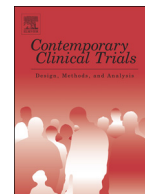




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Q1 Rationale and design of a patient-centered medical home
 2 intervention for patients with end-stage renal disease
 3 on hemodialysis

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ABSTRACT

In the U.S., more than 400,000 individuals with end-stage renal disease (ESRD) require hemodialysis (HD) for renal replacement therapy. ESRD patients experience a high burden of morbidity, mortality, resource utilization, and poor quality of life (QOL). Under current care models, ESRD patients receive fragmented care from multiple providers at multiple locations. The Patient-Centered Medical Home (PCMH) is a team approach, providing coordinated care across the healthcare continuum. While this model has shown some early benefits for complex chronic diseases such as diabetes, it has not been applied to HD patients. This study is a non-randomized quasi-experimental intervention trial implementing a Patient-Centered Medical Home for Kidney Disease (PCMH-KD). The PCMH-KD extends the existing dialysis care team (comprised of a nephrologist, dialysis nurse, dialysis technician, social worker, and dietitian) by adding a general internist, pharmacist, nurse coordinator, and a community health worker, all of whom will see the patients together, and separately, as needed. The primary goal is to implement a comprehensive, multidisciplinary care team to improve care coordination, quality of life, and healthcare use for HD patients. Approximately 240 patients will be recruited from two sites; a non-profit university-affiliated dialysis center and an independent for-profit dialysis center. Outcomes include (i) patient-reported outcomes, including QOL and satisfaction; (ii) clinical outcomes, including blood pressure and diet; (iii) healthcare use, including emergency room visits and hospitalizations; and (iv) staff perceptions. Given the significant burden that patients with ESRD on HD experience, enhanced care coordination provides an opportunity to reduce this burden and improve QOL.

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1. Introduction

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Over 400,000 people in the U.S. receive hemodialysis for end-stage renal disease (ESRD) [1]. Despite the relatively low

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49

50 prevalence of ESRD, healthcare expenditures for these patients
51 are disproportionately high [1,2], and individuals experience
52 high morbidity, mortality, and poor quality of life (QOL) [1,3–6].
53 In 2012, Medicare expenditures for ESRD totaled \$28.6 billion [1].
54 Patients with ESRD on hemodialysis spend 12 days in inpatient
55 care yearly on average and have mortality rates exceeding 150
56 deaths per 1000 patient-years [1]. Additionally, ESRD patients'
57 self-reported QOL is consistently below that of the general
58 population [5].

59 While some of the excess morbidity, mortality, and poor
60 QOL associated with ESRD are due to ESRD itself and asso-
61 ciated comorbid illnesses [3], the effects of these illnesses
62 may be amplified by fragmented healthcare delivery. ESRD
63 patients undergo dialysis treatments for 3–5 h thrice
64 weekly. This rigorous schedule creates difficulty in manag-
65 ing comorbid illnesses, so patients often have increased
66 complications as well as the use of emergency healthcare.
67 Improved care coordination between primary care physi-
68 cians and nephrologists could potentially help alleviate this
69 problem [7].

70 An attempt to address the gaps in care coordination has
71 been tested through the Patient-Centered Medical Homes
72 (PCMH) model. PCMH uses a team approach to provide
73 comprehensive care for patients, has been implemented for
74 patients with chronic complex illnesses such as diabetes, and
75 has been found to reduce hospitalizations, emergency room
76 visits, and healthcare costs [8,9]. For example, among patients
77 with chronic kidney disease not yet requiring dialysis, the use
78 of a multidisciplinary care team, a key element of PCMH,
79 reduced the rate of kidney function decline [10]. However, to
80 date, the implementation of a PCMH has not been tested
81 among U.S. hemodialysis patients [11]. Although the current
82 U.S. dialysis care team is multidisciplinary in its inclusion of a
83 nephrologist, nurse, dietician, and social worker [12], it lacks
84 integration with primary care [7]. The current model also does
85 not include other professionals, such as pharmacists, who have
86 been recognized to improve care for other chronic illnesses
87 [13]. Moreover, the current care model does not include
88 nonprofessional team members such as community health
89 workers (CHW) functioning as health promoters, who are
90 individuals without a formal medical background but who
91 receive specialized training as peer educators and liaisons
92 between patients and healthcare professionals to assist in
93 providing culturally sensitive care. In several studies of
94 PCMH for chronic diseases other than ESRD, CHWs have
95 been shown to improve clinical outcomes and reduce care costs
96 [14–16].

97 The purpose of this study is to examine a comprehensive,
98 multidisciplinary care model in ESRD patients within the
99 hemodialysis setting. We will implement a Patient-Centered
100 Medical Home for Kidney Disease (PCMH-KD) and expect to
101 enroll approximately 240 in-center hemodialysis patients.
102 We expect that the PCMH-KD will enhance dialysis care
103 by adding a primary care physician, nurse coordinator,
104 pharmacist, and CHW to the care team. This manuscript
105 describes the design and methodology of the trial. The
106 primary goal of the project is to evaluate the effectiveness of
107 the PCMH-KD model compared to the current care model for
108 improving patient- and caregiver-reported outcomes,
109 clinical outcomes, avoidable healthcare utilization and staff
110 perceptions.

2. Materials and methods 111

2.1. Hypotheses 112

This study will test whether, compared to the current 113
standard care model for ESRD patients on hemodialysis, imple- 114
mentation of the PCMH-KD care model will 115

- improve patient quality of life 116
- improve patient knowledge about hemodialysis 117
- increase patient access to care for conditions other than ESRD 118
- improve care coordination 119
- improve medication adherence 120
- improve compliance with diet and fluid restrictions 121
- reduce emergency care use and hospitalizations 122

2.2. Study design 123

This study is a non-randomized quasi-experimental inter- 124
vention trial of implementation of a PCMH-KD over 2 years at 125
two dialysis units. Patients under care at each site will be 126
observed in the current care model for six months prior to the 127
implementation of the PCMH-KD model. During this observa- 128
tion period, patient-reported outcomes, clinical outcomes, 129
healthcare use, and staff perceptions will be measured and 130
will provide the basis for comparison with the PCMH-KD 131
measures throughout the 18-month intervention period. Study 132
procedures have been approved by the University of Illinois at 133
Chicago Institutional Review Board. 134

2.3. Participants, setting, and recruitment 135

Eligible participants will be English- or Spanish-speaking 136
adults (≥ 18 years) with ESRD receiving maintenance hemodi- 137
alysis treatments at two dialysis units in Chicago: (1) University 138
of Illinois Hospital and Health Sciences System Dialysis Center 139
(UIHS-D) and (2) Fresenius Medical Care Chicago Westside 140
Dialysis Center (FMC). UIHS-D is a non-profit, university- 141
affiliated dialysis unit, and FMC is an independent for-profit 142
center owned and operated by Fresenius Medical Care, Inc. 143
Nephrologists from the University of Illinois at Chicago comprise 144
the medical staff at both the UIHS-D and FMC units. Approxi- 145
mately 200 patients currently receive hemodialysis care at the 146
two sites. All patients at each dialysis unit will be offered the 147
intervention but may decline to participate. The patient 148
population at the participating dialysis centers is reflective of 149
the population in the centers' surrounding service area and has a 150
higher proportion of minority and low-income patients than the 151
national average, as well as a high burden of comorbid illness 152
(Table 1). Only patients receiving in-center hemodialysis (and 153
not peritoneal dialysis) were included in this study due to the 154
significant differences in dialysis care delivery and management 155
between the two types of dialysis. 156

Prior to enrollment in the study, patients at both dialysis 157
units will be provided with an informational, IRB-approved 158
pamphlet about the study during one of their regularly 159
scheduled dialysis treatments. After patients have reviewed 160
information about the study, a research staff member will 161
approach patients individually during their dialysis treatments 162
to answer any additional questions and, if the patient is willing 163
to participate, to obtain informed consent. Patients who do not 164

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