

1. Protocol

Protocol Title

Aligning the Visit Priorities of Complex Patients and their Primary Care Providers – PCORI 1403-11992

Principal Investigator

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Form Author

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Objectives

For **Aim 1** our study objectives were to obtain patient and provider views of their priorities for primary care visits and how to format a PC tablet based tool designed to help complex patients determine their top priorities for their upcoming primary care appointment. In Aim 1, we conducted an iterative series of separate one-on-one interviews with complex patients and their PCPs to characterize the process of prioritization, understand how patients and their providers differ in setting priorities, and create a process for how these differences can be negotiated during time-limited primary care visits.

In **Aim 2** we developed a simple web-based application that can be loaded onto a Tablet PC to be used in the waiting room prior to the visit. This tool was designed to guide patients to define and discuss their top priorities for the visit. IRB approval was not required for this aim as it did not involve human subjects.

In **Aim 3**, we examined the impact of this tool on both patient-centered and clinical care outcomes. We compared complex patients in intervention vs. control arms to test the following hypotheses:

H1: The intervention increases patient satisfaction, autonomy, perceived patient-centeredness, and quality of communication (patient-centered outcomes).

H2: The intervention reduces quality care gaps (clinical outcome).

H3: The intervention improves collaboration (patient/provider outcomes).

2. Background

a. Scientific Background

Patients are Increasingly Complex: The aging of the US population coupled with better disease prevention and treatment efficacy means that more patients are living with multiple comorbidities that require complicated medical regimens.^{1,2} By 2020 there will be an estimated 130 million Americans with one or more chronic conditions.^{3,4} Patients with multiple chronic conditions have more outpatient visits per year, are often prescribed up to 20 medications, generate more health care costs, have more adverse events, and have lower health-related quality of life.⁵ For this proposal, we define “**complex patients**” as patients with two or more chronic conditions who are not receiving the full potential benefit of health

care, often due to competing health concerns such as active symptoms, cost or other access barriers, medication side effects and adherence, and treatment preferences.^{6,7} Effective management of these complex patients presents a major challenge in our current primary care system.⁸⁻¹¹

Physicians Have More to Do: In parallel with increasing patient complexity, there has been a substantial rise in guidelines and quality metrics that primary care providers (PCPs) must address at each visit.^{12,13} For example, the number of tasks addressed during a typical primary care visit increased from 5.4 in 1997 to 7.1 in 2005 ($p < 0.001$).¹² Ostbye *et al* estimated it would require up to 10.6 hours per day for a primary care physician (PCP) to deliver high quality care for a typical patient panel if chronic diseases were not already under good control.¹⁴ This confluence of increasing patient complexity and increasing primary care tasks despite unchanging (or even decreasing) visit lengths places significant stress on the traditional primary care visit and creates barriers to productive interactions. Without new tools to improve the primary care of complex patients, millions of Americans will continue to receive sub-optimal care despite the availability of effective therapies and interventions that reduce health risks and improve health.¹⁵ Optimizing care for this growing patient population is a national priority.^{15,16}

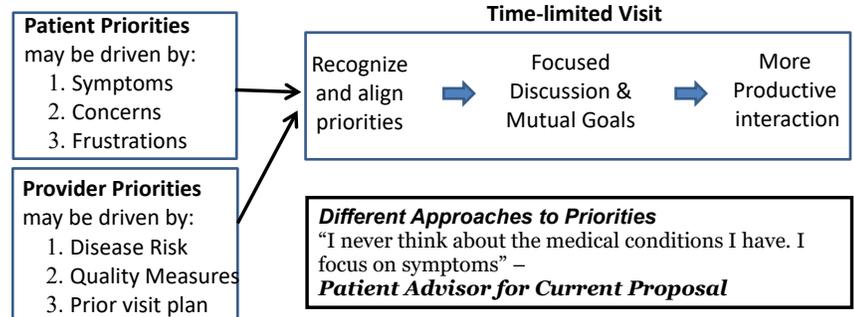
The Solution to Competing Demands is Effective Prioritization: While team care and non-visit based interactions are increasingly common for managing complex patients, the primary care visit remains a critical opportunity for patients and providers to directly engage in shared decision making. For patients with multiple concurrent conditions, however, a critical and often underappreciated first step in this process is the decision about which issues to discuss first. Prior research using videotaped encounters has shown that the first item addressed during the primary care visit receives the bulk of the attention (5 minutes vs. 1.1 minutes for the next 5 of six total topics addressed during the typical 15 minute visit).¹⁷ Neglecting this critical aspect of patient-provider communication and collaboration may have important negative consequences for complex patients with multiple health-related (and non-health-related) concerns. Indeed, other visit content analyses have found that more complex patients are less likely to have medication changes compared to less complex patients,¹⁸ and the likelihood of preventive screening declines with each additional concern brought up by patients.¹⁹

While the basic concept of encouraging patients to prepare for their physician appointments and to ask questions during the visit is not new,²⁰ there is a paucity of data demonstrating the clinical impact and the optimal implementation of this approach for complex patients.^{21,22} Truly patient-centered care requires that care interactions include consideration of patient priorities. For example, pain symptoms in older patients have been associated with a 3-fold greater difficulty taking medications prescribed for other chronic conditions, and thus addressing a patient's pain would likely lead to more effective medication management for these other conditions.²³ Research by our group and others has demonstrated that it is not simply the number of concurrent diagnoses, but the influence of behavioral, emotional, and social factors that create substantial barriers to effective clinical care.^{24,25}

Defining and Aligning Priorities: While it is certain that health issues need to be prioritized, it is less clear how to align the potentially different priorities of patient and provider. Physicians are trained to address disease prevention and risk reduction and evidence suggests that their priorities may be influenced by quality metrics. For example, one study found that PCPs may place relatively higher priority on lower impact interventions (e.g. microalbuminuria screening) when these are used as performance measures,²⁶ whereas patients often have other concerns that outweigh these treatment goals.²⁷ For example, older patients report valuing functional ability²⁸ and place a high priority on

avoiding drug side effects.²⁹ Research by our group and others has found only modest concordance in how patients and their providers prioritize health issues.^{30,31}

The **Figure** shows our conceptual model for how recognizing and aligning patient and provider priorities can lead to more productive interactions. In our intervention, we will facilitate the process for patients to identify their top priorities prior to the time-limited visit. Studies have shown that PCPs can substantially improve their assessments when patients more effectively and proactively communicate their preferences.^{32,33} Indeed, current research suggests that patient-provider interactions could become *more effective* if providers better understood the patient’s current priorities³⁴⁻³⁸ and were more aware of “unvoiced” agendas.^{39,40} This supports the hypothesis that supporting patients in identifying and articulating their care priorities will improve provider knowledge and lead to more productive visit interactions.



System-level change: The key conceptual innovation of this study is to focus on creating an effective, easy-to-use tool for patients with multiple concurrent conditions to identify and discuss their top care priorities for their upcoming primary care visit. We will conduct foundational work to better understand the different goals and values of patient and providers as they relate to setting priorities (**Aim 1**); apply this knowledge to design a simple web-based tool that can be used in the waiting room (**Aim 2**); and then test the impact of this approach in a rigorous randomized trial that will measure both patient-relevant and clinical care outcomes (**Aim 3**). The intervention follows the framework of the Chronic Care Model (CCM), with a specific focus on creating “informed, activated patients” through delivery system re-design that enables patients preparing for primary care visits to identify which items are of greatest priority for them at that time.⁴¹ We have successfully applied the CCM in prior research.⁴²⁻⁵⁹ By providing complex patients with both the opportunity to identify their priorities prior to their visit and the tools to more effectively discuss these priorities with their PCPs, this intervention seeks to improve patient-centered care by optimizing patient-provider visit interactions.

b. Preliminary Data

Eligible PCPs are primary care physicians who plan on remaining in their current practice for at least another two years with at least 40 potentially eligible patients in their patient panels. There are over 300 PCPs managing ~250,000 adult patients at primary practices within these 3 centers. Based on our preliminary analyses, there are at least 30,000 patients meeting study eligibility criteria (103 eligible patients/PCP).

3. **Study Design**

Aim 1 consists of patient and provider interviews.

In Step 1 we interview up to 25 complex patients who have had a visit with their PCP within the prior 6 months. For this proposal we define **complex patients** as patients with 2 or more chronic conditions *and*

not meeting one or more evidence-based primary care management outcomes related to preventive screening [e.g. cancer screening], disease management [i.e. risk factor testing or control], or medication taking [evidence of non-adherence based on pharmacy dispensing or self-report]). In these Step 1 interviews, we focus on understanding whether and how patients prepare for upcoming visits and how they conceptualize the relative importance of different health issues. For each participant, we also elicit a specific list of their current health care priorities that they want to discuss with their physician. With each patient's prior consent, in Step 2 we interview each participant's physician. In the Step 2 interviews we elicit the physician's priorities for the patient, compare the physician and patient listed priorities, and investigate how each physician would seek to balance any differences between the two sets of priorities. Finally, in Step 3 we close the loop by returning to the patient. In the Step 3 interviews, we present patients with physician priorities and investigate how the patient perceives any differences between his/her priorities and PCPs.

Aim 2 is the IT development of the tablet application and does not involve human subjects.

Aim 3 Clinical Trial

We conducted a 2-arm parallel group clinical trial with random, concealed allocation at the level of PCP. Both PCPs and patients provided informed written consent. Patients, providers, and waiting room research assistants cannot be blinded to randomization status because treatment patients are given the Visit Planner tool in the waiting room while control patients are not. However, collection of post-visit survey data and assembly of analytic datasets is masked to randomization status. For **Aim 3**, we enroll PCPs and their patients from KPNC primary care practices in Oakland and San Francisco. PCPs are recruited via their weekly practice meetings and through individual in-person contacts.

Intervention

Intervention patients are provided the Visit Planner on a tablet tool in the waiting room. The tool starts off with a video that explained the purpose of the application and educated patients about the importance of bringing up their concerns early rather than later in the visit. Then, the tool prompts them to choose their top 1 or 2 concerns for the visit from 6 categories (New Problem, Medicines, Need something from the doctor, Old Problem, Stress at home or at work, A personal concern or other). Within each category, patients have the option of choosing 3-4 sub-categories and of inputting additional comments in a free-text field. After identifying their top visit priorities, patients are then prompted to identify how they would use their time during or after the visit to stay involved with their care (e.g., Take notes during the visit, Ask my doctor questions during the visit, Review with a friend or loved one, Check online patient portal after the visit). All patient responses are subsequently printed out as a Visit Planner Summary for the patient to bring into their visit.

Control

Control patients are also met in the waiting room before eligible visits. Control patients are given a 1-page healthy lifestyle education handout.

Patients in both study arms otherwise receive usual care throughout the clinical trial period.

4. Study Population

a. Number of Subjects

Aim 3 clinical trial = 750 patients (modified)

b. Inclusion and Exclusion Criteria

PCP Eligibility: Providers are eligible for inclusion if they have at least 5 potentially study-eligible patients within their patient panel and plan to remain at their current practice for the following year.

Patient Eligibility: We use the KPNC electronic clinical data repository to identify a broad spectrum of potentially eligible patients within each participating PCP's patient panel. Patient eligibility is defined as having **2 or more chronic conditions** (defined using our validated clinical data algorithms for the following common chronic conditions: type 2 diabetes, hypertension, cardiovascular disease, dyslipidemia, chronic obstructive pulmonary disease/asthma, depression, renal insufficiency, cancer, and symptomatic arthritis) and **1 or more Quantitative Clinical Care gaps** defined using KPNC-implemented quality metric algorithms (e.g. preventive cancer screening for breast, cervical, and/or colorectal cancer screening among screen-eligible patients; and to chronic disease management including annual HbA1c testing and **result < 8.0%** for patients with diabetes; annual blood pressure measurement and systolic blood pressure (SBP) < 140 mg Hg for patients with diabetes, hypertension, or cardiovascular disease (CVD); annual cholesterol measurement and LDL < 100 mg/dL for patients with diabetes or CVD). We exclude patients with psychosis or dementia or other deficits that significantly impair communication or use of computers. Screening is conducted via electronic record review and patient phone calls. We retain information from decliners so that subjects are not re-contacted after declining.

c. Vulnerable Populations

We do not make any special effort to include or exclude vulnerable populations, however our study only includes adult members with at least two complex conditions who can participate in an English or Spanish language interview. Each subject, including those in a vulnerable population listed above who may be randomly selected into our study sample, have the opportunity to decline participation and avoid further contact by study staff by returning the mailed reply postcard or by phoning the study coordinator. Given the very low-risk nature of study participation, i.e. survey completion on a PC tablet or interview participation, no additional safeguards, beyond standard confidentiality safeguards, are employed. TPMG physicians are assured that no individual identifiable responses gathered during interviews will be shared with others outside of the study team.

Decisionally Impaired Adults

- a. If you will obtain surrogate consent, describe detailed research plan to the surrogate, including present and future decisions to be made. A documented assessment of decisional capacity as part of the procedures for obtaining surrogate consent should be included.

N/A

Other Populations Targeted for Recruitment

N/A

d. Setting

The clinical trial was conducted within KPNC primary care practices located at Oakland and San Francisco – Mission Bay. Study procedures were conducted by research personnel.

e. Recruitment Methods

On 1/22/16, the IRB approved the “Aligning Patient and Providers” clinical trial. Intervention arm patients have the opportunity to use the Align Waiting Room Tool (an iPad based application that helps them prepare for their visit) while control patients receive a KP-designed handout on healthy lifestyle advice.

We have the following research protocol for our clinical trial:

- 1) As with our procedure for our similar ongoing clinical trial (CN-13-1579 – Pre-Visit Prioritization for Complex Patients with Diabetes), Dr. Grant contacts Primary Care Practice Leaders (via e-mail or in-person) to request permission to present the “Aligning Patient and Providers” clinical trial at a weekly practice meeting. At this meeting, Dr. Grant explains the purpose for his visit, describes the study, and identifies providers willing to participate. With help from research staff, Dr. Grant then obtains written informed consent from willing physicians. Consenting physicians also review a list of their own potentially eligible patients to approve contacts and complete the 5-item baseline questionnaire at this time. This entire process takes 20-30 minutes.
- 2) PCP-approved patients are then sent a letter explaining the study. The letter includes a phone number and e-mail address for patients who wish to participate or opt out of the study. After 1 week, we contact patients who have not yet responded and – using our phone script – invite patients to participate in our study.
- 3) We obtain verbal informed consent during this phone call to administer a brief patient baseline questionnaire and arrange with patients to meet ahead of time at their primary care practice on the day of their next scheduled visit. For visits that occur > 1 week after the initial phone enrollment, we also make a reminder phone call. Our team has previously created an informatics tool that alerts us when study participants have scheduled an appointment with their primary care physician.
- 4) At the primary care practice prior to their visit, the research assistant obtains written informed consent. Patients allocated to the intervention arm are then given the pre-loaded iPad with the Visit Planner Waiting Room Tool that helps them prepare for their visit. This tool takes approximately 4 minutes to complete. On completion of the program, the research assistant prints out the patient’s answers and the patient can bring this page into the exam room to remind themselves of their visit priorities and plans. As is clearly explained to the patient, none of the answers entered by the patient become part of the medical record and are only for the patient’s own use. Control patients receive the “Healthy Living/Physical Activity - Every Move Matters” KP-designed 2-page pamphlet.
- 5) Patients are called within 2 days after their visit at a previously arranged time and asked to complete the post-visit survey. All patients completing these surveys receive a \$20 gift card mailed to their home.

f. Informed Consent Process

The study investigator or project manager reviews and presents the consent form before the scheduled interview in the waiting room. We ask if the individual has any questions, provide answers, and obtain signed informed consent prior to the interview beginning.

We do not enroll participants if they cannot provide informed consent due to severe cognitive impairment, language issues, or other incapacity. We screen for these issues during the recruitment telephone call. However, any issues of this nature not evident during that call and noted during the consenting process are handled on a case by case basis by the person obtaining informed consent.

Waiver of Informed Consent

N/A

Waiver of Signed Informed Consent

N/A

Alteration of Informed Consent

N/A

Non-English-Speaking Subjects

On 5/25/16, The IRB approved the Spanish version created in close collaboration with the KPNC Regional Health Education/Salud Permanente Team responsible for creating all of the Spanish-language materials for KPNC members and for creating the Salud Permanente web-site within My Doctor Online.

Assent of Children and Parent Permission

IMPORTANT NOTE: Consent may be obtained in certain situations. For example, conducting family planning or sexually transmitted disease (STD) research. In addition, for older children ages 16 and up who participate in an adult study, the consent document can be used in place of the assent document.

N/A

Adults Unable to Consent/Decisionally Impaired

If you will obtain surrogate consent, describe detailed research plan to the surrogate, including present and future decisions to be made.

N/A

g. HIPAA Privacy Rule Authorization – if study will use or disclose Protected Health Information (PHI)

The use and disclosure of PHI for this study presents no more than a minimal risk to the privacy and confidentiality of the individuals whose PHI will be accessed, and will be assured by the standard protocols in place at DOR that all study staff will follow. Participant privacy and confidentiality will also be ensured by securing storage of physical data (e.g., papers) in locked files, and securing storage of digital data (computer files, digital audio) in password-protected files on password protected computers. All study staff rated current in HIPAA and IRB training.

Waiver of HIPAA Privacy Rule Authorization

N/A

5. Study Procedures

Procedures to monitor subjects for safety, including who will review the data and at what frequency for safety issues. All patient participants continue with their usual care and are managed medically by their PCPs. The

intervention is extremely low-risk and is designed to help patients and providers communicate during visits. There is no formal safety monitoring.

Procedures performed to lessen the probability or magnitude of risks. The main risk is loss of confidentiality. KPNC DOR researchers are accustomed to maintaining processes to ensure confidentiality. No notations are made in the participant's medical chart. Subjects are advised that some of the interview questions are of a personal nature, but that all data are handled with confidentiality. Subjects are further assured of their right to refuse to answer any questions. Participant privacy and confidentiality is ensured by:

1. Securing storage of physical data (e.g., papers) in locked files, and securing storage of digital data (computer files, digital audio) in password-protected files on password protected computers.
2. Making data that may contain identifying features accessible only to members of the research team working under the direction of the investigators during the duration of the project.
3. Use of a study ID on all audio files and transcripts. The transcriptionist do not transcribe any identifying information. Study staff review hard copy transcripts and remove any remaining identifying information (such as names, place names, etc.). All audio files are destroyed after transcription.
4. Ensuring that no data are collected or maintained by investigators which participants do not want to have preserved.
5. Ensuring no participant can be identified in any presentations or publications about this study.
6. All study staff rated current in HIPAA and IRB training.

All drugs and devices used in the research and the purpose of their use, and their regulatory approval status. NA
The source records that will be used to collect data about subjects. Data are collected from the medical record and via patient and provider surveys.

What data will be collected including long-term follow-up. Long-term follow-up is based on data from the medical record collected as part of routine care.

The duration of an individual subject's participation in the study. Physicians were recruited at monthly physician meetings where the study was presented. The first eligible patient visit occurred on 3/31/2016 while the last visit occurred on 6/30/17.

The duration anticipated to enroll all study subjects. Enrollment of physicians began 2/2016 and was completed by 2/2017. Follow-up was assessed through 12/31/2017— 6 months after the final visit. We chose a 6-month follow-up period to balance factors of providing sufficient time for the intervention to make an impact while also reducing loss to follow-up.

a. Data Analysis

Study outcomes

Our primary clinical outcome is the closing of quality care gaps within 6 months of study visits. Individual care gaps are measured at baseline and 6-month follow-up as a total count of any care gap at both time periods. Change in aggregated care gaps from baseline to follow-up is also assessed in four ways: closure of all baseline gaps, closure of any baseline gaps, opening of new care gaps, and presence of no gaps at the end of the study.

Our primary patient-reported outcomes regarding their care experiences are obtained during post-visit telephone calls using questions drawn from validated survey instruments. Surveys are conducted within 1 week of the eligible primary care visit. We measure outcomes in the domains of patient satisfaction, autonomy, perceived involvement in care, and satisfaction with care.²⁹⁻³⁴ Modeled on the structure of these validated items, we also add several study-specific questions to obtain more detailed information about bringing up top concerns at the beginning of the visit, taking notes and asking questions during the visit, and following up post-visit with friends

and loved ones. Finally, we examine responses to a 5-item PCP survey administered at baseline during study enrollment.

Statistical Methods

We examine baseline characteristics of patients and providers by randomization status using chi-square, t-test, and non-parametric tests as appropriate. For our clinical trial outcomes, we construct generalized linear mixed models (SAS Proc GLIMMIX) with the dichotomized response as a dependent variable (with a logit link), treatment/control arm as a fixed effect and PCP as a random effect to adjust for clustering of patients within PCP. For secondary survey outcomes, the patient reports are dichotomized and analyzed in the same type of mixed models. We also conduct a priori analyses of English vs. Spanish-speaking patients in sub-analyses to determine any differential effects by language. We use SAS version 9.3, SAS Institute, Cary NC.

b. Sharing of Results with Subjects

Results will not be directly shared with patients.

c. Data and/or Specimen Banking

NA

6. Privacy, Confidentiality and Data Security

Names and other identifying information on study subjects will be retrieved from the KPNC automated databases. We will have the link between MRN and original study ID number, and at the end of the study, this link will be destroyed. Only KPNC workforce staff directly involved in the study will have access to data identifying individual subjects (PI, co-investigators, project manager, & programmer). No individuals will be identified in any reports from this study. All data will be presented in aggregate in reports and publications; i.e., no identifiers will be shown. Records with any identifying information will be kept in locked drawers when not in use. Access to computerized information on the KPNC network requires simultaneous knowledge of the databases, programming language, file names, and multiple passwords. Therefore, we can ensure data security. All study staff rated current in HIPAA and IRB training.

Describe the plan for storage of data and/or specimens.

NA

Collection of data from subjects electronically

N/A

Does this study involve the disclosure of PHI to a collaborator?

N/A

7. Provisions to Monitor Data to Ensure the Safety of Subjects

N/A

8. Risks and Benefits

a. Risks to Subjects

We anticipate no physical, social, or economic risks to research participants in this study. Risks to participants in Aim 1 are very small given that participation involves interviews. Participants will be assured they are free not to answer any questions and/or refuse participation at any time, thus guarding against the risk of psychological or emotional upset.

b. Potential Benefits to Subjects

The effective primary care of complex patients remains an important and increasing challenge both for KP and nation-wide. There are a wide range of treatments that reduce risk for morbidity and mortality, but translating these benefits for all patients has been difficult to achieve. We hypothesize that understanding and addressing the issue of prioritization prior to the primary care visit may represent one innovative approach to addressing these challenges by making the time-limited primary care visit encounter more productive.

9. Economic Burden to Subjects

N/A

10. Compensation to Participants

\$20 gift card will be provided to study participants completing the post-visit survey.

11. Resources Available

All study staff rated current in HIPAA and IRB training.

12. Prior Approvals

N/A

13. Drugs or Devices

N/A

14. Multi-Site Research

N/A

15. Community-Based Participatory Research

N/A

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