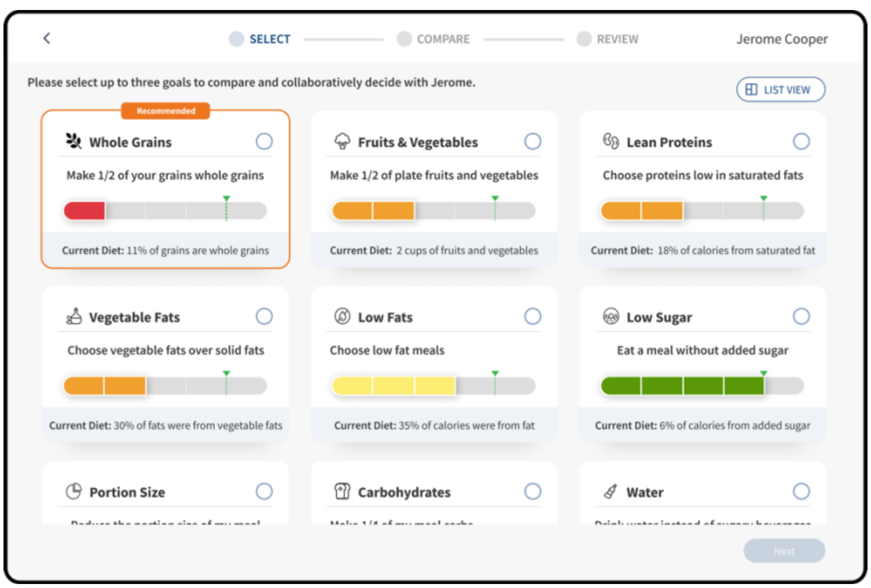


Figure 5: Initial Nutri Prototype Interface

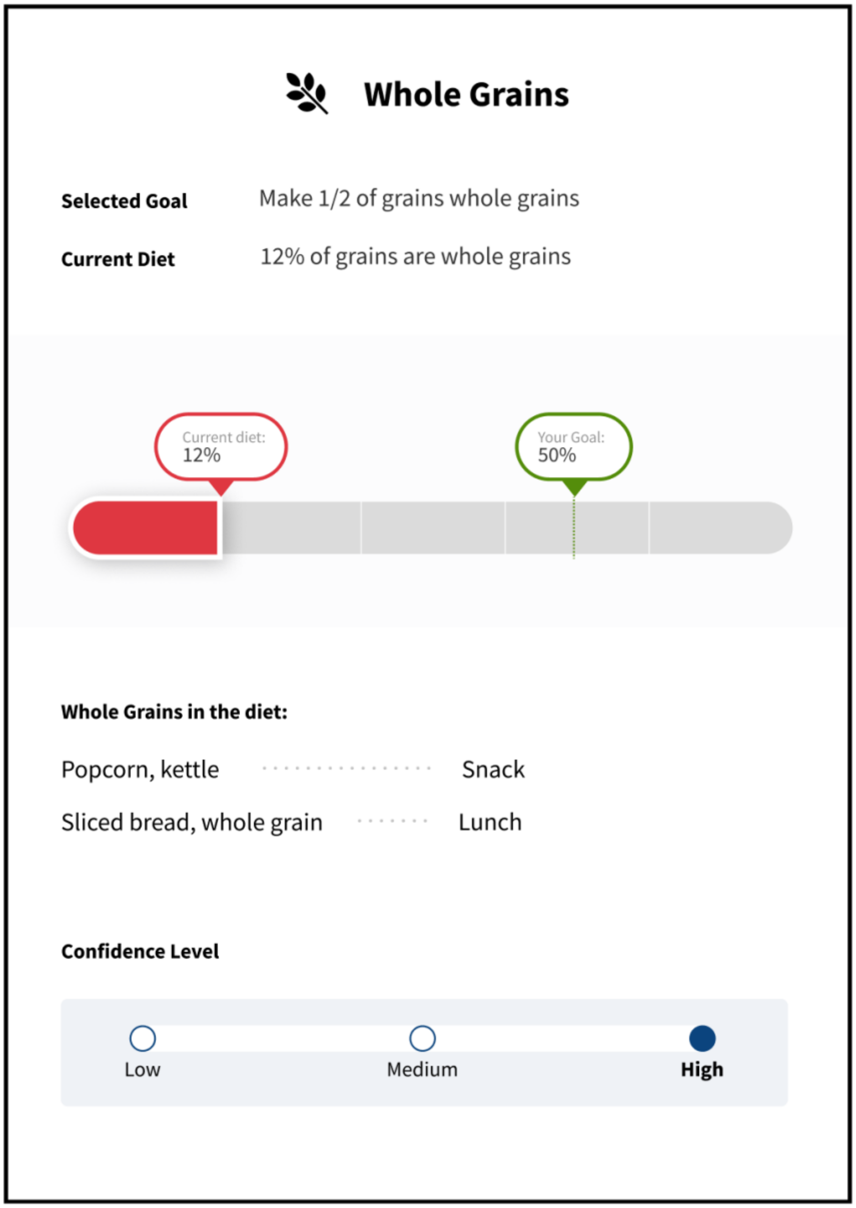


Figure 6: Initial Nutri Patient Handout

Phase II Results: Usability Interviews

Participants

Ten providers (five medical doctors and five nurse practitioners) were recruited for usability interviews. Clinic and sociodemographic information were collected prior to the interviews (Table 2). The patients who participated were the same from phase 1 (table 1).

Variable	
PCPs (n = 10)	mean (SD) or n (%)
Age – yr.	44.7 ± 10.03
Female Sex — no. (%)	6 (60%)
Provider Type — no. (%)	
Medical Doctor	5 (50%)
Nurse Practitioner	5 (50%)
Years of Post-Graduate Practice	14.5 ± 11.59
Clinic Type — no. (%)	
FQHC	6 (60%)
Academic primary care clinic	4 (40%)

Table 2: Participant Clinic and Sociodemographic Characteristics (Phase 2)

Usability Results for PCPs

Heuristic coding segments were created from transcribed interviews. Of the six heuristic coding categories (Table 3), a total of 215 heuristic coding segments were identified. The heuristic category that generated the bulk of the coding segments was Nutri comprehension with a total of 87 coding segments ~ 40% of the total segments. 80 of these were neutral statements from PCPs who inquired about the navigation or purpose of Nutri components. The second highest heuristic category was content clarity with a total of 38 coding segments ~18% of the total segments. The other 4 heuristic coding categories ranged from 19 to 29 coding segments with an average of 23 segments each.

Heuristic Code	Definition	Example Statement
Usability	Ease of use of Nutri, ability to use with minimal effort, (i.e., time, clicks, mental energy).	"I think the more that somebody interacts with it, the easier it will become." (PCP 7) "I think, um, you know, it took a little bit of processing at first. Um, the first couple of minutes, but once you are familiar with the lay of it, I actually like it." (PCP 13)
Content Clarity	Consistency and accuracy of the images or text.	"Current 35% of calories were from fat... so there's a green line, right? What does it mean that they - do they need more fats?" (PCP 7) "I'm looking to see what the 4 is. I'm not sure if that's cups or ounces or liters." (PCP 8)
Content Comprehensiveness	The extent to which displayed information is adequate, comprehensive, or missing value-added components.	"One of the things I was trying to see about Jerome, what is height? What is weight... because that's really going to take into account how much calories they're going to have per day as well." (PCP 8) "She's only really reflective of 24 hours. So, uh how would we account for that." (PCP 12)

Table 3: Heuristic Codes

Heuristic Code	Definition	Example Statement
Nutri Comprehension	Ability to comprehend the meaning of text, instructions, and the purpose of Nutri components.	“I wasn't totally sure if it was like how confident I am? Or how confident the patient is?” (PCP 16) “I'm guessing these are data that they have, in the diet composition data that they have put in, or that I've gathered?” (PCP 11)
Workflow	How Nutri incorporates into the natural flow of events in a typical patient encounter.	“...hopefully it will flow seamlessly with my EHR in order for me to use this because you know we do get a lot of tools, but if it doesn't flow seamlessly through the EHR... I may not use it.” (PCP 10) “I have twenty minutes for follow-up... it's hard to do this, so you've got to make this very user-friendly, but you also have to make sure your providers have a reason to do this.” (PCP 13)
Usefulness	Reference to Nutri (and information provided from it) assisting in clinical decision making, patient-provider communication, improving speed, or decreasing workload during encounters.	“It gives them…I mean you have--you have the assessment right there, so it speeds up the conversation.” (PCP 14) “Having long term dietary recall data on the patient and track them over time and calculate the changes... [would be] useful.” (PCP 1)

Table 3: Heuristic Codes (continued)

Round 1 Observations: PCPs displayed interesting goal selection behavior throughout the first round of usability interviews. Initially, PCPs instinctually leveraged patient's diet data to formulate a diet goal solution: "I'm looking at his food sources. I see that most of his fluids come from sugary drinks, beverages, which unfortunately are empty calories, so he's going to need more water intake" (PCP 8). However, when it was time to select goals on the diet goal results screen, PCPs gravitated towards goals that they were familiar with or commonly suggested rather than the high priority goal recommended by Nutri's data-driven algorithm: "I do a lot more counseling about more of a plant-based diet that's focusing more on the fruits and vegetables and portion control, rather than specifically talking about the types of proteins or vegetable fat they should be having" (PCP 11). Additionally, some PCPs were confused regarding the overall purpose of Nutri and frequently requested support, particularly on the diet goal results screen.

Given these results, the primary focus for the first Nutri prototype iteration was to improve the frequency of high-impact goals selected on the diet goal results screen by improving content clarity and overall usability (figure 7). To improve content clarity, diet goal cards were simplified by replacing the horizontal bar graph with a less obtrusive color-coordinated priority label which explicitly stated the goal's priority. To improve usability, we introduced two clearly defined groups: recommended goals and achieved (or nearly achieved) goals. Other changes included more detailed descriptions for each screen and explicit labels for features such as the food consumption lists to improve Nutri comprehension as PCPs navigated through the prototype.

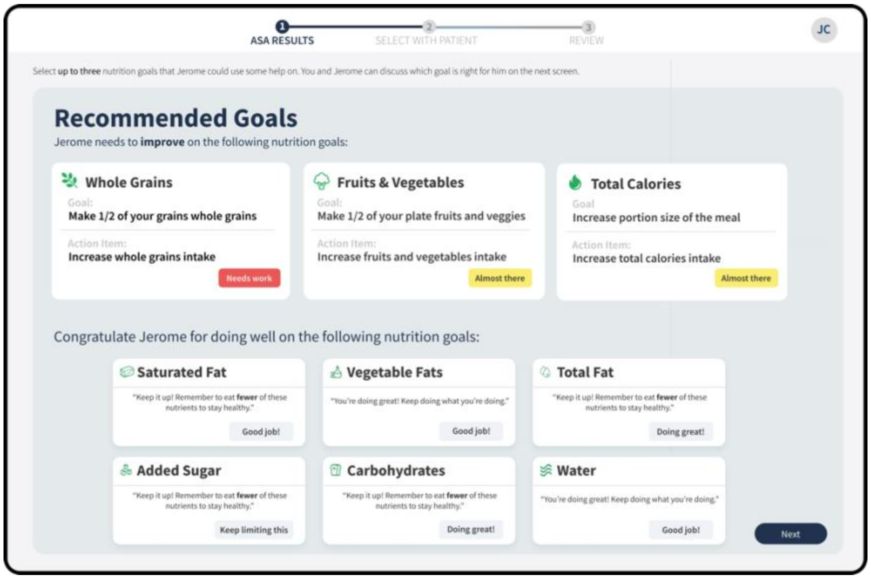


Figure 7: Nutri Interface Iteration 1

Round 2 Observations: In the second round of usability interviews, we witnessed a notable improvement in the quality of goals PCPs selected. All three PCPs selected the highest priority goals. Additionally, PCPs were able to navigate through the steps more independently and responded favorably to the overall purpose of Nutri. They described it as a timesaving tool by informing them of the most pertinent nutrition topics to discuss with their patient: “It makes it nicer to have a talking point versus having the breadth of nutrition in the visit and not knowing what to start with” (PCP 15). Participants were also fond of the data-driven nature of diet goals: “I love it, it makes the conversation so much easier. I'm huge with the quantifying everything to make a point and so [laughs] I think this does that…” (PCP 14). However, regardless of their improved comprehension of Nutri components, PCPs requested additional information, most commonly patient’s diet data, to support their goal recommendation: “Will we be able to see their raw data? Because it says, ‘almost there’ but we don't know why they're not at goal....” (PCP 15). Ultimately, PCPs were cognizant of the goal priority, but sought out additional information to define the diet problem before they selected goals for their patient. Additionally, some PCPs expressed concern regarding the representativeness of the 24-hour diet recall in comparison to the patient's actual diet.

Given these observations, the final Nutri prototype included minor changes to better support PCPs in the diet goal decision making process by improving content comprehensiveness (figure 8). To account for PCPs tendency to define the problem before selecting diet goals, we reworded the goal cards to follow problem-solution statements that are more traditional in the clinic environment. PCPs desire to see additional data regarding the patient diet goal recommendations drove the inclusion of a patient macronutrient summary. To account for PCPs request for other pieces of patient information, we included a pop-up box to include extra content without sacrificing usability. Lastly, we responded to PCP concerns regarding the representativeness of a patient's 24-hour recall by adding a patient rating for the representativeness their 24-hour dietary recall.

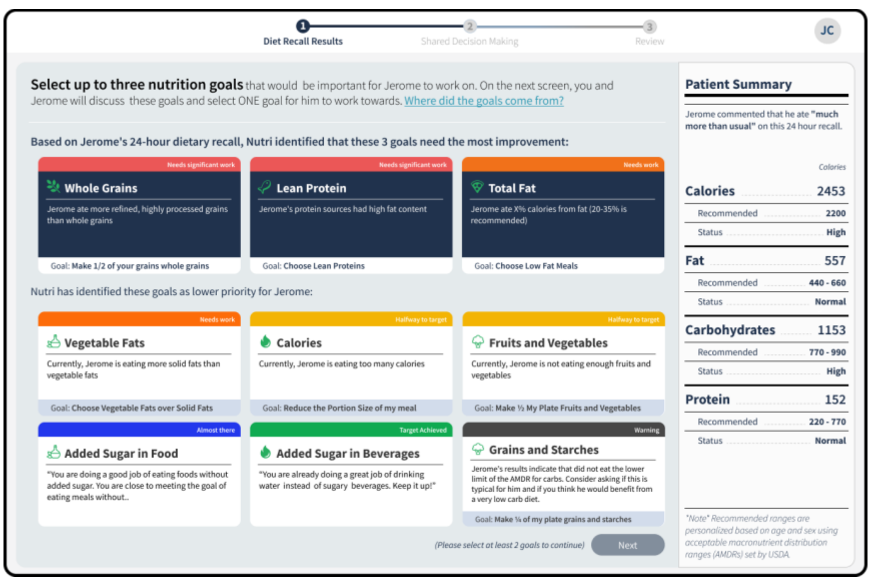
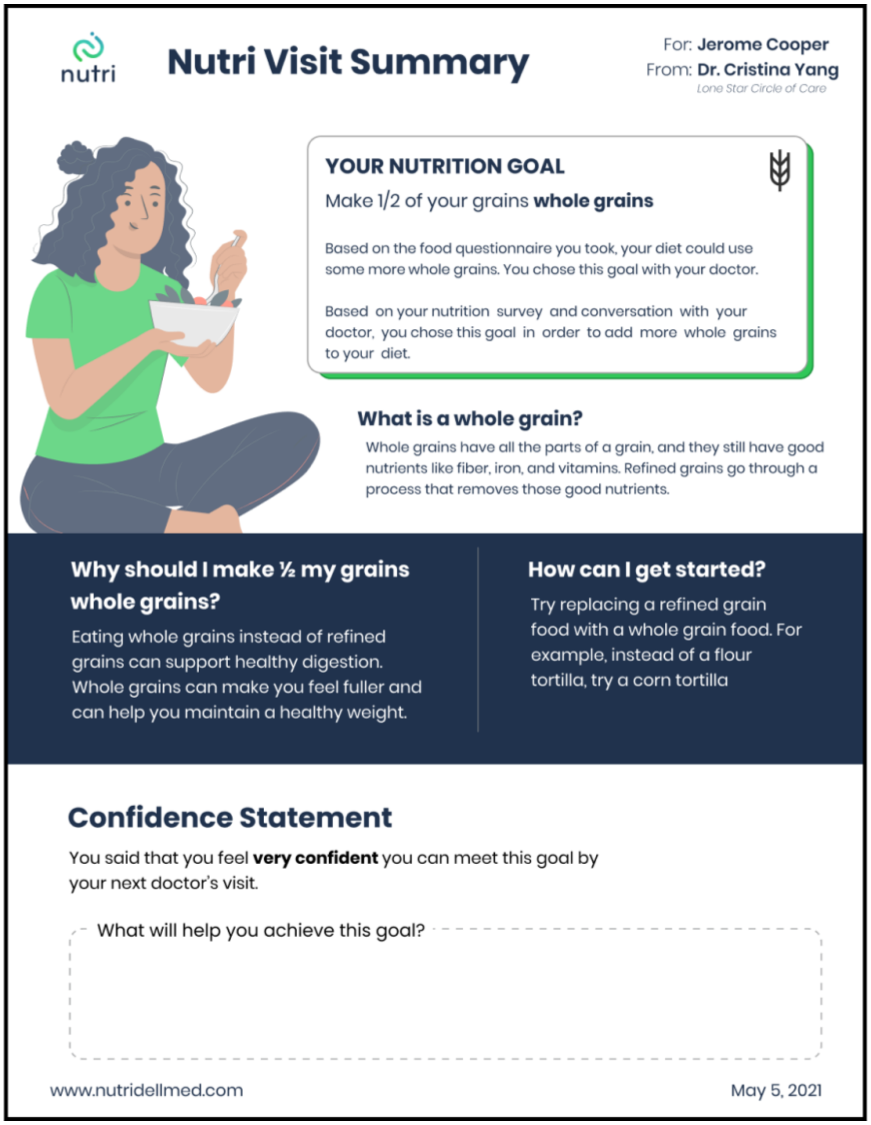


Figure 8: Nutri Interface Iteration 2

Usability Results for Patients

Patients responded favorably to the Nutri handout and described it as a benchmark to monitor their diet goal progress overtime: “This will be like a point of reference where at any time I can go there to check and see if I’m doing the right thing as far as nutrition is concerned.” (Patient 3). Participants liked the collaborative nature of Nutri’s goal setting workflow and stated that they would rely on their PCP to help them understand the different components of the Nutri handout in more detail: “if the doctor gives me a paper like this, um... I would want him to explain to me again what it means” (Patient 3). It is important to note that although the graph depicting goal progress was deemed as helpful, some patients found the visuals and accompanying labels were hard to comprehend. In addition, patients desired more guidance, through recipe ideas and serving sizes, to achieve diet goals: “Instead of a progress report, like we see here, which is the goal and then all of my progress with the vegetables I’ve eaten, maybe more of a more detailed or step driven plan to meet that goal of five cups.” (Patient 6). Thus, we found that although collaborative diet goal setting was perceived positively among patients, the handout could better support next steps to achieve the goal.

In response to these observations, changes were made to support content clarity and comprehensiveness of the handout (figure 9). This included replacing the data visualization with a box highlighting their goal along with motivating and facilitating information to help them reach it. A confidence box was added to promote reflection and motivation. Lastly, the colors were improved and a figure was included to improve the overall attractiveness of the handout.



nutri

Nutri Visit Summary

For: **Jerome Cooper**
From: **Dr. Cristina Yang**
Lone Star Circle of Care

YOUR NUTRITION GOAL

Make 1/2 of your grains **whole grains**

Based on the food questionnaire you took, your diet could use some more whole grains. You chose this goal with your doctor.

Based on your nutrition survey and conversation with your doctor, you chose this goal in order to add more whole grains to your diet.

What is a whole grain?

Whole grains have all the parts of a grain, and they still have good nutrients like fiber, iron, and vitamins. Refined grains go through a process that removes those good nutrients.

Why should I make ½ my grains whole grains?

Eating whole grains instead of refined grains can support healthy digestion. Whole grains can make you feel fuller and can help you maintain a healthy weight.

How can I get started?

Try replacing a refined grain food with a whole grain food. For example, instead of a flour tortilla, try a corn tortilla

Confidence Statement

You said that you feel **very confident** you can meet this goal by your next doctor's visit.

What will help you achieve this goal?

www.nutridellmed.com

May 5, 2021

Figure 9: Patient Handout Iteration

DISCUSSION

We used qualitative methods to explore PCPs' and patients' experiences with and preferences for diet counseling in primary care. Providers and patients valued diet as part of primary care and expressed interest in data-driven conversations about dietary behavior change. However, participants described diet counseling during primary care encounters as hampered by limited time, ad hoc diet data collection, non-specific diet advice, and difficulty with follow up. These findings, along with refinements identified in usability interviews, guided our iterative user-centered design of Nutri, a clinical decision support for data-driven collaborative diet goal setting in primary care.

Prior studies have found that patients have a desire to discuss their diet with their PCP.[131,132] In addition, several studies have demonstrated that providers value and acknowledge the importance of nutrition conversations[133,134]. Our findings expand on these studies by clarifying how patients and providers want to anchor these conversations in data to objectively monitor goal progress over time and improve communication regarding the patient's diet status. This is corroborated in a recent pilot study of a CDS that demonstrated how patient step count data was effective in improving physical activity among low-resource patients who collaboratively set goals with their PCP.[74] Importantly, while the CDS leveraged patients' data for physical activity goals, it relied on patients to simply choose their preference from a static list of diet goals and was not effective in changing diet.[74] This study demonstrates the potential for a CDS to leverage patients' diet data to make nutrition conversations data-driven for improved diet outcomes. Thus, we designed Nutri to facilitate data-driven nutrition conversations via the ASA24 dietary assessment.

The most commonly reported barrier to diet counseling and goal setting as perceived by PCPs is time.[134] Previous dietary behavioral change intervention studies have acknowledged this challenge and have attempted to address it through brief diet assessment questionnaires;[74] however, PCPs are still required to make sense of the data through screeners and/or provider keys.[135] Therefore, although these assessments may speed up the data collection process, determining an appropriate course of action has been reported to increase diet counseling time up to nine minutes.[135] Given that providers only have <2-3 minutes to discuss diet with patients,[55] these assessment tools are inconducive for quick and effective diet goal setting. Therefore, we designed Nutri to synthesize ASA24 dietary recall data via a series of computational rules to automatically present a prioritized list of personalized diet goals. Computerizing this process ensures that time can be spent on collaborative goal setting rather than on the collection and analysis of data.

We found ad hoc diet data collection to be another challenge for effective diet counseling in primary care. Previous studies have indicated that patient-generated data is viewed with skepticism among PCPs, who doubt the patient's ability to correctly report diet data.[136–138] Given the inherent limitations with patient-generated data, including accuracy and reliability, patient forgetfulness, technology literacy, and patients' self-bias,[136] this concern is warranted and may illuminate PCPs reliance on dietary recall interviewing methods instead. Nonetheless, we found that methods practiced among PCPs were non-standardized, subjective, and inconsistent with established dietary recall interviewing strategies. Methods varied among providers and lasted only for a few minutes – just enough time to give them an idea of what the patient is consuming but may not capture a comprehensive picture due to the subjective nature of questioning. Therefore, to improve the objectivity of diet data, it is imperative to use validated dietary assessment tools help PCPs feel comfortable using patient-generated data for it to be leveraged successfully in collaborative goal setting. We are doing this with Nutri by using the validated ASA24 dietary recall, the gold standard of self-reported diet data.[83,139] In addition, several studies have demonstrated ASA24s potential with low-income populations.[139–142] Future research should examine how PCPs and patients perceive this non-conversational data collection method.

Non-specific diet advice was identified as another challenge to providing effective diet counseling in primary care. Several studies have indicated the need for specific and behaviorally tailored goals in order to change diet behavior.[143–145] Our finding that patients desire personalized diet goal recommendations as opposed to generic diet advice supports this. Nevertheless, our interviews with PCPs revealed that the quality and degree of diet counseling may be guided by quick and obvious characteristics, such as BMI, severity of chronic condition, and lab values; resulting in patients with needs not as visible being overlooked. Given the preventative nature of a quality diet, this is a missed opportunity for PCPs to identify diet concerns and act before they develop into life-altering and expensive chronic conditions. Improving the number of patients who receive quality diet counseling, could improve the state of population health with associated benefits for the economic cost of chronic disease. Therefore, we accounted for this in Nutri by including nine tailored dietary behavior change goals with reference values based on the Dietary Guidelines for Americans[146] to make specific and personalized dietary goal setting possible for all patients.

The lack of an effective documentation and follow-up strategy to monitor diet progress over time was highlighted as another challenge for effective diet counseling. PCPs reported that their current workflow consists of documenting the diet conversation in the EHR note; however, this requires the patient to remember what was said once they leave the appointment and initiate dietary self-management. Given that PCPs reported having to discuss the same diet topics in subsequent visits with patients, this strategy is counterproductive. In addition, without a standardized method of reporting a patient's dietary intake, objectively monitoring diet goal progress between visits can be challenging.

To address these challenges, Nutri was designed to generate a patient specific handout at the end of the Nutri workflow to remind patients of their diet goal after the appointment. In addition, Nutri was designed to facilitate automated EHR documentation of diet counseling via pre-populated form fields based on the ASA24 assessment and the PCPs interactions with Nutri. This enables the PCP to participate in effective follow-ups by quickly and objectively comparing a patient's previous goal metric to their most current goal metric in future visits.

The iterative design and evaluation of Nutri helped refine our initial prototype and patient handout for improved PCP and patient usability and satisfaction. Given that time was found to be a major barrier to providing personalized diet counseling,[147] we initially designed the Nutri prototype for maximum efficiency by clearly indicating the highest priority goal at the top of the screen for easy access. However, PCPs' surprising preference for lower-priority goals that they were familiar with revealed that our focus on maximizing efficiency proved futile for goal setting efficacy. Two aspects may explain this observation. First, the lack of content clarity among goal cards, stemming from the inconsistent data visualization, may have added to PCPs cognitive load and thereby induced non-ideal goal selections. Second, the goal cards were designed to quickly inform the PCP of the solution for each goal without sufficiently detailing a justification or explanation for the solution. We found that PCPs instinctually gathered patient information at the beginning of their tasks to support their understanding of the problem and provide an informed recommendation at the conclusion of the visit. Avoiding potential cognitive overload and PCP workflow discrepancies by removing data visualizations to emphasize goal priority, introducing groupings by recommended goals verses achieved (or nearly achieved goals), and reorganizing the content on the cards into problem-solution statements resulted in PCPs selection of higher priority goals.

Similarly, the patient handout was initially designed to clearly indicate the diet goal the patient had selected with their PCP and their current goal status. However, when presented to patents, they were distracted with and expressed confusion regarding the data visualization. In addition, they desired more guidance to achieve their diet goal through recipe ideas and nutrition education. Therefore, simplifying the handout to emphasize the diet goal and including motivating and facilitating nutrition education information improved patients' perceptions of the handout. These results provide a case study for how usability interviews can be leveraged to refine insights captured from traditional qualitative approaches to generate a richer understanding of participant behavior through human-computer interaction.

This study has several limitations. First, we obtained participants from a convenience sample of volunteers rather than a representative sample. An existing interest or background in nutrition could have prompted participants to volunteer. Second, since a researcher was present in both phases on the study, participants may had modified their behavior or opinion of the tool because they were being observed. Lastly, we did not conduct the testing in a natural clinical environment. It is possible that participants may have different opinions and attitudes towards to tool when used in an actual clinical encounter with the added components of time pressure and patient communication. These limitations are commonplace in usability studies.

Conclusions

The results from this study demonstrate the potential of a data-driven CDS for collaborative diet goal setting in primary care. The 2-phase user-centered iterative design process we used to design Nutri demonstrates how usability interviews can refine the operationalization of insights generated from traditional qualitative approaches. Follow-up studies will test Nutri in a clinic setting. By applying CDS to deliver data-driven insight to PCPs we aim to better align dietary interventions with the Chronic Care Model by coordinating self-management and clinical care for improved patient outcomes.

CHAPTER 3: FUTURE DIRECTIONS AND CAREER PLANS

When I started my Nutritional Sciences graduate program at The University of Texas at Austin, I had an interest in how technology could make healthcare more accessible and equitable. This research project has effectively combined this interest with my educational background in Nutrition Science from my undergraduate program. This qualitative study explored PCP and low-resource patient perspectives on Nutri, a novel CDS diet goal setting software, through user-centered design methodologies and revealed themes and insights which have implications for future studies and health technology development.

The results from this study supported the prototype development of a CDS for personalized diet goal setting in primary care. To our knowledge, this is the first CDS study to incorporate shared decision-making principles and data-driven diet goal setting for improved chronic disease prevention and management outcomes. Researchers who are seeking to develop a diet related CDS with these components can use the qualitative insights generated from this study to support the development of their prototype before pursuing software development. In addition, researchers from preventative fields can use this study as an example for how CDS can expand on traditional CDS use cases (i.e., physician prescribing and diagnosing behaviors) to apply CDS to their respective areas of study.

This study revealed an interesting dichotomy between the accuracy of patient-generated and provider collected diet data. Because health technologies are increasingly leveraging patient data to improve clinical forecasts and goal recommendations, obtaining high quality data is imperative to fuel models and algorithms for the analysis of data. Thus, future studies should build upon the themes generated from this study regarding PCP perspectives on and preferences for diet data collection so that this data can be better obtained and ultimately utilized in future interventions. The results from these studies may improve clinical outcomes of diet related health technologies (including CDS) use by expanding on higher-quality dietary data collection methods which are suitable for PCPs to implement in practice.

Applying a 2-phase user-centered design process generated a deeper understanding of our PCP and patient users by building upon the insights obtained from the generative interviews during the usability phase. This highlights the importance of complimenting traditional qualitative methods with user-centered design strategies to deepen a researcher’s understanding regarding their user group. Using this multi-dimensional approach presents the opportunity to further test and refine conclusions and address usability problems to ensure user satisfaction before starting expensive and time-consuming software development. As user-centered design increases in popularity among academic fields, establishing guidelines to standardize this practice may improve the quality of insight generated from studies as well as the transferability of knowledge across research teams.

Over the past two years, I have been grateful to work on the innovative Nutri project. I joined the project when it was in its infancy and have watched it grow from a concept to a fully designed and workable prototype. It has been a rewarding journey that few graduate students can say they have experienced and for that I am extremely grateful. Although I will not be working on Nutri post-graduation, I look forwarding to following along the journey to how see Nutri performs in live testing (testing Nutri under simulating conditions and patient actors) and eventually a full pilot trial with a FQHC in 2022.

Although I entered this program with a strong foundation in nutrition science, this project has enabled me to develop additional skills that will be beneficial as I continue my career. First, I have developed a level of professionalism when it comes to study design and data analysis. Interviewing and surveying participants requires certain level of objectivity to obtain the most accurate results to appropriately support or refute a given hypothesis. This is true of any field from bench work to user research to product development. In addition, with the support and patience of the user experience team, I have learned how to design and prototype using Figma software, a highly transferrable skill to the tech industry. Lastly, this project has introduced me to a range of technology topics including rules engines, machine learning, application programming interface (API), and of course clinical decision support.

Given the multidisciplinary nature of this project, I have also gained several business-related skills which complement my research. Following prototype development, I contributed to the Nutri pitch deck and completed a competitive analysis in preparation to eventually bring this research to market. I created a Nutri presentation deck with marketing language for the team to build and strengthen partnerships with clinics in the area. In addition, by working with a diverse team of researchers, engineers, designers, and stakeholders in weekly and various one-on-one meetings, I have gained an appreciation for effective team collaboration. I learned that the best outcomes result from diverse and supportive teams, with each member sharing their ideas while being open to learn from those who bring a different perspective. In doing this, good ideas can transform into great ones.

My experience in academia has been objective and data-driven. Decisions were supported by rigorous study protocols and existing research in the literature. Unfortunately, this is a stark contrast to how research tends to be conducted in the private sector, where tech products are developed under competing goals and priorities. Thus, as I consider my career, I see myself entering the health tech industry to apply the skills I developed throughout my master’s program to build technology that not only fulfills business objectives, but also enables underserved people to live better and healthier lives. Ultimately, my research, design, and business skills coupled with my desire to collaborate with diverse teams will make me an ideal product manager in this industry. However, my passion for nutrition science and objective lens developed through my experience in academia will complement these skills in a way to support the development of impactful and life changing health technology.

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