

### Original Clinical Research Qualitative

# Process Evaluation Alongside a Cluster-Randomized Trial of a Multicomponent Intervention Designed to Improve Patient Access to Kidney Transplantation

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#### **Abstract**

**Background:** In a cluster-randomized trial, we learned that a novel multicomponent intervention designed to improve access to kidney transplantation did not significantly increase the rate of completed steps toward receiving a kidney transplant. Alongside the trial, we conducted a process evaluation to help interpret our findings.

**Objective:** To determine whether the intervention addressed targeted barriers to transplant and whether the implementation occurred as planned.

Design: Mixed-methods process evaluation informed by implementation science theories.

**Setting:** Chronic kidney disease (CKD) programs in Ontario, Canada. These programs, providing care to patients with advanced CKD, participated in the trial from November 1, 2017 to December 31, 2021 (either in the intervention or usual care group).

Participants: Health care providers (eg, nurses, managers) at Ontario's 27 CKD programs.

**Methods:** We conducted surveys (n = 114/162 [70.4%]) and semi-structured interviews (n = 17/26 [65.4%]) with providers in CKD programs in Ontario, Canada. In both the intervention-group and control-group surveys, using the Theoretical Domains Framework, we assessed perceived barriers to transplant and how barriers changed throughout the trial period. In the intervention-group surveys and interviews, using the normalization process theory, we assessed the extent to which the intervention was embedded into daily routines. In the intervention-group surveys, and by completing an implementation checklist, we assessed fidelity of implementation.

**Results:** Perceived barriers to transplant did not substantially differ between providers in the intervention and usual care groups, and both groups reported disagreeing or feeling neutral that the targeted barriers impeded transplant access. Intervention-group providers reported that intervention activities were becoming a regular part of their work and that they engaged with its components. However, they also felt the intervention was complex and described needing more resources, a better execution plan, and more buy-in from frontline staff. Fidelity was high for administrative support, quality improvement teams, delivery of educational resources, and patient peer support. The use of performance reports was low. **Conclusions:** We identified several possible reasons why the intervention was unsuccessful. Improving access to kidney transplantation remains a high priority for health care systems. We will continue to foster a quality improvement culture, and our results will guide future interventions.

Limitations: Two of the 13 intervention-group CKD programs did not participate in this evaluation.

Trial Registration: ClinicalTrials.gov Identifier: NCT03329521

#### **A**brégé

Contexte: Lors d'un essai randomisé en grappes, nous avons découvert qu'une nouvelle intervention à composantes multiples conçue pour améliorer l'accès à la transplantation rénale n'avait pas permis d'augmenter de façon significative le taux d'étapes complétées menant à la réception d'une greffe. Parallèlement à cet essai, nous avons évalué le processus pour faciliter l'interprétation des résultats.

**Objectif:** Déterminer si l'intervention a permis de lever les obstacles à la transplantation et si sa mise en œuvre s'est déroulée comme prévu.

Conception: Évaluation d'un processus par le biais de méthodes mixtes s'appuyant sur les théories scientifiques de la mise en œuvre.

Cadre: Les programmes d'insuffisance rénale chronique (IRC) de l'Ontario (Canada). Ces programmes, qui dispensent des soins aux patients atteints d'IRC avancée, ont participé à l'essai du 1 novembre 2017 au 31 décembre 2021, soit dans le groupe intervention, soit dans le groupe témoin (soins habituels).

**Personnes participantes:** Les prestataires de soins de santé (p. ex. personnel infirmier, gestionnaires) qui participent aux 27 programmes d'IRC de l'Ontario.

**Méthodologie:** Nous avons mené des sondages (n = 114/162 [70%]) et des entrevues semi-structurées (n = 17/26 [65 %]) auprès des prestataires de soins des programmes d'IRC de l'Ontario, au Canada. Les sondages menés à l'aide du « Theoretical Domains Framework » auprès des groupes témoin et d'intervention, nous ont permis d'évaluer les obstacles perçus à la transplantation et leur évolution au cours de la période de l'essai. Dans le groupe d'intervention, les entrevues et sondages menés à l'aide de la « Normalization Process Theory » nous ont permis d'évaluer dans quelle mesure l'intervention était intégrée dans les soins habituels au quotidien. Enfin, les sondages menés auprès du groupe d'intervention et la complétion d'une liste de contrôle de la mise en œuvre nous ont permis d'évaluer la fidélité de la mise en œuvre.

**Résultats:** Les obstacles perçus à la transplantation n'étaient pas fondamentalement différents entre les prestataires du groupe d'intervention et ceux du groupe témoin. Les prestataires des deux groupes ont également indiqué être neutres ou en désaccord avec le fait que les obstacles ciblés entravaient l'accès à la transplantation. Les prestataires du groupe d'intervention ont mentionné que les activités d'intervention devenaient une partie intégrante de leur travail et qu'ils participaient à ses composantes. Ils ont cependant jugé l'intervention complexe, et déclaré avoir besoin de plus de ressources, d'un meilleur plan d'exécution et d'une plus grande adhésion de la part du personnel de première ligne. La fidélité était élevée pour le soutien administratif, les équipes d'amélioration de la qualité, la fourniture de ressources éducatives et le soutien des patients par les pairs. L'utilisation des rapports de rendement était faible.

**Conclusion:** Nous avons identifié plusieurs raisons pouvant expliquer l'échec de l'intervention. L'amélioration de l'accès à la transplantation rénale demeure une importante priorité des systèmes de santé. Nous continuerons d'encourager une culture d'amélioration de la qualité et nos résultats guideront les futures interventions.

Limites: Deux des treize programmes d'IRC du groupe d'intervention n'ont pas participé à cette évaluation.

#### **Keywords**

transplantation, living kidney donation, implementation science, qualitative

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# Introduction

The best treatment option for most patients with advanced chronic kidney disease (CKD) is a kidney transplant.<sup>1,2</sup> Compared with the alternative treatment of maintenance dialysis, patients who receive a kidney transplant experience a better quality of life and survival and have lower health care systems costs.<sup>1,3,4</sup> Unfortunately, there are not enough deceased donor kidneys to meet the demand, and rates of living kidney donation have stagnated.<sup>5,6</sup> Many barriers prevent patients from receiving a kidney transplant.<sup>7-9</sup>

The Enhance Access to Kidney Transplant and Living Kidney Donation cluster-randomized trial (EnAKT LKD) done in CKD programs in Ontario, Canada, found that a novel multicomponent intervention did not significantly increase the rate of patients completing steps toward receiving a kidney transplant when compared with usual care. <sup>10</sup> We conducted a process evaluation alongside the EnAKT LKD trial to help understand the trial findings. We assessed whether the intervention addressed intended barriers and whether the implementation occurred as planned.

### **Methods**

# Overview of the EnAKT LKD Cluster-Randomized Trial

In 2023, in Ontario, Canada, 27 CKD programs delivered kidney care to over 24000 patients with advanced CKD (ie, patients approaching the need for dialysis or receiving maintenance dialysis). In 2016, patients, health care professionals, and government agencies overseeing kidney and transplant care came together to develop a multicomponent intervention to address critical barriers preventing access to kidney transplantation and living kidney donation. We evaluated the effects of this intervention in a pragmatic, 2-arm, parallel-group, open-label, registry-based, superiority, clusterrandomized clinical trial conducted in all of Ontario's CKD programs (clusters) (the EnAKT LKD trial). 10 At the time of randomization, we allocated 13 of Ontario's 26 CKD programs to receive the intervention from November 1, 2017 to December 31, 2021 (4.2-year trial period), while the remaining CKD programs received usual care. There were 26 CKD programs when the trial started in November 2017; in April 2018, 1 program split into 2. For the primary trial analysis, this program was treated as 1 program, but for this process evaluation, we treated it as 2 separate CKD programs.

The trial included over 20000 potentially transplanteligible patients with advanced CKD.<sup>10</sup> The primary outcome was the rate of steps completed toward receiving a kidney transplant, with each patient being able to complete up to 4 steps, including (1) being referred to a transplant center for evaluation, (2) having a potential living donor contact a transplant center for evaluation, (3) being added to the deceased donor waitlist, and (4) receiving a transplant from a living or deceased donor. The intervention included 4 main components, which are summarized in Table 1 with more details in **Supplemental** Table 1. The 4 main components were (1) administrative support to establish local quality improvement (QI) teams, (2) transplant educational resources, (3) an initiative for transplant recipients and living donors to share stories and experiences (Transplant Ambassador Program [TAP]), and (4) program-level performance reports and oversight by administrative leaders. Chronic kidney disease programs had flexibility in implementing each of the intervention components. A provincial core operations group, which included a part-time medical lead and 3 full-time personnel from kidney and transplant government-funded agencies, supported QI teams at each CKD program. The provincial core operations group also organized monthly collaborative calls as a forum to address challenges and share best practices.

# Overview of the EnAKT LKD Process Evaluation

We conducted a mixed-methods process evaluation where our objective was to assess health care professionals' perception of how well the intervention addressed barriers to kidney transplantation and to determine how well the planned intervention was executed in practice (referred to as fidelity of implementation). We asked about perceived barriers to transplant over time to understand whether the intervention targeted the true barriers health care providers perceived they were experiencing and whether there was a change in those experienced barriers with the implementation of the intervention. We coupled the analysis of barriers with an analysis of fidelity to understand how well the intervention was implemented. Poor implementation of one or more intervention components would provide insight into why targeted barriers may not have changed over time. These data together would allow us to optimize the intervention by either addressing different barriers by modifying intervention components or by improving the implementation of certain intervention components.

We administered an online survey to health care professionals in both groups to examine the barriers and enablers experienced before the trial and during the trial (**Supplemental Appendices 1-2**). We also administered surveys and semistructured interviews with health care professionals in the intervention group to understand how the intervention activities became embedded into routine practice (**Supplemental Appendix 3**). To assess fidelity of intervention implementation, we analyzed documents provided by the provincial core team that contained information on how the trial components were delivered (**Supplemental Appendix 4**). We also evaluated potential usual care group contamination through an online survey (**Supplemental Appendix 2**). Figure 1 provides an overview of the study objectives, methods of evaluation, and associated theoretical frameworks. We followed

Table 1. Description of the EnAKT LKD intervention components.

#### Description Intervention component I. Administrative support Each CKD program established a local quality improvement team that was provided with training, to establish local quality administrative support, and resources to implement the intervention. A central operations group, improvement (QI) teams including a part-time medical lead and 3 full-time personnel (ie, manager, analyst, strategist) supported the QI team. Quality improvement team members were invited to attend provincial rounds monthly to share experiences, successes and barriers to the strategy. Financial support of \$10000 CAN per year was provided to each QI teams to support their activities 2. Transplant education and Educational resources were developed and delivered to CKD program staff, patients, and living kidney resources for staff, patients, donor candidates (ontariorenalnetwork.ca/en/kidney-care-resources/clinical-tools/transplantation) and living donor candidates 3. Support from kidney The Transplant Ambassador Program (TAP: www.transplantambassadors.ca) connects patients with transplant recipients and kidney disease and their families to kidney transplant recipients and living kidney donors who can living donors share their lived experience with transplantation and living kidney donation and provide emotional support and hope Data reports were provided to CKD programs about their transplant-related performance (CKD 4. Program-level performance reports and oversight by program performance reports) and of patients who appeared to be eligible for transplant referral who were not yet referred (transplant referral eligibility reports). There were annual one-on-one program leaders performance meetings between leaders of each CKD program and the provincial renal agency

Note. Further details on the intervention components can be found in the trial protocol. 11

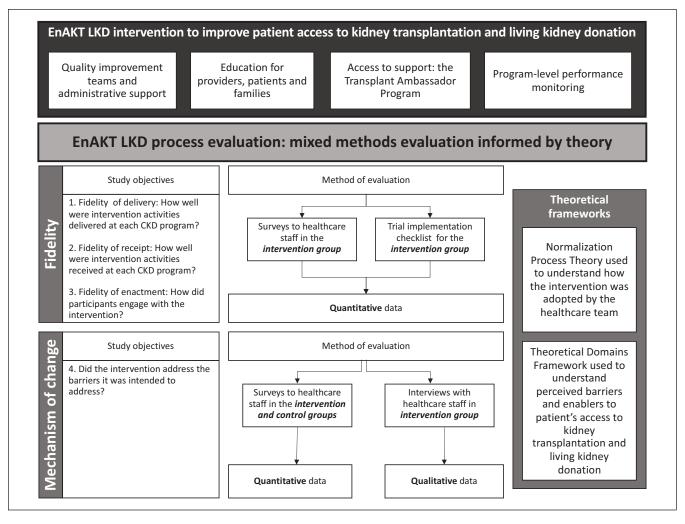


Figure 1. Design of the EnAKT LKD process evaluation. <sup>13</sup>

Note. This figure was previously published in Yohanna S, Wilson M, Naylor KL, et al. Protocol for a Process Evaluation of the Quality Improvement Intervention to Enhance Access to Kidney Transplantation and Living Kidney Donation (EnAKT LKD) Cluster-Randomized Clinical Trial. Can J Kidney Health Dis. 2022;9:20543581221084502.

the UK Medical Research Council guidance on conducting and reporting process evaluations of complex interventions. <sup>12</sup> We conducted surveys and interviews from December 2020 to June 2021. Our protocol provides further details about the methods used. <sup>13</sup> Online surveys were reported following the Checklist for Reporting Results of Internet E-Surveys (**Supplemental** Table 2) and interviews were reported following the Standard for Reporting Qualitative Research (SRQR) checklist (**Supplemental** Table 3). <sup>14,15</sup>

#### Theoretical Frameworks

To inform the process evaluation, we used 2 theoretical frameworks, the normalization process theory (NPT) and the theoretical domains framework (TDF). In brief, NPT describes factors that promote and inhibit implementing and embedding new processes into routine practice, such that, they are no longer visible as distinct from what is normally done. 16-18 Normalization process theory proposes 4 constructs to nuance how new practices become embedded in health care settings: 16 (1) Coherence (sense-making)—the extent to which individuals and teams understand the intervention elements and why a new set of practices are being introduced in their workflow. (2) Cognitive participation (engagement)—the extent to which individuals believe and buy into the intervention and the relational work (eg, building and sustaining engagement and collaboration) they do to prepare for it. (3) Collective action (enacting)—the degree to which individuals and teams have the confidence, training, skills, resources, working relationships and management support to embed new practices into their workflow. (4) Reflexive monitoring (appraisal)—how individuals and teams track how they are doing. 17-20 The TDF synthesizes over 30 theories of behavior change into 14 domains that can be used as categories of barriers and enablers that are targeted by an intervention to assess whether the intervention affected the barriers it was designed to address. <sup>21,22</sup> Using the TDF, we assessed perceived barriers in the intervention group at the following time points: before the EnAKT LKD intervention began (prior to Fall 2017), after the EnAKT LKD intervention began but before the COVID-19 pandemic (Fall 2017 to March 2020), and barriers at the time of the survey (December 2020-June 2021). For CKD programs in the usual care group, participants reported on barriers perceived before the COVID-19 pandemic (prior to March 2020), during the first wave of the COVID-19 pandemic (March-May 2020) and barriers at the time of the survey (December 2020-June 2021). We embedded these frameworks into the surveys and interview guide.

# Semi-Structured Interviews

We used an NPT-based directed content analysis to understand the process of implementing and integrating the EnAKT LKD intervention at CKD programs.<sup>23</sup> Interview

transcript analysis involved 5 steps: (1) familiarization, (2) coding participant responses to specific NPT constructs, (3) inductively generating sub-themes within each construct, (4) grouping themes across constructs, and (5) defining and naming themes. Two analysts (MW and SY) reviewed the codebook to assess the accuracy of data representation. The analysts co-developed an overarching thematic framework throughout several iterative meetings. Where differences in interpretation of the data arose, the 2 analysts discussed interpretations until arriving at one that best accounted for participant views and experiences.

We obtained ethics approval from the Ottawa Health Sciences Research Ethics Board, and written informed consent was obtained from all participants (REB 20200426-01H).

Participants. For the online survey, we aimed to survey 162 health care professionals: 2 nephrologists, 2 dialysis nurses, and 2 specialized kidney clinic team members from each of the 27 CKD programs. For the semi-structured interviews (intervention group only), a research coordinator (MW) aimed to conduct 26 semi-structured interviews by phone or videoconference: 13 with QI team leads and 13 with other health care professionals.

Data collection. The online survey was administered from December 2020 to June 2021. The online survey for the intervention group collected information on perceived barriers to kidney transplant, implementation evaluation, and fidelity. The online survey for the usual care group collected information on perceived barriers to kidney transplant and contamination (use of intervention components in the usual care group). The semi-structured interviews were conducted with participants from the intervention group between December 2020 and June 2021; these interviews collected information on implementation evaluation.

Perceived barriers to kidney transplant (intervention and usual care groups). As part of the online survey, participants were asked to recall current and past barriers at 3 points: before the trial before the pandemic, during the trial but before the pandemic, and during the trial and during the pandemic. Selected barriers were those intended to be addressed by the intervention. The presence of each barrier was rated using a 5-point Likert scale (strongly disagree to strongly agree).

Implementation evaluation (intervention group only):

a. Online survey. The extent to which the intervention was embedded into daily routines was evaluated using a validated 23-item survey<sup>24</sup> adapted for our trial. The survey included 1 item to assess the degree of normalization of the intervention using a 10-point scale (0 [not at all] to 10 [completely]), and 22 items to assess coherence, cognitive participation, collective action, and reflexive monitoring; these items were assessed

- on a 5-point Likert scale (*strongly agree* to *strongly disagree*, or not relevant).
- b. Semi-structured interview. We developed interview guides to elicit content on 4 constructs (coherence, cognitive participation, collective action, and reflexive monitoring) and additional open-ended prompts to elicit participants' reflection about their experience with each intervention component. We also asked specific questions to prompt views on how the COVID-19 pandemic influenced their use of the intervention.

Fidelity (intervention group only). We included questions about the frequency of intervention activities, use of educational resources, and perceived usefulness of intervention components. For the TAP, ambassadors completed monthly reports that summarized the number of meaningful interactions with patients, family members or potential living donors. A meaningful interaction was defined as a conversation about kidney transplantation lasting at least 5 minutes.

Document analysis. Using data from the provincial core team, a research coordinator (MW) completed a document analysis to examine intervention fidelity within CKD programs in the intervention group. For example, how often members of the CKD program participated in the monthly collaborative calls (**Supplemental** Table 4).<sup>13</sup>

Analysis. Results are summarized using descriptive statistics. Each response was weighted equally, acknowledging the number of responses per CKD program varied. Categorical variables are presented as counts and proportions, and continuous variables as means (standard deviations [SDs]), medians (25th, 75th percentiles), or ranges, as appropriate. Where applicable, we assessed the internal consistency of items within each construct using Cronbach's alpha for survey data. Higher scores indicated greater integration of the intervention into the respondents' workflow. We audiorecorded interviews and transcribed them verbatim, which were then verified by the interviewer (MW), de-identified and analyzed using NVivo 11. 13

#### **Results**

# **Participants**

In total, 114 health professionals completed the online survey (70% response rate). Of 78 invited professionals in the intervention group, 53 (68%) completed the online survey (10 nephrologists, 2 nurse educators, 11 specialized kidney clinic nurses, 13 dialysis nurses, 3 social workers, 3 managers, 3 coordinators, 8 other health professionals). Respondents represented 11 of the 13 CKD programs in the intervention group (2-7 respondents per program). Of 84 invited professionals in the usual care group, 61 (72%) completed the survey, representing 13 of the 14 programs in the usual care

group (1-6 respondents per program). Of the 26 invited professionals in the intervention group, 17 (65%) participated in interviews, representing 11 of the 13 programs (the same 11 CKD programs that completed the online surveys). Of the 17 respondents, 11 were QI team leads, and 6 were other QI team members. On average, the respondents had worked at the CKD programs for 13 years (SD = 8).

# Perceived Barriers to Kidney Transplant

Table 2 reports health care professionals' perceived barriers to kidney transplant in the intervention and usual care groups. In the intervention group, there was a slight improvement over time in mean scores for all reported barriers, particularly between the pre-trial and post-trial pre-pandemic period. In most cases, responses were similar in both groups, including both groups generally reporting they disagreed or felt neutral that the intervention targeted barriers that impeded transplant access.

# Extent to Which the Intervention was Embedded Into Daily Routines

In brief, when assessing the overall normalization of the intervention into daily work, respondents indicated they were relatively familiar with the intervention (mean = 7.1 of 10, with a score of 10 indicating they were thoroughly knowledgeable, SD = 2.9); most felt the intervention was currently a regular part of their work (mean = 6.9 of 10, with a score of 10 indicating completely integrated, SD = 3.0) and felt the intervention would become a more substantial part of their regular work in the future (mean = 8.1 of 10, SD = 2.6) (Table 3). When assessing key factors that led to successful intervention implementation, most participants were neutral about the work required to understand the intervention and the new activities associated with it, the work to understand who was responsible for different aspects of the implementation process, and the work needed to evaluate success.

# Interview Results

From the interview data, we developed overarching themes representing implementation challenges and opportunities as expressed by the health care professionals tasked with integrating the EnAKT LKD intervention activities into their daily work. We have summarized these 5 themes in Table 4, which includes a summary, an example, a representative quote, and suggestions for intervention improvement. Briefly, respondents indicated that the intervention's complexity and breadth led some respondents to perceive it as being unfocused and lacking specificity, which some felt made it challenging to implement. A lack of clarity about the roles and responsibilities of each health care professional to engage with and deliver the different intervention

**Table 2.** Potential Barriers to Kidney Transplantation at the Level of the Provider, Chronic Kidney Disease Program, Patient, and Living Donor in the Usual Care and Intervention Group as Reported by Health Care Professionals.

Level of barrier	Theoretical domains framework	Potential barriers	Group	Before trial (prior to Fall 2017)	During trial before pandemic (prior to March 2020)	During trial after pandemic (December 2020 June 2021)
Health care	Knowledge	I am not sure which patients are eligible for	Usual care	_	2.14 (1.09)	2.12 (1.04)
provider-		transplant	Intervention	2.21 (.86)	2.02 (.90)	2.06 (.94)
related barriers		I am not sure when to refer a patient to a	Usual care	_	2.05 (1.02)	2.12 (1.05)
		transplant center	Intervention	2.19 (.99)	1.98 (.99)	1.98 (.97)
		I am not sure what the process is for	Usual care		1.81 (.96)	1.85 (.94)
		referring eligible patients for transplant at my program	Intervention	2.02 (1.01)	1.83 (.96)	1.83 (.96)
		I don't know enough about living kidney	Usual care		1.85 (.98)	1.80 (.91)
		donation to promote it to my patients	Intervention	2.13 (1.08)	1.85 (1.06)	1.87 (1.04)
		I am not sure which patients would benefit	Usual care	_	2.20 (1.17)	2.19 (1.15)
		from a living donor kidney transplant versus a deceased donor kidney transplant	Intervention	2.43 (1.12)	2.15 (1.12)	2.17 (1.13)
	Skills	I am not sure how to help my patients find a	Usual care		2.42 (1.16)	2.37 (1.10)
		living kidney donor	Intervention	2.68 (1.09)	2.40 (1.04)	2.32 (1.02)
	Beliefs about	I am not confident in my ability to promote	Usual care	_	2.10 (1.14)	2.34 (1.14)
	capabilities	kidney transplant and living donation	Intervention	2.57 (1.16)	2.40 (1.25)	2.47 (1.25)
		I am not comfortable enough talking about	Usual care		1.78 (.93)	1.69 (.82)
		living kidney donation with my patients	Intervention	2.13 (1.06)	1.79 (.95)	1.81 (.92)
Chronic Kidney	Environmental	I do not have access to the necessary data	Usual care		2.59 (1.19)	2.66 (1.21)
Disease Program- related barriers	context and resources	to understand how well patients in our program are completing steps toward receiving a kidney transplant	Intervention	2.83 (1.24)	2.68 (1.24)	2.62 (1.19)
		I do not have access to the necessary	Usual care	_	2.27 (.98)	2.29 (.98)
		information to know if a patient is potentially eligible to receive a kidney transplant	Intervention	2.66 (1.01)	2.30 (.88)	2.26 (.92)
		I am not provided with effective educational	Usual care		2.68 (1.18)	2.78 (1.18)
		resources to promote kidney transplant	Intervention	2.47 (1.25)	2.06 (1.01)	2.09 (1.08)
		Resources (including time) are not allocated	Usual care		2.49 (1.38)	2.71 (1.45)
		to promoting transplant in our program	Intervention	2.74 (1.36)	2.43 (1.33)	2.36 (1.26)
	Social influences	There is insufficient communication with	Usual care		2.36 (1.08)	2.42 (1.09)
		transplant centers to help move my patients through the evaluation process	Intervention	2.68 (1.10)	2.34 (.98)	2.32 (.96)
	Motivation and	Transplant is not a priority in our program	Usual care		1.85 (1.26)	1.97 (1.38)
	goals		Intervention	2.00 (1.08)	1.64 (.82)	1.72 (.93)
Patient-related	Knowledge	Patients do not demonstrate enough	Usual care	_	3.17 (1.10)	3.24 (1.14)
barriers		knowledge about transplant	Intervention	3.13 (1.06)	2.77 (1.03)	2.77 (1.03)
		Patients demonstrate misconceptions about	Usual care		3.51 (.99)	3.61 (.93)
		their eligibility for transplant	Intervention	3.49 (.95)	3.36 (.87)	3.30 (.98)
	Environmental context and	Patients are not provided with transplant education that includes their family/	Usual care Intervention	2.70 (1.06)	2.41 (1.07) 2.13 (.82)	2.53 (1.09) 2.17 (.87)
	resources	support system			2.20 (1.20)	
		Patients do not have access to educational materials about kidney transplantation and	Usual care Intervention	2.49 (1.04)	2.29 (1.00) 1.91 (.65)	2.46 (1.04) 1.98 (.79)
	Casial indexes	living kidney donation	Llaural		2.00 / 77\	2 24 / 75)
	Social influences	Patients indicate the absence of interactions with past recipients and living kidney donors to understand the transplant	Usual care Intervention	3.06 (.97)	3.08 (.77) 2.47 (.80)	3.24 (.75) 2.53 (.91)
Listan dan	Knowled	process from a patient perspective	Llaural		3 30 / 05)	2 27 / 00\
Living donor-	Knowledge	Potential living donors demonstrate a lack of	Usual care		3.29 (.95)	3.37 (.98)
related barriers	C:-1 : 0	knowledge about living kidney donation	Intervention	3.47 (.75)	3.11 (.81)	3.09 (.86)
	Social influences	Potential living donors indicate a lack of peer support to help them through the living donor evaluation process	Usual care Intervention	3.34 (.76)	3.27 (.78) 3.04 (.75)	3.34 (.78) 3.09 (.88)

Barriers were rated using a 5-point Likert scale from strongly disagree (1) to strongly agree (5). Data reported as mean (standard deviation). Respondents were asked to consider barriers from the perspective of the health care provider, CKD program, patients with CKD and living kidney donor candidates. All data were collected at one timepoint from December 2020 to June 2021; responses to earlier timepoints are retrospective accounts.

Table 3. NoMAD Instrument Results Presenting the Implementation and Integration of the EnAKT LKD Intervention.

Implementation and integration of the Access to Kidney Transplant (AKT) multicomponent intervention

	General questions about the intervention		
Item		Scale of 0-10  N = 46  Mean (SD)	
When you engage in the Access Kidney Transplant (AKT)* 10—feels very familiar)	Kidney Transplant (AKT)* Strategy, how familiar does it feel? (0—still feels very new to	7.11 (2.95)	
Do you feel that the AKT Strategy is currently a normal pa	sgy is currently a normal part of your work? 10—completely	<b>6.91</b> (3.02)	
Do you feel that the AKT Strate 10—completely)	Do you feel that the AKT Strategy will become a normal part of your work? (0—not at all to 5—somewhat to 10—completely)	8.09 (2.60)	
	Detailed questions about the intervention		
NPT construct Mean (SD)	Item	Scale of I—strongly disagree to 5—strongly agree Mean (SD)	Not relevant <sup>€</sup> , n
		N = 46	
Coherence $(\alpha = .70)$	I can see how the AKT Strategy differs from usual ways of working	3.33 (.76)	9
Mean score: <b>3.58</b> (.65)	Staff in this organization have a shared understanding of the purpose of the AKT Strategy	3.24 (.93)	_
	I understand how the AKT Strategy affects the nature of my own work	3.59 (.95)	2
	I can see the potential value of the AKT Strategy for my work	4.04 (.64)	_
Cognitive participation ( $lpha=.69$ )	There are key people who drive the AKT Strategy forward and get others involved	3.95 (.78)	2
Mean score: <b>4.06</b> (.39)	I believe that participating in the AKT Strategy is a legitimate part of my role	3.95 (.68)	2
	I'm open to working with colleagues in new ways to use the AKT Strategy	4.09 (.63)	_
	I will continue to support the AKT Strategy	$\sim$	_
Collective action	I can easily integrate the AKT Strategy into my existing work	3.55 (.79)	2
$(\alpha = .73)$	The AKT Strategy <b>does not</b> disrupt working relationships	3.77 (.86)	2
Mean score: <b>3.43</b> (.82)	I have confidence in other people's ability to use the AKT Strategy		_
	Work is assigned to those with skills appropriate to the AKT Strategy	3.50 (.76)	2
	Sufficient training is provided to enable staff to implement the AKT Strategy	3.02 (1.15)	2
	Sufficient resources are available to support the AKT Strategy	<b>3.09</b> (1.04)	æ
	Management adequately supports the AKT Strategy	3.60 (.84)	_
Reflexive monitoring	The staff agree that the AKT Strategy is worthwhile	3.51 (.66)	_
(lpha=.84)	I value the effects that the AKT Strategy has had on my work	<b>3.81</b> (.59)	æ
Mean score: <b>3.75</b> (.38)	Feedback about the AKT Strategy can be used to improve it in the future	<b>3.96</b> (.56)	_
	I can modify how I work with the AKT Strategy	<b>3.70</b> (.59)	2

\*Throughout the survey and interview questions, we refer to the EnAKT LKD intervention as the AKT Strategy, which is the name of the initiative used by the regional CKD programs. 

Epor some questions, participants could indicate "not relevant to my role," "not relevant at this stage" or "not relevant to EnAKT LKD."

 Table 4.
 Summary, Example, Representative Quote, and Next Steps for the 5 Themes Obtained From Interviews.

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Theme

meme 1. Considerable deput and breadth of the intervention	ervention		
Summary	Example	Representative quote	Next steps
The intervention's breadth led some respondents to perceive it to be unfocused and lacking specificity, which some felt made it challenging to implement     Participants indicated the implementation of the intervention components was fragmented and delivered differently across units within a CKD program, possibly because not enough work was done to ensure all program areas were equally engaged, resulting in a perception of varying levels of awareness and buy-in	The intervention education toolkits provided several types of educational materials that could be used by programs. Respondents reported that this made the intervention seem complex	• " it took me a while to get a sense of what this project was all about, what is it exactly that they wanted us to do and how do I transition"	More focused intervention and clear instructions to all staff may be needed in future iterations
	Theme 2: Remaining areas of uncertainty	of uncertainty	
Summary	Example	Representative quote	Next steps
A lack of clarity about the roles and responsibilities of each health care professional to engage with and deliver the intervention components was noted by some participants	When referencing the education component, some respondents were not sure whether to use existing transplant education materials or new EnAKT LKD educational materials	When a respondent was asked about how they supported the implementation of the Transplant Ambassador Program, they indicated that: "really, in my role, I feel greener than green and not totally sure what my role is"	<ul> <li>More role clarity may be needed to further guide health professionals toward new responsibilities and workflow changes</li> </ul>
	Theme 3: Resources	seo	
Summary	Example	Representative quote	Next steps
<ul> <li>Several respondents reported that there were not enough resources (time, funding, and staff) to implement the intervention. This was exacerbated by the COVID-19 pandemic and all participants reported this</li> <li>Some respondents indicated that because this work was not tied to funding reimbursement, they did not see the implementation as a necessary responsibility</li> <li>CKD programs that allocated a staff champion felt it helped to balance the intervention responsibilities and supported its implementation</li> </ul>	Respondents reported that responsibilities associated with new program initiatives often were tasked to CKD program managers: "Every time another initiative rolls out—there's not a whole lot that has decreased it's always the same managers".  Staff turnover and the need to continually reorient new staff to the intervention was a challenge	"We're dealing with outbreaks. We're dealing with cleaning in between patients getting dialysis and going out. We don't have the staff to do that basically. That comes down to that with all the sick calls and everything. So this priority is not right now. Not because it's not important, it's just because it's not feasible"	Participants provided suggestions of resources needed to facilitate implementation: eg, dedicated personnel to support transplant education, transplant coordinator to support transplant work ups and data collection, financial support to host patient and staff education events, and clinic space to integrate TAP ambassadors

Table 4. (continued)

	Theme 4: Buy-in		
Summary	Example	Representative quote	Next steps
<ul> <li>Respondents identified that staff at CKD programs, especially those not involved in implementing the EnAKT LKD intervention, may not have enough transplant knowledge to be comfortable having transplant discussions where they could advocate for the benefits of transplant over other modalities. This may have hindered buy-in to the EnAKT LKD intervention and transplant more broadly</li> <li>Respondents felt that some measures in the quarterly performance reports were not under their direct control or were too hard to achieve (eg, number of transplants), leading to frustration with the intervention which may have hindered buy-in and normalization of intervention activities</li> </ul>	There were challenges in the accuracy and timeliness of the quarterly performance reports and transplant eligibility lists, which led to participants losing confidence in their usefulness which potentially affected overall intervention buy-in	• Some staff did not think they should be promoting transplant as the best treatment option and preferred to present options in a more neutral way: "Some of them felt that we were—it was too aggressive to being sharing that the option of living transplant, that we were offering a bias that it's the best treatment They thought that we should be providing all information in a neutral way, that you can do home hemo, home PD, that you can go to in-centre, you can be on a waitlist for a transplant, whether it's deceased or living, but that they all get shared neutrally, equally, that one's not better than the other, and that was such a sticky point for them."	Respondents reported that collaborative events held early in the EnAKT LKD intervention events re-ignited their motivation to focus on improving access to kidney transplant, suggesting that "booster" sessions may be needed to maintain momentum
	Theme 5: Opportunities for relationship building	ttionship building	
Summary	Example	Representative quote	Next steps
Respondents valued strong relationships that were cultivated through the EnAKT LKD intervention, specifically within their CKD program, across other CKD programs and with their corresponding transplant center	Respondents felt that a strong relationship with the transplant center led to better patient outcomes, such as a more efficient transplant evaluation process     Respondents were inspired by the connections they made during collaborative events to learn about the EnAKT LKD intervention, share implementation challenges and identify solutions	"I think hearing about other people's experiences, it shows us different options that are working for people and then we do a little bit of maybe that would work here, or maybe that wouldn't and so on"	Continue to foster this emergent     community of practice

Note. Each theme draws upon 1 or more normalization process theory constructs.

**Table 5.** Survey Results Examining the Frequency of Planned, Held and Attended Quality Improvement (QI) Team Meetings Prior to the COVID-19 Pandemic and During the COVID-19 Pandemic.<sup>¥</sup>

	Prior to COVID-19 pandemic (prior to March 2020)*	During the first wave of the COVID-19 pandemic (March-May 2020)*
Planned QI team meetings	Monthly: 8 (26.7)	Monthly: 2 (6.7)
	Quarterly: 13(43.3)	Quarterly: 9 (30.0)
	Bi-annually: 0	Bi-annually: 0
	Annually: 0	Annually: 0
	Other: 2 (6.7)	Other: 2 (6.7)
	Not at all: 0	Not at all: 10 (33.3)
	Unsure/Missing: 7 (23.3)	Unsure/Missing: 7 (23.3)
QI team meetings held	Monthly: 6 (20.0)	<b>Monthly</b> : 2 (6.7)
5	Quarterly: 11 (36.6)	Quarterly: 2 (6.7)
	Bi-annually: 2 (6.7)	Bi-annually: 0
	Annually: 0	Annually: 1 (3.3)
	Other: 2 (6.7)	Other: 1 (3.3)
	Not at all: 0	Not at all: 12 (40.0)
	Unsure/Missing: 9 (30.0)	Unsure/Missing: 12 (40.0)
Attendance at OI team	Always: 9 (30.0)	Always: 3 (10.0)
meetings	Often: 9 (30.0)	Often: I (3.3)
3	<b>Sometimes:</b> 6 (20.0)	Sometimes: 1 (3.3)
	Rarely: 2 (6.7)	Rarely:   (3.3)
	Never: 0	Never: 3 (10.0)
	Not part of the QI team at that time: 3 (10.0) Missing: 1 (3.3)	Not part of the QI team at that time: 2 (6.7) Missing: 19 (63.3)

<sup>\*</sup>There were a total of 30 survey respondents (ie, individuals on the QI team).

components was noted by some participants. Several respondents reported feeling that there were not enough resources (time, funding, and staff) to be able to implement the EnAKT LKD intervention components. This was exacerbated by the COVID-19 pandemic and all participants reported this. Respondents identified that staff at CKD programs, especially those not involved in implementing the EnAKT LKD intervention, may not have enough transplant knowledge and experience to be comfortable having focused transplant discussions where they could advocate for the benefits of transplant over other modalities for treating kidney failure. This may have hindered buy-in to the EnAKT LKD intervention and transplant more broadly. The intervention did provide an opportunity for relationship building within their CKD program and with their corresponding transplant center, which was highly valued by respondents and was felt to lead to better patient outcomes.

#### **Fidelity**

We examined whether each of the 4 components of the intervention were implemented as planned.

Intervention component 1: local QI teams and administrative needs. All intervention-group CKD programs established a local QI team and created a team charter that was updated

yearly. An average of 5 CKD program QI teams had a team member with formal QI training throughout the trial period. The provincial core operations group hosted regular collaborative calls for QI teams, for which attendance was moderate. For example, in 2019, there were 9 calls hosted, with a median attendance of 8 of the 13 CKD programs. With the onset of the COVID-19 pandemic, only 3 calls were hosted in 2020, with a median attendance of 3 of the 13 CKD programs. During the trial, the provincial core operations group conducted 2 transplant performance meetings and 1 check-in call with each CKD program, and the provincial medical lead conducted at least 1 in-person site visit at 7 of 13 programs for a total of 9 visits. The provincial core operations group met over 100 times. Table 5 describes how often the QI team meetings occurred before and during the pandemic. For example, while 60% of respondents indicated they always or often attended QI meetings before the pandemic, this decreased to 13% during the first pandemic wave.

Table 6 provides survey results for participation in building a QI team, including participation and perceived helpfulness of creating a team charter, mapping the transplant referral process, and mapping the transplant education pathway. Participation in all 3 activities was  $\geq$  60%, and perceived helpfulness was  $\geq$  80%. However, participation in QI team activities was impacted by the pandemic, with an average of 1 (range = 0-6, SD = 1.3) Plan-Do-Study-Act cycles completed per quarter before the pandemic, which decreased

<sup>\*</sup>Data are presented as n (%).

**Table 6.** Survey Results for Participation in Building a Quality Improvement (QI) Team, Including the Participation and Perceived Helpfulness of Creating a Team Charter, Mapping the Transplant Referral Process, and Mapping the Transplant Education Pathway.

Activity	Participated in the activity (yes) <sup>¥</sup> n (%)	Perceived the activity to be helpful (yes) $^\dagger$ n (%)
Creating a QI team charter with specific aims	21 (70.0)	17 (81.0)
Mapping the transplant referral process	18 (60.0)	17 (94.4)
Mapping the transplant education pathway	19 (63.3)	18 (94.7)

<sup>\*</sup>There were a total of 30 survey respondents (ie, individuals on the quality improvement team). Response options included: yes, I participated; no, unsure/missing; or not part of the quality improvement team at the time.

**Table 7.** Survey Results for Examining Participation in Educational Activities and Perceived Helpfulness of Educational Activities for Quality Improvement Teams.\*

Activity	Participation in activity (yes)* n (%)	Perceived the activity to be helpful (yes)† n (%)
Explore Transplant Ontario workshop in Fall 2017	19 (63.3)	17 (89.5)
Presentation on "How to Find a Living Kidney Donor?"	10 (33.3)	10 (100.0)
Teleconference with Dr Amy Waterman aimed at enhancing transplant education at the CKD program	16 (53.3)	15 (93.8)
In-person meeting with Dr Amy Waterman aimed at enhancing transplant education at your CKD program	8 (26.7)	6 (75.0)
Teleconference with any of the education support personnel	17 (56.7)	17 (100.0)
In-person meeting with any of the education support personnel	18 (60.0)	18 (100.0)

<sup>\*</sup>Data are presented as n (%).

to 0.1 per quarter (range = 0-1, SD = 0.34) during the first wave of the pandemic.

Intervention component 2: transplant education and resources. In the fiscal year prior to the intervention launch, 297 patients with advanced CKD received greater than 30 minutes of transplant education. This increased after the EnAKT LKD intervention launched to 908 patients between April 2018 and March 2019 and 1452 patients from April 2019 to March 2020. With the onset of the COVID-19 pandemic, fewer patients received transplant education (eg, 1026 patients from April 2020 to March 2021). All programs had initial site visits by the education task group, and 8 programs had follow-up meetings (either in person or virtually). As shown in Table 7, 27% to 63% of QI team members participated in transplant educational activities offered and 75% to 100% of individuals who used them perceived them to be helpful. Educational resources were used by 8% to 58% of health care professionals, and their perceived helpfulness ranged from 75% to 100% (**Table 8**). As shown in Table 9, the use of all educational resources declined during the first wave of the pandemic, with resource use increasing later; however, usage never returned to pre-pandemic levels.

Support from prior transplant recipients and living donors. Although it took some time to establish the patient-led TAP (https://transplantambassadors.ca/) in each CKD program, in 2018, a total of 1679 meaningful interactions occurred across all programs between transplant ambassadors and patients with advanced CKD, their family members or potential living kidney donors. Interactions decreased when hospital volunteer programs paused during the pandemic. At that time, ambassador interactions moved to a virtual environment. In 2020, there were 411 interactions, and in 2021, 452 interactions. In 2018, there was a median of 6 ambassadors per CKD program (range = 1-9), a value that decreased to 4 (range = 1-11) during the pandemic. In 2018, only 1 CKD program did not have a TAP lead, in all subsequent years (ie, 2019-2021), 2 CKD programs had no TAP lead.

Program-level performance reports and oversight. The CKD programs were to receive performance reports each quarter (ie, approximately 16 times during the trial period). However, the provincial renal agency only distributed 7 performance reports and 4 transplant referral eligibility reports. The work to create the reports was more than initially

<sup>&</sup>lt;sup>†</sup>The denominator was based on how many individuals responded to "yes the participated in the activity."

<sup>\*</sup>There were a total of 30 survey respondents (ie, individuals on the quality improvement team). Response options included: yes, I participated; no, unsure/missing; or not part of the quality improvement team at the time.

<sup>&</sup>lt;sup>†</sup>The denominator was based on how many individuals responded to "yes the participated in the activity."

**Tables 8.** Survey Results for Examining Utilization of Educational Resources and Perceived Helpfulness of Educational Support for Quality Improvement Teams and Educational Resources for Other Health Care Professionals.\*

	Educational resources for quality improvement teams		Educational resources for health care professionals	
Resource	Utilization of resource <sup>€</sup>	Perceived the resource to be helpful (yes) <sup>µ</sup>	Utilization of resource <sup>¶</sup>	Perceived the resource to be helpful (yes) <sup>µ</sup>
Provider Resource Hub (transplant resources) for health care providers on the Ontario Renal Network website	17 (56.7)	15 (88.2)	8 (30.8)	7 (87.5)
Infographic "Would your Patient Benefit from a Kidney Transplant Referral"	20 (66.7)	20 (100)	12 (46.2)	11 (91.7)
Infographic "How to Talk about Living Kidney Donation"	22 (73.3)	20 (90.9)	14 (53.8)	14 (100)
Infographic "Becoming a living kidney donor in Ontario"	20 (66.7)	19 (95)	10 (38.5)	10 (100)
Infographic "Living Kidney Donation outside Canada"	12 (40)	12 (100)	4 (15.4)	3 (75.0)
At least I video from the Core Transplant Curriculum Webinars (eg, risks and benefits of kidney transplantation compared with other renal replacement modalities)	12 (40)	12 (100)	6 (23.1)	6 (100)
Dialysis versus kidney transplant estimated survival in Ontario risk calculator website or app	5 (16.7)	5 (100)	2 (7.7)	2 (100)
At least 1 Explore Transplant Ontario video	23 (76.7)	18 (78.2)	12 (46.2)	10 (83.3)
Read the Explore Transplant Ontario brochures	23 (76.7)	19 (82.6)	15 (57.7)	15 (100)
Provided any of the Explore Transplant Ontario videos and/ or brochures to patients or family members	19 (63.3)	Not applicable	14 (53.8)	Not applicable

<sup>\*</sup>Data presented as n (%)

**Table 9.** Educational Resource Usage Presented Using a Likert Scale, With 1 Indicating the Resource was Never Used and 5 Indicating the Resource was Always Used. \*

Question		Prior to the COVID-19 pandemic Mean ± SD (no. of respondents)	During the first wave of the COVID-19 pandemic (March 2020-May 2020)  Mean ± SD (no. of respondents)	At the time of the survey (December 2020-June 2021)  Mean ± SD (no. of respondents)
How often did you use the infographic: How to talk about living	Quality improvement team	3.23 ± 0.92 (22)	2.00 ± 1.07 (22)	2.77 ± 1.07 (22)
kidney donation?	Other health care professional	3.14 ± 0.77 (14)	2.14 ± 0.86 (14)	2.77 ± 0.83 (13)
How often did you use the infographic: Becoming a living kidney	Quality improvement team	3.25 ± 0.85 (20)	2.00 ± 1.08 (20)	2.65 ± 0.62 (20)
donor in Ontario?	Other health care professional	3.50 ± 0.53 (10)	2.70 ± 1.16 (10)	3.10 ± 0.88 (10)
How often did you use the infographic: living kidney donation	Quality improvement team	$3.25\pm0.62$ (12)	2.25 ± 1.29 (12)	$2.91 \pm 0.94 (11)$
outside Canada?	Other health care professional	2.75 ± 0.50 (4)	2.25 ± 0.96 (4)	$2.75 \pm 0.50$ (4)
How often did you use the dialysis versus kidney transplant estimated	Quality improvement team	3.80 ± 0.45 (5)	1.80 ± 1.10 (5)	$3.40 \pm 0.89 (5)$
survival in Ontario risk calculator website or app?	Other health care professional	3.00 ± 0.00 (2)	1.50 ± 0.71 (2)	$2.50 \pm 0.71$ (2)
How often did you give any of the Explore Transplant Ontario videos	Quality improvement team	4.16 ± 0.69 (19)	2.53 ± 1.31 (19)	3.63 ± 1.07 (19)
and/or brochures to patients or family members?	Other health care professional	3.79 ± 0.80 (14)	2.21 ± 1.12 (14)	2.71 ± 1.07 (14)

<sup>\*</sup>Denominators are restricted to quality improvement team members and health care professionals who indicated that they used the resource.

<sup>&</sup>lt;sup>€</sup>There were a total of 30 survey respondents (ie, individuals on the quality improvement team). Response options included: yes, I participated; no, or unsure/missing.

<sup>&</sup>lt;sup>µ</sup>The denominator was based on how many individuals responded to "yes they participated in the activity."

There were a total of 26 survey respondents (ie, other health care professionals). Response options included: yes, I participated; no, or unsure/missing.

Table 10. Dissemination of Program-Level Performance Reports.

	Health care professional reported participation and perceived helpfulness
Fidelity of receipt and enactment	Yes, n (%)
Dissemination of the program-level performance reports	
Shared information from the program-level performance reports with other members of your CKD program (besides QI team members). This question was only given to the quality Improvement team lead ( $n=8$ )	6 (75)
Outside of your QI team, other health care professionals reviewed information from the program-level performance reports. This question was only given to quality improvement team members other than the QI team lead ( $n=20$ )	5 (25)
Reviewed at least one of the program-level performance reports. This question was only given to health care professionals who were not a member of the quality improvement team $(n=26)$	5 (19)
Found the program-level performance reports helpful. This question was only given to health care professionals who were not a member of the quality improvement team and who reviewed the report $(n = 5)$	4 (80)
Dissemination of the transplant referral eligibility reports	
Shared information from the transplant referral eligible patient reports with other members of the CKD program (besides QI team members). This question was only given to the quality improvement team lead ( $n=8$ )	2 (25)
Outside of your quality improvement team, other health care professionals reviewed the transplant referral eligible patient reports. This question was only given to quality improvement team members other than the QI team lead $(n = 19)$	4 (21)
Reviewed at least one of the transplant referral eligible patient reports. This question was only given to health care professionals who were not a member of the quality improvement team $(n=26)$	4 (15)
Found the transplant referral eligible patient reports helpful. This question was only given to health care professionals who were not a member of the quality improvement team who reviewed the report $(n=4)$	3 (75)

anticipated, which included the time needed to reconcile data concerns.

Chronic kidney disease program QI teams reviewed an average of 4.1 (SD = 2.7) of the 7 program-level performance reports and 1.6 (SD = 1.7) of the transplant referral eligibility reports. These reports were usually not distributed beyond the QI team; only 19% of surveyed health care professionals outside the team indicated they reviewed at least one performance report (Table 10). Using a 5-point Likert scale, health care professionals were mainly neutral regarding the ease of interpreting these reports (mean = 3.4) and their perceived usefulness (mean = 3.4) (Table 11).

# Additional Fidelity Results

**Supplemental** Table 4 includes additional fidelity indicators grouped by intervention component. **Supplemental Table 5** includes fidelity indicators not reported due to unavailable data, and **Supplemental Table 6** includes fidelity indicators not reported due to poor utilization of the transplant referral eligible patient report.

#### Contamination

The online survey confirmed a lack of contamination (ie, programs in the usual care group did not appear to use the intervention components during the trial; data not shown).

# **Discussion**

The EnAKT LKD trial found that a novel multicomponent intervention compared with usual care did not significantly increase the rate of patients completing steps toward receiving a kidney transplant. Alongside the trial, we conducted a process evaluation. We learned that the intervention engaged providers; however, there were implementation challenges and a need to better integrate some components into routine care.

We surveyed CKD program staff on the perceived barriers to accessing kidney transplants. Over time, the views expressed by staff in the intervention and usual care groups were consistent; however, both groups disagreed or felt neutral that the targeted barriers impeded transplant access. We acknowledge the limitations of our approach, which include asking health care providers to rate barriers experienced by

Table 11. Program-Level Performance Reports Usage.

Quarterly performance reports	$Mean \pm SD$	Range/scale
Number of quality improvement snapshot reports reviewed by the quality improvement team $(n=30)$	4.1 ± 2.7	0-7; 0 represents 0 reports were reviewed and 7 represents all reports were reviewed
Quality improvement snapshot reports were easy to interpret $(n = 21)$	$3.4\pm0.9$	Scale I—strongly disagree to 5—
Quality improvement snapshot reports were useful for understanding how many patients in our CKD program took steps to receive a kidney transplant ( $n=20$ )	3.5 ± 0.9	strongly agree Respondents indicating they did not review any of the quality
Quality improvement snapshot reports contributed to more patients in our CKD program being assessed for transplant referral eligibility ( $n=21$ )	3.4 ± 0.8	improvement snapshot reports did not respond to these follow-up
Quality improvement snapshot reports contributed to more patients in our CKD program being referred to transplant centers ( $n=21$ )	3.3 ± 0.7	questions
Quality improvement snapshot reports contributed to more individuals contacting a transplant center about living kidney donation for a patient in our CKD program ( $n=21$ )	3.1 ± 0.8	
My CKD program is likely to continue using the quality improvement snapshot reports to track our progress in improving patient access to kidney transplant and living donation $(n = 21)$	3.5 ± 0.6	
How often were quality improvement snapshot reports shared outside of the QI team (QI team leads) ( $n=6$ ). QI team leads only responded to this question if they indicated that reports were shared outside of the QI team	3.5 ± 0.5	Scale I—rarely to 4—always
How often were quality improvement snapshot reports shared outside of the QI team (QI team members) ( $n=3$ ). QI team members only responded to this question if they indicated that reports were shared outside of the QI team	2.3 ± 0.6	
Transplant referral eligible patient report		
Transplant referral eligible patient reports reviewed by QI team $(n = 27)$	1.6 ± 1.7	Range 0-4 (maximum number of transplant referral eligibility reports that could be received is 4)
Transplant referral eligible patient reports were easy to interpret $^{*}$ (n = 14)	$3.7\pm0.9$	Scale I—strongly disagree to 5—
Transplant referral eligible patient reports were useful* (n = 14)	$3.6 \pm 0.9$	strongly agree
Transplant referral eligible patient reports resulted in more patients being assessed for transplant referral $(n = 14)$	3.4 ± 0.8	
Transplant referral eligible patient reports resulted in more patients being referred to transplant centers $^{4}$ (n = 14)	3.4 ± 0.8	
My CKD program is likely to continue using the transplant referral eligible patient reports to improve patient access to kidney transplant and living donation $^*$ (n = 14)	3.6 ± 0.7	

<sup>\*</sup>Respondents indicating they did not review any of the transplant referral eligible patient reports did not respond to these follow-up questions.

patients and living donors (rather than asking patients and living donors directly), asking providers to recall barriers over a long time period, and asking health care providers who were most experienced and knowledgeable in transplant and likely experience fewer barriers to helping their patients get a transplant.

Survey respondents were those most directly involved in key transplant activities, such as providing education and coordinating transplant referrals at the CKD program. Overall, respondents did not perceive a lack of transplant knowledge as a barrier. Still, in interviews, QI team leads expressed their belief that frontline dialysis nurses needed more transplant knowledge and experience to help their patients navigate the transplant process. While QI teams

were to work out how to deliver health professional education to those who needed it the most, in the future, we can better guide them on how to do this. Specifically, we suggest assessing barriers to transplant in frontline staff that may not routinely engage in transplant processes (ie, those who are not part of the QI team), but who spend significant time with patients throughout their kidney care journey during which education, guidance and navigation are provided, and to tailor future educational interventions according to their perceived barriers. Fidelity data supported that while some educational resources had moderate-to-high use, others, such as the core curriculum webinars, were not used by health professionals as often as intended.

It makes intuitive sense that CKD programs must regularly review their performance on key transplant metrics to effectively guide their improvement efforts. There is good evidence that audit and feedback is helpful.<sup>26</sup> We established data-sharing agreements that allowed CKD programs to receive summary performance reports on how well patients in their program were completing key steps toward receiving a transplant. However, survey data showed that QI teams, on average, only reviewed 4 of 7 reports. Reports were also rarely distributed beyond QI team membership. The implementation may be improved using best practices in audit and feedback and recommending specific actions for the report recipient.<sup>26,27</sup>

The COVID-19 pandemic hindered intervention delivery and the response rate for this process evaluation. Many CKD program staff left their positions or deployed to other hospital areas. The monthly collaborative calls, QI team meetings, and patient education efforts were all paused. Patient transplant ambassadors could not enter the hospital, and their interactions shifted to virtual.

The document analysis showed we successfully established a QI infrastructure. All 13 CKD programs in the intervention group formed QI teams, each with a team charter. Members participated in monthly provincial collaborative calls and, before the pandemic, held regular team meetings. Surveys and interviews show we engaged providers with the intervention. Respondents indicated optimism about its ongoing integration and valued the new relationships they built to support local process improvement. The findings support an assertion that initiatives to improve access to kidney transplantation and living kidney donation are acceptable to providers as a new part of their work. However, the breadth and complexity of the intervention led survey respondents to report difficulty making sense of it, understanding what work was required to implement it, and how it differed from usual processes. They indicated the substantial scope led to challenges in operationalizing and executing intervention components. Participants wanted more training on intervention components and suggested more staff and resources would be helpful to support implementation. For example, the provincial renal agency asked CKD programs to form QI teams and engage in process improvement work, yet only provided 1 training day at the start of the trial. We asked each QI team to include a local team member with formal QI training. However, such a person was only available in some programs (average of 5 of 13 CKD programs throughout the trial). Given the high staff turnover experienced at CKD programs over the 4-year trial period, many providers implementing the intervention were initially absent and never received training on its components. Future efforts should better delineate sustainability plans and address the need for retraining with staff turnover.

In 2021, the provincial renal agency provided a small amount of funding for transplant coordination at each CKD program. While helpful, during interviews, the QI leads

stated they needed more support to complete transplant referrals and navigate patients through the transplant process efficiently. Quality improvement leads also cited complex communication processes with transplant centers to move their patients throughout the transplant process. These are targets for future QI efforts.

Limitations of our study are worth noting. Approximately, 30% of CKD program staff did not respond, and 2 of the 13 intervention CKD programs did not participate. Respondents were experienced in their roles and were amongst the CKD program staff most engaged with intervention implementation. Providers who did not participate in our process evaluation were likely less familiar with or involved with intervention implementation. Finally, we did not survey or interview patients.

In conclusion, we established a QI culture and infrastructure in Ontario to improve access to kidney transplantation and living kidney donation. While the intervention in its tested form was insufficient to improve access, this process evaluation provides several suggestions for intervention improvement.

# **Declaration of Conflicting Interest**

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#### **Ethics Approval**

We obtained ethics approval from the Ottawa Health Sciences Research Ethics Board, and written informed consent was obtained from all participants (REB 20200426-01H).

#### **Consent to Participate**

Written informed consent was obtained from all participants (REB 20200426-01H).

#### **Consent for Publication**

All authors consent to the publication of this study.

#### Availability of Data and Materials

The data for this study is held securely at the Ottawa Hospital Research Institute and are available upon reasonable request.

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### Supplemental Material

Supplemental material for this article is available online.

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