## Factors associated with suboptimal initiation of dialysis despite early nephrologist referral

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### Abstract

**Background.** STARRT recently demonstrated that many patients experience suboptimal dialysis starts (defined as initiation as an inpatient and/or with a central venous catheter), even when followed by a nephrologist for >12 months (NDT 2011). However, STARRT did not identify the factors associated with suboptimal initiation of dialysis. The objectives of this study were to extend the results of STARRT by ascertaining the factors leading to suboptimal initiation of dialysis in patients who were referred at least 12 months prior to commencement of dialysis.

**Methods.** At each of the three Toronto centers, charts of consecutive incident RRT patients were identified from 1 January 2009 to 31 December 2010, with predetermined data extracted.

**Results.** A total of 436 incident RRT patients were studied; 52.4% were followed by a nephrologist for >12 months prior to the initiation of dialysis. Suboptimal starts occurred in 56.4% of these patients. No attempt at arteriovenous fistula (AVF) or arteriovenous graft (AVG) prior to initiation was made in 65% of these starts. Factors contributing to suboptimal starts despite early referral included patient-related delays (31.25%), acute-on-chronic kidney disease (31.25%), surgical delays (16.41%), late decision-making (8.59%) and others (12.50%). The percentage of optimal starts with early referral among 14 nephrologists ranged from 33 to 72%.

**Conclusions.** Most patients started dialysis in a suboptimal manner, despite an extended period of pre-dialysis care. Nephrologists should take responsibility for suboptimal initiation of dialysis despite early referral and test methods that attempt to prevent this.

Keywords: AV access; chronic kidney disease; modality selection; predialysis

## Introduction

The quality of medical care a patient receives in the months prior to the initiation of renal replacement therapy (RRT) can prepare the patient for an optimal dialysis start [1, 2]. More specifically, a higher quality of pre-dialysis care allows more consideration of elements vital to optimal dialysis starts, such as dialysis education, modality selection and creation of a permanent access [3–5]. A shorter duration of pre-dialysis care has been associated with worse dialysis outcomes, including mortality and hospitalization [6–11].

Despite the potentially improved quality of initiation associated with a longer duration of pre-dialysis care, the Study to Assess Renal Replacement Therapy (STARRT), recently published by our group [12], demonstrated that many patients still initiate dialysis suboptimally [defined as initiation as an inpatient and/or with a central venous catheter (CVC)] despite early nephrologist referral and care for >12 months. Suboptimal initiation was associated with an increased mortality in the first 6 months of dialysis. This finding of suboptimal initiation despite early referral has been reported previously [13-15], but has not received much attention. STARRT was not designed to identify the factors associated with a suboptimal start despite early referral. This study of three dialysis programs in Toronto, Canada, aimed primarily to extend the results of the STARRT study by identifying and quantifying the factors that contribute to suboptimal starts in patients who have been followed by a nephrologist for >12 months. The secondary objective was to examine variations in the predialysis care of patients by center and by most responsible nephrologist.

### Methods

STARRT, an extension study, was designed to determine the factors contributing to suboptimal starts in patients receiving long-term pre-dialysis

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care. The study design and protocol was approved by the local research ethics board at each of the three participating centers (Humber River Regional Hospital, Sunnybrook Health Science Centers and St Michael's Hospital). All the three programs use a multidisciplinary pre-dialysis team-based approach to pre-dialysis care, which includes a nephrologist, nurse clinician/educator, social worker, dietician and pharmacist, as is the standard of care in Ontario [16]. The study utilized a retrolective design and studied all patients initiating either hemodialysis (HD) or peritoneal dialysis at home, satellite or in-center between 1 January 2009 and 31 December 2010. Patients re-initiating dialysis upon transfer from another dialysis starts in Ontario is essential for program funding, and therefore, the patient lists provided by the hospitals are considered highly reliable. The charts of eligible patients were studied from the time of primary nephrology referral until the initiation of the dialysis treatment.

Creatinine values were documented for each patient at three critical events during pre-dialysis care: initiation of education on renal disease and dialysis modalities, modality choice and initial attempt at access creation. Data were also collected for initial RRT modality as well as the primary access used. Using the four-variable, abbreviated Modification of Diet in Renal Disease (MDRD) formula, estimated glomerular filtration rates (eGFRs) were calculated from creatinine levels and patient. Ne-phrologists with six or fewer patients who initiated dialysis during the 2-year study period were excluded from the nephrologist comparison.

A number of demographic data were also collected, including age and relevant comorbidities. Dialysis initiation was also determined to be either optimal or suboptimal as defined in the original STARRT study; a start was classified as optimal if (i) the patient initiated RRT as an outpatient and (ii) dialysis was initiated with a permanent access [arteriovenous graft (AVG) or arteriovenous fistula (AVF) for HD or a peritoneal catheter for peritoneal dialysis (PD)]. We determined the length of predialysis care received by each patient by calculating the interval between the date of the initial visit and the date of the initiation of dialysis. The focus of this analysis was on those patients followed by a nephrologist for >12 months prior to RRT initiation.

When a patient was identified as having started dialysis suboptimally, we used a series of definitions to classify the cause. Patient-related delay was determined when the medical record documented delay caused by hesitation on the part of the patient to receive further education, consider vascular access and/or reluctance to comply with nephrologist-recommended steps of pre-dialysis care. Acute-on-chronic kidney disease (CKD) was determined if a sudden and unforeseeable deterioration of kidney function occurred (often caused by other medical conditions). Surgical delays were determined when timely education and decisions were made, but wait times for surgical consults and/or access surgery were >1 month, and prevented an optimal start, as well as when problems with initial access creation or maturation prevented cannulation and led to CVC insertion. Late decision-making by the nephrologist was determined when the medical record showed evidence of failure on the part of the nephrologist to recommend pre-dialysis care decision-making in a timely manner, with no evidence for any of the other three factors listed earlier.

The data were summarized using descriptive statistics (number and percentages for categorical data, mean and standard deviation for normally distributed continuous variables and median and range for continuous data with a non-normal distribution). Optimal and suboptimal data were compared using *t*-tests. Percentages were calculated using the quantity of the reported data, as full data were not available for every patient. Analyses were two-tailed, and a P-value of <0.05 being considered statistically significant.

#### Results

Demographics of the 436 patients who make up the entire cohort are shown in Table 1. For three patients, duration of pre-dialysis care could not be determined, and for two of these three, location of initiation of dialysis could not be determined. These patients were excluded from all analyses where optimal or suboptimal status was considered.

Table 2 depicts the main clinical outcomes. The majority of patients initiated dialysis as outpatients

(53.7%). Most of the patients (79.8%) initiated HD, whereas 20.2% started on PD. The access used for initial RRT were CVC (66.9%), PD catheter (20.2%), AVF (12.4%) and AVG (0.5%); 52.4% of patients were followed by a nephrologist for >12 months.

Table 3 shows rates of optimal starts for both the entire sample and for the early and late referral groups. Overall, 30% of patients initiated optimally; with >12 months of pre-dialysis care, this rate was 43.6%. Among the 227 patients followed for >1 year, 51.5% initiated dialysis with a CVC, 20.7% with an AVF and 27.8% with a PD catheter.

The factors associated with suboptimal initiation of dialysis in 128 patients followed for >12 months are listed in Table 4. Acute-on-CKD (31.3%) and patient-related delays (31.3%) were the most common factors. Surgical delays were also a prominent contributing factor (16.4%), as well as late decision-making by nephrology, which accounted for 8.6% of the suboptimal starts.

Table 5 denotes mean eGFRs at various stages of predialysis care, in the optimal patient group. The mean eGFR at referral to nephrology was 28.1 mL/min, with modality education beginning at a mean of 16.1 mL/min. Access creation was performed at 11.8 mL/min and average eGFR upon initiation of dialysis was 10.2 mL/ min. Similar comparative calculations for the suboptimal

**Table 1.** Demographics of all patients (n = 436)

	All ( <i>n</i> = 436)	Optimal $(n = 130)$	Suboptimal $(n = 304)$	P-value
Mean age (years)	$67 \pm 16$	$69 \pm 15$	$66 \pm 16$	0.06
Male (%)	57.6	55.7	59.2	0.81
Diabetes (%)	52.2	55.4	50.7	0.37
Hypertension (%)	75.4	73.8	76	0.64
Heart disease (%)	19.3	17.7	20.1	0.57
Cerebrovascular (%)	2.5	2.3	2.6	0.84
PVD (%)	10.3	6.9	11.8	0.12

The P-value represents a comparison of optimal and suboptimal groups

 Table 2. Primary pre-specified outcomes of the 436 patients

	All	All		Optimal		Suboptimal	
	п	%	п	%	п	%	
Location							
Outpatient	233	53.7	130	100	103	33.9	
Inpatient	201	46.3	0		201	66.1	
Unknown	2						
Initial access							
AVG	2	0.5	2	1.5	0	0	
AVF	54	12.4	46	35.4	8	2.6	
PD Catheter	88	20.2	82	63.1	5	1.7	
CVC	291	66.9	0	0	291	95.7	
Unknown	1						
Duration of pre-di	alysis car	e					
<1 month	122	28.2	3	2.3	119	39.1	
1–3 months	41	9.5	11	8.5	30	9.9	
4-12 months	43	9.9	16	12.4	27	8.9	
>12 months Unknown	227 3	52.4	99	76.7	128	42.1	

**Table 3.** Rates of optimal RRT starts and suboptimal starts for all patients (n = 434), characterized by early versus late referral group

Initiation characteristic	All		<12 months		>12 months	
	n	%	n	%	n	%
Optimal start	130	30.0	30	14.6	99	43.6
Suboptimal start	304	70.0	176	85.4	128	56.4

Optimal initiation is defined as an outpatient start with permanent access (AVF, AVG or PD catheter). Two patients for whom location at initiation could not be determined are excluded.

**Table 4.** Causes of suboptimal initiation in early-referral patients (n = 128)

	>12 months	
	N	%
Patient-related delays	40	31.25
Acute-on-CKD	40	31.25
Surgical delays	21	16.41
Late decision-making by the nephrologist	11	8.59
Other	16	12.50

group could not be performed because of missing data, since the eGFR could not be documented in patients who did not reach each critical point in the process. For example, 83 of 128 patients (65%) had no attempt at AVF/AVG despite the >1-year follow-up by a nephrologist.

Figure 1 compares percentages of optimal starts across the three participating centers. Centers 1, 2 and 3 had optimal start rates of 36.8, 45.5 and 47.9%, respectively. Figure 2 depicts rates of optimal and suboptimal starts across the 14 primary nephrologists who started 7 or more patients on dialysis. Optimal start percentage ranged from 33.3 to 71.4%.

#### Discussion

This study confirms and extends the results of STARRT [12]. In STARRT, an optimal start was associated with a 53% reduction in the 6-month composite end point of survival, hospitalization and transfusion. Furthermore, the potential benefit of an early referral was lost when a suboptimal start occurred. Definitions concerning the length of time that constitutes a late referral vary widely between studies and are usually 4 months or less [6, 7, 17–20]; however, STARRT used an early referral definition of >12 months prior to end-stage renal disease (ESRD) [12]. The STARRT study found that 56% of patients initiated dialysis suboptimally despite early referral [12], and an identical result was found in the current study.

For clinical nephrologists, it is important to focus efforts on potentially modifiable factors that cause suboptimal initiation of dialysis despite early referral, which was the reason why this extension study was conducted. A leading cause was acute-on-CKD, which accounted for S.A. Hughes et al.

**Table 5.** The mean eGFR at key points of pre-dialysis care in the early-referral, optimal initiation subgroup (n = 99)

	eGFR (mL/min)
Referral to nephrology	$28.1 \pm 17.2$
Initiation of relevant education	16.1 ± 6.9
Modality selection	$14.0 \pm 4.4$
Primary access creation	$11.8 \pm 6.0$
Initiation of RRT	$10.0 \pm 6.2$

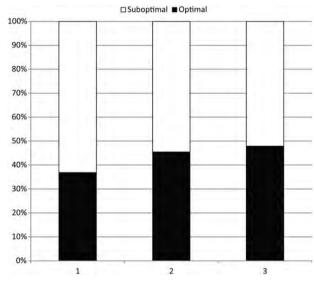


Fig. 1. Percentages of optimal and suboptimal starts by center.

31.3% of suboptimal initiation. However, owing to the unpredictable and rapid onset of this parameter, there may be little that can be done to reduce its frequency. However, it may be possible to determine a subgroup of pre-dialysis patients who are at a high risk of acute-on-CKD. A testable hypothesis is that this group has multiple comorbidities, especially co-existing heart disease. If such a group could be identified, then earlier modality selection and access decisions might prevent suboptimal initiation in this situation.

The impact of patient-related delays seems readily modifiable and accounted for an equal proportion of suboptimal initiations as acute-on-CKD. These delays included factors such as non-compliance with appointments and reluctance to consider modality and dialysis options. Furthermore, many patients were resistant to making decisions concerning dialysis despite having lengthy multidisciplinary care and thorough education on ESRD. We suggest that methods to identify and overcome this problem must be investigated and subsequently disseminated.

Surgical issues in Canada have been noted previously [21] and may be modifiable by actions taken locally, provincially and nationally. A recent national report makes many recommendations intended to overcome these surgical barriers to optimal vascular access [22]. Finally, we note that late decision-making by nephrologists, while not common, is completely under the control of the physician and is modifiable.

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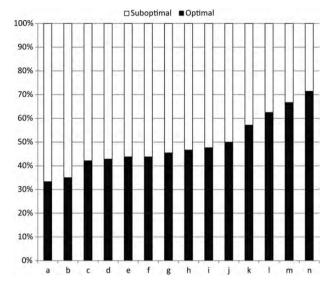


Fig. 2. Percentages of optimal and suboptimal starts by primary nephrologist.

Hakim and Himmelfarb suggested commencement of renal education at an eGFR of <30 mL/min, followed by a decision concerning modality between 20 and 30 mL/ min, and at 20 mL/min, referral for a surgical consult if pursuing hemodialysis [23]. A similar recommendation was made recently by the Canadian Society of Nephrology Vascular Access Working Group (CSN VAWG) [22]. However, each patient experiences a variable rate of decline and as such, these eGFR checkpoints serve as mere recommendations. However, as noted earlier, failure on the part of the nephrologist to advance patients' predialysis care within appropriate time frames can contribute to suboptimal initiation as it reduces the time available for access creation and maturation. Analysis of eGFRs at critical decision points in the optimal group showed that patients, on average, crossed decision thresholds at a lower eGFR than has been recommended. Most notable was the initiation of education at 16.2 mL/min, as opposed to the recommended 30 mL/min. A similar problem with late initiation of education was reported recently from Australia, where a mean eGFR of 13.3 mL/min was determined to be the time when information was first presented [24]. Of more concern is that eGFR assessment at the time of task completion in the suboptimal group is even worse than in the optimal group, as highlighted by 83 of 128 patients (65%) who had no attempt at AVF/AVG despite the >1-year follow-up by a nephrologist.

It is of interest to note that a recent publication from Australia compared the providers' perception of barriers to AVF/G creation with what the actual barriers were [25]. The providers had a perception that patient-related delay was a barrier, but this was not borne out in the observational study. This differs from our result in this study. The Australians did show that tasks related to securing appropriate vascular access were done very late. For example, the eGFR at the time of access surgery was 7 mL/min. We found similar problems with low eGFR's at VA surgery, or no attempt at AVF/AVG (discussed above). Indeed, ranking of reasons leading to suboptimal initiation of dialysis may vary by jurisdiction.

The study also compared pre-dialysis care across the three centers studied (Figure 1). Overall optimal versus suboptimal rates were fairly similar across centers. However, much more significant variations were noted between nephrologists (Figure 2). While we did not adjust for possible differences in patient characteristics, this suggests potential differences in the quality of predialysis care given by nephrologists. It is noteworthy that current quality improvement efforts focus more on the process of team-based care than on targeting individual performance. Within each center, the multidisciplinary team was constant, but the nephrologist varied by patient. Focusing solely on the center or team would miss identifying the highly variable performance among nephrologists. It is tempting to speculate that nephrologists with the highest rates of optimal starts have more empathy, better communication skills and more success with influence and persuasion, and hence more often overcome patient-related delays. Empirical study of these differences seems likely to reveal opportunities to improve pre-dialysis care.

The following practical recommendations are offered to nephrologists as an interim, opinion-based guide to improve pre-dialysis care, while we await future studies. They are based upon recently published recommendations from the Canadian Society of Nephrology Vascular Access Working Group (CSN VAWG) [22]. (i) Initiate modality education at an eGFR of 30 mL/min in most patients with rates of decline of 2-5 mL/min/year, if they are suitable candidates for dialysis or transplantation. Provision of this education might occur through classroom-type teaching to small groups of patients and families, by providing written materials and/or by recommending Internet-based materials. (ii) Aim for final modality decisions at an eGFR of 20 mL/min. (iii) Nephrologists should present all options, but have an obligation to more actively promote home dialysis for suitable patients and to actively promote early creation of AVF/AVG for patients who choose home- or hospitalbased HD. Valuable ways to stimulate decision making are to include family members in these discussions, and stating bluntly, the impact of delaying decisions on prognosis, including survival and hospitalization, are often valuable ways to stimulate decision-making. (iv) Nephrologists should measure and track their own rates of suboptimal initiation of dialysis despite early referral, and modifiable factors. Including the non-physician members of the pre-dialysis team in such audits is recommended, and applying the principles of continuous quality improvement methodology to their own practice would seem justifiable.

It is of interest to note that efforts can be made immediately after the initiation of dialysis that can help overcome some of the issues related to suboptimal starts. Recent publications suggest that patient outcomes are improved with an algorithmic, multiple intervention approach [26, 27]. It makes sense that a similar approach would be beneficial if it were directed at pre-dialysis patient months and/or years before the initiation of dialysis. This would be amenable to empirical study and would be the next logical step.

Ontario has a newly established Ontario Renal Network. A formal Ontario Renal Plan has recently been published online (http://orp.renalnetwork.on.ca/) and includes prioritization and resources focused upon efforts to improve home dialysis rates, improve vascular access performance and to reduce suboptimal starts. Methods to achieve these goals and implementation are works in progress, but may include algorithms and/or guidelines around pre-dialysis care and transition onto dialysis.

This study has a number of limitations. Patients were not randomly selected and the facilities that participated represent a convenience sample. Secondly, and perhaps more importantly, this study was limited by its small sample size and retrolective and observational nature. The chart review methodology is subject to scarcity of primary data, chart abstraction errors and data entry errors. No validation of data accuracy was performed because of resource constraints. The study sites were limited to only one city in Canada. These limitations mean that the associations we find should be considered hypothesis generating and do not prove causation.

Whether the results of this study, with the aforementioned limitations, are generalizable to other jurisdictions has not yet been established. Certainly, both DOPPS and the USRDS annual reports document the same problem of initiation of HD with a CVC despite >1 year of nephrology follow-up [28, 29]. Furthermore, DOPPS shows marked variation in incident patient CVC usage, with >60% in the UK, Sweden, Belgium, Canada and the USA, and <30% in Japan and Germany [30]. Finally, suboptimal initiation of dialysis despite early referral is reported from the USA [13], Spain [14], the UK [15] and Canada [12]. On the basis of this, we suspect that the factors we identified operate similarly in many other jurisdictions, but perhaps not in all. However, we acknowledge that there is insufficient published information available to make this claim with any certainty. Nonetheless, nephrologists must take responsibility for understanding and overcoming suboptimal initiation of dialysis despite early referral. Therefore, we strongly encourage future studies in other jurisdictions, which should follow large cohorts of patients prospectively in order to obtain more thorough information concerning the implications of various pre-dialysis measures for the quality of RRT initiation.

The rate of suboptimal starts despite early referral is 56.4%. Of the factors identified, patient-related delays would appear to be modifiable, and reducing the frequency of this would be expected to improve the quality of dialysis initiation and subsequent outcomes. Nephrologists should support efforts to confirm and extend our findings and to test methods that prevent suboptimal initiation of dialysis despite early referral.

*Conflict of interest statement.* The results presented in this paper have not been published previously in whole or part, except in abstract format. The authors have no conflicts of interest to declare.

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# Exploring the role of pharmacists in outpatient dialysis centers: a qualitative study of nephrologist views

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#### Abstract

**Background.** Implementation of pharmacy services in dialysis centers seems to be limited and requires acceptance from nephrologists. The aim of this study was to explore the opinions of Australian and Portuguese nephrologists toward a potential future provision of clinical pharmacy services in outpatient dialysis centers.

**Methods.** A qualitative study using semistructured interviews was conducted with a purposeful sample of 7 Australian and 14 Portuguese nephrologists. The audiotaped interviews were transcribed verbatim and thematically analyzed.

Results. Three themes emerged from the analysis: 'attitudes of nephrologists towards pharmacist involvement', 'types of pharmacy services' and 'consequences of implementation of pharmacy services'. Australian nephrologists showed positive attitudes and reported several pharmacy services that could be performed by pharmacists in dialysis centers, whereas Portuguese nephrologist views restricted pharmacists to administrative duties. In addition, Portuguese nephrologists showed concerns with professional boundaries and demonstrated lack of awareness and knowledge of pharmacist skills. Pharmacy services suggested by Australian nephrologists included medication review, medication reconciliation, medication history update, patient and staff education, patient compliance improvement and development and implementation of anemia protocols.

Nephrologists expected economic benefits from the services implementation by minimizing the inappropriate use of drugs, avoiding medication errors, and reducing drug wastage due to noncompliance.

**Conclusions.** Australian and Portuguese nephrologists hold different views regarding the future provision of pharmacy services in outpatient dialysis centers. Acceptability seems to be related to a previous acquaintance with pharmacists and pharmacy services. Different health policies in the two countries that promote collaborative practice between physicians and pharmacists may also account for the differences.

Keywords: Australia; dialysis centers; nephrologist opinions; pharmacists; Portugal

## Introduction

Collaboration between physicians and pharmacists has been advocated to improve health care [1, 2] and it has contributed to better patient outcomes [3, 4]. Physicians' opinions and expectations of pharmacists have been assessed as a way of improving or adjusting future pharmacist interventions.

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