



Putting patients at the center of kidney care transitions: PREPARE NOW, a cluster randomized controlled trial

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Abbreviations: CKD, Chronic kidney disease; EHR, Electronic health record.

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ABSTRACT

Care for patients transitioning from chronic kidney disease to kidney failure often falls short of meeting patients' needs. The PREPARE NOW study is a cluster randomized controlled trial studying the effectiveness of a pragmatic health system intervention, 'Patient Centered Kidney Transition Care,' a multi-component health system intervention designed to improve patients' preparation for kidney failure treatment. Patient-Centered Kidney Transition Care provides a suite of new electronic health information tools (including a disease registry and risk prediction tools) to help providers recognize patients in need of Kidney Transitions Care and focus their attention on patients' values and treatment preferences. Patient-Centered Kidney Transition Care also adds a 'Kidney Transitions Specialist' to the nephrology health care team to facilitate patients' self-management empowerment, shared-decision making, psychosocial support, care navigation, and health care team communication. The PREPARE NOW study is conducted among eight [8] outpatient nephrology clinics at Geisinger, a large integrated health system in rural Pennsylvania. Four randomly selected nephrology clinics employ the Patient Centered Kidney Transitions Care intervention while four clinics employ usual nephrology care. To assess intervention effectiveness, patient reported, biomedical, and health system outcomes are collected annually over a period of 36 months via telephone questionnaires and electronic health records. The PREPARE NOW Study may provide needed evidence on the effectiveness of patient-centered health system interventions to improve nephrology patients' experiences, capabilities, and clinical outcomes, and it will guide the implementation of similar interventions elsewhere.

Trial registration: [NCT02722382](https://clinicaltrials.gov/ct2/show/study/NCT02722382)

1. Introduction

Over 115,000 patients develop kidney failure each year [1]. Patients with kidney failure have high rates of mortality [2–4] and must receive treatment to replace their kidney function, such as dialysis or a kidney transplant, to survive. Due to the morbidity of kidney disease and the demands of kidney failure treatments, patients with kidney failure often experience drastic changes in their physical and mental health that are often devastating not only for patients but also for their families [5–12]. Ideally, patients should receive substantial advance preparation before initiating kidney failure treatments. Optimal treatment preparation involves educating patients regarding numerous treatment options, assisting patients in treatment decision-making, and ensuring patients receive a number of preparatory clinical evaluations, including evaluations for vascular surgery, kidney transplantation, or home dialysis treatments.

Unfortunately, many patients are unprepared for kidney failure treatments—even when they have been under nephrology specialty care for years [13–15]. A number of factors contribute to patients' poor preparation. For instance, nephrologists are often unable to predict with precision the timing of when patients' kidney failure will occur, as many patients with advanced kidney disease never progress to kidney failure [16]. As a result, nephrologists may feel hesitant to discuss kidney failure with patients too early. However, some patients with advanced kidney disease experience very rapid declines in their kidney function. Most of these patients have no symptoms, and their kidney disease may progress so rapidly that nephrologists have little time to help patients prepare in advance. As a result, many patients experience unplanned, chaotic, and psychologically traumatic treatment initiation [17–21]. Even when patients are aware of their declining kidney function in advance of treatment, they may fail to obtain recommended consultations to facilitate their advance preparation for dialysis or transplantation [22–25].

Hence, interventions are needed to improve the identification of patients in need of advance preparation, educate patients on their treatment options, help patients navigate multiple preparatory clinical evaluations for kidney failure treatment, and help patients obtain adequate psychosocial support for potentially traumatic kidney care transitions.

Efficacious interventions exist to help patients experience better kidney transitions, but their effectiveness in the real world may be limited by their disjointed or piecemeal implementation. For instance, risk prediction tools are now available to help physicians recognize when patients are at risk of kidney failure and could most benefit from kidney transitions care [26–29]. Further, randomized trials have shown that patients who receive education and psychosocial support for their kidney disease experience 43% fewer hospitalizations and prolonged time to kidney failure [30–32]. Randomized trials in patients at risk of kidney disease have also shown that when patients learn skills to overcome problems they feel empowered and better manage their kidney disease risks [33,34]. Studies also suggest that when patients receive assistance to make decisions and navigate complex care plans, they are up to 30% more likely to pursue self-care treatment options such as kidney transplantation or peritoneal dialysis [31,35]. To date, these promising interventions have not been implemented in a coordinated fashion to improve patients' care experiences and outcomes in a comprehensive manner.

2. Materials and methods

2.1. Overview

The PREPARE NOW study is a pragmatic cluster randomized controlled trial designed to quantify the effectiveness of integrated health system interventions to improve patients' preparation for kidney failure treatments. Based in Geisinger health system and working with

Geisinger Health Plan, the study takes advantage of existing health system and health plan informatics, clinics, and care-management resources. In PREPARE NOW, a new intervention, called ‘Patient Centered Kidney Transitions Care’ has been deployed among four [4] of eight [8] randomly assigned nephrology clinics at Geisinger. Patient reported, biomedical, and health system outcomes are being measured over 36 months through telephone questionnaires, Geisinger electronic health records (EHR), and administrative data (Fig. 1). All study procedures have been approved through single IRB agreement oversight at Duke University.

2.2. Study setting and patient population

2.2.1. Health system and health plan

Geisinger is a large integrated health system that provides care for over 4 million residents in 50 rural and suburban counties in Pennsylvania and New Jersey. The counties that Geisinger serves are substantially rural (40% population) with moderate to low education (57% with high school or less education), advanced age (20% age > 65 years), and low household income (52% with annual household income < \$50,000). Outpatient nephrology care is delivered in nine clinical practice sites to approximately 4000 patients with chronic kidney disease (CKD) not on dialysis. There are one (1) to three (3) nephrology providers per clinic depending on the size of each clinic, and some providers practice in more than one clinic. Patients receiving CKD care in Geisinger have demographic characteristics reflective of the overall health system, but with a higher proportion of persons over the age of 65 years (76% versus 20% in overall health system) since the prevalence of CKD increases with age. Geisinger uses a common electronic health record system (Epic® System) across all nephrology clinical practice sites. About one-third of Geisinger patients are also insured by the health system, through Geisinger Health Plan. Geisinger Health Plan manages care for over 580,000 members, insured through commercial, employer-based, and public payers. It deploys disease and care management programs for over 69,000 members, and it provides wellness programs for over 75,000 members. Geisinger Health Plan features a robust care-management program, providing nurse care management for patients with a number of complex chronic illnesses including congestive heart failure, advanced pulmonary disease, and kidney disease [36].

2.2.2. Nephrology clinics and patient population

The PREPARE NOW intervention was piloted at one of nine Geisinger nephrology clinic sites from December 2016 through June 2017. The study is being conducted formally among the remaining other eight (8) nephrology clinic sites, from July 2017 through December 2020. Clinics vary in terms of their size but are largely similar with regard to the distribution of demographic characteristics of patients receiving care in clinics (Table 1). All clinics are located within Central Pennsylvania and draw from a primarily rural population.

The PREPARE NOW study targets all adults receiving care in the eight (8) Geisinger nephrology practices who are older than 18 years of age and who have advanced kidney disease (all patients with a “very high risk” prognosis based on Kidney Disease Improving Global Outcomes (KDIGO) classification) [37,38]. A computer algorithm continuously identifies all eligible patients via a disease registry

implemented as part of the study. Patients are not excluded from enrollment in Patient Centered Kidney Transitions Care based on their language preference, however non-English speakers are excluded from telephone questionnaire assessments.

2.2.3. Intervention overview and conceptual framework

Patient-Centered Kidney Transitions Care is designed to help patients overcome obstacles to optimal kidney disease transitions by (1) improving health system infrastructure, (2) employing educational programs and established behavioral approaches (e.g. motivational interviewing and self-management training) [33,39], (3) providing patient navigation to help patients make high-quality informed treatment decisions [40], and (4) helping patients achieve their preference-aligned treatment goals in a timely manner [41,42]. The Chronic Care Model [43,44] provides a framework for the design of Patient-Centered Kidney Transitions Care (Table 2).

The intervention provides a suite of new electronic health information tools to help health care providers recognize patients in need of Kidney Transitions Care and to help health care providers focus their attention on patients’ values and treatment preferences related to kidney disease. The intervention also adds a ‘Kidney Transitions Specialist’ to the health care team who provides and facilitates integrated delivery of programs that provide patients with knowledge, skills, and assistance to manage their disease, make high-quality treatment decisions, obtain needed psychosocial support, and navigate complex treatment plans (Fig. 2). Kidney Transitions Care is driven by the Kidney Transitions Specialist and occurs independent of other providers (e.g., nephrologists and primary care providers) who are not trained to change their usual practice patterns aside from being prompted to utilize the electronic tools available at intervention sites.

2.3. Intervention electronic health information tools

Patient Centered Kidney Transitions Care electronic health information tools include (1) a continually updated disease registry paired with a real-time validated risk prediction tool, (2) a tool to electronically assess patients’ values to facilitate treatment decision-making, (3) a care navigation and tracking tool, and (4) mechanisms for ‘broadcasting’ patients’ kidney failure treatment preferences in advance of kidney failure (Table 3). These tools are only available to be used at intervention sites as part of Kidney Transitions Care.

2.3.1. Disease registry and risk prediction electronic tools

To identify patients at increased risk of progression to kidney failure and therefore at greatest need for intervention, we have implemented a population based kidney disease registry (i.e., continually updated electronic list, called the ‘Kidney Transitions Registry’) which incorporates an automated risk prediction tool alongside the Geisinger electronic health record platform. The Kidney Transitions Registry classifies patients as being on the registry based on staging criteria from Kidney Disease Improving Global Outcomes (KDIGO). The registry is designed to include all patients with a “very high risk” prognosis based on eGFR and albuminuria categories (stages G3aA3, G3bA2-A3, G4A1-A3, and G5A1-A3) [37]. Outpatient data from the electronic health record are processed nightly to identify qualifying patients. Patients remain in the registry throughout all their care at Geisinger until six (6)

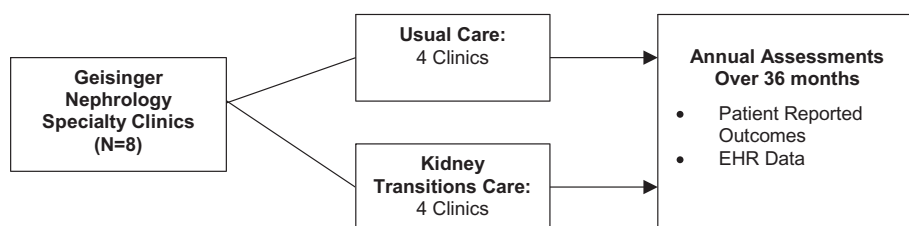


Fig. 1. Study design.

Table 1
Demographics of adult patient population in Geisinger nephrology practices.

Practice name	Total CKD patients ^a	eGFR < 30	White	African American	Hispanic	Female	Age > 65 years
Pilot site ^b	1754	593	98%	2%	0%	51%	69%
Study site 1	132	51	99%	2%	0%	58%	74%
Study site 2	126	50	95%	4%	0%	64%	71%
Study site 3	861	248	99%	1%	0%	62%	82%
Study site 4	172	54	98%	1%	0%	53%	81%
Study site 5	221	58	100%	0%	0%	62%	82%
Study site 6	582	112	97%	2%	0%	56%	79%
Study site 7	116	46	99%	1%	0%	51%	82%
Study site 8	76	34	100%	0%	0%	66%	82%
Grand total	4040	1246	98%	2%	0%	56%	76%

^a All patients > 18 years with 2 eGFR measures < 60 ml/min/1.73m² > 90 days apart, not on dialysis, with at least 1 visit at each respective study site.

^b One Geisinger nephrology clinic served only as Pre-Trial Intervention Refinement Site.

months after they transition to care for kidney failure (i.e., for dialysis or kidney transplant).

The automated risk prediction tool is a well-validated computer algorithm designed to help providers identify individuals with a high predicted risk of developing kidney failure within 2 years based on their personal characteristics, including their demographics and their most recent commonly obtained laboratory measures (age, gender, eGFR, urine albumin-to-creatinine ratio, calcium, phosphorus, albumin, and bicarbonate) [26,45]. The risk prediction algorithm is applied nightly to all patients on the registry to detect any changes in patients' individual risk profiles based on outpatient laboratory values. When the algorithm identifies a patient at imminent risk of progression within 2 years (i.e., predicted risk > 10% to occur within 2 years), the health care team is alerted to the need for interventions to prompt shared decision-making about kidney failure treatments and to navigate patients through preparation care.

2.3.2. Patient values electronic tool

The 'Patient Values Tool' enables patients to enter their own lifestyle and treatment values directly into their health records. Patients use a secure web-based values clarification tool, adapted from an existing tool developed by Medical Education Institute [46]. The tool asks patients a series of questions to help them clarify their lifestyle and treatment values as a starting point for establishing their informed preferences for kidney failure treatment. Patients rate the importance of a set of values previously identified as meaningful to kidney patients, such as fertility, ability to work or travel, quality of life, physical symptoms, and survival [20,42,50]. A report is then generated with the patient's ranked values from most to least important. Patients are able to complete the tool on their own (i.e., at home through the electronic health portal) or with assistance from a Kidney Transitions Specialist (see below). Clinical interpreter services are used to assist non-English speakers in completing the tool. As intervention patients complete the tool, their values are directly transferred into their personal EHRs

through a secure electronic interface. Providers are able to view patients' values during visits, providing a basis for engaging in shared and informed decisions about kidney failure treatments. Patients are invited to complete the tool at any time and to update their treatment preferences if they change.

2.3.3. Kidney transitions specialist care navigation and tracking electronic tool

The 'Care Navigation and Tracking Tool' (Fig. 3) creates an electronic workspace to facilitate Kidney Transitions Specialists' comprehensive care planning and tracking for individual patients receiving Patient-Centered Kidney Transitions Care. Kidney Transitions Specialists plan, initiate, and track support they provide to individual patients receiving Patient-Centered Kidney Transitions Care using this tool. The tool enables Kidney Transitions Specialists in the intervention clinics to type free text notes about interactions with patients in reports that are uploaded to patients' EHRs for other health care providers to view. The tool pairs with the Kidney Transitions Registry which provides Kidney Transitions Specialists with continually updated lists of patients qualifying for Kidney Transitions Care as well as continually updated information on patients' risk (imminent versus not) of developing kidney failure.

2.3.4. Treatment preferences electronic broadcast in patient health records

The 'Treatment Preferences Broadcast' makes all providers aware of treatments patients want before they develop kidney failure. After patients identify their preferred kidney failure treatment, Kidney Transitions Specialists "broadcast" patients' preferences widely throughout the EHR by posting preferences on the problem list for all providers to see. Options for treatment preferences include in-center hemodialysis, home hemodialysis, peritoneal dialysis, transplant, conservative care (i.e., no dialysis or transplant therapy), or undecided. The problem list is reviewed during each clinical encounter as part of routine care. In addition, an alert banner displays within the electronic

Table 2
Chronic Care Model elements targeted by "Patient Centered Kidney Transitions Care" intervention.

Chronic care model element	Patient-centered kidney transitions intervention component addressing model
Health system culture	<ul style="list-style-type: none"> ● Prompt providers to engage in patient-centered transitions care ● Broadcast patient preferences for kidney failure treatments as advanced directives ● Embed Kidney Transitions Specialists into health care team
Clinical information system	<ul style="list-style-type: none"> ● Kidney Transitions registry ● Enable entry and display of patient values and preferences in Electronic Health Record ● Enable personalized Kidney Transitions Care planning
Health delivery system design	<ul style="list-style-type: none"> ● Enable education, psychosocial, and biomedical care coordination support
Decision support	<ul style="list-style-type: none"> ● (For providers): Prompts to engage in shared decision-making and develop plans that are aligned with patients' preferences ● (For patients): Provide resources and support informed shared decision-making
Self-management support	<ul style="list-style-type: none"> ● Provide self-management education ● Build self-management skills through Empowerment Training
Community resources	<ul style="list-style-type: none"> ● Facilitate patients' access to clinic and community resources for professional and peer psychosocial support

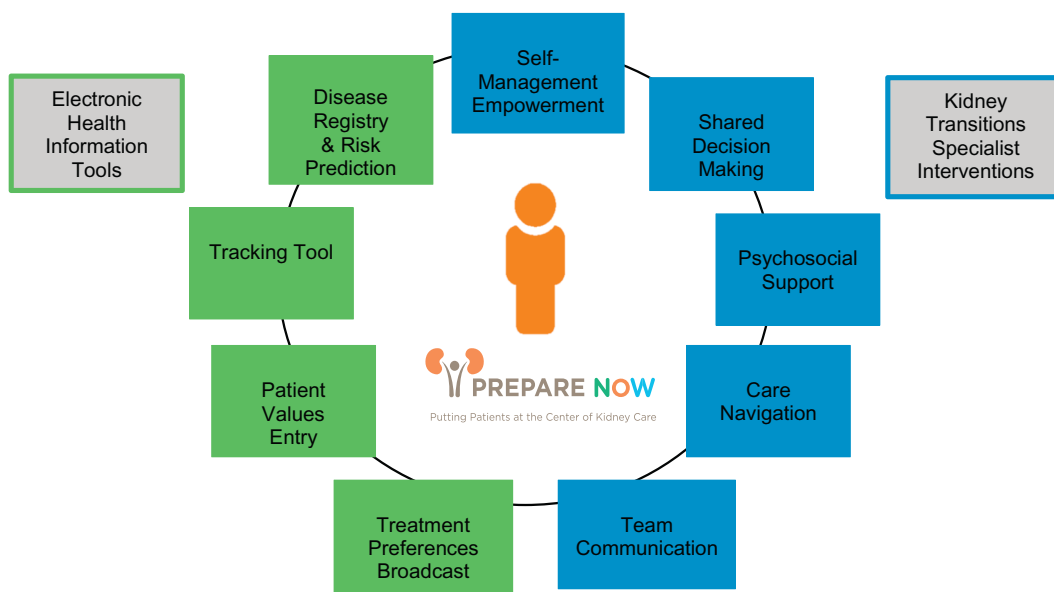


Fig. 2. Components of Patient Centered Kidney Transitions Care Intervention.

health record for any patient enrolled in Kidney Transitions Care to direct providers to the problem list to view kidney failure treatment preferences. This banner is visible to all providers within the health system, including primary care, subspecialists, and emergency room providers.

2.4. Intervention kidney transitions specialist activities

Kidney Transitions Specialists (N = 2) are registered nurses with special behavioral and navigation skills training who are supported jointly through research and Geisinger Health Plan Funding. Their activities are managed completely through Geisinger Health Plan, who partnered with the research team to co-develop the roles, responsibilities, and workflows of the Kidney Transitions Specialists to ensure they would be feasible and sustainable. By leveraging the disease registry to identify the highest risk patients, the target patient census is approximately 100 patients per specialist at any given time, which is consistent with goals for specialty care management services across the health system.

Kidney Transitions Specialists conduct five key activities: (1) empowering patients' self-management; (2) facilitating patients' shared and informed decisions about kidney failure treatments; (3) offering patients psychosocial support; (4) providing care navigation; and (5) facilitating team communication. Kidney Transitions Specialists provide and facilitate an individually tailored, multi-component intervention featuring evidence-based [47-50] patient support programs to impart patients with knowledge, skills, and assistance throughout kidney transitions care (Table 4). All interactions reinforce principles of self-care to slow kidney disease progression and encourage informed decision-making and planning for the possibility of future kidney failure, when appropriate.

Kidney Transitions Specialists tailor their approach to each

individual patient's readiness for making self-care behavior changes or decisions about kidney failure treatments as well as their risks of imminent kidney failure (i.e., within 2 years based on personalized risk prediction tool). The goal of this tailored approach is to help guide patients toward necessary changes 'at their own pace' and without overwhelming them, while also ensuring that patients begin planning for and making decisions about kidney failure treatments when they are most likely to need it. Using motivational interviewing techniques [39], Kidney Transitions Specialists assess patients' psychological readiness to engage in kidney disease self-care and treatment planning. They also refer to the risk prediction tool (see above) to determine whether discussion of kidney failure treatment modalities should be accelerated (e.g., when patients' risks of imminent kidney failure are 'high').

2.4.1. Self-management empowerment

Kidney Transitions Specialists ascertain patients' knowledge of kidney disease self-care principles or treatment options and provide patient education on kidney disease self-management through a range of avenues. These include: (1) reviewing education materials with patients, emphasizing core aspects of self-management that can slow kidney disease progression and decrease risk (e.g., diabetes and hypertension self-care including monitoring and medication adherence, diet and exercise, and avoidance of medications that are toxic to kidneys); (2) referring patients to dieticians for recommended dietary education [51,52], and (3) conducting nine-week group 'Living with Kidney Disease' classes.

'Living with Kidney Disease' classes have been rigorously developed, successfully implemented in ambulatory care settings [53], and shown in clinical trials to improve the self-management of patients with risk factors for kidney disease progression, including diabetes and hypertension [33]. They have also been shown to improve perceived empowerment and self-efficacy among patients with kidney disease

Table 3 Features and Goals of New Electronic Health Information Tools

Feature	Goals
Disease registry and risk prediction tool	<ul style="list-style-type: none"> ● Create a registry that identifies all patients needing Kidney Transitions Care and those at greatest risk of kidney failure ● Prompt providers to let them know patients need Kidney Transitions Care
Patient values tool	<ul style="list-style-type: none"> ● Allow patients to enter their own values and treatment preferences directly into their health records
Care navigation and tracking tool	<ul style="list-style-type: none"> ● Create a special place in the Health Information System and Electronic Health Record to plan care for patients' CKD transitions
Treatment preferences broadcast	<ul style="list-style-type: none"> ● Make all providers aware of treatments patients want <i>before</i> they develop kidney failure

Hemodialysis		
	Date	Outcome
Vascular Access		
Offered	1/2/2018	Interested
Referral Order	1/5/2018	Completed
Appointment	2/15/2018	Completed
AVF/G Placed	3/27/2018	Pending

Fig. 3. Sample screenshot from ‘Care Navigation and Tracking Tool’.

[34]. During two-hour sessions held weekly, patients are encouraged to consider a range of self-identified obstacles they face with regard to engaging in or reinforcing personal awareness of kidney disease and kidney disease self-management behaviors, including adherence to lifestyle recommendations, adherence to prescribed medical care, and engagement in treatment decisions. Strategies employed in education and skills training sessions include group instruction, handouts, teaching metaphors, prompting, modeling, behavioral rehearsal, homework assignments (performed in a workbook), reinforcement and feedback. Initial classes review principles of kidney disease self-management behaviors (including monitoring of risk factors for kidney disease progression such as diabetes and hypertension and avoidance of nephrotoxins). Emphasis of the classes is to empower patients to

prevent kidney disease progression and to take an active role in treatment decision-making through self-care and by overcoming barriers, including impulsive or careless (e.g., denial) coping behaviors. Class material and content were adapted from prior work in patients with diabetes and hypertension [33,53] to focus participants' attention on managing risk factors to mitigate kidney disease progression. All written materials for patients are developed at a 4th grade reading level to accommodate patients with low health literacy.

2.4.2. Shared and informed decision-making

Support for shared and informed decision-making begins during Living with Kidney Disease classes, when patients receive information about the progressive nature of kidney disease and the often-

Table 4
Kidney transition specialist activities and goals.

Activities	Goals
Self-management empowerment	Enable patients' self-care and activation
<ul style="list-style-type: none"> ● Provide and refer for education on CKD self-management ● Conduct “Problem Solving Self-Care Empowerment Classes” 	
Facilitate shared decision-making	Improve patients' informed decision-making about kidney failure treatments
<ul style="list-style-type: none"> ● Assess patients' readiness to engage in CKD self-care and CKD decision-making and tailor intervention to patient readiness ● Help patients comprehend CKD diagnosis and potential need for long-term planning about kidney failure treatments ● Support shared decision-making ● Ascertain values and enter in electronic health record ● Review educational information on treatment modalities ● Refer to kidney failure treatment modality classes ● Help patient document their treatment preferences 	
Offer psychosocial support	Connect patients to mental health and social support
<ul style="list-style-type: none"> ● Connect to behavioral and mental health services ● Connect to peer-mentors program (National Kidney Foundation) ● Identify caregiver support needs and facilitate support 	
Provide care navigation	Navigate patients through multi-step medical plans (e.g., referrals and tests)
<ul style="list-style-type: none"> ● Promote timely movement through multi-step referrals and tests (education, encouragement, assistance) ● Create link between disconnected CKD clinics and dialysis or transplant centers through letters and phone calls 	
Facilitate team communication	Advocate to align patients' care with their values
<ul style="list-style-type: none"> ● Communicate with care team to encourage alignment of care with patients' preferences 	

unpredictable decline of function to kidney failure. Information includes an overview of treatment options for kidney failure, emphasizing the importance that patients begin to consider their lifestyle and treatment values early. When patients are deemed to be at high risk of imminent kidney failure, Kidney Transitions Specialists refer patients to kidney failure treatment modality education classes, where patients learn about differences in kidney failure treatments during a one-time class (two hours) facilitated by the Kidney Transitions Specialist. During this class, patients complete the Values Tool to help clarify their personal lifestyle and treatment values. Groups watch a video and review written materials about treatment options using an evidence-based decision aid (PREPARED Decision Aid) [54]. This decision aid was rigorously developed following International Patient Decision Aids Standards [55] and includes information on all treatment modalities (kidney transplant, in-center hemodialysis, home hemodialysis, peritoneal dialysis, and treatment with no dialysis or transplant). It is available in both English and Spanish. The facilitator provides an overview of the goal of treatments and how they are delivered. They discuss a range of factors patients should consider when selecting a treatment option (including differences in the frequency and intensity of treatments, the amount of self-care they want to perform, concerns about surgery for transplant, quality of life, and financial concerns).

Patients are provided their own copies of decision aids to take home and are encouraged to review materials at home with family members or caregivers. After treatment modality education classes, Kidney Transitions Specialists contact patients to arrange 1-on-1 meetings for individual decision support. In meetings, Kidney Transitions Specialists follow principles of the Ottawa Decision Support Framework [40] to (1) help patients clarify the decision to be made regarding kidney failure treatments and their needs for information or support to make a decision; (2) review decision aids with facts and probabilities on risks with different treatments; (3) help patients clarify their values; (4) iteratively guide patients in their deliberation; and (5) monitor and facilitate patients' progress with decision-making.

2.4.3. Psychosocial support

Kidney Transitions Specialists refer all patients to an initial mental health evaluation, conducted by a Behavioral Medicine/Adult Psychology group, which provides psychological support for patients transitioning through a number of chronic or terminal disease transitions (e.g., congestive heart failure and cancer). These groups are part of usual care provided by Geisinger. Mental health professionals screen patients for mental health concerns, provide ongoing care for depression or anxiety, and assess social support, coping styles, communication preferences, and barriers to decision-making or adherence. They also provide counseling and grief support as needed. They are available along the continuum of patients' kidney disease care and maintain ongoing communication with Kidney Transitions Specialists throughout the course of patients' care.

Kidney Transitions Specialists also connect patients to peer support through a direct partnership with the National Kidney Foundation's "NKF Peers Program" [56]. In this program, patients are linked with trained peer mentors who offer support as patients face challenges with kidney disease self-care or kidney failure treatment decisions. The NKF Peers Program staff conducts a phone evaluation and pair patients with appropriate peer mentors. The NKF currently has approximately 60 trained peer mentors with dialysis and/or transplant experience.

2.4.4. Patient care navigation

Kidney Transitions Specialists support patients' timely accomplishment of complex treatment plans and help them overcome barriers to completing plans. They assist with planning and making appointments for education and to obtain procedures and tests needed to prepare for renal replacement therapy of their choice (e.g., evaluation for transplant, referral for fistula placement, vascular surgery appointments). Kidney Transition Specialists also follow a standard protocol to

facilitate goals of care conversations and end-of-life-care. For patients choosing conservative care (i.e., no dialysis or transplant), Kidney Transition Specialists monitor patients' symptoms, assist with completion of advance directives, and facilitate referrals to palliative medicine and/or hospice as clinically indicated. Kidney Transitions Specialists also assess a number of social and behavioral determinants of health and chronic disease self-management (e.g., transportation needs, environmental risks to health (e.g., lack of heat), food insecurity, and financial needs). Kidney Transitions Specialists are also trained registered nurses (RNs) who play a role in the clinical management of patients' chronic conditions, as acute situations arise and health status changes. The Kidney Transitions Specialists collaborate with patients' primary care providers, nephrologists and other healthcare team members to ensure care is coordinated and that non-biomedical quality of life issues are also addressed.

2.4.5. Team communication

Kidney Transitions Specialists partner with patients and act as 'champions' on their behalfs to advocate for treatments patients want. With patients' permission, Kidney Transitions Specialists (1) communicate with inpatient hospital teams if patients are admitted to initiate dialysis and (2) communicate with patients' non-Geisinger dialysis care teams. If patients are admitted to a Geisinger hospital, the Kidney Transitions Registry list identifies patients, allowing Kidney Transitions Specialists to review inpatient notes to determine if dialysis has been initiated or is being planned during the hospitalization. Kidney Transitions Specialists contact the inpatient hospital care team to let the team know of the patient's preference and advocate for preference aligned care. If patients initiate dialysis in a non-Geisinger hospital or are discharged to an outpatient dialysis clinic, Kidney Transitions Specialists contact providers (e.g., dialysis facility physician, nurse director, or social worker) via letters and phone calls to alert them about patients' preferences for care.

Kidney Transitions Specialists also directly communicate with primary care providers to keep them informed about the clinical status of their patients. When a patient is enrolled in Kidney Transitions Care, a letter is sent to the primary care provider notifying them that their patient is now at high-risk for progressing to kidney failure and will begin discussions about renal replacement therapy options. Primary care providers are invited to participate in these conversations and are notified once the patient has made a final decision about their kidney failure treatment choice.

2.5. Control condition: usual nephrology care at study practice sites

Usual Nephrology Care consists of patients' routine visits with their nephrologists. Patients receive medical care as prescribed by nephrologists with preparation for kidney disease transitions as deemed appropriate by nephrologists. Nephrologists document their care in the EHR. There is currently no Kidney Transitions Registry list, no routine 'flag' or prompt for providers to initiate kidney transitions care, no computer application to collect patients' values, track care, report patients' preferred care plans or broadcast treatment preferences. As kidney disease progresses, nephrologists refer patients to kidney failure treatment modality group education classes and discuss treatment options on an ad-hoc basis. Classes feature an industry-sponsored educational video and are facilitated by a social worker or nurse. Nephrologists make referrals to prepare patients for kidney transitions (e.g., for fistula placement or transplant evaluation) through routine mechanisms (e.g., referrals through the EHR) without the assistance of dedicated personnel. Peer mentoring and behavioral health services are not routinely offered. Usual nephrology care does not feature any system-supported CKD care coordination.

Table 5
Measures collected to assess outcomes and correlates in the PREPARE NOW study.

Primary outcomes	Source
Patient 'control', decision-making	
• Empowerment score	Q [59]
• Confidence (self-efficacy) with self care score	Q [60]
• % Patients deciding to initiate self-care treatment	Q, EHR
Medical	
• Hospitalizations	EHR, Q
Health system culture	
• % Patients with advance care plans or kidney failure treatment preferences broadcast in EHR	EHR
Secondary outcomes	
• % Patients with self-care biomedical care plans (PD, Home Hemodialysis, or Transplant referrals)	EHR
• % Patients achieving values aligned care within 6 months of kidney failure treatment initiation	Q
• Values and preferences documented in EHR	EHR
• Emergency dialysis initiation	EHR, Q
• Time to kidney failure	EHR, Q
• Vascular access (e.g., fistula) in place at hemodialysis initiation	EHR, Q
Demographics	
• Age, gender, ethnicity/race, education, health insurance status, employment, income, financial well being	EHR [†] , Q [61] [§]
Physical and mental health status	
• Kidney Function (glomerular filtration rate)	EHR [62]
• Presence and control of kidney disease progression risk factors [blood pressure, blood glucose, lipids, body mass index]	EHR [63–67]
• Comorbid Health Conditions	EHR [68]
• Depression, anxiety, need for mental health support	Q [69]
• Quality of Life	Q [70]
Self-care behaviors	
• Self-management, diet, exercise	Q [60]
• Medication adherence	Q [71], MPR ^a
Nephrology care	
• Duration and frequency of care	EHR, Q
• Patient centeredness of care	Q [72]
Health literacy and numeracy	
• Health literacy	Q [73–75]
Decision-making	
• Decisional conflict	Q [76]
• Preferred involvement in decisions-making	Q [77]
• Confidence in decision-making (decision self-efficacy)	Q [78]
• Control (locus of control)	Q [79]
Medical care plans	
• Barriers to complex treatment plans	Q
Intervention fidelity, feasibility and sustainability	
• Kidney Transitions Specialist adherence to protocol	O [†]
• Sustainability (RE-AIM) [80] ^a	Q, FG [§] , DI [±]

*Annual assessments over 36 months. EHR = electronic health record; Q = questionnaire; O = Observation; FG = Focus group; DI = Directed Interview.

^a MPR = Medication possession ratio from Geisinger Health Plan claims data.

2.6. Clinic randomization procedure

In the cluster randomized trial, eight Geisinger nephrology clinics have been randomly assigned to employ Patient Centered Kidney Transitions Care (intervention arm, 4 sites) or Usual Nephrology Care (control arm, 4 sites). Clinics were randomized to the two arms of the study, constrained to be marginally balanced by clinic size (> 500 vs. < 200 in 2016) and region of service (Central, Western), using the SURVEYSELECT procedure in the SAS v9. 4 statistical software.

2.7. Intervention implementation and assessment of fidelity

Two Kidney Transitions Specialists have been hired and trained to implement the intervention via a standard protocol. Each Kidney Transitions Specialist covers 2 intervention sites, which are assigned based on clinic size and region. Throughout the study, data are

collected to measure fidelity to the intervention as an indication of the quality of the implementation of the intervention [57,58]. A nurse manager within Geisinger Health Plan reviews documentation of the Kidney Transition Specialists meetings, phone calls, and self-care empowerment classes and assesses the extent to which the Specialists adhere to established protocols. Re-training is provided as needed. Monthly reports are generated from EHR data and the Care Management and Tracking Tool to examine the extent to which Kidney Transitions Specialists coordinate services and the extent to which patients adhere to Kidney Transitions' Specialists recommendations (i.e., attend scheduled classes or 1-on-1 meetings for decision-making).

2.8. Outcomes

We hypothesize the integrated components of Patient-Centered Kidney Transitions Care will improve several patient reported, biomedical, and health system outcomes. We will conduct the same outcomes assessments among patients with advanced kidney disease in intervention and control clinics. We will also collect data on potential correlates of intervention effectiveness. All assessments will occur through (a) participating patients' self-reported responses to telephone questionnaires or (b) data extracted from patients' EHRs (Table 5). In separate analyses, we will investigate the effectiveness of the intervention compared to usual care on each of five primary outcomes. We will seek evidence that the intervention has an effect on any of these outcomes individually.

2.8.1. Patient reported outcomes

Three primary patient reported outcomes will measure patients' perceptions of their empowerment, capability with self-management, and decisions to initiate self-care kidney failure treatments via telephone questionnaires. Secondarily, we will measure evidence of patients' enactment of care plans reflecting their preferred kidney treatments that align with their values (Table 5).

2.8.2. Biomedical outcomes

One primary biomedical outcome will measure patients' rate of all-cause hospitalizations through EHR data. We will also explore associations between the intervention and cause-specific as well as types of (e.g., planned versus unplanned) hospitalizations. A majority of Geisinger nephrology patients receive hospital care within Geisinger Health System. We will also ask patients to report the presence and number of non-Geisinger health system hospitalizations they have experienced in the 12 months prior via questionnaire. Secondarily, we will measure outcomes reflecting patients' improved self-management of kidney disease (including time to kidney failure from index registry date) and patients' less chaotic or risky transitions to kidney failure (e.g., planned versus emergency initiation of dialysis [37] or initiation of dialysis with a fistula versus infection-prone catheters [81]).

2.8.3. Health system outcomes

One primary health system outcome will measure the proportion of patients in nephrology clinics who have completed plans for possible future kidney failure therapy (preparatory steps for kidney failure treatments such as referrals to vascular surgery or transplant) or have kidney failure treatment preferences broadcast in the EHR. Completion of any of these actions reflects a critical step toward nephrologists' patient-centered facilitation of patients' preferred treatments. Currently, physicians in usual care are able to enter kidney failure treatment preferences on the EHR problem list, although this practice is not routinely encouraged in patients' kidney care plans. The intervention will encourage these behaviors through improved electronic health system tools. We will query the EHR for evidence of kidney failure treatment preferences broadcast across all study patients in intervention and control clinics. Because advance care plans may also be documented in patient progress notes that are not easily queried as

discrete data elements using routine computer algorithms, we will also conduct manual reviews of notes in EHRs (performed by a trained study nurse) for all study patients to document evidence of these advance care plans or EHR broadcasts indicating patients' kidney failure treatment preferences.

2.9. Statistical analysis

2.9.1. Sample size estimates

Among all study clinics, we estimate approximately 1000 patients will qualify for the disease registry and therefore will be eligible for observation and enrollment in PREPARE NOW. Each year, we will attempt to contact the entire sample of patients actively listed on the disease registry within the prior 12 months and invite them to participate in a study questionnaire. Within each year, we expect at least 500 patients will respond to the study telephone questionnaires [82,83]. Recruitment of 500 participants for study questionnaires will enable adequate statistical power at the end of the study to detect clinically significant minimum estimated differences between intervention versus control clinics for each of the patient centered primary study outcomes. Because we will have medical records on all disease registry participants, we will also be able to capture and summarize all biomedical and health system outcomes measured through the EHR. Power estimates are based on 0.05 level, two-sided *t*-test comparisons of study arms, and account for a cluster-randomized design with eight (8) clinics and a 0.05 intra-class correlation coefficient, extrapolating from cluster randomized studies with similar design [84]. (Table 6) While this approach is a simplification of the proposed analysis plan for all measurements over time, it should provide a conservative estimate of expected power to detect such overall changes by the end of the study.

2.10. Statistical analysis

The initial exploration of outcome variables (summary measures, graphical displays) will be used to assess the reasonableness of distributional assumptions and observed balance in key predictor variables. All primary analyses comparing the effect of the intervention strategy over time on our primary and secondary outcomes will be by intention-to-treat, including all eligible study participants with relevant and permissible data as appropriate to the outcome. We will also track patient visit locations and address any potential contamination due to patient crossover between clinics. Among the primary outcomes, several are binary (e.g., presence/absence in EHR of advance care plans or EHR broadcasts, and self-care treatment decisions), two are scaled scores (empowerment and self-efficacy with self-care), and time until first hospitalization could be treated as time-to-event, with the first year of eligibility as the start time. If the hospitalization date(s) is not captured in the EHR (e.g., hospitalizations outside the Geisinger system) for a substantial proportion of patients (thus requiring reliance on recall) or if the likelihood of multiple hospitalizations per year in this population is substantial, then we would treat hospitalization as a count variable to obtain rates per year, rather than using a time-to-event analysis over the entire study period.

We will collect all measures at baseline and at nine (9) to twelve (12) month intervals for three years. A questionnaire tracking database will be used to schedule a window in which a participant should receive his/her next call. Thus we will have correlated trajectory data over time at the individual level, and can expect some correlation within clinics as well, due to practice patterns, interactions among health care providers, etc. Generalized linear mixed models will be our preferred methodology, which includes (as special cases) hierarchical models. Participants will be considered nested within clinics, reflective of the intent-to-treat strategy for treatment assignment.

Table 6
Power and sample size estimates and assumptions.

Outcome	Assumed baseline (SD)	Previously observed change	Min diff to detect	Sample size	Power
Patient reported outcomes					
Empowerment					
Intervention	98.40 (SD 9.19)	+ 6.64 points [34]	6.64	500	91.4%
Control	98.40 (SD 9.19)	+ 0 points		550	91.9%
				600	92.3%
				997	93.9%
Self-efficacy with self-care					
Intervention	89.56 (SD 14.23)	+ 6.96 points [34]	8.8 points	500	81.7%
Control	89.56 (SD 14.23)	+ 0 points		550	82.5%
				600	83.2%
				997	86.1%
Decision to start self-care treatment					
Intervention	17%	+ 48% [31]	+ 22%	500	82.8%
Control	17%	+ 5%	+ 5%	550	83.6%
				600	84.3%
				997	87.2%
Patient biomedical outcomes					
Hospitalizations (per 1000 patient months)					
Intervention	134	76 [7,85] (- 43%)	130 (- 3%)	500	86.3%
Control	134	134 (- 0%)		550	86.7%
				600	87.1%
				997	88.8%
Health system culture					
Advance directives or orders documented in EHR					
Intervention	12%	+ 65% [86]	+ 24%	500	80.5%
Control	12%	+ 6%	+ 6%	550	81.3%
				600	82.1%
				997	85.2%

We will assume the following for each outcome: (a) the patient-level trajectory over time will vary among patients in both slope and intercept; (b) the average slope and intercept within each clinic could be different. These two assumptions would lead to including both random slopes and intercepts at the patient and clinic levels in initial analyses. Graphical and statistical assessments will be used to check whether such assumptions are reasonable. Likelihood ratio tests will be used to test the reasonableness of those assumptions by testing whether the variance components of those random effects are significantly larger than 0. We expect that clinic size could be a major cluster-level confounder, and could be included in the model as a fixed effect altering the overall average trajectory as function of size.

Baseline patient demographics and health status are also potential confounders. Time-dependent measures of health could be mediators of the impact of the intervention, in that they may be influenced by the intervention and will also influence the impact of the intervention. Initial analyses will assume that changes in these mediators will be randomly distributed across intervention and control patients, aside from the influence of the intervention on these mediators. In other words, these mediators will not be included in initial models. We will obtain the conditional average treatment effect for the first four outcomes by means of generalized linear models, assuming normality when we can for the continuous outcomes (including scaled measures) and either the binomial or Poisson distribution for count variables, accounting for time-on-study. Canonical links will be used (e.g., logit link for binary data). Hypothesis tests will focus on the difference between study groups on the changes observed over time, rather than repeated testing each year. In other words, we will be looking to find changes in the average or “typical” outcome profile over time that differs from one study arm to the other. Two-sided tests will be used, although we are hypothesizing an improvement in these measures over time in the intervention arm.

The above modeling approach will be considered primary, but there are other questions we would like to address that would require enhanced models. While the same basic framework will be used, we want to assess whether time-dependent measures of health (e.g., risk level for kidney failure, blood pressure or serum glucose control) and/or time-stationary basic demographics (age, gender, education), are mediating the impact of the intervention. The modeling approach described allows us to augment the above models with both time-varying and time-stationary covariates and test for a mediation impact. It is possible that we will then be able to create principal strata among which we can use structural equation models to account for mediation in a proposed causal pathway.

A key assumption of our design is that clinics are similar in patient composition and resources. If some clinics care for more predominately elderly patient panels, the types of support and care plans could differ substantially. For example, elderly populations may need more support or make different decisions on care. To test this assumption, we will characterize clinics by panel size and their composition of elderly patients. We will perform sensitivity analyses by employing models with interaction terms accounting for differences we find. We will also assess heterogeneity of treatment effects across various considerations, including clinics' panel burden of comorbidity.

3. Discussion

To our knowledge, the PREPARE NOW Study will be among the first U.S. studies to rigorously quantify the effectiveness of a comprehensive and fully integrated health system intervention to improve kidney transitions care among patients with chronic kidney disease as they transition toward kidney failure. As the number of efficacious approaches to improving kidney patients' self-management and biomedical outcomes continues to increase, effective strategies to implement these interventions in real world clinical settings are needed. PREPARE NOW will provide important evidence on the effectiveness of

implementing these real world interventions to improve the experiences, capabilities, and clinical outcomes of patients with chronic kidney disease.

PREPARE NOW interventions address the full Chronic Care Model [43], through programs employing information technologies (e.g., continually updated disease registry and continuous population risk stratification) and through patient centered services that not only address patients' care coordination needs, but also address a number of other needs to empower patients with knowledge, resources, and skills to improve their own care and clinical outcomes. PREPARE NOW outcomes assessments, which will capture both the effectiveness of interventions through patients' reports as well as through their health records, will provide a holistic view of programs' success and value. In addition, PREPARE NOW is also collecting information on the process of implementing the intervention and barriers and facilitators to achieving intervention fidelity. As a result, findings from PREPARE NOW will answer important questions regarding the feasibility and effectiveness of a number of kidney care strategies that have been studied individually but have not routinely been jointly implemented in a coordinated fashion. Finally, since our outcomes assessments will include details of planning and initiation of renal replacement therapy, we will be able to quantify ‘Optimal End Stage Renal Disease Starts’ (receipt of a preemptive kidney transplant, initiating home dialysis, or initiating outpatient in-center hemodialysis via arteriovenous fistula or arteriovenous graft), a measure endorsed by the National Quality Forum [87].

We anticipate findings from PREPARE NOW will help inform the implementation of similar interventions among health systems across the U.S. We also anticipate they will provide numerous stakeholders, including patients, their families, health care providers, and payers with critically needed evidence to support the implementation of these interventions in other settings. Nonetheless, we anticipate some potential limitations. First, since Geisinger is an integrated health system which shares a unified electronic health record and informatics platform, some innovations deployed in PREPARE NOW may not be fully portable to nephrology care in other settings. Similarly, not all nephrology practices will have capabilities enabled through the Geisinger Health Plan, such as care management. In addition, since PREPARE NOW is being conducted within a single health system in rural Pennsylvania, our findings may not be generalizable to all populations of patients. While the Geisinger population is not racially diverse, the low education and low income levels are similar to national rates. In addition, the Geisinger CKD population has a larger proportion of patients age > 65 which is consistent with national trends showing that the elderly have the highest incident ESRD growth rate. It is also possible that patients may not progress to kidney failure in the time period that we observe them. However, patients' experiences and preparation for potential kidney care transitions are important proximal outcomes reflecting their likelihood of achieving optimum transitions when they do occur. For this reason, we have chosen to focus on patient-centered outcomes (e.g., perceived empowerment, confidence with care decisions, or achievement of referrals) that occur proximal to the development of kidney failure. Finally, since our program is being implemented within nephrology specialty care, it is possible that we are missing high-risk patients who have never been referred to nephrology. However, primary care providers are encouraged to refer high-risk patients to nephrology through the use of a best-practice alert. Despite these potential limitations, we believe PREPARE NOW will provide critically needed insight into the effectiveness of patient centered interventions to enhance kidney care and patients' clinical outcomes.

4. Conclusion

The PREPARE NOW Study may provide key evidence on the effectiveness of comprehensive patient-centered interventions to improve patients' care as they transition to kidney failure. If they are effective,

these interventions could be broadly disseminated to improve the care and outcomes of patients across the U.S. and elsewhere.

Competing interests

We have no competing interests to report.

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Authors' contributions

JAG: study conception/design, data acquisition, data analysis, data interpretation, draft/revising manuscript; **PLe:** study conception/design, data acquisition, data analysis, data interpretation, drafting/revising manuscript; **FBH-B:** study conception/design, data acquisition, data analysis, data interpretation, drafting/revising manuscript; **TB:** study conception/design, data acquisition, data analysis, data interpretation, drafting/revising manuscript; **TSS:** study conception/design, data acquisition, data analysis, data interpretation, drafting/revising manuscript; **CLH:** study conception/design, data acquisition, data analysis, data interpretation, drafting/revising manuscript; **RAS:** study conception/design, data acquisition, data analysis, data interpretation, drafting/revising manuscript; **JDD:** study conception/design; **UDP:** study conception/design; **KL-L:** study conception/design, data acquisition, data interpretation, drafting/revising manuscript; **BLB:** study conception/design, data acquisition, data interpretation, drafting/revising manuscript; **SAB:** study conception/design, data acquisition, data interpretation, drafting/revising manuscript; **PD:** study conception/design, data acquisition, data interpretation, drafting/revising manuscript; **SR:** study conception/design, data acquisition, data interpretation, drafting/revising manuscript; **LS:** study conception/design, data acquisition, data interpretation, drafting/revising manuscript; **AS:** study conception/design, data acquisition, data interpretation, drafting/revising manuscript; **PW:** study conception/design, data acquisition, data interpretation, drafting/revising manuscript; **BV:** study conception/design, data interpretation, drafting/revising manuscript; **DL:** study conception/design, data acquisition, data analysis, data interpretation, drafting/revising manuscript; **GJ:** study conception/design, data acquisition, data analysis, data interpretation, drafting/revising manuscript; **JFP:** study conception/design, data acquisition, data analysis, data interpretation, drafting/revising manuscript; **JSCR:** study conception/design, data acquisition, data analysis, data interpretation, drafting/revising manuscript; **KC:** study conception/design, data acquisition, data analysis, data interpretation, drafting/revising manuscript; **NE:** study conception/design, data acquisition, data analysis, data interpretation, drafting/revising manuscript; **IDB:** study conception/design; **SK:** study conception/design; **CC:** study conception/design; **DD:** study conception/design; **JdP:** study conception/design, data acquisition, data analysis, data interpretation, drafting/revising manuscript; **DM:** study conception/design; **CJD:** study conception/design, data acquisition, data analysis, data interpretation, drafting/revising manuscript; **SF:** study conception/design, data acquisition, data analysis, data interpretation, drafting/revising manuscript; **JM:** study conception/design, data acquisition, data analysis, data interpretation, drafting/revising manuscript; **DS:** study contribution/design, data acquisition, data analysis, data interpretation; drafting/revising manuscript; **NT:** study conception/design, data acquisition, data analysis,

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