Title: Coordinating Pragmatic Primary Care Population Management for Obesity

Clinical Trials Record Number: NCT03998046

Date: 7/1/2020

PROTOCOL TITLE: *Coordinating Pragmatic Primary care Population management for Obesity (C3PO) Study*

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VERSION NUMBER: *6.0*

VERSION DATE: *July 1, 2020*

STUDY SUMMARY:

Investigational Agent(s) (Drugs or Devices)	N/A
IND / IDE / HDE #	N/A
Indicate Special Population(s)	☐ Children ☐ Children who are wards of the state ☐ Adults Unable to Consent ☐ Cognitively Impaired Adults ☐ Neonates of Uncertain Viability ☐ Pregnant Women ☐ Prisoners (or other detained/paroled individuals) ☒ Students/Employees
Sample Size	205
Funding Source	National Institutes of Health
Indicate the type of consent to be obtained	☒Written ☒Verbal/Waiver of Documentation of Informed Consent ☒Waiver of HIPAA Authorization ☒Waiver/Alteration of Consent Process
Site	☐ Lead Site (For A Multiple Site Research Study) ☐ Data Coordinating Center (DCC)
Research Related Radiation Exposure	☐Yes ☒ No
DSMB / DMC / IDMC	☐Yes ☒No

OBJECTIVES:

The purpose of this study is to develop and pretest the feasibility and preliminary effectiveness of a pragmatic approach for population-level obesity management that has a high potential for replication and sustainability in busy primary care settings. This initial study protocol describes the approaches and procedures that will be used to develop and pretest usability of intervention components.

BACKGROUND:

Collectively, heart diseases, stroke, diabetes, and hypertension account for one-third of all deaths in the U.S. and cost more than $300 billion annually.[27,28] Overweight and obesity are reversible health states that are linked with cardiovascular risks and more than 20 other chronic conditions.[14,29] Half of Americans have at least one major cardiovascular risk factor, more than one in three is obese, and an additional third is overweight.[30] Among obese adults, the prevalence of diabetes, hypertension, and dyslipidemia is 14%, 30%, and 34%, respectively, whereas those same conditions affect only 3%, 12%, and 7% of adults with normal body mass.[31] Not surprisingly, recommendations for healthy behavioral changes and weight loss are considered a cornerstone of both public health and health system efforts to address both overweight/obesity and cardiovascular risk.

POPULATION HEALTH MANAGEMENT – AN ORGANIZING FRAMEWORK FOR PRIMARY CARE: Population health management (PHM) is an approach used increasingly by health systems for the strategic deployment of healthcare resources and interventions to systematically address the preventive and chronic care needs of every patient, with the goal of promoting health and reducing the future need for more costly healthcare services.[23,24] PHM involves the coordination of systems, personnel, health IT, policies, and partnerships to enable proactive patient engagement and an expanded focus on health behavior and lifestyle changes.[24,25] Most prior PHM research has focused on preventing excessive healthcare encounters by "super-utilizers," as well as the role of patient-centered medical homes to prevent complications and co-morbidities for persons with complex chronic conditions.[26] Because of the common and chronic nature of overweight and obesity, the PHM approach provides a natural scaffold for coordinating the primary care management of a full population of overweight and obese patients. The proposed study will address prevailing gaps between evidence and practice by engaging patients and other stakeholders in specific steps needed to design and pre-test a pragmatic and generalizable framework for population management of obesity that leverages existing primary care professionals and technologies to support: 1) proactive patient outreach and assessment; 2) weight loss goal setting & action planning; 3) targeted linkages to evidence-driven intensive lifestyle resources in both clinical and community settings; and 4) the integration of self-weighing data to refine both the form and intensity of follow up support services overseen primarily by a nurse coordinator via existing patient portal, telephone, and occasionally face-to-face channels.

STUDY ENDPOINTS:

The primary endpoint for this initial study is to develop a prototype intervention approach for offering evidence-based obesity management services that uses a population health management framework and leverages widely available electronic health record system (EHRS) technologies, existing members of the primary care workforce, and linkages to extant community-based intensive lifestyle intervention resources. *This initial study will involve two phases (Figure 1): Intervention Development and Intervention Evaluation. Intervention Development will use 2 research activities: interviews of healthcare professionals (n=15); patient usability testing (n=10). Intervention Evaluation also involves 2 research activities: a randomized pilot trial of the weight loss intervention (n=80); post-intervention interviews with patients targeted for and exposed to different patient engagement and health promotion interventions (n=20).*

STUDY ACTIVITIES:

Phase 1: Intervention Development

Patient goal setting, brief behavioral counseling, and linkages to intensive lifestyle programs are already part of the practice guidelines for overweight or obese primary care patients with cardiovascular risk factors, our research has been designed to help the Northwestern Medical Group to deploy different available intervention

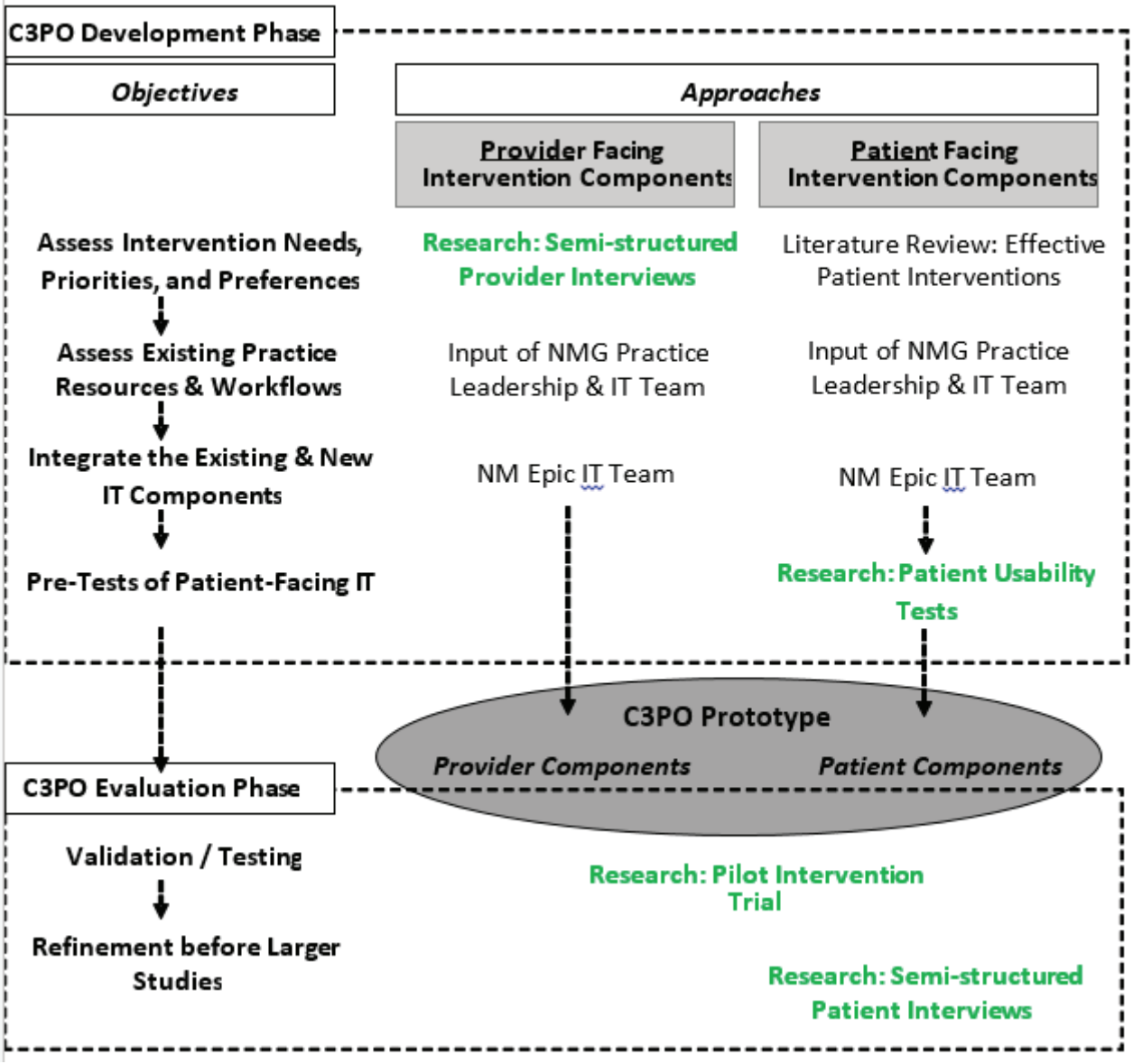
components in ways that prove most engaging to patients and most effective in achieving healthy weight management. The intervention personnel and technologies already exist and are being used to support patient care in many areas. However, we will use several forms of research that pose no more than minimal risk to patients in order to optimize the use of these interventions in busy practice settings.

The goal of the Intervention Development Phase is to use multi-stakeholder input to assist primary care providers within Northwestern Medical Group Primary Care to design and offer a coordinated lifestyle intervention “package” that is engaging to patients and optimally effective in promoting healthy weight management across the entire patient population. Primary care leadership and IT support experts will ultimately make the final decisions about how available intervention components will be used. Our team of communications experts, behavioral scientists, and implementation researchers will use theory and strong research designs to help inform the intervention choices.

Research activities used during the Intervention Development phase include semi-structured interviews with 15 health professionals and usability tests of technology components with 10 eligible patients. The 15 semi-structured interviews with relevant health care providers will assess intervention needs, priorities, and preferences of clinicians. Using this input, the team will combine new forms of support offered by existing health professionals (primarily a care coordination nurse) with technology components used for outreach to patients; supporting patient goal setting; and providing longitudinal support for healthy lifestyle behaviors and weight management that will be guided by use of a cellular-enabled electronic body weight scale that each patient may use in their home to connect information about their progress and weight loss success to the NMG electronic health record. Prior to studying these interventions using a pilot intervention trial in phase 2 of the research, we will conduct limited usability tests of new patient-facing intervention IT components with 10 primary care patients. This phase will likely inform small intervention refinements prior to advancing to the pilot intervention trial.

Phase 2: Intervention Evaluation
The novel combination of existing lifestyle intervention components resulting from phase 1 of the research will subsequently be evaluated using a pragmatic randomized intervention design. The goal of this research is to evaluate the new cluster of interventions, which we call Coordinating Pragmatic Primary care Population management for Obesity (C3PO), among a sample of patients who are representative of all patients who might be offered the intervention in routine practice. Thus, instead of recruiting highly selected research volunteers for the pilot trial, we will use a pragmatic randomization design that will use a “behind the scenes” randomization approach to assign 80 eligible patients to receive Basic Resources and Services for healthy lifestyle support (n=40) or the C3PO pilot intervention (n=40). We will not collect data for research purposes only in this trial. Rather, we will use routinely collected clinical data (i.e. available from the electronic health record) for each patient. Following completion of the 4-month pilot trial phase, we will then recruit and consent 20 patients who were eligible for the intervention to complete semi-structured interviews to assess patient experiences, perceptions, and barriers faced during the intervention period. This final step will help to inform any additional relevant intervention refinements prior to conducting a larger and more definitive future trial of the intervention’s effectiveness.

Figure 1. Development & Pre-Testing of a Novel Intervention for Coordinating Pragmatic Primary care Population management for Obesity (C3PO)



THE INTERVENTION DEVELOPMENT PHASE HAS 4 GENERAL OBJECTIVES:

1) **ASSESS HEALTHCARE PROVIDER PERCEPTIONS REGARDING C3PO INTERVENTION NEEDS, PRIORITIES, AND PREFERENCES**
2) **ASSESS EXISTING RESOURCES & WORKFLOWS**
3) **INTEGRATE EXISTING WORKFORCE, WORKFLOW, AND IT COMPONENTS NEEDED FOR POPULATION HEALTH MANAGEMENT TO BE EFFICIENT AND EFFECTIVE**
4) **PRETEST IT COMPONENTS USING LIMITED PATIENT USABILITY TESTING**

INTERVENTION DEVELOPMENT OBJECTIVES 1 & 2: ASSESS C3PO INTERVENTION NEEDS, PRIORITIES, AND PREFERENCES; ASSESS EXISTING RESOURCES & WORKFLOWS: The C3PO intervention requires both provider- and patient-facing communication and behavioral support tools. The needs, priorities, and preferences of providers for supporting health behaviors, weight loss, and cardiovascular risk factor management of their own overweight and obese patients is not well understood. We will conduct semi-structured healthcare provider interviews with 15 members of the primary care team to elicit these needs and preferences, as well as any recommendations for how best to use existing practice resources and IT to fulfill those needs.

There is an extensive published literature regarding the essential patient-facing components of interventions that are most successful supporting the adoption of physical activity, healthier eating, and weight loss goals

among adult patients. These components have been abstracted from the published literature and will be incorporated into the existing NMG practice IT resources and workflows in ways that are pragmatic and sustainable. These evidence based intervention components, and the proposed process for incorporating them into C3PO is explained below under **Intervention Development Objective 3.**

INTERVENTION DEVELOPMENT OBJECTIVE 3: INTEGRATE EXISTING PRACTICE ACTIVITIES WITH NEW IT COMPONENTS NEEDED FOR POPULATION HEALTH MANAGEMENT TO BE EFFICIENT AND EFFECTIVE: Integration of new intervention components into existing IT resources and workflows will be needed in both provider- and patient-facing directions. Because the population management of obesity and of cardiovascular risk have become priorities of NMG practice leadership, intervention development is not considered a research-only activity, but rather, it is a practice driven priority that will be supported by our research. Thus, all technology development and programming will be led by the Northwestern Medicine Epic IT team, with collaborative input from the local NMG practice leadership and our academic research team.

Provider-facing IT Development: Informed by semi-structured interviews with members of the primary healthcare team, the deployment of C3PO will leverage existing clinical IT and workflows within EpicCare's provider-facing Ambulatory EHRS application. Drawing upon existing population health management tools currently used by NMG providers to support the care of other population groups, such as patients with congestive heart failure, we anticipate that providers will express some need for an overweight/obesity population management dashboard, tools for individual- or batch-outreach communications with patients within this population; and some means to efficiently track and filter the entire overweight patient population based on whether or not patients have achieved specific goals or outcomes relating to weight management or cardiovascular risk. The classification of a group of patients with a particular condition or health risk such as overweight/obesity into a dedicated list that can be used for clinical communications and care coordination is commonly called a patient registry. As NM Epic IT builds such a clinical patient registry for NMG providers, we will work with the Epic IT team to ensure that the needs, priorities, and preferences expressed during semi-structured interviews with providers (below) are considered in the design of these provider-facing intervention development components.

Patient-facing IT Development: Building on extensive prior research, the C3PO intervention will apply evidence-based principles for providing the essential components of effective behavioral weight management interventions, including: 1) Individualized goal setting; 2) Self-monitoring of body weight; 3) Supportive accountability for achieving self-management goals and objectives; 4) Linkages to community or clinical intensive lifestyle support programs; and 5) Targeted, person-centered follow-up support. Technology platforms tethered to the EHRS will help coordinate communication and the delivery of different forms of support between clinical encounters. Existing members of the primary care team will provide support at a minimum level necessary. The intensity of human support will be guided by each patient's decisions about goal setting, their self-weighing behavior, and weekly progress toward their individual weight goal. Supportive communication, the negotiation of individual goals, and targeted problem solving will be facilitated by existing bidirectional messaging and patient survey functions within the EpicCare MyChart patient portal. An existing primary care nurse coordinator will function as a population health management (PHM) nurse, who will manage the outreach messaging with all patients included in the clinical patient registry. C3PO will utilize secure patient-facing EHRS technologies to deliver recommendations of the patient's own primary care provider via the practice team's PHM nurse. For patients who request additional information or assistance in goal setting or decision making, the PHM nurse will offer a telephone or face-to-face encounter as an alternative. The planned approaches for supporting goal setting, self-monitoring, and intensive intervention linkages are described further below.

1) **Individualized Goal Setting:** Even in the presence of strong external support, adherence to a particular behavior is unlikely unless one understands the reasons for the behavior and has explicit expectations about the intended goal(s).[13] Providing support for goal setting involves helping a patient to articulate a clear expectation for which he/she will feel committed and accountable.[78] The C3PO intervention will stimulate goal setting among eligible patients by using semi-automated outreach messages that are delivered via EpicCare's MyChart patient portal. Outreach messages will adopt

components of the 5Rs of tobacco cessation to briefly frame the relevance, risks, and rewards of lifestyle changes leading to modest weight loss.[79,80] Using MyChart's branching logic survey function, patients will then be guided through the steps of a brief action planning procss,[68] which are rooted in principles of brief motivational interviewing.[66,70]

Patients will be asked routinely if there is anything they would like to begin doing now to try to reach a lower body weight. Patients who are not ready to begin doing something now will be asked if it is okay for the PHM nurse to check back in a few weeks to assess if their interests have changed. Patients who do indicate readiness will be guided through simple steps to set a SMART goal (Specific, Measurable, Achievable, Relevant, and Timed) for weight loss. Brief probing questions will guide development of this goal, and individual patient responses will be stored in the EHRS. The branching logic of each step will automate the bulk of this process for most patients, while preserving a patient's perspective that he/she is communicating directly with the PHM nurse, who is working with his/her own PCP. Based on individual patient responses at each step, the branching logic will trigger a specific next step of validation, motivational messaging, and additional brief questioning, which are guided by the patient's level of readiness and perceived self-efficacy. For example, individuals who indicate needing suggestions for a goal will be presented with two to three ideas that "other patients have told us are very helpful." If this helps the individual choose a goal area, the questionnaire will then confirm a commitment statement, for example: "Just to make sure we understand your plan correctly, you want to X. Is that correct?" After confirming the commitment, the patient will be asked about their confidence with reaching the goal. Those expressing high confidence will be given encouragement and asked about their preference for when we should check in with them again. Patients with only modest or low confidence will be asked if they have ideas about what might raise their confidence. Patients with low confidence will receive reassurance and an offer for a telephone call from the PHM nurse to discuss steps to help build their confidence.

2) **Self-monitoring of Body Weight:** Prior research suggests that process accountability (e.g. accountability over self-weighing) increases completion of a target behavior even more than outcome accountability alone (e.g. accountability over achieving a weight loss goal).[13] Self-weighing is a form of behavioral self-monitoring that past research has found to be strongly predictive of weight loss success.[12] C3PO will provide each patient with a BodyTrace electronic scale (eScale), which transmits weight data wirelessly to a secure, private repository using digital mobile telecommunications technology (i.e. the same cellular networks as a smartphone). The manufacturer reports accuracy within +/-0.1 kg to a weight limit of about 150 kg (330 lbs.).[81] This approach, used in prior research by our group,[82] also enables the seamless integration of self-weighing information back into the EpicCare EHRS (i.e. back to the registry as well as to the PHM nurse). This integration will allow dynamic individualized feedback from the nurse back to each patient in a way that further strengthens supportive accountability and progress toward weight goals. More details are provided below.

3) **Supportive Accountability for Achieving Self-management Goals and Objectives:** Nurse-patient interactions, largely facilitated by the patient portal, will be designed to strengthen each patient's commitment toward their goal, as well as a greater sense of "**supportive accountability**." Accountability toward a behavior exists when an individual has an expectation that he/she may be called upon to justify his/her actions or inactions to another person.[13] Accountability requires real or perceived social interactions with another human (i.e. a coach) who the patient views as trustworthy and possessing suitable expertise. This relationship may be established in person, by telephone, or via an electronic channel. C3PO will utilize secure patient-facing EHRS technologies to deliver recommendations of the patient's own primary care provider via the practice team's PHM nurse. For patients who request additional information or assistance in goal setting or decision making, the PHM nurse will offer a telephone or face-to-face encounter as an alternative. The planned approaches for supporting goal setting, self-monitoring, and intensive intervention linkages are described further below.

4) **Linkages to Evidence-based Lifestyle Interventions**: Once patients have set a goal and begun using their eScale, the PHM intervention will utilize MyChart messaging to offer a selection of links to

available lifestyle programs and services, with brief summary information about benefits and attributes to help in making choices among them, or to facilitate a request for additional information or assistance from the PHM nurse. Based on the key characteristics of evidence-based intensive lifestyle programs,[12,14] we have identified an array of extant lifestyle interventions to include in a menu of initial program choices for each patient.

5) **Targeted, Person-centered Follow-up Support:** The PHM framework attempts to provide basic support to all patients and uses "lighter touches" with patients who are engaged and having success; more intensive support is reserved for patients who are less successful. C3PO will use the frequency and results of self-weighing to stratify patients to different forms of support. Immediately after a patient sets a weight goal, the PHM nurse will ship him/her an eScale and welcome package, including additional support materials and instructions for initializing the scale and registering a first body weight. If there is no weight received from the eScale within 1 week, the patient will receive a short message offering assistance or to talk to the nurse for help troubleshooting technical issues or revisiting action planning steps if engagement has diminished. Patients who do register their first weight will receive a MyChart message offering praise and relisting a short menu of linkages where the patient can find further information about evidence-based community programs. All messages will also offer an option of telephonic support from the PHM nurse.

   After the eScale is initialized and weight #1 is received, each patient will be classified weekly by their frequency of self-weighing (i.e. weekly vs. less than weekly) and whether they do/don't meet or exceed their target weight for the week. Patients who continue to self-weigh but who are not at their progress goal will receive an automated MyChart message praising them for their self-weighing and summarizing their weight loss progress. They will be offered additional help and the opportunity to speak directly with the PHM nurse to identify barriers and reassess and refine their action plan if desired. Patients who request different lifestyle resources will be given information about other linkages, such as a nearby fitness facility that offers intensively support programs as well as access to registered dietitians who provide medical nutrition therapy with direct payment by most commercial payers in our region.

   Patients who are continuing to self-weigh and who are reaching or exceeding the progress target for their individual weight loss goal will receive a MyChart message summarizing weight loss progress, along with praise and positive feedback to reinforce actions and behaviors that are helping. Links to community and clinical resources to provide ongoing support will again be listed. The timing and exact content of these messages will be developed and refined during the first 6 months of intervention delivery, with input from clinicians, patients, and behavioral and communications experts who comprise the research team.

INTERVENTION DEVELOPMENT OBJECTIVE 4: PRETESTS OF PATIENT-FACING IT COMPONENTS:

RESEARCH ACTIVITIES TO INFORM INTERVENTION REFINEMENT AND PRE-TESTING

Research Activity #1: Conduct 15 semi-structured interviews with relevant health care providers to assess intervention needs, priorities, and preferences of clinicians.

Research Activity #2: Conduct limited usability tests of new patient-facing intervention IT components with 10 primary care patients to inform any necessary refinements needed to enhance the human-IT interaction prior to advancing to a future pilot trial evaluation of the integrated intervention.

PROCEDURES INVOLVED:

Research Activity #1: Stakeholder interviews with primary care professional staff will be framed as a discussion about experiences with primary care services and electronic communication tools to support weight mangagment by primary care patients. Interviews will be recorded with a digital voice recorder and transcribed verbatim by an experienced transcriptionist. Interviewees will also be asked to complete a basic sociodemographic form. The provider interview guide and sociodemographic form are as follows:

INTERVIEWER NOTE: TURN RECORDER ON

Background & Objective:

Why we are doing interviews:

We are interested in whether new technologies and communication tools that are linked to the Epic EHR can help primary care teams support their patients' goals around healthier eating, physical activity, and weight loss. Before studying whether these technologies will work, we want to ensure that they benefit the healthcare team and are easy and efficient to use. They also should fit into existing practice workflows not interfere with other functions of different members of the care team.
The purpose of this interview is to gather insights from healthcare professionals like you to both better understand your current work flow, as well as obtain your opinions as to how the addition of new technologies could help you manage your patients without generating additional work for the care team.

Current Workflow
The following questions relate to your roles and the current workflow in the primary care relevant to supporting weight loss and management among the patients you serve.

1. **What is your role in supporting healthy eating, exercise, and weight loss by your patients?**

   PROBE: What are the roles of other team members? For example, Nurses? Medical Assistants? Care Coordination Nurses? Other members of the care team?

2. **In your opinion, what have you found to be most motivating for your patients to help them achieve…**

   Healthy eating?
   Exercise?
   Weight loss?

3. **How does the care team communicate with each other, if at all, regarding healthy eating, exercise and weight loss relevant to patients in need of these services?**

   PROBE: How do care team members communicate verbally, via documentation in Epic, or through other channels?
   PROBE: What are existing challenges related to these communication channels?
   PROBE: What suggestions or thoughts do you have based on your experiences that you think could overcome the challenges you identified?

4. **What is the role of other resources and services available to patients of Northwestern Medicine? (Such as referrals to services like, SEE BELOW)**

   PROBE: The Northwestern Medicine Health Learning Center?
   PROBE: The Northwestern Medicine Lifestyle Medicine Clinic?
   PROBE: Other resources and services in the community? (i.e. DPP, Weight Watchers)

Overview of the Intervention:
The goal of this intervention is to use existing Epic platforms and remote intervention technologies to improve goal setting, self-weighing, and ongoing support for overweight and obese patients while MINIMIZING any additional work for members of the primary care team. We plan to do this by reaching out to eligible patients

via an automated MyChart message, sending them a wireless eScale that transmits weight data back into Epic, and providing tailored support through automated MyChart messaging with support from a nurse care coordinator (like "STAFF NAME") over a 10-week period.
We'd like to get your initial impressions on the implications for the practice and recommendations for a successful rollout of this intervention.

5. **What, if anything, do you foresee as being potential barriers to implementing this intervention?**

   PROBE: What challenges, if any, do you think we might face in implementing this intervention?
   PROBE: For example, a patient may message physicians directly in response to outreach messaging, how might we prepare the practice so this is not a problem?

6. **How would you recommend we introduce this to the practice to make sure the broader care team is aware of this intervention when it goes live?**

7. **Our intervention plans to collect weight loss goals and patient weights every time they step on the scale, and goal setting progress. Which of these data would you want to see?**

   PROBE: What is your preferred method for viewing/receiving these data (i.e., weight graphs, total amount of weight lost, most recent weight prior to primary care visit) and how often?

Wrap-up:

8. **Is there anything else you think we should know or consider regarding how to support primary care teams to assist patients in increasing their physical activity, eating better, or losing weight?**

9. **Is there anything else I didn't ask you today that you'd like to comment on?**

Thank you for your time.

INTERVIEWER NOTE: TURN RECORDER OFF, COLLECT DEMOGRAPHIC INFORMATION, PROVIDE PARTICIPANT COMPENSATION AND COMPLETE *form

SOCIO-DEMOGRAPHIC SURVEY

1. Are you…

   ☐ Male ☐ Female ☐ Transgender ☐ Prefer not to respond

2. What is your specific title: _____

3. Year you completed training: _____

4. Year you began current employment at Northwestern:_____

Research Activity #2: Each patient participant (n=10) will take part in a 60 to 90-minute videotaped session during which they will go through all steps of the logging in, opening the MyChart message, entering responses to the goal setting / action planning survey prompts, and navigating community resource links and other associated patient decision support. Mr. Kaiser and Dr. Ackermann will facilitate and observe all usability testing, noting preferred navigation paths and the nature of any errors or sources of confusion. Noldus software will record user-system interaction (i.e., logging mouse click, keystrokes) and will organize the data and analyses. After the first three participants, Dr. Ackermann and Mr. Kaiser will meet with the Epic programmers to review key findings and refine the system interfaces to enhance usability. After the second wave, any remaining enhancements to optimize workflow integration will be made before launch of the future pilot trial.

THE INTERVENTION EVALUATION PHASE HAS 2 GENERAL OBJECTIVES:

1) **CONDUCT A PILOT INTERVENTION TRIAL ASSESSING FEASIBILITY AND PRELIMINARY EFFECTS SIZES FOR THE IMPLEMENTATION STRATEGY/INTERVENTION.**
2) **REFINE INTERVENTION IMPLEMENTATION APPROACHES PRIOR TO DESIGNING A FUTURE MORE DEFINITIVE EFFECTIVENESS TRIAL**

INTERVENTION EVALUATION OBJECTIVE 1: CONDUCTING THE PILOT TRIAL: The pilot trial will include 2 general research activities that are designed to assess feasibility and preliminary reach and effectiveness of the intervention implementation approaches. Findings of the evaluation will be used to inform intervention refinements prior to designing and conducting a future larger scale effectiveness trial.

RESEARCH ACTIVITIES INCLUDED DURING THE PILOT TRIAL:

Research Activity #3: For the pilot intervention trial, each patient participant will be randomized to receive either Basic Resources and Services or the C3PO intervention. Patients assigned to Basic Resources and Services (BRS) will receive approaches 1-4 described in detail above in **Objective 3, "Patient-Facing IT Development**" which include 1. Individualized goal setting, 2. Self-monitoring of body weight, 3. Supportive accountability for achieving self-management goals and objectives and 4. Linkages to evidence-based lifestyle interventions. Patients assigned to C3PO will also receive BRS approaches 1-4 described above as well as approach 5. Targeted, person-centered follow up support. From among all patients who are deemed eligible but who are not recruited, a no-intervention comparison group of 80 additional patients also will be selected for additional comparisons. Routinely collected clinical data for participants will be analyzed after trial completion.

Research Activity #4: After the pilot phase, 20 semi-structured interviews will be completed by the study team with eligible patients to assess patient experiences, perceptions, and barriers faced during the intervention period.

SHARING RESULTS WITH PARTICIPANTS

Study results and individual participant results will not be shared with participants or anyone else. Only the PI can give permission for the release of aggregated study data. No confidential information will be released without the expressed written consent of the study participants.

STUDY TIMELINES

Table 1. Timeline for Steps of Intervention Development

Milestone	Q1	Q2	Q3	Q4
Weekly meetings of core research team	X	X	X	X
Kick off presentation at practice monthly business meeting	X			
Biweekly meetings with practice director and population health nurse	X	X		
Clinical provider interviews (n=15)	X	X		
Focused pretesting of outreach message content with patients		X	X	
Finalize language of outreach messages & action planning algorithms			X	
Programming of action planning items for collection in the EHRS patient portal			X	
Usability tests of patient-facing survey navigation and goal setting functions (n=10)			X	X
Assist NMG Epic IT to integrate health IT into their OW/OB patient registry	X	X		
Complete integration of electronic Scale data feeds into registry		X	X	
Develop patient registry tracking dashboard for PHM nurse view		X	X	
"Dry" runs of all health IT components with dummy patients				X

INCLUSION AND EXCLUSION CRITERIA FOR EACH RESEARCH ACTIVITY

Research Activity #1: With approval of the NMG practice director, 15 primary care professionals will be recruited as participants, including the PHM nurse, practice administrators, physicians, and other primary care team members (e.g. nurses; health educators). Inclusion and exclusion criteria are as follows:

Table 2. Inclusion and Exclusion Criteria for Professionals Completing Interviews

Inclusions	Exclusions
Staff members **employed at Northwestern Medical Group (e.g. MD, NP, PA, health educator, care manager, practice administrator) involved in the management** of cardiovascular risk data collection and o**besity management**	NMG staff involved in protocol development

Research Activities #2, #3, and #4: With approval of the NMG practice director, eligible patients will be identified by an NMG clinical data manager performing an electronic health record data query. The query will identify patients who meet the eligibility criteria for the clinical weight management services, as detailed in Table 3 below. In this development and preliminary evaluation phase, patients targeted for the clinical services will have had 1 or more routine (non-urgent) visits to the NMG primary care practice and will have an active MyChart account with one or more log-in attempts within 12 months. Body mass index (BMI) will be determined using the last available height and weight (must be within 12 months). BMI is calculated as (weight in kg) ÷ (height in meters)^2. CVD risk conditions will be determined by evidence of one of the following: 1) a diagnosis of hypertension, hyperlipidemia, diabetes, or prediabetes (i.e. one or more ambulatory encounter with an ICD encounter diagnosis code or active problem specifying either type 2 diabetes, prediabetes, hypertension, or abnormal blood cholesterol); 2) an active prescription drug order for an antilipidemic class medication, long or intermediate acting insulin analog, or oral antiglycemic medication. Pregnant women will be excluded from the study, as participation involves setting a weight loss goal, which may not be medically appropriate for all pregnant women.

Patient usability testing of technology components (Research Activity #2) will occur before the pilot trial. The clinical database manager will draw names randomly from the patient eligibility list for the clinical service (Table 3), and patients will be recruited until 10 patients have completed the usability tests.

The pragmatic trial (Research Activity #3) will be completed following development and usability testing of the new intervention technology components. The pragmatic trial will target all patients eligible for the clinical service (Table 3). All patients meeting these eligibility criteria who open an outreach MyChart message that offers the intervention components and who indicate their interest in receiving weight management support from the clinical team will be included in the evaluation until 80 patients have been accrued. From among all patients who are deemed eligible but who are not recruited, a no-intervention comparison group of 80 additional patients also will be selected for additional comparisons.

Semi-structured interviews (Research Activity #4) will be conducted at the conclusion of the trial. To identify participants, the database manager will draw names randomly from the pragmatic trial recruitment list (regardless of their response to the MyChart message or their use of intervention resources/materials) until 20 patients have completed the interview.

Table 3. Inclusion and Exclusion Criteria for Patients Completing Usability Tests and Semi-structured Interviews

Inclusions	Exclusions
Age 18 or older	Evidence of hospitalization in past 30 days
BMI ≥27 kg/m2 plus	Most recent blood pressure >180/105
≥1 CVD risk condition (hypertension, dyslipidemia, prediabetes, or type 2 diabetes)	Cancer (non-skin) treatment within the past 2 years
Registered in EpicCare's MyChart patient portal, with 1 or more log-on episodes in the past 12 months	Encounter diagnosis for hypoglycemia in past 30 days
	Actively receiving care from the bariatric surgery service or a bariatric medication order in the past 100 days
	A medication order in the past 100 days that is known to cause weight change or prevent weight loss (e.g., >21 day supply of oral glucocorticoid, atypical antipsychotic, or bariatric medication)
	Unable to provide consent Unable to understand English sufficiently to complete the informed consent process or follow instructions needed to complete usability tests
	Individuals who are not yet adults (infants, children, teenagers) Pregnant women Prisoners

PARTICIPANT POPULATION(S)

A non-intervention group of 80 participants, described above in "Research Activity #3" under the STUDY ACTIVITIES section, has been added, increasing the total targeted accrual number to 205.

Targeted Accrual Numbers	Category/Group: (Adults/Children Special/Vulnerable Populations)	Consented: Maximum Number to be Consented or Reviewed/Collected/Screened	Enrolled: Number to Complete the Study or Needed to Address the Research Question
Local	Adults: 205 Children/Vulnerable: 0	Adults: 45 Children/Vulnerable: 0	Adults: 205 Children/Vulnerable: 0
Other Sites Study-wide	Adults: 0 Children/Vulnerable: 0	Adults: 0 Children/Vulnerable: 0	Adults: 0 Children/Vulnerable: 0
Total:	Adults: 205 Children/Vulnerable: 0	Adults: 45 Children/Vulnerable: 0	Adults: 205 Children/Vulnerable: 0

RECRUITMENT METHODS

Research Activity #1: After securing approval from the NMG practice operations director and quality committee to proceed with recruitment, the PI will obtain from the operations director a list of all practice employees who are involved in the care of overweight or obese patients. Working off this list, 15 professionals from Northwestern Medical Group will be recruited. Recruitment efforts will target a broad mix of professionals, including the population health management (PHM) nurse, practice administrators, physicians, and other primary care team members (e.g. nurses; health educators). Practice leadership will not be involved in recruitment efforts aside from providing the initial list of staff members.

Study team members will visit the NMG primary care clinic and present details of the study to the practice leaders and medical staff during a weekly practice business meeting. Interested providers can sign up to be

contacted for participation. After this meeting, the providers and staff will also receive an email (example below) from the study project manager, describing the research once again, identifying Dr. Ackermann as the PI, and inviting their participation. Providers who do not reply to the email will be phoned (script below) as an alternative approach to confirm interest and proceed with scheduling. Volunteers will be offered $75 to complete the interview. Research staff will assist the volunteers to schedule the interview in a private location at or near the clinical practice site and at a time and date that is mutually convenient. A template and phone script for provider recruitment materials can be found appended to the protocol.

Research Activity #2: Ten overweight or obese patients with at least one cardiovascular risk factor will be recruited for limited usability testing of new patient-facing technologies to support weight loss. With approval of the NMG practice director, eligible patients will be identified by an NMG clinical data manager performing an electronic health record data query. The query will identify patients who meet the eligibility criteria in Table 3 above, who have had 1 or more routine (non-urgent) visits to the NMG primary care practice, and who have an active MyChart account with one or more log-in attempts within 12 months. The clinical data manager will randomly select and generate a shorter list of 40 eligible patients from the complete eligibility list, attempting to target patients who are already scheduled for an upcoming non-urgent healthcare visit with their primary care provider. Identifying patients who have upcoming visits will be done because scheduling the usability test in conjunction with an upcoming clinical visit may be desirable to some patients to minimize the burden of traveling back to the clinic for the research procedure alone. After generating this shorter list, the clinical database manager will follow a standard process for patient recruitment approved by the NMG primary care practice site by sending a MyChart staff message to each primary care provider (PCP) of those 40 patients. PCPs will be notified via Epic email regarding which of their patients are eligible and will be given the option of excluding any specific patient(s) from being recruited. PCPs will be given 5 days to respond to Epic message to exclude a patient. No response will be considered assent to recruit patient. This is a standard protocol that the NMG practice has approved, as it provides sufficient advanced notification to providers, with the ability to exclude any patients as needed, while presenting minimal administrative burden to provider's existing workload.

Once eligible patients are identified, an opt-out recruitment letter will be mailed to eligible patients with a number to call to remove themselves from further recruitment contacts.

Five days following mailing the letter, study staff will call patients who have not opted-out to explain the nature of the project and the procedures for the study. To be included in the study, participants must be willing to undergo screening.

Research Activity #3: For the pilot intervention trial, 80 overweight or obese patients with at least one cardiovascular risk factor will be recruited. With approval of the NMG practice director, eligible patients will be identified by an NMG clinical data manager performing an electronic health record data query. The query will identify patients for the clinical weight management services, as detailed in Table 3 above. Based on these criteria defining whom to target with the new clinical services, patients included in the evaluation will reflect the entire target group, having had 1 or more routine (non-urgent) visits to the NMG primary care practice, and who have an active MyChart account with one or more log-in attempts within 12 months. The clinical data manager will randomly select and generate a shorter list of 100 eligible patients from the complete eligibility list, attempting to target patients who completed a recent clinic encounter (in the preceding 1 to 3 week period). After generating this shorter list, the clinical database manager will follow a standard process for patient recruitment approved by the NMG primary care practice site by sending a MyChart staff message to each primary care provider (PCP) of those 100 patients. PCPs will be notified via Epic email regarding which of their patients are eligible and will be given the option of excluding any specific patient(s) from being recruited. PCPs will be given 5 days to respond to Epic message to exclude a patient. No response will be considered assent to recruit patient. This process will be repeated every 2 weeks until target enrollment goal (n=80) is reached. This is a standard protocol that the NMG practice has approved, as it provides sufficient advanced notification to providers, with the ability to exclude any patients as needed, while presenting minimal administrative burden to provider's existing workload.

Once eligible patients are identified, a recruitment message will be sent via Epic MyChart inviting patients to complete a MyChart survey assessing weight loss interest and goal setting as described above in ***Patient-facing IT Development***. All eligible patients who receive the MyChart message and affirm their weight loss interest and goals will be included in the pragmatic evaluation sample and randomized.

For the no-intervention comparison arm, patients will be identified from the list of approximately 1,800 remaining patients who were deemed eligible but not yet recruited before all 80 pilot intervention patients are accrued. From this list, we will select 80 patients with similar age and sex characteristics as trial participants. Patients in this no-intervention comparison group will not be contacted, will receive no intervention, and only their routinely collected clinical data will be used for the retrospective comparison evaluation (i.e. the same existing clinical data elements used to assess outcomes for the trial groups), so they will not receive contact or specific recruitment materials. Detailed information about consent and HIPAA waivers is described below in "CONSENT PROCESS" section

Research Activity #4: For the semi-structured interviews, the database manager will draw names randomly from the pragmatic trial recruitment list until 20 patients have completed the interview. After obtaining approval from the primary care provider, a research assistant (RA) will send a lead letter by email to patients and then contact each patient by phone between 8 and 12 weeks after being sent their initial MyChart message. Purposeful sampling will be used to ensure that the sample is representative of between 5 and 10 patients who did not complete the goal setting step and 10 to 15 patients who did complete that step. Phone interviews will be conducted for both patients who did not complete the goal setting step and patients who did complete the goal setting step. The RA will explain the research and assist interested participants to provide informed consent prior to completion of a one-time interview.

COMPENSATION FOR PARTICIPATION IN RESEARCH ACTIVITIES

Research Activity #1: Each volunteering health care professional (n=15) will be compensated $75 for their participation in a 60 minute interview. Health care professional participants will be paid in the form of a Visa gift card. Research Activity #2: Patient participants (n=10 patients) will be reimbursed $75 for their participation in a 60-90 minute usability test. Patient participants will be paid in the form of a Visa gift card. Research Activity #4: For phone interviews, each patient participant will be compensated $25 for their participation in a 20 minute interview. For in-person interviews, each patient participant will be compensated $75 for their participation in a 60 minute interview. Patient participants will be paid in the form of a Visa gift card.

WITHDRAWAL OF PARTICIPANTS

Participants may withdraw from the study at any time. There are no specific criteria for administratively removing a patient from the study. However, a patient will be removed if continued participation is determined by the PI to constitute a danger to the patient's health or well-being. The PI and study staff will perform all necessary evaluations. If the PI determines the patient must be removed from the study immediately, the patient will be removed and all appropriate referrals will be made. The IRB will be informed.

RISKS TO PARTICIPANTS

Research Activity #1: It is possible that some interview topics relating to how different members of the NMG clinical staff support weight management and healthy lifestyle behaviors of their patients could be frustrating for an employee to discuss. Any participants who have an adverse reaction to discussing sensitive topics during in-person interviews will be comforted, allowed to stop the interview, and referred for further support, if requested, by medical providers in primary care or in employee health at NMG. All clinical provider participants who complete the consent process will be informed that participation may result in a loss of privacy, since persons other than the investigators may view their study data if deemed necessary for oversight purposes. However, they will be informed that their NMG employers, supervisors, and practice leadership will only receive information about the general conclusions of all interview findings, in aggregate; no individual interview audio recordings or the transcription of these activities will be shared beyond the research team, except if

required by regulatory oversight bodies. Even though our study will store all data on secure, password protected, Northwestern University network drive folders, all audio files will be destroyed once the research is completed.

Research Activity #2: It is possible that discussing sensitive topics such as body mass can sometimes be distressing to some patients. Usability tests also may cause distress or stigma for some individuals who feel uncomfortable being directly observed in their work roles. All participants who complete the consent process will be informed that participation may result in a loss of privacy, since persons other than the investigators may view their study data if deemed necessary for oversight purposes. However, they will be informed that their health care providers and NMG practice leadership will only receive information about the general conclusions of the usability testing, in aggregate; no individual interview video recordings or the transcription of these activities will be shared with care providers at the clinic who are not part of the research team, except if required by regulatory oversight bodies. Even though our study will store all data on secure, password protected, Northwestern University network drive folders, all video files will be destroyed once the research is completed.

Research Activity #3: It is possible that completing a survey on weight loss, engaging in weight loss goal setting, and/or weight loss activities can sometimes be distressing to some patients. All participants will be provided with the option of speaking with their primary care provider or another member of their health care team about their questions or concerns when completing the MyChart survey and when receiving all additional outreach and follow up messaging via My Chart.

Research Activity #4: It is possible that discussing sensitive topics such as body mass can sometimes be distressing to some patients. Any participants who have an adverse reaction to discussing sensitive topics during in-person interviews will be comforted, allowed to stop the interview, and referred for further support, if requested, by medical providers in primary care. All participants who complete the consent process will be informed that participation may result in a loss of privacy, since persons other than the investigators may view their study data if deemed necessary for oversight purposes. However, they will be informed that their health care providers and NMG practice leadership will only receive information about the general conclusions of the interviews, in aggregate; no individual interview recordings or transcription will be shared with care providers at the clinic who are not part of the research team, except if required by regulatory oversight bodies. Even though our study will store all data on secure, password protected, Northwestern University network drive folders, all video files will be destroyed once the research is completed.

All research staff who participate in patient usability tests and provider and patient interviews will have completed human subjects training, including sensitivity regarding the potential for survey procedures or direct observation to cause anxiety and other forms of emotional adverse effects. Staff members will be trained by the PI to recognize discomfort and to ask periodically “if it is okay to continue.” Patient participants who become visibly upset or who express the desire to stop will be asked whether the tests are causing them to feel uncomfortable. Any participant who expresses upset or anxiety will be asked if they prefer to stop the test. Participants who stop prematurely will still be compensated and thanked for their time. Those who terminate the test early or who state at the conclusion that the tests were upsetting will be asked if they wish to speak to Dr. Ackermann or to another healthcare provider from the clinic. Patients requesting additional emotional support will be offered immediate full clinical services of the Northwestern Medical Group.

Measures to decrease risk will involve conducting all provider/staff/patient interviews and patient usability tests in a private and discreet fashion and giving persons an opportunity to ask questions or voice concerns. All participants who complete the consent process will be informed that participation may result in a loss of privacy, since persons other than the investigators may view their study data if deemed necessary for oversight purposes. However, they will be informed that only general conclusions about the aggregate results of our research will be shared with other health providers, NMG leadership, or supervisors; no individual audio or video recordings or the transcription of these activities will be shared with anyone who is not part of the

research team. Even though our study will store all data on secure, password protected, Northwestern University network drive folders, all audio and video files and other identifying information will be destroyed once the research is completed. In compliance with guidelines for comparative effectiveness trials, we will also establish an internal data and safety monitoring plan to ensure the safety of study subjects. Protections against these risks are described further below. (see ***Data and Safety Monitoring Plan*** below).

POTENTIAL BENEFITS TO PARTICIPANTS

The proposed study has the potential to improve community and healthcare clinical strategies for cardiovascular health promotion and disease prevention for a large number of overweight and obese adults. The interventions are designed to build capacity, improve practice, and enhance overall population health.

The health IT and primary care delivery system interventions under evaluation will be designed to address a critical gap in health care delivery systems and has great promise for expanding the reach and effectiveness of health promotion efforts involving the coordination of clinical and community resources and services to address overweight and obesity. Our evaluation will provide critical information for stakeholders to help them make more informed decisions about whether it is feasible and effective to use existing new technologies in the management of overweight and obesity to improve the prevention and care for adults cardiovascular risk conditions.

For patients, the study will help to answer whether it is worthwhile to conduct additional research regarding novel interventions that use health IT to provide new information, referrals, and feedback about health promotion resources across clinical and community settings to improve knowledge about community resources, increase goal setting, support behavior change, and result in greater weight loss success.

DATA MANAGEMENT AND CONFIDENTIALITY

Best practices will be employed by investigators and study staff to protect the integrity of the data. The participant tracking database will use Research Electronic Data Capture (REDCap) through a FSM computer with secure wireless VPN connection to Northwestern servers. Once the study is complete and data have been collected and passed the audit process, the research manager will make the data available to the PI and Co-Investigators. Only copies of the finalized data will be released so that original data can remain untouched.

Interviews with primary care professionals will be digitally audio recorded and then transcribed verbatim by an experienced, externally contracted transcriptionist. Content analysis of transcripts will be used to code small portions of the text representing unique concepts. Methods of open and axial coding will be employed to analyze the data. Digital audio files of interviews collected will be kept on a password-secured computer with the study ID as the identifier. After completion of the study, the digital audio tapes will be deleted. All participants will be identified by an identification number and not by a name in the research database and in the digital audio files, so that their identity and personal information will be kept as confidential as possible.

For usability tests, Noldus software will record user-system interaction (i.e., logging mouse click, keystrokes) and will organize the data and analyses. Digital video files and transcripts of usability tests, and digital audio files and transcripts of provider interviews, will be stored under a filename identified by a coded studyID (not a participant's name) on a password-secured Northwestern University network folder. Participant names, contact information, any other personal identifiers, and a key file linking those identifiers with coded studyID's will be stored in a separate password-secured file folder. After completion of the study, all digital files will be deleted.

Interviews with patients will be digitally audio recorded and then transcribed verbatim by an experienced, externally contracted transcriptionist. Participants will receive a lead letter with the option to opt out of phone recruitment. Interviewers will conduct all phone interviews in a private space. Content analysis of transcripts will be used to code small portions of the text representing unique concepts. Methods of open and axial coding will be employed to analyze the data. Digital audio files of interviews collected will be kept on a password-secured computer with the study ID as the identifier. After completion of the study, the digital audio tapes will be deleted. All participants will be identified by an identification number and not by a name in the research

database and in the digital audio files, so that their identity and personal information will be kept as confidential as possible.

In addition, to help us protect the confidentiality of participants we have a Certificate of Confidentiality from the National Institutes of Health, which will protect against attempts by law enforcement or other government agencies from accessing data. To help us protect patient's privacy, a Certificate of Confidentiality from the National Institutes of Health is in place. The researchers can use this Certificate to legally refuse to disclose information that may identify patients in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify patients. The Certificate of Confidentiality does not prevent patients from voluntarily releasing information about themselves or involvement in this research. If an insurer, medical care provider, or other person obtains a participant's written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

PROVISIONS TO MONITOR THE DATA TO ENSURE THE SAFETY OF PARTICIPANTS

It is important to understand that the intervention is not an experimental drug or device but represents the introduction of new electronic tools and workflows into healthcare delivery (changes that could be adopted by the participating systems without the need for this research). Commensurate with the very low level of risk to participants, we will use a data safety and monitoring plan that is led by the study PI and involves the remainder of the study team. The plan includes prompt reporting of any unanticipated or serious adverse events that become known to the study team through process measurement and semi-structured patient interviews. In such cases, these findings will be communicated immediately to the sponsor (NIDDK) and to the NU Institutional Review Board. The study PI will have ultimate responsibility over insuring the fidelity of this plan. Study investigators will monitor the integrity of the research and the safety of participants. The IRB and Dr. Ackermann (PI) will assess after any such events if revisions are required to the study procedures.

PROVISIONS TO PROTECT THE PRIVACY INTERESTS OF PARTICIPANTS

Healthcare providers who work in the primary care practice will be asked to participate after a general announcement is made at a routine business meeting about the purpose of the research. Secure emails will be sent by the PI and research team directly to those employees, enabling them to discreetly opt out of further contact. Recruitment procedures will not involve supervisors or other members of the practice leadership. All interviews will be conducted in a discreet setting at or near the practice setting, where voices cannot be overheard by others. Only minimal identifying information that is needed to conduct this research will be collected, stored, and analyzed. Audio recordings of interviews will be transcribed, analyzed, and then destroyed. When sharing results / findings beyond the research team, only general aggregate findings, illustrative quotes, or themes will be used. No data or results will be shared in a way that could identify an individual participant.

Patients who are recruited for limited usability testing will be identified using a clinical electronic health record query conducted by a NM data manager. Primary care providers of those patients will be informed of the study and asked if they believe there is a reason why one or more of their own patients should not be contacted to participate. Only patients who are believed eligible and potentially interested after these filtering steps will be recruited. Emailed letters will be sent directly to those patients by the PI and research team, enabling them to learn about the study and to discreetly and easily opt out of further contact. Recruitment procedures will not directly involve the patient's own primary care provider. The study team will conduct all telephone recruitment calls and subsequent usability testing in a discreet setting at or near the practice setting, where voices cannot be overheard by others. Only minimal patient identifiers and PHI needed to conduct this research will be collected, stored, and analyzed. Video recordings of usability tests will be transcribed, analyzed, and then destroyed. When sharing results / findings beyond the research team, only general aggregate findings, illustrative quotes, or themes will be used. No data or results will be shared in a way that could identify an individual participant.

All research personnel have received training in research related to Human Subjects. Access will remain consistent to those on the Authorized Personnel list of the IRB approved protocol. Study documentation will be retained for a period of five years following completion of data analysis, manuscript preparation, and report submission. All research databases will be password protected and accessible only to the research team and the Institutional Review Board (IRB). Any key files that link coded identifiers with NM patient identifiers will not be shared with the study team. Using these methods, which we have used in prior studies, we will be compliant with the “Standards for Privacy of Individual Identifiable Health Information” under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule. We will obtain approval from our IRB prior to the study start date.

ECONOMIC BURDEN TO PARTICIPANTS
Participants should have no additional costs because of participation in the research.

CONSENT PROCESS
This Human Subject Research falls under Biomedical Research with minimal risk to participants. The research will involve usability tests involving individual patients and interviews with primary care professionals, a pilot intervention trial, and follow up interviews with eligible participants. The consent process for each activity varies and is described in detail below:

Research Activity #1: Primary care professional staff will be presented with a written explanation of the study and given an opportunity to have any potential questions answered. Prior to their participation in individual interviews, participants will provide written informed consent. The consent form outlines the potential risks, expected benefits, and the manner in which confidentiality will be maintained. The consent form also offers assurances that the participant can withdraw from the study at any time without penalty.

At the agreed upon time of the staff member’s interview, the research assistant (RA) or PI will take him/her to a quiet, closed-door office and will read the consent document and explain the details of the study in such a way that the staff member understands what it would be like to take part in the research study. The RA or PI collecting the informed consent will stop after each section of the consent process and ask if the staff member has any questions. If the staff member has any questions, the RA or PI will answer them clearly, verifying that the patient has understood and has no further questions before proceeding. If at any point in the process the participant indicates that he or she does not want to take part in the research study, the process will stop, and the RA will thank the patient for their time. After signing the informed consent, the RA will off the participant a signed copy. A second signed copy of the consent form will be filed in a locked, limited access file cabinet at Northwestern research offices and each participant will also be given a copy of the consent form.

Research Activity #2: Primary care providers will be informed of this research study during routine business meetings of the participating practice and subsequently in writing. PCPs will be notified via Epic email of which of their patients are eligible for participation and given the option of excluding any from being recruited. PCPs will be given 5 days to respond to Epic message to exclude a patient. No response will be considered assent to recruit patient. This process follows the standard approach for patient recruitment within the participating clinical practice location and is described in detail under “Recruitment Methods” above. Eligible patients will then be informed of the research by lead letter and then via an outreach phone call placed by the research team. Patients interested in proceeding to volunteer for usability testing will be scheduled and enrolled face-to-face by completing written, informed consent, prior to completing those tests.

Consent will be documented in writing. In accordance with Northwestern University’s Biomedical Template Consent Document, the consent form explains the study, potential risks, expected benefits, and the manner in which confidentiality will be maintained. The consent form includes information regarding protections afforded by the Certificate of Confidentiality. The consent form also offers assurances that the participant can withdraw from the study at any time without penalty.

At the agreed upon time of a patient’s usability test, the research assistant (RA) will take him/her to a quiet, closed-door office and will read the consent document and explain the details of the study in such a way that

the patient understands what it would be like to take part in the research study. The RA will stop after each section of the consent process and ask if the patient has any questions. If there are questions, the RA will answer them clearly, verifying that the patient has understood and has no further questions before proceeding. If at any point in the process the patient has questions that he/she does not believe have been addressed adequately by the RA, the RA will page the PI, who will attempt to answer the patient's question(s) more completely. If at any point in the process the participant indicates that he or she does not want to take part in the research study, the process will stop, and the RA will thank the patient for their time. After signing the informed consent, the RA will offer the participant a signed copy. A second signed copy of the consent form will be filed in a locked, limited access file cabinet at Northwestern research offices, and each participant will also be given a copy of the consent form.

Research Activity #3: For the pilot intervention trial, primary care providers will be informed of this research study during routine business meetings of the participating practice and subsequently in writing. PCPs will be notified via Epic email of which of their patients are eligible for participation and given the option of excluding any from being recruited. PCPs will be given 5 days to respond to Epic message to exclude a patient. No response will be considered assent to recruit patient. This process follows the standard approach for patient recruitment within the participating clinical practice location and is described in detail under "Recruitment Methods" above. As described in detail below under "Protected Health Information (PHI and HIPAA), a HIPAA waiver of consent will apply to patients participating in the pragmatic pilot trial, as the use of participants' PHI involves no more than minimal risk to the participant, is not collected for research purposes alone, and a detailed plan to protect participant identifiers from improper use and disclosure is in place.

For the no-intervention comparison group, patients will not be contacted, will receive no intervention, and only their routinely collected clinical data will be used for the retrospective comparison evaluation (i.e. the same existing clinical data elements used to assess outcomes for the trial groups) so a waiver of consent will apply to participants in this group. As described in detail below under "Protected Health Information (PHI and HIPAA), a HIPAA waiver of consent will also apply to participants in this no-intervention comparison group, as the use of participants' PHI involves no more than minimal risk to the participant, is not collected for research purposes alone, and a detailed plan to protect participant identifiers from improper use and disclosure is in place.

Research Activity #4: For phone interviews: The research assistant will contact patient by phone and read the verbal consent document and explain the details of the study in such a way that the patient understands what it would be like to take part in the research study. The RA will stop after each section of the consent process and ask if the patient has any questions. If there are questions, the RA will answer them clearly, verifying that the patient has understood and has no further questions before proceeding. If at any point in the process the patient has questions that he/she does not believe have been addressed adequately by the RA, the RA will page the PI, who will attempt to answer the patient's question(s) more completely. If at any point in the process the participant indicates that he or she does not want to take part in the research study, the process will stop, and the RA will thank the patient for their time. After the RA signs the informed consent, s/he will offer to email the participant a copy. A second copy of the consent form signed by the RA will be electronically stored in a password protected, limited access shared file on the Northwestern FSM server.

During study consent and initial enrollment, all participants also will be given information about the protections afforded by the Certificate of Confidentiality from the National Institutes of Health. A copy of the consent form signed by the RA will be electronically stored in a password protected, limited access shared file on the Northwestern FSM server.

PROTECTED HEALTH INFORMATION (PHI AND HIPAA)

The goal of the evaluation is to assess the reach/uptake and effectiveness of specific new implementation strategies used to offer common health behavioral preventive services to "usual" patients under "usual" circumstances. Research procedures that introduce additional participant risks or that selectively recruit only motivated volunteers into the evaluation activities would be disruptive of busy clinical workflows and would alter

the findings of the evaluation in ways that are unpredictable and potentially misleading. For this reason, the pilot trial has been designed as a pragmatic, “whole population” study using data collected routinely within the clinical IT systems. The pragmatic nature of the pilot trial component (Research Activity #3) of this evaluation dictates that it could not practicably be conducted without a HIPAA waiver. This HIPAA waiver applies to the intervention, control, and no intervention groups described above under Research Activity #3. The protected health information necessary for the purposes of this evaluation are those routinely collected through clinical care and not for the sole purposes of the research. As described above, the use of this PHI involves no more than a minimal risk to the privacy of participants and a detailed plan to protect participant identifiers from improper use and disclosure is in place, as well as written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information for which an authorization or opportunity to agree or object is not required.

For all other research activities (provider interviews; patient usability tests; patient semi-structured interviews), a HIPAA Authorization will be obtained from all participants. We are requesting the minimum necessary data available from the electronic health record that will be needed to identify potentially eligible patients who will be recruited for usability tests. Videotaped usability tests will then collect only the minimum necessary information needed to assess and improve the human-IT interaction. As we are only requesting data related to the preventive services being studied, we have made all reasonable efforts to limit the information to the minimum necessary to accomplish our intended purpose for the data set.

For Research Activity #1, this study will utilize the following information about clinical staff member participants (not PHI):
- *Names (first and last)*
- *Work telephone numbers, Email addresses*
- *Professional role (e.g. staff physician, PA, NP, RN, LPN, MA, care coordinator, clerk, etc)*
- *Sex/Gender*
- *Year completing training*
- *Year beginning current employment at NMG*
- *Attitudes and beliefs about role in patient weight management support and use of health IT to achieve this*

For Research Activities #2 & 4, this study will utilize the following information about patient participant, collected directly from the participant or from administrative and clinical data systems during routine care delivery and queried at the individual level via the Northwestern Medicine Enterprise Data Warehouse (includes (includes PHI):
- *Names (first and last)*
- *Elements of patient’s address including street address, city, county, ZIP code*
- *Telephone numbers, Email addresses*
- *Age*
- *Sex/Gender*
- *Race/Ethnicity*
- *Primary or preferred language*
- *MyChart Status (Active vs. Not Active)*
- *Body Weight measured at the last clinical patient visit*
- *Cardiovascular risk factors (High Blood Pressure; dyslipidemia; diabetes; prediabetes) indicated in the EPIC active patient problem list*
- *Healthy lifestyle goals*
- *Video and audio recordings of the patient during use of MyChart and a wireless home scale (Research Activity #2)*
- *Perceptions of healthy behavioral clinical services and support tools, including perceived benefits, barriers, and suggestions for improvements (Research Activities #2 and #4)*

For Research Activity #3 (trial with waiver of HIPAA authorization), this study will utilize the following information about patient participants, all collected from administrative and clinical data systems during routine

care delivery and queried at the individual level via the Northwestern Medicine Enterprise Data Warehouse (includes (includes PHI):

- *Age*
- *Sex/Gender*
- *Race/Ethnicity*
- *Primary or preferred language*
- *Body Weight and Height measured at clinical patient visits during the follow up period*
- *Cardiovascular risk factors (High Blood Pressure; dyslipidemia; diabetes; prediabetes) indicated in the EPIC active patient problem list*
- *A1C and glucose values measured at clinical patient visits during the follow up period*
- *Systolic blood pressure measured at clinical patient visits during the follow up period*
- *Total and non-HDL cholesterol measured at clinical patient visits during the follow up period*
- *Changes in antidiabetic, cholesterol, and blood pressure management medications during the follow up period*
- *Number of visits during the follow up period*
- *Healthy lifestyle goals as entered by a patient and/or care team members into the MyChart portal*
- *Patient message reports for study-specific outbound messages**
- *Individual questionnaire responses for study-specific MyChart questionnaires**
- *Information about patterns of an individual's use of a wireless home body weight scale, along with the date/time and value of each recorded weight that is transmitted to the Epic electronic health record system during the evaluation period**

**Not applicable to no-intervention comparison arm patient participants.*

QUALIFICATIONS TO CONDUCT RESEARCH AND RESOURCES AVAILABLE

Our research team is multi-disciplinary and experienced in areas of health promotion, disease prevention, health communication, health behavior, and sustainable implementation of evidence-based programs and services to prevent and manage chronic conditions across primary care and community settings. **RONALD ACKERMANN** has 15 years of experience in stakeholder-engaged health promotion and disease prevention research focusing on the sustainable implementation of evidence-based lifestyle interventions spanning primary care and the community. **KENZIE CAMERON** is a health communications expert with extensive expertise in qualitative research and survey design. **BRIAN HITSMAN** is a behavioral scientist with expertise in the implementation of theory-driven health promotion interventions that span the interface of healthcare practice and community settings. **DAVID LISS** is an expert in evaluating health care professional and delivery system interventions using experimental, quasi-experimental, and qualitative research designs. **ANDREW COOPER** has considerable experience in the management and analysis of large multi-source healthcare and public health data sources. Research assistants and other project coordination and management staff have completed CITI training and good practice, such as in areas of the proper collection of informed consent, data collection and entry, and how to manage adverse events (both anticipated and unanticipated) in the course of routine research.

Because the proposed trial is a pilot and feasibility study, we have chosen a sample size needed to design the intervention to be implemented and sustained within routine practice workflows and to be usable to patients. Primary care practices in the Northwestern Medical Group (NMG) central region deliver care to more about 183,000 unique adult patients annually. Our pilot study will take place at the Galter Primary Care (GPC) site, which is relatively close to the medical campus and sees a patient case mix that mirrors the larger NMG patient population. About 70% of GPC patients have used MyChart in the past year, and 32% of those (N=5,967) meet the study's eligibility criteria. Thus, recruitment of the proposed sample will be feasible.