Impact of Navigators on Completion of Steps in the Kidney Transplant Process: A Randomized, Controlled Trial

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Summary
Background and objectives Many patients with ESRD, particularly minorities and women, face barriers in completing the steps required to obtain a transplant. These eight sequential steps are as follows: medical suitability, interest in transplant, referral to a transplant center, first visit to center, transplant workup, successful candidate, waiting list or identify living donor, and receive transplant. This study sought to determine the effect of navigators on completion of steps.

Design, setting, participants, & measurements Cluster randomized, controlled trial at 23 Ohio hemodialysis facilities. One hundred sixty-seven patients were recruited between January 2009 and August 2009 and were followed for up to 24 months or until study end in February 2011. Trained kidney transplant recipients met monthly with intervention participants (n=92), determined their step in the transplant process, and provided tailored information and assistance in completing the step. Control participants (n=75) continued to receive usual care. The primary outcome was the number of transplant process steps completed.

Results Starting step did not significantly differ between the two groups. By the end of the trial, intervention participants completed more than twice as many steps as control participants (3.5 versus 1.6 steps; difference, 1.9 steps; 95% confidence interval, 1.3–2.5 steps). The effect of the intervention on step completion was similar across race and sex subgroups.

Conclusions Use of trained transplant recipients as navigators resulted in increased completion of transplant process steps.

Introduction
Compared with long-term dialysis treatment, kidney transplantation generally offers a longer life span and better quality of life (1,2). Obtaining a kidney transplant requires patients to complete a series of steps (Table 1): medical suitability, interest in transplant, referral to a transplant center, first visit to center, transplant workup, successful candidate, waiting list or identify living donor, and receive transplant (3). Medical suitability refers to the absence of absolute contraindications to transplantation (e.g., a systemic infection or recent malignancy) (4). The transplant center workup typically requires several visits and involves a medical history and physical examination, psychosocial assessment, evaluation and treatment of medical conditions, and laboratory studies (5). Patients who complete this workup and are found to be successful transplant candidates may be placed on a deceased-donor waiting list or may obtain a kidney transplant from a living donor.

Many patients, particularly minorities and women, face barriers in completing the steps required to obtain a transplant (3,6–10). These barriers include inadequate assessment of medical suitability, lack of information about transplantation, reliance on nephrologists to make referrals to transplant centers, and difficulty completing the transplant center workup (3,6–11). We hypothesized that navigators might help patients complete transplant process steps in a more efficient and equitable manner. Navigators are individuals who educate patients and help them navigate through the medical system (12). We reasoned that kidney transplant recipients may be ideal navigators for other patients because of a shared experience with ESRD (13). Similar peer-mediated interventions have been successful in educational settings (14).

Materials and Methods
Participants and Facilities
All 23 hemodialysis facilities that belong to the three largest chains in Cuyahoga County, Ohio, participated. A data manager used a random-number

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We hired and trained three study coordinators who were kidney transplant recipients to act as navigators for intervention group participants. Their training included instruction on the kidney transplant process, human subjects protection, medical records abstraction, and motivational interviewing. A transplant navigator met monthly with each intervention participant during a dialysis treatment, reviewed his or her medical record, and determined the participant’s current step. On the basis of the current step, the navigator carried out the following tasks for the first seven steps:

**Step 1. Suitability for Referral to Transplant Center.** Patients with absolute contraindications to kidney transplantation listed in their medical records were not eligible to participate. However, some patients were told by providers that they were unsuitable for transplantation but had no absolute contraindications listed in their records. In these cases, study staff contacted the participant’s nephrologist for clarification. Participants with absolute contraindications remained at this step. Participants without absolute contraindications moved forward to the next step.

**Step 2. Interest in Transplantation.** Participants were educated about the advantages and disadvantages of transplantation, the steps in the transplant process, and what to expect after transplantation. Navigators also shared their personal experiences with dialysis and transplantation.

**Step 3. Referral Call to Transplant Center.** Participants were given the phone numbers of local transplant centers, a list of the information that they might be asked to provide, and questions to ask.

**Step 4. First Visit to Transplant Center.** Participants were given directions to the transplant center, a list of things to take, and questions to ask. In addition, navigators explored transportation options for getting to the transplant center and reminded participants of upcoming appointments.

**Step 5. Transplant Center Workup.** Navigators explained to participants what to expect in a transplant center workup. Navigators also monitored completion of specific aspects of the workup, communicated with transplant center staff about outstanding tasks, and encouraged participants to complete the workup in a timely fashion.

**Step 6. Successful Transplant Candidate.** Navigators served as an ongoing source of support and information. Navigators also educated participants about how to discuss living donation with potential donors.

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**Table 1. Steps involved in obtaining a deceased-donor or living-donor kidney transplant**

<table>
<thead>
<tr>
<th>Step</th>
<th>Step Completion</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Suitability for referral to transplant center</td>
<td>Dialysis facility records or nephrologist indicates that patient has no absolute contraindications to kidney transplantation.</td>
</tr>
<tr>
<td>2. Interest in transplantation</td>
<td>Patient expresses an interest in considering a deceased- or living-donor transplant.</td>
</tr>
<tr>
<td>3. Referral call to transplant center</td>
<td>Transplant center records indicate that referral was made by patient, nephrologist, or dialysis facility.</td>
</tr>
<tr>
<td>4. First visit to transplant center</td>
<td>Transplant center records indicate that patient made an initial visit to transplant center.</td>
</tr>
<tr>
<td>5. Transplant center workup</td>
<td>Transplant center records indicate that patient completed workup.</td>
</tr>
<tr>
<td>6. Successful transplant candidate</td>
<td>Transplant center records indicate that patient is a successful transplant candidate.</td>
</tr>
<tr>
<td>7. On waiting list or evaluate potential living donor</td>
<td>Transplant center records indicate that patient is on a deceased-donor waiting list or a potential living donor is being evaluated.</td>
</tr>
<tr>
<td>8. Receive transplant</td>
<td>Transplant center records indicate that patient received a deceased- or living-donor kidney transplant.</td>
</tr>
</tbody>
</table>
Step 7. On Waiting List or Evaluate Potential Living Donor. Navigators served as an ongoing source of support and information. Navigators monitored participants’ status on the waiting list and results of living-donor evaluation.

Control Group
Control participants continued to receive care from their nephrologists and dialysis facilities. A study coordinator who was not a transplant recipient assessed control participants every 3 months. This assessment included medical record abstraction and a brief interview to determine participants’ current step.

Follow-up Procedures
Participants were recruited between January 2009 and August 2009 and were followed up for 24 months or until they died, moved, withdrew, or reached the study end in February 2011. Study coordinators abstracted medical records and interviewed participants to determine their final step. Because of the sequential nature of the transplant process, completion of a particular step implied that prior steps had also been completed (see Table 1). To parallel the categorization of baseline step, the final step was defined as the farthest step that was incomplete at the end of the study. If intervention participants were unable to complete specific steps by the end of the study, navigators noted whether this was due to a medical limitation, financial concerns, patient reluctance, or ending the trial early.

Outcomes
The primary outcome measure was the number of steps completed, defined as the difference between final and baseline steps. Secondary outcomes were impediments to step completion among intervention participants.

Statistical Analyses
We used mixed-effects models for continuous variables and generalized estimating equation (GEE) models for categorical variables to compare the baseline characteristics of intervention and control participants while accounting for clustering within facilities (16). Intervention effects were assessed using an F-test (in mixed-effects models) or generalized score test (in GEE analyses). We used GEEs to assess the mean baseline and final number of steps for each group, the difference (total number of steps completed) for each group, and the difference in total steps between the two groups (assuming a Poisson distribution and using a linear link). The identity link for the latter subgroups defined by key baseline covariates (sex, race, and baseline step). We also verified the analyses of the primary outcome with a GEE model assuming that the number of completed steps (out of the potential number of steps given the baseline number) follows a binomial distribution and using a logit link (with the model otherwise the same as before). This analysis gave similar results, which are not presented. All analyses were performed using SAS software, version 9.2 (SAS Institute, Cary, NC).

On the basis of prior work, we anticipated that the SD of the number of steps completed would be approximately 2.0 steps. To detect a clinically important effect size of 1.0 step (or standardized effect size of 0.5) would require 126 total participants with a two-tailed \( \alpha \) level of 0.05 and 80% power (19). However, these estimates must be increased to account for the possible nonindependence of patients clustered within facilities. We found a small amount of clustering of outcomes by facility in our previous work (intraclass cluster coefficient, \( \rho < 0.025 \)). This gives an inflation factor of \( 1 + (m-1) \rho \), where \( m \) is the average number of patients at each facility (in this study, 126 patients divided by 23 facilities). This gives an inflation factor of 1.11 and a total sample size requirement of 140 patients for our primary outcome.

Results
Participant Characteristics
Figure 1 shows the flow of participants through the trial. One hundred sixty-seven patients began the trial: 92 intervention participants and 75 control participants. We excluded 377 patients in intervention facilities because their nephrologists had more patients in control facilities; we therefore assigned these patients to the control group.
Similarly, we excluded 432 patients in control facilities because their nephrologists had more patients in intervention facilities. A total of 1617 patients did not meet eligibility criteria. One hundred sixty-nine eligible patients declined to participate. Compared with the 167 participants, these 169 nonparticipants were somewhat older (58 versus 55 years; \(P=0.01\)) and had been undergoing hemodialysis longer (4.0 versus 3.0 years; \(P=0.0001\)) but did not differ in other demographic characteristics. Intervention and control participants had generally similar baseline characteristics (Table 2).

**Completion of Steps in Transplant Process**

Intervention patients completed more than twice as many steps as control patients (3.5 versus 1.6 steps; difference, 1.9 steps; 95% confidence interval, 1.3–2.5 steps; Table 3). The effect of the intervention on step completion was similar across race and sex subgroups.

By the end of the trial, 17 (18%) intervention participants and 6 (8%) control participants were on a deceased-donor transplant waiting list (\(P=0.07\)). In addition, potential living donors were identified for 3 (3%) intervention participants and 0 (0%) control participants (\(P=0.06\)). However, no deceased- or living-donor transplants occurred by the end of the trial. No adverse events or adverse effects were associated with the intervention.

**Reasons for Failing to Complete Steps**

Even though our intervention was an overall success, many intervention participants failed to become successful transplant candidates. Table 4 lists the specific reasons that...
intervention participants were unable to complete their final step. For example, 24 intervention participants did not make a referral call to a transplant center by the end of the trial. Sixteen participants had medical limitations, such as acute or chronic conditions, that they wanted to address before calling. Three participants had concerns about the cost of transplantation or immunosuppressive medications. Ten participants were reluctant to call because of fears regarding surgery and rejection or because they felt fine on dialysis. Twelve participants died or left the dialysis facility before the trial ended.
Discussion

We found that using trained transplant recipients as navigators resulted in increased completion of steps in the kidney transplant process. Moreover, the effect of the intervention on step completion was similar across race and sex subgroups. Although our trial was not designed to determine the effect of navigators on transplantation, completion of sequential steps in the transplant process is necessary for transplantation to occur. Moreover, we found promising results related to the number of intervention participants who reached the penultimate step in the transplant process (deceased-donor waiting list or evaluate potential living donor).

Previous randomized, controlled trials of navigators have generally focused on cancer screening or treatment but have not used patients as navigators (20–27). Our intervention has the advantage of being simple but also easily tailored to the circumstances of individual patients. By engaging the participation of almost all dialysis facilities in a large geographic area, we enhanced the generalizability of our findings. With the exception of race, participant characteristics were similar to those of dialysis patients nationally (1). The large number of black participants reflects the inner-city location of many of the participating dialysis facilities.

Our results have important implications for patients, providers, and health policy makers. Patients with ESRD may benefit from learning more about kidney transplantation and obtaining help in completing steps in the transplant process. In the absence of formal navigators, patients may need to actively obtain this knowledge and assistance from their physicians and dialysis facilities, local transplant centers and kidney transplant recipients, and family and friends. Providers should realize that usual care is insufficient to adequately educate patients and help them achieve access to kidney transplantation. In particular, we found that many patients are inappropriately categorized as unsuitable for referral. Even though we restricted our study sample to patients without absolute contraindications to transplantation, 89 participants were categorized by their providers as medically unsuitable for referral at baseline (Table 2). However, our intervention was very successful among this subgroup, with intervention participants completing an average of 4.2 steps (95% confidence interval, 3.9–4.5 steps; Table 2). Policy makers may consider funding navigators to work at each of the more than 5000 dialysis facilities nationwide (1). This would not only help patients complete steps in the transplant process but also create meaningful job opportunities for the many kidney transplant recipients who are currently unemployed (28).

Several limitations must be considered in interpreting our results. A much larger sample size and follow-up duration would be necessary to determine the effect of navigation on actual transplantation. As a result, future navigator programs should carefully evaluate the effect of navigation on transplantation. The transplant process experiences of our 167 study participants may not be representative of the experiences of all patients at the 23 participating facilities (see Figure 1). The results rely on a large amount of imputed data. Because of funding limitations, the study end date could not be extended beyond February 2011. As a result, participants who were recruited after March 2009 were unable to complete 24 months of follow-up. Our navigators were paid the same salaries as study coordinators and spent much of their time collecting research data. Such data collection would be unnecessary if navigators were used in clinical settings. We were unable to determine whether cost would impede setting up navigator programs. Increasing the number of individuals receiving living donor transplants will increase the total number of transplants performed. However, increasing the number of individuals on the deceased-donor waiting list will not increase the total number of transplants performed. As a result, continued efforts to increase organ donation are necessary. Although our intervention was an overall success, many intervention patients did not become transplant candidates (Table 4). Note that navigation is unlikely to influence medical limitations or patients who die or have moved. However, further refinements to our approach may increase its potency to influence financial concerns and patient reluctance.

In conclusion, we found that navigators increase completion of steps in the transplant process among all patients as well as among race and sex subgroups. Further work is needed to determine the effect of navigators on actual transplantation and on race and sex disparities. We recommend that nephrologists, dialysis facilities, and regulatory agencies use the transplant process steps we identified (Table 1) to develop clinical performance measures to monitor and improve access to transplantation.

### Table 4. Reasons that patients in intervention group did not become successful transplant candidates

<table>
<thead>
<tr>
<th>Final Step</th>
<th>Total Patients (n)</th>
<th>Patients with Specific Reasons (n)</th>
<th>Medical Limitation</th>
<th>Financial Concern</th>
<th>Patient Reluctance</th>
<th>Died or Left Facility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interest</td>
<td>2</td>
<td>1</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Referral call</td>
<td>24</td>
<td>16</td>
<td>3</td>
<td>10</td>
<td>12</td>
<td>5</td>
</tr>
<tr>
<td>First visit</td>
<td>15</td>
<td>11</td>
<td>1</td>
<td>6</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>First workup</td>
<td>23</td>
<td>11</td>
<td>3</td>
<td>11</td>
<td>6</td>
<td>0</td>
</tr>
<tr>
<td>Successful candidate</td>
<td>8</td>
<td>8</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Some patients had more than one reason.
Using peer navigators may also be useful in other settings and for other conditions as a way to both improve care and reduce disparities.

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