INTERNATIONAL VARIATION IN DIALYSIS DISCONTINUATION

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Abbreviations used

CCRC	comprehensive conservative renal care
CI	confidence interval
DOPPS	Dialysis Outcomes and Practice Patterns study
HR	hazard ratio
UK	United Kingdom
US	United States of America

Abstract

Background

We were interested in how conservative approaches to the care of patients with advanced kidney disease, in particular the use of dialysis discontinuation, has extended, internationally, across clinical practice.

Methods

We used an observational cohort study design using data collected from patients maintained on chronic hemodialysis between 1996 and 2015 in facilities across 12 developed countries participating in the Dialysis Outcomes and Practice Patterns Study (DOPPS). The main outcome was discontinuation of dialysis therapy.

Results

Overall, 12% of all decedents discontinued dialysis before death. Rates of discontinuation were higher within the first months after initiation of dialysis, in older adults and in those with a greater number of comorbidities, or living in an institution. After adjustment for age, sex, dialysis vintage, diabetes, and dialysis era, rates of discontinuation were highest in Canada, the US, and Australia/New Zealand (33.8, 31.4 and 21.5 per 1000/year, respectively), and lowest in Japan and Italy (<0.1 per 1000/year). Crude discontinuation rates were highest in dialysis facilities that were more likely to offer comprehensive conservative renal care to older adults.

Interpretation

We found marked persistence of international variation in average rates of dialysis discontinuation that are not explained by differences in patient case mix but likely reflect physician-, facility- and society-level differences in clinical practice. Further international collaboration on how to improve and implement access to dialysis discontinuation care is required.

Funding

Information about funding sources for the DOPPS project can be found at our website, https://www.dopps.org/AboutUs/Support.aspx. All support is provided without restrictions on publications.

Introduction

Over the last 50 years, there has been a marked increase in the availability of dialysis therapy for the treatment of both acute and chronic kidney disease, as well as shifts in the characteristics of patients treated with dialysis. While dialysis treatment has extended life for many patients, the widespread availability of this therapy regardless of age and health status also raises questions about the role of technology in extending life and prolonging the dying process. Questions about whether and when to initiate and discontinue dialysis treatment, and the appropriateness of care, can often be extremely challenging for individual patients, families and providers[1].

Evidence from the US and elsewhere suggests that decisions about dialysis are often strongly shaped by sociocultural and system-level factors rather than the priorities and values of individual patients.[2-4] Although often framed as a life-extending treatment, dialysis is not a cure for patients' underlying kidney disease but rather a supportive or palliative intervention. Dialysis can treat the signs and symptoms of advanced kidney disease, support patients with acute kidney injury until their renal function recovers, or provide a bridge to transplantation.[5] Reports from several developed countries indicate that a significant portion of patients with end-stage renal disease ultimately discontinue maintenance dialysis treatments, with as many as 10-20% of deaths in patients maintained on dialysis occurring after a decision is made to stop dialysis therapy[6-9 10-12].

Rates of dialysis discontinuation vary across countries, the highest reported from the United States, Canada, Australia and New Zealand and United Kingdom, and lowest from southern Europe and Japan.[6,8,9,13,14] Geographic differences in discontinuation rates likely reflect differences across countries in patient case-mix, physician attitudes[15-17], and rates of commencing dialysis but may also reflect variability in the definition/interpretation of the phrase dialysis discontinuation. In recent years, dialysis initiation in frail, older individuals has become more common despite mounting evidence that it may not restore health or prolong life, particularly in those with multiple comorbidities.[18]

The Dialysis Outcomes and Practice Patterns Study (DOPPS) (http://www.dopps.org) is an ongoing, study of more than 250,000 patients undergoing dialysis treatment across 12 countries that has evolved over 5 funding phases from 1996 to 2015 [Phases 1 (1996-2001), 2 (2002-04), 3 (2006-08), 4 (2009-11), and 5 (2012-15)]. We describe dialysis discontinuation rates by country and over time, and identify patient and facility factors associated with discontinuation.

Methods

Data Sources

All data were derived from data collection instruments used in DOPPS between 1996 and 2015. Dialysis facility selection, and the selection of DOPPS sample study participants, was done using a stratified random sampling process.[19] All participating facilities submitted a list of all patients (DOPPS census) from whom detailed information (DOPPS sample) were gathered about individual patients selected at random (Figure 1). Facilities with fewer than 20 patients were excluded. All patients who received hemodialysis at participating facilities from 1996 to 2015 in Australia, Belgium, Canada, France, Germany, Italy, Japan, New Zealand, Spain, Sweden, the UK, and the United States were captured on a census report. Patients were followed until censoring at the end of study-follow-up (30 Jun 2015), or at the time each DOPPS patient left the facility due to dialysis discontinuation (described below), transplantation, transfer to another facility or death. In addition to census data, detailed data are collected prospectively on patients selected randomly. This process is designed to ensure representation across different practice units in each country.

Dialysis Discontinuation

The primary outcome was discontinuation of dialysis during the study period. Dialysis discontinuation was determined from data entered by facility personnel who collected information on the reason patients left the facility. Mutually exclusive options listed on the data collection documents for leaving the facility were death, dialysis discontinuation, transplantation, transferring to another facility, and regaining kidney function. Date of death

was obtained for any patient who died while undergoing care at, or within 30 days of leaving, the facility. Discontinuation data were unavailable for one large dialysis organization in the United States during phases 4 and 5.

Covariates and Exposures

Data from three different components of the DOPPS dataset were used (Figure 1). Dialysis discontinuation rates across different countries and time periods were described using DOPPS census data (a listing of all hemodialysis patients being treated in every eligible DOPPS facility); patient characteristics associated with dialysis discontinuation were ascertained from data in the DOPPS sample (http://www.dopps.org). Health care professional attitudes and practices were determined from the DOPPS medical director survey.

The DOPPS has approval from a central institutional review board, with additional study approval and patient consent being obtained as required by national and local ethics committee regulations.

Data Analysis

The age at dialysis initiation was calculated from the age and dialysis vintage at study entry. DOPPS Census data were used to estimate rates of discontinuation across the different participating DOPPs countries by phase, adjusted for age at time of dialysis initiation, time on

dialysis at the start of DOPPS study, gender, and diabetic status. The outcome of primary interest is discontinuation of dialysis.

Clinical factors associated with dialysis discontinuation were determined from the DOPPS sample data (N=65,003). Time at risk started at study enrollment and ended at the time of death (including in those who discontinued dialysis), 7 days after leaving the facility due to transplant or transfer, 7 days after changing modality, or loss to patient-follow-up. Standard descriptive statistics were used to characterize DOPPS participants, and compare the characteristics of the DOPPS sample with those of all prevalent patients receiving care in participating facilities (DOPPS Census). Cox regression was used to analyze the association between patient characteristics (age at dialysis initiation, gender, diabetes, time on dialysis at study entry) and time to discontinuation, stratified by country and phase, accounting for facility clustering using robust sandwich covariance estimators. A time-dependent model, adjusted for case-mix, was used to evaluate discontinuation within the first 4 months following dialysis initiation vs. discontinuation later, where each patient could contribute time to each category based on when they entered the study. Standardized rates were calculated by weighting the withdrawal event and time-at-risk for each patient according to the overall distribution of age (<80 v. 80+ years) and time on dialysis (<6 months v. 6+ months), as age and time on dialysis were the two case-mix factors that seemed to have the strongest association with withdrawal.

Results

A total of 259,343 patients were included. Of these, 48,688 (19%) died during study-follow-up. Dialysis discontinuation was listed as the reason for leaving the facility for 5,953 patients (12% of all deaths). Among the 5808 patients for whom the exact date of death was recorded, 256 (4%) died more than 30 days after dialysis discontinuation. The median time from dialysis discontinuation to death was 7 days (IQR 5 to 9 days). When compared to decedents who did not discontinue dialysis, those who discontinued dialysis were on average older and more likely to be female (Table 1a). Age was strongly associated with discontinuation with a 1.9-fold (95% CI 1.8,2.1) higher hazard ratio of discontinuation seen for patients aged 70-79 years, compared to those 60-69 year old, and 3.3- fold (3.0,3.7) amongst those aged 80-89, and 5.8 (4.5,7.4) for those aged over 90 years.

The characteristics of participants who discontinued dialysis were similar in both the DOPPS sample and the DOPPS census (*Supplementary data*). Among patients included in the DOPPS sample (N= 65,003), those who discontinued dialysis were more likely to require assistance with eating and/or transfers, be living in an institution, and have a higher number of comorbid conditions at study entry compared to those who died of other causes (Table 1b). Of 1077 patients with detailed information about the reasons for discontinuation, 388 (36%) discontinued dialysis following an acute medical condition and 291 (27%) following chronic progressive deterioration in health. A total of 840 (78%) patients discontinued after the patient and/or family requested to stop dialysis. Most of those who stopped dialysis received hospice or palliative care prior to death (n=743 of 1077; 69%).

In all DOPPS phases there was marked international variation in rates of dialysis discontinuation, with no apparent change over time (data available on request). In all DOPPS study phases, dialysis discontinuation was most common in Canada (33/1000 patient-years), the US (27/1000 patient-years) and Australia/New Zealand (21/1000 patient-years); discontinuation was least common in Spain (5/1000 patient-years), Japan (0/1000 patient-years) and Italy (0/1000 patient-years) (Table 2). These differences persisted even after adjustment for differences in the baseline characteristics of patients undergoing dialysis (Figure 2). Patients living in countries with higher rates of discontinuation such as the US, Canada, Australia/New Zealand, and Belgium were also more likely to discontinue dialysis within 4 months of starting treatment compared to after 4 months of treatment (Figure 3). The HRs (adjusted for age at dialysis initiation, gender and diabetes) for discontinuation before-4 months versus after-4 months in the US, Canada, Australia/New Zealand, and Belgium ranged from 1.5 for the US and Belgium to 1.9 for Canada ($p< 0.05$). The median age, diabetes status, and median dialysis vintage at the time of dialysis discontinuation differed little across countries with high or low discontinuation rates (data available on request).

There were substantial differences across countries in responses to the medical director survey (577 responses of 686 survey requests). Medical directors for the majority (93%) of units in Australia/New Zealand reported that they "always or usually discussed" comprehensive conservative renal care. In contrast, 98% of units in Japan "never or seldom discussed" comprehensive conservative renal care (CCRC). There was a positive linear association between the frequency of discussing CCRC with older dialysis patients and facility discontinuation rates

(Figure 4). However, there was greater consistency of medical director survey responses among facilities within than between countries. Thus, even though the overall linear trend appeared to be strong when not adjusted for country ($p<0.0001$), this relationship became much weaker when adjusted for country ($p=0.56$). Discontinuation rates were also higher in units where the medical director reported that that the facility's practice was to usually or always recommend discontinuation after an event causing irreversible neurological damage ($p < 0.0001$ unadjusted, $p =0.38$ after adjustment for country). Overall, 16% of the facilities responded that physicians in their area would 'never' or 'seldom' refer patients greater than 80 years old to dialysis (at least one facility in every country), and these responses were associated with much lower facility discontinuation rates ($p=0.17$ unadjusted, $p=0.04$ after adjustment for country and age). Medical director responses to the question about dialysis discontinuation practices for patients with metastatic cancer and a life expectancy of less than 6 months were not associated with discontinuation rates ($p=0.16$ unadjusted, $p=0.87$ after adjustment for country).

Interpretation

We found there is significant ongoing international variation in dialysis discontinuation rates, despite increased awareness of the limited benefits of dialysis for frail older adults.[18] Dialysis care remains one of the most expensive and invasive treatments available. While some countries struggle with resources to provide access to dialysis for patients dying of renal failure, in much of the developed world, dialysis initiation has become the default treatment for advanced kidney disease, raising concerns about overtreatment.[3,4] Our observation that international variations in dialysis discontinuation practices are not well explained by the patient case-mix alone, rather that unit practices and physician philosophies influence discontinuation rates, raises questions as to the main drivers, outside of patient values and preferences, that influence dialysis treatment decisions.[3] Among medical directors at participating facilities, there was considerable variation in responses to several questions related to dialysis discontinuation, with a strong association between responses and rates of dialysis discontinuation at each facility. This association is consistent with other studies suggesting that treatment patterns on dialysis are largely shaped by provider- and system-level factors rather than the preferences of individual patients.[17,20-23] Patients were more likely to discontinue dialysis early in the course of treatment, perhaps highlighting the intertwined nature of decision-making about dialysis initiation, discontinuation and approach to advance care planning such as willingness to offer dialysis.[13] High rates of discontinuation were often associated with high rates of *early* discontinuation, perhaps reflecting a more liberal approach

to dialysis initiation and/or greater use of time-limited trials of therapy with the option of planned discontinuation.

As with all observational studies, interpretation of findings is limited by the nature of the available data. For example, only patients who started dialysis were included in the study. Rates of CCRC differ between countries [24] and patients who opt for CCRC instead of dialysis may differ from those who decide to discontinue after starting dialysis. In addition, factors such as transplant wait times, distance to travel to dialysis, and availability and quality of palliative care services can influence the patient-experience and affect discontinuation rates. Importantly interpretation of the term discontinuation may vary, with previous data suggesting the term is used differently, across countries, regions, and between nephrologists within the same units [12,16,25-27] and our results may reflect how individuals completing the data collection forms have incorporated their personal, or local cultural values into the interpretation.

Our findings however raise questions about how regional differences in physician experience and training, societal expectations and medico-legal regulations impact patient care, particularly for those individuals who may not feel well served by long-term dialysis[20,22,28]. Assuming the mission of most nephrology providers is to provide care along the complete spectrum of kidney disease from early chronic kidney disease care through dialysis and transplant until the final days, our data suggest an ongoing need to increase training, and possibly align clinical practices, to better meet the needs of our patients.

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Figure 1: DOPPS Study Design and Data Sources

Figure showing study design, with randomized selection (represented by ®) of both patients and facilities. The dotted box lines represent those data used to determine dialysis discontinuation information.

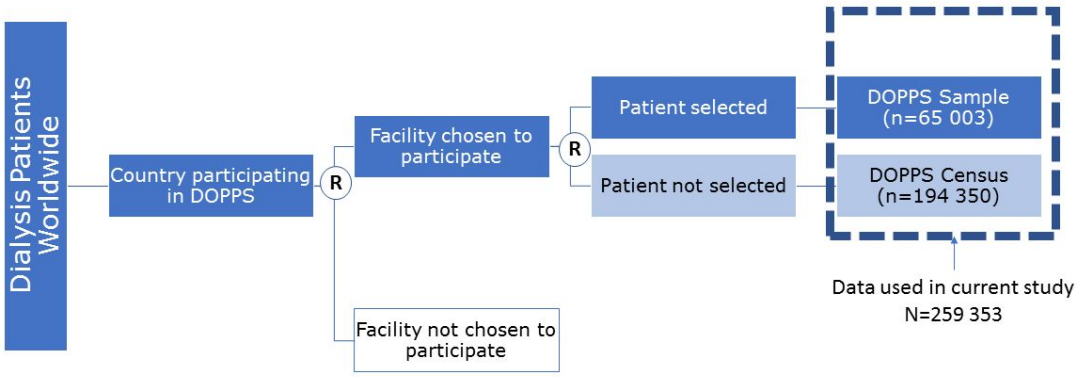
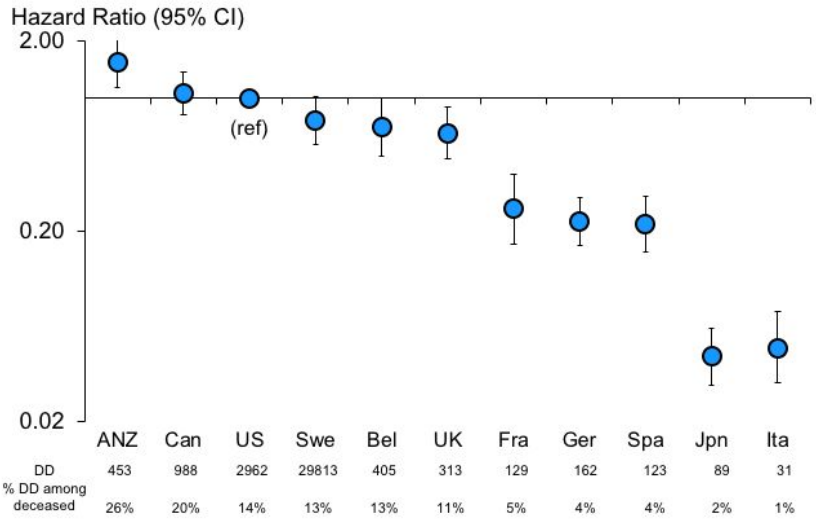
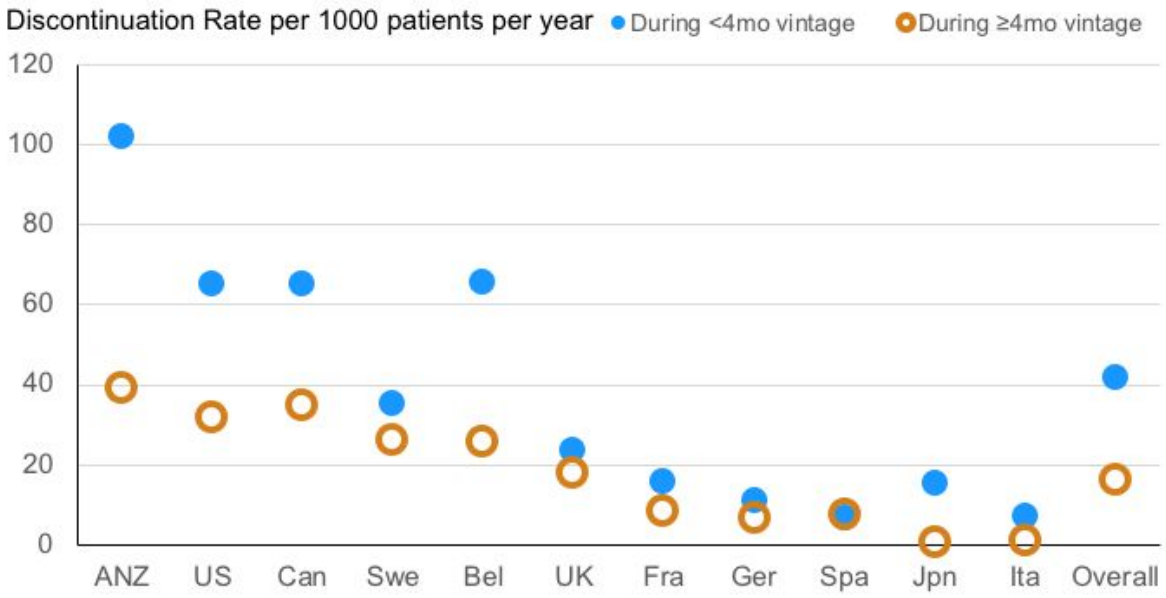


Figure 2: Adjusted dialysis discontinuation rate by country (hazard log scale)



Footnote: Data shown: phases 1-5, excluding Phase 5 Large Dialysis Organization (LDO)· Model Cox model adjusted for country, age, time on dialysis, sex, diabetes; censoring any death events

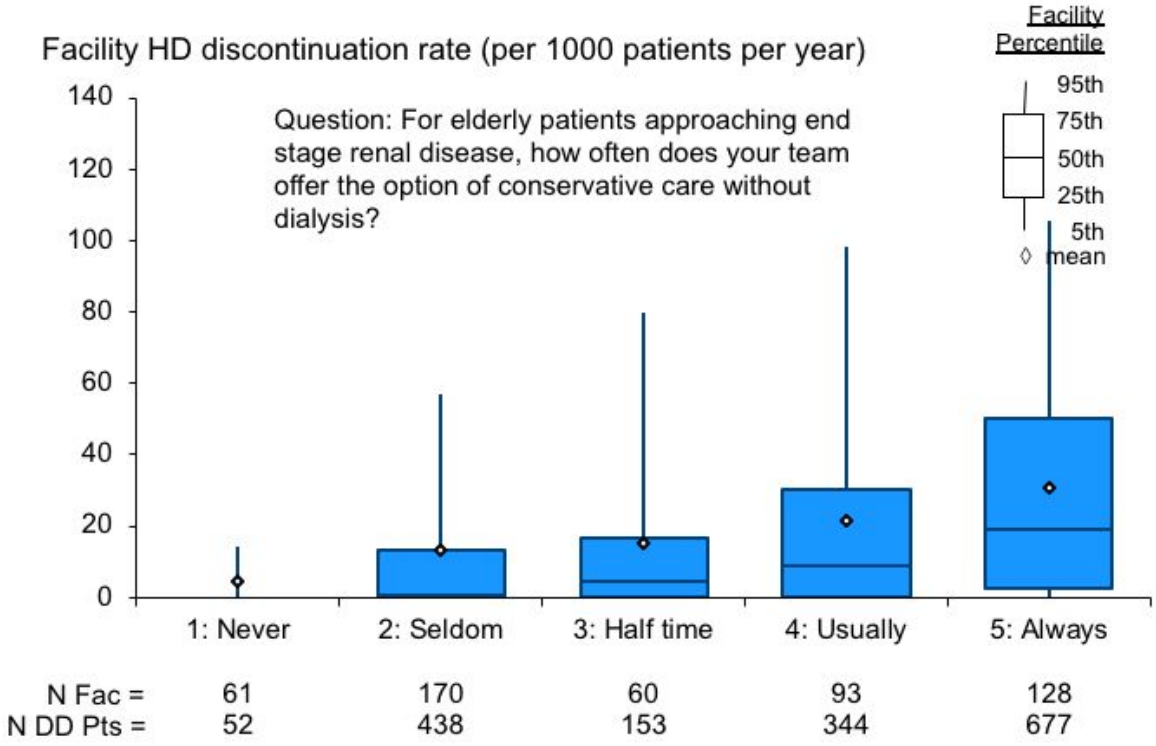
Figure 3: Unadjusted discontinuation rates by country during first 4 months post dialysis initiation and during subsequent follow up·



Footnote: Data shown from phase 1-5 excluding one US Large Dialysis Organization, raw data unmodeled, each patient could contribute time to both categories

Figure 4: Distribution of facility discontinuation rates according to medical director's willingness to offer CCRC instead of dialysis initiation (unadjusted).

When modeled as a linear trend in the facility-level discontinuations per 1000 patients per year, the association between discussing CCRC and observed discontinuation rate was 6.1 (95% confidence interval 4.1 to 8.1, $p < 0.0001$) per single-category increase in the CCRC response (e.g. from "seldom" to "half the time"), but when adjusting for country this trend decreased to 0.8 (95% confidence interval -1.5 to 3.2, $p = 0.49$).



Footnote: Data from phases 4 & 5 (2009-2015) medical director survey aligned with facilities' corresponding discontinuation rate among all HD patients that received care during study phase, excludes LDOs

Medical directors were asked "For elderly patients approaching end stage renal disease, how often does your team offer the option of conservative care without dialysis?" With response options: never, seldom, half the time, usually, or always·

Table 1a: Demographic details from Census population from DOPPS

	Dialysis discontinuation	Died (Other causes)	Alive at study end
Number of patients	5953	43282	210108
Percent of all patients	2%	17%	81%
Age in years (SD)	73 (12)	69 (13)	62 (15)
Years on dialysis at study start(SD)	2·5 (3·6)	3·5 (4·6)	3·4 (5·1)
Male gender (%)	53%	59%	60%
Diabetic	43%	43%	36%
Study follow up time in years (range)	0·7 [0·3,1·4]	0·8 [0·3,1·5]	1·3 [0·4,2·3]

SD: standard deviation

* Data shown: Phases 1-5 census patients (all patients in participating facilities).
Data excluded: Those from Russia, China, Turkey and Gulf Cooperation Council (GCC) countries; Phase 5 data from one large US dialysis organization were excluded as dialysis discontinuation information were not reported.

Table 1b Patient characteristics (DOPPS Sample data)

	Dialysis discontinuation	Died (Other causes)	Alive at study end
Number of Patients	1547 (2%)	12975 (20%)	50481 (78%)
Age in years (SD)	72·9 (11·8)	69·3 (12·5)	61·1 (15·0)
Years on dialysis (SD)	2·6 (3·7)	3·6 (4·6)	3·7 (5·3)
BMI	24·9 (5·8)	24·7 (5·8)	25·2 (5·9)
Male gender (%)	53%	59%	59%
Labs			
Albumin g/dl (SD)	3·5 (0·6)	3·5 (0·6)	3·7 (0·5)
Creatinine µmol/l (SD)	601 (221)	672 (239)	778 (283)
Comorbidity Information			
Coronary Heart Disease	61%	57%	37%
Other Cardiovascular Disease	48%	46%	28%
Cerebrovascular Disease	28%	24%	14%
Congestive Heart Failure	49%	45%	26%
Diabetes	49%	48%	38%
GI Bleeding	10%	9%	5%
HIV	1%	1%	1%
Hypertension	84%	82%	82%
Lung Disease	24%	20%	10%
Neurologic Disease	21%	16%	9%
Psychiatric Disorder	28%	23%	16%
Peripheral Vascular Disease	41%	40%	22%
Recurrent Cellulitis, Gangrene	13%	14%	6%
Cancer other than skin	24%	18%	11%
Cachexia	22%	18%	8%
Living and Functional Status (%)			
Lives alone	19%	17%	17%
Lives with family or friend	62%	70%	76%
Lives in nursing home or institution	16%	9%	3%
Eats independently	93%	94%	98%
Able to transfer independently	70%	73%	90%

Data shown: phases 1-5 patients selected for study participation. BMI=Body mass index

Table 2: Standardized and crude dialysis discontinuation rates across participating DOPPS countries

	Unadjusted	Standardized
Overall	5·3	4·8
US	26·7	31·4
Canada	33·3	33·8
Australia & New Zealand	21·4	21·5
UK	12·2	10·9
Sweden	13·3	15·6
Belgium	8·3	7·1
France	0·0	0·9
Germany	3·1	3·3
Italy	0·0	0·0
Spain	4·8	3·6
Japan	0·0	0·0

Table shows median facility DD rates per 1000 patient years by country in DOPPS phases 4 and 5. The standardized rate used as a reference the overall DOPPS distribution during these phases in terms of age (<80 v. 80+ years) and time on dialysis (<6 months v. 6+ months) Standardized rates excluded patients with missing time on dialysis (1·7%) or missing age (0·3%), leaving 86641 patients. The difference in unadjusted and standardized facility DD rates was median (IQR)= 0 (0, 1·1) per 1000 patient years.