INVESTIGATION OF PRACTICE FACILITATOR WORKFLOWS FOR ENROLLMENT ENHANCEMENT IN ICD-PIECES STUDY

by

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ABSTRACT
INVESTIGATION OF PRACTICE FACILITATOR WORKFLOWS FOR ENROLLMENT ENHANCEMENT IN ICD-PIECES STUDY

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Background: Care for patients with multi-morbidities is challenging and often suboptimal. Earlier detection of patients with coexisting Chronic Kidney Disease (CKD), diabetes and hypertension served by our health care systems will allow us to institute appropriate care for the right patient at the right time with the right intervention thereby providing the greatest benefit. Implementation of interventions to treat CKD, diabetes, and hypertension and to treat associated conditions should reduce cardiovascular mortality and morbidity, improve clinical status, and reduce hospitalization and costs. A collaborative model approach to care for patients with multiple chronic conditions using the unique and novel technology platform, Pieces (Parkland intelligent e-coordination and evaluation system) is being investigated via pragmatic clinical trial.

Objective: The main hypothesis is that patients with CKD, hypertension and diabetes who receive care with a collaborative model of primary care-subspecialty care enhanced by novel information technology (Pieces) will have fewer hospitalizations, readmissions, CV events and deaths than patients receiving standard medical care.

Methods: The study employs a prospective stratified cluster randomization design involving four healthcare systems which are the stratum: Parkland Health & Hospital Systems, Texas Health Resources (THR), North Texas Veterans Affairs, and ProHealth Physicians of Connecticut. Each of the four healthcare systems are unique in the populations that they serve, the electronic medical records that they utilize, and the qualifications of the practice facilitators that they employ. Practice facilitators at each of the participating sites received training on how to leverage the enhanced resources provided by Pieces. The practice facilitators are a crucial link that ensure consistent incorporation of Pieces technology into the care of patients selected for the intervention group of the study. The four unique practice facilitator workflows were diagrammed and proofed for accuracy. Challenges in the process identified by the practice facilitator were also cataloged. Similarities and differences noted in the workflows allowed the identification of the highest yield areas for improvement. Comparison of each of the four unique workflows to the original, “generic” workflow as well as to each other helped identify challenges consistent across all of the systems as well as ones unique to each system.

Results: The major challenge identified by each practice facilitator was the accuracy of the generated confirmed and candidate patient lists that they have been receiving. This led to decreased patient enrollments and resulted in the practice facilitators performing

a manual survey of each patient. The inaccuracy of the lists was primarily the result of changes to the electronic medical records that affect patient selection and not the selection algorithm itself. A review of control patients demonstrated that the algorithm accurately identified 87% of eligible patients with the remaining unidentified primarily due to absence of a recent lab. Other challenges identified by every practice facilitator included initial resistance from PCPs, missed appointments, and obtaining labs prior to appointments. Individually, each practice facilitator identified challenges that were unique to their situation. These challenges included the inability to sign lab orders, high overall workloads for pharmacists, and the inability to determine if PCPs had taken note of protocol recommendations.

Conclusion: Investigation and comparison of the practice facilitator workflows at each of the four healthcare systems aided in the identification of shortfalls and challenges that have hindered the patient enrollment process. These workflows will be useful in future pragmatic studies that utilize the EMR in the identification of a patient population. It is also generally instructive for studies that seek to utilize EMRs to identify patient populations. Despite the theoretical efficacy of informatics application in healthcare, there is still much progress to be made in this arena. Nevertheless, the study as a whole will be an important part of the growing collection of pragmatic trials due to their increased external validity compared to traditional explanatory trials. It will also ultimately be a valuable learning tool in the construct and execution of future pragmatic trials and hopefully demonstrate that a collaborative model of primary care-subspecialty care that leverages information technology can improve the quality of patient care.

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Chapter 1
Introduction

1.1 Problem Description

Chronic kidney disease (CKD), diabetes and hypertension are common chronic medical conditions in the United States general population that put a significant strain on our healthcare system. It is estimated that approximately 31% of adults have hypertension, 14% have CKD, and 10% have diabetes.[1-4] The projected lifetime incidence of CKD in an individual between aged 30-49 years is projected to be 54%.[5] The estimated lifetime risk of developing diabetes in an individual born in 2000 is 32.8% for males and 38.5% for females.[6] The estimated lifetime risk of developing hypertension in middle-aged men and women is 90%.[7] Exacerbating the problem is the fact that the two most common causes of CKD in the US are diabetes and hypertension.[5] This triad of medical conditions has a significant morbidity and mortality risk associated with it.[8-12] Risk of death, particularly cardiovascular risk, is elevated in adults with CKD and is closely associated to reductions in glomerular filtration rate (GFR).[13,14] The presence of multiple co-morbidities is worrisome, especially in patients with the triad of CKD, diabetes, and hypertension. Studies have demonstrated that patients with CKD and diabetes have a much higher mortality rate than those with either condition alone.[9] In addition, patients with the combination of CKD and hypertension as well as diabetes and hypertension also exhibit similarly increased risk of mortality.[15,16] In addition, vulnerable populations to include minorities, the elderly, and those living in lower socioeconomic areas are disproportionately affected by CKD.[1-3]

Patients with multiple co-morbidities such as the triad of CKD, diabetes, and hypertension are a challenge for healthcare professionals. As a result, these patients often receive suboptimal care which further exacerbates their already dire condition. Care for these patients should focus on early detection, slowing of disease progression, decreasing cardiovascular risks, and treatment of complications.[5,17] Early detection is particularly important for CKD as therapies initiated early in the disease course can prevent progression to end stage renal disease (ESRD). This can be accomplished with basic lab tests such as serum creatinine and urine protein/albumin. However, it appears that a significant number of patients that are at high risk for CKD are not having these lab tests performed as it is estimated that less than half of Medicare patients with diabetes and/or hypertension have a claim for urine albumin.[2] If left untreated, CKD's progression to ESRD leads to costly interventions such as dialysis and kidney transplantation. These patients also are afflicted by a host of comorbidities to include depression, stroke, and heart attack.[1,2,4,18-21] In addition, CKD detection has shown to be low in healthcare systems with integrated electronic health records (EHR). However, institution of automated GFR reporting has generally resulted in greater identification of patients with CKD.[22,23] Detection of the other two triad conditions is also an issue. It is estimated that 24% of individuals with diabetes in the United States are undiagnosed. To make matters worse, an additional 34% of the adult population has prediabetes.[24] In U.S. adults with hypertension, about 22% are unaware of their condition and over half that were aware did not have their condition under control.[25]

In addition to increased morbidity and mortality, failed detection of CKD, diabetes, and hypertension has an enormous financial impact on our already expensive

healthcare system. CKD alone cost Medicare over $80 billion in 2010.[26,27] The total expenditures related to diabetes care was $245 billion in 2012.[28] Finally, hypertension related expenditures cost $46 billion in 2011.[29] Improving detection of these conditions can clearly have a great impact in the care of patients and decrease the overall financial burden on our healthcare system.

1.2 Available Knowledge

Effective management of patients with CKD, diabetes, and hypertension aims to slow CKD progression and reduce the risk of cardiovascular disease. Interventions include blood pressure control, blockade of the renin-angiotensin-aldosterone system, improvement of glycemic control, and control of dyslipidemia.[17,30-34] Despite available recommendations for management, many of these patients do not have appropriate strategies implemented in their care. It is estimated that less than half of adults with CKD have adequate blood pressure control.[2] Concurrently only half of adults with diabetes have appropriate control of blood pressure, glycemic levels, or LDL cholesterol.[35] Additionally, the use of medications for control of CKD and associated risk factors is woefully inadequate in this population.[1,2,17] To make matter worse, these patients also suffer from additional morbidity and mortality from adverse safety events (such as hypoglycemia and hyperkalemia) due to the complexity of their care and impaired renal function.[36-39] Several strategies have shown promise to advance the care of patients with CKD, diabetes and hypertension. Multidisciplinary care models, automated eGFR reporting, electronic CKD checklists, coordination of patient care transitions, creation of patient registries, patient directed education and self-management tools, utilization of patient navigators, and clinician decision support

models have shown promise in improving care for these patients.[22,40-50] Despite evidence for the effectiveness of some of these recommendations, implementation remains a challenge. A growing body of health services research indicates that the design of the system, not physician specialties, is the primary determinant of quality care for chronic conditions.[51,52] Thus, quality improvement strategies seem to be a high yield target of opportunity in improving care for patients with CKD, diabetes, and hypertension.

A NIH grant-funded project, "Improving CKD Detection and Care in a High Risk and Underserved Population," that implemented a collaborative model of primary care and subspecialty interventions utilizing a novel technology platform (Pieces™) has shown the ability to improve detection of CKD and improve blood pressure control.[53] Pieces™ software has also been successful in developing a variety of clinical predictive models as well as identifying patients with diabetes.[54-58]

1.3 Rationale

The study "Improving Chronic Disease Management with Pieces™," is a $5.8 million NIH funded pragmatic clinical trial that seeks to improve the identification, management, and outcomes for patients with the disease triad of CKD, hypertension, and diabetes. The main goal of the trial is to improve the care of patients with the triad of CKD, diabetes, and hypertension using a collaborative model of primary care-subspecialty care recommendations enhanced by a novel information technology that leverages the electronic health record to identify patients, facilitate implementation of best care practices, monitor clinical measures and outcomes, and guide therapies. The main hypothesis is that patients with CKD, hypertension, and diabetes who receive care

with a collaborative model of primary care-subspecialty care enhanced by novel information technology (Pieces) will have fewer hospitalizations, readmissions, cardiovascular events, and deaths than patients receiving standard medical care. The Pieces™ platform will utilize the electronic medical record (EMR) for data collection, early disease detection and monitoring and care coordination for patients with the disease triad. The study employs a prospective stratified cluster randomization design involving four healthcare systems which are the stratum: Parkland Health & Hospital Systems, Texas Health Resources, North Texas Veterans Affairs, and ProHealth Physicians of Connecticut. The unit of randomization is each primary care clinic. Thus, primary care practices were stratified by healthcare systems and randomly allocated to either intervention group or standard medical care group using a randomized permutation block within the stratum. Based on the assignment of the clinic where a patient goes, each patient will be assigned either to the intervention group or the standard medical care group.

All eligible patients of clinics who are randomized to the study will be included in the comparison of the two intervention groups regardless of intervention compliance (intention-to-treat analysis) to investigate if patients in intervention group have significantly less disease-specific hospitalizations than those in the standard medical care group. Evaluation will also be performed to determine treatment effects on all-cause hospitalizations, ER visits, cardiovascular events and deaths. The target number of patients to be studied is 10,991 with the breakdown by healthcare systems and clinics listed in Table 1.

Healthcare System	Target # of Practices	Target # of Patients
Parkland Health and Hospital System	**13** (out of 25)	**1,684** (out of 3,367)
Texas Health Resources	**20** (out of 40)	**1,805** (out of 3,610)
ProHealth of Connecticut	**25** (out of 50)	**1,591** (out of 3,181)
North Texas VA	**5** (out of 9)	**417** (out of 833)
Total Enrollment	**63** (out of 124)	**5497** (out of 10,991)

Table 1: Enrollment Targets by Healthcare System

Study enrollment began in earnest in early 2016 and will continue over a period of two or more years depending on the pace of enrollment within each healthcare system. Each subject participant enrolled in the study will be monitored for 12 months.

The primary outcome that will be measured during the trial is the 12-month hospitalization rate for all the study participants. Secondary outcomes to be measured during the trial include 30-day disease-specific readmissions (for all patients with an index hospitalization), all-cause hospitalizations, emergency room visits, cardiovascular event and deaths.

Participants in the study must be 18-85 years of age and have the triad of CKD, diabetes, and hypertension. The specific inclusion criteria for each disease entity is shown below.

CKD Inclusion Criteria (present at least ≥ 3 months apart)

1. There will be two or more eGFRs less than 60ml/minute or
2. Two or more positive tests for albuminuria and/or proteinuria

Albuminuria/proteinuria can be defined by quantitative criteria with albumin/creatinine ratio greater than 30, urine protein creatinine ratio greater than 200 or positive dipstick with protein detection (adjusted for urinary concentration/specific gravity).

Diabetes Inclusion Criteria

Only patients with type 2 diabetes will be enrolled in this study.

1. Random blood glucose greater than 200mg/dL
2. Hemoglobin A1C greater than 6.5%
3. Use of hypoglycemic agents other than metformin
4. Type 2 diabetes included in problem list

Hypertension Inclusion Criteria

1. Systolic blood pressure greater than 140mmHg on two different occasions at least one week apart
2. Diastolic blood pressure greater than 90mmHg on two occasions at least one week apart
3. Use of antihypertensive agents except thiazide diuretics
4. Hypertension included in problem list

AHA and ACCOG Guidelines as of November 17, 2017 now define hypertension as 130/80 as a result of the SPRINT trial. The study may follow suit and expand the inclusion criteria pending a decision from the DSMB.

Primary care practitioners participating in the study have the ability to utilize their clinical judgement in implementing the recommended interventions. Patients also have the option to opt-out of the study if they choose. A generalized workflow for the study is diagrammed in Figures 1 and 2.

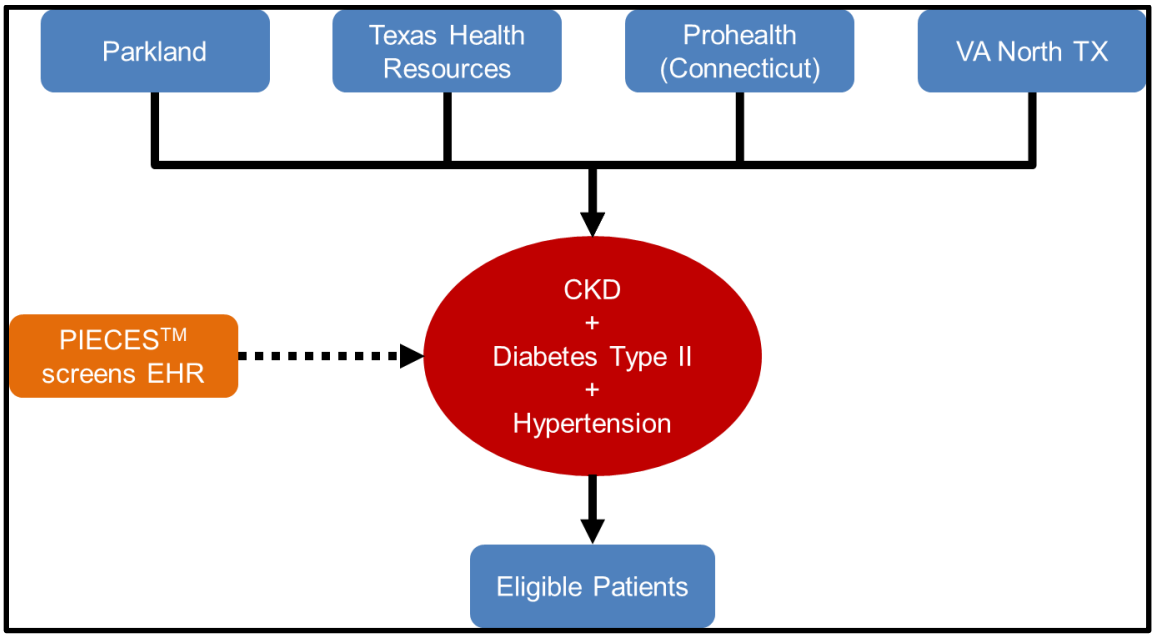

Figure 1: Workflow of Patient Selection

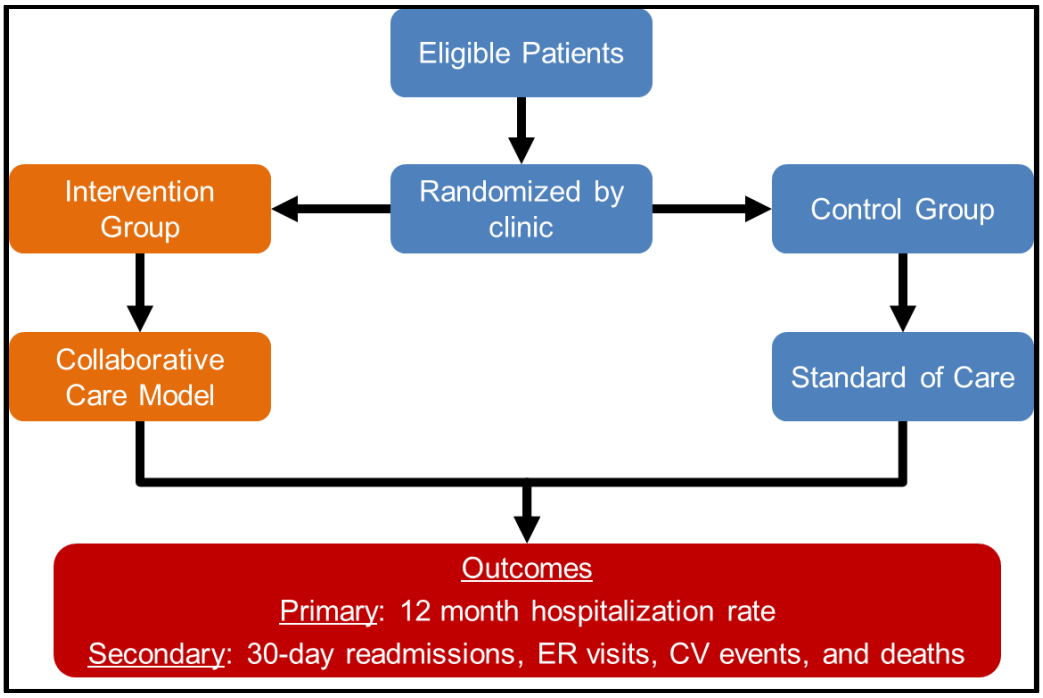

Figure 2: Workflow of Patient Randomization

Once a patient is identified as eligible for the study, a practice facilitator (PF) assists the PCPs in enrolling patients in the study (Figure 3).

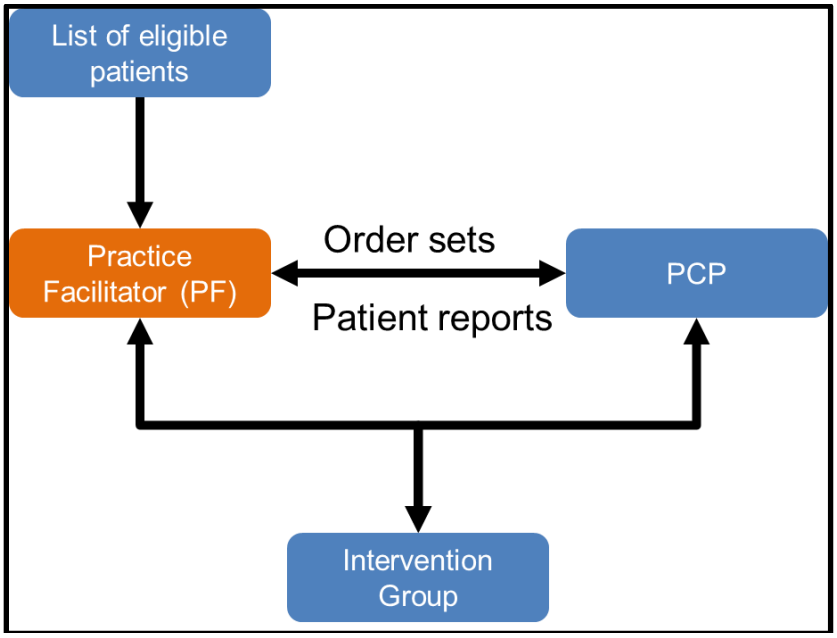

Figure 3: Workflow of Practice Facilitator interaction with PCP

PCPs have the option of initiating protocols (and smartsets if available) for CKD, diabetes, and hypertension management. Enrolled participants also receive patient education. Figures 4-9 outline the generalized practice facilitator workflow.

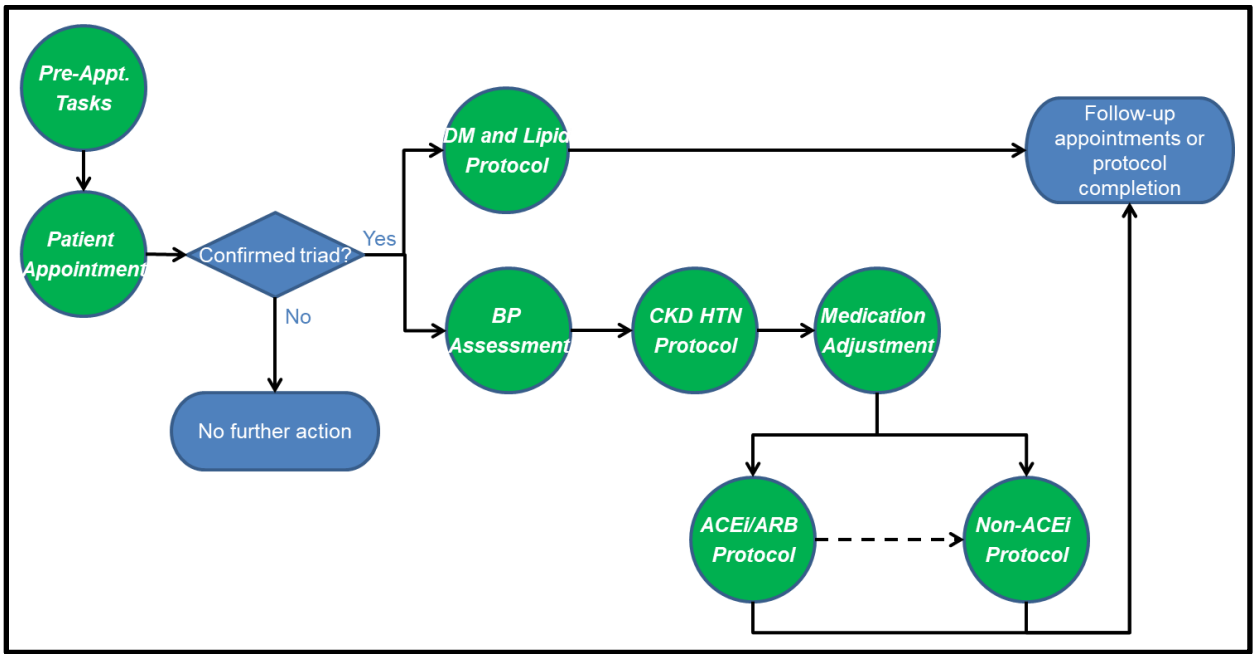

Figure 4: Overview of Practice Facilitator Workflow

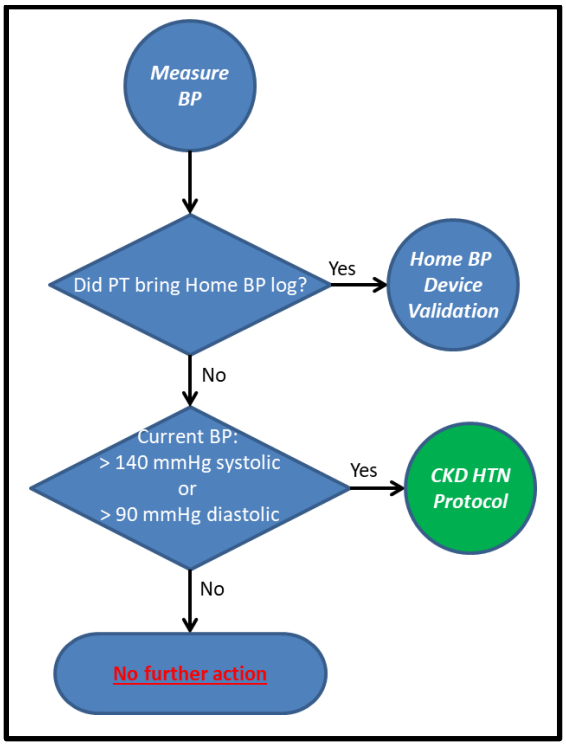

Figure 5: Practice Facilitator Workflow – BP measurement

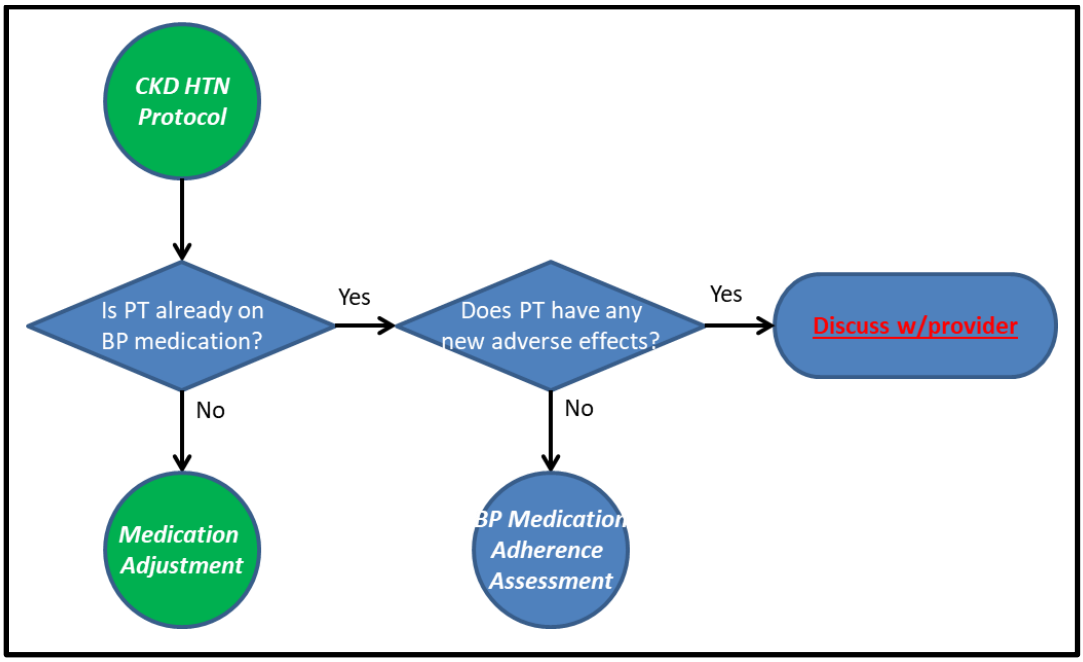

Figure 6: Practice Facilitator Workflow – CKD HTN Protocol

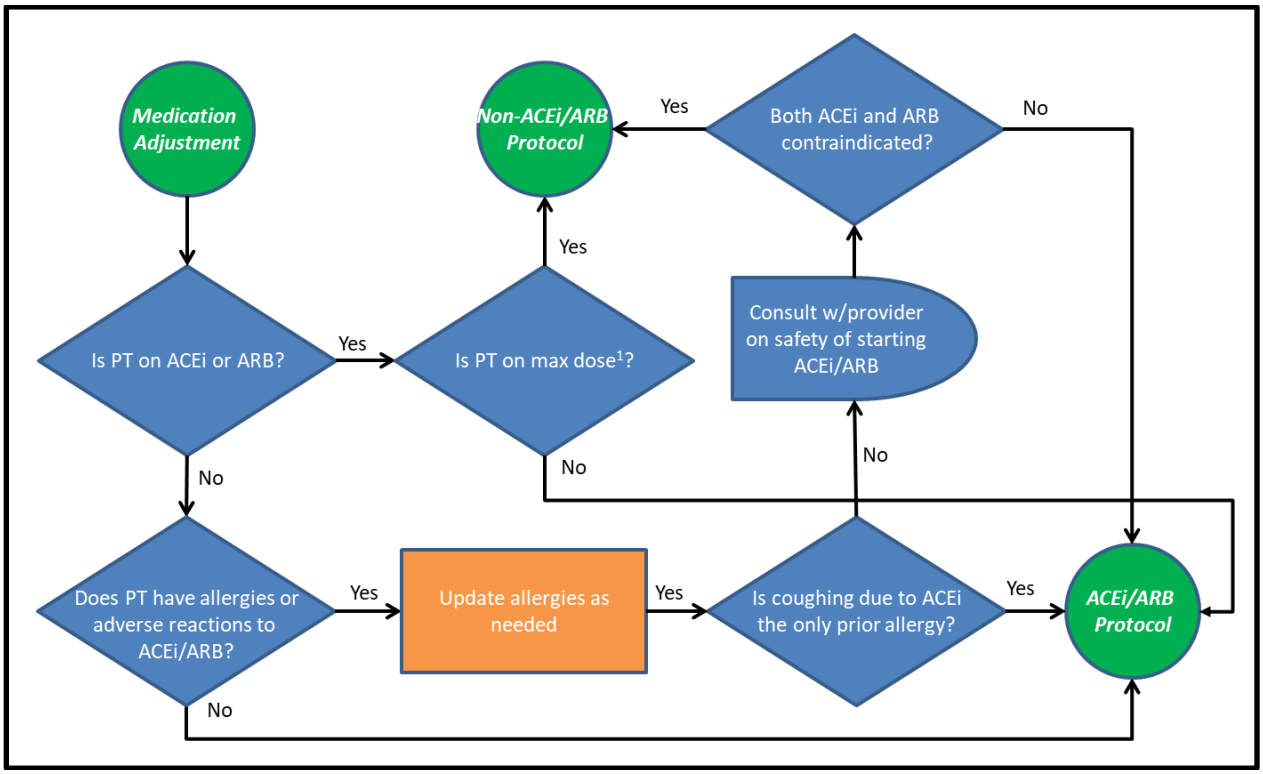

Figure 7: Practice Facilitator Workflow – Medication Adjustment Protocol

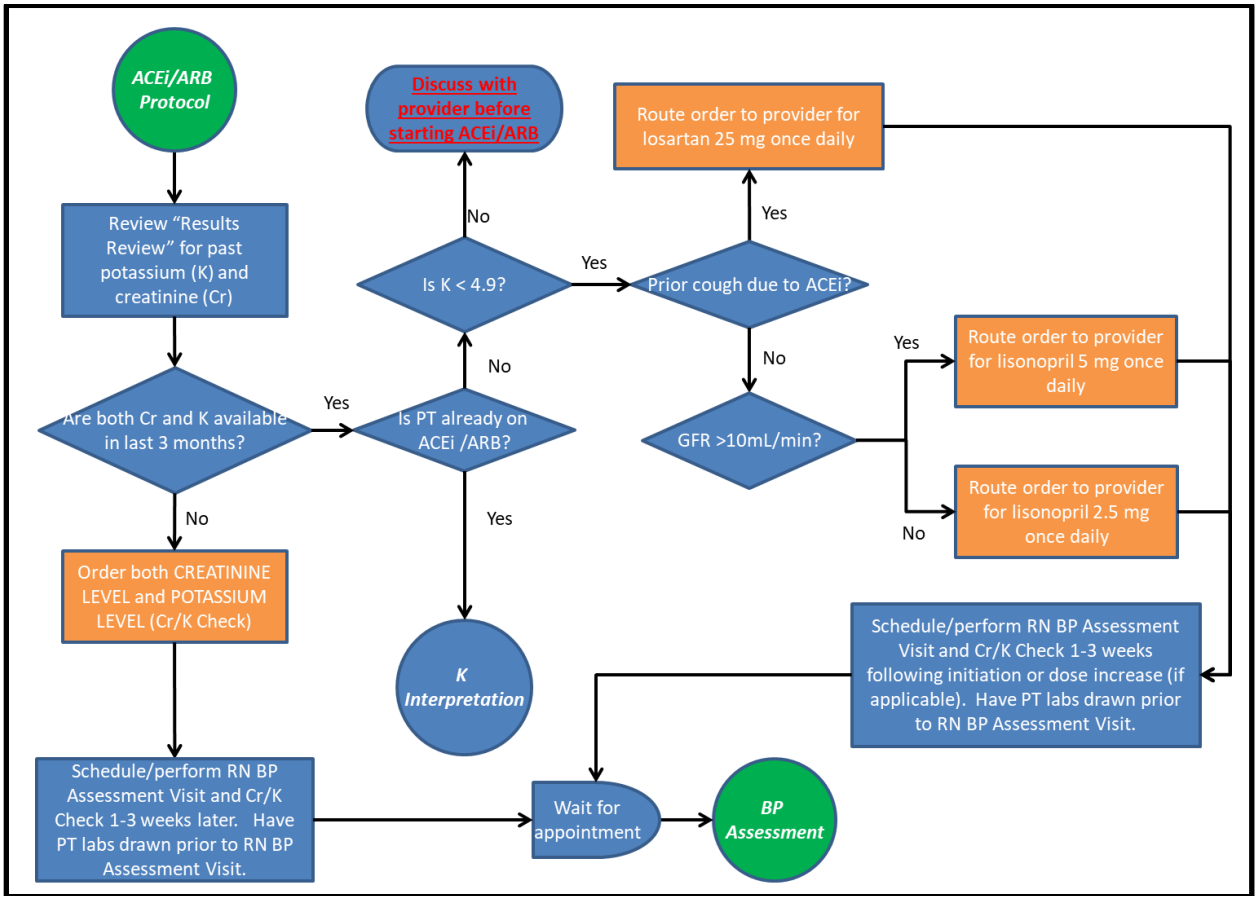

Figure 8: Practice Facilitator Workflow – ACEi/ARB protocol

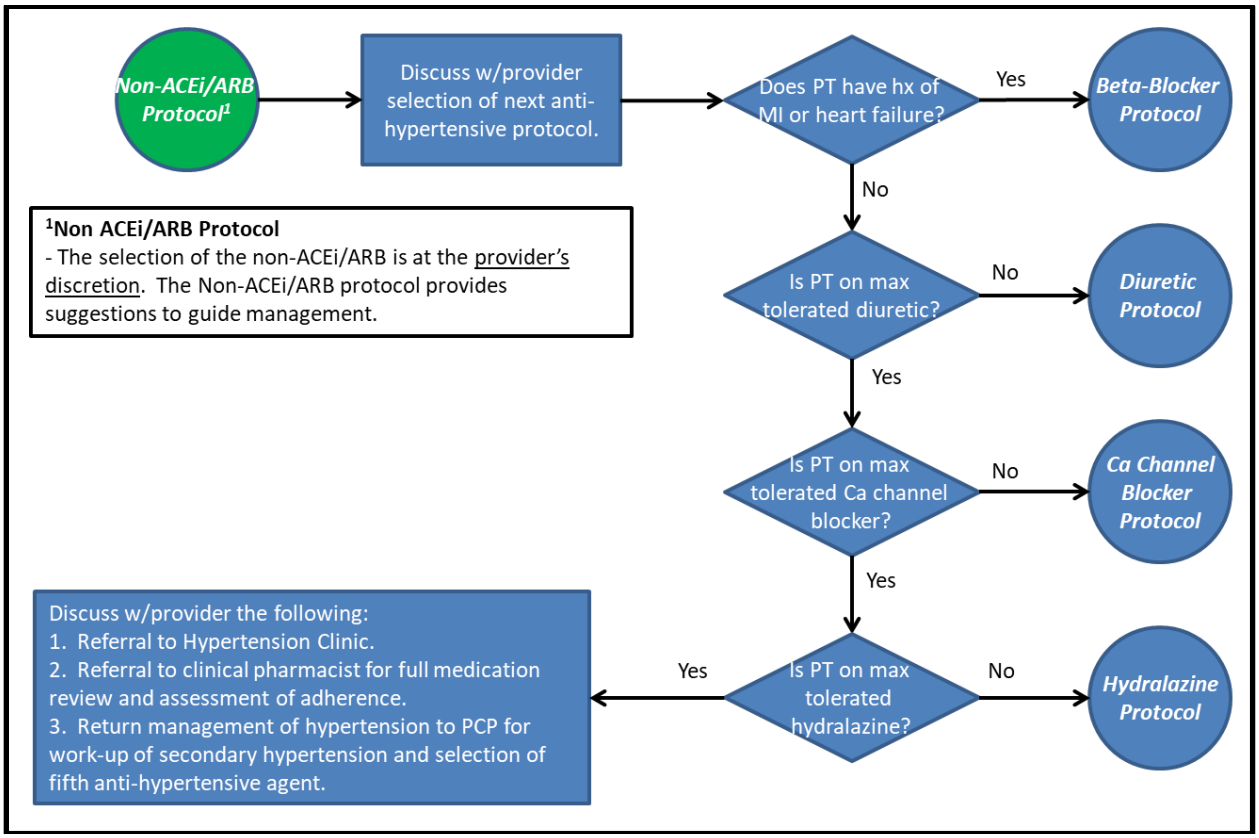

Figure 9: Practice Facilitator Workflow – Non-ACEi/ARB protocol

Given the critical role of the practice facilitator in the enrollment and protocol initiation processes, closer examination of the execution of their duties was deemed crucial in optimizing accurate and efficient enrollment of patients for the study.

1.4 Specific Aims

The purpose of this report is to compare the original practice facilitator workflow with the actual workflows being implemented within each healthcare system in order to identify opportunities to optimize enrollment in the study.

Chapter 2
Methods

2.1 Context

Each of the four healthcare systems is unique in the populations that they serve, the electronic medical records that they utilize, and the qualifications of the practice facilitators that they employ. Parkland Health &Hospital System serves as a safety net hospital for the underserved and uninsured residents of Dallas County. Texas Health Resources (THR) is one of the largest non-profit health systems in the United States serving a population of approximately 1 million individuals in North Central Texas. The North Texas Veterans Affairs (VA) Healthcare System serves more than 100,000 veterans in North Texas. ProHealth Physicians of Connecticut is one of the largest healthcare providers in Connecticut providing care to more than 250,000 adults spread across numerous individual practices. Both Parkland Health and Hospital System and Texas Health Resources utilize EPIC for their EHR. On the other hand, Veterans Affairs utilizes CPRS while Pro Health Physicians of Connecticut utilizes Allscripts. Each healthcare system also employs practice facilitators from different medical backgrounds. Parkland Health & Hospital System employs a registered nurse with a MSN assisted by an LVN. Texas Health Resources employs a nurse practitioner, assisted by a CRNA in training. The North Texas VA employs a foreign physician (MBBS) with a MPH with assistance from Pharmacist in the VA system. Lastly, Pro Health of Connecticut employs a pharmacist with assistance from a research coordinator These differences simultaneously enhance the robustness and external validity of the study, but also create challenges in its execution.

2.2 Intervention

The differences in structure of each healthcare system, EHR types, and practice facilitator qualifications resulted in unique workflows for each of the four unique entities.

Careful detailing of each of the practice facilitator workflows is necessary in order to identify efficiencies and deficiencies in each process. The details of each workflow was unearthed via in-person meetings, phone conversations, and e-mail exchanges with each of the practice facilitators. Challenges and areas for improvement were also discussed.

2.3 Study of the Intervention

The four unique practice facilitator workflows were diagrammed and proofed for accuracy. Challenges in the process identified by the practice facilitator were also cataloged. In the long-term, correction of deficiencies and their impact on study enrollment will be a useful means of assessing implemented changes in the workflows.

2.4 Measures

Similarities and differences noted in the workflows will allow the identification of the highest yield areas for improvement. Corrections in the process that impacts all the workflows should have the greatest impact across all healthcare systems while challenges isolated to a single healthcare system are not likely correctable by entities outside of their purview. In the long-term, enrollment numbers should be utilized as the objective measure due to changes in the practice facilitator workflows. In theory, correction of inefficiencies in each workflow should lead to an improved ability to identify and enroll patients in the study. Qualitative feedback from each of the practice facilitators can also be a useful tool for assessing the impact of changes in processes. This feedback should also include time spent by each practice facilitator before and after any interventions were employed.

2.5 Analysis

Comparison of each of the four unique workflows to the original, “generic” workflow as well as to each other will help to identify challenges consistent across all of the systems as well as ones unique to each system. Comparison of qualitative feedback provided by each of the practice facilitators will also be utilized for the same objective.

In the long-term, changes in the pace of enrollment should be utilized to measure the impact of modifications in the various workflows. Feedback from each practice facilitator on the perceived impact (e.g. improved ease vs. increased difficulty) of the modifications as well as time spent performing their duties will also be valuable information to gather. Modifications to the process should be limited to what is perceived to be impactful and achievable. Due to the relatively short duration of the study, observations and assessment of the impact of changes should be documented every six months. Any changes to the practice facilitator workflows that results in decreasing the pace of enrollment should be immediately halted.

2.6 Ethical Considerations

I would like to acknowledge the time and effort that Oliaku Idigo, Velile Nkolomi, Anuoluwapo Adelodun, and Alli Levine provided in developing the practice facilitator workflows and for their candid disclosure of challenges in the process. The study overall has addressed the ethics and regulatory issues seen in pragmatic trials with outcomes of the study contributing to future discussion on this evolving topic.[59-62]

Chapter 3
Results

3.1 Results

The practice facilitator workflows for each healthcare system follow a similar general scheme compared to Figure 4, yet have their own unique features that distinguish them from each other. In the Parkland Health &Hospital System workflow (Figure 10), candidate patients (those who require an additional lab value to confirm the presence of the disease triad) are able to obtain labs prior to their appointment. This allows the potential for patients to be enrolled during their scheduled appointment which is ideal. The Parkland system also features robust Best Practice Advisories and Smart Sets within their EHR which theoretically increases PCP adherence to recommended guidelines. The Parkland workflow also differs from the other healthcare systems in that a nurse provides the patient education prior to completion of the patient's appointment.

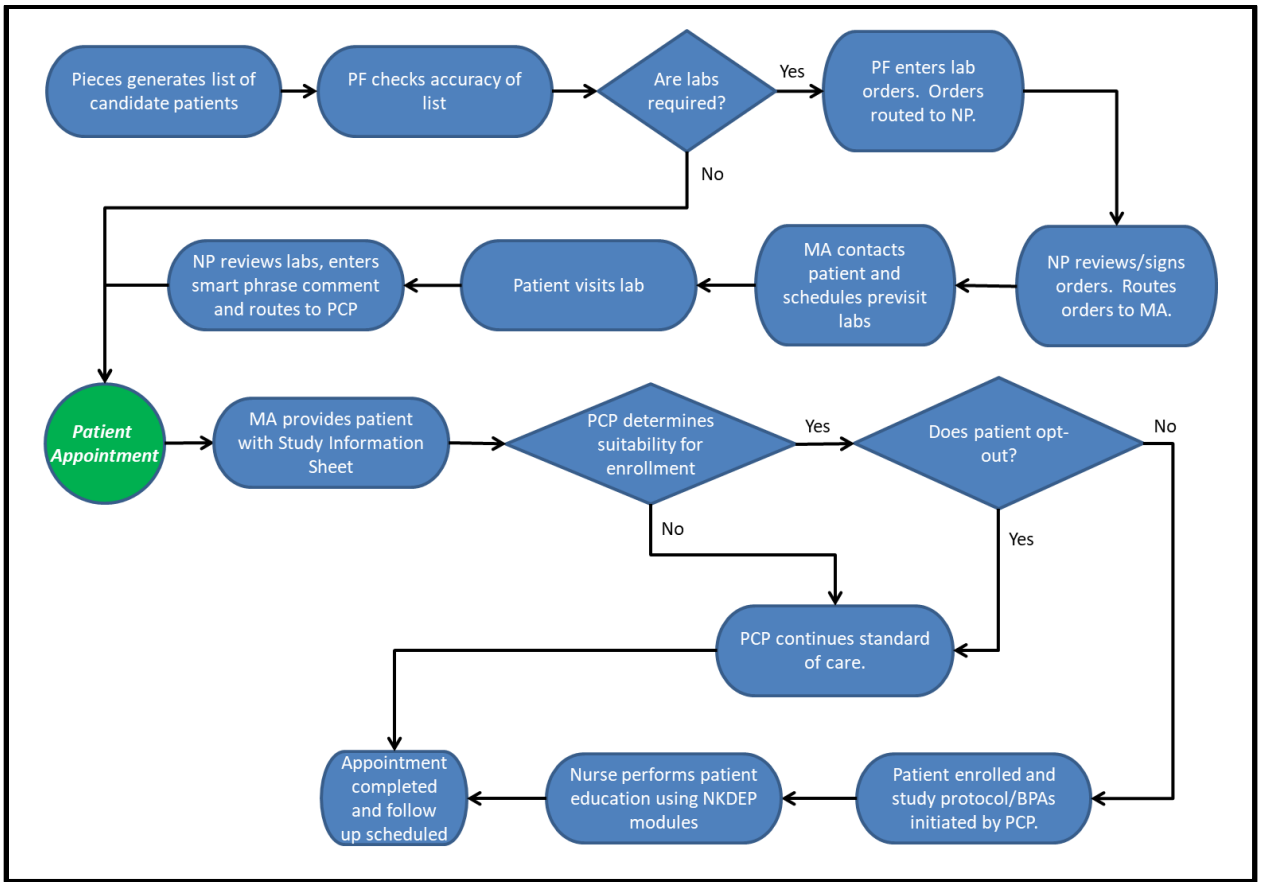

Figure 10: Parkland Health and Hospital System Practice Facilitator Workflow

The workflow at Texas Health Resources (Figure 11) is very similar to Parkland's with one main difference. Unlike the Parkland workflow, candidate patients in the THR system typically do not get their labs before their appointment. This results in candidate patients not being enrolled until their next appointment (assuming their labs confirm that they have the disease triad). THR also depends primarily on medical assistants to perform their patient education.

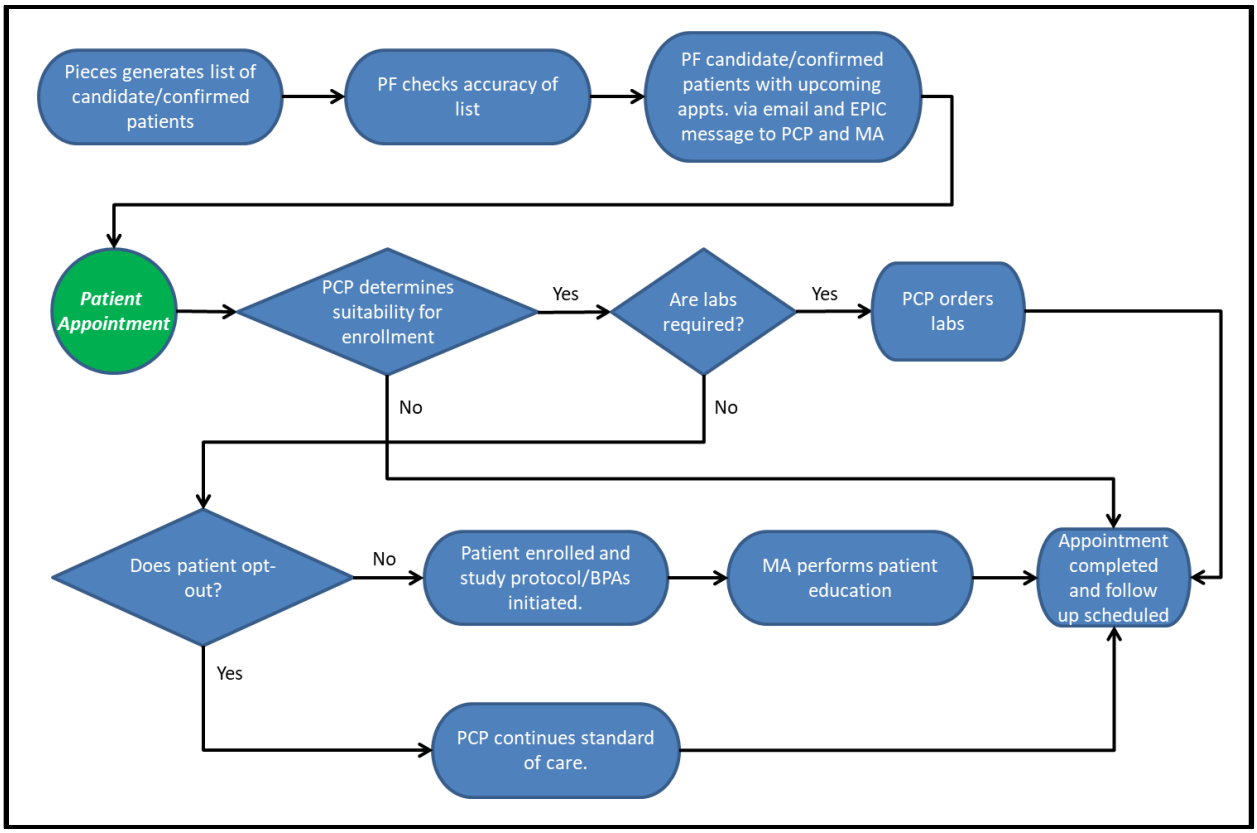

Figure 11: Texas Health Resources Practice Facilitator Workflow

The workflow for the North Texas VA (Figure 12) is different due to an additional step that takes place when the practice facilitator notifies a pharmacist about candidate patients (as opposed directly to PCPs). The pharmacist then sends best practice recommendations based off of the study protocol to the PCP. This system also does not leverage IT via smart sets and best practice advisories in the manner that the previously mentioned systems do. Licensed vocational nurses (LVNs) are also utilized for patient education along with the PCPs.

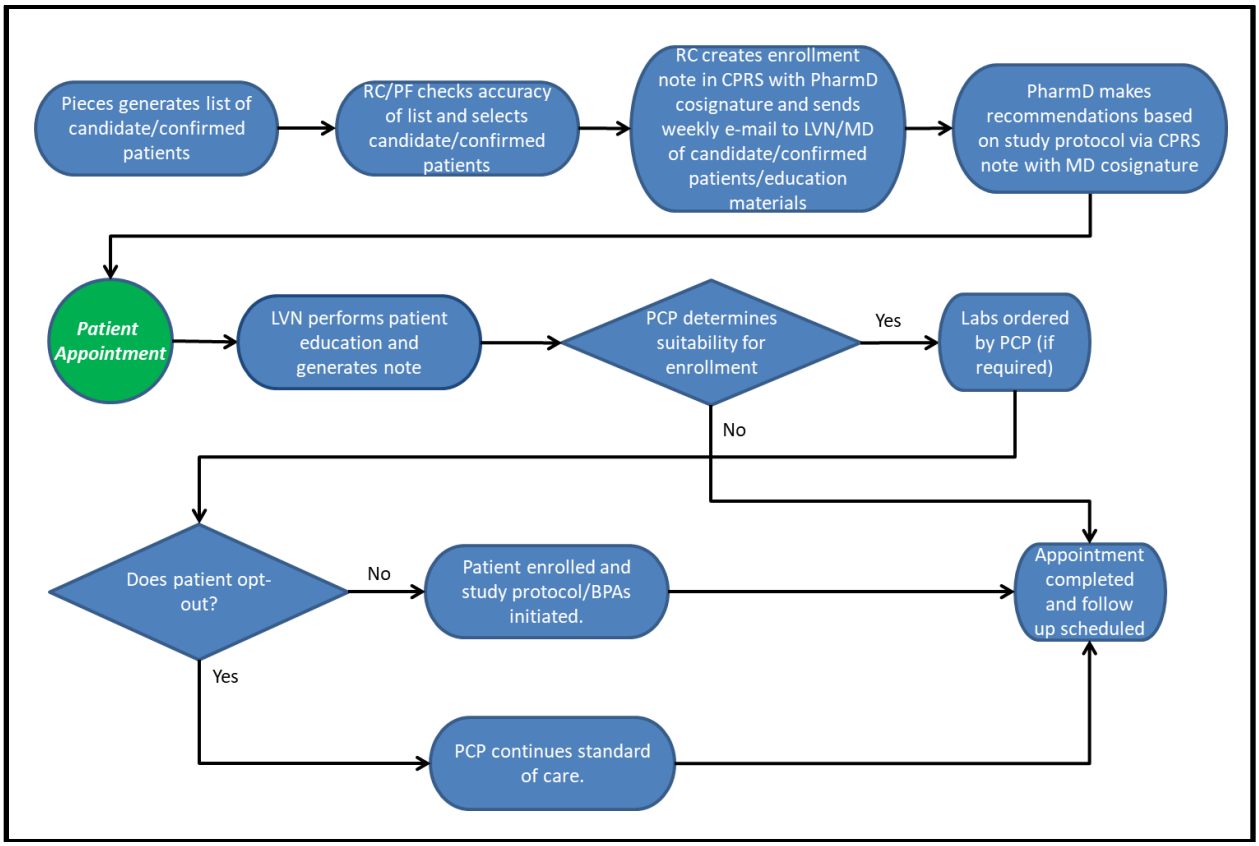

Figure 12: North Texas Veterans Affairs Practice Facilitator Workflow

The workflow for Pro Health Physicians of Connecticut (Figure 13) is similar to THR in that candidate patients typically do not get labs completed before their scheduled appointment. Since the practice facilitator is a pharmacist, they do not have the additional step like the VA and directly provide best practice recommendations to the PCPs. Similarly to the VA, this system does not leverage IT via smart sets and best practice advisories. The practice facilitator/pharmacist also takes on an additional role in being charged with close follow-up of high risk patients. It is presumed that the PCPs provide the patient education although this is difficult to determine due to the highly independent and individualized nature of this system.

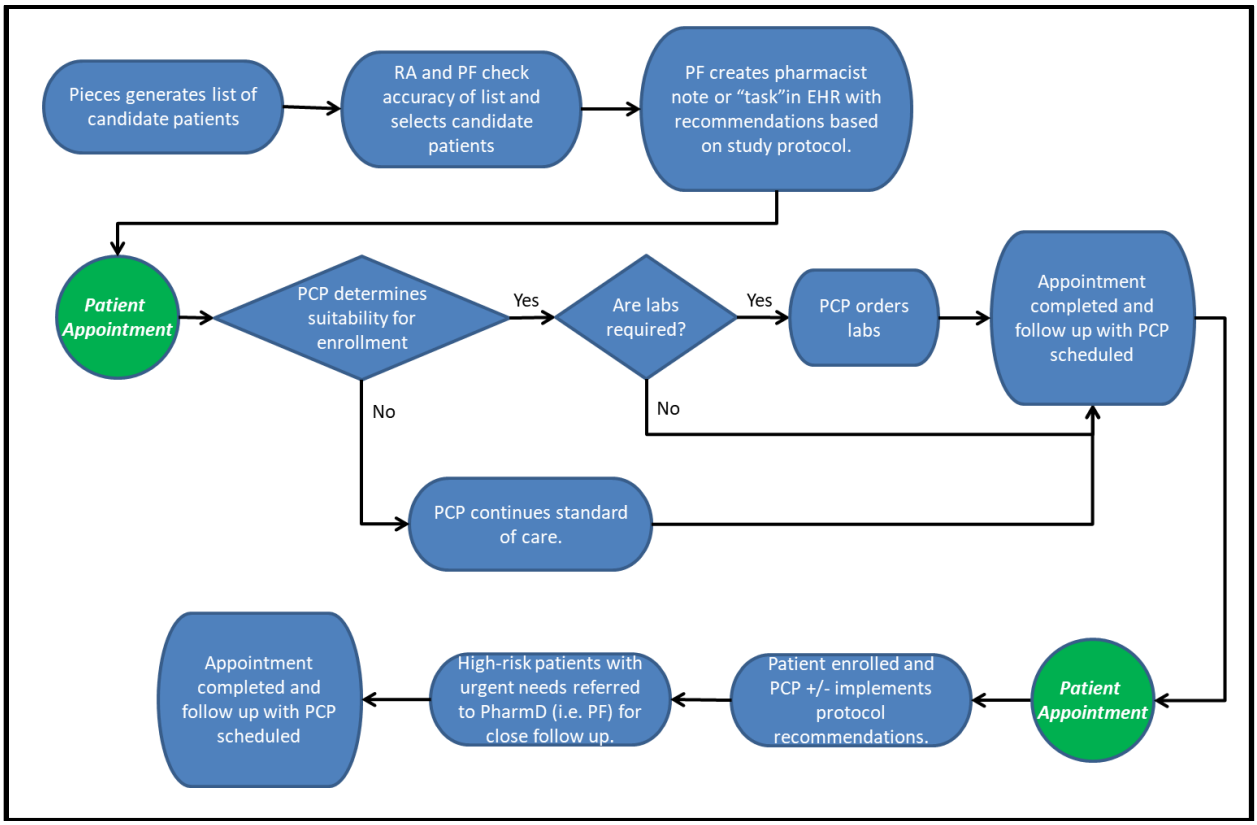

Figure 13: Pro Health Physicians of Connecticut Practice Facilitator Workflow

The major challenge identified by each practice facilitator is the accuracy of the generated confirmed and candidate patient lists that they have been receiving. They estimated that on average, approximately half of the patients were erroneously placed on their lists. This group of patients includes confirmed patients who occasionally appear on the candidate list. This specific error results in an immediate missed opportunity to enroll that patient. In addition, the inaccuracy of the lists has resulted in the practice facilitators performing a manual survey of each patient in order to identify actual confirmed and candidate patients. The inaccuracy of the lists was primarily the result of changes to the electronic medical records that affect patient selection and not the selection algorithm itself. A review of control patients demonstrated that the algorithm accurately identified 87% of eligible patients with the remaining unidentified

primarily due to absence of a recent lab. This has resulted in decreased patient enrollment since the practice facilitators may not be able to successfully "comb" through the entire list of patients before their appointments. In addition, the inaccuracy of the list leads one to question if all candidate patients are being identified. The practice facilitators have also been maintaining running databases of all confirmed and candidate patients. This has been particularly necessary for the systems in which labs cannot be obtained prior to appointments. Without these databases, patients confirmed to meet inclusion criteria after their appointment run the risk of "falling off" the list.

In the initial stages of enrollment, each practice facilitator indicated varying degrees of resistance from providers in initiating the study protocol. Most of this resistance was due to the perception that the study was creating additional work or dictating how they are running their practices. Due to various interventions, the practice facilitators now feel that this is largely a non-issue and that this is no longer a detractor from enrollment.

Another factor that has negatively impacted enrollment in each healthcare system has been patients missing their scheduled appointments. Although this is an inherent part of a pragmatic study, it is nonetheless a source of missed opportunity.

Another challenge experienced at all the healthcare systems has been getting candidate patients to the lab prior to appointments. Either the practice facilitator does not have the authority to order labs (VA, THR, ProHealth) or patients sometimes cannot be contacted (Parkland). This problem is further exacerbated when a patient then misses his follow-up appointment in which he would be getting enrolled.

Individually, each practice facilitator identified challenges that were unique to their situation. At Parkland, the practice facilitators are unable to sign lab orders (due to credentials) which has occasionally resulted in questionable adherence to the study protocol and delays in enrollment. At THR, the practice facilitator is also unable to sign lab orders as it is the responsibility of each clinic site to do so. This results in decreased enrollment pace as previously mentioned. At North Texas VA, the high overall workload of the pharmacist has resulted in the inability to provide protocol recommendations to the PCP for every patient prior to their appointments. This "bottleneck" has an obvious slowing effect on the enrollment process. Finally, at ProHealth, there is no way to identify whether or not a PCP has read the pharmacist note that contains the protocol recommendations. While this would not cause enrollment issues, it could have an impact on outcome measures for the overall study.

Chapter 4

Discussion

4.1 Summary

In my interactions with the practice facilitators the topic that they overwhelming wished to discuss was the accuracy of the patient lists. The increased time spent by the practice facilitators in verifying candidate and confirmed patients undoubtedly has decreased the pace of enrollment both directly and indirectly by taking away their ability to intervene in clinical site specific issues. Another key finding is the inability of some of the healthcare systems to obtain labs prior to appointments. This variation from the

idealized workflow significantly delays enrollment for patients who meet inclusion criteria and might have resulted in those patients not being identified later by the patient identification algorithm if not for the vigilant work of the practice facilitators. However, despite these challenges, the outcome measures for the study should not be impacted although the pace of enrollment is not optimized. These two aforementioned findings present the greatest actionable opportunities for improvement in patient enrollment pace and ease of execution.

4.2 Interpretation

The primary factor in the workflows that is slowing the enrollment process is the inaccuracy of the patient lists that the practice facilitators are receiving. The root cause of the error in the candidate/confirmed patient lists seems to lie in the the integration of EMR changes that have occurred without notice. Previous studies have shown that case-finding algorithms can be very accurate in the identification of patients with a variety of disease conditions with the algorithm for this study also demonstrating good accuracy.[54,63-69] However, this study is unique in that the algorithm seeks to identify patients with a triad of conditions spanning four healthcare systems and three different EHR types. To the best of our knowledge, this is the only study to attempt this. The additional layers of complexity due to multiple disease conditions and EHR systems is the apparent culprit for some of the error with initial qualitative assessment seeming to indicate that CKD is the most prevalent misidentified disease condition.

Another potentially actionable issue that has slowed enrollment across all the healthcare systems is the inability to obtain labs prior to appointments. For a potentially confirmed patient, this can result in an enrollment delay of up to several months

depending on when the follow-up appointment is scheduled for. This delay can be further extended if the patient misses or reschedules their appointment. Granting practice facilitators (THR, VA, Prohealth) the ability to schedule needed labs prior to appointments would likely aid in expediting enrollment. However, we realize that this may be a difficult undertaking due to established rules and regulations that are in place at each of these healthcare systems.

4.3 Limitations

One of the main limitations when examining the practice facilitator workflows is the macro-level at which they take place. These workflows do not account for the unavoidable variability that occurs at individual practice locations. This variability likely increases further for systems in which each PCP practices at a different location (e.g. ProHealth). This could potentially introduce variation in protocol adherence, especially in the healthcare systems (VA, Prohealth) without robust BPAs and smart sets. As such, interventions should be generalizable to entire healthcare systems in order to exert maximal effects. Practice facilitators should also periodically perform their own quality assurance at individual practice sites.

Another limitation of this investigation was the lack of quantitative data. Information that would be particularly useful is the accuracy of the patient lists and the average length of delay due to not obtaining labs prior to appointments. These data points would allow for future quantitative assessment of interventions to the workflow.

4.4 Conclusions

Investigation and comparison of the practice facilitator workflows at each of the four healthcare systems aided in the identification of shortfalls and challenges that have hindered the patient enrollment process. These workflows would also be useful in future pragmatic studies that utilize the EMR in the identification of a patient population. It also generally instructive for studies that seek to utilize EMRs to identify patient populations. Despite the theoretical efficacy of informatics application in healthcare, there is still much progress to be made in this arena.

Overall, the study as a whole will be an important part of the growing collection of pragmatic trials due to their increased external validity compared to traditional explanatory trials. Potential next steps include validation of the patient selection algorithm (before and after modifications), continued tracking of enrollment progression, and logging the time spent by practice facilitators “proofing the patient list”. This would allow one to examine the effects of algorithm changes in three distinct ways. It would also be beneficial to explore the possibility of enabling practice facilitators the ability to schedule lab visits prior to the visit with their PCP as this would further enhance the pace of enrollment. The study itself will ultimately be a valuable learning tool in the construct and execution of future pragmatic trials and hopefully demonstrate that a collaborative model of primary care-subspecialty care that leverages information technology can improve the quality of patient care.

Chapter 5
Other Information

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